Consent for the use of human biological samples for biomedical research – a mixed methods study exploring the UK public's preferences

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Consent for the use of human biological samples for biomedical research – a mixed methods study exploring the UK public's preferences

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ABSTRACT

Objective: A mixed methods study exploring the UK general public's views towards consent for the use of biosamples for biomedical research.

Setting: Cross-sectional population-based focus groups followed by an online survey.

Participants: Twelve focus groups (81 participants) selectively sampled to reflect a range of demographic groups; 1110 survey responders recruited through a stratified sampling method with quotas set on sex, age, geographical location, socio-economic group and ethnicity.

Main outcome measures: 1) Views on the importance of consent when donating residual biosamples for medical research; 2) preferences for opt-in or opt-out consent approaches; 3) preferences for different consent models.

Results: Participants believed obtaining consent for use of residual biosamples was important as it was "morally correct" to ask, and enabled people to make an active choice and retain control over their biosamples. Survey responders preferred opt-in consent (55%); the strongest predictor was being from a low socio-economic group (OR 2.22, 95% CI 1.41-3.57, p=0.001) and having a religious affiliation (OR 1.36, 95% CI 1.01-1.81, p=0.04). Focus group participants had a slight preference for opt-out consent because by using this approach more biosamples would be available and facilitate research. Concerning preferred models of consent for research use of biosamples, survey responders preferred specific consent with re-contact for each study for which their biosamples are eligible. Focus group participants preferred generic consent as it provided "flexibility for researchers" and reduced the likelihood that biosamples would be wasted. The strongest predictor for preferring specific consent was preferring opt-in consent (OR 4.58, 95% CI 3.30-6.35, p=0.015) followed by non-'White' ethnicity (OR 2.94, 95% CI 1.23-7.14, p<0.001).

Conclusions: There is a preference amongst the UK public for ongoing choice and control over donated biosamples, however increased knowledge and opportunity for discussion is associated with acceptance of less restrictive consent models for some people.

ARTICLE SUMMARY

Article focus

- To explore views of the UK public on the importance of consent being sought to the use of residual biosamples for medical research;
- The publics' preferences for opt-in or opt-out approaches to consent;
- The publics' preferences for generic, tiered or specific consent.

Key messages

- Obtaining consent for the use of residual biosamples for biomedical research was perceived as important by members of the general public.
- Survey participants exhibited a desire to retain active choice and control when donating biosamples and over the uses to which their biosamples might be put, preferring an opt-in system and specific consent, however these results differ from those reported during focus group discussions, where preference was for less restrictive consent models (an opt-out system and generic consent) that are likely to increase availability of biosamples.
- These differences might be accounted for by the fact that focus group participants were given more background information about the use of residual biosamples in research and had time to consider the benefits and disadvantages of the different approaches.

Strengths and limitations of this study

- This study contributes further to our understanding of the UK public's views and preferences towards consent for the use of biosamples in medical research. Our study supports the premise that increased knowledge and opportunity for discussion is associated with acceptance of less restrictive consent models.
- Due to the hypothetical nature of the study, the findings may not necessarily correlate with actual behaviour.

INTRODUCTION

Human biological samples (biosamples), including organs, tissues, biofluids such as blood, and their derivatives, are increasingly important resources for biomedical research[1,2]. For example, they can help us to understand how we diagnose, categorise and treat a whole variety of medical conditions including cancer[1] and are particularly important when studying rare diseases or conditions where biosamples are hard to obtain. Biosamples are donated by either healthy volunteers or patients, either through specific research studies or as residual tissues or biofluids surplus to diagnostic requirements, or post mortem. Biosamples can be used fresh or can be first stored in a biobank, a collection of biosamples often linked with the donors' clinical and demographic information, as biosample attributes. Here, the quality of the data linked to the biosample is as important as the quality of the biosamples themselves, providing essential context within which to design analyses and interpret results or carry our further experimental studies. Clinical data may also be enriched with lifestyle and environmental information[3].

It is widely accepted that that donor consent should be sought and obtained before biosamples can be used in research[4,5]. Consent in research ethics relates to ensuring respect for the autonomy and dignity of the donors (research participants) and protecting them from abuse[5] and In fact, in England, Wales and Northern Ireland, the Human Tissue Act establishes donor consent as the baseline principle for the retention and use of organs and tissue for purposes beyond diagnosis and treatment, although further statutory consent exemptions do exist in certain circumstances, notably use of anonymised tissue from the living for research ethics committee (REC) approved research projects[6]. The value of biobanks, in supporting broad, long-term research purposes, means that the model of the consent process needs to be considered in order to ensure that it is valid and appropriate. A number of different consent frameworks which address consent scope and process have been proposed as a result[5]. However, there is continued debate as to which is the most appropriate in various situations[4,7,8].

Both the Human Tissue Authority[9] and National Research Ethics Service[10] recommend generic consent (Table 1), a view that has also been endorsed by UK research funders[11] and the Nuffield Council on Bioethics[12]. One commonly cited criticism of generic consent is that it is not sufficiently 'informed' as future research uses are not known at the time of donation[13]. Empirical research examining public and patient preferences has highlighted that there is no clear consensus on the issue, with

specific consent being identified as the most favoured form of consent in some studies[14,15], and generic consent in others[16-18].

Table 1: Approaches to consent of biosamples

Initial consent methods	
Opt-in consent	The storage and use of biosamples for research on the basis that the donor has actively agreed to do so.
Opt-out consent	The storage and use of samples for research on the basis that the donor has not objected, after previously being given the opportunity to do so.
Opt-in consent methods	
Consent once for life	Consent is provided once for life for use of any residual samples for research with the option of withdrawing permission at a later stage if the donor wishes to do so.
Consent at certain points	Consent is provided at certain points for use of residual biosamples for research, e.g. every 10 years or at the beginning of a particular episode of care.
Consent every time	Consent is requested every time residual biosamples may become available for use in research.
Consent for research use of biosamples	
Generic consent	Consent to the use of donated samples for a range of unknown uses, on the basis of general information about those possible uses and about the governance arrangements in place.
Tiered consent	A more restricted form of consent for use of samples, where the donor is invited to agree to the use of their samples in unknown projects, but given the option of specifying particular categories of research that they wish to exclude e.g. embryonic research.
Specific consent –once only	Consent to the use of donated samples for a specified study only, on the basis of information provided about that study. Any residual sample will be discarded at the end of that study.
Specific consent – for every new study	Consent to the use of donated samples for a specified study, on the basis of information provided about that study. However, participants are re-contacted and asked to consider participating in every new study for which their biosamples are eligible.

The 2011 Nuffield Council report on donation of human material for medicine and research also recommends that research funders should work to increase public awareness of the key role of donated tissue in scientific and clinical research[12]. Public trust and confidence in the consent process is of paramount importance to maintain and

increase public support for donation and use of biosamples for biomedical research in the UK. For this reason, it is important to understand and inform public opinion to ensure consent models are aligned to public expectations and preferences. Whilst numerous international studies have been conducted which focus on consent preferences, research conducted in the UK has tended to focus on large scale population biobanks, such as UK Biobank[19] or Generation Scotland[20], which require ongoing contact with donors, or on the views of patients on the donation of residual biosamples[21]. The current study was conducted to broaden our understanding of the UK public's views on biosample donation for biomedical research. Moreover, the findings are intended to inform a biobanking policy for STRATUM (Strategic Tissue Repository Alliance Through Unified Methods), a Technology Strategy Board[i] and pharmaceutical industry-funded project seeking to address the problem of insufficient numbers of biosamples and associated clinical data of adequate quality to fully support biomedical research in the UK.

The specific aims of this study were to 1) identify participants' views on the importance of consent when donating residual biosamples for medical research; 2) explore preferences for opt-in or opt-out approaches to consent; and 3) explore preferences for different consent models (Table 1). Public willingness to donate biosamples, views on donation of different biosample types, and conditions of their use are reported elsewhere (Public views on the donation and use of human biological samples in biomedical research – a mixed methods study, 2013, unpublished manuscript).

METHODS

This was a mixed methods study comprising qualitative focus groups and a quantitative on-line survey. Ethical approval for the study was granted by the University of Manchester Research Ethics Committee in April 2012.

Focus groups

Twelve focus groups (including one pilot group) were conducted between May and July 2012 in six different geographic locations across the UK. Participants were recruited face-to-face in the street by a market research company The Focus Group. Participants were purposively sampled; each group chosen to reflect a particular demographic (age, socio-economic group (SEG), ethnicity) in order to gather a wide spectrum of views and enable comparisons across groups. Two 'patient' groups were also included, comprising people who had had an operation in the past two years requiring an overnight hospital stay, and people who currently have, or have had, either a serious or chronic illness, or

[i] under the Stratified Medicines Programme: Business Models Value Systems

disability. The latter group comprised people diagnosed with diabetes, cancer, heart disease, asthma and the genetic condition Marfan syndrome. A further group consisted of generally healthy people who had donated a biosample specifically for research purposes.

Before agreeing to take part, potential participants were given a participant information sheet telling them about the study (see supplementary data file Appendix I). Those that were interested were screened through a questionnaire containing demographic questions to assess their suitability for a particular focus group. These were held in 'neutral' locations such as hotel conference rooms or church halls and facilitated by an experienced facilitator (CL). Before each group discussion, participants were sent a short information leaflet about the use of biosamples in biomedical research to provide some background context for the discussion and to prompt them to think about the key issues (see supplementary data file Appendix II). This information was written by a core team of authors drawn from across academia and industry, including patient representation. It was reviewed by three members of the patient organisation Genetic Alliance UK as well as the science communication charity Sense about Science to ensure readability and non-bias. Before focus group discussions began, participants were asked to sign a consent form. Each participant received a small honorarium for taking part. Focus groups lasted 90 minutes and digital audio recordings were taken.

A detailed discussion guide was developed to explore participant views and preferences towards consent scope and process (see supplementary data file Appendix III). The main focus related to the use of biosamples surplus to diagnostic requirements following surgery or a medical procedure. Questions were informed by other empirical studies of consent in biobanking[16,22], developed by the authors, and addressed the topics described above. To enhance understanding around the different consent models, participants were given a sheet presenting three different scenarios, each of which elaborated on one of the three consent models chosen for discussion (see supplementary data file Appendix IV). For each topic, discussion began by asking the group to consider the benefits and disadvantages of each particular approach. Once no new themes were emerging, each participant was asked to complete an accompanying anonymous questionnaire which asked them to select their preferred consent model. The discussion guide, scenario sheet and questionnaire were piloted at the first focus group which resulted in some minor amendments to wording.

Recordings were fully transcribed and transcriptions checked. The software package Nvivo version 9 (QSR International, Pty Ltd) was used to help organise the data for analysis. This comprised grouping responses to questions into broad thematic categories

which were then refined through sub-codes. Coding was conducted by CL and verified by a second researcher to ensure inter-rater reliability. Any discrepancies were discussed between the two researchers until consensus was reached.

Survey

Once data analysis had been conducted on the focus group transcripts, the findings were used to inform development of a quantitative survey which was used to canvas public opinion on the issues of interest across a representative sample of the UK population (see supplementary data file Appendix V). The survey was carried out by the market research company Research Now using their online panel community of UK residents. A stratified sampling method was used: quotas were set on sex, age, geographical location, SEG and ethnicity, in line with data provided by the Office of National Statistics (ONS) to ensure the sample was as representative of the UK population as possible. Within each category, a random sample was selected from the Research Now database containing 451,185 active respondents. We aimed to recruit 1,000 responders in total. In order to reduce any on-line bias in our sample, 100 face-to-face interviews with non-internet users were conducted. An additional 'boost' sample of 100 people (not included in the main sample analysis) was also conducted with people from three minority ethnic groups ('Black', 'Chinese', 'S. Asian') so that we could conduct sub-group analysis between the groups.

The survey questions were developed by the authors and piloted with 60 members of Research Now's online panel community who were from low SEG's. Members of the pilot group were then invited to take part in a subsequent telephone interview asking about the survey. Interviews were conducted with 25 pilot survey responders. Questions focused on question clarity, survey length and whether responders felt the survey to be neutral. Some minor amendments to wording were made in light of the responses. The main survey was then conducted in September 2012. Surveys recorded online took, on average, 17 minutes to complete.

Survey data were organised and analysed using SPSS statistical software version 20 (Chicago, IL: SPSS Inc; 2011). Initial univariate descriptive statistics were obtained for the entire study. Pearson Chi-square was used to examine demographic factors associated with willingness to donate and preference for different consent models. Those associations that were found to be significant ($p \leq 0.05$) were then entered into a multiple logistic regression to explore the predictivity of these variables. Before running the model, we tested for multicollinearity among the independent variables. No multicollinearity issues were found.

RESULTS

Study populations

Participant characteristics are detailed in Table 2.

Table 2: Participant characteristics

Characteristic	Focus group N=81	Survey N=1110
Gender		
Male	33; 41%	504; 45%
Female	48; 59%	606; 55%
Age		
18-24	13; 16%	135; 12%
25-34	18; 22%	184; 17%
35-44	19; 23%	198; 18%
45-54	10; 12%	184; 17%
55-64	16; 20%	176; 16%
65+	5; 6%	233; 21%
Socio-economic group		
A	9; 11%	41; 4%
B	22; 27%	215; 19%
C1	24; 30%	311; 28%
C2	14; 17%	233; 21%
D	6; 7%	145; 13%
E	6; 7%	165; 15%
Region		
East of England	7; 7%	92; 8%
East Midlands	-	57; 5%
London	18; 22%	213; 19%
North East	-	40; 4%
North West	-	121; 11%
Northern Ireland	-	30; 3%
Scotland	14; 17%	76; 7%
South East	14; 17%	165; 15%
South West	-	81; 7%
Wales	-	51; 5%
West Midlands	14; 17%	94; 8%
Yorkshire/Humberlands	14; 17%	90; 8%
Ethnicity		
White or White British	54; 67%	1057; 95%
Mixed race	1; 1%	7; 1%
Asian or Asian British	10; 12%	18; 2%
Black or Black British	9; 11%	19; 2%
Chinese or Chinese British	7; 9%	2; 0%
Other ethnic group	0; 0%	4; 0%
Prefer not to say	0; 0%	3; 0%
Religion		
Christianity		677; 61%
Islam		13; 1%
Hinduism		6; 1%
Sikhism		0; 0%
Judaism		6; 1%
Buddhism		11; 1%
Other religion		15; 1%

No religion		370; 33%
Prefer not to say		12; 1%
Religiosity		
Not at all religious		234; 32%
Moderately religious		422; 58%
Very religious		64; 9%
Prefer not to say		8; 1%
Education		
No formal qualification	15; 19%	70; 6%
GCSE, O level, Scottish Standard Grade or equivalent	19; 23%	264; 24%
GCE, A-level, Scottish Higher or similar	17; 21%	214; 19%
Vocational (BTEC/NVQ/Diploma)	-	230; 21%
Degree level or above	30; 37%	317; 29%
Prefer not to say	-	15; 1%
Self reported knowledge of medical research process		
No knowledge		463; 42%
Some knowledge		603; 54%
Good knowledge		44; 4%
Have you been affected by a disability or illness?		
Yes		399; 36%
No		711; 64%
Has a close family member been affected by a disability or illness?		
Yes		767; 69%
No		343; 31%
Have you had blood or tissue removed during a medical procedure?		
Yes		446; 40%
No		553; 50%
Don't know		111; 10%
Have you ever been asked to donate blood or tissue for medical research?		
Yes		182; 16%
No		904; 81%
Don't know		24; 2%
If so, did you agree to donate?		
Yes		155; 85%
No		23; 13%
Don't know		4; 2%

Note: percentages may not add up to 100 due to rounding.

Focus groups

One hundred and eighty-two members of the public who were approached were eligible to participate (i.e. they fitted the criteria for a particular focus group) and 81 people agreed to participate (45% participation rate; 48 women, 33 men).

Survey

Four thousand six hundred and seven people were invited to take part in the survey; 2014 did not respond, 860 began completing the survey but did not finish, 102 did not qualify to continue (e.g. they were under 18 years old), 521 qualified for the survey but the quota was full and 1110 completed the questionnaire (28% response rate excluding those who did not qualify and where the quota was full). This response rate is comparable to similar studies on this topic[16]. Our participant quotas closely, though not exactly, matched our targets based on the UK population data as provided by the ONS. For this reason we carried out both weighted and un-weighted analyses. There was no difference in the conclusions we reached by either method. In this paper we present the un-weighted results (weighted results can be found at supplementary data file Appendix VI).

Importance of asking for consent

The majority of survey and focus group participants believed that obtaining consent for the use of residual biosamples was either extremely important (55%) or important (25%). Only 4% selected 'not at all important'. Reasons as to why consent was important, as cited by focus group participants, included that it was "polite", "respectful" and "morally correct" to ask permission; that it enabled people to feel they had made a contribution and an active choice; that it provided control, in particular for those people that might not want their biosamples to be used, for example for religious reasons; that taking without asking was akin to theft; and that it was important in order to maintain trust between patients and doctors.

"It then doesn't allow them to take liberties or advantage of the fact that you're out cold having an operation and someone says 'Oh we need a bit of that'." Male, patient – had operation in past 2 years.

A small minority did not feel that consent was important, the main reasons being that they did not want the tissue back, that once it was removed it no longer 'belonged to them', and that the tissue would just go to waste otherwise.

Survey participants were asked what would be their preferred method of consenting to donate leftover biosamples for research use. The majority (65%) wanted to do so face-to-face with a health professional; 15% wanted to complete a form and return it by post.

Preference for 'opt-in' or 'opt-out' consent

Participants were asked whether they preferred an opt-in or opt-out model of consent for donating residual biosamples. The results of the survey showed that opt-in consent was preferred by over half of the participants (55%), 28% preferred opt-out, 14% had no

preference and 4% selected 'don't know'. Participants who were significantly more likely to prefer opt-in consent were: from a low SEG (E) (79.8% vs. 64.1%, X^2=11.13(1), p=0.001); over 65 years (75.1% vs. 64%, X^2=7.68(1), p=0.006); had a religious affiliation (68.8% vs. 61.2%, X^2=4.84(1), p=0.028); and had an education level of GCSE or lower (71.1% vs. 63.9%, X^2=3.89(1), p=0.048). The strongest significant predictor for preferring opt-in consent was being from a low SEG (E) (OR=2.22, 95% CI 1.41-3.57, p=0.001) followed by having a religious affiliation (OR=1.36, 95% CI 1.01-1.81, p=0.04) (Table 3).

Table 3: Multiple logistic regression of participant preferences for consent models

Participant characteristic	Coefficient	95% CI	Odds ratio	p value
Preference for opt-in consent				
Socio-economic group	0.806	1.41, 3.57	2.22	0.001
Religion	0.304	1.01, 1.81	1.36	0.04
Preference for consent every time				
Religion	0.72	1.05, 4.00	2.04	0.036
Age	0.47	1.07, 2.41	1.60	0.023
Preference for specific consent				
Opt-in	1.52	3.30, 6.35	4.58	<0.001
Ethnicity	1.08	1.23, 7.14	2.94	0.015
Preference for generic consent				
Opt-out	1.52	3.13, 6.67	4.55	<0.001
Religion	0.04	1.08, 2.72	1.56	0.021
Knowledge of medical research process	0.44	1.06, 2.28	1.56	0.024

Demographic items were excluded from this table if none was statistically significant. All variables were entered into the models as categorical variables.
CI: Confidence Interval.

Focus group participants preferred opt-out consent (*n*=46; 57%) over opt-in consent (*n*=29; 36%), with 6 participants (7%) unsure, after in-depth discussion around the benefits and disadvantages of each approach. The main benefit of opt-out consent cited by participants was that more biosamples would be available and consequently spur research. Other reasons included: that it would be less costly administratively; that it maximised the value of left over biosamples; that patients wouldn't have to consider it every time they were having an operation or blood test; that those that did not want to donate still had the opportunity to opt-out; and that it would 'normalise' donating leftover biosamples which would be a positive step.

"It would an incentive for society if everyone knew that this is what happens routinely, but you can choose not to be involved. It would be more like 'that's normal'." Male, aged 18-24 group

Those that preferred the opt-in approach cited the following reasons as to why: an active choice was preferable to a passive choice; it enabled people to have more control over

their biosamples; it was truly 'informed consent' in the context of donating surplus samples for research (rather than as part of a clinical trial; clinical trials were outside the scope of the study) and hence more ethically acceptable; it enabled people to feel that they were making a positive contribution and would prevent the problem of vulnerable groups not being aware they were automatically 'opted-in'.

"There are going to be members of the public who are not going to always be able to consider rationally themselves what it actually means." Female, healthy volunteer

Whist the majority of focus group participants overall preferred opt-out consent, the results were different for the three minority ethnic groups (''Black'', ''S. Asian'', ''Chinese''), where opt-in consent was favoured by the majority.

Consent once for life or consent every time

The most prevalent system in current use for donating new biosamples that are surplus to clinical requirements in the UK is the opt-in approach, with potential donors being asked for consent every time a procedure is performed that may result in a biosample becoming available for research. (The law allows for the use of diagnostic archives for research without consent as long as certain criteria are met). Participants were therefore asked to consider variations on this model and state whether they preferred: (1) consent once for life, covering all subsequent biosamples, until or unless the donor decides to withdraw consent; (2) consent every time samples surplus to diagnostic requirements may become available, or (3) consent at certain points in life. Consent every time (43%) was preferred by the majority of survey participants, followed by consent at certain points (27%) and consent once for life, e.g. at aged 18, (21%). Seven percent had no preference and 2% didn't know. Groups who were significantly more likely to prefer consent every time compared to consent once for life were: under 55 years (70.3% vs. 60.9%; X^2=5.88(1), p=0.015); had no knowledge of the research process (72.3% vs. 63.4%; X^2=5.77(1), p=0.016); or were either not at all or moderately religious (70.2% vs. 51.3%; X^2=5.1(1), p=0.024). When entered into the regression analysis, the strongest significant predictor for preferring consent every time was being not at all or moderately religious (OR=2.04; 95% CI 1.05-4.00, p=0.036) followed by being under 55 years (OR=1.60; 95% CI 1.07-2.41, p=0.023) (Table 3).

Unlike survey responders, focus group participants favoured consent once for life (*n*=35; 43%) followed by consent every time samples surplus to diagnostic requirements may become available (*n*=27; 33%) and consent at certain points (*n*=16; 20%) with three choosing don't know (4%). Like opt-out consent, consent once for life was seen to be better as it was "quicker" and "easier" administratively and prevented researchers from

"losing out". Consent provided most control for participants as you would "know the specific purpose of it", particularly if the sample was considered to be sensitive e.g. eggs; allowed "no room for error"; and enabled people to change their mind easily.

"You may feel differently [depending on] what tissue is being donated and for what purpose the research is being carried out." Female, aged 18-24 group

Some participants had concerns about how consent preferences (e.g. what types of research they were willing to donate a biosample for), would follow them across the healthcare system if a 'consent once for life' model was adopted. Consent at certain points was seen by some as a good middle ground as patients would still have some control, but would not have to go through the consent process every time they had a medical procedure. Examples of consent at certain points included every "five or ten years", or at the beginning of particular episodes of care such as pregnancy or cancer treatment.

Models of consent for research use of biosamples

Survey participants were presented with four consent models (Table 1), and asked whether they would consider consenting residual biosamples to each of them, providing the research had been approved by a research ethics committee (described as a committee usually made up of doctors, scientist, patients and the general public which ensure any research allowed to be done is for the benefit of patients). Eighty percent would agree to specific consent – once only; 77% would consent to specific consent – for every new study; 71% would agree to tiered consent; and 67% of participants would agree to generic consent. When asked which model they preferred, specific consent - for every new study, was the first choice amongst those who had a preference (30% of participants overall), followed by generic consent and specific consent- once only, jointly second (both 18%), and lastly tiered consent (14%). Sixteen percent had no preference and 6% didn't know.

After collapsing the two specific consent models together (specific consent - for every new study and specific consent – once only), those participants who preferred specific consent were significantly more likely to: have a religious affiliation (63.9% vs. 48.9%, X^2=16.88(1); p<0.001); live in the North East or Scotland (60.9% vs. 42.7%, X^2=10.23(1), p=0.001); be over 65 years (67.1% vs. 57.1%, X^2=5.31(1), p=0.021); and be of a non-'White' ethnicity (68.9% vs. 58%, X^2=4.17(1), p=0.041). Using the boost sample we found that 'Black' participants were significantly more likely to prefer specific consent models compared with 'White' participants (75.6% vs. 58%, X^2=4.31(1), p=0.038). Those people who preferred opt-in consent were also more likely

to prefer specific consent models (71.1% vs. 35.3%, X^2=91.72(1), p<0.001). The strongest significant predictor for preferring specific consent was preferring opt-in consent (OR=4.58, 95% CI 3.30-6.35, p<0.001) followed by being of non-'White' ethnicity (OR=2.94, 95% CI 1.23-7.14, p=0.015) (Table 3).

We also looked at who was most likely to prefer generic consent, the least restrictive of the proposed consent models. Those that preferred generic consent were significantly more likely to: have no religious affiliation (51.1% vs. 36.1%, X^2=15.97(1), p<0.001); have some or good knowledge of the medical research process (26.1% vs. 18.3%, X^2=6.79(1), p=0.009); be male (26.8% vs. 19.9%, X^2=5.40(1), p=0.02); and be from a higher SEG group (A-D) (24.3% vs. 15.1%, X^2=4.66(1), p=0.031). They were also significantly more likely to prefer opt-out consent (64.7% vs. 28.9%, X^2=91.72(1), p<0.001). The strongest significant predictor for preferring generic consent was preferring opt-out consent (OR=4.55, 95% CI 3.13-6.67, p<0.001) followed by having no religious affiliation (OR=1.56, 95% CI 1.08-2.72, p=0.021) and some or good knowledge of the medical research process (OR=1.56, 95% CI 1.06-2.28, p=0.024) (Table 3).

Focus group preferences differed from those of survey responders with generic consent being equally popular (n=36; 44% and n=35; 43% respectively). Specific consent – once only, was least popular (n=6; 7%) (this was the only specific consent model given to participants). Four participants (5%) didn't know. Generic consent was valued as it provides most "flexibility for researchers"; reduces the likelihood residual biosamples will go to waste; is more straightforward to put in place; is "simpler to understand"; and enables biosamples to be used for more than "one specific thing".

"It's better not to restrict the possible use of the sample because by restricting it you're increasing the chance that it'll go to waste. You want the highest probability that something good will come from it." Male, patient – affected by a condition

Tiered consent was also valued because it provided more control over donated biosamples than generic consent, allowing people to opt-out of certain types of research, and therefore provided "clarity and peace of mind". All but one participant in the 'Black' focus group and all participants who had donated biosamples as healthy volunteers preferred tiered consent. Whilst specific consent was seen to provide the most control and enabled participants to have "some understanding of what it might be used for", concerns raised were that it "can't be used for anything else", "could be wasted" and would require a time-consuming explanation from health professionals.

In both the survey and focus groups, the donation of potentially sensitive biosamples produced a preference for specific consent. In the survey, a quarter (25%) preferred specific consent – for every new study, 22% preferred specific consent – once only, 12% preferred generic consent and 9% preferred tiered consent. Nineteen percent had no preference and 13% didn't know. When discussing donation of eggs, one woman commented:

"People could reproduce a child or whatever and it's about the personal-ness of what's been taken from you. So if it's a bit of blood, yeah take it, I mean you just cut yourself and blood is gone, but if it's something that's quite personal you only have every now and again, that needs to be guarded." Female, 'Black' ethnicity group

We asked survey participants whether they would like to be kept up-to-date with research going on at a particular hospital or biobank to which they had donated a biosample. Eighty-five percent said they would be interested; the most popular methods to receive updates were via a website (27%), email (27%) or letter (22%).

DISCUSSION

This study contributes further to our understanding of the UK public's views and preferences towards consent for the use of biosamples in medical research. In summary, we have found that: 1) the consenting process was perceived as important in order to maintain trust between patients and health professionals and respect patient autonomy; 2) survey participants exhibited a desire to retain active choice and control when donating biosamples and over the uses to which their biosamples might be put, and 3) these results differ from those reported during focus group discussions, where preference was for less restrictive consent models that are likely to increase availability of biosamples. These differences might be accounted for by the fact that focus group participants were given more background information about the use of residual biosamples in research and had time to consider the benefits and disadvantages of the different approaches. These interventions may have allayed any anxieties participants had about relinquishing control of their biosamples and seem to have encouraged participants to choose approaches that maximised biosample access to researchers, highlighting the importance and potential impact of education on influencing public perception in this area.

The preference for opt-in consent identified in the survey is consistent with the results of other studies in this area[3,15,16]. One reason for this preference may be that it matches the current system for organ donation for transplant in the UK. Nevertheless,

the sizeable number of survey responders who preferred opt-out consent (27%) coupled with the preference for opt-out amongst focus group participants (57%) does suggest that there may be broader support than previously believed for this approach. This point is also supported by the finding that fewer than half of survey participants wanted to be consented every time a sample was taken and nearly 30% preferred consent at certain points. Alternate, more streamlined approaches to consenting should therefore be considered and evaluated. Interestingly, our results showed that preference for opt-out consent was associated with being younger (under 65 years), from a higher SEG and a higher education level. These demographic groups may be more trusting of medical institutions to use residual biosamples appropriately, or perhaps feel empowered to be able to opt-out if so desired, for example, online. Similar findings have been reported in relation to organ donation; a study by Gimbel et al. found an association between cadaveric donation rate and percentage of the population enrolled in third-tier education[23]. Internet access has also been found to correlate with increased organ donation[24].

Concerning consent models for research use of biosamples, the majority of people were willing to donate biosamples via the least restrictive model, generic consent. Nevertheless, our survey findings suggest that willingness to donate increased where greater choice and control over research participation is retained, although the difference between those who were willing to agree to generic compared to specific was only 13%. Similarly, when survey responders were asked about their preferred approach, their preference was also for specific consent for every new study that might be conducted using their biosample. This may indicate a general interest in how samples are being used. This notion is supported by the high number of people who wanted ongoing contact about the research leading from their donation. Moreover, they may have not considered the practicalities of being asked to consent every time their sample is used, and the high level of recontact they might receive from research teams. Nevertheless, it is important to take note of the fact that more tailored forms of consent represent an attractive approach to many people. While specific consent may be practical for individual research projects, this restriction would make biobanking challenging, as biobanks exist to facilitate access to samples for a wide variety of approved research projects without the need for additional consent. It may be that as more sophisticated biosample tracking and management systems are adopted, resources could become available to support more interactive forms of consent, and more biobanks could offer tiered consent, for example. Further public dialogue and information about the use of the samples may also provide the same assurances for people that arise from specific consent, as highlighted by the preference for less restrictive consent models amongst focus group participants.

Evidence from other empirical studies looking at preferences for consent models is mixed. UK studies focusing on donations purely for research by 'healthy volunteers' to biobanks (i.e. not donating residual biosamples) have identified a preference for specific consent,[19,25] as did a study conducted in the USA that also focused on healthy volunteers[15]. Other empirical work conducted in the USA and Sweden has shown that public preference is for generic consent[3,16,18]. These findings highlight the divergence of opinion on this issue, in particular in different contexts and with different information provision, although the difficulty of comparing across studies with different methodologies and backgrounds must also be taken into account. Notably, where participants had some or good knowledge of the research process and where there was in-depth discussion (i.e. during focus groups), participants were more likely to prefer generic consent, a finding that has also been identified elsewhere in the literature[26] and supports the need for information and education if increasing the acceptability of generic consent is deemed desirable. Preference for specific consent was also found to be associated with being over 65 years and from a non-'White' ethnicity, findings which resonate with other studies[3,27,28]. Consent documentation and written information targeted specifically at these particular groups may also help alleviate any specific concerns these groups may have.

This research into current public attitudes regarding biosample donation in the UK provides valuable guidance for biobanking governance. Whilst generic consent is the model largely endorsed by regulators and funders in the UK[9,11], the evidence from this study suggests that there is a need to address the potential concerns that some people may have about the minimal information and lack of control provided through this model. Education and opportunity for discussion may be one way to allay concerns, as demonstrated through focus groups. Keeping donors informed of current research taking place at the hospital or research institutions to which they donated also appears to be desirable and is likely to be both motivating and promote public trust and confidence in the research process, a finding reported elsewhere[29]. The opportunity for face-to-face discussion with an appropriately trained healthcare professional at the time of donation may also allay any potential concerns, and is indeed the approach usually taken in the UK at present. This approach has been found to yield high acceptance rates amongst patients of well over 90%[30-32].

Strengths and Limitations

This was a mixed methods study to explore public views and preferences towards consent for biosample donation. Integrating quantitative and qualitative approaches is valuable in exploratory research as it can strengthen the inferences made through

triangulation and allow for a more nuanced understanding of the topic[33]. This study presented participants with a series of hypothetical questions about their preferences and willingness to donate residual biosamples for medical research. By presenting questions as 'real life' scenarios, we hoped to make the questions as realistic as possible. However, as with any hypothetical scenario, the findings may not necessarily correlate with actual behaviour. The questions for both the focus groups and the survey were piloted to ensure they were clear and understandable and were not biased towards any particular viewpoint. Nevertheless, many of the issues covered were complex, particularly around the meaning of the different consent models which may have contributed to the dropout rate. Participants who did complete the survey may have done so because of strong feelings about the issues raised and this may have skewed the results; however, every effort was made to ensure that the results were as representative of the UK population as possible. The focus groups and survey were conducted in English and so the findings may not be representative of non-English speaking members of the general public. Future research might target these particular groups.

CONCLUSION

There is a general willingness amongst the UK population to donate biosamples for medical research. Our research suggests that there is a preference amongst the UK public for more information on the uses and outcomes of research, and ongoing choice and control over donated biosamples. Our study also supports the premise that increased knowledge and opportunity for discussion is associated with acceptance of less restrictive consent models.

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Competing interests: Lesley Stubbins is an employee of GlaxoSmithKline. Mark Robertson is an employee of AstraZeneca.

Contributors: J.C. conceived the study. All authors contributed to the study design. In addition to all the authors, Sarah Dickson, Jim Elliott and the late Neil Formstone also contributed towards the design of the study and development of the focus group and survey questions. C.L. facilitated the focus groups. Focus group recruitment was conducted by the company The Focus Group; the survey was conducted through the market research company Research Now. C.L. conducted data analysis and interpretation with the help of Samantha Reeve and Zheng Lei. The initial draft of the manuscript was prepared by C.L and then circulated repeatedly among the authors for critical revision. All authors approved the final manuscript.

Ethical approval This study was approved by the Ethics Review Board of the University of Manchester, reference 11459.

Data sharing statement Transcripts from the focus groups and full results of the survey are available from CL at celine@geneticalliance.org.uk. Supplementary material is also available at www.geneticalliance.org.uk/projects/stratum_docs.htm

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Appendix 1

Attitudes Towards Donating Human Tissue Samples for Research

Participant Information Sheet

We would like to invite you to take part in a research study to help us understand what people think about donating human biological samples, (such as blood, saliva, types of blood tissues such as lung tissue, liver tissue) or tissue (e.g. lung tissue, saliva), or post mortem tissue, for medical research. These samples could be left over from a surgical procedure or they may be donated specifically for research purposes. Currently, we know very little about what people think about this issue. Please take the time to read the following information to help you decide whether you would like to take part.

Who will conduct this research? The research is part of the STRATUM project, a project set up to try to increase the effectiveness of tissue sample provision in the UK. It is being conducted with the help of a national charity, Genetic Alliance UK that represents over 150 patient organisations. The Focus Group are a reputable research company helping us to recruit members of the public. This study has received ethics approval from Manchester University.

What is the aim of this research? The aim is to understand what people think about donating human tissue samples for medical research.

Why have I been chosen? As a member of the public, your views are important. Your views will help us understand people's opinions and ensure that the donation of biological samples for medical research is carried out in a way that reflects people's wishes.

What would I be asked to do if I took part? We are inviting you to attend a group discussion to discuss your opinions about donating tissue samples for medical research. Don't worry if you feel you don't know a lot about this topic because discussions will be led by a trained moderator. We have provided some basic information along with this sheet that gives you some background about the topic. There are no right or wrong views; everyone's opinions will be equally valid.

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What happens to the data collected? The information collected from these discussions will be used to write a report which will be used to influence National policy. The findings will also be used to publish academic papers in journals.

How is confidentiality maintained? Discussions will be digitally recorded so that we can get an accurate account of what was said. However, when these are typed up, all comments will be anonymous and your name will not appear anywhere on the document. The documents will be kept secure on an encrypted hard drive and backed up on an encrypted memory stick which will be kept in a locked office. These documents and the audio files will be kept for 5 years and then destroyed. This information will not be passed on to any other third party.

What happens if I do not want to take part or if I change my mind? It is up to you whether or not to take part. If you do decide to take part you will be asked to sign a consent form saying that you have agreed to take part and have the conversation recorded. If you decide to take part you are still free to withdraw at any time without giving a reason and without detriment to yourself.

Will I be paid for taking part? As a thank you for taking part you will be given £50 which will be given at the end of the discussion.

What is the duration of the research? There will be between 6-8 people in the group which will last approximately 1.5 hours.

Where will the research be conducted?

What are the benefits from me taking part? There is no direct benefit to yourself from taking part, but your views will help to shape future policy.

Who will be running the group? The person running the focus group is Celine Lewis, who is a researcher with Genetic Alliance UK. If you have any concerns or questions about taking part in this research before the group then please contact Celine on 0207 704 3141. If you have agreed to take part and then find nearer the time you are no longer able to make the group then please contact the person who recruited you directly so that you can be replaced.

What if something goes wrong? In the unlikely event that you want to make a complaint about the conduct of the research, or would like help or advice following the discussion, you can contact the head of the project, Julie Corfield:
Email: juliecorfield@areteva.com
Tel: 0115 812 0008

Many thanks,

Celine Lewis

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Appendix II

Donating biological samples for medical research

Introduction
Medical research is necessary to improve our understanding of what keeps us healthy and how diseases start and progress. It also means scientists can develop new and improved treatments.

Body fluid (such as blood, saliva, urine) and human tissue (such as fat, cancer tumours or muscle) are often used in scientific and medical research. Types of research that need body fluid and human tissue include:

- Looking at how the body works to fight disease.
- Testing new treatments for conditions such as heart disease and diabetes.
- Developing tests for different types of cancer.
- Researching how certain types of cells could be used to treat conditions like Parkinson's disease, Alzheimer's disease and multiple sclerosis.

Many of the tests and treatments used today resulted from people donating body fluid and human tissue (often called 'samples') for research years ago.

How are human samples collected?
There are a number of ways that human samples can be collected:

- Samples may be left over after surgery. Tissue may be removed during surgery so tests can be done on the tissue or to stop the diseased tissue spreading to other parts of the body. After any necessary tests have been done on the tissue, there may be some left over. This left over tissue may be destroyed or used for medical research.
- Samples may be left over from a medical test such as a blood test.
- Samples might be donated specifically for medical research.
- A person may give permission (known as 'consent' or 'authorisation') for a sample to be taken and used for research in the event of their death.
- A person's family may give permission for the person's organs, which would have been donated for transplant, to be used for research if they are not suitable for transplant or a suitable recipient is not available.

The collection and use of samples is tightly governed by law in the UK. The removal of samples from a person is always done with the donor's permission, and any research first has to be approved by a research ethics committee. This committee is usually made up of doctors, scientist, patients and the general public, and ensures any research allowed to be done is for the benefit of patients. In specific circumstances the law allows samples that have already been collected to be used for another purpose, as long as the donor cannot be identified and the use has been approved by an ethics committee.

What is done with the sample once it is collected?
Samples may be collected by a researcher and used immediately, or they may be collected for research purposes and kept. This may be in a researcher's laboratory or it may be in a storage place specifically for samples, known as a biobank.

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The biobank keeps the samples so they can be used by scientists for research. In other words, biobanks are a little like libraries of samples, and only a research team can use them if they have the appropriate approval. A biobank has to follow regulations and have a licence, granted by the Human Tissue Authority (a UK Government organisation), to be able to store human tissue samples for research.

These systems ensure that any research respects the privacy of the people who donated the samples and that the research is of benefit to society. In many cases, it can be very important to have a patient's medical records along with their sample so that scientists can make sense of the results of their research. Any identifying information, such as names or addresses, is removed and not included with the sample.

How long is the biological sample kept?
A sample may be used all at once. However, it is often the case that it won't all be used in one go. Therefore the sample may be stored and used over many years so that research can be done on it well into the future.

What are the benefits from donating biological samples to medical research?
The person donating the sample is unlikely to benefit directly from the research, as it can take many years for the research on samples to produce new treatments or cures for diseases. Nevertheless, donors often see a benefit from knowing that they have personally helped medical research.

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The following information was used during the making of this leaflet:
"Donating samples for research; Patient information" – Central England Haemoto-Oncology Research Biobank
"Donating your tissue for research"- Human Tissue Authority
"Active choice but not too active: Public perspectives on biobank consent models" Simon et al. 2011; Genetics in Medicine

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Appendix III

Focus Group – Discussion Guide

Introduction (5 minutes)

Thank them for coming
Aim of discussion – hear people's views, there are no right or wrong opinions, disagreement OK
Participation voluntary
Confidentiality – all info anonymous, personal details will not be passed on to any third party
Get permission for recording to be taped – no names or identifying features used when typed up
Guidelines – talk one at a time; am interested in everyone's views so will try and give everyone equal 'airtime'; no wrong answers – be honest and open.
Turn mobile phones off
Go round room. Ask everyone to say their name and one of their favourite foods.

Research (30 minutes)

On the information sheet you've been given, there is some general information about donating samples for research. Has everybody had a chance to read this information? (if not give participants a few minutes to read document). So, to summarise….*give a brief overview of information on the document.*

1. So to start off, does anyone have any questions about anything I've said so far?

So I'd like us to think now about the different types of samples someone might donate to medical research. Human biological samples can mean a variety of different things including body fluid such as blood, saliva and sperm, and human tissue such as fat, cancer tumours or muscle or even whole organs.

2. Do you think there are some types of samples which are more sensitive to give than others? Which ones? Why?

There are also various different ways that samples can be collected. They might be

- left over from routine procedures such as surgery;
- left over after a medical test such as a blood test;
- donated specifically for medical research, for example a cheek swab or an extra blood sample;
- donated after a person's death;
- a person's organs e.g. heart or kidneys, which would have been donated for transplant, may be used for research if they are not suitable for transplant or a suitable recipient is not available. The relevant clinical data may also be included and reviewed after death.

3. I'd like us to go through each of these in turn and discuss whether you have concerns about any of these ways that samples might be collected and why. GO THROUGH AND PROBE EACH POINT SPECIFICALLY (AFTER GROUP DISCUSSION: ask participants to complete associated question on questionnaire)

4. Do you see donation of human samples for medical research and organ donation for transplant similarly or do you think they are different?

5. Thinking specifically about donating tissue or organs after one's death, do you think if someone has indicated in writing that they are willing to donate these for research in the event of their death, their wishes can be overridden by their relatives?

Samples may be used for a variety of different types of research. This might include looking at how the body works to fight disease; testing new treatments for conditions such as heart disease and diabetes or developing ways of diagnosing earlier different types of cancer.

6. Are there any types of research you would not be happy for your sample to be used for? Why?
   (AFTER GROUP DISCUSSION: ask participants to complete associated question on questionnaire)

There are many places where research is performed, such as universities, NHS, charities such as cancer research, government labs and pharmaceutical companies. These are all groups that do research & sometimes they collaborate with each other in order to make medical progress.

7. Do you have any concerns about any particular types of organisations using donated samples. Which if any, and why?

   (AFTER GROUP DISCUSSION: ask participants to complete associated question on questionnaire)

8. What do you think about the organisations that conduct research on samples? Do you think they are generally doing a good thing for society? Do you have any concerns about what they do?

9. Institutions such as the government and ethics review committees make decisions about what research can and can't be done on human samples. Ethics review committees are usually made up of different experts such as of doctors, scientists, ethics experts and patients Do you generally trust these types of institutions to make decisions about what research can and can't be done using human tissue samples?

