Public views on the donation and use of human biological samples in biomedical research – a mixed methods study

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Complete List of Authors:	Lewis, Celine; Genetic Alliance UK, Unit 4D Leroy House Clotworthy, Margaret; Human Focused Testing, Hilton, Shona; Medical Research Council, CSO Social & Public Health Sciences Unit Magee, Caroline; National Cancer Research Institute, Confederation of Cancer Biobanks Robertson, Mark; AstraZeneca, Science Policy & Relations Stubbins, Lesley; GlaxoSmithKline, Medicines Research Centre Corfield, Jule; Areteva Ltd,
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Manuscript title: Public views on the donation and use of human biological samples in biomedical research – a mixed methods study

Celine Lewis[1], Margaret Clotworthy[2], Shona Hilton[3], Caroline Magee[4], Mark J Robertson[5], Lesley J Stubbins[6], Julie Corfield[7]

[1]Genetic Alliance UK, Unit 4D Leroy House, 436 Essex Road, London, N1 3LY, UK
[2]Human Focused Testing, 50 the Barns, Littleport, Cambridge, CB6 1GG, UK
[3]Medical Research Council/CSO Social & Public Health Sciences Unit, 4 Lilybank Gardens, Glasgow, G12 8RZ, UK
[4]Confederation of Cancer Biobanks, National Cancer Research Institute, Angel Building, 407 St John Street, London EC1V 4AD, UK
[5]AstraZeneca, Science Policy & Relations, 11G43 Mereside, Alderley Park, Macclesfield, Cheshire SK10 4TF, UK
[6]GlaxoSmithKline Medicines Research Centre, Gunnels Wood Road, Stevenage, Hertfordshire, SG1 2NY, UK
[7]Areteva Ltd, BioCity, Nottingham, NG1 1GF, UK

Running title: Views on donating and use of biosamples – the UK public's preferences

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Correspondence to:

Dr Celine Lewis

Genetic Alliance UK,

Unit 4D Leroy House,

436 Essex Road,

London,

N1 3QP

Email: celine@geneticalliance.org.uk

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ABSTRACT

Objective: A mixed methods study exploring the UK general public's willingness to donate human biosamples (HBS) for biomedical research.

Setting: Cross-sectional 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) identify participants' willingness to donate HBS for biomedical research; 2) explore acceptability towards donating different types of HBS in various settings; and 3) explore preferences regarding use and access to HBS.

Results: 87% of survey participants thought donation of HBS was important; 75% wanted to be asked to donate in general. Responders who self-reported having some or good knowledge of the medical research process were significantly more likely to want to donate ($p<0.001$). Reasons why focus group participants saw donation as important included: it was a good way of reciprocating for medical treatment received; it was an important way of developing drugs and treatments; residual tissue would otherwise go to waste; they or family members might benefit. The most controversial types of HBS to donate included: brain post mortem (29% would donate); eyes post mortem (35%); embryos (44%); spare eggs (48%) and sperm (58%). Concerning use of samples, there were concerns over animal research (34%), research conducted outside the UK (35%), and research conducted by pharmaceutical companies (56%), although education and discussion were found to alleviate such concerns during focus group discussions.

Conclusions: There is a high level of public support and willingness to donate HBS for biomedical research. Underlying concerns exist regarding the use of certain types of HBS and conditions under which they are used. Improved education and more controlled forms of consent for sensitive samples may mitigate such concerns.

ARTICLE SUMMARY

Article focus

- To explore the UK public's willingness to donate: residual biosamples following a medical procedure; biosamples donated as 'healthy volunteers'; additional biosamples during surgery; and biosamples post-mortem for medical research;
- The acceptability towards donating different types of biosamples in various settings;
- Preferences regarding use and access to biosamples.

Key messages

- There is a high level of public support for biomedical research and willingness to donate samples for this purpose.
- Those responders who self-reported having some or good knowledge of the medical research process were significantly more likely to want to be asked to donate, supporting the need for public education to improve understanding of the research process and the contribution HBS make to this.
- Concerns exist regarding the use of certain types of samples, the conditions under which they are used and data security; greater transparency and discussion of the safeguards that exist in research is likely to alleviate some of these concerns.

Strengths and limitations of this study

- This study contributes further to our understanding of the UK public's views regarding the types of human biological samples acceptable do donate, under what circumstances and for what research purposes. This study highlights the importance of involving the public in more transparent dialogue about the use of biosamples to encourage greater public involvement and support for this area.
- This study presented participants with a series of hypothetical questions about willingness to donate biosamples for medical research. Therefore the findings may not necessarily correlate with actual behaviour.

INTRODUCTION

A gradual shift in the approach to biomedical research has accelerated use of human biological samples (HBS) and the establishment of biobanks with associated skills and infrastructure (‘biobanking’) to acquire, preserve and distribute this increasingly valuable resource. Biobanks are important custodians of HBS collections, usually with access to the donors’ phenotypic and clinical data[1]. Samples can comprise human materials of all kinds, including organs, tissues, biofluids such as blood, and genetic materials, such as DNA. They may be obtained from a variety of donated sources: from healthy volunteers or as residual tissue surplus to diagnostic requirements following a medical procedure, or alternatively retrieved post-mortem. Sample collections may be population-based or disease-specific, originating from a wide range of people with differing demographics, health, behaviours and lifestyles. Moreover, they may be used by a variety of research organisations, including public and private enterprises.

Public willingness to donate HBS is essential to ensure the continued provision of samples for research[2]; hence numerous studies have been conducted to examine this issue[3-7]. These studies have shown that the public is generally positive towards research using donated HBS[4-6] and the majority is in principle willing to donate[3,7]. Less well known are the public’s views regarding the types of HBS acceptable to donate, under what circumstances and for what research purposes. These issues are important to address to provide an insight into the key drivers motivating or preventing people from donating. Knowledge of these can also help inform biobanking governance and ensure consent procedures and patient information addresses any concerns which the public may have. This is important to help the public understand the need for, and the use of, HBS in biomedical research as well as to increase transparency and engender trust with the public. This study was conducted to broaden our understanding in these areas. Moreover, the findings are intended to inform a biobanking policy for STRATUM (Strategic Tissue Repository Alliance Through Unified Methods), a UK Government Technology Strategy Board and Industry-funded project seeking to address the problem that there are insufficient numbers of HBS and associated clinical data of adequate quality to fully support biomedical research in the UK. This research will also help inform the design of new consent templates and deliver guidance and strategies around the consent process for biobanks and researchers.

The aims of this study were to 1) identify participants’ willingness to donate HBS for biomedical research; 2) explore acceptability towards donating different types of HBS in various settings; and 3) explore preferences regarding use and access to HBS. Public views and preferences regarding consent procedures were also investigated and are described elsewhere.

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. A more detailed presentation of the methods can be found in a second paper related to this study (Consent for the use of human biological samples for biomedical research – a mixed methods study exploring the UK public's preferences, 2013, unpublished manuscript).

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 the market research company The Focus Group. Participants were purposively sampled; each group chosen to reflect a particular demographic (age, socio-economic group (SEG), ethnicity, 'patients' who were affected by a condition or had had an operation in the past two years) in order to gather a wide spectrum of views and enable comparisons across groups. Prior to the day, participants were given an information sheet about the use of biosamples in research (Appendix I). Focus groups were held in 'neutral' locations such as hotel conference rooms or church halls, facilitated by an experienced facilitator (CL) and digitally recorded.

The topic guide explored participants' views on: willingness to donate and acceptability of donating different types of HBS; in what circumstances; for what purposes; and to whom (supplementary files: Appendix II). Recordings were transcribed and the software package NVivo version 9 (QSR International, Pty Ltd) used to facilitate data 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

The findings from the focus groups were used to inform development of a quantitative survey used to canvas public opinion on the issues of interest across a representative sample of the UK population (supplementary files: Appendix III). 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 main survey was then conducted in September 2012.

RESULTS

Study population

Participant characteristics are detailed in Table 1.

Table 1: 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%

Focus groups

One hundred and eighty-two members of the public who were approached were eligible and 81 people agreed to participate (45% response 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, 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[6]. Our quota sample was close to but not exactly matching our set targets. For this reason we carried out both weighted and unweighted analyses. There was no difference in the conclusions we reached by either method. In this paper we present the unweighted results (weighted results can be found at supplementary files: Appendix IV).

Interest in being asked to donate

We began by providing a brief description of the use of HBS in biomedical research and then asked survey participants whether, in general, they wanted to be asked to donate. Three quarters (75%) of survey participants wanted to be asked (29% definitely yes, 46% probably yes); 18% didn't want to (14% probably not and 4% definitely not); and 7% didn't know. When asked how important they thought it was to donate HBS for biomedical research, 87% said either extremely important (50%) or important (37%). Less than 1% of participants (n=5) thought it was not at all important.

Respondents who wanted to be asked to donate HBS were significantly more likely to be: either not religious or only moderately so (where they did have a religious affiliation) (79.7% vs. 59.7%, X^2=36.56(1), p=0.001); from higher SEG groups (A-D vs. E)(83.8% vs. 62.2%, X^2=36.55(1) p<0.001); had tissue removed during a medical or surgical procedure (87.2% vs. 73.1%, X^2=27.13(1), p<0.001); had some or good knowledge of the medical research process (84.4% vs. 75.1%, X^2=13.04(1), p<0.001); were under 55 years (84% vs. 75.1%, X^2=11.56(1), p=0.001); were 'White' (81.7% vs. 60.9%, X^2=10.9(1), p=0.001); have no religious affiliation (86.4% vs. 77.9%, X^2=9.9(1) p=0.002); and had an education level of A level or equivalent or higher (83.4% vs. 76.1%, X^2=7.18(1), p=0.007). Using the boost sample for ethnic minorities we found that 'Black' participants were significantly less likely to want to be asked to donate than 'White' participants (53.3% vs. 81.7%, $X^2=20.12(1)$, $p<0.001$). Participants who had a close family member affected by a condition were more willing to be asked to donate that those who hadn't, although the difference was not quite statistically significant (70.7% vs. 63.3%, $X^2=3.8(1)$, $p=0.051$).

Four independent variables were found to have a significant impact on participants' interest in being asked to donate tissue as shown in the logistic regression model in Table 2. The strongest predictor for wanting to be asked to donate was being from a higher socio-economic group (A-D vs. E) (OR=3.52, 95% CI 2.19-5.66, p<0.001) followed by having had tissue removed during a medical or surgical procedure (OR=2.51, 95% CI 1.65-3.84, p=0.001), being either not at all or only moderately religious (OR=2.42, 95% CI 1.31-4.47, p=0.005), and having self-reported some or good knowledge of the medical research process (OR=2.01, 95% CI 1.33-3.03, p=0.001).

Table 2. Multiple logistic regression examining participant willingness to donate tissue

Participant characteristic	**Coefficient**	**95% CI**	**Odds ratio**	**p value**
Socio-economic group	1.26	2.19, 5.66	3.52	<0.001
Religiosity	0.89	1.31, 4.47	2.42	0.005
Knowledge of medical research process	0.70	1.33, 3.03	2.01	0.001
Had tissue removed	0.99	1.65, 3.84	2.51	<0.001

Demographic items were excluded from this table if they were not statistically significant. All variables were entered into the models as categorical variables.
CI: Confidence Interval.

Focus group participants also showed a strong willingness to donate HBS for biomedical research. Four key reasons were provide by participants. First, it was a good way of reciprocating for medical treatment received in the past, second, it was viewed as an "important way of developing drugs and treatments", and third, that residual tissue, which participants did not have any strong emotional ties to, would otherwise go to waste. The fourth reason offered was one of personal benefit whereby participants themselves or a family member was affected by an illness or disease.

*"Someone in my family has got Alzheimer's so I'm particularly supportive" (*Female, 18-24 focus group)

A minority of focus group participants did raise concerns. These included surgeons taking "liberties or advantage of the fact that you're out cold", concerns about data privacy and mistrust of profit-making companies using donated HBS or the government regulating their use.

"The world's very corrupt, and if something needs to get pushed through, it gets pushed through." Female, 'Black' focus group

Whilst interest in donating appeared to be high, it was evident that knowledge of the medical research process was low. In the survey only 4% of respondents self-reported to have a 'good knowledge' of the research process; 54% said they had 'some knowledge' and 42% said they had 'no knowledge'. Similarly, a number of focus group participants commented that the information leaflet was the first time they had heard anything about the use of donated HBS in medical research.

Types of HBS

Residual HBS

The majority of survey participants were either definitely or probably willing to donate residual blood (92%); cancerous tissue (90%); fat (89%); skin tissue (88%); bone or cartilage (84%); and liver tissue (84%) following a medical procedure (Figure 1). Less than half of participants were willing to donate spare eggs (women only) (48%) or spare embryos (44%) left over following in vitro fertilisation (IVF).