Consent (40 minutes)

I'd like to now talk about getting permission, also known as consent, to use a person's sample for medical research. Most of us have probably had blood taken at some point and some of us will have had an operation. If we have blood taken for a test, there might be some blood left over after the test has been done. Similarly, tissue may be removed during an operation and there may be some left over after any necessary tests have been done on the tissue. So you would not have any additional tissue taken just for research purposes unless you had specifically given permission for this at the time it was going to be taken. In most cases, it is just the leftover blood or tissue that you might agree to donate to medical research.

10. Thinking about leftover blood or tissue being used for medical research, do you think a person needs to be asked for their consent? FOR EACH RESPONSE: Why/why not? How important is this to you?

11. What would you expect to happen to samples that are left over from clinical procedures?

12. The majority of the time, tissue that is left over is destroyed. How do you feel about that?

There are a number of different ways that a person could give their permission or consent for their sample to be used for medical research. I'd like us to think about some of these now and discuss what we like and what we dislike about these different types of consent.

I'd like us to start by thinking about whether we prefer what is known as an **opt-in** system, or whether we prefer an **opt-out** system of sample donation.

Opt-in means that a person has to say that, after they turn 18, they are willing to and actively agree to donate their sample for research. This is how the current system for organ donation works in the UK.

The other approach is an opt-out approach. In this system, it is assumed that a person is happy, after they turn 18, for their sample to be used for research unless they specifically say otherwise. However, there is a mechanism in place for a person who is not willing to donate to opt out.

So, to start with, lets think about the first option, OPT-IN.

13. What do you think are the pros and cons about this approach? Why?

14. Thinking now about the OPT-OUT approach, what you think are the pros and cons? Why?

15. Which do you prefer? How important is this to you? (AFTER GROUP DISCUSSION: ask participants to complete associated question on questionnaire)

The current system is an opt-in one, so I want us to think about this type of consent now. If you were going to be asked to donate any leftover blood or tissue for medical research there are two ways this could be done. You could be asked to give consent **every time** you have an operation or blood test, or you could give consent just **once for life for all your samples,** with the option of withdrawing at a later point if you wanted to.

16. Thinking about **consent every time**, what do you think are the advantages and disadvantages of this approach?

17. Thinking about **consent once for life**, what do you think are the advantages and disadvantages of this approach?

18. Can you think of any happy medium which might be better?

19. Which would you prefer? Why? How important is this to you? (AFTER GROUP DISCUSSION: ask participants to complete associated question on questionnaire)

20. If people gave consent just once, when and where do you think the best place would be to give consent?

21. If someone wanted to consent to donate their tissue or organs for medical research in the event of their death, do you think it should be obtained at the same time as consent for organ transplantation and recorded on the organ donor register?

In front of you, you have 3 different scenarios. In each one the story is essentially the same, however there are some slight differences and these are highlighted in bold. I'd like to discuss what you think of each of these in turn.

Read all 3 scenarios out loud highlighting the key differences between the three. Then go back and discuss each one in turn.

Scenario 1: Lisa is having surgery to remove a lump from her breast which the doctor is concerned may be cancerous. Before the surgery the surgeon explains that once the tissue is removed, they will take it to the laboratory to do tests on it to check what it is. The surgeon then explains that after these tests are done, there may be some tissue left over. He asks Lisa if she would like to donate this left over tissue for medical research. If it is not donated for medical research it will be destroyed. The surgeon doesn't know exactly what kinds of research the tissue might be used for, but it may be used to find better ways to diagnose, prevent and treat cancer. He also explains that before any research is done, it has to be approved by an independent ethics committee.

So, in this scenario:

- Lisa is asked to give consent once to donate the left over tissue for a range of future unknown uses
- Lisa is given some general information about the kind of research the tissue might be used for but nothing specific.
- This type of consent is known as GENERIC CONSENT

22. What do you think about this type of consent?

23. What do you **like** about this approach?

24. Do you have **any concerns** about this approach?

Scenario 2: Lisa is having surgery to remove a lump from her breast which the doctor is concerned may be cancerous. Before the surgery the surgeon explains that once the tissue is removed, they will take it to the laboratory to do tests on it to check what it is. The surgeon then explains that after these tests are done, there may be some tissue left over. He asks Lisa if she would like to donate this left over tissue for medical research. If it is not donated for medical research it will be destroyed. The surgeon doesn't know exactly what types of research the tissue might be used for, but it may be used to find better ways to diagnose, prevent and treat cancer. Lisa is asked to sign a consent form. The surgeon explains that **Lisa can indicate on the consent form whether there are any particular kinds of research which she doesn't want the tissue to be used for, for example research involving animals or research conducted outside the UK.** He also explains that before any research is done, it has to be approved by an independent ethics committee.

So, in this scenario:

- Lisa is asked to give consent once to donate the tissue for a range of future unknown uses;
- Lisa is given some general information about the kind of research the tissue might be used for;
- **Lisa can say if there are any particular kinds of research which she doesn't want the tissue to be used for.**
- This type of consent is known as TIERED CONSENT

25. What do you think about this type of consent?

26. What do you **like** about this approach?

27. Do you have any **concerns** about this approach?

Scenario 3: Lisa is having surgery to remove a lump from her breast which the doctor is concerned may be cancerous. Before the surgery the surgeon explains that once the tissue is removed, they will take it to the laboratory to do tests on it to check what it is. The surgeon then explains that after these tests are done, there may be some tissue left over. He asks Lisa if she would like to donate this left over tissue for medical research. If it is not

donated for medical research it will be destroyed. The surgeon explains that **the hospital are currently involved in a study looking at the growth of tumours. He informs her that if she gives permission for the left over tissue to be used, it would only be for this particular study.** He also explains that the study has been approved by an independent ethics committee.

So, in this scenario:

- **Lisa is only asked to give consent to a particular study and is given information about that study.**
- This type of consent is known as SPECIFIC CONSENT

28. What do you think about this type of consent?

29. What do you **like** about this approach?

30. Do you have any **concerns** about this approach?

31. In this exercise we have discussed three different types of consent. Which do you prefer and why? GO ROUND AND ASK PEOPLE (AFTER GROUP DISCUSSION: ask participants to complete associated question 6 & 7 on questionnaire)

32. Generic consent is the most practical type of consent as it is the least costly to put in place. Researchers try their very best to honour donors' wishes, but in some cases where they cannot do this with confidence, instead of risking using a sample for something the donor feels strongly against, it won't be used at all. If your first choice wasn´t generic consent, does this information change your preference? (AFTER GROUP DISCUSSION: ask participants to complete question 8.

33. So, we've discussed which type of consent you would like for left over samples. Would your preference be any different for samples that you might donate specifically for research, e.g. if you volunteered to took part in a study and had to give a saliva or blood sample?

34. Would your preference be any different if you were donating what you might consider to be more sensitive samples e.g. genetic data, stem cells?

35. If you decide to withdraw consent would you be happy for researchers to use the data that had already been generated up to that point using your sample?

36. Do you think a central website where you can find out about general research that your sample might be used for would be useful and something you would use?

Information (10 minutes)

Researchers often need to have access to the donor's medical records in order to be able to meaningfully interpret the results of the scientific research. However, information, such as names or addresses are always removed and not included with the sample. This is so that the person who donated the sample cannot be identified by the scientist conducting the research or anyone analysing the results of the research. However, the sample may have a code so that someone not involved in the research can identify the individual if necessary.

37. Would you be happy with your medical records being linked to your sample or would you have concerns? Why?

38. Are there any types of information you would not want to be associated with your sample?

Sometimes it can also be helpful for the researcher to have certain information about the lifestyle of the person who donated the sample, for example whether they smoked, drank alcohol, how often they exercised etc. This information might help them to better understand the particular condition they are investigating.

39. Would you be happy for this information to be made available or would you have concerns about your lifestyle information being associated with your sample? Why?

Ownership of sample (5 minutes)

40. What significance do you attach to a biological sample once it has been removed from your body? Do you still see it as yours or part of you in some way? Are you owed money if a drug is developed using your sample?

Appendix IV

CONSENT MODELS

GENERIC CONSENT

Scenario 1: Lisa is having surgery to remove a lump from her breast which the doctor is concerned may be cancerous. Before the surgery the surgeon explains that once the tissue is removed, they will take it to the lab to do tests on it to check what it is. After these tests are done, there may be some tissue left over. He asks Lisa if she would like to donate this left over tissue for medical research. If it is not donated for medical research it will be destroyed. The surgeon doesn't know exactly what kinds of research the tissue might be used for, but it may be used to find better ways to diagnose, prevent and treat cancer. He also explains that before any research is done, it has to be approved by an independent ethics committee.
So, in this scenario:

- Lisa is asked to give consent once to donate the left over tissue for a range of future unknown uses
- Lisa is given some general information about the kind of research the tissue might be used for but nothing specific.

TIERED CONSENT

Scenario 2: Lisa is having surgery to remove a lump from her breast which the doctor is concerned may be cancerous. Before the surgery the surgeon explains that once the tissue is removed, they will take it to the lab to do tests on it to check what it is. After these tests are done, there may be some tissue left over. He asks Lisa if she would like to donate this left over tissue for medical research. If it is not donated for medical research it will be destroyed. The surgeon doesn't know exactly what types of research the tissue might be used for, but it may be used to find better ways to diagnose, prevent and treat cancer. Lisa is asked to sign a consent form. The surgeon explains that **Lisa can indicate on the consent form whether there are any particular types of research which she doesn't want the tissue to be used for, e.g. research involving animals or research outside the UK.** He also explains that before any research is done, it has to be approved by an independent ethics committee.
So, in this scenario:

- Lisa is asked to give consent once to donate the tissue for a range of future unknown uses;
- Lisa is given some general information about the kind of research the tissue might be used for;
- **Lisa can say if there are any particular types of research which she doesn't want the tissue to be used for.**

SPECIFIC CONSENT

Scenario 3: Lisa is having surgery to remove a lump from her breast which the doctor is concerned may be cancerous. Before the surgery the surgeon explains that once the tissue is removed, they will take it to the lab to do tests on it to check what it is. After these tests are done, there may be some tissue left over. He asks Lisa if she would like to donate this left over tissue for medical research. If it is not donated for medical research it will be destroyed. The surgeon explains that **the hospital are currently involved in a study looking at the growth of tumours. He informs her that if she gives permission for the left over tissue to be used, it would only be for this particular study.** He also explains that the study has been approved by an independent ethics committee.

So, in this scenario:

- **Lisa is only asked to give consent to a particular study and is given information about that study.**

Appendix V

Survey looking at the publics' views on donating biological samples for medical research

This survey was originally conducted online in September 2012 and hosted by the market research company Research Now.

Q1. What age are you?

1. 18-24
2. 25-34
3. 35-44
4. 45-54
5. 55-64
6. 65+

Q2. Are you male or female?

1. Male
2. Female

Q3. What is the occupation of person who receives the highest income in your household?

1. Higher managerial/ professional/ administrative (e.g. established doctor, solicitor, board director in a large organisation (200+ employees, top level civil servant/public service employee)) **(A – Letters will be hidden)**
2. Intermediate managerial/ professional/ administrative (e.g. newly qualified (under 3 years) doctor, solicitor, board director small organisation, middle manager in large organisation, principle officer in civil service/local government) **(B)**
3. Supervisory or clerical level/ junior managerial/ professional/ administrative (e.g. office worker, student doctor, foreman with 25+ employees, salesperson, etc) **(C1)**
4. Student **(C1)**
5. Skilled manual worker (e.g. skilled bricklayer, carpenter, plumber, painter, bus/ ambulance driver, HGV driver, AA patrolman, pub/bar worker, etc) **(C2)**
6. Semi or unskilled manual work (e.g. manual workers, all apprentices to be skilled trades, caretaker, park keeper, non-HGV driver, shop assistant) **(D)**
7. Casual worker – not in permanent employment **(E)**
8. Housewife/househusband/ homemaker **(E)**
9. Retired and living on state pension **(E)**
10. Unemployed or not working due to long-term sickness **(E)**
11. Full-time carer of other household member **(E)**

98. Other (specify)

Q4. What region do you live in?

1. Channel Islands
2. East of England
3. East Midlands
4. London
5. North East
6. North West
7. Northern Ireland
8. Scotland
9. South East
10. South West
11. Wales
12. West Midlands
13. Yorkshire / Humberside
96. Not on Map

Q5. Please choose one option that best describes your ethnic group or background.

1. White or White British
2. Mixed race
3. Asian or Asian British (not Chinese)
4. Black or Black British
5. Chinese
6. Other ethnic group
96. Prefer not to say

Q6. Which religion do you most identify with?

1. Christianity
2. Islam
3. Hinduism
4. Sikhism
5. Judaism
6. Buddhism
7. Other religion
8. No religion
96. Prefer not to say

Q7. If you do have a religion you identify with, to what extent do you consider yourself religious?

1. Not at all religious
2. Moderately religious
3. Very religious
96. Prefer not to say

Q8. Please indicate which, if any, is the highest educational or professional qualification you have obtained.

1. No formal qualification
2. GCSE, O level, Scottish Standard Grade or equivalent
3. GCE, A-level, Scottish Higher or similar
4. Vocational (BTEC/NVQ/Diploma)
5. Degree level or above
96. Prefer not to say

Q9. How would you describe your own level of knowledge about the medical research process including the use of human tissue samples?

1. No knowledge
2. Some knowledge
3. Good knowledge

Q10. Are you or have you ever been affected by a long-standing illness, disability or infirmity which has required continuous or frequent medical attention (e.g. cancer, diabetes, heart disease, asthma, a genetic condition)?

1. Yes
2. No

Q11. Has a close family member ever been affected by a long-standing illness, disability or infirmity which has required continuous or frequent medical attention (e.g. cancer, diabetes, heart disease, asthma, a genetic condition)?

1. Yes
2. No

Q12. Have you ever had blood or tissue removed during a medical or surgical procedure?

1. Yes
2. No
97. Don't know

Q13. Have you ever been asked to donate any blood or tissue for medical research?

1. Yes
2. No
97. Don't know

ASK IF CODED 1 AT Q13.

Q14. Did you agree to donate?

1. Yes
2. No
97. Don't know

ASK IF CODED 2 AT Q14.

Q14a. Please tell us a little bit about your reasons for choosing not to donate.
There are no right or wrong answers – we're just interested in your honest opinion.

This survey is being done to help us understand public opinion about human tissue samples donated by people for medical research.

Medical research is essential to improve our understanding of what keeps us healthy and how diseases start and progress. It also means scientists can develop new and improved treatments. Body fluid such as blood, saliva and urine, and human tissue such as cells, skin, fat or even whole organs (in the event of someone's death), are often used in scientific and medical research. Usually these are referred to as samples.

Types of research that need samples include:

- Looking at how the body works to fight disease.
- Looking at why some people are more likely to develop certain diseases.
- Developing tests to diagnose conditions like cancer or dementia earlier on.
- Testing new treatments for conditions such as heart disease and diabetes.
- Researching how certain types of cells could be used to treat conditions like Parkinson's disease and Alzheimer's disease.

Many of the tests and treatments used today resulted from people donating samples for research previously. The removal of samples from a person is always done with the donor's permission. Samples that are donated for research are anonymised so that the researcher using the sample does not know who it came from. The types of research that are allowed to take place are highly regulated by both UK law and also by independent research ethics committees (usually made up of doctors, scientist, patients and the general public). These ensure any research allowed to be done is for the benefit of patients.

The next button will appear shortly. In the meantime take some time to read the information above as it relates to the remainder of the survey.

Q15. On a scale of 1 to 5 with 1 being Not At All Important and 5 being Extremely Important, how important do you think it is for people to donate samples for medical research?

SCALE:

1. Not at all important
2.

3.
4.
5. Extremely important
97. Don't know

Q16. Samples can be left over from surgery or a medical procedure, or they can be donated specifically for research. Left over samples that are not required for clinical diagnosis or donated for medical research are often destroyed.

In general, would you like to be asked to donate samples for medical research?

1. Definitely yes
2. Probably yes
3. Probably not
4. Definitely not
97. Don't know

RANDOMISE STATEMENTS

Q17. You are having a medical procedure to treat a health issue. Would you donate the following types of samples for medical research if they were left over (after necessary medical tests had been done) following the procedure?

SCALE:

1. Definitely yes
2. Probably yes
3. Probably not
4. Definitely not
97. Don't know

STATEMENTS:

1. Blood
2. Skin tissue
3. Fat
4. Cancerous tissue
5. Liver tissue
6. Bone or cartilage
7. Spare eggs not fertilised during IVF treatment (IVF is a process by which an egg is fertilised by a sperm outside the body and then transferred back into the body to establish a successful pregnancy) **ASK ONLY FEMALES**
8. Spare embryos (fertilised eggs) not transferred back into the body following IVF (IVF is a process by which an egg is fertilised by a sperm outside the body and then transferred back into the body to establish a successful pregnancy)

RANDOMISE STATEMENTS

Q18. You've gone to the hospital for an appointment and whilst you are in the waiting room the receptionist explains they are collecting samples for medical research. Would you agree to donate the following types of samples specifically for medical research, i.e. not as part of any medical procedure, put purely for the purposes of research?

Would you agree to donate the following types of samples specifically for medical research? Below are some definitions you might need to know in order to answer the questions.

Local anaesthetic - "A type of painkilling medication that is used to numb areas of the body during surgical procedures. You stay awake when you have a local anaesthetic"

General anaesthetic - "A medication that causes loss of sensation. It is used to give pain relief during surgery. General anaesthetic makes you completely lose consciousness so that surgery can be carried out without causing any pain or discomfort. Most healthy people don't have any problems when having a general anaesthetic. However, as with most medical procedures, there is a small risk of long-term complications and, rarely, death."

SCALE:

1. Definitely yes
2. Probably yes
3. Probably not
4. Definitely not
97. Don't know

STATEMENTS:

1. Saliva
2. Urine
3. Blood
4. Tissue collected requiring a local anaesthetic (e.g. a skin cell scraping)
5. Tissue collected requiring a general anaesthetic (e.g. a liver sample)
6. Sperm **ASK ONLY MALES**

Q19. In the event of your death, would you be willing to donate the following for medical research?

SCALE:

1. Definitely yes
2. Probably yes
3. Probably not
4. Definitely not
97. Don't know

STATEMENTS:

1. A small sample of the liver
2. A small sample of the brain
3. A whole liver
4. A whole brain

Q20. You are having surgery for a health issue which requires a general anaesthetic. The surgeon asks you whether you would be willing to consent to any additional tissue (i.e. tissue not needing to be removed as part of the health issue) being taken during the surgery for medical research. He assures you that any additional tissue taken would have no impact for you or your health and that no extra tissue would be removed without your consent.

A decision to consent or not to consent would be equally respected and would have no impact on the care you receive.

Would you be willing to donate the following types of samples for medical research?

General anaesthetic - "A medication that causes loss of sensation. It is used to give pain relief during surgery. General anaesthetic makes you completely lose consciousness so that surgery can be carried out without causing any pain or discomfort. Most healthy people don't have any problems when having a general anaesthetic. However, as with most medical procedures, there is a small risk of long-term complications and, rarely, death."

SCALE:

1. Definitely yes
2. Probably yes
3. Probably not
4. Definitely not

97. Don't know

STATEMENTS:

1. Samples taken from the same part of the body being operated on
2. Samples taken from an area close by
3. Samples involving an additional procedure e.g. taking bone marrow or a tissue sample whilst under the same general anaesthetic

RANDOMISE STATEMENTS

Q21. Samples may be used for lots of different types of research. The types of research that are allowed to take place are highly regulated by both UK law and also by research ethics committees. Would you be willing to donate samples for the following types of research?

Research ethics committee - "A committee usually made up of doctors, scientist, patients and the general public. These ensure any research allowed to be done is for the benefit of patients."

SCALE:

1. Definitely yes
2. Probably yes
3. Probably not
4. Definitely not
97. Don't know

STATEMENTS:

1. Understanding how our body fights disease
2. Understanding how our genetic makeup influences whether or not we will be affected by certain conditions
3. Testing new treatments
4. Research which involves using cells that come from embryos *(fertilised eggs)*
5. Research involving animals
6. Research conducted outside of the UK

RANDOMISE ORDER OF STATEMENTS.

Q22. There are many places where research is performed, such as universities, the NHS, medical research charities such as Cancer Research UK and Arthritis Research UK, pharmaceutical companies and diagnostic companies. These organisations work individually, and often in collaboration, to carry out research, to understand disease, develop tests for diseases and develop and test new treatments.

Would you be willing to donate samples to the following organisations to carry out approved medical research?

Diagnostic companies - "A company which develops and manufactures medical tests to diagnose diseases"

SCALE:

1. Definitely yes
2. Probably yes
3. Probably not
4. Definitely not
97. Don't know

STATEMENTS

1. NHS hospitals
2. Universities
3. Medical research charities
4. Pharmaceutical companies
5. Diagnostic companies

Q23. Samples left over following surgery and once any necessary tests have been done, can be anonymised and used for medical research. On a scale of 1 to 5 with 1 being Not At All Important and 5 being Extremely Important, how important do you think it is that you are first asked for your permission (often known as 'consent') for any left over samples to be used for medical research?
Anonymised - i.e. identifying features such as names and addresses are removed

SCALE:

1. Not at all important
2.
3.
4.
5. Extremely important

Q24. There are a number of different ways that a person could give consent for their left over samples to be used for medical research.

a) One way is an 'opt-in' system. Opt-in means that a person must specifically be asked for their permission before any leftover samples can be used in medical research.

b) The other way is an 'opt-out' system. In this system, it is assumed that a person is happy, after they turn 18 years old, for any leftover samples to be used for medical research unless they specifically say otherwise.

Which of the two systems to donating leftover samples do you prefer?

1. Opt-in
2. Opt-out
3. No preference
97. Don't know

Q25. The current system in the UK is an opt-in system. That means you have to say whether you want any leftover samples to be donated for medical research. If you were going to be asked to donate any leftover samples for medical research there are three ways this could be done.

a) You could be asked to give consent for left over samples to be used for research **every time** you have samples removed, or

b) you could be asked just **once for life** for any future left over samples to be used for medical research (with the option of withdrawing your permission at any later point if you wanted to),

c) you could be **asked at certain points** during your life, for example every 10 years by your GP, or at the start of treatment for a particular condition or health issue.

Which of these three approaches do you prefer?

1. Consent every time
2. Consent once for life
3. Consent at certain points
4. No preference
97. Don't know

Q26. If you were going to be asked to donate left over samples for medical research every time you had a medical procedure, would you rather this was discussed with you by a health professional before the medical procedure or afterwards?

1. Before
2. After
3. No preference
97. Don't know

Q27. If we adopted a consent once for life system in the UK for adults (i.e. aged 18 years and over), when would you prefer to be asked about consenting left over samples for medical research? *Choose up to 3 options.*

1. When registering at a GP surgery
2. During a routine GP appointment
3. When applying for a driving license
4. When applying for a passport
5. The first time I visit the hospital
6. The first time I have a medical procedure (e.g. blood test or surgery)
98. Other (please specify)

Q28. What would be your preferred way to register your consent to donate left over samples for medical research?

1. Face to face with a health professional
2. Letter
3. Email
4. Telephone
5. Via a website
6. Completing a form (from a GP surgery, post office, library or other community centre) and returning it by post
98. Other (please specify)
97. Don't know

Q29. If you later decided you didn't want your samples to be used for medical research, what would be your preferred way to withdraw that consent?

1. Face to face with a health professional
2. Letter
3. Email
4. Telephone
5. Via a website
6. Completing a form (from a GP surgery, post office, library or other community centre) and returning it by post

98. Other (please specify)
97. Don't know

Q30. Imagine you have agreed to donate a sample for medical research. There are a number of ways you can give consent for that particular sample to be used:

STATEMENTS

1. You can give consent once for your sample to be used in any future research that has been approved by a research ethics committee. This type of consent is called Generic Consent.

   Thinking about Generic Consent, if this was the type of consent you were asked to give, how likely would you be to donate samples for medical research?

   Research ethics committee. "A committee usually made up of doctors, scientist, patients and the general public. These ensure any research allowed to be done is for the benefit of patients."

2. You can give consent once for your sample to be used in any future research that has been approved by a research ethics committee but with the option of saying whether there are certain types of research you don't want your sample to be used for. This type of consent is called Tiered Consent.

   Thinking about Tiered Consent, if this was the type of consent you were asked to give, how likely would you be to donate samples for medical research?

   Research ethics committee. "A committee usually made up of doctors, scientist, patients and the general public. These ensure any research allowed to be done is for the benefit of patients."

3. You can give consent once for the sample to be used for a specific study that you have been told about, which has been approved by a research ethics committee. The sample will not be used for any other research other than the particular study you have given consent for. Any leftover tissue at the end of the study may be destroyed. This type of consent is called Specific Consent – once only.

   Thinking about Specific Consent – once only, if this was the type of consent you were asked to give, how likely would you be to donate samples for medical research?

   Research ethics committee. "A committee usually made up of doctors, scientist, patients and the general public. These ensure any research allowed to be done is for the benefit of patients."

4. **Lastly**, you can give consent every time for the sample to be used for a specific study that you have been told about, which has been approved by a research ethics committee. With this type of consent you would then be contacted and asked for your consent for every new study in which your sample might be used. This type of consent is called Consent for every new study.

   Thinking about Consent for every new study if this was the type of consent you were asked to give, how likely would you be to donate samples for medical research?

   Research ethics committee. "A committee usually made up of doctors, scientist, patients and the general public. These ensure any research allowed to be done is for the benefit of patients."

SCALE:

1. Definitely yes
2. Probably yes
3. Probably not
4. Definitely not
97. Don't know

Q31. Which of these four types of consent do you prefer? Please rank them in order of preference. Put 1 for your first preference; 2 for your second; 3 for your third preference and 4 for your last preference. If you don't have any preference, and like all 4 equally, tick the 'No preference' you don't know then tick ' Don't know'

1. Generic consent
2. Tiered consent
3. Specific consent – once only
4. Consent for every new study
5. No preference
97. Don't know

ASK TO THOSE PEOPLE WHO DID NOT RANK GENERIC CONSENT AS FIRST CHOICE

Q32. Generic consent is the most practical type of consent as it is the least costly to put in place. Researchers try their very best to honour donors' wishes, but in some cases where it is too costly to put Tiered or Specific Consent in place, instead of risking using a sample for something the donor feels strongly against, it won't be used at all. If Tiered or Specific consent was not available, what would you do?

1. I would agree to give generic consent
2. I would rather my sample was not used at all

97. Don't know

Q33. Some people feel there are certain types of samples that are more sensitive to donate, for example sperm or left over eggs. If there was a sample that you considered to be sensitive, but were still willing to donate for medical research, which of the four types of consent would you prefer to give?

1. Generic consent
2. Tiered consent
3. Specific consent – once only
4. Consent for every new study
5. No preference

97. Don't know

Q34. Researchers often need to have access to the donor's medical records to be able to interpret the results of their scientific research. However, information such as names or addresses are always removed and are not included with the sample. This is so that the person who donated the sample cannot be identified by the scientist conducting the research or anyone analysing the results of the research. However, the sample may have a code so that someone not involved in the research can identify the individual if necessary, for example, if there was a serious health issue the donor should be aware of.

Would you be willing to have your anonymised medical records linked to your sample?

1. Definitely yes
2. Probably yes
3. Probably not
4. Definitely not

97. Don't know

Q35. Sometimes it can also be helpful for the researcher to have certain information about the lifestyle of the person who donated the sample, for example whether they smoke, drink alcohol, how often they exercise etc. This information might help them to better understand the particular

condition they are investigating. Would you be willing to have your anonymised lifestyle information linked to your sample?

1. Definitely yes
2. Probably yes
3. Probably not
4. Definitely not
97. Don't know

Q36. For some people, it would be interesting to find out what type of medical research is going on. How would you like to get information on medical research including research on a particular condition that might use your sample?

1. Website
2. Newsletter
3. Email
4. Letter
5. Would not be interested in additional information

Q37. If you were considering donating whole organs for medical research in the event of your death, are there any particular organs you would **not** feel comfortable donating?
Please choose all that apply.

1. Brain
2. Eyes
3. Heart
4. Kidneys
5. Liver
6. Lungs
7. I would not donate any of my organs for medical research
8. None of the above apply as I would be happy to donate either all my organs or whole body for research

98. Other organs I would not donate (please state)

Q38. Sometimes, organs donated for transplant can't be transplanted because for some reason they are not suitable. However, these organs can still be very useful to researchers. Would you be willing to donate organs you had intended for transplant for medical research instead if the organ was not suitable?

1. Yes, I would donate an organ for research if it was not suitable for transplant
2. No, if they can't be used for transplant I would prefer they were not used at all
3. I would not agree to donate an organ for transplant

97. Don't know

Q39. If someone wanted to donate their tissue or organs for medical research in the event of their death, how do you think they should be able to provide their consent to do this?

1. It should be obtained at the same time as consent for organ transplantation and recorded on the organ donor register
2. It should be discussed at a GP appointment and recorded in the patients' notes
3. It should be discussed at a hospital and recorded in the patients' notes
98. Other (please specify)
97. Don't know

Q40. Someone has indicated in writing that they are willing to donate tissue or organs for medical research in the event of their death. After the donor's death the relatives decide they disagree with the donor's wishes. Do you think the relatives should be allowed to override the donor's wishes?

1. Yes
2. No
97. Don't know

Q41. If you have any particular views you would like to share with us about the topics raised in this questionnaire please feel free to write them here:

Appendix VI

Results of survey –unweighted and weighted

Demographic Data				
	Unweighted		Weighted	
	N	%	N	%
Sex				
Male	504	45%	544	49%
Female	606	55%	566	51%
Socioeconomic Group				
A	41	4%	44	4%
B	215	19%	244	22%
C1	311	28%	322	29%
C2	233	21%	233	21%
D	145	13%	178	16%
E	165	15%	89	8%
Age				
18-24	135	12%	133	12%
25-34	184	17%	189	17%
35-44	198	18%	200	18%
45-54	184	17%	189	17%
55-64	176	16%	167	15%
65+	233	21%	233	21%
Occupation				
Higher managerial	41	4%	44	4%
Intermediate managerial	215	19%	244	22%
Supervisory or clerical level	288	26%	299	27%
Student	23	2%	23	2%
Skilled manual worker	233	21%	233	21%
Semi or unskilled manual work	145	13%	178	16%
Casual worker	12	1%	6	1%
Housewife	9	1%	5	0%
Retired	81	7%	45	4%
Unemployed	46	4%	24	2%
Carer	17	2%	9	1%
Other	0	0%	0	0%
Region				
Channel Islands	0	0%	0	0%
East of England	92	8%	100	9%
East Midlands	57	5%	78	7%

Appendix VI

Results of survey –unweighted and weighted

London	213	19%	144	13%
North East	40	4%	44	4%
North West	121	11%	122	11%
Northern Ireland	30	3%	33	3%
Scotland	76	7%	89	8%
South East	165	15%	155	14%
South West	81	7%	89	8%
Wales	51	5%	55	5%
West Midlands	94	8%	100	9%
Yorkhire/Humberlands	90	8%	100	9%
Not on map	0	0%	0	0%
Ethnicity				
White or White British	1057	95%	1065	96%
Mixed race	7	1%	8	1%
Asian or Asian British (not Chinese)	18	2%	17	1%
Black or Black British	19	2%	12	1%
Chinese	2	0%	2	0%
Other ethnic group	4	0%	2	0%
Prefer not to say	3	0%	2	0%
Religion				
Christianity	677	61%	673	61%
Islam	13	1%	11	1%
Hinduism	6	1%	6	1%
Sikhism	0	0%	0	0%
Judaism	6	1%	4	1%
Buddhism	11	1%	1	0%
Other religion	15	1%	8	0%
No religion	370	33%	205	38%
Prefer not to say	12	1%	7	1%
To what extent do you consider yourself religious?				
Not at all religious	234	32%	234	32%
Moderately religious	422	58%	424	59%
Very religious	64	9%	56	8%
Prefer not to say	8	1%	7	1%
Education				
No formal qualification	70	6%	66	6%
GCSE, O level, Scottish Standard Grade or equivalent	264	24%	252	23%

Appendix VI

Results of survey –unweighted and weighted

GCE, A-level, Scottish Higher or similar	214	19%	214	19%
Vocational (BTEC/NVQ/Diploma)	230	21%	237	21%
Degree level or above	317	29%	330	30%
Prefer not to say	15	1%	10	1%

Q9 How would you describe your own level of knowledge about the medical research process including the use of human tissue samples?

	Unweighted		Weighted	
	N	%	N	%
No knowledge	463	42%	466	42 %
Some knowledge	603	54 %	602	54 %
Good knowledge	44	4 %	43	4 %

Q10 Are you or have you ever been affected by a long-standing illness, disability or infirmity which has required continuous or frequent medical attention

	Unweighted		Weighted	
	N	%	N	%
Yes	399	36 %	391	35%
No	711	64 %	719	65%

Q11 Has a close family member ever been affected by a long-standing illness, disability or infirmity which has required continuous or frequent medical attention

	Unweighted		Weighted	
	N	%	N	%
Yes	767	69 %	765	69%
No	343	31 %	345	31%

Q12 Have you ever had blood or tissue removed during a medical or surgical procedure?

	Unweighted	Weighted

Appendix VI

Results of survey –unweighted and weighted

	N	%	N	%
Yes	446	40 %	444	40%
No	553	50 %	551	50%
Don't Know	111	10 %	115	10%

Q13 Have you ever been asked to donate any blood or tissue for medical research?				
	Unweighted		Weighted	
	N	%	N	%
Yes	182	16 %	177	16%
No	904	81 %	907	82%
Don't Know	24	2 %	25	2%

Q14 Did you agree to donate?				
	Unweighted		Weighted	
	N	%	N	%
Yes	155	85 %	153	86%
No	23	13 %	21	12%
Don't Know	4	2 %	3	2%

Q15 On a scale of 1 to 5 with 1 being Not At All Important and 5 being Extremely Important, how important do you think it is for people to donate samples for medical research?				
	Unweighted		Weighted	
	N	%	N	%
1 Not at all important	5	0 %	4	0%
2	10	1 %	9	1%
3	78	7 %	76	7%
4	406	37 %	408	37%
5 Extremely important	554	50 %	567	51%
Don't know	57	5 %	46	4%

Appendix VI

Results of survey –unweighted and weighted

Q16 In general, would you like to be asked to donate samples for medical research?				
	Unweighted		Weighted	
	N	%	N	%
Definitely yes	317	29 %	327	29%
Probably yes	513	46 %	526	47%
Probably not	157	14 %	145	13%
Definitely not	42	4 %	35	3%
Don't know	81	7 %	77	7%

Q17 Would you donate the following types of samples for medical research if they were left over following the procedure?											
		Unweighted					Weighted				
		Def yes	Prob yes	Prob not	Def not	Don't know	Def yes	Prob yes	Prob not	Def not	Don't know
Blood	N	587	433	48	23	19	599	425	48	20	8
	%	53%	39%	4%	2%	2%	54%	38%	4%	2%	2%
Skin Tissue	N	520	451	72	32	35	533	451	67	28	32
	%	47%	41%	6%	3%	3%	48%	41%	6%	3%	3%
Fat	N	530	450	60	32	38	541	449	56	26	37
	%	48 %	41%	5%	3%	3%	49%	40%	5%	2%	3%
Cancerous Tissue	N	572	425	52	26	35	586	420	49	22	34
	%	52 %	38%	5%	2%	3%	53%	38%	4%	2%	3%
Liver Tissue	N	463	468	100	38	41	474	476	96	34	39
	%	42 %	42%	9%	3%	4%	43%	42%	9%	3%	4%
Bone or Cartilage	N	472	460	90	46	42	482	460	87	41	40
	%	43 %	41%	8%	4%	4%	43%	41%	8%	4%	4%
Spare eggs not fertilised during	N	133	159	121	104	89	128	149	111	93	86
	%	22 %	26%	20%	17%	15%	23%	26%	20%	16%	15%

Appendix VI

Results of survey –unweighted and weighted

IVF *											
Spare embryos	N	225	245	217	223	200	230	254	210	213	203
	%	20 %	22%	20%	20%	18%	21%	23%	19%	19%	18%

*Female Only

Q18 Would you agree to donate the following samples specifically for medical research?											
		Unweighted					Weighted				
		Def yes	Prob yes	Prob not	Def not	Don't know	Def yes	Prob yes	Prob not	Def not	Don't know
Saliva	N	568	423	54	30	35	581	413	55	27	34
	%	51 %	38%	5%	3%	3%	52%	37%	5%	2%	3%
Urine	N	553	432	61	33	31	566	424	60	30	30
	%	50 %	39%	5%	3%	3%	51%	38%	5%	3%	3%
Blood	N	455	448	118	47	42	496	446	107	46	42
	%	41 %	40%	11%	4%	4%	42%	40%	10%	4%	4%
Tissue collected requiring a local anaesthetic	N	273	463	197	100	77	283	471	190	88	78
	%	25 %	42%	18%	9%	7%	26%	42%	17%	8%	7%
Tissue collected requiring a general anaesthetic	N	166	286	310	235	113	172	300	309	214	115
	%	15 %	26%	28%	21%	10%	16%	27%	28%	19%	10%
Sperm *	N	120	171	104	66	43	135	188	111	64	46
	%	24 %	34%	21%	13%	9%	25%	35%	20%	12%	9%

*Men only

Appendix VI

Results of survey –unweighted and weighted

Q19 In the event of your death, would you be willing to donate the following samples for medical research?											
		Unweighted					Weighted				
		Def yes	Prob yes	Prob not	Def not	Don't know	Def yes	Prob yes	Prob not	Def not	Don't know
A small sample of your liver	N	485	390	88	51	96	491	391	84	48	96
	%	44 %	35%	8%	5%	9%	44%	35%	8%	4%	9%
A small sample of your brain	N	429	304	166	96	115	438	305	158	94	116
	%	39 %	27%	15%	9%	10%	39%	27%	14%	8%	10%
A whole liver	N	430	319	158	87	116	438	316	154	84	118
	%	39 %	29%	14%	8%	10%	39%	28%	14%	8%	11%
A whole brain	N	353	234	221	150	152	360	236	214	145	155
	%	32 %	21%	20%	14%	14%	32%	21%	19%	13%	14%

Q20 You are having surgery for a health issue which requires a general anaesthetic. The surgeon asks you whether you would be willing to consent to any additional tissue?											
		Unweighted					Weighted				
		Def yes	Prob yes	Prob not	Def not	Don't know	Def yes	Prob yes	Prob not	Def not	Don't know
From the same part of the body	N	328	530	115	51	86	342	523	112	50	83
	%	30 %	48%	10%	5%	8%	31%	47%	10%	5%	7%
Samples taken from an area close by	N	219	481	212	89	109	229	490	206	81	104
	%	20 %	43%	19%	8%	10%	21%	44%	19%	7%	9%
Samples involving an	N	154	336	298	204	118	164	348	301	180	118
	%	14 %	30%	27%	18%	11%	15%	31%	27%	16%	11%

Appendix VI

Results of survey –unweighted and weighted

additional procedure											

Q21 You are having surgery for a health issue which requires a general anaesthetic. The surgeon asks you whether you would be willing to consent to any additional tissue?

		Unweighted					Weighted				
		Def yes	Prob yes	Prob not	Def not	Don't know	Def yes	Prob yes	Prob not	Def not	Don't know
Understanding how our body fights disease	N	390	558	72	27	63	399	554	71	24	62
	%	35 %	50%	6%	2%	6%	36%	50%	6%	2%	6%
Understanding how our genetic makeup...	N	305	558	115	47	85	312	564	107	43	83
	%	27 %	50%	10%	4%	8%	28%	51%	10%	4%	8%
Research that is testing new treatments	N	318	511	132	52	97	325	502	133	50	99
	%	29 %	46%	12%	5%	9%	29%	45%	12%	5%	9%
Research involving cells from embryos	N	157	304	228	214	207	167	319	225	199	200
	%	14 %	27%	21%	19%	19%	15%	29%	20%	18%	18%
Research involving animals	N	107	270	281	318	134	117	285	271	304	132
	%	10%	24%	25%	29%	12%	11%	26%	24%	27%	12%
Research outside the UK	N	109	273	350	199	179	115	277	349	199	170
	%	10 %	25%	32%	18%	16%	10%	25%	31%	18%	15%

Appendix VI

Results of survey –unweighted and weighted

Q22 Would you be willing to donate samples to be used by the following organisations?											
		Unweighted					Weighted				
		Def yes	Prob yes	Prob not	Def not	Don't know	Def yes	Prob yes	Prob not	Def not	Don't know
NHS Hospitals	N	367	570	69	31	73	379	569	65	28	70
	%	33 %	51%	6%	3%	7%	34%	51%	6%	2%	6%
Universities	N	243	515	185	56	111	255	519	173	54	108
	%	22 %	46%	17%	5%	10%	23%	47%	16%	5%	10%
Medical Research Charities	N	307	563	107	41	92	311	561	108	39	91
	%	28 %	51%	10%	4%	8%	28%	51%	10%	4%	8%
Pharmaceutical Companies	N	138	487	233	93	159	139	490	227	95	161
	%	12 %	44%	21%	8%	14%	12%	44%	20%	9%	14%
Diagnostic Companies	N	187	515	180	74	154	182	511	183	74	159
	%	17 %	46%	16%	7%	14%	16%	46%	17%	7%	14%

Q23 How important do you think it is that you are first asked for your permission (often known as 'consent') for any leftover samples to be used for medical research?				
	Unweighted		Weighted	
	N	%	N	%
1 Not at all important	40	4 %	42	4%
2	41	4 %	43	4%
3	104	9 %	103	9%
4	274	25 %	268	24%
5 Extremely important	615	55 %	614	55%
Don't know	36	3 %	40	4%

Appendix VI

Results of survey –unweighted and weighted

Q24 How important do you think it is that you are first asked for your permission (often known as 'consent') for any leftover samples to be used for medical research?				
	Unweighted		Weighted	
	N	%	N	%
Opt-in	605	55 %	598	54%
Opt-out	308	28 %	321	29%
No preference	151	14 %	146	13%
Don't know	46	4 %	45	4%

Q25 Which of these three approaches do you prefer?				
	Unweighted		Weighted	
	N	%	N	%
Consent every time	472	43 %	480	43%
Consent once for life	231	21 %	237	21%
Consent at certain points	301	27 %	298	27%
No preference	82	7 %	72	7%
Don't know	24	2 %	22	2%

Q26 If you were going to be asked to donate left over samples for medical research every time you had a medical procedure, would you rather this was discussed with you by a health professional before the medical procedure or afterwards?				
	Unweighted		Weighted	
	N	%	N	%
Before	897	81 %	908	82%
After	48	4 %	48	4%
No preference	151	14 %	142	13%
Don't know	14	1 %	12	1%

Appendix VI

Results of survey –unweighted and weighted

Q27 If a consent once for life system was in place, when would you prefer to be asked about consenting left over samples for medical research?				
	Unweighted		Weighted	
	N	%	N	%
When registering at a GP surgery	425	39 %	419	38%
During a routine GP appointment	386	35 %	380	34%
When applying for a driving	83	8 %	88	8%
When applying for a passport	75	7 %	80	7%
The first time I visit the hospital	233	21 %	228	21%
The first time I have a medical	513	47 %	510	46%

Q28 If a consent once for life system was in place, when would you prefer to be asked about consenting left over samples for medical research?				
	Unweighted		Weighted	
	N	%	N	%
Face to face with a health professional	720	65 %	727	65%
Letter	66	6 %	64	6%
Email	30	3 %	32	3%
Telephone	14	1 %	13	1%
Via a website	60	5 %	61	6%
Completing a form and returning it by post	161	15 %	160	14%
Other (please specify)	4	0 %	4	0%
Don't know	55	5 %	49	4%

Q29 If you later decided you didn't want your samples to be used for medical research, what would be your preferred way to withdraw that consent?				
	Unweighted		Weighted	
	N	%	N	%
Face to face with a health professional	421	38 %	424	38%
Letter	95	9 %	92	8%
Email	89	8 %	93	8%
Telephone	56	5 %	51	5%
Via a website	137	12 %	144	13%

Appendix VI

Results of survey –unweighted and weighted

Completing a form and returning it by post	243	22 %	244	22%
Other (please specify)	8	1 %	6	1%
Don't know	61	5 %	55	5%

Q30 How likely would you be to donate samples for medical research using the following models of consent?