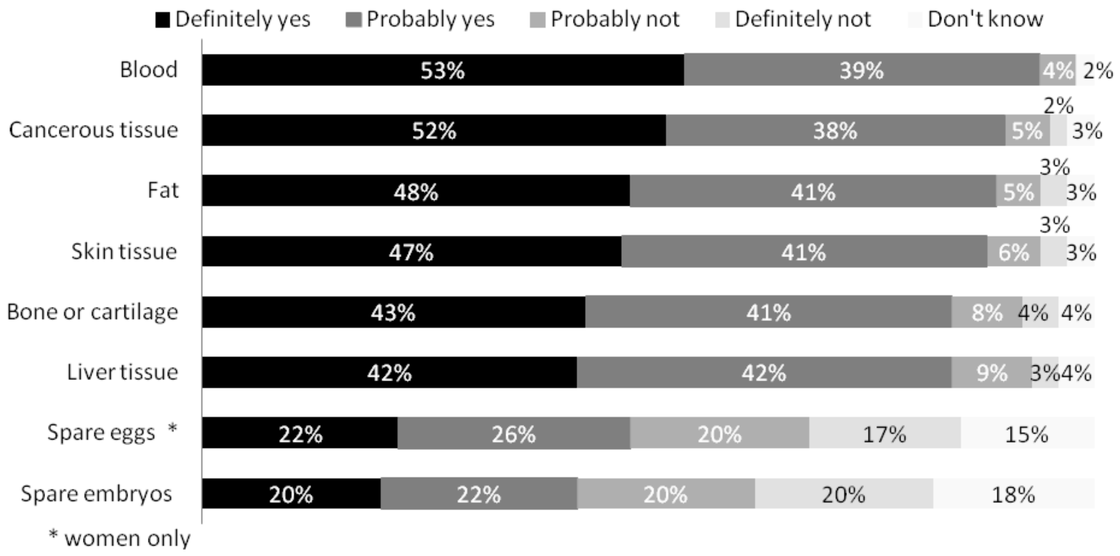


Figure 1: Would you donate the following types of samples for medical research if they were left over (after any necessary medical tests had been done) following a medical procedure?

Note: percentages may not add up to 100% due to rounding.
Chi-square was conducted to examine effects of participant characteristics on willingness to donate spare eggs and spare embryos as these two tissue types caused most divide amongst participants. Willingness to donating spare embryos was significantly associated with being: male (55.9% vs. 48.3%, $X^2=4.87(1)$, $p=0.023$); under 55 years (55.1% vs. 45.3%, $X^2=7.55(1)$, $p=0.005$); from a higher (A-D) socio-economic group (54.9% vs. 32%, $X^2=22.05(1)$, $p<0.001$); White ethnicity (53% vs. 27.7%, $X^2=10.48(1)$, $p=0.001$), having a religious affiliation (63.5% vs. 45.9%, $X^2=24.13(1)$, $p<0.001$), being not at all or moderately religious where they did have a religious affiliation (48.1% vs. 25.5%, $X^2=9.38(1)$, $p=0.002$); and had had tissue removed during a medical procedure (56.9% vs. 46%, $X^2=9.41(1)$, $p=0.002$). Women who were willing to donate spare eggs

were significantly more likely to be: from a higher socio-economic group (A-D) (58.5% vs. 44.7%, $X^2=4.45(1)$, p=0.035); White ethnicity (58.1% vs. 17.4%, $X^2=13.21(1)$, p<0.001); have no religious affiliation (71.5% vs. 50.4%, $X^2=18.47(1)$, p<0.001); be not at all or moderately religious where they did have a religious affiliation (53.5% vs. 23.7%, $X^2=10.88(1)$, p=0.001); and had had tissue removed during a medical procedure (62.8% vs. 50.4%, $X^2=6.77(1)$, p=0.009).

These results confirm our focus group findings, where most people were willing to donate residual tissue but donation of reproductive tissue raised concerns for a significant number of participants. A key concern was that reproductive tissue would be used for reproductive purposes without the knowledge of the donor.

"Although they said it's [ethical approval process] very strict, I still in the back of my mind have a thing where someone could take my egg and have my child" Female, had operation in past two years

A further concern related to whether it was 'right' from an ethical or religious perspective, to be conducting research on reproductive tissue.

"I would be really worried...an embryo is a baby. I know it's still very, very early days, but you're playing God." Female – patient affected by a condition

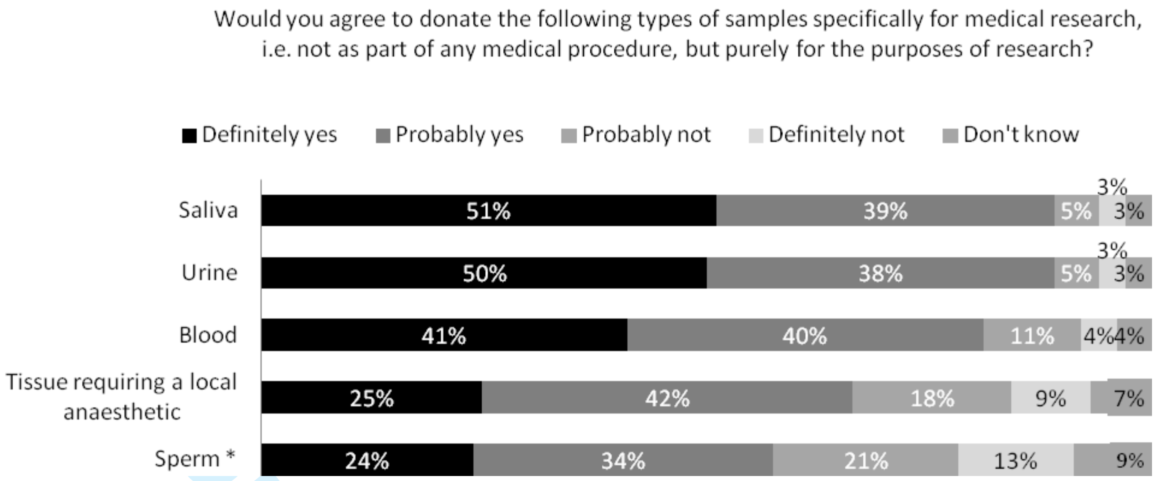
Those people who were willing to donate reproductive tissue underscored the benefits that could results from such research.

"You have to remove yourself from the situation and imagine yourself as an infertile person and maybe someone that could benefit immensely from that research." Female – 18-24 focus group

Some did, however, highlight the importance of being informed as to how reproductive tissue would be used because of its sensitive nature.

'Healthy' volunteers

Survey participants were then presented with a scenario in which they were asked to imagine that they are in a hospital waiting room awaiting an appointment and are asked whether they would donate certain types of HBS specifically for the purposes of medical research (Figure 2). Most responderswere either definitely or probably willing to donate urine (89%), saliva (89%) and blood (81%), however, fewer people would donate tissue taken during a local anaesthetic (67%) or sperm (men only) (58%).



Note: percentages may not add up to 100% due to rounding.
Chi-square was conducted to examine effects of participant characteristics on willingness to donate tissue requiring a local anaesthetic and sperm as these two tissue types caused most divide amongst participants. Willingness to donate tissue requiring a local anaesthetic was significantly associated with: being over 25 years (72.9% vs. 59.3%, X^2=9(1), p=0.003); from a higher socio-economic group (A-D) (73.1% vs. 60.9%, X^2=9.03(1); p=0.003), White ethnicity (72.3% vs. 48.9%, X^2=10.87(1), p=0.001); being not at all or moderately religious where they had a religious affiliation (71.4% vs. 49.2%, X^2= 11.53(1), p=0.001); having good knowledge of the medical research process (75.8% vs. 64.5%, X^2=14.96(1), p=0.001), had had tissue removed during a medical procedure (77.9% vs. 64%, X^2=20.77(1), p<0.001), and had agreed to donate left over tissue (82.8% vs. 45.5%, X^2=13.51(1), p<0.001). Men who were willing to donate sperm were significantly more likely to be: from a higher socio-economic group (A-D) (66.8% vs. 42%, X^2=14.47(1), p<0.001); White ethnicity (65.8% vs. 22.2%, X^2=18.95%1), p<0.001), and be either not at all or moderately religious where they did have a religious affiliation (64.3% vs. 36.4%, X^2=5.61(1), p=0.018).

Focus group participants were also generally positive towards donating HBS specifically for research purposes, although some commented that they would not want to undergo an invasive procedure.

“Depends on what they wanted, if it’s not invasive or nothing then I’d say yes.” Female – ‘Black’ focus group

A number said they would be more likely to donate HBS if they did not have to travel somewhere specifically to do so. Focus group participants also appeared to want more information about how their sample would be used if they were donating HBS as ‘healthy’ volunteers.

“I’d want to know the purpose behind it but if I’m helping something then why not?” Male – ‘Chinese’ focus group

Additional HBS during surgery

Finally, survey participants were presented with a scenario in which they are having surgery which requires a general anaesthetic, and asked whether they would be willing to have additional tissue taken not required to be removed for therapeutic benefit. Over three quarters of responders (78%) were willing to donate HBS taken from the same part of the body being operated on, 63% were willing to donate HBS taken from an area close by, and 44% would donate HBS involving an additional procedure e.g. taking bone marrow whilst under the same general anaesthetic.

This scenario was not explored explicitly with focus group participants, but was included in the survey as a number had aired concerns about surgeons taking additional tissue during surgery without consent.

"I would be worried about giving consent before they performed an operation in case the main task of the operation is to remove cancer...and they take some tissue for research. I think it would be OK but only if they asked." Male, 18-24 group

Donation of HBS in the event of one's death

We explored whether the public were willing to donate tissue and whole organs in the event of their death. First, we compared survey responders' views concerning the donation of tissue taken from an organ compared to donating a whole organ using the liver and brain as examples. We found that tissue type had a greater impact on people's willingness to donate than amount of tissue: 89% of people were willing to donate liver tissue; 68% a whole liver; 66% brain tissue; 53% a whole brain. On presenting participants with a list of organs and asking them whether there were any whole organs they would not consider donating for medical research in the event of their death, 71% would not donate their brain, 65% would not donate their eyes, 27% would not donate their heart, 14% would not donate their liver; 14% would not donate their lungs and 13% would not donate their kidneys. Five people (0.5%) said they would not donate reproductive tissue in the free text box. Seventeen percent would not donate any organs for medical research.

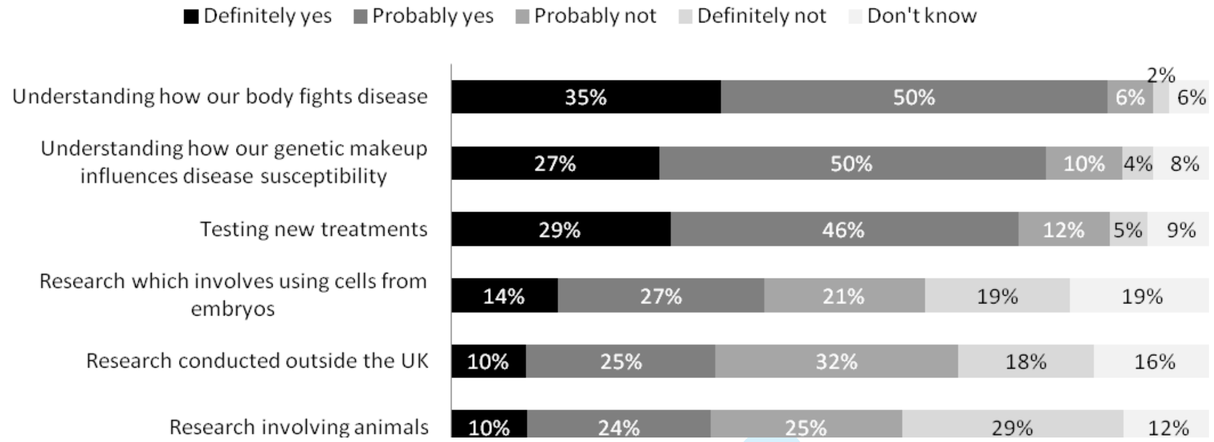
Donating whole organs for medical research in the event of one's death caused unease for a number of focus group participants. Some had concerns about the impact on family members, citing that it was a "sensitive subject" that may make them feel "uncomfortable". A woman in the South Asian group cited religious reasons for not wanting to donate organs. Others didn't like the idea of their body being "chopped up like on a butcher's board" and preferred "to remain whole" and "untouched". A few participants erroneously believed that their organs would not be useful to researchers because they were old or unhealthy. When focusing on particular organs, eyes were found to be most contentious and made participants feel “funny” or “squeamish”. They also had concerns that eyes were “identifiable”.