		Unweighted					Weighted				
		Def yes	Prob yes	Prob not	Def not	Don't know	Def yes	Prob yes	Prob not	Def not	Don't know
Generic	N	216	528	163	64	139	228	538	154	52	38
	%	19 %	48%	15%	6%	13%	21%	48%	14%	5%	12%
Tiered	N	242	549	125	55	139	244	560	124	49	133
	%	22 %	49%	11%	5%	13%	22%	50%	11%	4%	12%
Specific	N	336	553	88	28	105	339	551	89	29	102
	%	30 %	50%	8%	3%	9%	31%	50%	8%	3%	9%
Specific consent for every new study	N	293	560	110	27	120	300	560	109	26	115
	%	26 %	50%	10%	2%	11%	27%	50%	10%	2%	10%

Q31 Which of these four types of consent do you prefer?

Preferences	Unweighted		Weighted	
	N	%	N	%
Generic				
1st	200	18%	207	19%
2nd	159	14%	163	15%
3rd	168	15%	168	15%
4th	344	31%	327	30%
Tiered				
1st	156	14%	152	14%
2nd	246	22%	252	23%

Appendix VI

Results of survey –unweighted and weighted

3rd	360	32%	355	32%
4th	105	10%	106	10%
Specific (once only)				
1st	198	18%	183	17%
2nd	306	28%	304	27%
3rd	202	18%	209	19%
4th	161	15%	169	15%
Specific (every time)				
1st	341	31%	323	29%
2nd	157	14%	146	13%
3rd	138	12%	133	12%
4th	258	23%	263	24%
Don't Know	63	6%	62	6%
No Preference	181	16%	183	17%

Q32 If your preferred system of consent was not available, what would you do?

	Unweighted		Weighted	
	N	%	N	%
I would agree to give generic consent	348	52 %	350	53%
I would rather my sample was not used at all	187	28 %	172	26%
Don't know	133	20 %	135	21%

Q33 If there was a sample that you considered to be sensitive, but were still willing to donate for medical research, which of the four types of consent would you prefer to give?

	Unweighted		Weighted	
	N	%	N	%
Generic Consent	131	12 %	135	12%
Tiered Consent	105	9 %	101	9%
Specific Consent – once only	246	22 %	228	21%
Consent for every new study	278	25 %	288	26%

Appendix VI

Results of survey –unweighted and weighted

No Preference	206	19 %	216	19%
Don't Know	144	13 %	142	13%

Q34 Would you be willing to have your anonymised medical records linked to your sample?

	Unweighted		Weighted	
	N	%	N	%
Definitely yes	266	24 %	279	25%
Probably yes	493	44 %	497	45%
Probably not	165	15 %	157	14%
Definitely not	77	7 %	71	6%
Don't know	109	10 %	107	10%

Q35 Would you be willing to have your anonymised lifestyle information linked to your sample?

	Unweighted		Weighted	
	N	%	N	%
Definitely yes	377	34 %	398	35%
Probably yes	530	48 %	527	47%
Probably not	90	8 %	90	8%
Definitely not	48	4 %	43	4%
Don't know	65	6 %	61	5%

Q36 How would you like to get information on medical research including research on a particular condition that might use your sample?

	Unweighted		Weighted	
	N	%	N	%
Website	295	27 %	304	27%
Newsletter	104	9 %	97	9%
Email	302	27 %	315	28%
Letter	241	22 %	228	21%
Would not be interested in additional information	168	15 %	166	15%

Appendix VI

Results of survey –unweighted and weighted

Q37 Are there any particular organs you would not feel comfortable donating in the event of your death?				
	Unweighted		Weighted	
	N	%	N	%
Brain	337	31%	329	30%
Eyes	307	28%	308	28%
Heart	128	12%	121	11%
Kidneys	60	5 %	59	5%
Liver	68	6 %	65	6%
Lungs	67	6%	63	6%

Q38 If you were considering donating whole organs for medical research in the event of your death, are there any particular organs you would not feel comfortable donating?				
	Unweighted		Weighted	
	N	%	N	%
Yes, I would donate an organ for research if it was not suitable for transplant	755	68 %	766	69%
No, if they can't be used for transplant I would prefer they were not used at all	125	11 %	121	11%
I would not agree to donate an organ for transplant	96	9 %	95	9%
Don't know	134	12 %	128	12%

Appendix VI

Results of survey –unweighted and weighted

Q40 Would you be willing to have your anonymised lifestyle information linked to your sample?)	Unweighted		Unweighted	Weighted	Weighted	
	N	%	N	%	N	%
It should be obtained at the same time as consent for organ transplantation and recorded on the organ donor register						
Yes	174	16 %		166		15%
No	789	71 %	580	52 %	579	52%
Don't know	147	13 %		144		13%
It should be discussed at a GP appointment and recorded in the patients' notes			270	24 %	267	24%
It should be discussed at a hospital and recorded in the patients' notes			140	13 %	143	13%
Other			13	1 %	14	1%
Don't know			107	10 %	108	10%

Note: percentages may not add up to 100% due to rounding.

Consent for the use of human biological samples for biomedical research – a mixed methods study exploring the UK public's preferences

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Consent for the use of human biological samples for biomedical research – a mixed methods study exploring the UK public's preferences

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ABSTRACT

Objective: A mixed methods study exploring the UK general public's views towards consent for the use of biosamples for biomedical research.

Setting: Cross-sectional population-based focus groups followed by an online survey.

Participants: Twelve focus groups (81 participants) selectively sampled to reflect a range of demographic groups; 1110 survey responders recruited through a stratified sampling method with quotas set on sex, age, geographical location, socio-economic group and ethnicity.

Main outcome measures: 1) Views on the importance of consent when donating residual biosamples for medical research; 2) preferences for opt-in or opt-out consent approaches; 3) preferences for different consent models.

Results: Participants believed obtaining consent for use of residual biosamples was important as it was "morally correct" to ask, and enabled people to make an active choice and retain control over their biosamples. Survey responders preferred opt-in consent (55%); the strongest predictor was being from a low socio-economic group (OR 2.22, 95% CI 1.41-3.57, p=0.001) and having a religious affiliation (OR 1.36, 95% CI 1.01-1.81, p=0.04). Focus group participants had a slight preference for opt-out consent because by using this approach more biosamples would be available and facilitate research. Concerning preferred models of consent for research use of biosamples, survey responders preferred specific consent with re-contact for each study for which their biosamples are eligible. Focus group participants preferred generic consent as it provided "flexibility for researchers" and reduced the likelihood that biosamples would be wasted. The strongest predictor for preferring specific consent was preferring opt-in consent (OR 4.58, 95% CI 3.30-6.35, p=0.015) followed by non-'White' ethnicity (OR 2.94, 95% CI 1.23-7.14, p<0.001).

Conclusions: There is a preference amongst the UK public for ongoing choice and control over donated biosamples, however increased knowledge and opportunity for discussion is associated with acceptance of less restrictive consent models for some people.

ARTICLE SUMMARY

Article focus

- To explore views of the UK public on the importance of consent being sought to the use of residual biosamples for medical research;
- The publics' preferences for opt-in or opt-out approaches to consent;
- The publics' preferences for generic, tiered or specific consent.

Key messages

- Obtaining consent for the use of residual biosamples for biomedical research was perceived as important by members of the general public.
- Survey participants exhibited a desire to retain active choice and control when donating biosamples and over the uses to which their biosamples might be put, preferring an opt-in system and specific consent, however these results differ from those reported during focus group discussions, where preference was for less restrictive consent models (an opt-out system and generic consent) that are likely to increase availability of biosamples.
- These differences might be accounted for by the fact that focus group participants were given more background information about the use of residual biosamples in research and had time to consider the benefits and disadvantages of the different approaches.

Strengths and limitations of this study

- This study contributes further to our understanding of the UK public's views and preferences towards consent for the use of biosamples in medical research. Our study supports the premise that increased knowledge and opportunity for discussion is associated with acceptance of less restrictive consent models.
- Due to the hypothetical nature of the study, the findings may not necessarily correlate with actual behaviour.

INTRODUCTION

Human biological samples (biosamples), including organs, tissues, biofluids such as blood, and their derivatives, are increasingly important resources for biomedical research[1,2]. For example, they can help us to understand how we diagnose, categorise and treat a whole variety of medical conditions including cancer[1] and are particularly important when studying rare diseases or conditions where biosamples are hard to obtain. Biosamples are donated by either healthy volunteers or patients, either through specific research studies or as residual tissues or biofluids surplus to diagnostic requirements, or post mortem. Biosamples can be used fresh or can be first stored in a biobank, a collection of biosamples often linked with the donors' clinical and demographic information, as biosample attributes. Here, the quality of the data linked to the biosample is as important as the quality of the biosamples themselves, providing essential context within which to design analyses and interpret results or carry our further experimental studies. Clinical data may also be enriched with lifestyle and environmental information[3].

It is widely accepted that that donor consent should be sought and obtained before biosamples can be used in research[4,5]. Consent in research ethics relates to ensuring respect for the autonomy and dignity of the donors (research participants) and protecting them from abuse[5] and In fact, in England, Wales and Northern Ireland, the Human Tissue Act establishes donor consent as the baseline principle for the retention and use of organs and tissue for purposes beyond diagnosis and treatment, although further statutory consent exemptions do exist in certain circumstances, notably use of anonymised tissue from the living for research ethics committee (REC) approved research projects[6]. The value of biobanks, in supporting broad, long-term research purposes, means that the model of the consent process needs to be considered in order to ensure that it is valid and appropriate. A number of different consent frameworks which address consent scope and process have been proposed as a result[5]. However, there is continued debate as to which is the most appropriate in various situations[4,7,8].

Both the Human Tissue Authority[9] and National Research Ethics Service[10] recommend generic consent (Table 1), a view that has also been endorsed by UK research funders[11] and the Nuffield Council on Bioethics[12]. One commonly cited criticism of generic consent is that it is not sufficiently 'informed' as future research uses are not known at the time of donation[13]. Empirical research examining public and patient preferences has highlighted that there is no clear consensus on the issue, with

specific consent being identified as the most favoured form of consent in some studies[14,15], and generic consent in others[16-18].

Table 1: Approaches to consent of biosamples

Initial consent methods	
Opt-in consent	The storage and use of biosamples for research on the basis that the donor has actively agreed to do so.
Opt-out consent	The storage and use of samples for research on the basis that the donor has not objected, after previously being given the opportunity to do so.
Opt-in consent methods	
Consent once for life	Consent is provided once for life for use of any residual samples for research with the option of withdrawing permission at a later stage if the donor wishes to do so.
Consent at certain points	Consent is provided at certain points for use of residual biosamples for research, e.g. every 10 years or at the beginning of a particular episode of care.
Consent every time	Consent is requested every time residual biosamples may become available for use in research.
Consent for research use of biosamples	
Generic consent	Consent to the use of donated samples for a range of unknown uses, on the basis of general information about those possible uses and about the governance arrangements in place. Also referred to as 'broad' or 'blanket' consent.
Tiered consent	A more restricted form of consent for use of samples, where the donor is invited to agree to the use of their samples in unknown projects, but given the option of specifying particular categories of research that they wish to exclude e.g. embryonic research. Also referred to as 'categorical' consent.
Specific consent –once only	Consent to the use of donated samples for a specified study only, on the basis of information provided about that study. Any residual sample will be discarded at the end of that study.
Specific consent – for every new study	Consent to the use of donated samples for a specified study, on the basis of information provided about that study. However, participants are re-contacted and asked to consider participating in every new study for which their biosamples are eligible.

Note: Consent terms were selected based on common usage within the UK biobanking system (for example, generic consent is the term used by the Human Tissue Authority, National Research Ethics Service, and National Cancer Research Institute) and definitions chosen in consultation with a team of representatives from universities, hospital biobank staff, pathologists and industry.

The 2011 Nuffield Council report on donation of human material for medicine and research also recommends that research funders should work to increase public awareness of the key role of donated tissue in scientific and clinical research[12]. Public trust and confidence in the consent process is of paramount importance to maintain and increase public support for donation and use of biosamples for biomedical research in the UK. For this reason, it is important to understand and inform public opinion to ensure consent models are aligned to public expectations and preferences. Whilst numerous international studies have been conducted which focus on consent preferences, research conducted in the UK has tended to focus on large scale population biobanks, such as UK Biobank[19] or Generation Scotland[20], which require ongoing contact with donors, or on the views of patients on the donation of residual biosamples[21]. The current study was conducted to broaden our understanding of the UK public's views on biosample donation for biomedical research. Moreover, the findings are intended to inform a biobanking policy for STRATUM (Strategic Tissue Repository Alliance Through Unified Methods), a Technology Strategy Board[i] and pharmaceutical industry-funded project seeking to address the problem of insufficient numbers of biosamples and associated clinical data of adequate quality to fully support biomedical research in the UK.

The specific aims of this study were to 1) identify participants' views on the importance of consent when donating residual biosamples for medical research; 2) explore preferences for opt-in or opt-out approaches to consent; and 3) explore preferences for different consent models (Table 1). Public willingness to donate biosamples, views on donation of different biosample types, and conditions of their use (by which organisations and for which types of research) are reported elsewhere (Public views on the donation and use of human biological samples in biomedical research – a mixed methods study, 2013, unpublished manuscript).

METHODS

This was a mixed methods study comprising qualitative focus groups and a quantitative on-line survey. Ethical approval for the study was granted by the University of Manchester Research Ethics Committee in April 2012.

Focus groups

Twelve focus groups (including one pilot group) were conducted between May and July 2012 in six different geographic locations across the UK. Participants were recruited face-to-face in the street by a market research company The Focus Group. Participants

[i] under the Stratified Medicines Programme: Business Models Value Systems

were purposively sampled; each group chosen to reflect a particular demographic (age, socio-economic group (SEG), ethnicity) in order to gather a wide spectrum of views and enable comparisons across groups. Two 'patient' groups were also included, comprising people who had had an operation in the past two years requiring an overnight hospital stay, and people who currently have, or have had, either a serious or chronic illness, or disability. The latter group comprised people diagnosed with diabetes, cancer, heart disease, asthma and the genetic condition Marfan syndrome. A further group consisted of generally healthy volunteers who had donated a biosample specifically for research purposes.

Before agreeing to take part, potential participants were given a participant information sheet telling them about the study (see supplementary data file Appendix I). Those that were interested were screened through a questionnaire containing demographic questions to assess their suitability for a particular focus group. These were held in 'neutral' locations such as hotel conference rooms or church halls and facilitated by an experienced facilitator (CL). Before each group discussion, participants were sent a short information leaflet about the use of biosamples in biomedical research to provide some background context for the discussion and to prompt them to think about the key issues (see supplementary data file Appendix II). This information was written by a core team of authors drawn from across academia and industry, including patient representation. It was reviewed by three members of the patient organisation Genetic Alliance UK as well as the science communication charity Sense about Science to ensure readability and non-bias. Before focus group discussions began, participants were asked to sign a consent form. Each participant received £50 for taking part to cover time and travel costs. Focus groups lasted 90 minutes and digital audio recordings were taken.

A detailed discussion guide was developed to explore participant views and preferences towards consent scope and process (see supplementary data file Appendix III). The main focus related to the use of biosamples surplus to diagnostic requirements following surgery or a medical procedure. Questions were informed by other empirical studies of consent in biobanking[16,22], developed by the authors, and addressed the topics described above. To enhance understanding around the different consent models, participants were given a sheet presenting three different scenarios, each of which elaborated on one of the three consent models chosen for discussion (see supplementary data file Appendix III,p.4). For each topic, discussion began by asking the group to consider the benefits and disadvantages of each particular approach. Once no new themes were emerging, each participant was asked to complete an accompanying anonymous questionnaire which asked them to select their preferred consent model. The

discussion guide, scenario sheet and questionnaire were piloted at the first focus group which resulted in some minor amendments to wording.

Recordings were fully transcribed and transcriptions checked. The software package Nvivo version 9 (QSR International, Pty Ltd) was used to help organise the data for analysis. This comprised grouping responses to questions into broad thematic categories which were then refined through sub-codes. Coding of all 12 transcripts was conducted by CL. The first six transcripts to be coded were also independently coded by a second researcher (SR). Codes were then compared to assess consistency of coding and ensure inter-rater reliability. Any discrepancies were discussed until consensus was reached. The remainder of the transcripts were then coded according to the agreed coding framework. **Survey**

Once data analysis had been conducted on the focus group transcripts, the findings were used to inform development of a quantitative survey which was used to canvas public opinion on the issues of interest across a representative sample of the UK population (see supplementary data file Appendix IV). The survey was carried out by the market research company Research Now using their online panel community of UK residents. A stratified sampling method was used: quotas were set on sex, age, geographical location, SEG and ethnicity, in line with data provided by the Office of National Statistics (ONS) to ensure the sample was as representative of the UK population as possible. Within each category, a random sample was selected from the Research Now database containing 451,185 active respondents. We aimed to recruit 1,000 responders in total. The sample size required depends on the number of predictors, the expected effect size and the level of power. According to Miles and Shevlin [23], if we are expecting a small effect size, a sample size of 600 is considered adequate to achieve a high level of power 0f 0.8 (a benchmark suggested by Cohen [24]) for four predictors. As highlighted in Table 2 we can formulate at least four hypothesis, for example, people from a higher socio-economic group are more likely to donate biosamples than those from lower socio-economic group. With a sample size of 1,000, this study would provide highly reliable results. In order to reduce any on-line bias in our sample, 100 face-to-face interviews with non-internet users were conducted. An additional 'boost' sample of 100 people (not included in the main sample analysis) was also conducted with people from three minority ethnic groups ('Black', 'Chinese', 'S. Asian') so that we could conduct sub-group analysis between the groups.

The survey questions were developed by the authors and piloted with 60 members of Research Now's online panel community who were from low SEG's. Members of the pilot group were then invited to take part in a subsequent telephone interview asking about

the survey. Interviews were conducted with 25 pilot survey responders. Questions focused on question clarity, survey length and whether responders felt the survey to be neutral. Some minor amendments to wording were made in light of the responses. The main survey was then conducted in September 2012. Surveys recorded online took, on average, 17 minutes to complete and each responder received a small payment (around £2) from Research Now.

Survey data were organised and analysed using SPSS statistical software version 20 (Chicago, IL: SPSS Inc; 2011). Initial univariate descriptive statistics were obtained for the entire study. Pearson Chi-square was used to examine demographic factors associated with willingness to donate and preference for different consent models. Those associations that were found to be significant ($p \leq 0.05$) were then entered into a multiple logistic regression to explore the predictivity of these variables. Before running the model, we tested for multicollinearity among the independent variables. No multicollinearity issues were found.

RESULTS

Study populations

Participant characteristics are detailed in Table 2.

Table 2: Participant characteristics

Characteristic	Focus group N=81	Survey N=1110
Gender		
Male	33; 41%	504; 45%
Female	48; 59%	606; 55%
Age		
18-24	13; 16%	135; 12%
25-34	18; 22%	184; 17%
35-44	19; 23%	198; 18%
45-54	10; 12%	184; 17%
55-64	16; 20%	176; 16%
65+	5; 6%	233; 21%
Socio-economic group		
A	9; 11%	41; 4%
B	22; 27%	215; 19%
C1	24; 30%	311; 28%
C2	14; 17%	233; 21%
D	6; 7%	145; 13%
E	6; 7%	165; 15%
Region		
East of England	7; 7%	92; 8%
East Midlands	-	57; 5%
London	18; 22%	213; 19%
North East	-	40; 4%
North West	-	121; 11%

Northern Ireland	-	30; 3%
Scotland	14; 17%	76; 7%
South East	14; 17%	165; 15%
South West	-	81; 7%
Wales	-	51; 5%
West Midlands	14; 17%	94; 8%
Yorkshire/Humberlands	14; 17%	90; 8%
Ethnicity		
White or White British	54; 67%	1057; 95%
Mixed race	1; 1%	7; 1%
Asian or Asian British	10; 12%	18; 2%
Black or Black British	9; 11%	19; 2%
Chinese or Chinese British	7; 9%	2; 0%
Other ethnic group	0; 0%	4; 0%
Prefer not to say	0; 0%	3; 0%
Religion		
Christianity		677; 61%
Islam		13; 1%
Hinduism		6; 1%
Sikhism		0; 0%
Judaism		6; 1%
Buddhism		11; 1%
Other religion		15; 1%
No religion		370; 33%
Prefer not to say		12; 1%
Religiosity		
Not at all religious		234; 32%
Moderately religious		422; 58%
Very religious		64; 9%
Prefer not to say		8; 1%
Education		
No formal qualification	15; 19%	70; 6%
GCSE, O level, Scottish Standard Grade or equivalent	19; 23%	264; 24%
GCE, A-level, Scottish Higher or similar	17; 21%	214; 19%
Vocational (BTEC/NVQ/Diploma)	-	230; 21%
Degree level or above	30; 37%	317; 29%
Prefer not to say	-	15; 1%
Self reported knowledge of medical research process		
No knowledge		463; 42%
Some knowledge		603; 54%
Good knowledge		44; 4%
Have you been affected by a disability or illness?		
Yes		399; 36%
No		711; 64%
Has a close family member been affected by a disability or illness?		
Yes		767; 69%
No		343; 31%
Have you had blood or tissue removed during a medical procedure?		
Yes		446; 40%
No		553; 50%

Don't know		111; 10%
Have you ever been asked to donate blood or tissue for medical research?		
Yes		182; 16%
No		904; 81%
Don't know		24; 2%
If so, did you agree to donate?		
Yes		155; 85%
No		23; 13%
Don't know		4; 2%

Note: percentages may not add up to 100 due to rounding.

Focus groups

One hundred and eighty-two members of the public who were approached were eligible to participate (i.e. they fitted the criteria for a particular focus group) and 81 people agreed to participate (45% participation rate; 48 women, 33 men). There were seven participants in each focus group apart from the 18-25 age group and high SEG group (eight participants in each); serious/chronic illness group and healthy volunteers group (six participants in each) and the pilot group (five participants).

Survey

Four thousand six hundred and seven people were invited to take part in the survey; 2014 did not respond, 860 began completing the survey but did not finish, 102 did not qualify to continue (e.g. they were under 18 years old), 521 qualified for the survey but the quota was full and 1110 completed the questionnaire (28% response rate excluding those who did not qualify and where the quota was full). This response rate is comparable to similar studies on this topic[16]. Our participant quotas closely, though not exactly, matched our targets based on the UK population data as provided by the ONS. For this reason we carried out both weighted and un-weighted analyses. There was no difference in the conclusions we reached by either method. In this paper we present the un-weighted results (weighted results can be found at supplementary data file Appendix V).

Importance of asking for consent

The majority of survey participants believed that obtaining consent for the use of residual biosamples was either extremely important (55%) or important (25%). Only 4% selected 'not at all important'. Focus group participants also saw the consent process as important and cited reasons including: that it was "polite", "respectful" and "morally correct" to ask permission; that it enabled people to feel they had made a contribution and an active choice; that it provided control, in particular for those people that might not want their biosamples to be used, for example for religious reasons; that taking

without asking was akin to theft; and that it was important in order to maintain trust between patients and doctors.

"It then doesn't allow them to take liberties or advantage of the fact that you're out cold having an operation and someone says 'Oh we need a bit of that'." Male, patient – had operation in past 2 years.

A small minority did not feel that consent was important, the main reasons being that they did not want the tissue back, that once it was removed it no longer 'belonged to them', and that the tissue would just go to waste otherwise.

Survey participants were asked what would be their preferred method of consenting to donate leftover biosamples for research use. The majority (65%) wanted to do so face-to-face with a health professional; 15% wanted to complete a form and return it by post. This issue was not specifically addressed with focus group participants due to time constraints.

Preference for 'opt-in' or 'opt-out' consent

Participants were asked whether they preferred an opt-in or opt-out model of consent for donating residual biosamples. The results of the survey showed that opt-in consent was preferred by over half of the participants (55%), 28% preferred opt-out, 14% had no preference and 4% selected 'don't know'. Participants who were significantly more likely to prefer opt-in consent were: from a low SEG (E) (79.8% vs. 64.1%, X^2=11.13(1), p=0.001); over 65 years (75.1% vs. 64%, X^2=7.68(1), p=0.006); had a religious affiliation (68.8% vs. 61.2%, X^2=4.84(1), p=0.028); and had an education level of GCSE or lower (71.1% vs. 63.9%, X^2=3.89(1), p=0.048). The strongest significant predictor for preferring opt-in consent was being from a low SEG (E) (OR=2.22, 95% CI 1.41-3.57, p=0.001) followed by having a religious affiliation (OR=1.36, 95% CI 1.01-1.81, p=0.04) (Table 3).

Table 3: Multiple logistic regression of participant preferences for consent models

Participant characteristic	Coefficient	95% CI	Odds ratio	p value
Preference for opt-in consent				
Socio-economic group	0.806	1.41, 3.57	2.22	0.001
Religion	0.304	1.01, 1.81	1.36	0.04
Preference for consent every time				
Religion	0.72	1.05, 4.00	2.04	0.036
Age	0.47	1.07, 2.41	1.60	0.023
Preference for specific consent				
Opt-in	1.52	3.30, 6.35	4.58	<0.001
Ethnicity	1.08	1.23, 7.14	2.94	0.015
Preference for generic consent				
Opt-out	1.52	3.13, 6.67	4.55	<0.001

Religion	0.04	1.08, 2.72	1.56	0.021
Knowledge of medical research process	0.44	1.06, 2.28	1.56	0.024

Demographic items were excluded from this table if none was statistically significant. All variables were entered into the models as categorical variables.
CI: Confidence Interval.

Focus group participants preferred opt-out consent (*n*=46; 57%) over opt-in consent (*n*=29; 36%), with 6 participants (7%) unsure, after in-depth discussion around the benefits and disadvantages of each approach. The main benefit of opt-out consent cited by participants was that more biosamples would be available and consequently spur research. Other reasons included: that it would be less costly administratively; that it maximised the value of left over biosamples; that patients wouldn't have to consider it every time they were having an operation or blood test; that those that did not want to donate still had the opportunity to opt-out; and that it would 'normalise' donating leftover biosamples which would be a positive step.

"It would an incentive for society if everyone knew that this is what happens routinely, but you can choose not to be involved. It would be more like 'that's normal'." Male, aged 18-24 group

Those that preferred the opt-in approach cited the following reasons as to why: an active choice whereby participants had to act on a decision to take part was preferable to a passive choice whereby consent was assumed; it enabled people to have more control over their biosamples; it was truly 'informed consent' in the context of donating surplus samples for research (rather than as part of a clinical trial; clinical trials were outside the scope of the study) and hence more ethically acceptable; it enabled people to feel that they were making a positive contribution and would prevent the problem of vulnerable groups not being aware they were automatically 'opted-in'.

"There are going to be members of the public who are not going to always be able to consider rationally themselves what it actually means." Female, healthy volunteer

Whist the majority of focus group participants overall preferred opt-out consent, the results were different for the three minority ethnic groups (''Black'', ''S. Asian'', ''Chinese''), where opt-in consent was favoured by the majority.

Consent once for life or consent every time

The most prevalent system in current use for donating new biosamples that are surplus to clinical requirements in the UK is the opt-in approach, with potential donors being asked for consent every time a procedure is performed that may result in a biosample becoming available for research. (The law allows for the use of diagnostic archives for

research without consent as long as certain criteria are met). Participants were therefore asked to consider variations on this model and state whether they preferred: (1) consent once for life, covering all subsequent biosamples, until or unless the donor decides to withdraw consent; (2) consent every time samples surplus to diagnostic requirements may become available, or (3) consent at certain points in life. Consent every time (43%) was preferred by the majority of survey participants, followed by consent at certain points (27%) and consent once for life, e.g. at aged 18, (21%). Seven percent had no preference and 2% didn't know. Groups who were significantly more likely to prefer consent every time compared to consent once for life were: under 55 years (70.3% vs. 60.9%; X^2=5.88(1), p=0.015); had no knowledge of the research process (72.3% vs. 63.4%; X^2=5.77(1), p=0.016); or were either not at all or moderately religious (70.2% vs. 51.3%; X^2=5.1(1), p=0.024). When entered into the regression analysis, the strongest significant predictor for preferring consent every time was being not at all or moderately religious (OR=2.04; 95% CI 1.05-4.00, p=0.036) followed by being under 55 years (OR=1.60; 95% CI 1.07-2.41, p=0.023) (Table 3).

Unlike survey responders, focus group participants favoured consent once for life (*n*=35; 43%) followed by consent every time samples surplus to diagnostic requirements may become available (*n*=27; 33%) and consent at certain points (*n*=16; 20%) with three choosing don't know (4%). Like opt-out consent, consent once for life was seen to be better as it was "quicker" and "easier" administratively and prevented researchers from "losing out". Consent provided most control for participants as you would "know the specific purpose of it", particularly if the sample was considered to be sensitive e.g. eggs; allowed "no room for error"; and enabled people to change their mind easily.

"You may feel differently [depending on] what tissue is being donated and for what purpose the research is being carried out." Female, aged 18-24 group

Some participants had concerns about how consent preferences (e.g. what types of research they were willing to donate a biosample for), would follow them across the healthcare system if a 'consent once for life' model was adopted. Consent at certain points was seen by some as a good middle ground as patients would still have some control, but would not have to go through the consent process every time they had a medical procedure. Examples of consent at certain points included every "five or ten years", or at the beginning of particular episodes of care such as pregnancy or cancer treatment.

Models of consent for research use of biosamples

Survey participants were presented with four consent models (Table 1), and asked whether they would consider consenting residual biosamples to each of them, providing the research had been approved by a research ethics committee (described as a committee usually made up of doctors, scientist, patients and the general public which ensure any research allowed to be done is for the benefit of patients). Eighty percent would agree to specific consent – once only; 77% would consent to specific consent – for every new study; 71% would agree to tiered consent; and 67% of participants would agree to generic consent. When asked which model they preferred, specific consent - for every new study, was the first choice amongst those who had a preference (30% of participants overall), followed by generic consent and specific consent- once only, jointly second (both 18%), and lastly tiered consent (14%). Sixteen percent had no preference and 6% didn't know.

After collapsing the two specific consent models together (specific consent - for every new study and specific consent – once only), those participants who preferred specific consent were significantly more likely to: have a religious affiliation (63.9% vs. 48.9%, X^2=16.88(1); p<0.001); live in the North East or Scotland (60.9% vs. 42.7%, X^2=10.23(1), p=0.001); be over 65 years (67.1% vs. 57.1%, X^2=5.31(1), p=0.021); and be of a non-'White' ethnicity (68.9% vs. 58%, X^2=4.17(1), p=0.041). Using the boost sample we found that 'Black' participants were significantly more likely to prefer specific consent models compared with 'White' participants (75.6% vs. 58%, X^2=4.31(1), p=0.038). Those people who preferred opt-in consent were also more likely to prefer specific consent models (71.1% vs. 35.3%, X^2=91.72(1), p<0.001). The strongest significant predictor for preferring specific consent was preferring opt-in consent (OR=4.58, 95% CI 3.30-6.35, p<0.001) followed by being of non-'White' ethnicity (OR=2.94, 95% CI 1.23-7.14, p=0.015) (Table 3).

We also looked at who was most likely to prefer generic consent, the least restrictive of the proposed consent models. Those that preferred generic consent were significantly more likely to: have no religious affiliation (51.1% vs. 36.1%, X^2=15.97(1), p<0.001); have some or good knowledge of the medical research process (26.1% vs. 18.3%, X^2=6.79(1), p=0.009); be male (26.8% vs. 19.9%, X^2=5.40(1), p=0.02); and be from a higher SEG group (A-D) (24.3% vs. 15.1%, X^2=4.66(1), p=0.031). They were also significantly more likely to prefer opt-out consent (64.7% vs. 28.9%, X^2=91.72(1), p<0.001). The strongest significant predictor for preferring generic consent was preferring opt-out consent (OR=4.55, 95% CI 3.13-6.67, p<0.001) followed by having no religious affiliation (OR=1.56, 95% CI 1.08-2.72, p=0.021) and some or good knowledge of the medical research process (OR=1.56, 95% CI 1.06-2.28, p=0.024) (Table 3).

Focus group preferences differed from those of survey responders with generic and tiered consent being equally popular (n=36; 44% and n=35; 43% respectively). Specific consent – once only, was least popular (n=6; 7%) (this was the only specific consent model given to participants). Four participants (5%) didn't know. Generic consent was valued as it provides most "flexibility for researchers"; reduces the likelihood residual biosamples will go to waste; is more straightforward to put in place; is "simpler to understand"; and enables biosamples to be used for more than "one specific thing".

"It's better not to restrict the possible use of the sample because by restricting it you're increasing the chance that it'll go to waste. You want the highest probability that something good will come from it." Male, patient – affected by a condition

It was also the consent model favoured by all participants who were affected by an illness or disability.

Tiered consent was valued because it provided more control over donated biosamples than generic consent, allowing people to opt-out of certain types of research, and therefore provided "clarity and peace of mind". All but one participant in the 'Black' focus group and all participants who had donated biosamples as healthy volunteers preferred tiered consent. Whilst specific consent was seen to provide the most control and enabled participants to have "some understanding of what it might be used for", concerns raised were that it "can't be used for anything else", "could be wasted" and would require a time-consuming explanation from health professionals.

In both the survey and focus groups, the donation of potentially sensitive biosamples produced a preference for specific consent. In the survey, a quarter (25%) preferred specific consent – for every new study, 22% preferred specific consent – once only, 12% preferred generic consent and 9% preferred tiered consent. Nineteen percent had no preference and 13% didn't know. When discussing donation of eggs, one woman commented:

"People could reproduce a child or whatever and it's about the personal-ness of what's been taken from you. So if it's a bit of blood, yeah take it, I mean you just cut yourself and blood is gone, but if it's something that's quite personal you only have every now and again, that needs to be guarded." Female, 'Black' ethnicity group

We asked survey participants whether they would like to be kept up-to-date with research going on at a particular hospital or biobank to which they had donated a

biosample. Eighty-five percent said they would be interested; the most popular methods to receive updates were via a website (27%), email (27%) or letter (22%).

DISCUSSION

This study contributes further to our understanding of the UK public's views and preferences towards consent for the use of biosamples in medical research. In summary, we have found that: 1) the consenting process was perceived as important in order to maintain trust between patients and health professionals and respect patient autonomy; 2) survey participants exhibited a desire to retain active choice and control when donating biosamples and over the uses to which their biosamples might be put, and 3) these results differ from those reported during focus group discussions, where preference was for less restrictive consent models that are likely to increase availability of biosamples. These differences might be accounted for by the fact that focus group participants were given more background information about the use of residual biosamples in research and had time to consider the benefits and disadvantages of the different approaches. These interventions may have allayed any anxieties participants had about relinquishing control of their biosamples and seem to have encouraged participants to choose approaches that maximised biosample access to researchers, highlighting the importance and potential impact of education on influencing public perception in this area.

The preference for opt-in consent identified in the survey is consistent with the results of other studies in this area[3,15,16]. One reason for this preference may be that it matches the current system for organ donation for transplant in the UK. It was also perceived as being truly informed consent by some participants (although it is worth noting that it is the information provided to potential donors that guarantees consent is informed rather than the consent mechanism). Nevertheless, the sizeable number of survey responders who preferred opt-out consent (27%) coupled with the preference for opt-out amongst focus group participants (57%) does suggest that there may be broader support than previously believed for this approach. This point is also supported by the finding that fewer than half of survey participants wanted to be consented every time a sample was taken and nearly 30% preferred consent at certain points. Alternate, more streamlined approaches to consenting should therefore be considered and evaluated. Interestingly, our results showed that preference for opt-out consent was associated with being younger (under 65 years), from a higher SEG and a higher education level. These demographic groups may be more trusting of medical institutions to use residual biosamples appropriately, or perhaps feel empowered to be able to opt-out if so desired, for example, online. Similar findings have been reported in relation to

organ donation; a study by Gimbel et al. found an association between cadaveric donation rate and percentage of the population enrolled in third-tier education[25]. Internet access has also been found to correlate with increased organ donation[26].

Concerning consent models for research use of biosamples, the majority of people (69%) were willing to donate biosamples via the least restrictive model, generic consent. A study conducted in Sweden found a similar percentage of the general public were happy to agree to generic consent (67%), whereby surrogate decisions were performed by a research ethics committee[27]. Other national studies have found the acceptability of generic consent amongst the general public and in particular patients to be higher, between 79%-95%[4,28-31]. Nevertheless, our survey findings suggest that willingness to donate increased where greater choice and control over research participation is retained, although the difference between those who were willing to agree to generic compared to specific was only 13%. Similarly, when survey responders were asked about their preferred approach, their preference was also for specific consent for every new study that might be conducted using their biosample. This may indicate a general interest in how samples are being used. This notion is supported by the high number of people who wanted ongoing contact about the research leading from their donation. Moreover, they may have not considered the practicalities of being asked to consent every time their sample is used, and the high level of recontact they might receive from research teams. Nevertheless, it is important to take note of the fact that more tailored forms of consent represent an attractive approach to many people. While specific consent may be practical for individual research projects, this restriction would make biobanking challenging, as biobanks exist to facilitate access to samples for a wide variety of approved research projects without the need for additional consent. It may be that as more sophisticated biosample tracking and management systems are adopted, resources could become available to support more interactive forms of consent, and more biobanks could offer tiered consent, for example. Further public dialogue and information about the use of the samples may also provide the same assurances for people that arise from specific consent, as highlighted by the preference for less restrictive consent models amongst focus group participants.

Evidence from other empirical studies looking at preferences for consent models is mixed. UK studies focusing on donations purely for research by 'healthy volunteers' to biobanks (i.e. not donating residual biosamples) have identified a preference for specific consent,[19,32] as did a study conducted in the USA that also focused on healthy volunteers[15]. In a pan-European survey, the majority of the UK public also preferred specific consent for every new study, although the percentage that did was slightly lower than the overall European average (65% compared to 67%)[33]. It was, however,

higher than in Denmark and Finland, where the percentage of people who wanted to be re-contacted for every new study was lower at 51% and 54% respectively. These countries were also found to have very few concerns about the collection of personal information by biobanks and had high levels of trust in ethics committees. Other empirical work conducted in the USA, Canada, Sweden and Spain has shown that public preference is for generic consent[3,16,18,34,35]. These findings highlight the divergence of opinion on this issue, in particular in different contexts and with different information provision, although the difficulty of comparing across studies with different methodologies and backgrounds must also be taken into account. Notably, where participants had some or good knowledge of the research process and where there was in-depth discussion (i.e. during focus groups), participants were more likely to prefer generic consent, a finding that has also been identified elsewhere in the literature[36] and supports the need for information and education if increasing the acceptability of generic consent is deemed desirable. Focus group participants affected by an illness or disability were also found to prefer generic consent, and is likely to reflect the fact that they have greater interests at stake[37]. Preference for specific consent was found to be associated with being over 65 years and from a non-'White' ethnicity, findings which resonate with other studies[3,38,39]. Consent documentation and written information targeted specifically at these particular groups may also help alleviate any specific concerns these groups may have.

This research into current public attitudes regarding biosample donation in the UK provides valuable guidance for biobanking governance. Whilst generic consent is the model largely endorsed by regulators and funders in the UK[9,11], the evidence from this study suggests that there is a need to address the potential concerns that some people may have about the minimal information and lack of control provided through this model. Education and opportunity for discussion may be one way to allay concerns, as demonstrated through focus groups. Keeping donors informed of current research taking place at the hospital or research institutions to which they donated also appears to be desirable and is likely to be both motivating and promote public trust and confidence in the research process, a finding reported elsewhere[40]. The opportunity for face-to-face discussion with an appropriately trained healthcare professional at the time of donation may also allay any potential concerns, and is indeed the approach usually taken in the UK at present. This approach has been found to yield high acceptance rates amongst patients of well over 90%[41-43].

Strengths and Limitations

This was a mixed methods study to explore public views and preferences towards consent for biosample donation. Integrating quantitative and qualitative approaches is valuable in exploratory research as it can strengthen the inferences made through triangulation and allow for a more nuanced understanding of the topic[44]. This study presented participants with a series of hypothetical questions about their preferences and willingness to donate residual biosamples for medical research. By presenting questions as 'real life' scenarios, we hoped to make the questions as realistic as possible. However, as with any hypothetical scenario, the findings may not necessarily correlate with actual behaviour.

The questions for both the focus groups and the survey were piloted to ensure they were clear and understandable and were not biased towards any particular viewpoint. Nevertheless, many of the issues covered were complex, particularly around the meaning of the different consent models which may have contributed to the dropout rate. Focus groups participants were not presented with the option of 'specific consent – for every new study' (they were only given 'specific consent – once only'). This may have been an attractive option for some given that a concern raised was biosamples being wasted. However, given that the key reasons participants' valued generic consent were because it provided most flexibility to researchers and was most straightforward to administer, this seems unlikely. In addition, given time and resource constraints we were unable to explore whether 'stronger' consent models would have been preferable for organisations that donors trusted less. This is an area that would be worth exploring further in future research. Participants who did complete the survey may have done so because of strong feelings about the issues raised and this may have skewed the results; however, every effort was made to ensure that the results were as representative of the UK population as possible. The focus groups and survey were conducted in English and so the findings may not be representative of non-English speaking members of the general public. Future research might target these particular groups.

CONCLUSION

There is a general willingness amongst the UK population to donate biosamples for medical research. Our research suggests that there is a preference amongst the UK public for more information on the uses and outcomes of research, and ongoing choice and control over donated biosamples. Our study also supports the premise that increased knowledge and opportunity for discussion is associated with acceptance of less restrictive consent models.

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Ethical approval This study was approved by the Ethics Review Board of the University of Manchester, reference 11459.

Data sharing statement Transcripts from the focus groups and full results of the survey are available from CL at celine@geneticalliance.org.uk. Supplementary material is also available at www.geneticalliance.org.uk/projects/stratum_docs.htm

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Consent for the use of human biological samples for biomedical research – a mixed methods study exploring the UK public's preferences

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Running title: Consent for the use of biosamples - the UK public's preferences

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ABSTRACT

Objective: A mixed methods study exploring the UK general public's views towards consent for the use of biosamples for biomedical research.

Setting: Cross-sectional population-based focus groups followed by an online survey.

Participants: Twelve focus groups (81 participants) selectively sampled to reflect a range of demographic groups; 1110 survey responders recruited through a stratified sampling method with quotas set on sex, age, geographical location, socio-economic group and ethnicity.

Main outcome measures: 1) Views on the importance of consent when donating residual biosamples for medical research; 2) preferences for opt-in or opt-out consent approaches; 3) preferences for different consent models.

Results: Participants believed obtaining consent for use of residual biosamples was important as it was "morally correct" to ask, and enabled people to make an active choice and retain control over their biosamples. Survey responders preferred opt-in consent (55%); the strongest predictor was being from a low socio-economic group (OR 2.22, 95% CI 1.41-3.57, p=0.001) and having a religious affiliation (OR 1.36, 95% CI 1.01-1.81, p=0.04). Focus group participants had a slight preference for opt-out consent because by using this approach more biosamples would be available and facilitate research. Concerning preferred models of consent for research use of biosamples, survey responders preferred specific consent with re-contact for each study for which their biosamples are eligible. Focus group participants preferred generic consent as it provided "flexibility for researchers" and reduced the likelihood that biosamples would be wasted. The strongest predictor for preferring specific consent was preferring opt-in consent (OR 4.58, 95% CI 3.30-6.35, p=0.015) followed by non-'White' ethnicity (OR 2.94, 95% CI 1.23-7.14, p<0.001).

Conclusions: There is a preference amongst the UK public for ongoing choice and control over donated biosamples, however increased knowledge and opportunity for discussion is associated with acceptance of less restrictive consent models for some people.

ARTICLE SUMMARY

Article focus

- To explore views of the UK public on the importance of consent being sought to the use of residual biosamples for medical research;
- The publics' preferences for opt-in or opt-out approaches to consent;
- The publics' preferences for generic, tiered or specific consent.

Key messages

- Obtaining consent for the use of residual biosamples for biomedical research was perceived as important by members of the general public.
- Survey participants exhibited a desire to retain active choice and control when donating biosamples and over the uses to which their biosamples might be put, preferring an opt-in system and specific consent, however these results differ from those reported during focus group discussions, where preference was for less restrictive consent models (an opt-out system and generic consent) that are likely to increase availability of biosamples.
- These differences might be accounted for by the fact that focus group participants were given more background information about the use of residual biosamples in research and had time to consider the benefits and disadvantages of the different approaches.

Strengths and limitations of this study

- This study contributes further to our understanding of the UK public's views and preferences towards consent for the use of biosamples in medical research. Our study supports the premise that increased knowledge and opportunity for discussion is associated with acceptance of less restrictive consent models.
- Due to the hypothetical nature of the study, the findings may not necessarily correlate with actual behaviour.

INTRODUCTION

Human biological samples (biosamples), including organs, tissues, biofluids such as blood, and their derivatives, are increasingly important resources for biomedical research[1,2]. For example, they can help us to understand how we diagnose, categorise and treat a whole variety of medical conditions including cancer[1] and are particularly important when studying rare diseases or conditions where biosamples are hard to obtain. Biosamples are donated by either healthy volunteers or patients, either through specific research studies or as residual tissues or biofluids surplus to diagnostic requirements, or post mortem. Biosamples can be used fresh or can be first stored in a biobank, a collection of biosamples often linked with the donors' clinical and demographic information, as biosample attributes. Here, the quality of the data linked to the biosample is as important as the quality of the biosamples themselves, providing essential context within which to design analyses and interpret results or carry our further experimental studies. Clinical data may also be enriched with lifestyle and environmental information[3].

It is widely accepted that that donor consent should be sought and obtained before biosamples can be used in research[4,5]. Consent in research ethics relates to ensuring respect for the autonomy and dignity of the donors (research participants) and protecting them from abuse[5] and In fact, in England, Wales and Northern Ireland, the Human Tissue Act establishes donor consent as the baseline principle for the retention and use of organs and tissue for purposes beyond diagnosis and treatment, although further statutory consent exemptions do exist in certain circumstances, notably use of anonymised tissue from the living for research ethics committee (REC) approved research projects[6]. The value of biobanks, in supporting broad, long-term research purposes, means that the model of the consent process needs to be considered in order to ensure that it is valid and appropriate. A number of different consent frameworks which address consent scope and process have been proposed as a result[5]. However, there is continued debate as to which is the most appropriate in various situations[4,7,8].

Both the Human Tissue Authority[9] and National Research Ethics Service[10] recommend generic consent (Table 1), a view that has also been endorsed by UK research funders[11] and the Nuffield Council on Bioethics[12]. One commonly cited criticism of generic consent is that it is not sufficiently 'informed' as future research uses are not known at the time of donation[13]. Empirical research examining public and patient preferences has highlighted that there is no clear consensus on the issue, with

specific consent being identified as the most favoured form of consent in some studies[14,15], and generic consent in others[16-18].

Table 1: Approaches to consent of biosamples

Initial consent methods	
Opt-in consent	The storage and use of biosamples for research on the basis that the donor has actively agreed to do so.
Opt-out consent	The storage and use of samples for research on the basis that the donor has not objected, after previously being given the opportunity to do so.
Opt-in consent methods	
Consent once for life	Consent is provided once for life for use of any residual samples for research with the option of withdrawing permission at a later stage if the donor wishes to do so.
Consent at certain points	Consent is provided at certain points for use of residual biosamples for research, e.g. every 10 years or at the beginning of a particular episode of care.
Consent every time	Consent is requested every time residual biosamples may become available for use in research.
Consent for research use of biosamples	
Generic consent	Consent to the use of donated samples for a range of unknown uses, on the basis of general information about those possible uses and about the governance arrangements in place. Also referred to as 'broad' or 'blanket' consent.
Tiered consent	A more restricted form of consent for use of samples, where the donor is invited to agree to the use of their samples in unknown projects, but given the option of specifying particular categories of research that they wish to exclude e.g. embryonic research. Also referred to as 'categorical' consent.
Specific consent –once only	Consent to the use of donated samples for a specified study only, on the basis of information provided about that study. Any residual sample will be discarded at the end of that study.
Specific consent – for every new study	Consent to the use of donated samples for a specified study, on the basis of information provided about that study. However, participants are re-contacted and asked to consider participating in every new study for which their biosamples are eligible.

Note: Consent terms were selected based on common usage within the UK biobanking system (for example, generic consent is the term used by the Human Tissue Authority, National Research Ethics Service, and National Cancer Research Institute) and definitions chosen in consultation with a team of representatives from universities, hospital biobank staff, pathologists and industry.

The 2011 Nuffield Council report on donation of human material for medicine and research also recommends that research funders should work to increase public awareness of the key role of donated tissue in scientific and clinical research[12]. Public trust and confidence in the consent process is of paramount importance to maintain and increase public support for donation and use of biosamples for biomedical research in the UK. For this reason, it is important to understand and inform public opinion to ensure consent models are aligned to public expectations and preferences. Whilst numerous international studies have been conducted which focus on consent preferences, research conducted in the UK has tended to focus on large scale population biobanks, such as UK Biobank[19] or Generation Scotland[20], which require ongoing contact with donors, or on the views of patients on the donation of residual biosamples[21]. The current study was conducted to broaden our understanding of the UK public's views on biosample donation for biomedical research. Moreover, the findings are intended to inform a biobanking policy for STRATUM (Strategic Tissue Repository Alliance Through Unified Methods), a Technology Strategy Board[i] and pharmaceutical industry-funded project seeking to address the problem of insufficient numbers of biosamples and associated clinical data of adequate quality to fully support biomedical research in the UK.

The specific aims of this study were to 1) identify participants' views on the importance of consent when donating residual biosamples for medical research; 2) explore preferences for opt-in or opt-out approaches to consent; and 3) explore preferences for different consent models (Table 1). Public willingness to donate biosamples, views on donation of different biosample types, and conditions of their use (by which organisations and for which types of research) are reported elsewhere (Public views on the donation and use of human biological samples in biomedical research – a mixed methods study, 2013, unpublished manuscript).

METHODS

This was a mixed methods study comprising qualitative focus groups and a quantitative on-line survey. Ethical approval for the study was granted by the University of Manchester Research Ethics Committee in April 2012.

Focus groups

Twelve focus groups (including one pilot group) were conducted between May and July 2012 in six different geographic locations across the UK. Participants were recruited face-to-face in the street by a market research company The Focus Group. Participants

[i] under the Stratified Medicines Programme: Business Models Value Systems

were purposively sampled; each group chosen to reflect a particular demographic (age, socio-economic group (SEG), ethnicity) in order to gather a wide spectrum of views and enable comparisons across groups. Two 'patient' groups were also included, comprising people who had had an operation in the past two years requiring an overnight hospital stay, and people who currently have, or have had, either a serious or chronic illness, or disability. The latter group comprised people diagnosed with diabetes, cancer, heart disease, asthma and the genetic condition Marfan syndrome. A further group consisted of generally healthy volunteers~~people~~ who had donated a biosample specifically for research purposes.

Before agreeing to take part, potential participants were given a participant information sheet telling them about the study (see supplementary data file Appendix I). Those that were interested were screened through a questionnaire containing demographic questions to assess their suitability for a particular focus group. These were held in 'neutral' locations such as hotel conference rooms or church halls and facilitated by an experienced facilitator (CL). Before each group discussion, participants were sent a short information leaflet about the use of biosamples in biomedical research to provide some background context for the discussion and to prompt them to think about the key issues (see supplementary data file Appendix II). This information was written by a core team of authors drawn from across academia and industry, including patient representation. It was reviewed by three members of the patient organisation Genetic Alliance UK as well as the science communication charity Sense about Science to ensure readability and non-bias. Before focus group discussions began, participants were asked to sign a consent form. Each participant received ~~a~~ £50~~small honorarium~~ for taking part to cover time and travel costs. Focus groups lasted 90 minutes and digital audio recordings were taken.

A detailed discussion guide was developed to explore participant views and preferences towards consent scope and process (see supplementary data file Appendix III). The main focus related to the use of biosamples surplus to diagnostic requirements following surgery or a medical procedure. Questions were informed by other empirical studies of consent in biobanking[16,22], developed by the authors, and addressed the topics described above. To enhance understanding around the different consent models, participants were given a sheet presenting three different scenarios, each of which elaborated on one of the three consent models chosen for discussion (see supplementary data file Appendix III,p.4~~IV~~). For each topic, discussion began by asking the group to consider the benefits and disadvantages of each particular approach. Once no new themes were emerging, each participant was asked to complete an accompanying

anonymous questionnaire which asked them to select their preferred consent model. The discussion guide, scenario sheet and questionnaire were piloted at the first focus group which resulted in some minor amendments to wording.

Recordings were fully transcribed and transcriptions checked. The software package Nvivo version 9 (QSR International, Pty Ltd) was used to help organise the data for analysis. This comprised grouping responses to questions into broad thematic categories which were then refined through sub-codes. Coding of all 12 transcripts was conducted by CL. The first six transcripts to be coded were also independently coded by ~~and verified by~~ a second researcher (SR). Codes were then compared to assess consistency of coding and ensure inter-rater reliability. Any discrepancies were discussed until consensus was reached. The remainder of the transcripts were then coded according to the agreed coding framework. ~~to ensure inter rater reliability. Any discrepancies were discussed between the two researchers until consensus was reached.~~

Survey

Once data analysis had been conducted on the focus group transcripts, the findings were used to inform development of a quantitative survey which was used to canvas public opinion on the issues of interest across a representative sample of the UK population (see supplementary data file Appendix IV). The survey was carried out by the market research company Research Now using their online panel community of UK residents. A stratified sampling method was used: quotas were set on sex, age, geographical location, SEG and ethnicity, in line with data provided by the Office of National Statistics (ONS) to ensure the sample was as representative of the UK population as possible. Within each category, a random sample was selected from the Research Now database containing 451,185 active respondents. We aimed to recruit 1,000 responders in total. The sample size required depends on the number of predictors, the expected effect size and the level of power. According to Miles and Shevlin [23], if we are expecting a small effect size, a sample size of 600 is considered adequate to achieve a high level of power 0f 0.8 (a benchmark suggested by Cohen [24]) for four predictors. As highlighted in Table 2 we can formulate at least four hypothesis, for example, people from a higher socio-economic group are more likely to donate biosamples than those from lower socio-economic group. With a sample size of 1,000, this study would provide highly reliable results. In order to reduce any on-line bias in our sample, 100 face-to-face interviews with non-internet users were conducted. An additional 'boost' sample of 100 people (not included in the main sample analysis) was also conducted with people from three minority ethnic groups ('Black', 'Chinese', 'S. Asian') so that we could conduct sub-group analysis between the groups.

The survey questions were developed by the authors and piloted with 60 members of Research Now's online panel community who were from low SEG's. Members of the pilot group were then invited to take part in a subsequent telephone interview asking about the survey. Interviews were conducted with 25 pilot survey responders. Questions focused on question clarity, survey length and whether responders felt the survey to be neutral. Some minor amendments to wording were made in light of the responses. The main survey was then conducted in September 2012. Surveys recorded online took, on average, 17 minutes to complete and each responder received a small payment (around £2) from Research Now.

Survey data were organised and analysed using SPSS statistical software version 20 (Chicago, IL: SPSS Inc; 2011). Initial univariate descriptive statistics were obtained for the entire study. Pearson Chi-square was used to examine demographic factors associated with willingness to donate and preference for different consent models. Those associations that were found to be significant ($p \leq 0.05$) were then entered into a multiple logistic regression to explore the predictivity of these variables. Before running the model, we tested for multicollinearity among the independent variables. No multicollinearity issues were found.

RESULTS

Study populations

Participant characteristics are detailed in Table 2.

Table 2: Participant characteristics

Characteristic	Focus group N=81	Survey N=1110
Gender		
Male	33; 41%	504; 45%
Female	48; 59%	606; 55%
Age		
18-24	13; 16%	135; 12%
25-34	18; 22%	184; 17%
35-44	19; 23%	198; 18%
45-54	10; 12%	184; 17%
55-64	16; 20%	176; 16%
65+	5; 6%	233; 21%
Socio-economic group		
A	9; 11%	41; 4%
B	22; 27%	215; 19%
C1	24; 30%	311; 28%
C2	14; 17%	233; 21%
D	6; 7%	145; 13%
E	6; 7%	165; 15%
Region		
East of England	7; 7%	92; 8%

East Midlands	-	57; 5%
London	18; 22%	213; 19%
North East	-	40; 4%
North West	-	121; 11%
Northern Ireland	-	30; 3%
Scotland	14; 17%	76; 7%
South East	14; 17%	165; 15%
South West	-	81; 7%
Wales	-	51; 5%
West Midlands	14; 17%	94; 8%
Yorkshire/Humberlands	14; 17%	90; 8%
Ethnicity		
White or White British	54; 67%	1057; 95%
Mixed race	1; 1%	7; 1%
Asian or Asian British	10; 12%	18; 2%
Black or Black British	9; 11%	19; 2%
Chinese or Chinese British	7; 9%	2; 0%
Other ethnic group	0; 0%	4; 0%
Prefer not to say	0; 0%	3; 0%
Religion		
Christianity		677; 61%
Islam		13; 1%
Hinduism		6; 1%
Sikhism		0; 0%
Judaism		6; 1%
Buddhism		11; 1%
Other religion		15; 1%
No religion		370; 33%
Prefer not to say		12; 1%
Religiosity		
Not at all religious		234; 32%
Moderately religious		422; 58%
Very religious		64; 9%
Prefer not to say		8; 1%
Education		
No formal qualification	15; 19%	70; 6%
GCSE, O level, Scottish Standard Grade or equivalent	19; 23%	264; 24%
GCE, A-level, Scottish Higher or similar	17; 21%	214; 19%
Vocational (BTEC/NVQ/Diploma)	-	230; 21%
Degree level or above	30; 37%	317; 29%
Prefer not to say	-	15; 1%
Self reported knowledge of medical research process		
No knowledge		463; 42%
Some knowledge		603; 54%
Good knowledge		44; 4%
Have you been affected by a disability or illness?		
Yes		399; 36%
No		711; 64%
Has a close family member been affected by a disability or illness?		
Yes		767; 69%
No		343; 31%

Have you had blood or tissue removed during a medical procedure?		
Yes		446; 40%
No		553; 50%
Don't know		111; 10%
Have you ever been asked to donate blood or tissue for medical research?		
Yes		182; 16%
No		904; 81%
Don't know		24; 2%
If so, did you agree to donate?		
Yes		155; 85%
No		23; 13%
Don't know		4; 2%

Note: percentages may not add up to 100 due to rounding.

Focus groups

One hundred and eighty-two members of the public who were approached were eligible to participate (i.e. they fitted the criteria for a particular focus group) and 81 people agreed to participate (45% participation rate; 48 women, 33 men). There were seven participants in each focus group apart from the 18-25 age group and high SEG group (eight participants in each); serious/chronic illness group and healthy volunteers group (six participants in each) and the pilot group (five participants).

Survey

Four thousand six hundred and seven people were invited to take part in the survey; 2014 did not respond, 860 began completing the survey but did not finish, 102 did not qualify to continue (e.g. they were under 18 years old), 521 qualified for the survey but the quota was full and 1110 completed the questionnaire (28% response rate excluding those who did not qualify and where the quota was full). This response rate is comparable to similar studies on this topic[16]. Our participant quotas closely, though not exactly, matched our targets based on the UK population data as provided by the ONS. For this reason we carried out both weighted and un-weighted analyses. There was no difference in the conclusions we reached by either method. In this paper we present the un-weighted results (weighted results can be found at supplementary data file Appendix V~~I~~).

Importance of asking for consent

The majority of survey ~~and focus group~~ participants believed that obtaining consent for the use of residual biosamples was either extremely important (55%) or important (25%). Only 4% selected 'not at all important'. Focus group participants also saw the consent process as important and cited reasons including: ~~Reasons as to why consent~~

~~was important, as cited by focus group participants, included~~ that it was "polite", "respectful" and "morally correct" to ask permission; that it enabled people to feel they had made a contribution and an active choice; that it provided control, in particular for those people that might not want their biosamples to be used, for example for religious reasons; that taking without asking was akin to theft; and that it was important in order to maintain trust between patients and doctors.

"It then doesn't allow them to take liberties or advantage of the fact that you're out cold having an operation and someone says 'Oh we need a bit of that'." Male, patient – had operation in past 2 years.

A small minority did not feel that consent was important, the main reasons being that they did not want the tissue back, that once it was removed it no longer 'belonged to them', and that the tissue would just go to waste otherwise.

Survey participants were asked what would be their preferred method of consenting to donate leftover biosamples for research use. The majority (65%) wanted to do so face-to-face with a health professional; 15% wanted to complete a form and return it by post. This issue was not specifically addressed with focus group participants due to time constraints.

Preference for 'opt-in' or 'opt-out' consent

Participants were asked whether they preferred an opt-in or opt-out model of consent for donating residual biosamples. The results of the survey showed that opt-in consent was preferred by over half of the participants (55%), 28% preferred opt-out, 14% had no preference and 4% selected 'don't know'. Participants who were significantly more likely to prefer opt-in consent were: from a low SEG (E) (79.8% vs. 64.1%, X^2=11.13(1), p=0.001); over 65 years (75.1% vs. 64%, X^2=7.68(1), p=0.006); had a religious affiliation (68.8% vs. 61.2%, X^2=4.84(1), p=0.028); and had an education level of GCSE or lower (71.1% vs. 63.9%, X^2=3.89(1), p=0.048). The strongest significant predictor for preferring opt-in consent was being from a low SEG (E) (OR=2.22, 95% CI 1.41-3.57, p=0.001) followed by having a religious affiliation (OR=1.36, 95% CI 1.01-1.81, p=0.04) (Table 3).

Table 3: Multiple logistic regression of participant preferences for consent models

Participant characteristic	Coefficient	95% CI	Odds ratio	p value
Preference for opt-in consent				
Socio-economic group	0.806	1.41, 3.57	2.22	0.001
Religion	0.304	1.01, 1.81	1.36	0.04
Preference for consent every time				
Religion	0.72	1.05, 4.00	2.04	0.036

Age	0.47	1.07, 2.41	1.60	0.023
Preference for specific consent Opt-in	1.52	3.30, 6.35	4.58	<0.001
Ethnicity	1.08	1.23, 7.14	2.94	0.015
Preference for generic consent Opt-out	1.52	3.13, 6.67	4.55	<0.001
Religion	0.04	1.08, 2.72	1.56	0.021
Knowledge of medical research process	0.44	1.06, 2.28	1.56	0.024

Demographic items were excluded from this table if none was statistically significant. All variables were entered into the models as categorical variables.
CI: Confidence Interval.

Focus group participants preferred opt-out consent (*n*=46; 57%) over opt-in consent (*n*=29; 36%), with 6 participants (7%) unsure, after in-depth discussion around the benefits and disadvantages of each approach. The main benefit of opt-out consent cited by participants was that more biosamples would be available and consequently spur research. Other reasons included: that it would be less costly administratively; that it maximised the value of left over biosamples; that patients wouldn't have to consider it every time they were having an operation or blood test; that those that did not want to donate still had the opportunity to opt-out; and that it would 'normalise' donating leftover biosamples which would be a positive step.

"It would an incentive for society if everyone knew that this is what happens routinely, but you can choose not to be involved. It would be more like 'that's normal'." Male, aged 18-24 group

Those that preferred the opt-in approach cited the following reasons as to why: an active choice whereby participants had to act on a decision to take part was preferable to a passive choice whereby consent was assumed; it enabled people to have more control over their biosamples; it was truly 'informed consent' in the context of donating surplus samples for research (rather than as part of a clinical trial; clinical trials were outside the scope of the study) and hence more ethically acceptable; it enabled people to feel that they were making a positive contribution and would prevent the problem of vulnerable groups not being aware they were automatically 'opted-in'.

"There are going to be members of the public who are not going to always be able to consider rationally themselves what it actually means." Female, healthy volunteer

Whist the majority of focus group participants overall preferred opt-out consent, the results were different for the three minority ethnic groups (''Black'', ''S. Asian'', ''Chinese''), where opt-in consent was favoured by the majority.

Consent once for life or consent every time

The most prevalent system in current use for donating new biosamples that are surplus to clinical requirements in the UK is the opt-in approach, with potential donors being asked for consent every time a procedure is performed that may result in a biosample becoming available for research. (The law allows for the use of diagnostic archives for research without consent as long as certain criteria are met). Participants were therefore asked to consider variations on this model and state whether they preferred: (1) consent once for life, covering all subsequent biosamples, until or unless the donor decides to withdraw consent; (2) consent every time samples surplus to diagnostic requirements may become available, or (3) consent at certain points in life. Consent every time (43%) was preferred by the majority of survey participants, followed by consent at certain points (27%) and consent once for life, e.g. at aged 18, (21%). Seven percent had no preference and 2% didn't know. Groups who were significantly more likely to prefer consent every time compared to consent once for life were: under 55 years (70.3% vs. 60.9%; X^2=5.88(1), p=0.015); had no knowledge of the research process (72.3% vs. 63.4%; X^2=5.77(1), p=0.016); or were either not at all or moderately religious (70.2% vs. 51.3%; X^2=5.1(1), p=0.024). When entered into the regression analysis, the strongest significant predictor for preferring consent every time was being not at all or moderately religious (OR=2.04; 95% CI 1.05-4.00, p=0.036) followed by being under 55 years (OR=1.60; 95% CI 1.07-2.41, p=0.023) (Table 3).

Unlike survey responders, focus group participants favoured consent once for life (*n*=35; 43%) followed by consent every time samples surplus to diagnostic requirements may become available (*n*=27; 33%) and consent at certain points (*n*=16; 20%) with three choosing don't know (4%). Like opt-out consent, consent once for life was seen to be better as it was "quicker" and "easier" administratively and prevented researchers from "losing out". Consent provided most control for participants as you would "know the specific purpose of it", particularly if the sample was considered to be sensitive e.g. eggs; allowed "no room for error"; and enabled people to change their mind easily.

"You may feel differently [depending on] what tissue is being donated and for what purpose the research is being carried out." Female, aged 18-24 group

Some participants had concerns about how consent preferences (e.g. what types of research they were willing to donate a biosample for), would follow them across the healthcare system if a 'consent once for life' model was adopted. Consent at certain points was seen by some as a good middle ground as patients would still have some control, but would not have to go through the consent process every time they had a medical procedure. Examples of consent at certain points included every "five or ten

years", or at the beginning of particular episodes of care such as pregnancy or cancer treatment.

Models of consent for research use of biosamples

Survey participants were presented with four consent models (Table 1), and asked whether they would consider consenting residual biosamples to each of them, providing the research had been approved by a research ethics committee (described as a committee usually made up of doctors, scientist, patients and the general public which ensure any research allowed to be done is for the benefit of patients). Eighty percent would agree to specific consent – once only; 77% would consent to specific consent – for every new study; 71% would agree to tiered consent; and 67% of participants would agree to generic consent. When asked which model they preferred, specific consent - for every new study, was the first choice amongst those who had a preference (30% of participants overall), followed by generic consent and specific consent- once only, jointly second (both 18%), and lastly tiered consent (14%). Sixteen percent had no preference and 6% didn't know.

After collapsing the two specific consent models together (specific consent - for every new study and specific consent – once only), those participants who preferred specific consent were significantly more likely to: have a religious affiliation (63.9% vs. 48.9%, X^2=16.88(1); p<0.001); live in the North East or Scotland (60.9% vs. 42.7%, X^2=10.23(1), p=0.001); be over 65 years (67.1% vs. 57.1%, X^2=5.31(1), p=0.021); and be of a non-'White' ethnicity (68.9% vs. 58%, X^2=4.17(1), p=0.041). Using the boost sample we found that 'Black' participants were significantly more likely to prefer specific consent models compared with 'White' participants (75.6% vs. 58%, X^2=4.31(1), p=0.038). Those people who preferred opt-in consent were also more likely to prefer specific consent models (71.1% vs. 35.3%, X^2=91.72(1), p<0.001). The strongest significant predictor for preferring specific consent was preferring opt-in consent (OR=4.58, 95% CI 3.30-6.35, p<0.001) followed by being of non-'White' ethnicity (OR=2.94, 95% CI 1.23-7.14, p=0.015) (Table 3).

We also looked at who was most likely to prefer generic consent, the least restrictive of the proposed consent models. Those that preferred generic consent were significantly more likely to: have no religious affiliation (51.1% vs. 36.1%, X^2=15.97(1), p<0.001); have some or good knowledge of the medical research process (26.1% vs. 18.3%, X^2=6.79(1), p=0.009); be male (26.8% vs. 19.9%, X^2=5.40(1), p=0.02); and be from a higher SEG group (A-D) (24.3% vs. 15.1%, X^2=4.66(1), p=0.031). They were also significantly more likely to prefer opt-out consent (64.7% vs. 28.9%, X^2=91.72(1), p<0.001). The strongest significant predictor for preferring generic consent was

preferring opt-out consent (OR=4.55, 95% CI 3.13-6.67, p<0.001) followed by having no religious affiliation (OR=1.56, 95% CI 1.08-2.72, p=0.021) and some or good knowledge of the medical research process (OR=1.56, 95% CI 1.06-2.28, p=0.024) (Table 3).

Focus group preferences differed from those of survey responders with generic and tiered consent being equally popular (n=36; 44% and n=35; 43% respectively). Specific consent – once only, was least popular (n=6; 7%) (this was the only specific consent model given to participants). Four participants (5%) didn't know. Generic consent was valued as it provides most "flexibility for researchers"; reduces the likelihood residual biosamples will go to waste; is more straightforward to put in place; is "simpler to understand"; and enables biosamples to be used for more than "one specific thing".

"It's better not to restrict the possible use of the sample because by restricting it you're increasing the chance that it'll go to waste. You want the highest probability that something good will come from it." Male, patient – affected by a condition

It was also the consent model favoured by all participants who were affected by an illness or disability.

Tiered consent was ~~also~~ valued because it provided more control over donated biosamples than generic consent, allowing people to opt-out of certain types of research, and therefore provided "clarity and peace of mind". All but one participant in the 'Black' focus group and all participants who had donated biosamples as healthy volunteers preferred tiered consent. Whilst specific consent was seen to provide the most control and enabled participants to have "some understanding of what it might be used for", concerns raised were that it "can't be used for anything else", "could be wasted" and would require a time-consuming explanation from health professionals.

In both the survey and focus groups, the donation of potentially sensitive biosamples produced a preference for specific consent. In the survey, a quarter (25%) preferred specific consent – for every new study, 22% preferred specific consent – once only, 12% preferred generic consent and 9% preferred tiered consent. Nineteen percent had no preference and 13% didn't know. When discussing donation of eggs, one woman commented:

"People could reproduce a child or whatever and it's about the personal-ness of what's been taken from you. So if it's a bit of blood, yeah take it, I mean you just cut yourself and blood is gone, but if it's something that's quite personal you only have every now and again, that needs to be guarded." Female, 'Black' ethnicity group

We asked survey participants whether they would like to be kept up-to-date with research going on at a particular hospital or biobank to which they had donated a biosample. Eighty-five percent said they would be interested; the most popular methods to receive updates were via a website (27%), email (27%) or letter (22%).

DISCUSSION

This study contributes further to our understanding of the UK public's views and preferences towards consent for the use of biosamples in medical research. In summary, we have found that: 1) the consenting process was perceived as important in order to maintain trust between patients and health professionals and respect patient autonomy; 2) survey participants exhibited a desire to retain active choice and control when donating biosamples and over the uses to which their biosamples might be put, and 3) these results differ from those reported during focus group discussions, where preference was for less restrictive consent models that are likely to increase availability of biosamples. These differences might be accounted for by the fact that focus group participants were given more background information about the use of residual biosamples in research and had time to consider the benefits and disadvantages of the different approaches. These interventions may have allayed any anxieties participants had about relinquishing control of their biosamples and seem to have encouraged participants to choose approaches that maximised biosample access to researchers, highlighting the importance and potential impact of education on influencing public perception in this area.

The preference for opt-in consent identified in the survey is consistent with the results of other studies in this area[3,15,16]. One reason for this preference may be that it matches the current system for organ donation for transplant in the UK. It was also perceived as being truly informed consent by some participants (although it is worth noting that it is the information provided to potential donors that guarantees consent is informed rather than the consent mechanism). Nevertheless, the sizeable number of survey responders who preferred opt-out consent (27%) coupled with the preference for opt-out amongst focus group participants (57%) does suggest that there may be broader support than previously believed for this approach. This point is also supported by the finding that fewer than half of survey participants wanted to be consented every time a sample was taken and nearly 30% preferred consent at certain points. Alternate, more streamlined approaches to consenting should therefore be considered and evaluated. Interestingly, our results showed that preference for opt-out consent was associated with being younger (under 65 years), from a higher SEG and a higher

education level. These demographic groups may be more trusting of medical institutions to use residual biosamples appropriately, or perhaps feel empowered to be able to opt-out if so desired, for example, online. Similar findings have been reported in relation to organ donation; a study by Gimbel et al. found an association between cadaveric donation rate and percentage of the population enrolled in third-tier education[25]. Internet access has also been found to correlate with increased organ donation[26].

Concerning consent models for research use of biosamples, the majority of people (69%) were willing to donate biosamples via the least restrictive model, generic consent. A study conducted in Sweden found a similar percentage of the general public were happy to agree to generic consent (67%), whereby surrogate decisions were performed by a research ethics committee[27]. Other national studies have found the acceptability of generic consent amongst the general public and in particular patients to be higher, between 79%-95%[4,28-31]. Nevertheless, our survey findings suggest that willingness to donate increased where greater choice and control over research participation is retained, although the difference between those who were willing to agree to generic compared to specific was only 13%. Similarly, when survey responders were asked about their preferred approach, their preference was also for specific consent for every new study that might be conducted using their biosample. This may indicate a general interest in how samples are being used. This notion is supported by the high number of people who wanted ongoing contact about the research leading from their donation. Moreover, they may have not considered the practicalities of being asked to consent every time their sample is used, and the high level of recontact they might receive from research teams. Nevertheless, it is important to take note of the fact that more tailored forms of consent represent an attractive approach to many people. While specific consent may be practical for individual research projects, this restriction would make biobanking challenging, as biobanks exist to facilitate access to samples for a wide variety of approved research projects without the need for additional consent. It may be that as more sophisticated biosample tracking and management systems are adopted, resources could become available to support more interactive forms of consent, and more biobanks could offer tiered consent, for example. Further public dialogue and information about the use of the samples may also provide the same assurances for people that arise from specific consent, as highlighted by the preference for less restrictive consent models amongst focus group participants.

Evidence from other empirical studies looking at preferences for consent models is mixed. UK studies focusing on donations purely for research by 'healthy volunteers' to biobanks (i.e. not donating residual biosamples) have identified a preference for specific consent,[19,32] as did a study conducted in the USA that also focused on healthy

volunteers[15]. In a pan-European survey, the majority of the UK public also preferred specific consent for every new study, although the percentage that did was slightly lower than the overall European average (65% compared to 67%)[33]. It was, however, higher than in Denmark and Finland, where the percentage of people who wanted to be re-contacted for every new study was lower at 51% and 54% respectively. These countries were also found to have very few concerns about the collection of personal information by biobanks and had high levels of trust in ethics committees. Other empirical work conducted in the USA, Canada, ~~and~~ Sweden and Spain has shown that public preference is for generic consent[3,16,18,34,35]. These findings highlight the divergence of opinion on this issue, in particular in different contexts and with different information provision, although the difficulty of comparing across studies with different methodologies and backgrounds must also be taken into account. Notably, where participants had some or good knowledge of the research process and where there was in-depth discussion (i.e. during focus groups), participants were more likely to prefer generic consent, a finding that has also been identified elsewhere in the literature[36] and supports the need for information and education if increasing the acceptability of generic consent is deemed desirable. Focus group participants affected by an illness or disability were also found to prefer generic consent, and is likely to reflect the fact that they have greater interests at stake[37]. Preference for specific consent was ~~also~~ found to be associated with being over 65 years and from a non-'White' ethnicity, findings which resonate with other studies[3,38,39]. Consent documentation and written information targeted specifically at these particular groups may also help alleviate any specific concerns these groups may have.

This research into current public attitudes regarding biosample donation in the UK provides valuable guidance for biobanking governance. Whilst generic consent is the model largely endorsed by regulators and funders in the UK[9,11], the evidence from this study suggests that there is a need to address the potential concerns that some people may have about the minimal information and lack of control provided through this model. Education and opportunity for discussion may be one way to allay concerns, as demonstrated through focus groups. Keeping donors informed of current research taking place at the hospital or research institutions to which they donated also appears to be desirable and is likely to be both motivating and promote public trust and confidence in the research process, a finding reported elsewhere[40]. The opportunity for face-to-face discussion with an appropriately trained healthcare professional at the time of donation may also allay any potential concerns, and is indeed the approach usually taken in the UK at present. This approach has been found to yield high acceptance rates amongst patients of well over 90%[41-43].

Strengths and Limitations

This was a mixed methods study to explore public views and preferences towards consent for biosample donation. Integrating quantitative and qualitative approaches is valuable in exploratory research as it can strengthen the inferences made through triangulation and allow for a more nuanced understanding of the topic[44]. This study presented participants with a series of hypothetical questions about their preferences and willingness to donate residual biosamples for medical research. By presenting questions as 'real life' scenarios, we hoped to make the questions as realistic as possible. However, as with any hypothetical scenario, the findings may not necessarily correlate with actual behaviour.

The questions for both the focus groups and the survey were piloted to ensure they were clear and understandable and were not biased towards any particular viewpoint. Nevertheless, many of the issues covered were complex, particularly around the meaning of the different consent models which may have contributed to the dropout rate. Focus groups participants were not presented with the option of 'specific consent – for every new study' (they were only given 'specific consent – once only'). This may have been an attractive option for some given that a concern raised was biosamples being wasted. However, given that the key reasons participants' valued generic consent were because it provided most flexibility to researchers and was most straightforward to administer, this seems unlikely. In addition, given time and resource constraints we were unable to explore whether 'stronger' consent models would have been preferable for organisations that donors trusted less. This is an area that would be worth exploring further in future research. Participants who did complete the survey may have done so because of strong feelings about the issues raised and this may have skewed the results; however, every effort was made to ensure that the results were as representative of the UK population as possible. The focus groups and survey were conducted in English and so the findings may not be representative of non-English speaking members of the general public. Future research might target these particular groups.

CONCLUSION

There is a general willingness amongst the UK population to donate biosamples for medical research. Our research suggests that there is a preference amongst the UK public for more information on the uses and outcomes of research, and ongoing choice and control over donated biosamples. Our study also supports the premise that increased knowledge and opportunity for discussion is associated with acceptance of less restrictive consent models.

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Data sharing statement Transcripts from the focus groups and full results of the survey are available from CL at celine@geneticalliance.org.uk. Supplementary material is also available at www.geneticalliance.org.uk/projects/stratum_docs.htm

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Appendix 1

Attitudes Towards Donating Human Tissue Samples for Research

Participant Information Sheet

We would like to invite you to take part in a research study to help us understand what people think about donating human biological samples, (such as blood, saliva, types of blood tissues such as lung tissue, liver tissue) or tissue (e.g. lung tissue, saliva), or post mortem tissue, for medical research. These samples could be left over from a surgical procedure or they may be donated specifically for research purposes. Currently, we know very little about what people think about this issue. Please take the time to read the following information to help you decide whether you would like to take part.

Who will conduct this research? The research is part of the STRATUM project, a project set up to try to increase the effectiveness of tissue sample provision in the UK. It is being conducted with the help of a national charity, Genetic Alliance UK that represents over 150 patient organisations. The Focus Group are a reputable research company helping us to recruit members of the public. This study has received ethics approval from Manchester University.

What is the aim of this research? The aim is to understand what people think about donating human tissue samples for medical research.

Why have I been chosen? As a member of the public, your views are important. Your views will help us understand people's opinions and ensure that the donation of biological samples for medical research is carried out in a way that reflects people's wishes.

What would I be asked to do if I took part? We are inviting you to attend a group discussion to discuss your opinions about donating tissue samples for medical research. Don't worry if you feel you don't know a lot about this topic because discussions will be led by a trained moderator. We have provided some basic information along with this sheet that gives you some background about the topic. There are no right or wrong views; everyone's opinions will be equally valid.

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What happens to the data collected? The information collected from these discussions will be used to write a report which will be used to influence National policy. The findings will also be used to publish academic papers in journals.

How is confidentiality maintained? Discussions will be digitally recorded so that we can get an accurate account of what was said. However, when these are typed up, all comments will be anonymous and your name will not appear anywhere on the document. The documents will be kept secure on an encrypted hard drive and backed up on an encrypted memory stick which will be kept in a locked office. These documents and the audio files will be kept for 5 years and then destroyed. This information will not be passed on to any other third party.

What happens if I do not want to take part or if I change my mind? It is up to you whether or not to take part. If you do decide to take part you will be asked to sign a consent form saying that you have agreed to take part and have the conversation recorded. If you decide to take part you are still free to withdraw at any time without giving a reason and without detriment to yourself.

Will I be paid for taking part? As a thank you for taking part you will be given £50 which will be given at the end of the discussion.

What is the duration of the research? There will be between 6-8 people in the group which will last approximately 1.5 hours.

Where will the research be conducted?

What are the benefits from me taking part? There is no direct benefit to yourself from taking part, but your views will help to shape future policy.

Who will be running the group? The person running the focus group is Celine Lewis, who is a researcher with Genetic Alliance UK. If you have any concerns or questions about taking part in this research before the group then please contact Celine on 0207 704 3141. If you have agreed to take part and then find nearer the time you are no longer able to make the group then please contact the person who recruited you directly so that you can be replaced.

What if something goes wrong? In the unlikely event that you want to make a complaint about the conduct of the research, or would like help or advice following the discussion, you can contact the head of the project, Julie Corfield:
Email: juliecorfield@areteva.com
Tel: 0115 812 0008

Many thanks,

Celine Lewis

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Appendix II

Donating biological samples for medical research

Introduction
Medical research is necessary to improve our understanding of what keeps us healthy and how diseases start and progress. It also means scientists can develop new and improved treatments.

Body fluid (such as blood, saliva, urine) and human tissue (such as fat, cancer tumours or muscle) are often used in scientific and medical research. Types of research that need body fluid and human tissue include:

- Looking at how the body works to fight disease.
- Testing new treatments for conditions such as heart disease and diabetes.
- Developing tests for different types of cancer.
- Researching how certain types of cells could be used to treat conditions like Parkinson's disease, Alzheimer's disease and multiple sclerosis.

Many of the tests and treatments used today resulted from people donating body fluid and human tissue (often called 'samples') for research years ago.

How are human samples collected?
There are a number of ways that human samples can be collected:

- Samples may be left over after surgery. Tissue may be removed during surgery so tests can be done on the tissue or to stop the diseased tissue spreading to other parts of the body. After any necessary tests have been done on the tissue, there may be some left over. This left over tissue may be destroyed or used for medical research.
- Samples may be left over from a medical test such as a blood test.
- Samples might be donated specifically for medical research.
- A person may give permission (known as 'consent' or 'authorisation') for a sample to be taken and used for research in the event of their death.
- A person's family may give permission for the person's organs, which would have been donated for transplant, to be used for research if they are not suitable for transplant or a suitable recipient is not available.

The collection and use of samples is tightly governed by law in the UK. The removal of samples from a person is always done with the donor's permission, and any research first has to be approved by a research ethics committee. This committee is usually made up of doctors, scientist, patients and the general public, and ensures any research allowed to be done is for the benefit of patients. In specific circumstances the law allows samples that have already been collected to be used for another purpose, as long as the donor cannot be identified and the use has been approved by an ethics committee.

What is done with the sample once it is collected?
Samples may be collected by a researcher and used immediately, or they may be collected for research purposes and kept. This may be in a researcher's laboratory or it may be in a storage place specifically for samples, known as a biobank.

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The biobank keeps the samples so they can be used by scientists for research. In other words, biobanks are a little like libraries of samples, and only a research team can use them if they have the appropriate approval. A biobank has to follow regulations and have a licence, granted by the Human Tissue Authority (a UK Government organisation), to be able to store human tissue samples for research.

These systems ensure that any research respects the privacy of the people who donated the samples and that the research is of benefit to society. In many cases, it can be very important to have a patient's medical records along with their sample so that scientists can make sense of the results of their research. Any identifying information, such as names or addresses, is removed and not included with the sample.

How long is the biological sample kept?
A sample may be used all at once. However, it is often the case that it won't all be used in one go. Therefore the sample may be stored and used over many years so that research can be done on it well into the future.

What are the benefits from donating biological samples to medical research?
The person donating the sample is unlikely to benefit directly from the research, as it can take many years for the research on samples to produce new treatments or cures for diseases. Nevertheless, donors often see a benefit from knowing that they have personally helped medical research.

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The following information was used during the making of this leaflet:
"Donating samples for research; Patient information" – Central England Haemoto-Oncology Research Biobank
"Donating your tissue for research"- Human Tissue Authority
"Active choice but not too active: Public perspectives on biobank consent models" Simon et al. 2011; Genetics in Medicine

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Appendix III

Focus Group – Discussion Guide

Introduction (5 minutes)

Thank them for coming
Aim of discussion – hear people's views, there are no right or wrong opinions, disagreement OK
Participation voluntary
Confidentiality – all info anonymous, personal details will not be passed on to any third party
Get permission for recording to be taped – no names or identifying features used when typed up
Guidelines – talk one at a time; am interested in everyone's views so will try and give everyone equal 'airtime'; no wrong answers – be honest and open.
Turn mobile phones off
Go round room. Ask everyone to say their name and one of their favourite foods.

Research (30 minutes)

On the information sheet you've been given, there is some general information about donating samples for research. Has everybody had a chance to read this information? (if not give participants a few minutes to read document). So, to summarise….*give a brief overview of information on the document.*

1. So to start off, does anyone have any questions about anything I've said so far?

So I'd like us to think now about the different types of samples someone might donate to medical research. Human biological samples can mean a variety of different things including body fluid such as blood, saliva and sperm, and human tissue such as fat, cancer tumours or muscle or even whole organs.

2. Do you think there are some types of samples which are more sensitive to give than others? Which ones? Why?

There are also various different ways that samples can be collected. They might be

- left over from routine procedures such as surgery;
- left over after a medical test such as a blood test;
- donated specifically for medical research, for example a cheek swab or an extra blood sample;
- donated after a person's death;
- a person's organs e.g. heart or kidneys, which would have been donated for transplant, may be used for research if they are not suitable for transplant or a suitable recipient is not available. The relevant clinical data may also be included and reviewed after death.

3. I'd like us to go through each of these in turn and discuss whether you have concerns about any of these ways that samples might be collected and why. GO THROUGH AND PROBE EACH POINT SPECIFICALLY (AFTER GROUP DISCUSSION: ask participants to complete associated question on questionnaire)

4. Do you see donation of human samples for medical research and organ donation for transplant similarly or do you think they are different?

5. Thinking specifically about donating tissue or organs after one's death, do you think if someone has indicated in writing that they are willing to donate these for research in the event of their death, their wishes can be overridden by their relatives?

Samples may be used for a variety of different types of research. This might include looking at how the body works to fight disease; testing new treatments for conditions such as heart disease and diabetes or developing ways of diagnosing earlier different types of cancer.

6. Are there any types of research you would not be happy for your sample to be used for? Why?
   (AFTER GROUP DISCUSSION: ask participants to complete associated question on questionnaire)

There are many places where research is performed, such as universities, NHS, charities such as cancer research, government labs and pharmaceutical companies. These are all groups that do research & sometimes they collaborate with each other in order to make medical progress.

7. Do you have any concerns about any particular types of organisations using donated samples. Which if any, and why?

   (AFTER GROUP DISCUSSION: ask participants to complete associated question on questionnaire)

8. What do you think about the organisations that conduct research on samples? Do you think they are generally doing a good thing for society? Do you have any concerns about what they do?

9. Institutions such as the government and ethics review committees make decisions about what research can and can't be done on human samples. Ethics review committees are usually made up of different experts such as of doctors, scientists, ethics experts and patients Do you generally trust these types of institutions to make decisions about what research can and can't be done using human tissue samples?

Consent (40 minutes)

I'd like to now talk about getting permission, also known as consent, to use a person's sample for medical research. Most of us have probably had blood taken at some point and some of us will have had an operation. If we have blood taken for a test, there might be some blood left over after the test has been done. Similarly, tissue may be removed during an operation and there may be some left over after any necessary tests have been done on the tissue. So you would not have any additional tissue taken just for research purposes unless you had specifically given permission for this at the time it was going to be taken. In most cases, it is just the leftover blood or tissue that you might agree to donate to medical research.