When asked whether they would be willing to donate whole organs not suitable for transplant for research purposes instead, 68% of survey responders said they would, 11% would prefer they were not used at all if they couldn’t be used for transplant, 9% would not agree to donate an organ for transplant and 12% didn’t know.

Uses of HBS

The most controversial types of research were research involving HBS in combination with animals (only 34% of survey participants would donate for this purpose), research conducted outside the UK (35%), and research involving ‘cells from embryos’ (41%) (Figure 3). Research into understanding how our body fights disease was the least controversial (85%).

Figure 3: Would you be willing to donate samples for the following type of samples for research?



Note: percentages may not add up to 100% due to rounding.
Chi-square was conducted to examine effects of participant characteristics on willingness to donate samples for research outside the UK and research involving animals as these two research types had least support. Those participants who were less willing to donate samples for research outside the UK were significantly more likely to be: over 55 years (67.8% vs. 53.8% , $X^2=17.2(1)$, $P=0.001$); from a low socio-economic group (E) (72.8% vs. 56.6%, $X^2=11.92(1)$, $p=0.001$); non-white ethnicity (78% vs. 58%, $X^2=5.7(1)$, $p=0.017$); have a religious affiliation (63.4% vs. 49.8%, $X^2=14.83(1)$, $p=0.001$); have a lower education level (GCSE or equivalent or lower) (65.9% vs. 55.5%, $X^2=8.18(1)$, $p=0.004$); and had not had tissue removed during a medical procedure (62.5% vs. 55%, $X^2=4.57(1)$, $p=0.033$). Those participants who were less willingness to donate samples for research involving animals were significantly more likely to be: female (69.5% vs. 51.8%, $X^2=30.74(1)$, $p<0.001$); from a low socio-economic group (E) (78% vs. 58.4%, $X^2=19.9(1)$, $p<0.001$); non-white ethnicity (80% vs. 60.5%, $X^2=6.09(1)$, $p=0.014$); have a religious affiliation (63.6% vs. 56.7%, $X^2=4.02(1)$, $p=0.045$); be very religious whereby they did have a religious affiliation (78.7% vs. 61.9%, $X^2=5.99(1)$, $p=0.014$); have no knowledge of the medical research process (67.6% vs. 57.1%, $X^2=10.4(1)$; $p=0.001$) and had not agreed to donate leftover tissue for medical research (81% vs. 49.3%, $X^2=6.12(1)$, $p=0.013$).

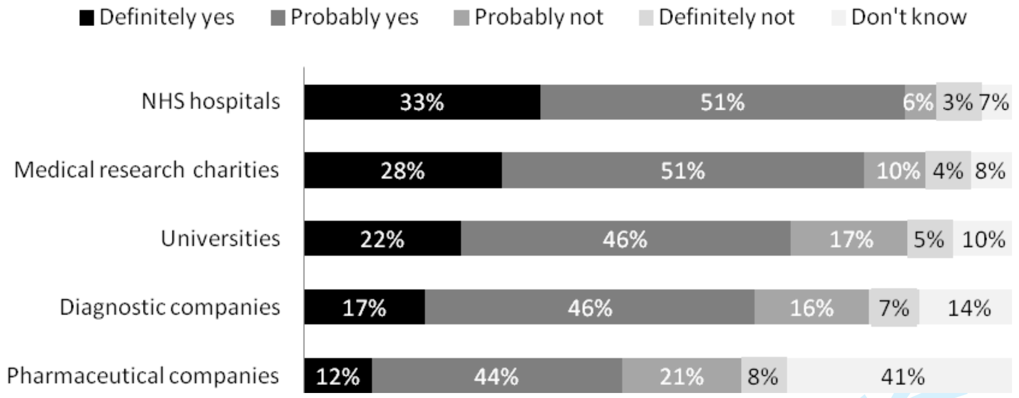
Research involving animals was cited as a cause for concern by a number of focus group participants, particularly if the research caused the animals "excessive pain". Others had concerns about the way animals were cared for in research settings. Nevertheless, a view held by a significant number of people was that research and drugs tested on animals was "not a nice thought...but in the long run the best option" and that "the information gained from watching [an animal used in research] might help thousands of people".

Research conducted outside the UK was a concern for some focus group participants because other countries might not have similarly strict governance arrangements as those that exist in the UK, or because HBS might be sold. Other types of research cited as being controversial included cloning, stem cell research, genetic engineering and "designer babies".

Access to HBS

Most survey responders were willing to donate HBS to NHS hospitals (84%), medical research charities (79%), universities (68%), diagnostic companies (63%) and pharmaceutical companies (56%) (Figure 4).

Figure 4: Would you be willing to donate samples to the following organisations to carry out approved research?



Note: percentages may not add up to 100% due to rounding.
Chi-square was conducted to examine effects of participant characteristics on willingness to donate samples for pharmaceutical companies as this organisation had the least support. Those participants who were less willing to donate samples to pharmaceutical companies were significantly more likely to be: over 55 years (39.4% vs. 31.3%, X²=6.16(1), p=0.013); from a low socio-economic group (E) (43.4% vs. 32.6%, X²=5.91(1); p=0.015), non-white ethnicity (60.9% vs. 32.9%, X²=14(1), p=0.001); live in London (45.1% vs. 31.7%, X²=11.02(1), p=0.001); have a religious affiliation (38.1% vs. 26.9%(1), X²=11.1(1), p=0.001); be very religious whereby they had a religious affiliation (54.5% vs. 36.7%, X²=6(1), p=0.014); have no knowledge of the medical research process (38.3% vs. 31.6%, X²=4.14(1), p=0.042); and had not had tissue removed during a medical procedure (38% vs. 29.8%, X²=6(1), p=0.014).

Focus group discussions highlighted that there was generally a high level of faith in the benefits of science, and trust towards the NHS, charities and universities, who were seen as contributing positively towards society. The role of ethics review boards and legal systems in providing oversight and control of medical research was considered important, nevertheless, it was acknowledged that most people are unaware of these safeguards.

"I do now know something about the process, and like the ethics side and presenting to a board, but before I wouldn't have known anything about the research process. So I guess I'm just thinking, how would I feel if I didn't know about those procedures?" Female – pilot group

Some initial negativity was found in relation to pharmaceutical companies conducting research because of their commercial, profit-making nature and concerns that they "exploit patients". However, such concerns were often addressed by other members of the group who acknowledged that commercialisation of research was "a fact of life" and that pharmaceutical companies "need to make money to keep their research going".

Medical records and lifestyle information

We asked participants whether they would be willing to have medical records and lifestyle information linked but de-identified (so that the sample is anonymous to the researcher but contains codes that would allow others to identify an individual from it) to their biosample. Sixty eight percent of survey responders would, 22% would not and 10% didn't know. Survey responders were more willing to have their de-identified lifestyle information linked to their biosample; 82% would, 12% would not, and 6% didn't know.

Concerns about linking medical records with HBS were raised by focus group participants. Data protection and privacy were two key concerns, for example, participants were worried that their personal data might be "hacked or mislaid". Others cited concerns about data being accessed by the police or insurance companies. Some participants felt uncomfortable about sensitive medical details such as sexual diseases or illegal drug use being seen by people unconnected with their health. Nevertheless, most participants understood the importance of linking medical records and lifestyle information to HBS as long as they were not identifiable.

"You want the sample to be as useful as possible so you want to give them the most complete picture. You want to give them all the information that is available." Male – had operation in past two years.

DISCUSSION

Results from this study are consistent with the findings from other empirical research that there is a high level of public support for biomedical research and willingness to donate HBS for this purpose[3-5,7-10]. However, by presenting participants with scenarios consisting of a variety of HBS types across a number of settings, and by using both qualitative and quantitative methods, we have been able to build a richer understanding of public attitudes. Whilst it is important to bear in mind that the opinions expressed are hypothetical and therefore do not necessarily correspond with how people would actually behave in practice, they still offer an intriguing insight into public attitudes which can help inform policy and practice.

The general willingness of the UK public to donate residual HBS is consistent with findings from other studies conducted in the UK, USA and Scandinavia where willingness to donate varied from 67%-88%[3-5,7-9]. Interestingly, people who themselves had had tissue removed were significantly more likely to want to be asked to donate than those that hadn’t (87% compared to 73%). A number of other studies conducted in the UK and elsewhere have found patient willingness to be high, between 83%-99%[11-16]. This is likely to be because donation of surplus tissue provides patients with an opportunity to reciprocate or demonstrate gratitude towards those involved in the therapeutic process[13] or because they have had the medical need explained to them and can relate to the experience more closely. Those responders who self-reported having some or good knowledge of the medical research process were also significantly more likely to want to be asked to donate. This finding supports the need for public education to improve understanding of the research process and the contribution HBS make to this. Another striking finding was the apparent discrepancy between people who saw biosample donation as important (87%) and those who wanted to be asked to donate (75%). It may be that although people see donation as important, other concerns e.g. around issues such as data privacy, or other ethical considerations such as commercial use of HBS may prevent some people from donating; concerns have been identified in this and other empirical studies[5,11,17,18].

Lower levels of support for HBS donation were identified amongst minority ethnic groups, a finding that has been seen elsewhere, particularly amongst African-Americans[10,19-21] and Asian-American women[22]. A study conducted in China also found that public and patient willingness to donate residual tissue was low compared to studies conducted in the UK, Scandinavia and the USA, at only 65%[23]. These differences may stem from different cultural attitudes towards donation, religious beliefs or low levels of trust in public institutions (which may stem from previous breaches of trust as highlighted by Ma et al.[23] amongst the ‘Chinese’ population). Mistrust of profit-making companies and the government were identified during focus group discussions with ethnic minority groups in this study, although not exclusively so. Information about the role of ethics review boards in safeguarding participants’ interests is therefore vital for ensuring public trust.

A large proportion of people were unwilling to donate reproductive tissue. This type of HBS donation raised a number of unique moral, ethical and social concerns, as exemplified by focus group discussions. Interestingly, the survey showed that men were more likely to donate semen than women were excess eggs following an IVF procedure (58% v 48%), which may indicate egg donation is a more contentious issue or that women feel a greater attachment to eggs than men to sperm[24]. Another possible reason may be the limited number of eggs that a woman has, and the greater effort and risk required to make them available *ex vivo*, resulting in a more judicious approach to their use; for example, women may prefer to keep excess eggs following IVF for future uses rather than donate them for research. More controlled forms of consent (tiered or specific) may be one way of alleviating concerns people may have about donating sensitive HBS.

When asked to consider post-mortem donation, eyes and brains were considered the least desirable organs to donate for research purposes, a finding that has been reported elsewhere[7]. As the donation of eyes is crucial for vision research and drug testing, and with donated brains being essential for research into conditions such as multiple sclerosis, Alzheimer’s and Parkinson’s disease, different ways of raising awareness and motivating donation need to be considered. For example, completely transparent discussion with families on the day prior to forensic post-mortem examination, conducted in a sensitive manner, has led to research authorisation and donation in a very high proportion of cases to the Sudden Death Brain and Tissue Bank in Edinburgh[25]. It may also be worth considering incentives to donation for research, as have already been discussed in depth elsewhere, although with a greater emphasis on donation for transplant[26]. Our research highlights that a significant number of people (68%) would be willing to donate whole organs not suitable for transplant for research purposes instead. Such soft incentives are likely to be welcomed by families, a finding which has also been reported by Womack et al.[27] where over 70% of family members consented for the retrieval of blood and tissue at the time of post-mortem examination.

The finding that 67% of people were willing to undergo a local anaesthetic to donate tissue seems unusually high at first glance. Nevertheless, such a finding should not be dismissed; women have been known to undergo local aesthetic to donate healthy breast tissue for breast cancer research, as evidenced by the 2800 women who have donated to the Komen Tissue Bank in the United States[28]. The finding that a significant proportion of the public are willing to donate as 'healthy volunteers' also supports the premise that there is a strong altruistic desire to contribute to medical research and a high level of trust in and support for the research process[29].

Research involving animals and research conducted outside the UK were the least supported research types in this study. Animal research remains a controversial topic and much empirical and ethical debate has focused on this issue[30-32]. However, the finding that a large proportion of the public do not want their HBS used for research outside the UK is intriguing. Our qualitative data show that concerns exist around regulation and commodification of HBS, findings supported elsewhere in the literature[33,34]. To address these concerns, potential donors should be provided with information related to the specific issues that relate to those countries where HBS are likely to be sent.