10. Thinking about leftover blood or tissue being used for medical research, do you think a person needs to be asked for their consent? FOR EACH RESPONSE: Why/why not? How important is this to you?

11. What would you expect to happen to samples that are left over from clinical procedures?

12. The majority of the time, tissue that is left over is destroyed. How do you feel about that?

There are a number of different ways that a person could give their permission or consent for their sample to be used for medical research. I'd like us to think about some of these now and discuss what we like and what we dislike about these different types of consent.

I'd like us to start by thinking about whether we prefer what is known as an **opt-in** system, or whether we prefer an **opt-out** system of sample donation.

Opt-in means that a person has to say that, after they turn 18, they are willing to and actively agree to donate their sample for research. This is how the current system for organ donation works in the UK.

The other approach is an opt-out approach. In this system, it is assumed that a person is happy, after they turn 18, for their sample to be used for research unless they specifically say otherwise. However, there is a mechanism in place for a person who is not willing to donate to opt out.

So, to start with, lets think about the first option, OPT-IN.

13. What do you think are the pros and cons about this approach? Why?

14. Thinking now about the OPT-OUT approach, what you think are the pros and cons? Why?

15. Which do you prefer? How important is this to you? (AFTER GROUP DISCUSSION: ask participants to complete associated question on questionnaire)

The current system is an opt-in one, so I want us to think about this type of consent now. If you were going to be asked to donate any leftover blood or tissue for medical research there are two ways this could be done. You could be asked to give consent **every time** you have an operation or blood test, or you could give consent just **once for life for all your samples,** with the option of withdrawing at a later point if you wanted to.

16. Thinking about **consent every time**, what do you think are the advantages and disadvantages of this approach?

17. Thinking about **consent once for life**, what do you think are the advantages and disadvantages of this approach?

18. Can you think of any happy medium which might be better?

19. Which would you prefer? Why? How important is this to you? (AFTER GROUP DISCUSSION: ask participants to complete associated question on questionnaire)

20. If people gave consent just once, when and where do you think the best place would be to give consent?

21. If someone wanted to consent to donate their tissue or organs for medical research in the event of their death, do you think it should be obtained at the same time as consent for organ transplantation and recorded on the organ donor register?

In front of you, you have 3 different scenarios. In each one the story is essentially the same, however there are some slight differences and these are highlighted in bold. I'd like to discuss what you think of each of these in turn.

Read all 3 scenarios out loud highlighting the key differences between the three. Then go back and discuss each one in turn.

Scenario 1: Lisa is having surgery to remove a lump from her breast which the doctor is concerned may be cancerous. Before the surgery the surgeon explains that once the tissue is removed, they will take it to the laboratory to do tests on it to check what it is. The surgeon then explains that after these tests are done, there may be some tissue left over. He asks Lisa if she would like to donate this left over tissue for medical research. If it is not donated for medical research it will be destroyed. The surgeon doesn't know exactly what kinds of research the tissue might be used for, but it may be used to find better ways to diagnose, prevent and treat cancer. He also explains that before any research is done, it has to be approved by an independent ethics committee.

So, in this scenario:

- Lisa is asked to give consent once to donate the left over tissue for a range of future unknown uses
- Lisa is given some general information about the kind of research the tissue might be used for but nothing specific.
- This type of consent is known as GENERIC CONSENT

22. What do you think about this type of consent?

23. What do you **like** about this approach?

24. Do you have **any concerns** about this approach?

Scenario 2: Lisa is having surgery to remove a lump from her breast which the doctor is concerned may be cancerous. Before the surgery the surgeon explains that once the tissue is removed, they will take it to the laboratory to do tests on it to check what it is. The surgeon then explains that after these tests are done, there may be some tissue left over. He asks Lisa if she would like to donate this left over tissue for medical research. If it is not donated for medical research it will be destroyed. The surgeon doesn't know exactly what types of research the tissue might be used for, but it may be used to find better ways to diagnose, prevent and treat cancer. Lisa is asked to sign a consent form. The surgeon explains that **Lisa can indicate on the consent form whether there are any particular kinds of research which she doesn't want the tissue to be used for, for example research involving animals or research conducted outside the UK.** He also explains that before any research is done, it has to be approved by an independent ethics committee.

So, in this scenario:

- Lisa is asked to give consent once to donate the tissue for a range of future unknown uses;
- Lisa is given some general information about the kind of research the tissue might be used for;
- **Lisa can say if there are any particular kinds of research which she doesn't want the tissue to be used for.**
- This type of consent is known as TIERED CONSENT

25. What do you think about this type of consent?

26. What do you **like** about this approach?

27. Do you have any **concerns** about this approach?

Scenario 3: Lisa is having surgery to remove a lump from her breast which the doctor is concerned may be cancerous. Before the surgery the surgeon explains that once the tissue is removed, they will take it to the laboratory to do tests on it to check what it is. The surgeon then explains that after these tests are done, there may be some tissue left over. He asks Lisa if she would like to donate this left over tissue for medical research. If it is not

donated for medical research it will be destroyed. The surgeon explains that **the hospital are currently involved in a study looking at the growth of tumours. He informs her that if she gives permission for the left over tissue to be used, it would only be for this particular study.** He also explains that the study has been approved by an independent ethics committee.

So, in this scenario:

- **Lisa is only asked to give consent to a particular study and is given information about that study.**
- This type of consent is known as SPECIFIC CONSENT

28. What do you think about this type of consent?

29. What do you **like** about this approach?

30. Do you have any **concerns** about this approach?

31. In this exercise we have discussed three different types of consent. Which do you prefer and why? GO ROUND AND ASK PEOPLE (AFTER GROUP DISCUSSION: ask participants to complete associated question 6 & 7 on questionnaire)

32. Generic consent is the most practical type of consent as it is the least costly to put in place. Researchers try their very best to honour donors' wishes, but in some cases where they cannot do this with confidence, instead of risking using a sample for something the donor feels strongly against, it won't be used at all. If your first choice wasn´t generic consent, does this information change your preference? (AFTER GROUP DISCUSSION: ask participants to complete question 8.

33. So, we've discussed which type of consent you would like for left over samples. Would your preference be any different for samples that you might donate specifically for research, e.g. if you volunteered to took part in a study and had to give a saliva or blood sample?

34. Would your preference be any different if you were donating what you might consider to be more sensitive samples e.g. genetic data, stem cells?

35. If you decide to withdraw consent would you be happy for researchers to use the data that had already been generated up to that point using your sample?

36. Do you think a central website where you can find out about general research that your sample might be used for would be useful and something you would use?

Information (10 minutes)

Researchers often need to have access to the donor's medical records in order to be able to meaningfully interpret the results of the scientific research. However, information, such as names or addresses are always removed and not included with the sample. This is so that the person who donated the sample cannot be identified by the scientist conducting the research or anyone analysing the results of the research. However, the sample may have a code so that someone not involved in the research can identify the individual if necessary.

37. Would you be happy with your medical records being linked to your sample or would you have concerns? Why?

38. Are there any types of information you would not want to be associated with your sample?

Sometimes it can also be helpful for the researcher to have certain information about the lifestyle of the person who donated the sample, for example whether they smoked, drank alcohol, how often they exercised etc. This information might help them to better understand the particular condition they are investigating.

39. Would you be happy for this information to be made available or would you have concerns about your lifestyle information being associated with your sample? Why?

Ownership of sample (5 minutes)

40. What significance do you attach to a biological sample once it has been removed from your body? Do you still see it as yours or part of you in some way? Are you owed money if a drug is developed using your sample?

Appendix V

Survey looking at the publics' views on donating biological samples for medical research

This survey was originally conducted online in September 2012 and hosted by the market research company Research Now.

Q1. What age are you?

1. 18-24
2. 25-34
3. 35-44
4. 45-54
5. 55-64
6. 65+

Q2. Are you male or female?

1. Male
2. Female

Q3. What is the occupation of person who receives the highest income in your household?

1. Higher managerial/ professional/ administrative (e.g. established doctor, solicitor, board director in a large organisation (200+ employees, top level civil servant/public service employee)) **(A – Letters will be hidden)**
2. Intermediate managerial/ professional/ administrative (e.g. newly qualified (under 3 years) doctor, solicitor, board director small organisation, middle manager in large organisation, principle officer in civil service/local government) **(B)**
3. Supervisory or clerical level/ junior managerial/ professional/ administrative (e.g. office worker, student doctor, foreman with 25+ employees, salesperson, etc) **(C1)**
4. Student **(C1)**
5. Skilled manual worker (e.g. skilled bricklayer, carpenter, plumber, painter, bus/ ambulance driver, HGV driver, AA patrolman, pub/bar worker, etc) **(C2)**
6. Semi or unskilled manual work (e.g. manual workers, all apprentices to be skilled trades, caretaker, park keeper, non-HGV driver, shop assistant) **(D)**
7. Casual worker – not in permanent employment **(E)**
8. Housewife/househusband/ homemaker **(E)**
9. Retired and living on state pension **(E)**
10. Unemployed or not working due to long-term sickness **(E)**
11. Full-time carer of other household member **(E)**

98. Other (specify)

Q4. What region do you live in?

1. Channel Islands
2. East of England
3. East Midlands
4. London
5. North East
6. North West
7. Northern Ireland
8. Scotland
9. South East
10. South West
11. Wales
12. West Midlands
13. Yorkshire / Humberside
96. Not on Map

Q5. Please choose one option that best describes your ethnic group or background.

1. White or White British
2. Mixed race
3. Asian or Asian British (not Chinese)
4. Black or Black British
5. Chinese
6. Other ethnic group
96. Prefer not to say

Q6. Which religion do you most identify with?

1. Christianity
2. Islam
3. Hinduism
4. Sikhism
5. Judaism
6. Buddhism
7. Other religion
8. No religion
96. Prefer not to say

Q7. If you do have a religion you identify with, to what extent do you consider yourself religious?

1. Not at all religious
2. Moderately religious
3. Very religious
96. Prefer not to say

Q8. Please indicate which, if any, is the highest educational or professional qualification you have obtained.

1. No formal qualification
2. GCSE, O level, Scottish Standard Grade or equivalent
3. GCE, A-level, Scottish Higher or similar
4. Vocational (BTEC/NVQ/Diploma)
5. Degree level or above
96. Prefer not to say

Q9. How would you describe your own level of knowledge about the medical research process including the use of human tissue samples?

1. No knowledge
2. Some knowledge
3. Good knowledge

Q10. Are you or have you ever been affected by a long-standing illness, disability or infirmity which has required continuous or frequent medical attention (e.g. cancer, diabetes, heart disease, asthma, a genetic condition)?

1. Yes
2. No

Q11. Has a close family member ever been affected by a long-standing illness, disability or infirmity which has required continuous or frequent medical attention (e.g. cancer, diabetes, heart disease, asthma, a genetic condition)?

1. Yes
2. No

Q12. Have you ever had blood or tissue removed during a medical or surgical procedure?

1. Yes
2. No
97. Don't know

Q13. Have you ever been asked to donate any blood or tissue for medical research?

1. Yes
2. No
97. Don't know

ASK IF CODED 1 AT Q13.

Q14. Did you agree to donate?

1. Yes
2. No
97. Don't know

ASK IF CODED 2 AT Q14.

Q14a. Please tell us a little bit about your reasons for choosing not to donate.
There are no right or wrong answers – we're just interested in your honest opinion.

This survey is being done to help us understand public opinion about human tissue samples donated by people for medical research.

Medical research is essential to improve our understanding of what keeps us healthy and how diseases start and progress. It also means scientists can develop new and improved treatments. Body fluid such as blood, saliva and urine, and human tissue such as cells, skin, fat or even whole organs (in the event of someone's death), are often used in scientific and medical research. Usually these are referred to as samples.

Types of research that need samples include:

- Looking at how the body works to fight disease.
- Looking at why some people are more likely to develop certain diseases.
- Developing tests to diagnose conditions like cancer or dementia earlier on.
- Testing new treatments for conditions such as heart disease and diabetes.
- Researching how certain types of cells could be used to treat conditions like Parkinson's disease and Alzheimer's disease.

Many of the tests and treatments used today resulted from people donating samples for research previously. The removal of samples from a person is always done with the donor's permission. Samples that are donated for research are anonymised so that the researcher using the sample does not know who it came from. The types of research that are allowed to take place are highly regulated by both UK law and also by independent research ethics committees (usually made up of doctors, scientist, patients and the general public). These ensure any research allowed to be done is for the benefit of patients.

The next button will appear shortly. In the meantime take some time to read the information above as it relates to the remainder of the survey.

Q15. On a scale of 1 to 5 with 1 being Not At All Important and 5 being Extremely Important, how important do you think it is for people to donate samples for medical research?

SCALE:

1. Not at all important
2.

3.
4.
5. Extremely important
97. Don't know

Q16. Samples can be left over from surgery or a medical procedure, or they can be donated specifically for research. Left over samples that are not required for clinical diagnosis or donated for medical research are often destroyed.

In general, would you like to be asked to donate samples for medical research?

1. Definitely yes
2. Probably yes
3. Probably not
4. Definitely not
97. Don't know

RANDOMISE STATEMENTS

Q17. You are having a medical procedure to treat a health issue. Would you donate the following types of samples for medical research if they were left over (after necessary medical tests had been done) following the procedure?

SCALE:

1. Definitely yes
2. Probably yes
3. Probably not
4. Definitely not
97. Don't know

STATEMENTS:

1. Blood
2. Skin tissue
3. Fat
4. Cancerous tissue
5. Liver tissue
6. Bone or cartilage
7. Spare eggs not fertilised during IVF treatment (IVF is a process by which an egg is fertilised by a sperm outside the body and then transferred back into the body to establish a successful pregnancy) **ASK ONLY FEMALES**
8. Spare embryos (fertilised eggs) not transferred back into the body following IVF (IVF is a process by which an egg is fertilised by a sperm outside the body and then transferred back into the body to establish a successful pregnancy)

RANDOMISE STATEMENTS

Q18. You've gone to the hospital for an appointment and whilst you are in the waiting room the receptionist explains they are collecting samples for medical research. Would you agree to donate the following types of samples specifically for medical research, i.e. not as part of any medical procedure, put purely for the purposes of research?

Would you agree to donate the following types of samples specifically for medical research? Below are some definitions you might need to know in order to answer the questions.

Local anaesthetic - "A type of painkilling medication that is used to numb areas of the body during surgical procedures. You stay awake when you have a local anaesthetic"

General anaesthetic - "A medication that causes loss of sensation. It is used to give pain relief during surgery. General anaesthetic makes you completely lose consciousness so that surgery can be carried out without causing any pain or discomfort. Most healthy people don't have any problems when having a general anaesthetic. However, as with most medical procedures, there is a small risk of long-term complications and, rarely, death."

SCALE:

1. Definitely yes
2. Probably yes
3. Probably not
4. Definitely not
97. Don't know

STATEMENTS:

1. Saliva
2. Urine
3. Blood
4. Tissue collected requiring a local anaesthetic (e.g. a skin cell scraping)
5. Tissue collected requiring a general anaesthetic (e.g. a liver sample)
6. Sperm **ASK ONLY MALES**

Q19. In the event of your death, would you be willing to donate the following for medical research?

SCALE:

1. Definitely yes
2. Probably yes
3. Probably not
4. Definitely not
97. Don't know

STATEMENTS:

1. A small sample of the liver
2. A small sample of the brain
3. A whole liver
4. A whole brain

Q20. You are having surgery for a health issue which requires a general anaesthetic. The surgeon asks you whether you would be willing to consent to any additional tissue (i.e. tissue not needing to be removed as part of the health issue) being taken during the surgery for medical research. He assures you that any additional tissue taken would have no impact for you or your health and that no extra tissue would be removed without your consent.

A decision to consent or not to consent would be equally respected and would have no impact on the care you receive.

Would you be willing to donate the following types of samples for medical research?

General anaesthetic - "A medication that causes loss of sensation. It is used to give pain relief during surgery. General anaesthetic makes you completely lose consciousness so that surgery can be carried out without causing any pain or discomfort. Most healthy people don't have any problems when having a general anaesthetic. However, as with most medical procedures, there is a small risk of long-term complications and, rarely, death."

SCALE:

1. Definitely yes
2. Probably yes
3. Probably not
4. Definitely not

97. Don't know

STATEMENTS:

1. Samples taken from the same part of the body being operated on
2. Samples taken from an area close by
3. Samples involving an additional procedure e.g. taking bone marrow or a tissue sample whilst under the same general anaesthetic

RANDOMISE STATEMENTS

Q21. Samples may be used for lots of different types of research. The types of research that are allowed to take place are highly regulated by both UK law and also by research ethics committees. Would you be willing to donate samples for the following types of research?

Research ethics committee - "A committee usually made up of doctors, scientist, patients and the general public. These ensure any research allowed to be done is for the benefit of patients."

SCALE:

1. Definitely yes
2. Probably yes
3. Probably not
4. Definitely not
97. Don't know

STATEMENTS:

1. Understanding how our body fights disease
2. Understanding how our genetic makeup influences whether or not we will be affected by certain conditions
3. Testing new treatments
4. Research which involves using cells that come from embryos *(fertilised eggs)*
5. Research involving animals
6. Research conducted outside of the UK

RANDOMISE ORDER OF STATEMENTS.

Q22. There are many places where research is performed, such as universities, the NHS, medical research charities such as Cancer Research UK and Arthritis Research UK, pharmaceutical companies and diagnostic companies. These organisations work individually, and often in collaboration, to carry out research, to understand disease, develop tests for diseases and develop and test new treatments.

Would you be willing to donate samples to the following organisations to carry out approved medical research?

Diagnostic companies - "A company which develops and manufactures medical tests to diagnose diseases"

SCALE:

1. Definitely yes
2. Probably yes
3. Probably not
4. Definitely not
97. Don't know

STATEMENTS

1. NHS hospitals
2. Universities
3. Medical research charities
4. Pharmaceutical companies
5. Diagnostic companies

Q23. Samples left over following surgery and once any necessary tests have been done, can be anonymised and used for medical research. On a scale of 1 to 5 with 1 being Not At All Important and 5 being Extremely Important, how important do you think it is that you are first asked for your permission (often known as 'consent') for any left over samples to be used for medical research?
Anonymised - i.e. identifying features such as names and addresses are removed

SCALE:

1. Not at all important
2.
3.
4.
5. Extremely important

Q24. There are a number of different ways that a person could give consent for their left over samples to be used for medical research.

a) One way is an 'opt-in' system. Opt-in means that a person must specifically be asked for their permission before any leftover samples can be used in medical research.

b) The other way is an 'opt-out' system. In this system, it is assumed that a person is happy, after they turn 18 years old, for any leftover samples to be used for medical research unless they specifically say otherwise.

Which of the two systems to donating leftover samples do you prefer?

1. Opt-in
2. Opt-out
3. No preference
97. Don't know

Q25. The current system in the UK is an opt-in system. That means you have to say whether you want any leftover samples to be donated for medical research. If you were going to be asked to donate any leftover samples for medical research there are three ways this could be done.

a) You could be asked to give consent for left over samples to be used for research **every time** you have samples removed, or

b) you could be asked just **once for life** for any future left over samples to be used for medical research (with the option of withdrawing your permission at any later point if you wanted to),

c) you could be **asked at certain points** during your life, for example every 10 years by your GP, or at the start of treatment for a particular condition or health issue.

Which of these three approaches do you prefer?

1. Consent every time
2. Consent once for life
3. Consent at certain points
4. No preference
97. Don't know

Q26. If you were going to be asked to donate left over samples for medical research every time you had a medical procedure, would you rather this was discussed with you by a health professional before the medical procedure or afterwards?

1. Before
2. After
3. No preference
97. Don't know

Q27. If we adopted a consent once for life system in the UK for adults (i.e. aged 18 years and over), when would you prefer to be asked about consenting left over samples for medical research? *Choose up to 3 options.*

1. When registering at a GP surgery
2. During a routine GP appointment
3. When applying for a driving license
4. When applying for a passport
5. The first time I visit the hospital
6. The first time I have a medical procedure (e.g. blood test or surgery)
98. Other (please specify)

Q28. What would be your preferred way to register your consent to donate left over samples for medical research?

1. Face to face with a health professional
2. Letter
3. Email
4. Telephone
5. Via a website
6. Completing a form (from a GP surgery, post office, library or other community centre) and returning it by post
98. Other (please specify)
97. Don't know

Q29. If you later decided you didn't want your samples to be used for medical research, what would be your preferred way to withdraw that consent?

1. Face to face with a health professional
2. Letter
3. Email
4. Telephone
5. Via a website
6. Completing a form (from a GP surgery, post office, library or other community centre) and returning it by post

98. Other (please specify)
97. Don't know

Q30. Imagine you have agreed to donate a sample for medical research. There are a number of ways you can give consent for that particular sample to be used:

STATEMENTS

1. You can give consent once for your sample to be used in any future research that has been approved by a research ethics committee. This type of consent is called Generic Consent.

   Thinking about Generic Consent, if this was the type of consent you were asked to give, how likely would you be to donate samples for medical research?

   Research ethics committee. "A committee usually made up of doctors, scientist, patients and the general public. These ensure any research allowed to be done is for the benefit of patients."

2. You can give consent once for your sample to be used in any future research that has been approved by a research ethics committee but with the option of saying whether there are certain types of research you don't want your sample to be used for. This type of consent is called Tiered Consent.

   Thinking about Tiered Consent, if this was the type of consent you were asked to give, how likely would you be to donate samples for medical research?

   Research ethics committee. "A committee usually made up of doctors, scientist, patients and the general public. These ensure any research allowed to be done is for the benefit of patients."

3. You can give consent once for the sample to be used for a specific study that you have been told about, which has been approved by a research ethics committee. The sample will not be used for any other research other than the particular study you have given consent for. Any leftover tissue at the end of the study may be destroyed. This type of consent is called Specific Consent – once only.

   Thinking about Specific Consent – once only, if this was the type of consent you were asked to give, how likely would you be to donate samples for medical research?

   Research ethics committee. "A committee usually made up of doctors, scientist, patients and the general public. These ensure any research allowed to be done is for the benefit of patients."

4. **Lastly**, you can give consent every time for the sample to be used for a specific study that you have been told about, which has been approved by a research ethics committee. With this type of consent you would then be contacted and asked for your consent for every new study in which your sample might be used. This type of consent is called Consent for every new study.

   Thinking about Consent for every new study if this was the type of consent you were asked to give, how likely would you be to donate samples for medical research?

   Research ethics committee. "A committee usually made up of doctors, scientist, patients and the general public. These ensure any research allowed to be done is for the benefit of patients."

SCALE:

1. Definitely yes
2. Probably yes
3. Probably not
4. Definitely not
97. Don't know

Q31. Which of these four types of consent do you prefer? Please rank them in order of preference. Put 1 for your first preference; 2 for your second; 3 for your third preference and 4 for your last preference. If you don't have any preference, and like all 4 equally, tick the 'No preference' you don't know then tick ' Don't know'

1. Generic consent
2. Tiered consent
3. Specific consent – once only
4. Consent for every new study
5. No preference
97. Don't know

ASK TO THOSE PEOPLE WHO DID NOT RANK GENERIC CONSENT AS FIRST CHOICE

Q32. Generic consent is the most practical type of consent as it is the least costly to put in place. Researchers try their very best to honour donors' wishes, but in some cases where it is too costly to put Tiered or Specific Consent in place, instead of risking using a sample for something the donor feels strongly against, it won't be used at all. If Tiered or Specific consent was not available, what would you do?

1. I would agree to give generic consent
2. I would rather my sample was not used at all
97. Don't know

Q33. Some people feel there are certain types of samples that are more sensitive to donate, for example sperm or left over eggs. If there was a sample that you considered to be sensitive, but were still willing to donate for medical research, which of the four types of consent would you prefer to give?

1. Generic consent
2. Tiered consent
3. Specific consent – once only
4. Consent for every new study
5. No preference
97. Don't know

Q34. Researchers often need to have access to the donor's medical records to be able to interpret the results of their scientific research. However, information such as names or addresses are always removed and are not included with the sample. This is so that the person who donated the sample cannot be identified by the scientist conducting the research or anyone analysing the results of the research. However, the sample may have a code so that someone not involved in the research can identify the individual if necessary, for example, if there was a serious health issue the donor should be aware of.

Would you be willing to have your anonymised medical records linked to your sample?

1. Definitely yes
2. Probably yes
3. Probably not
4. Definitely not
97. Don't know

Q35. Sometimes it can also be helpful for the researcher to have certain information about the lifestyle of the person who donated the sample, for example whether they smoke, drink alcohol, how often they exercise etc. This information might help them to better understand the particular

condition they are investigating. Would you be willing to have your anonymised lifestyle information linked to your sample?

1. Definitely yes
2. Probably yes
3. Probably not
4. Definitely not
97. Don't know

Q36. For some people, it would be interesting to find out what type of medical research is going on. How would you like to get information on medical research including research on a particular condition that might use your sample?

1. Website
2. Newsletter
3. Email
4. Letter
5. Would not be interested in additional information

Q37. If you were considering donating whole organs for medical research in the event of your death, are there any particular organs you would **not** feel comfortable donating?
Please choose all that apply.

1. Brain
2. Eyes
3. Heart
4. Kidneys
5. Liver
6. Lungs
7. I would not donate any of my organs for medical research
8. None of the above apply as I would be happy to donate either all my organs or whole body for research

98. Other organs I would not donate (please state)

Q38. Sometimes, organs donated for transplant can't be transplanted because for some reason they are not suitable. However, these organs can still be very useful to researchers. Would you be willing to donate organs you had intended for transplant for medical research instead if the organ was not suitable?

1. Yes, I would donate an organ for research if it was not suitable for transplant
2. No, if they can't be used for transplant I would prefer they were not used at all
3. I would not agree to donate an organ for transplant

97. Don't know

Q39. If someone wanted to donate their tissue or organs for medical research in the event of their death, how do you think they should be able to provide their consent to do this?

1. It should be obtained at the same time as consent for organ transplantation and recorded on the organ donor register
2. It should be discussed at a GP appointment and recorded in the patients' notes
3. It should be discussed at a hospital and recorded in the patients' notes
98. Other (please specify)
97. Don't know

Q40. Someone has indicated in writing that they are willing to donate tissue or organs for medical research in the event of their death. After the donor's death the relatives decide they disagree with the donor's wishes. Do you think the relatives should be allowed to override the donor's wishes?

1. Yes
2. No
97. Don't know

Q41. If you have any particular views you would like to share with us about the topics raised in this questionnaire please feel free to write them here:

Appendix VI

Results of survey –unweighted and weighted

Demographic Data				
	Unweighted		Weighted	
	N	%	N	%
Sex				
Male	504	45%	544	49%
Female	606	55%	566	51%
Socioeconomic Group				
A	41	4%	44	4%
B	215	19%	244	22%
C1	311	28%	322	29%
C2	233	21%	233	21%
D	145	13%	178	16%
E	165	15%	89	8%
Age				
18-24	135	12%	133	12%
25-34	184	17%	189	17%
35-44	198	18%	200	18%
45-54	184	17%	189	17%
55-64	176	16%	167	15%
65+	233	21%	233	21%
Occupation				
Higher managerial	41	4%	44	4%
Intermediate managerial	215	19%	244	22%
Supervisory or clerical level	288	26%	299	27%
Student	23	2%	23	2%
Skilled manual worker	233	21%	233	21%
Semi or unskilled manual work	145	13%	178	16%
Casual worker	12	1%	6	1%
Housewife	9	1%	5	0%
Retired	81	7%	45	4%
Unemployed	46	4%	24	2%
Carer	17	2%	9	1%
Other	0	0%	0	0%
Region				
Channel Islands	0	0%	0	0%
East of England	92	8%	100	9%
East Midlands	57	5%	78	7%

Appendix VI

Results of survey –unweighted and weighted

London	213	19%	144	13%
North East	40	4%	44	4%
North West	121	11%	122	11%
Northern Ireland	30	3%	33	3%
Scotland	76	7%	89	8%
South East	165	15%	155	14%
South West	81	7%	89	8%
Wales	51	5%	55	5%
West Midlands	94	8%	100	9%
Yorkhire/Humberlands	90	8%	100	9%
Not on map	0	0%	0	0%
Ethnicity				
White or White British	1057	95%	1065	96%
Mixed race	7	1%	8	1%
Asian or Asian British (not Chinese)	18	2%	17	1%
Black or Black British	19	2%	12	1%
Chinese	2	0%	2	0%
Other ethnic group	4	0%	2	0%
Prefer not to say	3	0%	2	0%
Religion				
Christianity	677	61%	673	61%
Islam	13	1%	11	1%
Hinduism	6	1%	6	1%
Sikhism	0	0%	0	0%
Judaism	6	1%	4	1%
Buddhism	11	1%	1	0%
Other religion	15	1%	8	0%
No religion	370	33%	205	38%
Prefer not to say	12	1%	7	1%
To what extent do you consider yourself religious?				
Not at all religious	234	32%	234	32%
Moderately religious	422	58%	424	59%
Very religious	64	9%	56	8%
Prefer not to say	8	1%	7	1%
Education				
No formal qualification	70	6%	66	6%
GCSE, O level, Scottish Standard Grade or equivalent	264	24%	252	23%

Appendix VI

Results of survey –unweighted and weighted

GCE, A-level, Scottish Higher or similar	214	19%	214	19%
Vocational (BTEC/NVQ/Diploma)	230	21%	237	21%
Degree level or above	317	29%	330	30%
Prefer not to say	15	1%	10	1%

Q9 How would you describe your own level of knowledge about the medical research process including the use of human tissue samples?

	Unweighted		Weighted	
	N	%	N	%
No knowledge	463	42%	466	42 %
Some knowledge	603	54 %	602	54 %
Good knowledge	44	4 %	43	4 %

Q10 Are you or have you ever been affected by a long-standing illness, disability or infirmity which has required continuous or frequent medical attention

	Unweighted		Weighted	
	N	%	N	%
Yes	399	36 %	391	35%
No	711	64 %	719	65%

Q11 Has a close family member ever been affected by a long-standing illness, disability or infirmity which has required continuous or frequent medical attention

	Unweighted		Weighted	
	N	%	N	%
Yes	767	69 %	765	69%
No	343	31 %	345	31%

Q12 Have you ever had blood or tissue removed during a medical or surgical procedure?

	Unweighted	Weighted

Appendix VI

Results of survey –unweighted and weighted

	N	%	N	%
Yes	446	40 %	444	40%
No	553	50 %	551	50%
Don't Know	111	10 %	115	10%

Q13 Have you ever been asked to donate any blood or tissue for medical research?				
	Unweighted		Weighted	
	N	%	N	%
Yes	182	16 %	177	16%
No	904	81 %	907	82%
Don't Know	24	2 %	25	2%

Q14 Did you agree to donate?				
	Unweighted		Weighted	
	N	%	N	%
Yes	155	85 %	153	86%
No	23	13 %	21	12%
Don't Know	4	2 %	3	2%

Q15 On a scale of 1 to 5 with 1 being Not At All Important and 5 being Extremely Important, how important do you think it is for people to donate samples for medical research?				
	Unweighted		Weighted	
	N	%	N	%
1 Not at all important	5	0 %	4	0%
2	10	1 %	9	1%
3	78	7 %	76	7%
4	406	37 %	408	37%
5 Extremely important	554	50 %	567	51%
Don't know	57	5 %	46	4%

Appendix VI

Results of survey –unweighted and weighted

Q16 In general, would you like to be asked to donate samples for medical research?				
	Unweighted		Weighted	
	N	%	N	%
Definitely yes	317	29 %	327	29%
Probably yes	513	46 %	526	47%
Probably not	157	14 %	145	13%
Definitely not	42	4 %	35	3%
Don't know	81	7 %	77	7%

Q17 Would you donate the following types of samples for medical research if they were left over following the procedure?											
		Unweighted					Weighted				
		Def yes	Prob yes	Prob not	Def not	Don't know	Def yes	Prob yes	Prob not	Def not	Don't know
Blood	N	587	433	48	23	19	599	425	48	20	8
	%	53%	39%	4%	2%	2%	54%	38%	4%	2%	2%
Skin Tissue	N	520	451	72	32	35	533	451	67	28	32
	%	47%	41%	6%	3%	3%	48%	41%	6%	3%	3%
Fat	N	530	450	60	32	38	541	449	56	26	37
	%	48 %	41%	5%	3%	3%	49%	40%	5%	2%	3%
Cancerous Tissue	N	572	425	52	26	35	586	420	49	22	34
	%	52 %	38%	5%	2%	3%	53%	38%	4%	2%	3%
Liver Tissue	N	463	468	100	38	41	474	476	96	34	39
	%	42 %	42%	9%	3%	4%	43%	42%	9%	3%	4%
Bone or Cartilage	N	472	460	90	46	42	482	460	87	41	40
	%	43 %	41%	8%	4%	4%	43%	41%	8%	4%	4%
Spare eggs not fertilised during	N	133	159	121	104	89	128	149	111	93	86
	%	22 %	26%	20%	17%	15%	23%	26%	20%	16%	15%

Appendix VI

Results of survey –unweighted and weighted

IVF *											
Spare embryos	N	225	245	217	223	200	230	254	210	213	203
	%	20 %	22%	20%	20%	18%	21%	23%	19%	19%	18%

*Female Only

Q18 Would you agree to donate the following samples specifically for medical research?											
		Unweighted					Weighted				
		Def yes	Prob yes	Prob not	Def not	Don't know	Def yes	Prob yes	Prob not	Def not	Don't know
Saliva	N	568	423	54	30	35	581	413	55	27	34
	%	51 %	38%	5%	3%	3%	52%	37%	5%	2%	3%
Urine	N	553	432	61	33	31	566	424	60	30	30
	%	50 %	39%	5%	3%	3%	51%	38%	5%	3%	3%
Blood	N	455	448	118	47	42	496	446	107	46	42
	%	41 %	40%	11%	4%	4%	42%	40%	10%	4%	4%
Tissue collected requiring a local anaesthetic	N	273	463	197	100	77	283	471	190	88	78
	%	25 %	42%	18%	9%	7%	26%	42%	17%	8%	7%
Tissue collected requiring a general anaesthetic	N	166	286	310	235	113	172	300	309	214	115
	%	15 %	26%	28%	21%	10%	16%	27%	28%	19%	10%
Sperm *	N	120	171	104	66	43	135	188	111	64	46
	%	24 %	34%	21%	13%	9%	25%	35%	20%	12%	9%

*Men only

Appendix VI

Results of survey –unweighted and weighted

Q19 In the event of your death, would you be willing to donate the following samples for medical research?											
		Unweighted					Weighted				
		Def yes	Prob yes	Prob not	Def not	Don't know	Def yes	Prob yes	Prob not	Def not	Don't know
A small sample of your liver	N	485	390	88	51	96	491	391	84	48	96
	%	44 %	35%	8%	5%	9%	44%	35%	8%	4%	9%
A small sample of your brain	N	429	304	166	96	115	438	305	158	94	116
	%	39 %	27%	15%	9%	10%	39%	27%	14%	8%	10%
A whole liver	N	430	319	158	87	116	438	316	154	84	118
	%	39 %	29%	14%	8%	10%	39%	28%	14%	8%	11%
A whole brain	N	353	234	221	150	152	360	236	214	145	155
	%	32 %	21%	20%	14%	14%	32%	21%	19%	13%	14%

Q20 You are having surgery for a health issue which requires a general anaesthetic. The surgeon asks you whether you would be willing to consent to any additional tissue?											
		Unweighted					Weighted				
		Def yes	Prob yes	Prob not	Def not	Don't know	Def yes	Prob yes	Prob not	Def not	Don't know
From the same part of the body	N	328	530	115	51	86	342	523	112	50	83
	%	30 %	48%	10%	5%	8%	31%	47%	10%	5%	7%
Samples taken from an area close by	N	219	481	212	89	109	229	490	206	81	104
	%	20 %	43%	19%	8%	10%	21%	44%	19%	7%	9%
Samples involving an	N	154	336	298	204	118	164	348	301	180	118
	%	14 %	30%	27%	18%	11%	15%	31%	27%	16%	11%

Appendix VI

Results of survey –unweighted and weighted

additional procedure											

Q21 You are having surgery for a health issue which requires a general anaesthetic. The surgeon asks you whether you would be willing to consent to any additional tissue?

		Unweighted					Weighted				
		Def yes	Prob yes	Prob not	Def not	Don't know	Def yes	Prob yes	Prob not	Def not	Don't know
Understanding how our body fights disease	N	390	558	72	27	63	399	554	71	24	62
	%	35 %	50%	6%	2%	6%	36%	50%	6%	2%	6%
Understanding how our genetic makeup...	N	305	558	115	47	85	312	564	107	43	83
	%	27 %	50%	10%	4%	8%	28%	51%	10%	4%	8%
Research that is testing new treatments	N	318	511	132	52	97	325	502	133	50	99
	%	29 %	46%	12%	5%	9%	29%	45%	12%	5%	9%
Research involving cells from embryos	N	157	304	228	214	207	167	319	225	199	200
	%	14 %	27%	21%	19%	19%	15%	29%	20%	18%	18%
Research involving animals	N	107	270	281	318	134	117	285	271	304	132
	%	10%	24%	25%	29%	12%	11%	26%	24%	27%	12%
Research outside the UK	N	109	273	350	199	179	115	277	349	199	170
	%	10 %	25%	32%	18%	16%	10%	25%	31%	18%	15%

Appendix VI

Results of survey –unweighted and weighted

Q22 Would you be willing to donate samples to be used by the following organisations?											
		Unweighted					Weighted				
		Def yes	Prob yes	Prob not	Def not	Don't know	Def yes	Prob yes	Prob not	Def not	Don't know
NHS Hospitals	N	367	570	69	31	73	379	569	65	28	70
	%	33 %	51%	6%	3%	7%	34%	51%	6%	2%	6%
Universities	N	243	515	185	56	111	255	519	173	54	108
	%	22 %	46%	17%	5%	10%	23%	47%	16%	5%	10%
Medical Research Charities	N	307	563	107	41	92	311	561	108	39	91
	%	28 %	51%	10%	4%	8%	28%	51%	10%	4%	8%
Pharmaceutical Companies	N	138	487	233	93	159	139	490	227	95	161
	%	12 %	44%	21%	8%	14%	12%	44%	20%	9%	14%
Diagnostic Companies	N	187	515	180	74	154	182	511	183	74	159
	%	17 %	46%	16%	7%	14%	16%	46%	17%	7%	14%

Q23 How important do you think it is that you are first asked for your permission (often known as 'consent') for any leftover samples to be used for medical research?				
	Unweighted		Weighted	
	N	%	N	%
1 Not at all important	40	4 %	42	4%
2	41	4 %	43	4%
3	104	9 %	103	9%
4	274	25 %	268	24%
5 Extremely important	615	55 %	614	55%
Don't know	36	3 %	40	4%

Appendix VI

Results of survey –unweighted and weighted

Q24 How important do you think it is that you are first asked for your permission (often known as 'consent') for any leftover samples to be used for medical research?				
	Unweighted		Weighted	
	N	%	N	%
Opt-in	605	55 %	598	54%
Opt-out	308	28 %	321	29%
No preference	151	14 %	146	13%
Don't know	46	4 %	45	4%

Q25 Which of these three approaches do you prefer?				
	Unweighted		Weighted	
	N	%	N	%
Consent every time	472	43 %	480	43%
Consent once for life	231	21 %	237	21%
Consent at certain points	301	27 %	298	27%
No preference	82	7 %	72	7%
Don't know	24	2 %	22	2%

Q26 If you were going to be asked to donate left over samples for medical research every time you had a medical procedure, would you rather this was discussed with you by a health professional before the medical procedure or afterwards?				
	Unweighted		Weighted	
	N	%	N	%
Before	897	81 %	908	82%
After	48	4 %	48	4%
No preference	151	14 %	142	13%
Don't know	14	1 %	12	1%

Appendix VI

Results of survey –unweighted and weighted

Q27 If a consent once for life system was in place, when would you prefer to be asked about consenting left over samples for medical research?				
	Unweighted		Weighted	
	N	%	N	%
When registering at a GP surgery	425	39 %	419	38%
During a routine GP appointment	386	35 %	380	34%
When applying for a driving	83	8 %	88	8%
When applying for a passport	75	7 %	80	7%
The first time I visit the hospital	233	21 %	228	21%
The first time I have a medical	513	47 %	510	46%

Q28 If a consent once for life system was in place, when would you prefer to be asked about consenting left over samples for medical research?				
	Unweighted		Weighted	
	N	%	N	%
Face to face with a health professional	720	65 %	727	65%
Letter	66	6 %	64	6%
Email	30	3 %	32	3%
Telephone	14	1 %	13	1%
Via a website	60	5 %	61	6%
Completing a form and returning it by post	161	15 %	160	14%
Other (please specify)	4	0 %	4	0%
Don't know	55	5 %	49	4%

Q29 If you later decided you didn't want your samples to be used for medical research, what would be your preferred way to withdraw that consent?				
	Unweighted		Weighted	
	N	%	N	%
Face to face with a health professional	421	38 %	424	38%
Letter	95	9 %	92	8%
Email	89	8 %	93	8%
Telephone	56	5 %	51	5%
Via a website	137	12 %	144	13%

Appendix VI

Results of survey –unweighted and weighted

Completing a form and returning it by post	243	22 %	244	22%
Other (please specify)	8	1 %	6	1%
Don't know	61	5 %	55	5%

Q30 How likely would you be to donate samples for medical research using the following models of consent?

		Unweighted					Weighted				
		Def yes	Prob yes	Prob not	Def not	Don't know	Def yes	Prob yes	Prob not	Def not	Don't know
Generic	N	216	528	163	64	139	228	538	154	52	38
	%	19 %	48%	15%	6%	13%	21%	48%	14%	5%	12%
Tiered	N	242	549	125	55	139	244	560	124	49	133
	%	22 %	49%	11%	5%	13%	22%	50%	11%	4%	12%
Specific	N	336	553	88	28	105	339	551	89	29	102
	%	30 %	50%	8%	3%	9%	31%	50%	8%	3%	9%
Specific consent for every new study	N	293	560	110	27	120	300	560	109	26	115
	%	26 %	50%	10%	2%	11%	27%	50%	10%	2%	10%

Q31 Which of these four types of consent do you prefer?

Preferences	Unweighted		Weighted	
	N	%	N	%
Generic				
1st	200	18%	207	19%
2nd	159	14%	163	15%
3rd	168	15%	168	15%
4th	344	31%	327	30%
Tiered				
1st	156	14%	152	14%
2nd	246	22%	252	23%

Appendix VI

Results of survey –unweighted and weighted

3rd	360	32%	355	32%
4th	105	10%	106	10%
Specific (once only)				
1st	198	18%	183	17%
2nd	306	28%	304	27%
3rd	202	18%	209	19%
4th	161	15%	169	15%
Specific (every time)				
1st	341	31%	323	29%
2nd	157	14%	146	13%
3rd	138	12%	133	12%
4th	258	23%	263	24%
Don't Know	63	6%	62	6%
No Preference	181	16%	183	17%

Q32 If your preferred system of consent was not available, what would you do?

	Unweighted		Weighted	
	N	%	N	%
I would agree to give generic consent	348	52 %	350	53%
I would rather my sample was not used at all	187	28 %	172	26%
Don't know	133	20 %	135	21%

Q33 If there was a sample that you considered to be sensitive, but were still willing to donate for medical research, which of the four types of consent would you prefer to give?

	Unweighted		Weighted	
	N	%	N	%
Generic Consent	131	12 %	135	12%
Tiered Consent	105	9 %	101	9%
Specific Consent – once only	246	22 %	228	21%
Consent for every new study	278	25 %	288	26%

Appendix VI

Results of survey –unweighted and weighted

No Preference	206	19 %	216	19%
Don't Know	144	13 %	142	13%

Q34 Would you be willing to have your anonymised medical records linked to your sample?				
	Unweighted		Weighted	
	N	%	N	%
Definitely yes	266	24 %	279	25%
Probably yes	493	44 %	497	45%
Probably not	165	15 %	157	14%
Definitely not	77	7 %	71	6%
Don't know	109	10 %	107	10%

Q35 Would you be willing to have your anonymised lifestyle information linked to your sample?				
	Unweighted		Weighted	
	N	%	N	%
Definitely yes	377	34 %	398	35%
Probably yes	530	48 %	527	47%
Probably not	90	8 %	90	8%
Definitely not	48	4 %	43	4%
Don't know	65	6 %	61	5%

Q36 How would you like to get information on medical research including research on a particular condition that might use your sample?				
	Unweighted		Weighted	
	N	%	N	%
Website	295	27 %	304	27%
Newsletter	104	9 %	97	9%
Email	302	27 %	315	28%
Letter	241	22 %	228	21%
Would not be interested in additional information	168	15 %	166	15%

Appendix VI

Results of survey –unweighted and weighted

Q37 Are there any particular organs you would not feel comfortable donating in the event of your death?				
	Unweighted		Weighted	
	N	%	N	%
Brain	337	31%	329	30%
Eyes	307	28%	308	28%
Heart	128	12%	121	11%
Kidneys	60	5 %	59	5%
Liver	68	6 %	65	6%
Lungs	67	6%	63	6%

Q38 If you were considering donating whole organs for medical research in the event of your death, are there any particular organs you would not feel comfortable donating?				
	Unweighted		Weighted	
	N	%	N	%
Yes, I would donate an organ for research if it was not suitable for transplant	755	68 %	766	69%
No, if they can't be used for transplant I would prefer they were not used at all	125	11 %	121	11%
I would not agree to donate an organ for transplant	96	9 %	95	9%
Don't know	134	12 %	128	12%

Appendix VI

Results of survey –unweighted and weighted

Q40 Would you be willing to have your anonymised lifestyle information linked to your sample?)	Unweighted		Weighted		Unweighted	Weighted
	N	%	N	%	N	%
It should be obtained at the same time as consent for organ transplantation and recorded on the organ donor register	174	16 %	166	15%		
No	789	71 %	800	72%	580	52 %	579	52%
Don't know	147	13 %	144	13%		
It should be discussed at a GP appointment and recorded in the patients' notes					270	24 %	267	24%
It should be discussed at a hospital and recorded in the patients' notes					140	13 %	143	13%
Other					13	1 %	14	1%
Don't know					107	10 %	108	10%

Note: percentages may not add up to 100% due to rounding.

Consent for the use of human biological samples for biomedical research – a mixed methods study exploring the UK public's preferences

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Consent for the use of human biological samples for biomedical research – a mixed methods study exploring the UK public's preferences

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ABSTRACT

Objective: A mixed methods study exploring the UK general public's views towards consent for the use of biosamples for biomedical research.

Setting: Cross-sectional population-based focus groups followed by an online survey.

Participants: Twelve focus groups (81 participants) selectively sampled to reflect a range of demographic groups; 1110 survey responders recruited through a stratified sampling method with quotas set on sex, age, geographical location, socio-economic group and ethnicity.

Main outcome measures: 1) Views on the importance of consent when donating residual biosamples for medical research; 2) preferences for opt-in or opt-out consent approaches; 3) preferences for different consent models.

Results: Participants believed obtaining consent for use of residual biosamples was important as it was "morally correct" to ask, and enabled people to make an active choice and retain control over their biosamples. Survey responders preferred opt-in consent (55%); the strongest predictor was being from a low socio-economic group (OR 2.22, 95% CI 1.41-3.57, p=0.001) and having a religious affiliation (OR 1.36, 95% CI 1.01-1.81, p=0.04). Focus group participants had a slight preference for opt-out consent because by using this approach more biosamples would be available and facilitate research. Concerning preferred models of consent for research use of biosamples, survey responders preferred specific consent with re-contact for each study for which their biosamples are eligible. Focus group participants preferred generic consent as it provided "flexibility for researchers" and reduced the likelihood that biosamples would be wasted. The strongest predictor for preferring specific consent was preferring opt-in consent (OR 4.58, 95% CI 3.30-6.35, p=0.015) followed by non-'White' ethnicity (OR 2.94, 95% CI 1.23-7.14, p<0.001).

Conclusions: There is a preference amongst the UK public for ongoing choice and control over donated biosamples, however increased knowledge and opportunity for discussion is associated with acceptance of less restrictive consent models for some people.

ARTICLE SUMMARY

Article focus

- To explore views of the UK public on the importance of consent being sought to the use of residual biosamples for medical research;
- The publics' preferences for opt-in or opt-out approaches to consent;
- The publics' preferences for generic, tiered or specific consent.

Key messages

- Obtaining consent for the use of residual biosamples for biomedical research was perceived as important by members of the general public.
- Survey participants exhibited a desire to retain active choice and control when donating biosamples and over the uses to which their biosamples might be put, preferring an opt-in system and specific consent, however these results differ from those reported during focus group discussions, where preference was for less restrictive consent models (an opt-out system and generic consent) that are likely to increase availability of biosamples.
- These differences might be accounted for by the fact that focus group participants were given more background information about the use of residual biosamples in research and had time to consider the benefits and disadvantages of the different approaches.

Strengths and limitations of this study

- This study contributes further to our understanding of the UK public's views and preferences towards consent for the use of biosamples in medical research. Our study supports the premise that increased knowledge and opportunity for discussion is associated with acceptance of less restrictive consent models.
- Due to the hypothetical nature of the study, the findings may not necessarily correlate with actual behaviour.

INTRODUCTION

Human biological samples (biosamples), including organs, tissues, biofluids such as blood, and their derivatives, are increasingly important resources for biomedical research[1,2]. For example, they can help us to understand how we diagnose, categorise and treat a whole variety of medical conditions including cancer[1] and are particularly important when studying rare diseases or conditions where biosamples are hard to obtain. Biosamples are donated by either healthy volunteers or patients, either through specific research studies or as residual tissues or biofluids surplus to diagnostic requirements, or post mortem. Biosamples can be used fresh or can be first stored in a biobank, a collection of biosamples often linked with the donors' clinical and demographic information, as biosample attributes. Here, the quality of the data linked to the biosample is as important as the quality of the biosamples themselves, providing essential context within which to design analyses and interpret results or carry our further experimental studies. Clinical data may also be enriched with lifestyle and environmental information[3].

It is widely accepted that that donor consent should be sought and obtained before biosamples can be used in research[4,5]. Consent in research ethics relates to ensuring respect for the autonomy and dignity of the donors (research participants) and protecting them from abuse[5] and In fact, in England, Wales and Northern Ireland, the Human Tissue Act establishes donor consent as the baseline principle for the retention and use of organs and tissue for purposes beyond diagnosis and treatment, although further statutory consent exemptions do exist in certain circumstances, notably use of anonymised tissue from the living for research ethics committee (REC) approved research projects[6]. The value of biobanks, in supporting broad, long-term research purposes, means that the model of the consent process needs to be considered in order to ensure that it is valid and appropriate. A number of different consent frameworks which address consent scope and process have been proposed as a result[5]. However, there is continued debate as to which is the most appropriate in various situations[4,7,8].

Both the Human Tissue Authority[9] and National Research Ethics Service[10] recommend generic consent (Table 1), a view that has also been endorsed by UK research funders[11] and the Nuffield Council on Bioethics[12]. One commonly cited criticism of generic consent is that it is not sufficiently 'informed' as future research uses are not known at the time of donation[13]. Empirical research examining public and patient preferences has highlighted that there is no clear consensus on the issue, with

specific consent being identified as the most favoured form of consent in some studies[14,15], and generic consent in others[16-18].

Table 1: Approaches to consent of biosamples

Initial consent methods	
Opt-in consent	The storage and use of biosamples for research on the basis that the donor has actively agreed to do so.
Opt-out consent	The storage and use of samples for research on the basis that the donor has not objected, after previously being given the opportunity to do so.
Opt-in consent methods	
Consent once for life	Consent is provided once for life for use of any residual samples for research with the option of withdrawing permission at a later stage if the donor wishes to do so.
Consent at certain points	Consent is provided at certain points for use of residual biosamples for research, e.g. every 10 years or at the beginning of a particular episode of care.
Consent every time	Consent is requested every time residual biosamples may become available for use in research.
Consent for research use of biosamples	
Generic consent	Consent to the use of donated samples for a range of unknown uses, on the basis of general information about those possible uses and about the governance arrangements in place. Also referred to as 'broad' or 'blanket' consent.
Tiered consent	A more restricted form of consent for use of samples, where the donor is invited to agree to the use of their samples in unknown projects, but given the option of specifying particular categories of research that they wish to exclude e.g. embryonic research. Also referred to as 'categorical' consent.
Specific consent –once only	Consent to the use of donated samples for a specified study only, on the basis of information provided about that study. Any residual sample will be discarded at the end of that study.
Specific consent – for every new study	Consent to the use of donated samples for a specified study, on the basis of information provided about that study. However, participants are re-contacted and asked to consider participating in every new study for which their biosamples are eligible.

Note: Consent terms were selected based on common usage within the UK biobanking system (for example, generic consent is the term used by the Human Tissue Authority, National Research Ethics Service, and National Cancer Research Institute) and definitions chosen in consultation with a team of representatives from universities, hospital biobank staff, pathologists and industry.

The 2011 Nuffield Council report on donation of human material for medicine and research also recommends that research funders should work to increase public awareness of the key role of donated tissue in scientific and clinical research[12]. Public trust and confidence in the consent process is of paramount importance to maintain and increase public support for donation and use of biosamples for biomedical research in the UK. For this reason, it is important to understand and inform public opinion to ensure consent models are aligned to public expectations and preferences. Whilst numerous international studies have been conducted which focus on consent preferences, research conducted in the UK has tended to focus on large scale population biobanks, such as UK Biobank[19] or Generation Scotland[20], which require ongoing contact with donors, or on the views of patients on the donation of residual biosamples[21]. The current study was conducted to broaden our understanding of the UK public's views on biosample donation for biomedical research. Moreover, the findings are intended to inform a biobanking policy for STRATUM (Strategic Tissue Repository Alliance Through Unified Methods), a Technology Strategy Board[i] and pharmaceutical industry-funded project seeking to address the problem of insufficient numbers of biosamples and associated clinical data of adequate quality to fully support biomedical research in the UK.

The specific aims of this study were to 1) identify participants' views on the importance of consent when donating residual biosamples for medical research; 2) explore preferences for opt-in or opt-out approaches to consent; and 3) explore preferences for different consent models (Table 1). Public willingness to donate biosamples, views on donation of different biosample types, and conditions of their use (by which organisations and for which types of research) are reported elsewhere (Public views on the donation and use of human biological samples in biomedical research – a mixed methods study, 2013, unpublished manuscript).

METHODS

This was a mixed methods study comprising qualitative focus groups and a quantitative on-line survey. Ethical approval for the study was granted by the University of Manchester Research Ethics Committee in April 2012.

Focus groups

Twelve focus groups (including one pilot group) were conducted between May and July 2012 in six different geographic locations across the UK. Participants were recruited face-to-face in the street by a market research company The Focus Group. Participants

[i] under the Stratified Medicines Programme: Business Models Value Systems

were purposively sampled; each group chosen to reflect a particular demographic (age, socio-economic group (SEG), ethnicity) in order to gather a wide spectrum of views and enable comparisons across groups. Two 'patient' groups were also included, comprising people who had had an operation in the past two years requiring an overnight hospital stay, and people who currently have, or have had, either a serious or chronic illness, or disability. The latter group comprised people diagnosed with diabetes, cancer, heart disease, asthma and the genetic condition Marfan syndrome. A further group consisted of generally healthy volunteers who had donated a biosample specifically for research purposes.

Before agreeing to take part, potential participants were given a participant information sheet telling them about the study (see supplementary data file Appendix I). Those that were interested were screened through a questionnaire containing demographic questions to assess their suitability for a particular focus group. These were held in 'neutral' locations such as hotel conference rooms or church halls and facilitated by an experienced facilitator (CL). Before each group discussion, participants were sent a short information leaflet about the use of biosamples in biomedical research to provide some background context for the discussion and to prompt them to think about the key issues (see supplementary data file Appendix II). This information was written by a core team of authors drawn from across academia and industry, including patient representation. It was reviewed by three members of the patient organisation Genetic Alliance UK as well as the science communication charity Sense about Science to ensure readability and non-bias. Before focus group discussions began, participants were asked to sign a consent form. Each participant received £50 for taking part to cover time and travel costs. Focus groups lasted 90 minutes and digital audio recordings were taken.

A detailed discussion guide was developed to explore participant views and preferences towards consent scope and process (see supplementary data file Appendix III). The main focus related to the use of biosamples surplus to diagnostic requirements following surgery or a medical procedure. Questions were informed by other empirical studies of consent in biobanking[16,22], developed by the authors, and addressed the topics described above. To enhance understanding around the different consent models, participants were given a sheet presenting three different scenarios, each of which elaborated on one of the three consent models chosen for discussion (see supplementary data file Appendix III,p.4). For each topic, discussion began by asking the group to consider the benefits and disadvantages of each particular approach. Once no new themes were emerging, each participant was asked to complete an accompanying anonymous questionnaire which asked them to select their preferred consent model. The

discussion guide, scenario sheet and questionnaire were piloted at the first focus group which resulted in some minor amendments to wording.

Recordings were fully transcribed and transcriptions checked. The software package Nvivo version 9 (QSR International, Pty Ltd) was used to help organise the data for analysis. This comprised grouping responses to questions into broad thematic categories which were then refined through sub-codes. Coding of all 12 transcripts was conducted by CL. The first six transcripts to be coded were also independently coded by a second researcher (SR). Codes were then compared to assess consistency of coding and ensure inter-rater reliability. Any discrepancies were discussed until consensus was reached. The remainder of the transcripts were then coded according to the agreed coding framework. **Survey**

Once data analysis had been conducted on the focus group transcripts, the findings were used to inform development of a quantitative survey which was used to canvas public opinion on the issues of interest across a representative sample of the UK population (see supplementary data file Appendix IV). The survey was carried out by the market research company Research Now using their online panel community of UK residents. A stratified sampling method was used: quotas were set on sex, age, geographical location, SEG and ethnicity, in line with data provided by the Office of National Statistics (ONS) to ensure the sample was as representative of the UK population as possible. Within each category, a random sample was selected from the Research Now database containing 451,185 active respondents. We aimed to recruit 1,000 responders in total. The sample size required depends on the number of predictors, the expected effect size and the level of power. According to Miles and Shevlin [23], if we are expecting a small effect size, a sample size of 600 is considered adequate to achieve a high level of power 0f 0.8 (a benchmark suggested by Cohen [24]) for four predictors. As highlighted in Table 2 we can formulate at least four hypothesis, for example, people from a higher socio-economic group are more likely to donate biosamples than those from lower socio-economic group. With a sample size of 1,000, this study would provide highly reliable results. In order to reduce any on-line bias in our sample, 100 face-to-face interviews with non-internet users were conducted. An additional 'boost' sample of 100 people (not included in the main sample analysis) was also conducted with people from three minority ethnic groups ('Black', 'Chinese', 'S. Asian') so that we could conduct sub-group analysis between the groups.

The survey questions were developed by the authors and piloted with 60 members of Research Now's online panel community who were from low SEG's. Members of the pilot group were then invited to take part in a subsequent telephone interview asking about

the survey. Interviews were conducted with 25 pilot survey responders. Questions focused on question clarity, survey length and whether responders felt the survey to be neutral. Some minor amendments to wording were made in light of the responses. The main survey was then conducted in September 2012. Surveys recorded online took, on average, 17 minutes to complete and each responder received a small payment (around £2) from Research Now.

Survey data were organised and analysed using SPSS statistical software version 20 (Chicago, IL: SPSS Inc; 2011). Initial univariate descriptive statistics were obtained for the entire study. Pearson Chi-square was used to examine demographic factors associated with willingness to donate and preference for different consent models. Those associations that were found to be significant ($p \leq 0.05$) were then entered into a multiple logistic regression to explore the predictivity of these variables. Before running the model, we tested for multicollinearity among the independent variables. No multicollinearity issues were found.

RESULTS

Study populations

Participant characteristics are detailed in Table 2.

Table 2: Participant characteristics

Characteristic	Focus group N=81	Survey N=1110
Gender		
Male	33; 41%	504; 45%
Female	48; 59%	606; 55%
Age		
18-24	13; 16%	135; 12%
25-34	18; 22%	184; 17%
35-44	19; 23%	198; 18%
45-54	10; 12%	184; 17%
55-64	16; 20%	176; 16%
65+	5; 6%	233; 21%
Socio-economic group		
A	9; 11%	41; 4%
B	22; 27%	215; 19%
C1	24; 30%	311; 28%
C2	14; 17%	233; 21%
D	6; 7%	145; 13%
E	6; 7%	165; 15%
Region		
East of England	7; 7%	92; 8%
East Midlands	-	57; 5%
London	18; 22%	213; 19%
North East	-	40; 4%
North West	-	121; 11%

Northern Ireland	-	30; 3%
Scotland	14; 17%	76; 7%
South East	14; 17%	165; 15%
South West	-	81; 7%
Wales	-	51; 5%
West Midlands	14; 17%	94; 8%
Yorkshire/Humberlands	14; 17%	90; 8%
Ethnicity		
White or White British	54; 67%	1057; 95%
Mixed race	1; 1%	7; 1%
Asian or Asian British	10; 12%	18; 2%
Black or Black British	9; 11%	19; 2%
Chinese or Chinese British	7; 9%	2; 0%
Other ethnic group	0; 0%	4; 0%
Prefer not to say	0; 0%	3; 0%
Religion		
Christianity		677; 61%
Islam		13; 1%
Hinduism		6; 1%
Sikhism		0; 0%
Judaism		6; 1%
Buddhism		11; 1%
Other religion		15; 1%
No religion		370; 33%
Prefer not to say		12; 1%
Religiosity		
Not at all religious		234; 32%
Moderately religious		422; 58%
Very religious		64; 9%
Prefer not to say		8; 1%
Education		
No formal qualification	15; 19%	70; 6%
GCSE, O level, Scottish Standard Grade or equivalent	19; 23%	264; 24%
GCE, A-level, Scottish Higher or similar	17; 21%	214; 19%
Vocational (BTEC/NVQ/Diploma)	-	230; 21%
Degree level or above	30; 37%	317; 29%
Prefer not to say	-	15; 1%
Self reported knowledge of medical research process		
No knowledge		463; 42%
Some knowledge		603; 54%
Good knowledge		44; 4%
Have you been affected by a disability or illness?		
Yes		399; 36%
No		711; 64%
Has a close family member been affected by a disability or illness?		
Yes		767; 69%
No		343; 31%
Have you had blood or tissue removed during a medical procedure?		
Yes		446; 40%
No		553; 50%

Don't know		111; 10%
Have you ever been asked to donate blood or tissue for medical research?		
Yes		182; 16%
No		904; 81%
Don't know		24; 2%
If so, did you agree to donate?		
Yes		155; 85%
No		23; 13%
Don't know		4; 2%

Note: percentages may not add up to 100 due to rounding.

Focus groups

One hundred and eighty-two members of the public who were approached were eligible to participate (i.e. they fitted the criteria for a particular focus group) and 81 people agreed to participate (45% participation rate; 48 women, 33 men). There were seven participants in each focus group apart from the 18-25 age group and high SEG group (eight participants in each); serious/chronic illness group and healthy volunteers group (six participants in each) and the pilot group (five participants).

Survey

Four thousand six hundred and seven people were invited to take part in the survey; 2014 did not respond, 860 began completing the survey but did not finish, 102 did not qualify to continue (e.g. they were under 18 years old), 521 qualified for the survey but the quota was full and 1110 completed the questionnaire (28% response rate excluding those who did not qualify and where the quota was full). This response rate is comparable to similar studies on this topic[16]. Our participant quotas closely, though not exactly, matched our targets based on the UK population data as provided by the ONS. For this reason we carried out both weighted and un-weighted analyses. There was no difference in the conclusions we reached by either method. In this paper we present the un-weighted results (weighted results can be found at supplementary data file Appendix V).

Importance of asking for consent

The majority of survey participants believed that obtaining consent for the use of residual biosamples was either extremely important (55%) or important (25%). Only 4% selected 'not at all important'. Focus group participants also saw the consent process as important and cited reasons including: that it was "polite", "respectful" and "morally correct" to ask permission; that it enabled people to feel they had made a contribution and an active choice; that it provided control, in particular for those people that might not want their biosamples to be used, for example for religious reasons; that taking

without asking was akin to theft; and that it was important in order to maintain trust between patients and doctors.

"It then doesn't allow them to take liberties or advantage of the fact that you're out cold having an operation and someone says 'Oh we need a bit of that'." Male, patient – had operation in past 2 years.

A small minority did not feel that consent was important, the main reasons being that they did not want the tissue back, that once it was removed it no longer 'belonged to them', and that the tissue would just go to waste otherwise.

Survey participants were asked what would be their preferred method of consenting to donate leftover biosamples for research use. The majority (65%) wanted to do so face-to-face with a health professional; 15% wanted to complete a form and return it by post. This issue was not specifically addressed with focus group participants due to time constraints.

Preference for 'opt-in' or 'opt-out' consent

Participants were asked whether they preferred an opt-in or opt-out model of consent for donating residual biosamples. The results of the survey showed that opt-in consent was preferred by over half of the participants (55%), 28% preferred opt-out, 14% had no preference and 4% selected 'don't know'. Participants who were significantly more likely to prefer opt-in consent were: from a low SEG (E) (79.8% vs. 64.1%, X^2=11.13(1), p=0.001); over 65 years (75.1% vs. 64%, X^2=7.68(1), p=0.006); had a religious affiliation (68.8% vs. 61.2%, X^2=4.84(1), p=0.028); and had an education level of GCSE or lower (71.1% vs. 63.9%, X^2=3.89(1), p=0.048). The strongest significant predictor for preferring opt-in consent was being from a low SEG (E) (OR=2.22, 95% CI 1.41-3.57, p=0.001) followed by having a religious affiliation (OR=1.36, 95% CI 1.01-1.81, p=0.04) (Table 3).

Table 3: Multiple logistic regression of participant preferences for consent models

Participant characteristic	Coefficient	95% CI	Odds ratio	p value
Preference for opt-in consent				
Socio-economic group	0.806	1.41, 3.57	2.22	0.001
Religion	0.304	1.01, 1.81	1.36	0.04
Preference for consent every time				
Religion	0.72	1.05, 4.00	2.04	0.036
Age	0.47	1.07, 2.41	1.60	0.023
Preference for specific consent				
Opt-in	1.52	3.30, 6.35	4.58	<0.001
Ethnicity	1.08	1.23, 7.14	2.94	0.015
Preference for generic consent				
Opt-out	1.52	3.13, 6.67	4.55	<0.001

Religion	0.04	1.08, 2.72	1.56	0.021
Knowledge of medical research process	0.44	1.06, 2.28	1.56	0.024

Demographic items were excluded from this table if none was statistically significant. All variables were entered into the models as categorical variables.
CI: Confidence Interval.

Focus group participants preferred opt-out consent (*n*=46; 57%) over opt-in consent (*n*=29; 36%), with 6 participants (7%) unsure, after in-depth discussion around the benefits and disadvantages of each approach. The main benefit of opt-out consent cited by participants was that more biosamples would be available and consequently spur research. Other reasons included: that it would be less costly administratively; that it maximised the value of left over biosamples; that patients wouldn't have to consider it every time they were having an operation or blood test; that those that did not want to donate still had the opportunity to opt-out; and that it would 'normalise' donating leftover biosamples which would be a positive step.

"It would an incentive for society if everyone knew that this is what happens routinely, but you can choose not to be involved. It would be more like 'that's normal'." Male, aged 18-24 group

Those that preferred the opt-in approach cited the following reasons as to why: an active choice whereby participants had to act on a decision to take part was preferable to a passive choice whereby consent was assumed; it enabled people to have more control over their biosamples; it was truly 'informed consent' in the context of donating surplus samples for research (rather than as part of a clinical trial; clinical trials were outside the scope of the study) and hence more ethically acceptable; it enabled people to feel that they were making a positive contribution and would prevent the problem of vulnerable groups not being aware they were automatically 'opted-in'.

"There are going to be members of the public who are not going to always be able to consider rationally themselves what it actually means." Female, healthy volunteer

Whist the majority of focus group participants overall preferred opt-out consent, the results were different for the three minority ethnic groups (''Black'', ''S. Asian'', ''Chinese''), where opt-in consent was favoured by the majority.

Consent once for life or consent every time

The most prevalent system in current use for donating new biosamples that are surplus to clinical requirements in the UK is the opt-in approach, with potential donors being asked for consent every time a procedure is performed that may result in a biosample becoming available for research. (The law allows for the use of diagnostic archives for

research without consent as long as certain criteria are met). Participants were therefore asked to consider variations on this model and state whether they preferred: (1) consent once for life, covering all subsequent biosamples, until or unless the donor decides to withdraw consent; (2) consent every time samples surplus to diagnostic requirements may become available, or (3) consent at certain points in life. Consent every time (43%) was preferred by the majority of survey participants, followed by consent at certain points (27%) and consent once for life, e.g. at aged 18, (21%). Seven percent had no preference and 2% didn't know. Groups who were significantly more likely to prefer consent every time compared to consent once for life were: under 55 years (70.3% vs. 60.9%; X^2=5.88(1), p=0.015); had no knowledge of the research process (72.3% vs. 63.4%; X^2=5.77(1), p=0.016); or were either not at all or moderately religious (70.2% vs. 51.3%; X^2=5.1(1), p=0.024). When entered into the regression analysis, the strongest significant predictor for preferring consent every time was being not at all or moderately religious (OR=2.04; 95% CI 1.05-4.00, p=0.036) followed by being under 55 years (OR=1.60; 95% CI 1.07-2.41, p=0.023) (Table 3).

Unlike survey responders, focus group participants favoured consent once for life (*n*=35; 43%) followed by consent every time samples surplus to diagnostic requirements may become available (*n*=27; 33%) and consent at certain points (*n*=16; 20%) with three choosing don't know (4%). Like opt-out consent, consent once for life was seen to be better as it was "quicker" and "easier" administratively and prevented researchers from "losing out". Consent provided most control for participants as you would "know the specific purpose of it", particularly if the sample was considered to be sensitive e.g. eggs; allowed "no room for error"; and enabled people to change their mind easily.

"You may feel differently [depending on] what tissue is being donated and for what purpose the research is being carried out." Female, aged 18-24 group

Some participants had concerns about how consent preferences (e.g. what types of research they were willing to donate a biosample for), would follow them across the healthcare system if a 'consent once for life' model was adopted. Consent at certain points was seen by some as a good middle ground as patients would still have some control, but would not have to go through the consent process every time they had a medical procedure. Examples of consent at certain points included every "five or ten years", or at the beginning of particular episodes of care such as pregnancy or cancer treatment.

Models of consent for research use of biosamples

Survey participants were presented with four consent models (Table 1), and asked whether they would consider consenting residual biosamples to each of them, providing the research had been approved by a research ethics committee (described as a committee usually made up of doctors, scientist, patients and the general public which ensure any research allowed to be done is for the benefit of patients). Eighty percent would agree to specific consent – once only; 77% would consent to specific consent – for every new study; 71% would agree to tiered consent; and 67% of participants would agree to generic consent. When asked which model they preferred, specific consent - for every new study, was the first choice amongst those who had a preference (30% of participants overall), followed by generic consent and specific consent- once only, jointly second (both 18%), and lastly tiered consent (14%). Sixteen percent had no preference and 6% didn't know.

After collapsing the two specific consent models together (specific consent - for every new study and specific consent – once only), those participants who preferred specific consent were significantly more likely to: have a religious affiliation (63.9% vs. 48.9%, X^2=16.88(1); p<0.001); live in the North East or Scotland (60.9% vs. 42.7%, X^2=10.23(1), p=0.001); be over 65 years (67.1% vs. 57.1%, X^2=5.31(1), p=0.021); and be of a non-'White' ethnicity (68.9% vs. 58%, X^2=4.17(1), p=0.041). Using the boost sample we found that 'Black' participants were significantly more likely to prefer specific consent models compared with 'White' participants (75.6% vs. 58%, X^2=4.31(1), p=0.038). Those people who preferred opt-in consent were also more likely to prefer specific consent models (71.1% vs. 35.3%, X^2=91.72(1), p<0.001). The strongest significant predictor for preferring specific consent was preferring opt-in consent (OR=4.58, 95% CI 3.30-6.35, p<0.001) followed by being of non-'White' ethnicity (OR=2.94, 95% CI 1.23-7.14, p=0.015) (Table 3).

We also looked at who was most likely to prefer generic consent, the least restrictive of the proposed consent models. Those that preferred generic consent were significantly more likely to: have no religious affiliation (51.1% vs. 36.1%, X^2=15.97(1), p<0.001); have some or good knowledge of the medical research process (26.1% vs. 18.3%, X^2=6.79(1), p=0.009); be male (26.8% vs. 19.9%, X^2=5.40(1), p=0.02); and be from a higher SEG group (A-D) (24.3% vs. 15.1%, X^2=4.66(1), p=0.031). They were also significantly more likely to prefer opt-out consent (64.7% vs. 28.9%, X^2=91.72(1), p<0.001). The strongest significant predictor for preferring generic consent was preferring opt-out consent (OR=4.55, 95% CI 3.13-6.67, p<0.001) followed by having no religious affiliation (OR=1.56, 95% CI 1.08-2.72, p=0.021) and some or good knowledge of the medical research process (OR=1.56, 95% CI 1.06-2.28, p=0.024) (Table 3).

Focus group preferences differed from those of survey responders with generic and tiered consent being equally popular (n=36; 44% and n=35; 43% respectively). Specific consent – once only, was least popular (n=6; 7%) (this was the only specific consent model given to participants). Four participants (5%) didn't know. Generic consent was valued as it provides most "flexibility for researchers"; reduces the likelihood residual biosamples will go to waste; is more straightforward to put in place; is "simpler to understand"; and enables biosamples to be used for more than "one specific thing".

"It's better not to restrict the possible use of the sample because by restricting it you're increasing the chance that it'll go to waste. You want the highest probability that something good will come from it." Male, patient – affected by a condition

It was also the consent model favoured by all participants who were affected by an illness or disability.

Tiered consent was valued because it provided more control over donated biosamples than generic consent, allowing people to opt-out of certain types of research, and therefore provided "clarity and peace of mind". All but one participant in the 'Black' focus group and all participants who had donated biosamples as healthy volunteers preferred tiered consent. Whilst specific consent was seen to provide the most control and enabled participants to have "some understanding of what it might be used for", concerns raised were that it "can't be used for anything else", "could be wasted" and would require a time-consuming explanation from health professionals.

In both the survey and focus groups, the donation of potentially sensitive biosamples produced a preference for specific consent. In the survey, a quarter (25%) preferred specific consent – for every new study, 22% preferred specific consent – once only, 12% preferred generic consent and 9% preferred tiered consent. Nineteen percent had no preference and 13% didn't know. When discussing donation of eggs, one woman commented:

"People could reproduce a child or whatever and it's about the personal-ness of what's been taken from you. So if it's a bit of blood, yeah take it, I mean you just cut yourself and blood is gone, but if it's something that's quite personal you only have every now and again, that needs to be guarded." Female, 'Black' ethnicity group

We asked survey participants whether they would like to be kept up-to-date with research going on at a particular hospital or biobank to which they had donated a

biosample. Eighty-five percent said they would be interested; the most popular methods to receive updates were via a website (27%), email (27%) or letter (22%).

DISCUSSION

This study contributes further to our understanding of the UK public's views and preferences towards consent for the use of biosamples in medical research. In summary, we have found that: 1) the consenting process was perceived as important in order to maintain trust between patients and health professionals and respect patient autonomy; 2) survey participants exhibited a desire to retain active choice and control when donating biosamples and over the uses to which their biosamples might be put, and 3) these results differ from those reported during focus group discussions, where preference was for less restrictive consent models that are likely to increase availability of biosamples. These differences might be accounted for by the fact that focus group participants were given more background information about the use of residual biosamples in research and had time to consider the benefits and disadvantages of the different approaches. These interventions may have allayed any anxieties participants had about relinquishing control of their biosamples and seem to have encouraged participants to choose approaches that maximised biosample access to researchers, highlighting the importance and potential impact of education on influencing public perception in this area.

The preference for opt-in consent identified in the survey is consistent with the results of other studies in this area[3,15,16]. One reason for this preference may be that it matches the current system for organ donation for transplant in the UK. It was also perceived as being truly informed consent by some participants (although it is worth noting that it is the information provided to potential donors that guarantees consent is informed rather than the consent mechanism). Nevertheless, the sizeable number of survey responders who preferred opt-out consent (27%) coupled with the preference for opt-out amongst focus group participants (57%) does suggest that there may be broader support than previously believed for this approach. This point is also supported by the finding that fewer than half of survey participants wanted to be consented every time a sample was taken and nearly 30% preferred consent at certain points. Alternate, more streamlined approaches to consenting should therefore be considered and evaluated. Interestingly, our results showed that preference for opt-out consent was associated with being younger (under 65 years), from a higher SEG and a higher education level. These demographic groups may be more trusting of medical institutions to use residual biosamples appropriately, or perhaps feel empowered to be able to opt-out if so desired, for example, online. Similar findings have been reported in relation to

organ donation; a study by Gimbel et al. found an association between cadaveric donation rate and percentage of the population enrolled in third-tier education[25]. Internet access has also been found to correlate with increased organ donation[26].

Concerning consent models for research use of biosamples, the majority of people (69%) were willing to donate biosamples via the least restrictive model, generic consent. A study conducted in Sweden found a similar percentage of the general public were happy to agree to generic consent (67%), whereby surrogate decisions were performed by a research ethics committee[27]. Other national studies have found the acceptability of generic consent amongst the general public and in particular patients to be higher, between 79%-95%[4,28-31]. Nevertheless, our survey findings suggest that willingness to donate increased where greater choice and control over research participation is retained, although the difference between those who were willing to agree to generic compared to specific was only 13%. Similarly, when survey responders were asked about their preferred approach, their preference was also for specific consent for every new study that might be conducted using their biosample. This may indicate a general interest in how samples are being used. This notion is supported by the high number of people who wanted ongoing contact about the research leading from their donation. Moreover, they may have not considered the practicalities of being asked to consent every time their sample is used, and the high level of recontact they might receive from research teams. Nevertheless, it is important to take note of the fact that more tailored forms of consent represent an attractive approach to many people. While specific consent may be practical for individual research projects, this restriction would make biobanking challenging, as biobanks exist to facilitate access to samples for a wide variety of approved research projects without the need for additional consent. It may be that as more sophisticated biosample tracking and management systems are adopted, resources could become available to support more interactive forms of consent, and more biobanks could offer tiered consent, for example. Further public dialogue and information about the use of the samples may also provide the same assurances for people that arise from specific consent, as highlighted by the preference for less restrictive consent models amongst focus group participants.

Evidence from other empirical studies looking at preferences for consent models is mixed. UK studies focusing on donations purely for research by 'healthy volunteers' to biobanks (i.e. not donating residual biosamples) have identified a preference for specific consent,[19,32] as did a study conducted in the USA that also focused on healthy volunteers[15]. In a pan-European survey, the majority of the UK public also preferred specific consent for every new study, although the percentage that did was slightly lower than the overall European average (65% compared to 67%)[33]. It was, however,

higher than in Denmark and Finland, where the percentage of people who wanted to be re-contacted for every new study was lower at 51% and 54% respectively. These countries were also found to have very few concerns about the collection of personal information by biobanks and had high levels of trust in ethics committees. Other empirical work conducted in the USA, Canada, Sweden and Spain has shown that public preference is for generic consent[3,16,18,34,35]. These findings highlight the divergence of opinion on this issue, in particular in different contexts and with different information provision, although the difficulty of comparing across studies with different methodologies and backgrounds must also be taken into account. Notably, where participants had some or good knowledge of the research process and where there was in-depth discussion (i.e. during focus groups), participants were more likely to prefer generic consent, a finding that has also been identified elsewhere in the literature[36] and supports the need for information and education if increasing the acceptability of generic consent is deemed desirable. Focus group participants affected by an illness or disability were also found to prefer generic consent, and is likely to reflect the fact that they have greater interests at stake[37]. Preference for specific consent was found to be associated with being over 65 years and from a non-'White' ethnicity, findings which resonate with other studies[3,38,39]. Consent documentation and written information targeted specifically at these particular groups may also help alleviate any specific concerns these groups may have.

This research into current public attitudes regarding biosample donation in the UK provides valuable guidance for biobanking governance. Whilst generic consent is the model largely endorsed by regulators and funders in the UK[9,11], the evidence from this study suggests that there is a need to address the potential concerns that some people may have about the minimal information and lack of control provided through this model. Education and opportunity for discussion may be one way to allay concerns, as demonstrated through focus groups. Keeping donors informed of current research taking place at the hospital or research institutions to which they donated also appears to be desirable and is likely to be both motivating and promote public trust and confidence in the research process, a finding reported elsewhere[40]. The opportunity for face-to-face discussion with an appropriately trained healthcare professional at the time of donation may also allay any potential concerns, and is indeed the approach usually taken in the UK at present. This approach has been found to yield high acceptance rates amongst patients of well over 90%[41-43].

Strengths and Limitations

This was a mixed methods study to explore public views and preferences towards consent for biosample donation. Integrating quantitative and qualitative approaches is valuable in exploratory research as it can strengthen the inferences made through triangulation and allow for a more nuanced understanding of the topic[44]. This study presented participants with a series of hypothetical questions about their preferences and willingness to donate residual biosamples for medical research. By presenting questions as 'real life' scenarios, we hoped to make the questions as realistic as possible. However, as with any hypothetical scenario, the findings may not necessarily correlate with actual behaviour.

The questions for both the focus groups and the survey were piloted to ensure they were clear and understandable and were not biased towards any particular viewpoint. Nevertheless, many of the issues covered were complex, particularly around the meaning of the different consent models which may have contributed to the dropout rate. Focus groups participants were not presented with the option of 'specific consent – for every new study' (they were only given 'specific consent – once only'). This may have been an attractive option for some given that a concern raised was biosamples being wasted. However, given that the key reasons participants' valued generic consent were because it provided most flexibility to researchers and was most straightforward to administer, this seems unlikely. In addition, given time and resource constraints we were unable to explore whether 'stronger' consent models would have been preferable for organisations that donors trusted less. This is an area that would be worth exploring further in future research. Participants who did complete the survey may have done so because of strong feelings about the issues raised and this may have skewed the results; however, every effort was made to ensure that the results were as representative of the UK population as possible. The focus groups and survey were conducted in English and so the findings may not be representative of non-English speaking members of the general public. Future research might target these particular groups.

CONCLUSION

There is a general willingness amongst the UK population to donate biosamples for medical research. Our research suggests that there is a preference amongst the UK public for more information on the uses and outcomes of research, and ongoing choice and control over donated biosamples. Our study also supports the premise that increased knowledge and opportunity for discussion is associated with acceptance of less restrictive consent models.

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Competing interests: Lesley Stubbins is an employee of GlaxoSmithKline. Mark Robertson is an employee of AstraZeneca.

Contributors: J.C. conceived the study. All authors contributed to the study design. In addition to all the authors, Sarah Dickson, Jim Elliott and the late Neil Formstone also contributed towards the design of the study and development of the focus group and survey questions. C.L. facilitated the focus groups. Focus group recruitment was conducted by the company The Focus Group; the survey was conducted through the market research company Research Now. C.L. conducted data analysis and interpretation with the help of Samantha Reeve and Zheng Lei. The initial draft of the manuscript was prepared by C.L and then circulated repeatedly among the authors for critical revision. All authors approved the final manuscript.

Ethical approval This study was approved by the Ethics Review Board of the University of Manchester, reference 11459.

Data sharing statement Transcripts from the focus groups and full results of the survey are available from CL at celine@geneticalliance.org.uk. Supplementary material is also available at www.geneticalliance.org.uk/projects/stratum_docs.htm

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Consent for the use of human biological samples for biomedical research – a mixed methods study exploring the UK public's preferences

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Running title: Consent for the use of biosamples - the UK public's preferences

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ABSTRACT

Objective: A mixed methods study exploring the UK general public's views towards consent for the use of biosamples for biomedical research.

Setting: Cross-sectional population-based focus groups followed by an online survey.

Participants: Twelve focus groups (81 participants) selectively sampled to reflect a range of demographic groups; 1110 survey responders recruited through a stratified sampling method with quotas set on sex, age, geographical location, socio-economic group and ethnicity.

Main outcome measures: 1) Views on the importance of consent when donating residual biosamples for medical research; 2) preferences for opt-in or opt-out consent approaches; 3) preferences for different consent models.

Results: Participants believed obtaining consent for use of residual biosamples was important as it was "morally correct" to ask, and enabled people to make an active choice and retain control over their biosamples. Survey responders preferred opt-in consent (55%); the strongest predictor was being from a low socio-economic group (OR 2.22, 95% CI 1.41-3.57, p=0.001) and having a religious affiliation (OR 1.36, 95% CI 1.01-1.81, p=0.04). Focus group participants had a slight preference for opt-out consent because by using this approach more biosamples would be available and facilitate research. Concerning preferred models of consent for research use of biosamples, survey responders preferred specific consent with re-contact for each study for which their biosamples are eligible. Focus group participants preferred generic consent as it provided "flexibility for researchers" and reduced the likelihood that biosamples would be wasted. The strongest predictor for preferring specific consent was preferring opt-in consent (OR 4.58, 95% CI 3.30-6.35, p=0.015) followed by non-'White' ethnicity (OR 2.94, 95% CI 1.23-7.14, p<0.001).

Conclusions: There is a preference amongst the UK public for ongoing choice and control over donated biosamples, however increased knowledge and opportunity for discussion is associated with acceptance of less restrictive consent models for some people.

ARTICLE SUMMARY

Article focus

- To explore views of the UK public on the importance of consent being sought to the use of residual biosamples for medical research;
- The publics' preferences for opt-in or opt-out approaches to consent;
- The publics' preferences for generic, tiered or specific consent.

Key messages

- Obtaining consent for the use of residual biosamples for biomedical research was perceived as important by members of the general public.
- Survey participants exhibited a desire to retain active choice and control when donating biosamples and over the uses to which their biosamples might be put, preferring an opt-in system and specific consent, however these results differ from those reported during focus group discussions, where preference was for less restrictive consent models (an opt-out system and generic consent) that are likely to increase availability of biosamples.
- These differences might be accounted for by the fact that focus group participants were given more background information about the use of residual biosamples in research and had time to consider the benefits and disadvantages of the different approaches.

Strengths and limitations of this study

- This study contributes further to our understanding of the UK public's views and preferences towards consent for the use of biosamples in medical research. Our study supports the premise that increased knowledge and opportunity for discussion is associated with acceptance of less restrictive consent models.
- Due to the hypothetical nature of the study, the findings may not necessarily correlate with actual behaviour.

INTRODUCTION

Human biological samples (biosamples), including organs, tissues, biofluids such as blood, and their derivatives, are increasingly important resources for biomedical research[1,2]. For example, they can help us to understand how we diagnose, categorise and treat a whole variety of medical conditions including cancer[1] and are particularly important when studying rare diseases or conditions where biosamples are hard to obtain. Biosamples are donated by either healthy volunteers or patients, either through specific research studies or as residual tissues or biofluids surplus to diagnostic requirements, or post mortem. Biosamples can be used fresh or can be first stored in a biobank, a collection of biosamples often linked with the donors' clinical and demographic information, as biosample attributes. Here, the quality of the data linked to the biosample is as important as the quality of the biosamples themselves, providing essential context within which to design analyses and interpret results or carry our further experimental studies. Clinical data may also be enriched with lifestyle and environmental information[3].

It is widely accepted that that donor consent should be sought and obtained before biosamples can be used in research[4,5]. Consent in research ethics relates to ensuring respect for the autonomy and dignity of the donors (research participants) and protecting them from abuse[5] and In fact, in England, Wales and Northern Ireland, the Human Tissue Act establishes donor consent as the baseline principle for the retention and use of organs and tissue for purposes beyond diagnosis and treatment, although further statutory consent exemptions do exist in certain circumstances, notably use of anonymised tissue from the living for research ethics committee (REC) approved research projects[6]. The value of biobanks, in supporting broad, long-term research purposes, means that the model of the consent process needs to be considered in order to ensure that it is valid and appropriate. A number of different consent frameworks which address consent scope and process have been proposed as a result[5]. However, there is continued debate as to which is the most appropriate in various situations[4,7,8].