Regarding access to donated HBS, overall findings indicate high levels of trust towards research organisations conducting biomedical research. Lowest trust was afforded to pharmaceutical companies, primarily because of their profit-making nature, a finding which concurs with other studies[5,35,36]. Greater transparency and education of the public by the research community about the role pharmaceutical companies play in research and drug development (as is currently being conducted through initiatives such as EUPATI; www.patientsacademy.eu), will help to highlight the collaborations that frequently exist between private and public enterprises. Emphasising the safeguards that exist in research through regulation and ethics review boards is also likely to alleviate some of these concerns.

Finally, our research reinforces the concerns held by the public regarding the linking of de-identified clinical data to HBS[11,18]. Discussion during the consent procedure around the value of associated clinical data, and the safeguards in place to ensure data security, may go some way to reducing these worries. Similarly, the strict governance arrangements around access to personal information by third parties including the police, insurance companies and employers should be made clear.

Strengths and Limitations

As with any qualitative research, the findings from this study rely on the researcher's interpretation of comments made by focus group participants. Nevertheless, we have used a methodology grounded in the data and ensured inter-rater reliability through cross-checking coding to ensure the interpretation was as close to the intended meaning as possible. Moreover, we have been able to verify focus group findings though the results from the survey. A major limitation of this study is its hypothetical nature; hence the results need to be interpreted with caution. Nevertheless, where possible, we presented questions as scenarios to try and make them as 'real' as possible. A further limitation is that the dropout rate was relatively high; participants that did complete the survey may have done so because of a strong attachment to 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. Finally, the focus groups and survey were conducted in English which excluded those people who were not competent English speakers and/or readers. Our findings are therefore not necessarily representative of the non-English speaking community living in the UK.

CONCLUSION

There is a high level of public support for, and willingness to contribute to biobanking and the research process. In particular, people appear keen to contribute to research above and beyond the donation of residual tissue. Nevertheless, underlying concerns exist regarding the use of certain types of HBS, the conditions under which they are used and data security. Improved public education in these areas, for example, through the development of a 'Frequently Asked Questions' document which includes information on the ethics infrastructure that exists in the UK may mitigate some of these concerns. More controlled forms of consent for sensitive types of HBS and donation incentives may also positively impact public willingness to donate. These suggestions should be considered by the research community and policy makers.

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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 I

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.

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

Appendix II

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?

Generic				
Preferences	Unweighted		Weighted	
	N	%	N	%
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	
	N	%	N	%
Yes	174	16 %	166	15%
No	789	71 %	800	72%
Don't know	147	13 %	144	13%

	Unweighted		Weighted	
	N	%	N	%
It should be obtained at the same time as consent for organ transplantation and recorded on the organ donor register	580	52 %	579	52%
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.

Public views on the donation and use of human biological samples in biomedical research – a mixed methods study

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Celine Lewis[1], Margaret Clotworthy[2], Shona Hilton[3], Caroline Magee[4], Mark J Robertson[5], Lesley J Stubbins[6], Julie Corfield[7]

[1]Genetic Alliance UK, Unit 4D Leroy House, 436 Essex Road, London, N1 3LY, UK
[2]Human Focused Testing, 50 the Barns, Littleport, Cambridge, CB6 1GG, UK
[3]Medical Research Council/CSO Social & Public Health Sciences Unit, 4 Lilybank Gardens, Glasgow, G12 8RZ, UK
[4]Confederation of Cancer Biobanks, National Cancer Research Institute, Angel Building, 407 St John Street, London EC1V 4AD, UK
[5]AstraZeneca, Science Policy & Relations, 11G43 Mereside, Alderley Park, Macclesfield, Cheshire SK10 4TF, UK
[6]GlaxoSmithKline Medicines Research Centre, Gunnels Wood Road, Stevenage, Hertfordshire, SG1 2NY, UK
[7]Areteva Ltd, BioCity, Nottingham, NG1 1GF, UK

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Correspondence to:

Dr Celine Lewis

Genetic Alliance UK,

Unit 4D Leroy House,

436 Essex Road,

London,

N1 3QP

Email: celine@geneticalliance.org.uk

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ABSTRACT

Objective: A mixed methods study exploring the UK general public's willingness to donate human biosamples (HBS) for biomedical research.

Setting: Cross-sectional 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) identify participants' willingness to donate HBS for biomedical research; 2) explore acceptability towards donating different types of HBS in various settings; and 3) explore preferences regarding use and access to HBS.

Results: 87% of survey participants thought donation of HBS was important; 75% wanted to be asked to donate in general. Responders who self-reported having some or good knowledge of the medical research process were significantly more likely to want to donate ($p<0.001$). Reasons why focus group participants saw donation as important included: it was a good way of reciprocating for medical treatment received; it was an important way of developing drugs and treatments; residual tissue would otherwise go to waste; they or family members might benefit. The most controversial types of HBS to donate included: brain post mortem (29% would donate); eyes post mortem (35%); embryos (44%); spare eggs (48%) and sperm (58%). Concerning use of samples, there were concerns over animal research (34%), research conducted outside the UK (35%), and research conducted by pharmaceutical companies (56%), although education and discussion were found to alleviate such concerns during focus group discussions.

Conclusions: There is a high level of public support and willingness to donate HBS for biomedical research. Underlying concerns exist regarding the use of certain types of HBS and conditions under which they are used. Improved education and more controlled forms of consent for sensitive samples may mitigate such concerns.

ARTICLE SUMMARY

Article focus

- To explore the UK public’s willingness to donate: residual biosamples following a medical procedure; biosamples donated as ‘healthy volunteers’; additional biosamples during surgery; and biosamples post-mortem for medical research;
- The acceptability towards donating different types of biosamples in various settings;
- Preferences regarding use and access to biosamples.

Key messages

- There is a high level of public support for biomedical research and willingness to donate samples for this purpose.
- Those responders who self-reported having some or good knowledge of the medical research process were significantly more likely to want to be asked to donate, supporting the need for public education to improve understanding of the research process and the contribution HBS make to this.
- Concerns exist regarding the use of certain types of samples, the conditions under which they are used and data security; greater transparency and discussion of the safeguards that exist in research is likely to alleviate some of these concerns. More focused communication may also help address the issue that certain subgroups are under-represented and that certain kinds of tissue are infrequently donated.

Strengths and limitations of this study

- This study contributes further to our understanding of the UK public’s views regarding the types of human biological samples acceptable to donate, under what circumstances and for what research purposes. This study highlights the importance of involving the public in more transparent dialogue about the use of biosamples to encourage greater public involvement and support for this area.
- This study presented participants with a series of hypothetical questions about willingness to donate biosamples for medical research. Therefore the findings may not necessarily correlate with actual behaviour.

INTRODUCTION

A gradual shift in the approach to biomedical research has accelerated use of human biological samples (HBS) and the establishment of biobanks with associated skills and infrastructure (‘biobanking’) to acquire, preserve and distribute this increasingly valuable resource. Biobanks are important custodians of HBS collections, usually with access to the donors’ de-identified phenotypic and clinical data[1]. Samples can comprise human materials of all kinds, including organs, tissues, biofluids such as blood, and genetic materials, such as DNA. They may be obtained from a variety of donated sources: from healthy volunteers or as residual tissue surplus to diagnostic requirements following a medical procedure, or alternatively retrieved post-mortem. Sample collections may be population-based or disease-specific, originating from a wide range of people with differing demographics, health, behaviours and lifestyles. Moreover, they may be used by a variety of research organisations, including public and private enterprises.

Public willingness to donate HBS is essential to ensure the continued provision of samples for research[2]; hence numerous studies have been conducted to examine this issue[3-7]. These studies have shown that the public is generally positive towards research using donated HBS[4-6] and the majority is in principle willing to donate[3,7]. Less well known are the public’s views regarding the types of HBS acceptable to donate, under what circumstances and for what research purposes, although some research does exist in these areas. For example, research has shown the public are generally willing to donate diseased tissue or ‘waste material’ (such as cancerous tissue or placental tissue) for biomedical research, however, donation of eyes, brains, lungs and bone is far more contentious[7-9]. Regarding access to tissues, research by publicly-funded academic researchers has been shown to cause few concerns, in comparison to research conducted by commercial entities[10-12]. These issues are important to address to provide an insight into the key drivers motivating or preventing people from donating. Knowledge of these can also help inform biobanking governance and ensure consent procedures and patient information addresses any concerns which the public may have. This is important to help the public understand the need for, and the use of, HBS in biomedical research as well as to increase transparency and engender trust with the public. This study was conducted to broaden our understanding in these areas. Moreover, the findings are intended to inform a biobanking policy for STRATUM (Strategic Tissue Repository Alliance Through Unified Methods), a UK Government Technology Strategy Board and Industry-funded project seeking to address the problem that there are insufficient numbers of HBS and associated clinical data of adequate quality to fully support biomedical research in the UK. This research will also help inform the design of new consent templates and deliver guidance and strategies around the consent process for biobanks and researchers.

The aims of this study were to 1) identify participants' willingness to donate HBS for biomedical research; 2) explore acceptability towards donating different types of HBS in various settings; and 3) explore preferences regarding use and access to HBS. Public views and preferences regarding consent procedures were also investigated and are described elsewhere (Consent for the use of human biological samples for biomedical research – a mixed methods study exploring the UK public's preferences, 2013, submitted manuscript).

METHODS

This was a mixed methods study comprising qualitative focus groups and a quantitative on-line survey. Focus groups were chosen as this method helps people explore and illuminate their views through debate within the group. They can also help facilitate the expression of ideas that might be left underdeveloped in an interview[13]. Focus groups have been used successfully to study the attitudes of the general public in relation to biobanking in previous research [14,15]. Ethical approval for the study was granted by the University of Manchester Research Ethics Committee in April 2012. A more detailed presentation of the methods can be found in the sister paper related to this study (Consent for the use of human biological samples for biomedical research – a mixed methods study exploring the UK public's preferences, 2013, submitted manuscript).

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 the market research company The Focus Group. Participants were purposively sampled; each group chosen to reflect a particular demographic (age, socio-economic group (SEG), ethnicity, 'patients' who were affected by a condition or had had an operation in the past two years) in order to gather a wide spectrum of views and enable comparisons across groups. Prior to the day, focus group participants were given an information sheet about the use of biosamples in research in order that they had some background knowledge about the subject matter and to get them thinking about the key issues (Appendix I). Focus groups were held in 'neutral' locations such as hotel conference rooms or church halls, facilitated by an experienced facilitator (CL) and digitally recorded.

The topic guide explored participants' views on: willingness to donate and acceptability of donating different types of HBS; in what circumstances; for what purposes; and to whom (supplementary files: Appendix II). Recordings were transcribed and the software package NVivo version 9 (QSR International, Pty Ltd) used to facilitate data 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

The findings from the focus groups were used to inform development of a quantitative survey used to canvas public opinion on the issues of interest across a representative sample of the UK population (supplementary files: Appendix III). Key themes that were discussed or emerged from focus group discussions were reframed as survey questions; in a number of cases answer options in the survey were informed by focus group discussions (e.g. the different types of residual HBS participants were presented with were raised by focus group participants). 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 main survey was then conducted in September 2012. Survey participants were not given the background information sheet about the use of biosamples in research which was given to all focus group participants. This was so that the survey responses represented the attitudes of the general public as far as possible. They were, however, given information during the survey to enable them to make informed decisions when answering the survey questions.

RESULTS

Study population

Participant characteristics are detailed in Table 1.

Table 1: 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%

Focus groups

One hundred and eighty-two members of the public who were approached were eligible and 81 people agreed to participate (45% response 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, 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[6]. Our quota sample was close to but not exactly matching our set targets.

For this reason we carried out both weighted and unweighted analyses. There was no difference in the conclusions we reached by either method. In this paper we present the unweighted results (weighted results can be found at supplementary files: Appendix IV).

Interest in being asked to donate

We began by providing a brief description of the use of HBS in biomedical research and then asked survey participants whether, in general, they wanted to be asked to donate. Three quarters (75%) of survey participants wanted to be asked (29% definitely yes, 46% probably yes); 18% didn’t want to (14% probably not and 4% definitely not); and 7% didn’t know. When asked how important they thought it was to donate HBS for biomedical research, 87% said either extremely important (50%) or important (37%). Less than 1% of participants (n=5) thought it was not at all important.

Respondents who wanted to be asked to donate HBS were significantly more likely to be: either not religious or only moderately so (where they did have a religious affiliation) (79.7% vs. 59.7%, $X^2=36.56(1)$, p=0.001); from higher SEG groups (A-D vs. E)(83.8% vs. 62.2%, $X^2=36.55(1)$ p<0.001); had tissue removed during a medical or surgical procedure (87.2% vs. 73.1%, $X^2=27.13(1)$, p<0.001); had some or good knowledge of the medical research process (84.4% vs. 75.1%, $X^2=13.04(1)$, p<0.001); were under 55 years (84% vs. 75.1%, $X^2=11.56(1)$, p=0.001); were ‘White’ (81.7% vs. 60.9%, $X^2=10.9(1)$, p=0.001); have no religious affiliation (86.4% vs. 77.9%, $X^2=9.9(1)$ p=0.002); and had an education level of A level or equivalent or higher (83.4% vs. 76.1%, $X^2=7.18(1)$, p=0.007). Using the boost sample for ethnic minorities we found that ‘Black’ participants were significantly less likely to want to be asked to donate than ‘White’ participants (53.3% vs. 81.7%, $X^2=20.12(1)$, p<0.001). Participants who had a close family member affected by a condition were more willing to be asked to donate that those who hadn’t, although the difference was not quite statistically significant (70.7% vs. 63.3%, $X^2=3.8(1)$, p=0.051).

Four independent variables were found to have a significant impact on participants’ interest in being asked to donate tissue as shown in the logistic regression model in Table 2. The strongest predictor for wanting to be asked to donate was being from a higher socio-economic group (A-D vs. E) (OR=3.52, 95% CI 2.19-5.66, p<0.001) followed by having had tissue removed during a medical or surgical procedure (OR=2.51, 95% CI 1.65-3.84, p=0.001), being either not at all or only moderately religious (OR=2.42, 95% CI 1.31-4.47, p=0.005), and having self-reported some or good knowledge of the medical research process (OR=2.01, 95% CI 1.33-3.03, p=0.001).

Table 2. Multiple logistic regression examining participant willingness to donate tissue

Participant characteristic	**Coefficient**	**95% CI**	**Odds ratio**	**p value**
Socio-economic group	1.26	2.19, 5.66	3.52	<0.001
Religiosity	0.89	1.31, 4.47	2.42	0.005
Knowledge of medical research process	0.70	1.33, 3.03	2.01	0.001
Had tissue removed	0.99	1.65, 3.84	2.51	<0.001

Demographic items were excluded from this table if they were not statistically significant. All variables were entered into the models as categorical variables.
CI: Confidence Interval.

Focus group participants also showed a strong willingness to donate HBS for biomedical research. Four key reasons were provide by participants. First, it was a good way of reciprocating for medical treatment received in the past, second, it was viewed as an "important way of developing drugs and treatments", and third, that residual tissue, which participants did not have any strong emotional ties to, would otherwise go to waste. The fourth reason offered was one of personal benefit whereby participants themselves or a family member was affected by an illness or disease.

*"Someone in my family has got Alzheimer's so I'm particularly supportive" (*Female, 18-24 focus group)

A minority of focus group participants did raise concerns. These included surgeons taking "liberties or advantage of the fact that you're out cold", concerns about data privacy and mistrust of profit-making companies using donated HBS or the government regulating their use.

"The world's very corrupt, and if something needs to get pushed through, it gets pushed through." Female, 'Black' focus group

Whilst interest in donating appeared to be high, it was evident that knowledge of the medical research process was low. In the survey only 4% of respondents self-reported to have a 'good knowledge' of the research process; 54% said they had 'some knowledge' and 42% said they had 'no knowledge'. Similarly, a number of focus group participants commented that the information leaflet was the first time they had heard anything about the use of donated HBS in medical research.

Types of HBS

Residual HBS

The majority of survey participants were either definitely or probably willing to donate residual blood (92%); cancerous tissue (90%); fat (89%); skin tissue (88%); bone or cartilage (84%); and liver tissue (84%) following a medical procedure (Figure 1). Less than half of participants were willing to donate spare eggs (women only) (48%) or spare embryos (44%) left over following in vitro fertilisation (IVF).

Note: percentages may not add up to 100% due to rounding.
Chi-square was conducted to examine effects of participant characteristics on willingness to donate spare eggs and spare embryos as these two tissue types caused most divide amongst participants. Willingness to donating spare embryos was significantly associated with being: male (55.9% vs. 48.3%, $X^2=4.87(1)$, p=0.023); under 55 years (55.1% vs. 45.3%, $X^2=7.55(1)$, p=0.005); from a higher (A-D) socio-economic group (54.9% vs. 32%, $X^2=22.05(1)$, p<0.001); White ethnicity (53% vs. 27.7%, $X^2=10.48(1)$, p=0.001), having a religious affiliation (63.5% vs. 45.9%, $X^2=24.13(1)$, p<0.001), being not at all or moderately religious where they did have a religious affiliation (48.1% vs. 25.5%, $X^2=9.38(1)$, p=0.002); and had had tissue removed during a medical procedure (56.9% vs. 46%, $X^2=9.41(1)$, p=0.002). Women who were willing to donate spare eggs were significantly more likely to be: from a higher socio-economic group (A-D) (58.5% vs. 44.7%, $X^2=4.45(1)$, p=0.035); White ethnicity (58.1% vs. 17.4%, $X^2=13.21(1)$, p<0.001); have no religious affiliation (71.5% vs. 50.4%, $X^2=18.47(1)$, p<0.001); be not at all or moderately religious where they did have a religious affiliation (53.5% vs. 23.7%, $X^2=10.88(1)$, p=0.001); and had had tissue removed during a medical procedure (62.8% vs. 50.4%, $X^2=6.77(1)$, p=0.009).

These results confirm our focus group findings, where most people were willing to donate residual tissue but donation of reproductive tissue raised concerns for a significant number of participants. A key concern was that reproductive tissue would be used for reproductive purposes without the knowledge of the donor.

"Although they said it's [ethical approval process] very strict, I still in the back of my mind have a thing where someone could take my egg and have my child" Female, had operation in past two years

A further concern related to whether it was 'right' from an ethical or religious perspective, to be conducting research on reproductive tissue.

"I would be really worried...an embryo is a baby. I know it's still very, very early days, but you're playing God." Female – patient affected by a condition

Those people who were willing to donate reproductive tissue underscored the benefits that could result from such research.

"You have to remove yourself from the situation and imagine yourself as an infertile person and maybe someone that could benefit immensely from that research." Female – 18-24 focus group

Some did, however, highlight the importance of being informed as to how reproductive tissue would be used because of its sensitive nature.

'Healthy' volunteers

Survey participants were then presented with a scenario in which they were asked to imagine that they are in a hospital waiting room awaiting an appointment and are asked whether they would donate certain types of HBS specifically for the purposes of medical research (Figure 2). Most responderswere either definitely or probably willing to donate urine (89%), saliva (89%) and blood (81%), however, fewer people would donate tissue taken during a local anaesthetic (67%) or sperm (men only) (58%).

Note: percentages may not add up to 100% due to rounding.
Chi-square was conducted to examine effects of participant characteristics on willingness to donate tissue requiring a local anaesthetic and sperm as these two tissue types caused most divide amongst participants. Willingness to donate tissue requiring a local anaesthetic was significantly associated with: being over 25 years (72.9% vs. 59.3%, $X^2=9(1)$, p=0.003); from a higher socio-economic group (A-D) (73.1% vs. 60.9%, $X^2=9.03(1)$; p=0.003), White ethnicity (72.3% vs. 48.9%, $X^2=10.87(1)$, p=0.001); being not at all or moderately religious where they had a religious affiliation (71.4% vs. 49.2%, $X^2= 11.53(1)$, p=0.001); having good knowledge of the medical research process (75.8% vs. 64.5%, $X^2=14.96(1)$, p=0.001), had had tissue removed during a medical procedure (77.9% vs. 64%, $X^2=20.77(1)$, p<0.001), and had agreed to donate left over tissue (82.8% vs. 45.5%, $X^2=13.51(1)$, p<0.001). Men who were willing to donate sperm were significantly more likely to be: from a higher socio-economic group (A-D) (66.8% vs. 42%, $X^2=14.47(1)$, p<0.001); White ethnicity (65.8% vs. 22.2%, $X^2=18.95\%1)$, p<0.001), and be either not at all or moderately religious where they did have a religious affiliation (64.3% vs. 36.4%, $X^2=5.61(1)$, p=0.018).

Focus group participants were also generally positive towards donating HBS specifically for research purposes, although some commented that they would not want to undergo an invasive procedure.

"Depends on what they wanted, if it's not invasive or nothing then I'd say yes." Female – 'Black' focus group

A number said they would be more likely to donate HBS if they did not have to travel somewhere specifically to do so. Focus group participants also appeared to want more information about how their sample would be used if they were donating HBS as 'healthy' volunteers.

"I'd want to know the purpose behind it but if I'm helping something then why not?" Male – 'Chinese' focus group

Additional HBS during surgery

Finally, survey participants were presented with a scenario in which they are having surgery which requires a general anaesthetic, and asked whether they would be willing to have additional tissue taken not required to be removed for therapeutic benefit. Over three quarters of responders (78%) were willing to donate HBS taken from the same part of the body being operated on, 63% were willing to donate HBS taken from an area close by, and 44% would donate HBS involving an additional procedure e.g. taking bone marrow whilst under the same general anaesthetic.

This scenario was not explored explicitly with focus group participants, but was included in the survey as a number had aired concerns about surgeons taking additional tissue during surgery without consent.

"I would be worried about giving consent before they performed an operation in case the main task of the operation is to remove cancer...and they take some tissue for research. I think it would be OK but only if they asked." Male, 18-24 group

Donation of HBS in the event of one's death

We explored whether the public were willing to donate tissue and whole organs in the event of their death. First, we compared survey responders' views concerning the donation of tissue taken from an organ compared to donating a whole organ using the liver and brain as examples. We found that tissue type had a greater impact on people's willingness to donate than amount of tissue: 89% of people were willing to donate liver tissue; 68% a whole liver; 66% brain tissue; 53% a whole brain. On presenting participants with a list of organs and asking them whether there were any whole organs they would not consider donating for medical research in the event of their death, 71% would not donate their brain, 65% would not donate their eyes, 27% would not donate their heart, 14% would not donate their liver; 14% would not donate their lungs and 13% would not donate their kidneys. Five people (0.5%) said they would not donate reproductive tissue in the free text box. Seventeen percent would not donate any organs for medical research.

Donating whole organs for medical research in the event of one's death caused unease for a number of focus group participants. Some had concerns about the impact on family members, citing that it was a "sensitive subject" that may make them feel "uncomfortable". A woman in the South Asian group cited religious reasons for not wanting to donate organs. Others didn't like the idea of their body being "chopped up like on a butcher's board" and preferred "to remain whole" and "untouched". A few participants erroneously believed that their organs would not be useful to researchers because they were old or unhealthy. When focusing on particular organs, eyes were found to be most contentious and made participants feel "funny" or "squeamish". They also had concerns that eyes were "identifiable".

When asked whether they would be willing to donate whole organs not suitable for transplant for research purposes instead, 68% of survey responders said they would, 11% would prefer they were not used at all if they couldn't be used for transplant, 9% would not agree to donate an organ for transplant and 12% didn't know.

Uses of HBS

The most controversial types of research were research involving HBS in combination with animals (only 34% of survey participants would donate for this purpose), research conducted outside the UK (35%), and research involving 'cells from embryos' (41%) (Figure 3). Research into understanding how our body fights disease was the least controversial (85%).

Note: percentages may not add up to 100% due to rounding.
Chi-square was conducted to examine effects of participant characteristics on willingness to donate samples for research outside the UK and research involving animals as these two research types had least support. Those participants who were less willing to donate samples for research outside the UK were significantly more likely to be: over 55 years (67.8% vs. 53.8% , X^2=17.2(1), P=0.001); from a low socio-economic group (E) (72.8% vs. 56.6%, X^2=11.92(1), p=0.001); non-white ethnicity (78% vs. 58%, X^2=5.7(1), p=0.017); have a religious affiliation (63.4% vs. 49.8%, X^2=14.83(1), p=0.001); have a lower education level (GCSE or equivalent or lower) (65.9% vs. 55.5%, X^2=8.18(1), p=0.004); and had not had tissue removed during a medical procedure (62.5% vs. 55%, X^2=4.57(1), p=0.033). Those participants who were less willingness to donate samples for research involving animals were significantly more likely to be: female (69.5% vs. 51.8%, X^2=30.74(1), p<0.001); from a low socio-economic group (E) (78% vs. 58.4%, X^2=19.9(1), p<0.001); non-white ethnicity (80% vs. 60.5%, X^2=6.09(1), p=0.014); have a religious affiliation (63.6% vs. 56.7%, X^2=4.02(1), p=0.045); be very religious whereby they did have a religious affiliation (78.7% vs. 61.9%, X^2=5.99(1), p=0.014); have no knowledge of the medical research process (67.6% vs. 57.1%, X^2=10.4(1); p=0.001) and had not agreed to donate leftover tissue for medical research (81% vs. 49.3%, X^2=6.12(1), p=0.013).