Both the Human Tissue Authority[9] and National Research Ethics Service[10] recommend generic consent (Table 1), a view that has also been endorsed by UK research funders[11] and the Nuffield Council on Bioethics[12]. One commonly cited criticism of generic consent is that it is not sufficiently 'informed' as future research uses are not known at the time of donation[13]. Empirical research examining public and patient preferences has highlighted that there is no clear consensus on the issue, with

specific consent being identified as the most favoured form of consent in some studies[14,15], and generic consent in others[16-18].

Table 1: Approaches to consent of biosamples

Initial consent methods	
Opt-in consent	The storage and use of biosamples for research on the basis that the donor has actively agreed to do so.
Opt-out consent	The storage and use of samples for research on the basis that the donor has not objected, after previously being given the opportunity to do so.
Opt-in consent methods	
Consent once for life	Consent is provided once for life for use of any residual samples for research with the option of withdrawing permission at a later stage if the donor wishes to do so.
Consent at certain points	Consent is provided at certain points for use of residual biosamples for research, e.g. every 10 years or at the beginning of a particular episode of care.
Consent every time	Consent is requested every time residual biosamples may become available for use in research.
Consent for research use of biosamples	
Generic consent	Consent to the use of donated samples for a range of unknown uses, on the basis of general information about those possible uses and about the governance arrangements in place. Also referred to as 'broad' or 'blanket' consent.
Tiered consent	A more restricted form of consent for use of samples, where the donor is invited to agree to the use of their samples in unknown projects, but given the option of specifying particular categories of research that they wish to exclude e.g. embryonic research. Also referred to as 'categorical' consent.
Specific consent –once only	Consent to the use of donated samples for a specified study only, on the basis of information provided about that study. Any residual sample will be discarded at the end of that study.
Specific consent – for every new study	Consent to the use of donated samples for a specified study, on the basis of information provided about that study. However, participants are re-contacted and asked to consider participating in every new study for which their biosamples are eligible.

Note: Consent terms were selected based on common usage within the UK biobanking system (for example, generic consent is the term used by the Human Tissue Authority, National Research Ethics Service, and National Cancer Research Institute) and definitions chosen in consultation with a team of representatives from universities, hospital biobank staff, pathologists and industry.

The 2011 Nuffield Council report on donation of human material for medicine and research also recommends that research funders should work to increase public awareness of the key role of donated tissue in scientific and clinical research[12]. Public trust and confidence in the consent process is of paramount importance to maintain and increase public support for donation and use of biosamples for biomedical research in the UK. For this reason, it is important to understand and inform public opinion to ensure consent models are aligned to public expectations and preferences. Whilst numerous international studies have been conducted which focus on consent preferences, research conducted in the UK has tended to focus on large scale population biobanks, such as UK Biobank[19] or Generation Scotland[20], which require ongoing contact with donors, or on the views of patients on the donation of residual biosamples[21]. The current study was conducted to broaden our understanding of the UK public's views on biosample donation for biomedical research. Moreover, the findings are intended to inform a biobanking policy for STRATUM (Strategic Tissue Repository Alliance Through Unified Methods), a Technology Strategy Board[i] and pharmaceutical industry-funded project seeking to address the problem of insufficient numbers of biosamples and associated clinical data of adequate quality to fully support biomedical research in the UK.

The specific aims of this study were to 1) identify participants' views on the importance of consent when donating residual biosamples for medical research; 2) explore preferences for opt-in or opt-out approaches to consent; and 3) explore preferences for different consent models (Table 1). Public willingness to donate biosamples, views on donation of different biosample types, and conditions of their use (by which organisations and for which types of research) are reported elsewhere (Public views on the donation and use of human biological samples in biomedical research – a mixed methods study, 2013, unpublished manuscript).

METHODS

This was a mixed methods study comprising qualitative focus groups and a quantitative on-line survey. Ethical approval for the study was granted by the University of Manchester Research Ethics Committee in April 2012.

Focus groups

Twelve focus groups (including one pilot group) were conducted between May and July 2012 in six different geographic locations across the UK. Participants were recruited face-to-face in the street by a market research company The Focus Group. Participants

[i] under the Stratified Medicines Programme: Business Models Value Systems

were purposively sampled; each group chosen to reflect a particular demographic (age, socio-economic group (SEG), ethnicity) in order to gather a wide spectrum of views and enable comparisons across groups. Two 'patient' groups were also included, comprising people who had had an operation in the past two years requiring an overnight hospital stay, and people who currently have, or have had, either a serious or chronic illness, or disability. The latter group comprised people diagnosed with diabetes, cancer, heart disease, asthma and the genetic condition Marfan syndrome. A further group consisted of generally healthy volunteers~~people~~ who had donated a biosample specifically for research purposes.

Before agreeing to take part, potential participants were given a participant information sheet telling them about the study (see supplementary data file Appendix I). Those that were interested were screened through a questionnaire containing demographic questions to assess their suitability for a particular focus group. These were held in 'neutral' locations such as hotel conference rooms or church halls and facilitated by an experienced facilitator (CL). Before each group discussion, participants were sent a short information leaflet about the use of biosamples in biomedical research to provide some background context for the discussion and to prompt them to think about the key issues (see supplementary data file Appendix II). This information was written by a core team of authors drawn from across academia and industry, including patient representation. It was reviewed by three members of the patient organisation Genetic Alliance UK as well as the science communication charity Sense about Science to ensure readability and non-bias. Before focus group discussions began, participants were asked to sign a consent form. Each participant received ~~a~~ £50~~small honorarium~~ for taking part to cover time and travel costs. Focus groups lasted 90 minutes and digital audio recordings were taken.

A detailed discussion guide was developed to explore participant views and preferences towards consent scope and process (see supplementary data file Appendix III). The main focus related to the use of biosamples surplus to diagnostic requirements following surgery or a medical procedure. Questions were informed by other empirical studies of consent in biobanking[16,22], developed by the authors, and addressed the topics described above. To enhance understanding around the different consent models, participants were given a sheet presenting three different scenarios, each of which elaborated on one of the three consent models chosen for discussion (see supplementary data file Appendix III,p.4~~IV~~). For each topic, discussion began by asking the group to consider the benefits and disadvantages of each particular approach. Once no new themes were emerging, each participant was asked to complete an accompanying

anonymous questionnaire which asked them to select their preferred consent model. The discussion guide, scenario sheet and questionnaire were piloted at the first focus group which resulted in some minor amendments to wording.

Recordings were fully transcribed and transcriptions checked. The software package Nvivo version 9 (QSR International, Pty Ltd) was used to help organise the data for analysis. This comprised grouping responses to questions into broad thematic categories which were then refined through sub-codes. Coding of all 12 transcripts was conducted by CL. The first six transcripts to be coded were also independently coded by ~~and verified by~~ a second researcher (SR). Codes were then compared to assess consistency of coding and ensure inter-rater reliability. Any discrepancies were discussed until consensus was reached. The remainder of the transcripts were then coded according to the agreed coding framework. ~~to ensure inter rater reliability. Any discrepancies were discussed between the two researchers until consensus was reached.~~

Survey

Once data analysis had been conducted on the focus group transcripts, the findings were used to inform development of a quantitative survey which was used to canvas public opinion on the issues of interest across a representative sample of the UK population (see supplementary data file Appendix IV). The survey was carried out by the market research company Research Now using their online panel community of UK residents. A stratified sampling method was used: quotas were set on sex, age, geographical location, SEG and ethnicity, in line with data provided by the Office of National Statistics (ONS) to ensure the sample was as representative of the UK population as possible. Within each category, a random sample was selected from the Research Now database containing 451,185 active respondents. We aimed to recruit 1,000 responders in total. The sample size required depends on the number of predictors, the expected effect size and the level of power. According to Miles and Shevlin [23], if we are expecting a small effect size, a sample size of 600 is considered adequate to achieve a high level of power 0f 0.8 (a benchmark suggested by Cohen [24]) for four predictors. As highlighted in Table 2 we can formulate at least four hypothesis, for example, people from a higher socio-economic group are more likely to donate biosamples than those from lower socio-economic group. With a sample size of 1,000, this study would provide highly reliable results. In order to reduce any on-line bias in our sample, 100 face-to-face interviews with non-internet users were conducted. An additional 'boost' sample of 100 people (not included in the main sample analysis) was also conducted with people from three minority ethnic groups ('Black', 'Chinese', 'S. Asian') so that we could conduct sub-group analysis between the groups.

The survey questions were developed by the authors and piloted with 60 members of Research Now's online panel community who were from low SEG's. Members of the pilot group were then invited to take part in a subsequent telephone interview asking about the survey. Interviews were conducted with 25 pilot survey responders. Questions focused on question clarity, survey length and whether responders felt the survey to be neutral. Some minor amendments to wording were made in light of the responses. The main survey was then conducted in September 2012. Surveys recorded online took, on average, 17 minutes to complete and each responder received a small payment (around £2) from Research Now.

Survey data were organised and analysed using SPSS statistical software version 20 (Chicago, IL: SPSS Inc; 2011). Initial univariate descriptive statistics were obtained for the entire study. Pearson Chi-square was used to examine demographic factors associated with willingness to donate and preference for different consent models. Those associations that were found to be significant ($p \leq 0.05$) were then entered into a multiple logistic regression to explore the predictivity of these variables. Before running the model, we tested for multicollinearity among the independent variables. No multicollinearity issues were found.

RESULTS

Study populations

Participant characteristics are detailed in Table 2.

Table 2: Participant characteristics

Characteristic	Focus group N=81	Survey N=1110
Gender		
Male	33; 41%	504; 45%
Female	48; 59%	606; 55%
Age		
18-24	13; 16%	135; 12%
25-34	18; 22%	184; 17%
35-44	19; 23%	198; 18%
45-54	10; 12%	184; 17%
55-64	16; 20%	176; 16%
65+	5; 6%	233; 21%
Socio-economic group		
A	9; 11%	41; 4%
B	22; 27%	215; 19%
C1	24; 30%	311; 28%
C2	14; 17%	233; 21%
D	6; 7%	145; 13%
E	6; 7%	165; 15%
Region		
East of England	7; 7%	92; 8%

East Midlands	-	57; 5%
London	18; 22%	213; 19%
North East	-	40; 4%
North West	-	121; 11%
Northern Ireland	-	30; 3%
Scotland	14; 17%	76; 7%
South East	14; 17%	165; 15%
South West	-	81; 7%
Wales	-	51; 5%
West Midlands	14; 17%	94; 8%
Yorkshire/Humberlands	14; 17%	90; 8%
Ethnicity		
White or White British	54; 67%	1057; 95%
Mixed race	1; 1%	7; 1%
Asian or Asian British	10; 12%	18; 2%
Black or Black British	9; 11%	19; 2%
Chinese or Chinese British	7; 9%	2; 0%
Other ethnic group	0; 0%	4; 0%
Prefer not to say	0; 0%	3; 0%
Religion		
Christianity		677; 61%
Islam		13; 1%
Hinduism		6; 1%
Sikhism		0; 0%
Judaism		6; 1%
Buddhism		11; 1%
Other religion		15; 1%
No religion		370; 33%
Prefer not to say		12; 1%
Religiosity		
Not at all religious		234; 32%
Moderately religious		422; 58%
Very religious		64; 9%
Prefer not to say		8; 1%
Education		
No formal qualification	15; 19%	70; 6%
GCSE, O level, Scottish Standard Grade or equivalent	19; 23%	264; 24%
GCE, A-level, Scottish Higher or similar	17; 21%	214; 19%
Vocational (BTEC/NVQ/Diploma)	-	230; 21%
Degree level or above	30; 37%	317; 29%
Prefer not to say	-	15; 1%
Self reported knowledge of medical research process		
No knowledge		463; 42%
Some knowledge		603; 54%
Good knowledge		44; 4%
Have you been affected by a disability or illness?		
Yes		399; 36%
No		711; 64%
Has a close family member been affected by a disability or illness?		
Yes		767; 69%
No		343; 31%

Have you had blood or tissue removed during a medical procedure?		
Yes		446; 40%
No		553; 50%
Don't know		111; 10%
Have you ever been asked to donate blood or tissue for medical research?		
Yes		182; 16%
No		904; 81%
Don't know		24; 2%
If so, did you agree to donate?		
Yes		155; 85%
No		23; 13%
Don't know		4; 2%

Note: percentages may not add up to 100 due to rounding.

Focus groups

One hundred and eighty-two members of the public who were approached were eligible to participate (i.e. they fitted the criteria for a particular focus group) and 81 people agreed to participate (45% participation rate; 48 women, 33 men). There were seven participants in each focus group apart from the 18-25 age group and high SEG group (eight participants in each); serious/chronic illness group and healthy volunteers group (six participants in each) and the pilot group (five participants).

Survey

Four thousand six hundred and seven people were invited to take part in the survey; 2014 did not respond, 860 began completing the survey but did not finish, 102 did not qualify to continue (e.g. they were under 18 years old), 521 qualified for the survey but the quota was full and 1110 completed the questionnaire (28% response rate excluding those who did not qualify and where the quota was full). This response rate is comparable to similar studies on this topic[16]. Our participant quotas closely, though not exactly, matched our targets based on the UK population data as provided by the ONS. For this reason we carried out both weighted and un-weighted analyses. There was no difference in the conclusions we reached by either method. In this paper we present the un-weighted results (weighted results can be found at supplementary data file Appendix V~~I~~).

Importance of asking for consent

The majority of survey ~~and focus group~~ participants believed that obtaining consent for the use of residual biosamples was either extremely important (55%) or important (25%). Only 4% selected 'not at all important'. Focus group participants also saw the consent process as important and cited reasons including: ~~Reasons as to why consent~~

~~was important, as cited by focus group participants, included~~ that it was "polite", "respectful" and "morally correct" to ask permission; that it enabled people to feel they had made a contribution and an active choice; that it provided control, in particular for those people that might not want their biosamples to be used, for example for religious reasons; that taking without asking was akin to theft; and that it was important in order to maintain trust between patients and doctors.

"It then doesn't allow them to take liberties or advantage of the fact that you're out cold having an operation and someone says 'Oh we need a bit of that'." Male, patient – had operation in past 2 years.

A small minority did not feel that consent was important, the main reasons being that they did not want the tissue back, that once it was removed it no longer 'belonged to them', and that the tissue would just go to waste otherwise.

Survey participants were asked what would be their preferred method of consenting to donate leftover biosamples for research use. The majority (65%) wanted to do so face-to-face with a health professional; 15% wanted to complete a form and return it by post. This issue was not specifically addressed with focus group participants due to time constraints.

Preference for 'opt-in' or 'opt-out' consent

Participants were asked whether they preferred an opt-in or opt-out model of consent for donating residual biosamples. The results of the survey showed that opt-in consent was preferred by over half of the participants (55%), 28% preferred opt-out, 14% had no preference and 4% selected 'don't know'. Participants who were significantly more likely to prefer opt-in consent were: from a low SEG (E) (79.8% vs. 64.1%, X^2=11.13(1), p=0.001); over 65 years (75.1% vs. 64%, X^2=7.68(1), p=0.006); had a religious affiliation (68.8% vs. 61.2%, X^2=4.84(1), p=0.028); and had an education level of GCSE or lower (71.1% vs. 63.9%, X^2=3.89(1), p=0.048). The strongest significant predictor for preferring opt-in consent was being from a low SEG (E) (OR=2.22, 95% CI 1.41-3.57, p=0.001) followed by having a religious affiliation (OR=1.36, 95% CI 1.01-1.81, p=0.04) (Table 3).

Table 3: Multiple logistic regression of participant preferences for consent models

Participant characteristic	Coefficient	95% CI	Odds ratio	p value
Preference for opt-in consent				
Socio-economic group	0.806	1.41, 3.57	2.22	0.001
Religion	0.304	1.01, 1.81	1.36	0.04
Preference for consent every time				
Religion	0.72	1.05, 4.00	2.04	0.036

Age	0.47	1.07, 2.41	1.60	0.023
Preference for specific consent Opt-in	1.52	3.30, 6.35	4.58	<0.001
Ethnicity	1.08	1.23, 7.14	2.94	0.015
Preference for generic consent Opt-out	1.52	3.13, 6.67	4.55	<0.001
Religion	0.04	1.08, 2.72	1.56	0.021
Knowledge of medical research process	0.44	1.06, 2.28	1.56	0.024

Demographic items were excluded from this table if none was statistically significant. All variables were entered into the models as categorical variables.
CI: Confidence Interval.

Focus group participants preferred opt-out consent (*n*=46; 57%) over opt-in consent (*n*=29; 36%), with 6 participants (7%) unsure, after in-depth discussion around the benefits and disadvantages of each approach. The main benefit of opt-out consent cited by participants was that more biosamples would be available and consequently spur research. Other reasons included: that it would be less costly administratively; that it maximised the value of left over biosamples; that patients wouldn't have to consider it every time they were having an operation or blood test; that those that did not want to donate still had the opportunity to opt-out; and that it would 'normalise' donating leftover biosamples which would be a positive step.

"It would an incentive for society if everyone knew that this is what happens routinely, but you can choose not to be involved. It would be more like 'that's normal'." Male, aged 18-24 group

Those that preferred the opt-in approach cited the following reasons as to why: an active choice whereby participants had to act on a decision to take part was preferable to a passive choice whereby consent was assumed; it enabled people to have more control over their biosamples; it was truly 'informed consent' in the context of donating surplus samples for research (rather than as part of a clinical trial; clinical trials were outside the scope of the study) and hence more ethically acceptable; it enabled people to feel that they were making a positive contribution and would prevent the problem of vulnerable groups not being aware they were automatically 'opted-in'.

"There are going to be members of the public who are not going to always be able to consider rationally themselves what it actually means." Female, healthy volunteer

Whist the majority of focus group participants overall preferred opt-out consent, the results were different for the three minority ethnic groups (''Black'', ''S. Asian'', ''Chinese''), where opt-in consent was favoured by the majority.

Consent once for life or consent every time

The most prevalent system in current use for donating new biosamples that are surplus to clinical requirements in the UK is the opt-in approach, with potential donors being asked for consent every time a procedure is performed that may result in a biosample becoming available for research. (The law allows for the use of diagnostic archives for research without consent as long as certain criteria are met). Participants were therefore asked to consider variations on this model and state whether they preferred: (1) consent once for life, covering all subsequent biosamples, until or unless the donor decides to withdraw consent; (2) consent every time samples surplus to diagnostic requirements may become available, or (3) consent at certain points in life. Consent every time (43%) was preferred by the majority of survey participants, followed by consent at certain points (27%) and consent once for life, e.g. at aged 18, (21%). Seven percent had no preference and 2% didn't know. Groups who were significantly more likely to prefer consent every time compared to consent once for life were: under 55 years (70.3% vs. 60.9%; X^2=5.88(1), p=0.015); had no knowledge of the research process (72.3% vs. 63.4%; X^2=5.77(1), p=0.016); or were either not at all or moderately religious (70.2% vs. 51.3%; X^2=5.1(1), p=0.024). When entered into the regression analysis, the strongest significant predictor for preferring consent every time was being not at all or moderately religious (OR=2.04; 95% CI 1.05-4.00, p=0.036) followed by being under 55 years (OR=1.60; 95% CI 1.07-2.41, p=0.023) (Table 3).

Unlike survey responders, focus group participants favoured consent once for life (*n*=35; 43%) followed by consent every time samples surplus to diagnostic requirements may become available (*n*=27; 33%) and consent at certain points (*n*=16; 20%) with three choosing don't know (4%). Like opt-out consent, consent once for life was seen to be better as it was "quicker" and "easier" administratively and prevented researchers from "losing out". Consent provided most control for participants as you would "know the specific purpose of it", particularly if the sample was considered to be sensitive e.g. eggs; allowed "no room for error"; and enabled people to change their mind easily.

"You may feel differently [depending on] what tissue is being donated and for what purpose the research is being carried out." Female, aged 18-24 group

Some participants had concerns about how consent preferences (e.g. what types of research they were willing to donate a biosample for), would follow them across the healthcare system if a 'consent once for life' model was adopted. Consent at certain points was seen by some as a good middle ground as patients would still have some control, but would not have to go through the consent process every time they had a medical procedure. Examples of consent at certain points included every "five or ten

years", or at the beginning of particular episodes of care such as pregnancy or cancer treatment.

Models of consent for research use of biosamples

Survey participants were presented with four consent models (Table 1), and asked whether they would consider consenting residual biosamples to each of them, providing the research had been approved by a research ethics committee (described as a committee usually made up of doctors, scientist, patients and the general public which ensure any research allowed to be done is for the benefit of patients). Eighty percent would agree to specific consent – once only; 77% would consent to specific consent – for every new study; 71% would agree to tiered consent; and 67% of participants would agree to generic consent. When asked which model they preferred, specific consent - for every new study, was the first choice amongst those who had a preference (30% of participants overall), followed by generic consent and specific consent- once only, jointly second (both 18%), and lastly tiered consent (14%). Sixteen percent had no preference and 6% didn't know.

After collapsing the two specific consent models together (specific consent - for every new study and specific consent – once only), those participants who preferred specific consent were significantly more likely to: have a religious affiliation (63.9% vs. 48.9%, X^2=16.88(1); p<0.001); live in the North East or Scotland (60.9% vs. 42.7%, X^2=10.23(1), p=0.001); be over 65 years (67.1% vs. 57.1%, X^2=5.31(1), p=0.021); and be of a non-'White' ethnicity (68.9% vs. 58%, X^2=4.17(1), p=0.041). Using the boost sample we found that 'Black' participants were significantly more likely to prefer specific consent models compared with 'White' participants (75.6% vs. 58%, X^2=4.31(1), p=0.038). Those people who preferred opt-in consent were also more likely to prefer specific consent models (71.1% vs. 35.3%, X^2=91.72(1), p<0.001). The strongest significant predictor for preferring specific consent was preferring opt-in consent (OR=4.58, 95% CI 3.30-6.35, p<0.001) followed by being of non-'White' ethnicity (OR=2.94, 95% CI 1.23-7.14, p=0.015) (Table 3).

We also looked at who was most likely to prefer generic consent, the least restrictive of the proposed consent models. Those that preferred generic consent were significantly more likely to: have no religious affiliation (51.1% vs. 36.1%, X^2=15.97(1), p<0.001); have some or good knowledge of the medical research process (26.1% vs. 18.3%, X^2=6.79(1), p=0.009); be male (26.8% vs. 19.9%, X^2=5.40(1), p=0.02); and be from a higher SEG group (A-D) (24.3% vs. 15.1%, X^2=4.66(1), p=0.031). They were also significantly more likely to prefer opt-out consent (64.7% vs. 28.9%, X^2=91.72(1), p<0.001). The strongest significant predictor for preferring generic consent was

preferring opt-out consent (OR=4.55, 95% CI 3.13-6.67, p<0.001) followed by having no religious affiliation (OR=1.56, 95% CI 1.08-2.72, p=0.021) and some or good knowledge of the medical research process (OR=1.56, 95% CI 1.06-2.28, p=0.024) (Table 3).

Focus group preferences differed from those of survey responders with generic and tiered consent being equally popular (n=36; 44% and n=35; 43% respectively). Specific consent – once only, was least popular (n=6; 7%) (this was the only specific consent model given to participants). Four participants (5%) didn't know. Generic consent was valued as it provides most "flexibility for researchers"; reduces the likelihood residual biosamples will go to waste; is more straightforward to put in place; is "simpler to understand"; and enables biosamples to be used for more than "one specific thing".

"It's better not to restrict the possible use of the sample because by restricting it you're increasing the chance that it'll go to waste. You want the highest probability that something good will come from it." Male, patient – affected by a condition

It was also the consent model favoured by all participants who were affected by an illness or disability.

Tiered consent was ~~also~~ valued because it provided more control over donated biosamples than generic consent, allowing people to opt-out of certain types of research, and therefore provided "clarity and peace of mind". All but one participant in the 'Black' focus group and all participants who had donated biosamples as healthy volunteers preferred tiered consent. Whilst specific consent was seen to provide the most control and enabled participants to have "some understanding of what it might be used for", concerns raised were that it "can't be used for anything else", "could be wasted" and would require a time-consuming explanation from health professionals.

In both the survey and focus groups, the donation of potentially sensitive biosamples produced a preference for specific consent. In the survey, a quarter (25%) preferred specific consent – for every new study, 22% preferred specific consent – once only, 12% preferred generic consent and 9% preferred tiered consent. Nineteen percent had no preference and 13% didn't know. When discussing donation of eggs, one woman commented:

"People could reproduce a child or whatever and it's about the personal-ness of what's been taken from you. So if it's a bit of blood, yeah take it, I mean you just cut yourself and blood is gone, but if it's something that's quite personal you only have every now and again, that needs to be guarded." Female, 'Black' ethnicity group

We asked survey participants whether they would like to be kept up-to-date with research going on at a particular hospital or biobank to which they had donated a biosample. Eighty-five percent said they would be interested; the most popular methods to receive updates were via a website (27%), email (27%) or letter (22%).

DISCUSSION

This study contributes further to our understanding of the UK public's views and preferences towards consent for the use of biosamples in medical research. In summary, we have found that: 1) the consenting process was perceived as important in order to maintain trust between patients and health professionals and respect patient autonomy; 2) survey participants exhibited a desire to retain active choice and control when donating biosamples and over the uses to which their biosamples might be put, and 3) these results differ from those reported during focus group discussions, where preference was for less restrictive consent models that are likely to increase availability of biosamples. These differences might be accounted for by the fact that focus group participants were given more background information about the use of residual biosamples in research and had time to consider the benefits and disadvantages of the different approaches. These interventions may have allayed any anxieties participants had about relinquishing control of their biosamples and seem to have encouraged participants to choose approaches that maximised biosample access to researchers, highlighting the importance and potential impact of education on influencing public perception in this area.

The preference for opt-in consent identified in the survey is consistent with the results of other studies in this area[3,15,16]. One reason for this preference may be that it matches the current system for organ donation for transplant in the UK. It was also perceived as being truly informed consent by some participants (although it is worth noting that it is the information provided to potential donors that guarantees consent is informed rather than the consent mechanism). Nevertheless, the sizeable number of survey responders who preferred opt-out consent (27%) coupled with the preference for opt-out amongst focus group participants (57%) does suggest that there may be broader support than previously believed for this approach. This point is also supported by the finding that fewer than half of survey participants wanted to be consented every time a sample was taken and nearly 30% preferred consent at certain points. Alternate, more streamlined approaches to consenting should therefore be considered and evaluated. Interestingly, our results showed that preference for opt-out consent was associated with being younger (under 65 years), from a higher SEG and a higher

education level. These demographic groups may be more trusting of medical institutions to use residual biosamples appropriately, or perhaps feel empowered to be able to opt-out if so desired, for example, online. Similar findings have been reported in relation to organ donation; a study by Gimbel et al. found an association between cadaveric donation rate and percentage of the population enrolled in third-tier education[25]. Internet access has also been found to correlate with increased organ donation[26].

Concerning consent models for research use of biosamples, the majority of people (69%) were willing to donate biosamples via the least restrictive model, generic consent. A study conducted in Sweden found a similar percentage of the general public were happy to agree to generic consent (67%), whereby surrogate decisions were performed by a research ethics committee[27]. Other national studies have found the acceptability of generic consent amongst the general public and in particular patients to be higher, between 79%-95%[4,28-31]. Nevertheless, our survey findings suggest that willingness to donate increased where greater choice and control over research participation is retained, although the difference between those who were willing to agree to generic compared to specific was only 13%. Similarly, when survey responders were asked about their preferred approach, their preference was also for specific consent for every new study that might be conducted using their biosample. This may indicate a general interest in how samples are being used. This notion is supported by the high number of people who wanted ongoing contact about the research leading from their donation. Moreover, they may have not considered the practicalities of being asked to consent every time their sample is used, and the high level of recontact they might receive from research teams. Nevertheless, it is important to take note of the fact that more tailored forms of consent represent an attractive approach to many people. While specific consent may be practical for individual research projects, this restriction would make biobanking challenging, as biobanks exist to facilitate access to samples for a wide variety of approved research projects without the need for additional consent. It may be that as more sophisticated biosample tracking and management systems are adopted, resources could become available to support more interactive forms of consent, and more biobanks could offer tiered consent, for example. Further public dialogue and information about the use of the samples may also provide the same assurances for people that arise from specific consent, as highlighted by the preference for less restrictive consent models amongst focus group participants.

Evidence from other empirical studies looking at preferences for consent models is mixed. UK studies focusing on donations purely for research by 'healthy volunteers' to biobanks (i.e. not donating residual biosamples) have identified a preference for specific consent,[19,32] as did a study conducted in the USA that also focused on healthy

volunteers[15]. In a pan-European survey, the majority of the UK public also preferred specific consent for every new study, although the percentage that did was slightly lower than the overall European average (65% compared to 67%)[33]. It was, however, higher than in Denmark and Finland, where the percentage of people who wanted to be re-contacted for every new study was lower at 51% and 54% respectively. These countries were also found to have very few concerns about the collection of personal information by biobanks and had high levels of trust in ethics committees. Other empirical work conducted in the USA, Canada, ~~and~~ Sweden and Spain has shown that public preference is for generic consent[3,16,18,34,35]. These findings highlight the divergence of opinion on this issue, in particular in different contexts and with different information provision, although the difficulty of comparing across studies with different methodologies and backgrounds must also be taken into account. Notably, where participants had some or good knowledge of the research process and where there was in-depth discussion (i.e. during focus groups), participants were more likely to prefer generic consent, a finding that has also been identified elsewhere in the literature[36] and supports the need for information and education if increasing the acceptability of generic consent is deemed desirable. Focus group participants affected by an illness or disability were also found to prefer generic consent, and is likely to reflect the fact that they have greater interests at stake[37]. Preference for specific consent was ~~also~~ found to be associated with being over 65 years and from a non-'White' ethnicity, findings which resonate with other studies[3,38,39]. Consent documentation and written information targeted specifically at these particular groups may also help alleviate any specific concerns these groups may have.

This research into current public attitudes regarding biosample donation in the UK provides valuable guidance for biobanking governance. Whilst generic consent is the model largely endorsed by regulators and funders in the UK[9,11], the evidence from this study suggests that there is a need to address the potential concerns that some people may have about the minimal information and lack of control provided through this model. Education and opportunity for discussion may be one way to allay concerns, as demonstrated through focus groups. Keeping donors informed of current research taking place at the hospital or research institutions to which they donated also appears to be desirable and is likely to be both motivating and promote public trust and confidence in the research process, a finding reported elsewhere[40]. The opportunity for face-to-face discussion with an appropriately trained healthcare professional at the time of donation may also allay any potential concerns, and is indeed the approach usually taken in the UK at present. This approach has been found to yield high acceptance rates amongst patients of well over 90%[41-43].

Strengths and Limitations

This was a mixed methods study to explore public views and preferences towards consent for biosample donation. Integrating quantitative and qualitative approaches is valuable in exploratory research as it can strengthen the inferences made through triangulation and allow for a more nuanced understanding of the topic[44]. This study presented participants with a series of hypothetical questions about their preferences and willingness to donate residual biosamples for medical research. By presenting questions as 'real life' scenarios, we hoped to make the questions as realistic as possible. However, as with any hypothetical scenario, the findings may not necessarily correlate with actual behaviour.

The questions for both the focus groups and the survey were piloted to ensure they were clear and understandable and were not biased towards any particular viewpoint. Nevertheless, many of the issues covered were complex, particularly around the meaning of the different consent models which may have contributed to the dropout rate. Focus groups participants were not presented with the option of 'specific consent – for every new study' (they were only given 'specific consent – once only'). This may have been an attractive option for some given that a concern raised was biosamples being wasted. However, given that the key reasons participants' valued generic consent were because it provided most flexibility to researchers and was most straightforward to administer, this seems unlikely. In addition, given time and resource constraints we were unable to explore whether 'stronger' consent models would have been preferable for organisations that donors trusted less. This is an area that would be worth exploring further in future research. Participants who did complete the survey may have done so because of strong feelings about the issues raised and this may have skewed the results; however, every effort was made to ensure that the results were as representative of the UK population as possible. The focus groups and survey were conducted in English and so the findings may not be representative of non-English speaking members of the general public. Future research might target these particular groups.

CONCLUSION

There is a general willingness amongst the UK population to donate biosamples for medical research. Our research suggests that there is a preference amongst the UK public for more information on the uses and outcomes of research, and ongoing choice and control over donated biosamples. Our study also supports the premise that increased knowledge and opportunity for discussion is associated with acceptance of less restrictive consent models.

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Ethical approval This study was approved by the Ethics Review Board of the University of Manchester, reference 11459.

Data sharing statement Transcripts from the focus groups and full results of the survey are available from CL at celine@geneticalliance.org.uk. Supplementary material is also available at www.geneticalliance.org.uk/projects/stratum_docs.htm

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Appendix 1

Attitudes Towards Donating Human Tissue Samples for Research

Participant Information Sheet

We would like to invite you to take part in a research study to help us understand what people think about donating human biological samples, (such as blood, saliva, types of blood tissues such as lung tissue, liver tissue) or tissue (e.g. lung tissue, saliva), or post mortem tissue, for medical research. These samples could be left over from a surgical procedure or they may be donated specifically for research purposes. Currently, we know very little about what people think about this issue. Please take the time to read the following information to help you decide whether you would like to take part.

Who will conduct this research? The research is part of the STRATUM project, a project set up to try to increase the effectiveness of tissue sample provision in the UK. It is being conducted with the help of a national charity, Genetic Alliance UK that represents over 150 patient organisations. The Focus Group are a reputable research company helping us to recruit members of the public. This study has received ethics approval from Manchester University.

What is the aim of this research? The aim is to understand what people think about donating human tissue samples for medical research.

Why have I been chosen? As a member of the public, your views are important. Your views will help us understand people's opinions and ensure that the donation of biological samples for medical research is carried out in a way that reflects people's wishes.

What would I be asked to do if I took part? We are inviting you to attend a group discussion to discuss your opinions about donating tissue samples for medical research. Don't worry if you feel you don't know a lot about this topic because discussions will be led by a trained moderator. We have provided some basic information along with this sheet that gives you some background about the topic. There are no right or wrong views; everyone's opinions will be equally valid.

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What happens to the data collected? The information collected from these discussions will be used to write a report which will be used to influence National policy. The findings will also be used to publish academic papers in journals.

How is confidentiality maintained? Discussions will be digitally recorded so that we can get an accurate account of what was said. However, when these are typed up, all comments will be anonymous and your name will not appear anywhere on the document. The documents will be kept secure on an encrypted hard drive and backed up on an encrypted memory stick which will be kept in a locked office. These documents and the audio files will be kept for 5 years and then destroyed. This information will not be passed on to any other third party.

What happens if I do not want to take part or if I change my mind? It is up to you whether or not to take part. If you do decide to take part you will be asked to sign a consent form saying that you have agreed to take part and have the conversation recorded. If you decide to take part you are still free to withdraw at any time without giving a reason and without detriment to yourself.

Will I be paid for taking part? As a thank you for taking part you will be given £50 which will be given at the end of the discussion.

What is the duration of the research? There will be between 6-8 people in the group which will last approximately 1.5 hours.

Where will the research be conducted?

What are the benefits from me taking part? There is no direct benefit to yourself from taking part, but your views will help to shape future policy.

Who will be running the group? The person running the focus group is Celine Lewis, who is a researcher with Genetic Alliance UK. If you have any concerns or questions about taking part in this research before the group then please contact Celine on 0207 704 3141. If you have agreed to take part and then find nearer the time you are no longer able to make the group then please contact the person who recruited you directly so that you can be replaced.

What if something goes wrong? In the unlikely event that you want to make a complaint about the conduct of the research, or would like help or advice following the discussion, you can contact the head of the project, Julie Corfield:
Email: juliecorfield@areteva.com
Tel: 0115 812 0008

Many thanks,

Celine Lewis

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Appendix II

Donating biological samples for medical research

Introduction
Medical research is necessary to improve our understanding of what keeps us healthy and how diseases start and progress. It also means scientists can develop new and improved treatments.

Body fluid (such as blood, saliva, urine) and human tissue (such as fat, cancer tumours or muscle) are often used in scientific and medical research. Types of research that need body fluid and human tissue include:

- Looking at how the body works to fight disease.
- Testing new treatments for conditions such as heart disease and diabetes.
- Developing tests for different types of cancer.
- Researching how certain types of cells could be used to treat conditions like Parkinson's disease, Alzheimer's disease and multiple sclerosis.

Many of the tests and treatments used today resulted from people donating body fluid and human tissue (often called 'samples') for research years ago.

How are human samples collected?
There are a number of ways that human samples can be collected:

- Samples may be left over after surgery. Tissue may be removed during surgery so tests can be done on the tissue or to stop the diseased tissue spreading to other parts of the body. After any necessary tests have been done on the tissue, there may be some left over. This left over tissue may be destroyed or used for medical research.
- Samples may be left over from a medical test such as a blood test.
- Samples might be donated specifically for medical research.
- A person may give permission (known as 'consent' or 'authorisation') for a sample to be taken and used for research in the event of their death.
- A person's family may give permission for the person's organs, which would have been donated for transplant, to be used for research if they are not suitable for transplant or a suitable recipient is not available.

The collection and use of samples is tightly governed by law in the UK. The removal of samples from a person is always done with the donor's permission, and any research first has to be approved by a research ethics committee. This committee is usually made up of doctors, scientist, patients and the general public, and ensures any research allowed to be done is for the benefit of patients. In specific circumstances the law allows samples that have already been collected to be used for another purpose, as long as the donor cannot be identified and the use has been approved by an ethics committee.

What is done with the sample once it is collected?
Samples may be collected by a researcher and used immediately, or they may be collected for research purposes and kept. This may be in a researcher's laboratory or it may be in a storage place specifically for samples, known as a biobank.

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The biobank keeps the samples so they can be used by scientists for research. In other words, biobanks are a little like libraries of samples, and only a research team can use them if they have the appropriate approval. A biobank has to follow regulations and have a licence, granted by the Human Tissue Authority (a UK Government organisation), to be able to store human tissue samples for research.

These systems ensure that any research respects the privacy of the people who donated the samples and that the research is of benefit to society. In many cases, it can be very important to have a patient's medical records along with their sample so that scientists can make sense of the results of their research. Any identifying information, such as names or addresses, is removed and not included with the sample.

How long is the biological sample kept?
A sample may be used all at once. However, it is often the case that it won't all be used in one go. Therefore the sample may be stored and used over many years so that research can be done on it well into the future.

What are the benefits from donating biological samples to medical research?
The person donating the sample is unlikely to benefit directly from the research, as it can take many years for the research on samples to produce new treatments or cures for diseases. Nevertheless, donors often see a benefit from knowing that they have personally helped medical research.

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2012

The following information was used during the making of this leaflet:
"Donating samples for research; Patient information" – Central England Haemoto-Oncology Research Biobank
"Donating your tissue for research"- Human Tissue Authority
"Active choice but not too active: Public perspectives on biobank consent models" Simon et al. 2011; Genetics in Medicine

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Appendix III

Focus Group – Discussion Guide

Introduction (5 minutes)

Thank them for coming
Aim of discussion – hear people's views, there are no right or wrong opinions, disagreement OK
Participation voluntary
Confidentiality – all info anonymous, personal details will not be passed on to any third party
Get permission for recording to be taped – no names or identifying features used when typed up
Guidelines – talk one at a time; am interested in everyone's views so will try and give everyone equal 'airtime'; no wrong answers – be honest and open.
Turn mobile phones off
Go round room. Ask everyone to say their name and one of their favourite foods.

Research (30 minutes)

On the information sheet you've been given, there is some general information about donating samples for research. Has everybody had a chance to read this information? (if not give participants a few minutes to read document). So, to summarise….*give a brief overview of information on the document.*

1. So to start off, does anyone have any questions about anything I've said so far?

So I'd like us to think now about the different types of samples someone might donate to medical research. Human biological samples can mean a variety of different things including body fluid such as blood, saliva and sperm, and human tissue such as fat, cancer tumours or muscle or even whole organs.

2. Do you think there are some types of samples which are more sensitive to give than others? Which ones? Why?

There are also various different ways that samples can be collected. They might be

- left over from routine procedures such as surgery;
- left over after a medical test such as a blood test;
- donated specifically for medical research, for example a cheek swab or an extra blood sample;
- donated after a person's death;
- a person's organs e.g. heart or kidneys, which would have been donated for transplant, may be used for research if they are not suitable for transplant or a suitable recipient is not available. The relevant clinical data may also be included and reviewed after death.

3. I'd like us to go through each of these in turn and discuss whether you have concerns about any of these ways that samples might be collected and why. GO THROUGH AND PROBE EACH POINT SPECIFICALLY (AFTER GROUP DISCUSSION: ask participants to complete associated question on questionnaire)

4. Do you see donation of human samples for medical research and organ donation for transplant similarly or do you think they are different?

5. Thinking specifically about donating tissue or organs after one's death, do you think if someone has indicated in writing that they are willing to donate these for research in the event of their death, their wishes can be overridden by their relatives?

Samples may be used for a variety of different types of research. This might include looking at how the body works to fight disease; testing new treatments for conditions such as heart disease and diabetes or developing ways of diagnosing earlier different types of cancer.

6. Are there any types of research you would not be happy for your sample to be used for? Why?
   (AFTER GROUP DISCUSSION: ask participants to complete associated question on questionnaire)

There are many places where research is performed, such as universities, NHS, charities such as cancer research, government labs and pharmaceutical companies. These are all groups that do research & sometimes they collaborate with each other in order to make medical progress.

7. Do you have any concerns about any particular types of organisations using donated samples. Which if any, and why?

   (AFTER GROUP DISCUSSION: ask participants to complete associated question on questionnaire)

8. What do you think about the organisations that conduct research on samples? Do you think they are generally doing a good thing for society? Do you have any concerns about what they do?

9. Institutions such as the government and ethics review committees make decisions about what research can and can't be done on human samples. Ethics review committees are usually made up of different experts such as of doctors, scientists, ethics experts and patients Do you generally trust these types of institutions to make decisions about what research can and can't be done using human tissue samples?

Consent (40 minutes)

I'd like to now talk about getting permission, also known as consent, to use a person's sample for medical research. Most of us have probably had blood taken at some point and some of us will have had an operation. If we have blood taken for a test, there might be some blood left over after the test has been done. Similarly, tissue may be removed during an operation and there may be some left over after any necessary tests have been done on the tissue. So you would not have any additional tissue taken just for research purposes unless you had specifically given permission for this at the time it was going to be taken. In most cases, it is just the leftover blood or tissue that you might agree to donate to medical research.

10. Thinking about leftover blood or tissue being used for medical research, do you think a person needs to be asked for their consent? FOR EACH RESPONSE: Why/why not? How important is this to you?

11. What would you expect to happen to samples that are left over from clinical procedures?

12. The majority of the time, tissue that is left over is destroyed. How do you feel about that?

There are a number of different ways that a person could give their permission or consent for their sample to be used for medical research. I'd like us to think about some of these now and discuss what we like and what we dislike about these different types of consent.

I'd like us to start by thinking about whether we prefer what is known as an **opt-in** system, or whether we prefer an **opt-out** system of sample donation.

Opt-in means that a person has to say that, after they turn 18, they are willing to and actively agree to donate their sample for research. This is how the current system for organ donation works in the UK.

The other approach is an opt-out approach. In this system, it is assumed that a person is happy, after they turn 18, for their sample to be used for research unless they specifically say otherwise. However, there is a mechanism in place for a person who is not willing to donate to opt out.

So, to start with, lets think about the first option, OPT-IN.

13. What do you think are the pros and cons about this approach? Why?

14. Thinking now about the OPT-OUT approach, what you think are the pros and cons? Why?

15. Which do you prefer? How important is this to you? (AFTER GROUP DISCUSSION: ask participants to complete associated question on questionnaire)

The current system is an opt-in one, so I want us to think about this type of consent now. If you were going to be asked to donate any leftover blood or tissue for medical research there are two ways this could be done. You could be asked to give consent **every time** you have an operation or blood test, or you could give consent just **once for life for all your samples,** with the option of withdrawing at a later point if you wanted to.

16. Thinking about **consent every time**, what do you think are the advantages and disadvantages of this approach?

17. Thinking about **consent once for life**, what do you think are the advantages and disadvantages of this approach?

18. Can you think of any happy medium which might be better?

19. Which would you prefer? Why? How important is this to you? (AFTER GROUP DISCUSSION: ask participants to complete associated question on questionnaire)

20. If people gave consent just once, when and where do you think the best place would be to give consent?

21. If someone wanted to consent to donate their tissue or organs for medical research in the event of their death, do you think it should be obtained at the same time as consent for organ transplantation and recorded on the organ donor register?