Research involving animals was cited as a cause for concern by a number of focus group participants, particularly if the research caused the animals "excessive pain". Others had concerns about the way animals were cared for in research settings. Nevertheless, a view held by a significant number of people was that research and drugs tested on animals was "not a nice thought...but in the long run the best option" and that "the information gained from watching [an animal used in research] might help thousands of people".

Research conducted outside the UK was a concern for some focus group participants because other countries might not have similarly strict governance arrangements as those that exist in the UK, or because HBS might be sold. Other types of research cited as being controversial included cloning, stem cell research, genetic engineering and "designer babies".

Access to HBS

Most survey responders were willing to donate HBS to NHS hospitals (84%), medical research charities (79%), universities (68%), diagnostic companies (63%) and pharmaceutical companies (56%) (Figure 4).

Note: percentages may not add up to 100% due to rounding.
Chi-square was conducted to examine effects of participant characteristics on willingness to donate samples for pharmaceutical companies as this organisation had the least support. Those participants who were less willing

to donate samples to pharmaceutical companies were significantly more likely to be: over 55 years (39.4% vs. 31.3%, $X^2=6.16(1)$, $p=0.013$); from a low socio-economic group (E) (43.4% vs. 32.6%, $X^2=5.91(1)$; $p=0.015$), non-white ethnicity (60.9% vs. 32.9%, $X^2=14(1)$, $p=0.001$); live in London (45.1% vs. 31.7%, $X^2=11.02(1)$, $p=0.001$); have a religious affiliation (38.1% vs. 26.9%(1), $X^2=11.1(1)$, $p=0.001$); be very religious whereby they had a religious affiliation (54.5% vs. 36.7%, $X^2=6(1)$, $p=0.014$); have no knowledge of the medical research process (38.3% vs. 31.6%, $X^2=4.14(1)$, $p=0.042$); and had not had tissue removed during a medical procedure (38% vs. 29.8%, $X^2=6(1)$, $p=0.014$).

Focus group discussions highlighted that there was generally a high level of faith in the benefits of science, and trust towards the NHS, charities and universities, who were seen as contributing positively towards society. The role of ethics review boards and legal systems in providing oversight and control of medical research was considered important, nevertheless, it was acknowledged that most people are unaware of these safeguards.

"I do now know something about the process, and like the ethics side and presenting to a board, but before I wouldn't have known anything about the research process. So I guess I'm just thinking, how would I feel if I didn't know about those procedures?" Female – pilot group

Some initial negativity was found in relation to pharmaceutical companies conducting research because of their commercial, profit-making nature and concerns that they "exploit patients". However, such concerns were often addressed by other members of the group who acknowledged that commercialisation of research was "a fact of life" and that pharmaceutical companies "need to make money to keep their research going".

Medical records and lifestyle information

We asked participants whether they would be willing to have medical records and lifestyle information linked but de-identified (so that the sample is anonymous to the researcher but contains codes that would allow others to identify an individual from it) to their biosample. Sixty eight percent of survey responders would, 22% would not and 10% didn't know. Survey responders were more willing to have their de-identified lifestyle information linked to their biosample; 82% would, 12% would not, and 6% didn't know.

Concerns about linking medical records with HBS were raised by focus group participants. Data protection and privacy were two key concerns, for example, participants were worried that their personal data might be "hacked or mislaid". Others cited concerns about data being accessed by the police or insurance companies. Some participants felt uncomfortable about sensitive medical details such as sexual diseases or illegal drug use being seen by people unconnected with their health. Nevertheless, most participants understood the importance of linking medical records and lifestyle information to HBS as long as they were not identifiable.

"You want the sample to be as useful as possible so you want to give them the most complete picture. You want to give them all the information that is available." Male – had operation in past two years.

DISCUSSION

Results from this study are consistent with the findings from other empirical research that there is a high level of public support for biomedical research and willingness to donate HBS for this purpose[3-5,7,16-18]. However, by presenting participants with scenarios consisting of a variety of HBS types across a number of settings, and by using both qualitative and quantitative methods, we have been able to build a richer understanding of public attitudes. Whilst it is important to bear in mind that the opinions expressed are hypothetical and therefore do not necessarily correspond with how people would actually behave in practice, they still offer an intriguing insight into public attitudes which can help inform policy and practice.

The general willingness of the UK public to donate residual HBS is consistent with findings from other studies conducted in the UK, USA and Scandinavia where willingness to donate varied from 67%-88%[3-5,7,16,17]. Interestingly, people who themselves had had tissue removed were significantly more likely to want to be asked to donate than those that hadn't (87% compared to 73%). A number of other studies conducted in the UK and elsewhere have found patient willingness to be high, between 83%-99%[19-24]. This is likely to be because donation of surplus tissue provides patients with an opportunity to reciprocate or demonstrate gratitude towards those involved in the therapeutic process[21] or because they have had the medical need explained to them and can relate to the experience more closely. Those responders who self-reported having some or good knowledge of the medical research process were also significantly more likely to want to be asked to donate. This finding supports the need for public education to improve understanding of the research process and the contribution HBS make to this. We identified that more people saw biosample donation as important (87%) than wanted to be asked to donate (75%). It may be that although people see donation as important, other concerns e.g. around issues such as data privacy, or other ethical considerations such as commercial use of HBS may prevent some people from donating; concerns have been identified in this and other empirical studies[5,15,19,25].

Lower levels of support for HBS donation were identified amongst minority ethnic groups, a finding that has been seen elsewhere, particularly amongst African-

Americans[18,26-28] and Asian-American women[29]. A study conducted in China also found that public and patient willingness to donate residual tissue was low compared to studies conducted in the UK, Scandinavia and the USA, at only 65%[30]. These differences may stem from different cultural attitudes towards donation, religious beliefs or low levels of trust in public institutions (which may stem from previous breaches of trust as highlighted by Ma et al.[30] amongst the 'Chinese' population). Mistrust of profit-making companies and the government were identified during focus group discussions with ethnic minority groups in this study, although not exclusively so. Information about the role of ethics review boards in safeguarding participants' interests is therefore vital for ensuring public trust.

A large proportion of people were unwilling to donate reproductive tissue. This type of HBS donation raised a number of unique moral, ethical and social concerns, as exemplified by focus group discussions. Interestingly, the survey showed that men were more likely to donate semen than women were excess eggs following an IVF procedure (58% v 48%), which may indicate egg donation is a more contentious issue or that women feel a greater attachment to eggs than men to sperm[31]. Another possible reason may be the limited number of eggs that a woman has, and the greater effort and risk required to make them available *ex vivo*, resulting in a more judicious approach to their use; for example, women may prefer to keep excess eggs following IVF for future uses rather than donate them for research. More controlled forms of consent (tiered or specific) may be one way of alleviating concerns people may have about donating sensitive HBS.

When asked to consider post-mortem donation, eyes and brains were considered the least desirable organs to donate for research purposes, a finding that has been reported elsewhere[7]. As the donation of eyes is crucial for vision research and drug testing, and with donated brains being essential for research into conditions such as multiple sclerosis, Alzheimer's and Parkinson's disease, different ways of raising awareness and motivating donation need to be considered. For example, completely transparent discussion with families on the day prior to forensic post-mortem examination, conducted in a sensitive manner, has led to research authorisation and donation in a very high proportion of cases to the Sudden Death Brain and Tissue Bank in Edinburgh[32]. It may also be worth considering incentives to donation for research, as have already been discussed in depth elsewhere, although with a greater emphasis on donation for transplant[33]. Our research highlights that a significant number of people (68%) would be willing to donate whole organs not suitable for transplant for research purposes instead. Such soft incentives are likely to be welcomed by families, a finding which has also been reported by Womack et al.[34] where over 70% of family members consented for the retrieval of blood and tissue at the time of post-mortem examination.

The finding that 67% of people were willing to undergo a local anaesthetic to donate tissue seems unusually high at first glance. Nevertheless, such a finding should not be dismissed; women have been known to undergo local aesthetic to donate healthy breast tissue for breast cancer research, as evidenced by the 2800 women who have donated to the Komen Tissue Bank in the United States[35]. The finding that a significant proportion of the public are willing to donate as 'healthy volunteers' also supports the premise that there is a strong altruistic desire to contribute to medical research and a high level of trust in and support for the research process[8].

Research involving animals and research conducted outside the UK were the least supported research types in this study. Animal research remains a controversial topic and much empirical and ethical debate has focused on this issue[36-38]. However, the finding that a large proportion of the public do not want their HBS used for research outside the UK is intriguing. Our qualitative data show that concerns exist around regulation and commodification of HBS, findings supported elsewhere in the literature[39,40]. To address these concerns, potential donors should be provided with information related to the specific issues that relate to those countries where HBS are likely to be sent.

Regarding access to donated HBS, overall findings indicate high levels of trust towards research organisations conducting biomedical research. Lowest trust was afforded to pharmaceutical companies, primarily because of their profit-making nature, a finding which concurs with other studies[5,10,11]. Greater transparency and education of the public by the research community about the role pharmaceutical companies play in research and drug development (as is currently being conducted through initiatives such as EUPATI; www.patientsacademy.eu), will help to highlight the collaborations that frequently exist between private and public enterprises. Emphasising the safeguards that exist in research through regulation and ethics review boards is also likely to alleviate some of these concerns.

Finally, our research reinforces the concerns held by the public regarding the linking of de-identified clinical data to HBS[19,25]. Discussion during the consent procedure around the value of associated clinical data, and the safeguards in place to ensure data security, may go some way to reducing these worries. Similarly, the strict governance arrangements around access to personal information by third parties including the police, insurance companies and employers should be made clear.

Strengths and Limitations

As with any qualitative research, the findings from this study rely on the researcher's interpretation of comments made by focus group participants. Nevertheless, we have used a methodology grounded in the data and ensured inter-rater reliability through cross-checking coding to ensure the interpretation was as close to the intended meaning as possible. Moreover, we have been able to verify focus group findings though the results from the survey. A major limitation of this study is its hypothetical nature; hence the results need to be interpreted with caution. Nevertheless, where possible, we presented questions as scenarios to try and make them as 'real' as possible. We also provided focus group participants with a background information sheet so that they had some knowledge about the subject matter before the discussion took place, and as such were likely to be more well informed than the general public. Survey participants were not given this information sheet and were only given selective background information that it was felt (by the authors) was necessary to enable them to make informed decision when answering the questions. This in itself, however, may have impacted the representativeness of the findings as they may have responded differently if no background information had been provided. A further limitation is that the dropout rate was relatively high; participants that did complete the survey may have done so because of a strong attachment to 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. Finally, the focus groups and survey were conducted in English which excluded those people who were not competent English speakers and/or readers. Our findings are therefore not necessarily representative of the non-English speaking community living in the UK.

CONCLUSION

There is a high level of public support for, and willingness to contribute to biobanking and the research process. In particular, people appear keen to contribute to research above and beyond the donation of residual tissue. Nevertheless, underlying concerns exist regarding the use of certain types of HBS, the conditions under which they are used and data security, although these issues did not necessarily preclude willingness to participate. Improved public education in these areas, for example, through the development of a 'Frequently Asked Questions' document which includes information on the ethics infrastructure that exists in the UK may mitigate some of these concerns. More controlled forms of consent and focused communication for sensitive types of HBS may also positively impact public willingness to donate infrequently donated tissue types. More focused communication may also address the finding that certain sub-groups, such as particular minority ethnic groups, are less likely to donate. Finally, greater transparency in the biomedical research process and the fostering of trust in those organisations involved throughout that process is vital to ensure the process of donating tissue to biobanks is satisfactory to all parties involved. These suggestions should be considered by the research community and policy makers.

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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

Figure legends

Figure 1 – Would you donate the the following types of samples for medical research if they were left over (after necessary medical tests had been done) following a medical procedure.

Figure 2 – Would you agree to donate the following type of samples for medical research, i.e. not as part of any medical procedure, but purely for the purposes of research?

Figure 3 – Would you be willing to donate samples for the following type of samples for research?

Figure 4 - Would you be willing to donate samples to the following organisations to carry out approved research?