In front of you, you have 3 different scenarios. In each one the story is essentially the same, however there are some slight differences and these are highlighted in bold. I'd like to discuss what you think of each of these in turn.

Read all 3 scenarios out loud highlighting the key differences between the three. Then go back and discuss each one in turn.

Scenario 1: Lisa is having surgery to remove a lump from her breast which the doctor is concerned may be cancerous. Before the surgery the surgeon explains that once the tissue is removed, they will take it to the laboratory to do tests on it to check what it is. The surgeon then explains that after these tests are done, there may be some tissue left over. He asks Lisa if she would like to donate this left over tissue for medical research. If it is not donated for medical research it will be destroyed. The surgeon doesn't know exactly what kinds of research the tissue might be used for, but it may be used to find better ways to diagnose, prevent and treat cancer. He also explains that before any research is done, it has to be approved by an independent ethics committee.

So, in this scenario:

- Lisa is asked to give consent once to donate the left over tissue for a range of future unknown uses
- Lisa is given some general information about the kind of research the tissue might be used for but nothing specific.
- This type of consent is known as GENERIC CONSENT

22. What do you think about this type of consent?

23. What do you **like** about this approach?

24. Do you have **any concerns** about this approach?

Scenario 2: Lisa is having surgery to remove a lump from her breast which the doctor is concerned may be cancerous. Before the surgery the surgeon explains that once the tissue is removed, they will take it to the laboratory to do tests on it to check what it is. The surgeon then explains that after these tests are done, there may be some tissue left over. He asks Lisa if she would like to donate this left over tissue for medical research. If it is not donated for medical research it will be destroyed. The surgeon doesn't know exactly what types of research the tissue might be used for, but it may be used to find better ways to diagnose, prevent and treat cancer. Lisa is asked to sign a consent form. The surgeon explains that **Lisa can indicate on the consent form whether there are any particular kinds of research which she doesn't want the tissue to be used for, for example research involving animals or research conducted outside the UK.** He also explains that before any research is done, it has to be approved by an independent ethics committee.

So, in this scenario:

- Lisa is asked to give consent once to donate the tissue for a range of future unknown uses;
- Lisa is given some general information about the kind of research the tissue might be used for;
- **Lisa can say if there are any particular kinds of research which she doesn't want the tissue to be used for.**
- This type of consent is known as TIERED CONSENT

25. What do you think about this type of consent?

26. What do you **like** about this approach?

27. Do you have any **concerns** about this approach?

Scenario 3: Lisa is having surgery to remove a lump from her breast which the doctor is concerned may be cancerous. Before the surgery the surgeon explains that once the tissue is removed, they will take it to the laboratory to do tests on it to check what it is. The surgeon then explains that after these tests are done, there may be some tissue left over. He asks Lisa if she would like to donate this left over tissue for medical research. If it is not

donated for medical research it will be destroyed. The surgeon explains that **the hospital are currently involved in a study looking at the growth of tumours. He informs her that if she gives permission for the left over tissue to be used, it would only be for this particular study.** He also explains that the study has been approved by an independent ethics committee.

So, in this scenario:

- **Lisa is only asked to give consent to a particular study and is given information about that study.**
- This type of consent is known as SPECIFIC CONSENT

28. What do you think about this type of consent?

29. What do you **like** about this approach?

30. Do you have any **concerns** about this approach?

31. In this exercise we have discussed three different types of consent. Which do you prefer and why? GO ROUND AND ASK PEOPLE (AFTER GROUP DISCUSSION: ask participants to complete associated question 6 & 7 on questionnaire)

32. Generic consent is the most practical type of consent as it is the least costly to put in place. Researchers try their very best to honour donors' wishes, but in some cases where they cannot do this with confidence, instead of risking using a sample for something the donor feels strongly against, it won't be used at all. If your first choice wasn´t generic consent, does this information change your preference? (AFTER GROUP DISCUSSION: ask participants to complete question 8.

33. So, we've discussed which type of consent you would like for left over samples. Would your preference be any different for samples that you might donate specifically for research, e.g. if you volunteered to took part in a study and had to give a saliva or blood sample?

34. Would your preference be any different if you were donating what you might consider to be more sensitive samples e.g. genetic data, stem cells?

35. If you decide to withdraw consent would you be happy for researchers to use the data that had already been generated up to that point using your sample?

36. Do you think a central website where you can find out about general research that your sample might be used for would be useful and something you would use?

Information (10 minutes)

Researchers often need to have access to the donor's medical records in order to be able to meaningfully interpret the results of the scientific research. However, information, such as names or addresses are always removed and not included with the sample. This is so that the person who donated the sample cannot be identified by the scientist conducting the research or anyone analysing the results of the research. However, the sample may have a code so that someone not involved in the research can identify the individual if necessary.

37. Would you be happy with your medical records being linked to your sample or would you have concerns? Why?

38. Are there any types of information you would not want to be associated with your sample?

Sometimes it can also be helpful for the researcher to have certain information about the lifestyle of the person who donated the sample, for example whether they smoked, drank alcohol, how often they exercised etc. This information might help them to better understand the particular condition they are investigating.

39. Would you be happy for this information to be made available or would you have concerns about your lifestyle information being associated with your sample? Why?

Ownership of sample (5 minutes)

40. What significance do you attach to a biological sample once it has been removed from your body? Do you still see it as yours or part of you in some way? Are you owed money if a drug is developed using your sample?

Appendix V

Survey looking at the publics' views on donating biological samples for medical research

This survey was originally conducted online in September 2012 and hosted by the market research company Research Now.

Q1. What age are you?

1. 18-24
2. 25-34
3. 35-44
4. 45-54
5. 55-64
6. 65+

Q2. Are you male or female?

1. Male
2. Female

Q3. What is the occupation of person who receives the highest income in your household?

1. Higher managerial/ professional/ administrative (e.g. established doctor, solicitor, board director in a large organisation (200+ employees, top level civil servant/public service employee)) **(A – Letters will be hidden)**
2. Intermediate managerial/ professional/ administrative (e.g. newly qualified (under 3 years) doctor, solicitor, board director small organisation, middle manager in large organisation, principle officer in civil service/local government) **(B)**
3. Supervisory or clerical level/ junior managerial/ professional/ administrative (e.g. office worker, student doctor, foreman with 25+ employees, salesperson, etc) **(C1)**
4. Student **(C1)**
5. Skilled manual worker (e.g. skilled bricklayer, carpenter, plumber, painter, bus/ ambulance driver, HGV driver, AA patrolman, pub/bar worker, etc) **(C2)**
6. Semi or unskilled manual work (e.g. manual workers, all apprentices to be skilled trades, caretaker, park keeper, non-HGV driver, shop assistant) **(D)**
7. Casual worker – not in permanent employment **(E)**
8. Housewife/househusband/ homemaker **(E)**
9. Retired and living on state pension **(E)**
10. Unemployed or not working due to long-term sickness **(E)**
11. Full-time carer of other household member **(E)**

98. Other (specify)

Q4. What region do you live in?

1. Channel Islands
2. East of England
3. East Midlands
4. London
5. North East
6. North West
7. Northern Ireland
8. Scotland
9. South East
10. South West
11. Wales
12. West Midlands
13. Yorkshire / Humberside
96. Not on Map

Q5. Please choose one option that best describes your ethnic group or background.

1. White or White British
2. Mixed race
3. Asian or Asian British (not Chinese)
4. Black or Black British
5. Chinese
6. Other ethnic group
96. Prefer not to say

Q6. Which religion do you most identify with?

1. Christianity
2. Islam
3. Hinduism
4. Sikhism
5. Judaism
6. Buddhism
7. Other religion
8. No religion
96. Prefer not to say

Q7. If you do have a religion you identify with, to what extent do you consider yourself religious?

1. Not at all religious
2. Moderately religious
3. Very religious
96. Prefer not to say

Q8. Please indicate which, if any, is the highest educational or professional qualification you have obtained.

1. No formal qualification
2. GCSE, O level, Scottish Standard Grade or equivalent
3. GCE, A-level, Scottish Higher or similar
4. Vocational (BTEC/NVQ/Diploma)
5. Degree level or above
96. Prefer not to say

Q9. How would you describe your own level of knowledge about the medical research process including the use of human tissue samples?

1. No knowledge
2. Some knowledge
3. Good knowledge

Q10. Are you or have you ever been affected by a long-standing illness, disability or infirmity which has required continuous or frequent medical attention (e.g. cancer, diabetes, heart disease, asthma, a genetic condition)?

1. Yes
2. No

Q11. Has a close family member ever been affected by a long-standing illness, disability or infirmity which has required continuous or frequent medical attention (e.g. cancer, diabetes, heart disease, asthma, a genetic condition)?

1. Yes
2. No

Q12. Have you ever had blood or tissue removed during a medical or surgical procedure?

1. Yes
2. No
97. Don't know

Q13. Have you ever been asked to donate any blood or tissue for medical research?

1. Yes
2. No
97. Don't know

ASK IF CODED 1 AT Q13.

Q14. Did you agree to donate?

1. Yes
2. No
97. Don't know

ASK IF CODED 2 AT Q14.

Q14a. Please tell us a little bit about your reasons for choosing not to donate.
There are no right or wrong answers – we're just interested in your honest opinion.

This survey is being done to help us understand public opinion about human tissue samples donated by people for medical research.

Medical research is essential to improve our understanding of what keeps us healthy and how diseases start and progress. It also means scientists can develop new and improved treatments. Body fluid such as blood, saliva and urine, and human tissue such as cells, skin, fat or even whole organs (in the event of someone's death), are often used in scientific and medical research. Usually these are referred to as samples.

Types of research that need samples include:

- Looking at how the body works to fight disease.
- Looking at why some people are more likely to develop certain diseases.
- Developing tests to diagnose conditions like cancer or dementia earlier on.
- Testing new treatments for conditions such as heart disease and diabetes.
- Researching how certain types of cells could be used to treat conditions like Parkinson's disease and Alzheimer's disease.

Many of the tests and treatments used today resulted from people donating samples for research previously. The removal of samples from a person is always done with the donor's permission. Samples that are donated for research are anonymised so that the researcher using the sample does not know who it came from. The types of research that are allowed to take place are highly regulated by both UK law and also by independent research ethics committees (usually made up of doctors, scientist, patients and the general public). These ensure any research allowed to be done is for the benefit of patients.

The next button will appear shortly. In the meantime take some time to read the information above as it relates to the remainder of the survey.

Q15. On a scale of 1 to 5 with 1 being Not At All Important and 5 being Extremely Important, how important do you think it is for people to donate samples for medical research?

SCALE:

1. Not at all important
2.

3.
4.
5. Extremely important
97. Don't know

Q16. Samples can be left over from surgery or a medical procedure, or they can be donated specifically for research. Left over samples that are not required for clinical diagnosis or donated for medical research are often destroyed.

In general, would you like to be asked to donate samples for medical research?

1. Definitely yes
2. Probably yes
3. Probably not
4. Definitely not
97. Don't know

RANDOMISE STATEMENTS

Q17. You are having a medical procedure to treat a health issue. Would you donate the following types of samples for medical research if they were left over (after necessary medical tests had been done) following the procedure?

SCALE:

1. Definitely yes
2. Probably yes
3. Probably not
4. Definitely not
97. Don't know

STATEMENTS:

1. Blood
2. Skin tissue
3. Fat
4. Cancerous tissue
5. Liver tissue
6. Bone or cartilage
7. Spare eggs not fertilised during IVF treatment (IVF is a process by which an egg is fertilised by a sperm outside the body and then transferred back into the body to establish a successful pregnancy) **ASK ONLY FEMALES**
8. Spare embryos (fertilised eggs) not transferred back into the body following IVF (IVF is a process by which an egg is fertilised by a sperm outside the body and then transferred back into the body to establish a successful pregnancy)

RANDOMISE STATEMENTS

Q18. You've gone to the hospital for an appointment and whilst you are in the waiting room the receptionist explains they are collecting samples for medical research. Would you agree to donate the following types of samples specifically for medical research, i.e. not as part of any medical procedure, put purely for the purposes of research?

Would you agree to donate the following types of samples specifically for medical research? Below are some definitions you might need to know in order to answer the questions.

Local anaesthetic - "A type of painkilling medication that is used to numb areas of the body during surgical procedures. You stay awake when you have a local anaesthetic"

General anaesthetic - "A medication that causes loss of sensation. It is used to give pain relief during surgery. General anaesthetic makes you completely lose consciousness so that surgery can be carried out without causing any pain or discomfort. Most healthy people don't have any problems when having a general anaesthetic. However, as with most medical procedures, there is a small risk of long-term complications and, rarely, death."

SCALE:

1. Definitely yes
2. Probably yes
3. Probably not
4. Definitely not
97. Don't know

STATEMENTS:

1. Saliva
2. Urine
3. Blood
4. Tissue collected requiring a local anaesthetic (e.g. a skin cell scraping)
5. Tissue collected requiring a general anaesthetic (e.g. a liver sample)
6. Sperm **ASK ONLY MALES**

Q19. In the event of your death, would you be willing to donate the following for medical research?

SCALE:

1. Definitely yes
2. Probably yes
3. Probably not
4. Definitely not
97. Don't know

STATEMENTS:

1. A small sample of the liver
2. A small sample of the brain
3. A whole liver
4. A whole brain

Q20. You are having surgery for a health issue which requires a general anaesthetic. The surgeon asks you whether you would be willing to consent to any additional tissue (i.e. tissue not needing to be removed as part of the health issue) being taken during the surgery for medical research. He assures you that any additional tissue taken would have no impact for you or your health and that no extra tissue would be removed without your consent.

A decision to consent or not to consent would be equally respected and would have no impact on the care you receive.

Would you be willing to donate the following types of samples for medical research?

General anaesthetic - "A medication that causes loss of sensation. It is used to give pain relief during surgery. General anaesthetic makes you completely lose consciousness so that surgery can be carried out without causing any pain or discomfort. Most healthy people don't have any problems when having a general anaesthetic. However, as with most medical procedures, there is a small risk of long-term complications and, rarely, death."

SCALE:

1. Definitely yes
2. Probably yes
3. Probably not
4. Definitely not

97. Don't know

STATEMENTS:

1. Samples taken from the same part of the body being operated on
2. Samples taken from an area close by
3. Samples involving an additional procedure e.g. taking bone marrow or a tissue sample whilst under the same general anaesthetic

RANDOMISE STATEMENTS

Q21. Samples may be used for lots of different types of research. The types of research that are allowed to take place are highly regulated by both UK law and also by research ethics committees. Would you be willing to donate samples for the following types of research?

Research ethics committee - "A committee usually made up of doctors, scientist, patients and the general public. These ensure any research allowed to be done is for the benefit of patients."

SCALE:

1. Definitely yes
2. Probably yes
3. Probably not
4. Definitely not
97. Don't know

STATEMENTS:

1. Understanding how our body fights disease
2. Understanding how our genetic makeup influences whether or not we will be affected by certain conditions
3. Testing new treatments
4. Research which involves using cells that come from embryos *(fertilised eggs)*
5. Research involving animals
6. Research conducted outside of the UK

RANDOMISE ORDER OF STATEMENTS.

Q22. There are many places where research is performed, such as universities, the NHS, medical research charities such as Cancer Research UK and Arthritis Research UK, pharmaceutical companies and diagnostic companies. These organisations work individually, and often in collaboration, to carry out research, to understand disease, develop tests for diseases and develop and test new treatments.

Would you be willing to donate samples to the following organisations to carry out approved medical research?

Diagnostic companies - "A company which develops and manufactures medical tests to diagnose diseases"

SCALE:

1. Definitely yes
2. Probably yes
3. Probably not
4. Definitely not
97. Don't know

STATEMENTS

1. NHS hospitals
2. Universities
3. Medical research charities
4. Pharmaceutical companies
5. Diagnostic companies

Q23. Samples left over following surgery and once any necessary tests have been done, can be anonymised and used for medical research. On a scale of 1 to 5 with 1 being Not At All Important and 5 being Extremely Important, how important do you think it is that you are first asked for your permission (often known as 'consent') for any left over samples to be used for medical research?
Anonymised - i.e. identifying features such as names and addresses are removed

SCALE:

1. Not at all important
2.
3.
4.
5. Extremely important

Q24. There are a number of different ways that a person could give consent for their left over samples to be used for medical research.

a) One way is an 'opt-in' system. Opt-in means that a person must specifically be asked for their permission before any leftover samples can be used in medical research.

b) The other way is an 'opt-out' system. In this system, it is assumed that a person is happy, after they turn 18 years old, for any leftover samples to be used for medical research unless they specifically say otherwise.

Which of the two systems to donating leftover samples do you prefer?

1. Opt-in
2. Opt-out
3. No preference
97. Don't know

Q25. The current system in the UK is an opt-in system. That means you have to say whether you want any leftover samples to be donated for medical research. If you were going to be asked to donate any leftover samples for medical research there are three ways this could be done.

a) You could be asked to give consent for left over samples to be used for research **every time** you have samples removed, or

b) you could be asked just **once for life** for any future left over samples to be used for medical research (with the option of withdrawing your permission at any later point if you wanted to),

c) you could be **asked at certain points** during your life, for example every 10 years by your GP, or at the start of treatment for a particular condition or health issue.

Which of these three approaches do you prefer?

1. Consent every time
2. Consent once for life
3. Consent at certain points
4. No preference
97. Don't know

Q26. If you were going to be asked to donate left over samples for medical research every time you had a medical procedure, would you rather this was discussed with you by a health professional before the medical procedure or afterwards?

1. Before
2. After
3. No preference
97. Don't know

Q27. If we adopted a consent once for life system in the UK for adults (i.e. aged 18 years and over), when would you prefer to be asked about consenting left over samples for medical research? *Choose up to 3 options.*

1. When registering at a GP surgery
2. During a routine GP appointment
3. When applying for a driving license
4. When applying for a passport
5. The first time I visit the hospital
6. The first time I have a medical procedure (e.g. blood test or surgery)
98. Other (please specify)

Q28. What would be your preferred way to register your consent to donate left over samples for medical research?

1. Face to face with a health professional
2. Letter
3. Email
4. Telephone
5. Via a website
6. Completing a form (from a GP surgery, post office, library or other community centre) and returning it by post
98. Other (please specify)
97. Don't know

Q29. If you later decided you didn't want your samples to be used for medical research, what would be your preferred way to withdraw that consent?

1. Face to face with a health professional
2. Letter
3. Email
4. Telephone
5. Via a website
6. Completing a form (from a GP surgery, post office, library or other community centre) and returning it by post

98. Other (please specify)
97. Don't know

Q30. Imagine you have agreed to donate a sample for medical research. There are a number of ways you can give consent for that particular sample to be used:

STATEMENTS

1. You can give consent once for your sample to be used in any future research that has been approved by a research ethics committee. This type of consent is called Generic Consent.

   Thinking about Generic Consent, if this was the type of consent you were asked to give, how likely would you be to donate samples for medical research?

   Research ethics committee. "A committee usually made up of doctors, scientist, patients and the general public. These ensure any research allowed to be done is for the benefit of patients."

2. You can give consent once for your sample to be used in any future research that has been approved by a research ethics committee but with the option of saying whether there are certain types of research you don't want your sample to be used for. This type of consent is called Tiered Consent.

   Thinking about Tiered Consent, if this was the type of consent you were asked to give, how likely would you be to donate samples for medical research?

   Research ethics committee. "A committee usually made up of doctors, scientist, patients and the general public. These ensure any research allowed to be done is for the benefit of patients."

3. You can give consent once for the sample to be used for a specific study that you have been told about, which has been approved by a research ethics committee. The sample will not be used for any other research other than the particular study you have given consent for. Any leftover tissue at the end of the study may be destroyed. This type of consent is called Specific Consent – once only.

   Thinking about Specific Consent – once only, if this was the type of consent you were asked to give, how likely would you be to donate samples for medical research?

   Research ethics committee. "A committee usually made up of doctors, scientist, patients and the general public. These ensure any research allowed to be done is for the benefit of patients."

4. **Lastly**, you can give consent every time for the sample to be used for a specific study that you have been told about, which has been approved by a research ethics committee. With this type of consent you would then be contacted and asked for your consent for every new study in which your sample might be used. This type of consent is called Consent for every new study.

   Thinking about Consent for every new study if this was the type of consent you were asked to give, how likely would you be to donate samples for medical research?

   Research ethics committee. "A committee usually made up of doctors, scientist, patients and the general public. These ensure any research allowed to be done is for the benefit of patients."

SCALE:

1. Definitely yes
2. Probably yes
3. Probably not
4. Definitely not
97. Don't know

Q31. Which of these four types of consent do you prefer? Please rank them in order of preference. Put 1 for your first preference; 2 for your second; 3 for your third preference and 4 for your last preference. If you don't have any preference, and like all 4 equally, tick the 'No preference' you don't know then tick ' Don't know'

1. Generic consent
2. Tiered consent
3. Specific consent – once only
4. Consent for every new study
5. No preference
97. Don't know

ASK TO THOSE PEOPLE WHO DID NOT RANK GENERIC CONSENT AS FIRST CHOICE

Q32. Generic consent is the most practical type of consent as it is the least costly to put in place. Researchers try their very best to honour donors' wishes, but in some cases where it is too costly to put Tiered or Specific Consent in place, instead of risking using a sample for something the donor feels strongly against, it won't be used at all. If Tiered or Specific consent was not available, what would you do?

1. I would agree to give generic consent
2. I would rather my sample was not used at all
97. Don't know

Q33. Some people feel there are certain types of samples that are more sensitive to donate, for example sperm or left over eggs. If there was a sample that you considered to be sensitive, but were still willing to donate for medical research, which of the four types of consent would you prefer to give?

1. Generic consent
2. Tiered consent
3. Specific consent – once only
4. Consent for every new study
5. No preference
97. Don't know

Q34. Researchers often need to have access to the donor's medical records to be able to interpret the results of their scientific research. However, information such as names or addresses are always removed and are not included with the sample. This is so that the person who donated the sample cannot be identified by the scientist conducting the research or anyone analysing the results of the research. However, the sample may have a code so that someone not involved in the research can identify the individual if necessary, for example, if there was a serious health issue the donor should be aware of.

Would you be willing to have your anonymised medical records linked to your sample?

1. Definitely yes
2. Probably yes
3. Probably not
4. Definitely not
97. Don't know

Q35. Sometimes it can also be helpful for the researcher to have certain information about the lifestyle of the person who donated the sample, for example whether they smoke, drink alcohol, how often they exercise etc. This information might help them to better understand the particular

condition they are investigating. Would you be willing to have your anonymised lifestyle information linked to your sample?

1. Definitely yes
2. Probably yes
3. Probably not
4. Definitely not
97. Don't know

Q36. For some people, it would be interesting to find out what type of medical research is going on. How would you like to get information on medical research including research on a particular condition that might use your sample?

1. Website
2. Newsletter
3. Email
4. Letter
5. Would not be interested in additional information

Q37. If you were considering donating whole organs for medical research in the event of your death, are there any particular organs you would **not** feel comfortable donating?
Please choose all that apply.

1. Brain
2. Eyes
3. Heart
4. Kidneys
5. Liver
6. Lungs
7. I would not donate any of my organs for medical research
8. None of the above apply as I would be happy to donate either all my organs or whole body for research

98. Other organs I would not donate (please state)

Q38. Sometimes, organs donated for transplant can't be transplanted because for some reason they are not suitable. However, these organs can still be very useful to researchers. Would you be willing to donate organs you had intended for transplant for medical research instead if the organ was not suitable?

1. Yes, I would donate an organ for research if it was not suitable for transplant
2. No, if they can't be used for transplant I would prefer they were not used at all
3. I would not agree to donate an organ for transplant

97. Don't know

Q39. If someone wanted to donate their tissue or organs for medical research in the event of their death, how do you think they should be able to provide their consent to do this?

1. It should be obtained at the same time as consent for organ transplantation and recorded on the organ donor register
2. It should be discussed at a GP appointment and recorded in the patients' notes
3. It should be discussed at a hospital and recorded in the patients' notes
98. Other (please specify)
97. Don't know

Q40. Someone has indicated in writing that they are willing to donate tissue or organs for medical research in the event of their death. After the donor's death the relatives decide they disagree with the donor's wishes. Do you think the relatives should be allowed to override the donor's wishes?

1. Yes
2. No
97. Don't know

Q41. If you have any particular views you would like to share with us about the topics raised in this questionnaire please feel free to write them here:

Appendix VI

Results of survey –unweighted and weighted

Demographic Data				
	Unweighted		Weighted	
	N	%	N	%
Sex				
Male	504	45%	544	49%
Female	606	55%	566	51%
Socioeconomic Group				
A	41	4%	44	4%
B	215	19%	244	22%
C1	311	28%	322	29%
C2	233	21%	233	21%
D	145	13%	178	16%
E	165	15%	89	8%
Age				
18-24	135	12%	133	12%
25-34	184	17%	189	17%
35-44	198	18%	200	18%
45-54	184	17%	189	17%
55-64	176	16%	167	15%
65+	233	21%	233	21%
Occupation				
Higher managerial	41	4%	44	4%
Intermediate managerial	215	19%	244	22%
Supervisory or clerical level	288	26%	299	27%
Student	23	2%	23	2%
Skilled manual worker	233	21%	233	21%
Semi or unskilled manual work	145	13%	178	16%
Casual worker	12	1%	6	1%
Housewife	9	1%	5	0%
Retired	81	7%	45	4%
Unemployed	46	4%	24	2%
Carer	17	2%	9	1%
Other	0	0%	0	0%
Region				
Channel Islands	0	0%	0	0%
East of England	92	8%	100	9%
East Midlands	57	5%	78	7%

Appendix VI

Results of survey –unweighted and weighted

London	213	19%	144	13%
North East	40	4%	44	4%
North West	121	11%	122	11%
Northern Ireland	30	3%	33	3%
Scotland	76	7%	89	8%
South East	165	15%	155	14%
South West	81	7%	89	8%
Wales	51	5%	55	5%
West Midlands	94	8%	100	9%
Yorkhire/Humberlands	90	8%	100	9%
Not on map	0	0%	0	0%
Ethnicity				
White or White British	1057	95%	1065	96%
Mixed race	7	1%	8	1%
Asian or Asian British (not Chinese)	18	2%	17	1%
Black or Black British	19	2%	12	1%
Chinese	2	0%	2	0%
Other ethnic group	4	0%	2	0%
Prefer not to say	3	0%	2	0%
Religion				
Christianity	677	61%	673	61%
Islam	13	1%	11	1%
Hinduism	6	1%	6	1%
Sikhism	0	0%	0	0%
Judaism	6	1%	4	1%
Buddhism	11	1%	1	0%
Other religion	15	1%	8	0%
No religion	370	33%	205	38%
Prefer not to say	12	1%	7	1%
To what extent do you consider yourself religious?				
Not at all religious	234	32%	234	32%
Moderately religious	422	58%	424	59%
Very religious	64	9%	56	8%
Prefer not to say	8	1%	7	1%
Education				
No formal qualification	70	6%	66	6%
GCSE, O level, Scottish Standard Grade or equivalent	264	24%	252	23%

Appendix VI

Results of survey –unweighted and weighted

GCE, A-level, Scottish Higher or similar	214	19%	214	19%
Vocational (BTEC/NVQ/Diploma)	230	21%	237	21%
Degree level or above	317	29%	330	30%
Prefer not to say	15	1%	10	1%

Q9 How would you describe your own level of knowledge about the medical research process including the use of human tissue samples?

	Unweighted		Weighted	
	N	%	N	%
No knowledge	463	42%	466	42 %
Some knowledge	603	54 %	602	54 %
Good knowledge	44	4 %	43	4 %

Q10 Are you or have you ever been affected by a long-standing illness, disability or infirmity which has required continuous or frequent medical attention

	Unweighted		Weighted	
	N	%	N	%
Yes	399	36 %	391	35%
No	711	64 %	719	65%

Q11 Has a close family member ever been affected by a long-standing illness, disability or infirmity which has required continuous or frequent medical attention

	Unweighted		Weighted	
	N	%	N	%
Yes	767	69 %	765	69%
No	343	31 %	345	31%

Q12 Have you ever had blood or tissue removed during a medical or surgical procedure?

	Unweighted	Weighted

Appendix VI

Results of survey –unweighted and weighted

	N	%	N	%
Yes	446	40 %	444	40%
No	553	50 %	551	50%
Don't Know	111	10 %	115	10%

Q13 Have you ever been asked to donate any blood or tissue for medical research?				
	Unweighted		Weighted	
	N	%	N	%
Yes	182	16 %	177	16%
No	904	81 %	907	82%
Don't Know	24	2 %	25	2%

Q14 Did you agree to donate?				
	Unweighted		Weighted	
	N	%	N	%
Yes	155	85 %	153	86%
No	23	13 %	21	12%
Don't Know	4	2 %	3	2%

Q15 On a scale of 1 to 5 with 1 being Not At All Important and 5 being Extremely Important, how important do you think it is for people to donate samples for medical research?				
	Unweighted		Weighted	
	N	%	N	%
1 Not at all important	5	0 %	4	0%
2	10	1 %	9	1%
3	78	7 %	76	7%
4	406	37 %	408	37%
5 Extremely important	554	50 %	567	51%
Don't know	57	5 %	46	4%

Appendix VI

Results of survey –unweighted and weighted

Q16 In general, would you like to be asked to donate samples for medical research?				
	Unweighted		Weighted	
	N	%	N	%
Definitely yes	317	29 %	327	29%
Probably yes	513	46 %	526	47%
Probably not	157	14 %	145	13%
Definitely not	42	4 %	35	3%
Don't know	81	7 %	77	7%

Q17 Would you donate the following types of samples for medical research if they were left over following the procedure?											
		Unweighted					Weighted				
		Def yes	Prob yes	Prob not	Def not	Don't know	Def yes	Prob yes	Prob not	Def not	Don't know
Blood	N	587	433	48	23	19	599	425	48	20	8
	%	53%	39%	4%	2%	2%	54%	38%	4%	2%	2%
Skin Tissue	N	520	451	72	32	35	533	451	67	28	32
	%	47%	41%	6%	3%	3%	48%	41%	6%	3%	3%
Fat	N	530	450	60	32	38	541	449	56	26	37
	%	48 %	41%	5%	3%	3%	49%	40%	5%	2%	3%
Cancerous Tissue	N	572	425	52	26	35	586	420	49	22	34
	%	52 %	38%	5%	2%	3%	53%	38%	4%	2%	3%
Liver Tissue	N	463	468	100	38	41	474	476	96	34	39
	%	42 %	42%	9%	3%	4%	43%	42%	9%	3%	4%
Bone or Cartilage	N	472	460	90	46	42	482	460	87	41	40
	%	43 %	41%	8%	4%	4%	43%	41%	8%	4%	4%
Spare eggs not fertilised during	N	133	159	121	104	89	128	149	111	93	86
	%	22 %	26%	20%	17%	15%	23%	26%	20%	16%	15%

Appendix VI

Results of survey –unweighted and weighted

IVF *											
Spare embryos	N	225	245	217	223	200	230	254	210	213	203
	%	20 %	22%	20%	20%	18%	21%	23%	19%	19%	18%

*Female Only

Q18 Would you agree to donate the following samples specifically for medical research?											
		Unweighted					Weighted				
		Def yes	Prob yes	Prob not	Def not	Don't know	Def yes	Prob yes	Prob not	Def not	Don't know
Saliva	N	568	423	54	30	35	581	413	55	27	34
	%	51 %	38%	5%	3%	3%	52%	37%	5%	2%	3%
Urine	N	553	432	61	33	31	566	424	60	30	30
	%	50 %	39%	5%	3%	3%	51%	38%	5%	3%	3%
Blood	N	455	448	118	47	42	496	446	107	46	42
	%	41 %	40%	11%	4%	4%	42%	40%	10%	4%	4%
Tissue collected requiring a local anaesthetic	N	273	463	197	100	77	283	471	190	88	78
	%	25 %	42%	18%	9%	7%	26%	42%	17%	8%	7%
Tissue collected requiring a general anaesthetic	N	166	286	310	235	113	172	300	309	214	115
	%	15 %	26%	28%	21%	10%	16%	27%	28%	19%	10%
Sperm *	N	120	171	104	66	43	135	188	111	64	46
	%	24 %	34%	21%	13%	9%	25%	35%	20%	12%	9%

*Men only

Appendix VI

Results of survey –unweighted and weighted

Q19 In the event of your death, would you be willing to donate the following samples for medical research?											
		Unweighted					Weighted				
		Def yes	Prob yes	Prob not	Def not	Don't know	Def yes	Prob yes	Prob not	Def not	Don't know
A small sample of your liver	N	485	390	88	51	96	491	391	84	48	96
	%	44 %	35%	8%	5%	9%	44%	35%	8%	4%	9%
A small sample of your brain	N	429	304	166	96	115	438	305	158	94	116
	%	39 %	27%	15%	9%	10%	39%	27%	14%	8%	10%
A whole liver	N	430	319	158	87	116	438	316	154	84	118
	%	39 %	29%	14%	8%	10%	39%	28%	14%	8%	11%
A whole brain	N	353	234	221	150	152	360	236	214	145	155
	%	32 %	21%	20%	14%	14%	32%	21%	19%	13%	14%

Q20 You are having surgery for a health issue which requires a general anaesthetic. The surgeon asks you whether you would be willing to consent to any additional tissue?											
		Unweighted					Weighted				
		Def yes	Prob yes	Prob not	Def not	Don't know	Def yes	Prob yes	Prob not	Def not	Don't know
From the same part of the body	N	328	530	115	51	86	342	523	112	50	83
	%	30 %	48%	10%	5%	8%	31%	47%	10%	5%	7%
Samples taken from an area close by	N	219	481	212	89	109	229	490	206	81	104
	%	20 %	43%	19%	8%	10%	21%	44%	19%	7%	9%
Samples involving an	N	154	336	298	204	118	164	348	301	180	118
	%	14 %	30%	27%	18%	11%	15%	31%	27%	16%	11%

Appendix VI

Results of survey –unweighted and weighted

additional procedure											

Q21 You are having surgery for a health issue which requires a general anaesthetic. The surgeon asks you whether you would be willing to consent to any additional tissue?

		Unweighted					Weighted				
		Def yes	Prob yes	Prob not	Def not	Don't know	Def yes	Prob yes	Prob not	Def not	Don't know
Understanding how our body fights disease	N	390	558	72	27	63	399	554	71	24	62
	%	35 %	50%	6%	2%	6%	36%	50%	6%	2%	6%
Understanding how our genetic makeup...	N	305	558	115	47	85	312	564	107	43	83
	%	27 %	50%	10%	4%	8%	28%	51%	10%	4%	8%
Research that is testing new treatments	N	318	511	132	52	97	325	502	133	50	99
	%	29 %	46%	12%	5%	9%	29%	45%	12%	5%	9%
Research involving cells from embryos	N	157	304	228	214	207	167	319	225	199	200
	%	14 %	27%	21%	19%	19%	15%	29%	20%	18%	18%
Research involving animals	N	107	270	281	318	134	117	285	271	304	132
	%	10%	24%	25%	29%	12%	11%	26%	24%	27%	12%
Research outside the UK	N	109	273	350	199	179	115	277	349	199	170
	%	10 %	25%	32%	18%	16%	10%	25%	31%	18%	15%

Appendix VI

Results of survey –unweighted and weighted

Q22 Would you be willing to donate samples to be used by the following organisations?											
		Unweighted					Weighted				
		Def yes	Prob yes	Prob not	Def not	Don't know	Def yes	Prob yes	Prob not	Def not	Don't know
NHS Hospitals	N	367	570	69	31	73	379	569	65	28	70
	%	33 %	51%	6%	3%	7%	34%	51%	6%	2%	6%
Universities	N	243	515	185	56	111	255	519	173	54	108
	%	22 %	46%	17%	5%	10%	23%	47%	16%	5%	10%
Medical Research Charities	N	307	563	107	41	92	311	561	108	39	91
	%	28 %	51%	10%	4%	8%	28%	51%	10%	4%	8%
Pharmaceutical Companies	N	138	487	233	93	159	139	490	227	95	161
	%	12 %	44%	21%	8%	14%	12%	44%	20%	9%	14%
Diagnostic Companies	N	187	515	180	74	154	182	511	183	74	159
	%	17 %	46%	16%	7%	14%	16%	46%	17%	7%	14%

Q23 How important do you think it is that you are first asked for your permission (often known as 'consent') for any leftover samples to be used for medical research?				
	Unweighted		Weighted	
	N	%	N	%
1 Not at all important	40	4 %	42	4%
2	41	4 %	43	4%
3	104	9 %	103	9%
4	274	25 %	268	24%
5 Extremely important	615	55 %	614	55%
Don't know	36	3 %	40	4%

Appendix VI

Results of survey –unweighted and weighted

Q24 How important do you think it is that you are first asked for your permission (often known as 'consent') for any leftover samples to be used for medical research?				
	Unweighted		Weighted	
	N	%	N	%
Opt-in	605	55 %	598	54%
Opt-out	308	28 %	321	29%
No preference	151	14 %	146	13%
Don't know	46	4 %	45	4%

Q25 Which of these three approaches do you prefer?				
	Unweighted		Weighted	
	N	%	N	%
Consent every time	472	43 %	480	43%
Consent once for life	231	21 %	237	21%
Consent at certain points	301	27 %	298	27%
No preference	82	7 %	72	7%
Don't know	24	2 %	22	2%

Q26 If you were going to be asked to donate left over samples for medical research every time you had a medical procedure, would you rather this was discussed with you by a health professional before the medical procedure or afterwards?				
	Unweighted		Weighted	
	N	%	N	%
Before	897	81 %	908	82%
After	48	4 %	48	4%
No preference	151	14 %	142	13%
Don't know	14	1 %	12	1%

Appendix VI

Results of survey –unweighted and weighted

Q27 If a consent once for life system was in place, when would you prefer to be asked about consenting left over samples for medical research?				
	Unweighted		Weighted	
	N	%	N	%
When registering at a GP surgery	425	39 %	419	38%
During a routine GP appointment	386	35 %	380	34%
When applying for a driving	83	8 %	88	8%
When applying for a passport	75	7 %	80	7%
The first time I visit the hospital	233	21 %	228	21%
The first time I have a medical	513	47 %	510	46%

Q28 If a consent once for life system was in place, when would you prefer to be asked about consenting left over samples for medical research?				
	Unweighted		Weighted	
	N	%	N	%
Face to face with a health professional	720	65 %	727	65%
Letter	66	6 %	64	6%
Email	30	3 %	32	3%
Telephone	14	1 %	13	1%
Via a website	60	5 %	61	6%
Completing a form and returning it by post	161	15 %	160	14%
Other (please specify)	4	0 %	4	0%
Don't know	55	5 %	49	4%

Q29 If you later decided you didn't want your samples to be used for medical research, what would be your preferred way to withdraw that consent?				
	Unweighted		Weighted	
	N	%	N	%
Face to face with a health professional	421	38 %	424	38%
Letter	95	9 %	92	8%
Email	89	8 %	93	8%
Telephone	56	5 %	51	5%
Via a website	137	12 %	144	13%

Appendix VI

Results of survey –unweighted and weighted

Completing a form and returning it by post	243	22 %	244	22%
Other (please specify)	8	1 %	6	1%
Don't know	61	5 %	55	5%

Q30 How likely would you be to donate samples for medical research using the following models of consent?

		Unweighted					Weighted				
		Def yes	Prob yes	Prob not	Def not	Don't know	Def yes	Prob yes	Prob not	Def not	Don't know
Generic	N	216	528	163	64	139	228	538	154	52	38
	%	19 %	48%	15%	6%	13%	21%	48%	14%	5%	12%
Tiered	N	242	549	125	55	139	244	560	124	49	133
	%	22 %	49%	11%	5%	13%	22%	50%	11%	4%	12%
Specific	N	336	553	88	28	105	339	551	89	29	102
	%	30 %	50%	8%	3%	9%	31%	50%	8%	3%	9%
Specific consent for every new study	N	293	560	110	27	120	300	560	109	26	115
	%	26 %	50%	10%	2%	11%	27%	50%	10%	2%	10%

Q31 Which of these four types of consent do you prefer?

Preferences	Unweighted		Weighted	
	N	%	N	%
Generic				
1st	200	18%	207	19%
2nd	159	14%	163	15%
3rd	168	15%	168	15%
4th	344	31%	327	30%
Tiered				
1st	156	14%	152	14%
2nd	246	22%	252	23%

Appendix VI

Results of survey –unweighted and weighted

3rd	360	32%	355	32%
4th	105	10%	106	10%
Specific (once only)				
1st	198	18%	183	17%
2nd	306	28%	304	27%
3rd	202	18%	209	19%
4th	161	15%	169	15%
Specific (every time)				
1st	341	31%	323	29%
2nd	157	14%	146	13%
3rd	138	12%	133	12%
4th	258	23%	263	24%
Don't Know	63	6%	62	6%
No Preference	181	16%	183	17%

Q32 If your preferred system of consent was not available, what would you do?

	Unweighted		Weighted	
	N	%	N	%
I would agree to give generic consent	348	52 %	350	53%
I would rather my sample was not used at all	187	28 %	172	26%
Don't know	133	20 %	135	21%

Q33 If there was a sample that you considered to be sensitive, but were still willing to donate for medical research, which of the four types of consent would you prefer to give?

	Unweighted		Weighted	
	N	%	N	%
Generic Consent	131	12 %	135	12%
Tiered Consent	105	9 %	101	9%
Specific Consent – once only	246	22 %	228	21%
Consent for every new study	278	25 %	288	26%

Appendix VI

Results of survey –unweighted and weighted

No Preference	206	19 %	216	19%
Don't Know	144	13 %	142	13%

Q34 Would you be willing to have your anonymised medical records linked to your sample?				
	Unweighted		Weighted	
	N	%	N	%
Definitely yes	266	24 %	279	25%
Probably yes	493	44 %	497	45%
Probably not	165	15 %	157	14%
Definitely not	77	7 %	71	6%
Don't know	109	10 %	107	10%

Q35 Would you be willing to have your anonymised lifestyle information linked to your sample?				
	Unweighted		Weighted	
	N	%	N	%
Definitely yes	377	34 %	398	35%
Probably yes	530	48 %	527	47%
Probably not	90	8 %	90	8%
Definitely not	48	4 %	43	4%
Don't know	65	6 %	61	5%

Q36 How would you like to get information on medical research including research on a particular condition that might use your sample?				
	Unweighted		Weighted	
	N	%	N	%
Website	295	27 %	304	27%
Newsletter	104	9 %	97	9%
Email	302	27 %	315	28%
Letter	241	22 %	228	21%
Would not be interested in additional information	168	15 %	166	15%

Appendix VI

Results of survey –unweighted and weighted

Q37 Are there any particular organs you would not feel comfortable donating in the event of your death?				
	Unweighted		Weighted	
	N	%	N	%
Brain	337	31%	329	30%
Eyes	307	28%	308	28%
Heart	128	12%	121	11%
Kidneys	60	5 %	59	5%
Liver	68	6 %	65	6%
Lungs	67	6%	63	6%

Q38 If you were considering donating whole organs for medical research in the event of your death, are there any particular organs you would not feel comfortable donating?				
	Unweighted		Weighted	
	N	%	N	%
Yes, I would donate an organ for research if it was not suitable for transplant	755	68 %	766	69%
No, if they can't be used for transplant I would prefer they were not used at all	125	11 %	121	11%
I would not agree to donate an organ for transplant	96	9 %	95	9%
Don't know	134	12 %	128	12%

Appendix VI

Results of survey –unweighted and weighted

Q40 Would you be willing to have your anonymised lifestyle information linked to your sample?)	Unweighted		Weighted		Unweighted	Weighted
	N	%	N	%	N	%
It should be obtained at the same time as consent for organ transplantation and recorded on the organ donor register	174	16 %	166	15%		
No	789	71 %	800	72%	580	52 %	579	52%
Don't know	147	13 %	144	13%		
It should be discussed at a GP appointment and recorded in the patients' notes					270	24 %	267	24%
It should be discussed at a hospital and recorded in the patients' notes					140	13 %	143	13%
Other					13	1 %	14	1%
Don't know					107	10 %	108	10%

Note: percentages may not add up to 100% due to rounding.