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Manuscript title: Public views on the donation and use of human biological samples in biomedical research – a mixed methods study

Celine Lewis[1], Margaret Clotworthy[2], Shona Hilton[3], Caroline Magee[4], Mark J Robertson[5], Lesley J Stubbins[6], Julie Corfield[7]

[1]Genetic Alliance UK, Unit 4D Leroy House, 436 Essex Road, London, N1 3LY, UK
[2]Human Focused Testing, 50 the Barns, Littleport, Cambridge, CB6 1GG, UK
[3]Medical Research Council/CSO Social & Public Health Sciences Unit, 4 Lilybank Gardens, Glasgow, G12 8RZ, UK
[4]Confederation of Cancer Biobanks, National Cancer Research Institute, Angel Building, 407 St John Street, London EC1V 4AD, UK
[5]AstraZeneca, Science Policy & Relations, 11G43 Mereside, Alderley Park, Macclesfield, Cheshire SK10 4TF, UK
[6]GlaxoSmithKline Medicines Research Centre, Gunnels Wood Road, Stevenage, Hertfordshire, SG1 2NY, UK
[7]Areteva Ltd, BioCity, Nottingham, NG1 1GF, UK

Running title: Views on donating and use of biosamples – the UK public's preferences

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Correspondence to:

Dr Celine Lewis

Genetic Alliance UK,

Unit 4D Leroy House,

436 Essex Road,

London,

N1 3QP

Email: celine@geneticalliance.org.uk

Word count: ~~4937~~ 5367

ABSTRACT

Objective: A mixed methods study exploring the UK general public's willingness to donate human biosamples (HBS) for biomedical research.

Setting: Cross-sectional 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) identify participants' willingness to donate HBS for biomedical research; 2) explore acceptability towards donating different types of HBS in various settings; and 3) explore preferences regarding use and access to HBS.

Results: 87% of survey participants thought donation of HBS was important; 75% wanted to be asked to donate in general. Responders who self-reported having some or good knowledge of the medical research process were significantly more likely to want to donate ($p<0.001$). Reasons why focus group participants saw donation as important included: it was a good way of reciprocating for medical treatment received; it was an important way of developing drugs and treatments; residual tissue would otherwise go to waste; they or family members might benefit. The most controversial types of HBS to donate included: brain post mortem (29% would donate); eyes post mortem (35%); embryos (44%); spare eggs (48%) and sperm (58%). Concerning use of samples, there were concerns over animal research (34%), research conducted outside the UK (35%), and research conducted by pharmaceutical companies (56%), although education and discussion were found to alleviate such concerns during focus group discussions.

Conclusions: There is a high level of public support and willingness to donate HBS for biomedical research. Underlying concerns exist regarding the use of certain types of HBS and conditions under which they are used. Improved education and more controlled forms of consent for sensitive samples may mitigate such concerns.

ARTICLE SUMMARY

Article focus

- To explore the UK public's willingness to donate: residual biosamples following a medical procedure; biosamples donated as 'healthy volunteers'; additional biosamples during surgery; and biosamples post-mortem for medical research;
- The acceptability towards donating different types of biosamples in various settings;
- Preferences regarding use and access to biosamples.

Key messages

- There is a high level of public support for biomedical research and willingness to donate samples for this purpose.
- Those responders who self-reported having some or good knowledge of the medical research process were significantly more likely to want to be asked to donate, supporting the need for public education to improve understanding of the research process and the contribution HBS make to this.
- Concerns exist regarding the use of certain types of samples, the conditions under which they are used and data security; greater transparency and discussion of the safeguards that exist in research is likely to alleviate some of these concerns. More focused communication may also help address the issue that certain subgroups are under-represented and that certain kinds of tissue are infrequently donated.

Strengths and limitations of this study

- This study contributes further to our understanding of the UK public's views regarding the types of human biological samples acceptable t~~d~~o donate, under what circumstances and for what research purposes. This study highlights the importance of involving the public in more transparent dialogue about the use of biosamples to encourage greater public involvement and support for this area.
- This study presented participants with a series of hypothetical questions about willingness to donate biosamples for medical research. Therefore the findings may not necessarily correlate with actual behaviour.

INTRODUCTION

A gradual shift in the approach to biomedical research has accelerated use of human biological samples (HBS) and the establishment of biobanks with associated skills and infrastructure (‘biobanking’) to acquire, preserve and distribute this increasingly valuable resource. Biobanks are important custodians of HBS collections, usually with access to the donors’ de-identified phenotypic and clinical data[1]. Samples can comprise human materials of all kinds, including organs, tissues, biofluids such as blood, and genetic materials, such as DNA. They may be obtained from a variety of donated sources: from healthy volunteers or as residual tissue surplus to diagnostic requirements following a medical procedure, or alternatively retrieved post-mortem. Sample collections may be population-based or disease-specific, originating from a wide range of people with differing demographics, health, behaviours and lifestyles. Moreover, they may be used by a variety of research organisations, including public and private enterprises.

Public willingness to donate HBS is essential to ensure the continued provision of samples for research[2]; hence numerous studies have been conducted to examine this issue[3-7]. These studies have shown that the public is generally positive towards research using donated HBS[4-6] and the majority is in principle willing to donate[3,7]. Less well known are the public’s views regarding the types of HBS acceptable to donate, under what circumstances and for what research purposes, although some research does exist in these areas. For example, research has shown the public are generally willing to donate diseased tissue or ‘waste material’ (such as cancerous tissue or placental tissue) for biomedical research, however, donation of eyes, brains, lungs and bone is far more contentious[7-9]. Regarding access to tissues, research by publicly-funded academic researchers has been shown to cause few concerns, in comparison to research conducted by commercial entities[10-12]. These issues are important to address to provide an insight into the key drivers motivating or preventing people from donating. Knowledge of these can also help inform biobanking governance and ensure consent procedures and patient information addresses any concerns which the public may have. This is important to help the public understand the need for, and the use of, HBS in biomedical research as well as to increase transparency and engender trust with the public. This study was conducted to broaden our understanding in these areas. Moreover, the findings are intended to inform a biobanking policy for STRATUM (Strategic Tissue Repository Alliance Through Unified Methods), a UK Government Technology Strategy Board and Industry-funded project seeking to address the problem that there are insufficient numbers of HBS and associated clinical data of adequate quality to fully support biomedical research in the UK. This research will also help inform the design of new consent templates and deliver guidance and strategies around the consent process for biobanks and researchers.

The aims of this study were to 1) identify participants' willingness to donate HBS for biomedical research; 2) explore acceptability towards donating different types of HBS in various settings; and 3) explore preferences regarding use and access to HBS. Public views and preferences regarding consent procedures were also investigated and are described elsewhere (Consent for the use of human biological samples for biomedical research – a mixed methods study exploring the UK public's preferences, 2013, submitted manuscript).

METHODS

This was a mixed methods study comprising qualitative focus groups and a quantitative on-line survey. Focus groups were chosen as this method helps people explore and illuminate their views through debate within the group. They can also help facilitate the expression of ideas that might be left underdeveloped in an interview[13]. Focus groups have been used successfully to study the attitudes of the general public in relation to biobanking in previous research [14,15]. Ethical approval for the study was granted by the University of Manchester Research Ethics Committee in April 2012. A more detailed presentation of the methods can be found in the sister~~a second~~ paper related to this study (Consent for the use of human biological samples for biomedical research – a mixed methods study exploring the UK public's preferences, 2013, submitted manuscript~~unpublished manuscript~~).

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 the market research company The Focus Group. Participants were purposively sampled; each group chosen to reflect a particular demographic (age, socio-economic group (SEG), ethnicity, 'patients' who were affected by a condition or had had an operation in the past two years) in order to gather a wide spectrum of views and enable comparisons across groups. Prior to the day, focus group participants were given an information sheet about the use of biosamples in research in order that they had some background knowledge about the subject matter and to get them thinking about the key issues (Appendix I). Focus groups were held in 'neutral' locations such as hotel conference rooms or church halls, facilitated by an experienced facilitator (CL) and digitally recorded.

The topic guide explored participants’ views on: willingness to donate and acceptability of donating different types of HBS; in what circumstances; for what purposes; and to whom (supplementary files: Appendix II). Recordings were transcribed and the software package NVivo version 9 (QSR International, Pty Ltd) used to facilitate data 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

The findings from the focus groups were used to inform development of a quantitative survey used to canvas public opinion on the issues of interest across a representative sample of the UK population (supplementary files: Appendix III). Key themes that were discussed or emerged from focus group discussions were reframed as survey questions; in a number of cases answer options in the survey were informed by focus group discussions (e.g. the different types of residual HBS participants were presented with were raised by focus group participants). 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 main survey was then conducted in September 2012. Survey participants were not given the background information sheet about the use of biosamples in research which was given to all focus group participants. This was so that the survey responses represented the attitudes of the general public as far as possible. They were, however, given information during the survey to enable them to make informed decisions when answering the survey questions.

RESULTS

Study population

Participant characteristics are detailed in Table 1.

Table 1: 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%

Focus groups

One hundred and eighty-two members of the public who were approached were eligible and 81 people agreed to participate (45% response 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, 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[6]. Our quota sample was close to but not exactly matching our set targets.

For this reason we carried out both weighted and unweighted analyses. There was no difference in the conclusions we reached by either method. In this paper we present the unweighted results (weighted results can be found at supplementary files: Appendix IV).

Interest in being asked to donate

We began by providing a brief description of the use of HBS in biomedical research and then asked survey participants whether, in general, they wanted to be asked to donate. Three quarters (75%) of survey participants wanted to be asked (29% definitely yes, 46% probably yes); 18% didn't want to (14% probably not and 4% definitely not); and 7% didn't know. When asked how important they thought it was to donate HBS for biomedical research, 87% said either extremely important (50%) or important (37%). Less than 1% of participants (n=5) thought it was not at all important.

Respondents who wanted to be asked to donate HBS were significantly more likely to be: either not religious or only moderately so (where they did have a religious affiliation) (79.7% vs. 59.7%, X^2=36.56(1), p=0.001); from higher SEG groups (A-D vs. E)(83.8% vs. 62.2%, X^2=36.55(1) p<0.001); had tissue removed during a medical or surgical procedure (87.2% vs. 73.1%, X^2=27.13(1), p<0.001); had some or good knowledge of the medical research process (84.4% vs. 75.1%, X^2=13.04(1), p<0.001); were under 55 years (84% vs. 75.1%, X^2=11.56(1), p=0.001); were 'White' (81.7% vs. 60.9%, X^2=10.9(1), p=0.001); have no religious affiliation (86.4% vs. 77.9%, X^2=9.9(1) p=0.002); and had an education level of A level or equivalent or higher (83.4% vs. 76.1%, X^2=7.18(1), p=0.007). Using the boost sample for ethnic minorities we found that 'Black' participants were significantly less likely to want to be asked to donate than 'White' participants (53.3% vs. 81.7%, X^2=20.12(1), p<0.001). Participants who had a close family member affected by a condition were more willing to be asked to donate that those who hadn't, although the difference was not quite statistically significant (70.7% vs. 63.3%, X^2=3.8(1), p=0.051).

Four independent variables were found to have a significant impact on participants' interest in being asked to donate tissue as shown in the logistic regression model in Table 2. The strongest predictor for wanting to be asked to donate was being from a higher socio-economic group (A-D vs. E) (OR=3.52, 95% CI 2.19-5.66, p<0.001) followed by having had tissue removed during a medical or surgical procedure (OR=2.51, 95% CI 1.65-3.84, p=0.001), being either not at all or only moderately religious (OR=2.42, 95% CI 1.31-4.47, p=0.005), and having self-reported some or good knowledge of the medical research process (OR=2.01, 95% CI 1.33-3.03, p=0.001).

Table 2. Multiple logistic regression examining participant willingness to donate tissue

Participant characteristic	**Coefficient**	**95% CI**	**Odds ratio**	**p value**
Socio-economic group	1.26	2.19, 5.66	3.52	<0.001
Religiosity	0.89	1.31, 4.47	2.42	0.005
Knowledge of medical research process	0.70	1.33, 3.03	2.01	0.001
Had tissue removed	0.99	1.65, 3.84	2.51	<0.001

Demographic items were excluded from this table if they were not statistically significant. All variables were entered into the models as categorical variables.
CI: Confidence Interval.

Focus group participants also showed a strong willingness to donate HBS for biomedical research. Four key reasons were provide by participants. First, it was a good way of reciprocating for medical treatment received in the past, second, it was viewed as an "important way of developing drugs and treatments", and third, that residual tissue, which participants did not have any strong emotional ties to, would otherwise go to waste. The fourth reason offered was one of personal benefit whereby participants themselves or a family member was affected by an illness or disease.

*"Someone in my family has got Alzheimer's so I'm particularly supportive" (*Female, 18-24 focus group)

A minority of focus group participants did raise concerns. These included surgeons taking "liberties or advantage of the fact that you're out cold", concerns about data privacy and mistrust of profit-making companies using donated HBS or the government regulating their use.

"The world's very corrupt, and if something needs to get pushed through, it gets pushed through." Female, 'Black' focus group

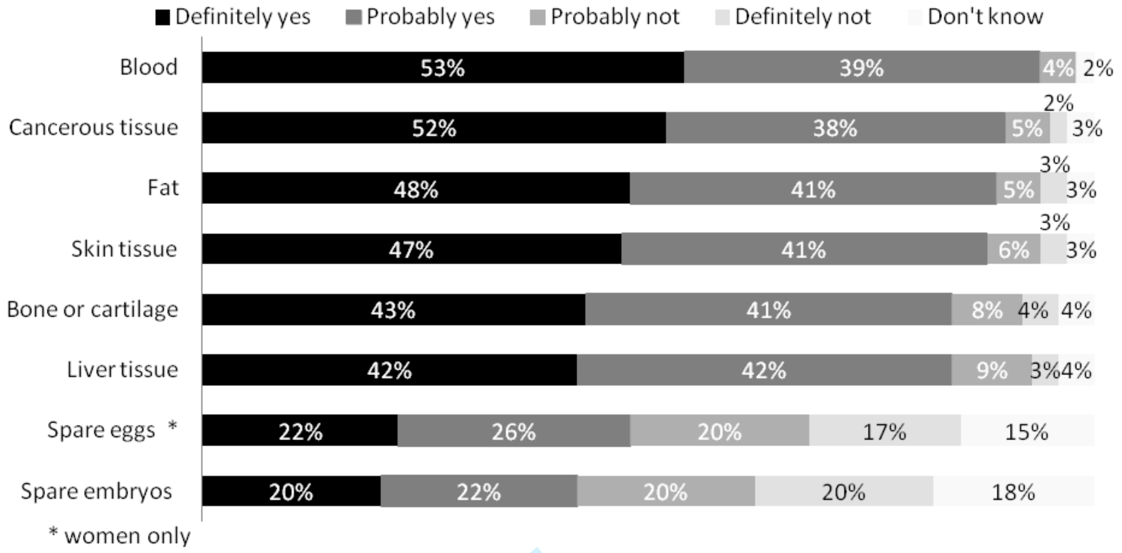
Whilst interest in donating appeared to be high, it was evident that knowledge of the medical research process was low. In the survey only 4% of respondents self-reported to have a 'good knowledge' of the research process; 54% said they had 'some knowledge' and 42% said they had 'no knowledge'. Similarly, a number of focus group participants commented that the information leaflet was the first time they had heard anything about the use of donated HBS in medical research.

Types of HBS

Residual HBS

The majority of survey participants were either definitely or probably willing to donate residual blood (92%); cancerous tissue (90%); fat (89%); skin tissue (88%); bone or cartilage (84%); and liver tissue (84%) following a medical procedure (Figure 1). Less than half of participants were willing to donate spare eggs (women only) (48%) or spare embryos (44%) left over following in vitro fertilisation (IVF).

Figure 1: Would you donate the following types of samples for medical research if they were left over (after any necessary medical tests had been done) following a medical procedure?



Note: percentages may not add up to 100% due to rounding.
Chi-square was conducted to examine effects of participant characteristics on willingness to donate spare eggs and spare embryos as these two tissue types caused most divide amongst participants. Willingness to donating spare embryos was significantly associated with being: male (55.9% vs. 48.3%, X^2=4.87(1), p=0.023); under 55 years (55.1% vs. 45.3%, X^2=7.55(1), p=0.005); from a higher (A-D) socio-economic group (54.9% vs. 32%, X^2=22.05(1), p<0.001); White ethnicity (53% vs. 27.7%, X^2=10.48(1), p=0.001), having a religious affiliation (63.5% vs. 45.9%, X^2=24.13(1), p<0.001), being not at all or moderately religious where they did have a religious affiliation (48.1% vs. 25.5%, X^2=9.38(1), p=0.002); and had had tissue removed during a medical procedure (56.9% vs. 46%, X^2=9.41(1), p=0.002). Women who were willing to donate spare eggs were significantly more likely to be: from a higher socio-economic group (A-D) (58.5% vs. 44.7%, X^2=4.45(1), p=0.035); White ethnicity (58.1% vs. 17.4%, X^2=13.21(1), p<0.001); have no religious affiliation (71.5% vs. 50.4%, X^2=18.47(1), p<0.001); be not at all or moderately religious where they did have a religious affiliation (53.5% vs. 23.7%, X^2=10.88(1), p=0.001); and had had tissue removed during a medical procedure (62.8% vs. 50.4%, X^2=6.77(1), p=0.009).

These results confirm our focus group findings, where most people were willing to donate residual tissue but donation of reproductive tissue raised concerns for a significant number of participants. A key concern was that reproductive tissue would be used for reproductive purposes without the knowledge of the donor.

"Although they said it's [ethical approval process] very strict, I still in the back of my mind have a thing where someone could take my egg and have my child" Female, had operation in past two years

A further concern related to whether it was 'right' from an ethical or religious perspective, to be conducting research on reproductive tissue.

"I would be really worried...an embryo is a baby. I know it's still very, very early days, but you're playing God." Female – patient affected by a condition

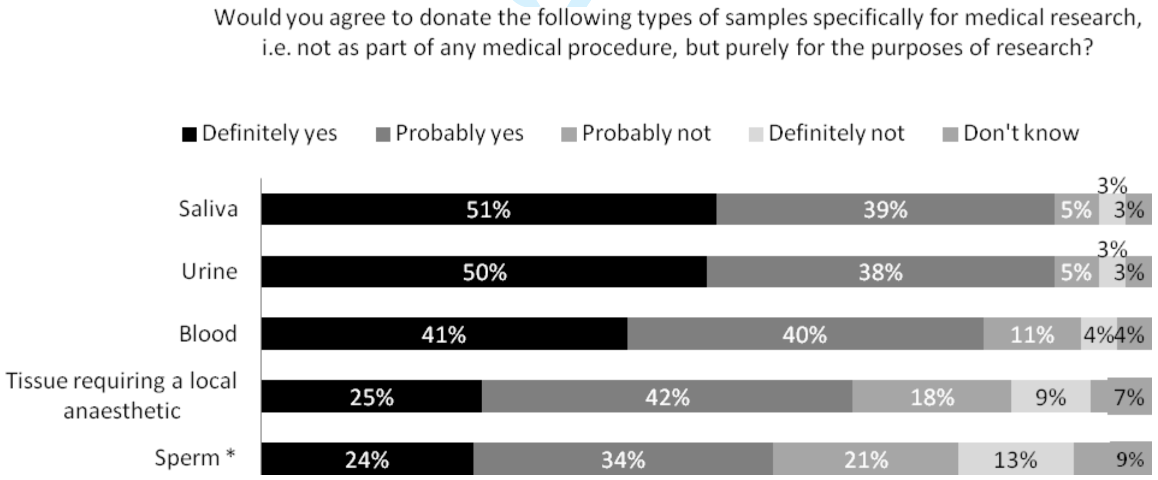
Those people who were willing to donate reproductive tissue underscored the benefits that could result~~s~~ from such research.

"You have to remove yourself from the situation and imagine yourself as an infertile person and maybe someone that could benefit immensely from that research." Female – 18-24 focus group

Some did, however, highlight the importance of being informed as to how reproductive tissue would be used because of its sensitive nature.

'Healthy' volunteers

Survey participants were then presented with a scenario in which they were asked to imagine that they are in a hospital waiting room awaiting an appointment and are asked whether they would donate certain types of HBS specifically for the purposes of medical research (Figure 2). Most responderswere either definitely or probably willing to donate urine (89%), saliva (89%) and blood (81%), however, fewer people would donate tissue taken during a local anaesthetic (67%) or sperm (men only) (58%).



Note: percentages may not add up to 100% due to rounding.
Chi-square was conducted to examine effects of participant characteristics on willingness to donate tissue requiring a local anaesthetic and sperm as these two tissue types caused most divide amongst participants. Willingness to donate tissue requiring a local anaesthetic was significantly associated with: being over 25 years (72.9% vs. 59.3%, X^2=9(1), p=0.003); from a higher socio-economic group (A-D) (73.1% vs. 60.9%, X^2=9.03(1); p=0.003), White ethnicity (72.3% vs. 48.9%, X^2=10.87(1), p=0.001); being not at all or moderately religious where they had a religious affiliation (71.4% vs. 49.2%, X^2= 11.53(1), p=0.001); having good knowledge of the medical research process (75.8% vs. 64.5%, X^2=14.96(1), p=0.001), had had tissue removed during a medical procedure (77.9% vs. 64%, X^2=20.77(1), p<0.001), and had agreed to donate left over tissue (82.8% vs. 45.5%, X^2=13.51(1), p<0.001). Men who were willing to donate sperm were significantly more likely to be: from a higher socio-economic group (A-D) (66.8% vs. 42%, X^2=14.47(1),

p<0.001); White ethnicity (65.8% vs. 22.2%, $X^2=18.95\%1$), p<0.001), and be either not at all or moderately religious where they did have a religious affiliation (64.3% vs. 36.4%, $X^2=5.61(1)$, p=0.018).

Focus group participants were also generally positive towards donating HBS specifically for research purposes, although some commented that they would not want to undergo an invasive procedure.

"Depends on what they wanted, if it's not invasive or nothing then I'd say yes." Female – 'Black' focus group

A number said they would be more likely to donate HBS if they did not have to travel somewhere specifically to do so. Focus group participants also appeared to want more information about how their sample would be used if they were donating HBS as 'healthy' volunteers.

"I'd want to know the purpose behind it but if I'm helping something then why not?" Male – 'Chinese' focus group

Additional HBS during surgery

Finally, survey participants were presented with a scenario in which they are having surgery which requires a general anaesthetic, and asked whether they would be willing to have additional tissue taken not required to be removed for therapeutic benefit. Over three quarters of responders (78%) were willing to donate HBS taken from the same part of the body being operated on, 63% were willing to donate HBS taken from an area close by, and 44% would donate HBS involving an additional procedure e.g. taking bone marrow whilst under the same general anaesthetic.

This scenario was not explored explicitly with focus group participants, but was included in the survey as a number had aired concerns about surgeons taking additional tissue during surgery without consent.

"I would be worried about giving consent before they performed an operation in case the main task of the operation is to remove cancer...and they take some tissue for research. I think it would be OK but only if they asked." Male, 18-24 group

Donation of HBS in the event of one's death

We explored whether the public were willing to donate tissue and whole organs in the event of their death. First, we compared survey responders' views concerning the donation of tissue taken from an organ compared to donating a whole organ using the liver and brain as examples. We found that tissue type had a greater impact on people's willingness to donate than amount of tissue: 89% of people were willing to donate liver tissue; 68% a whole liver; 66% brain tissue; 53% a whole brain. On presenting participants with a list of organs and asking them whether there were any whole organs they would not consider donating for medical research in the event of their death, 71% would not donate their brain, 65% would not donate their eyes, 27% would not donate their heart, 14% would not donate their liver; 14% would not donate their lungs and 13% would not donate their kidneys. Five people (0.5%) said they would not donate reproductive tissue in the free text box. Seventeen percent would not donate any organs for medical research.

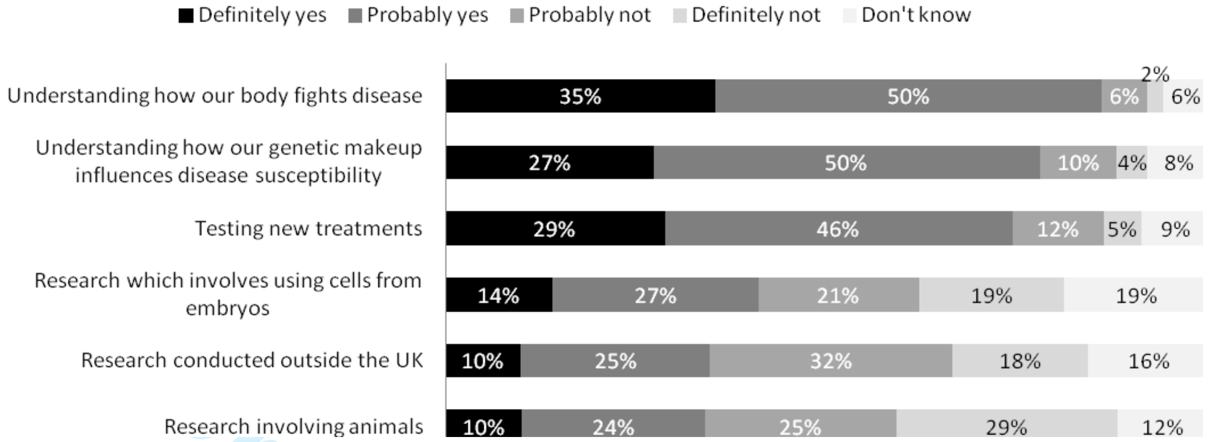
Donating whole organs for medical research in the event of one's death caused unease for a number of focus group participants. Some had concerns about the impact on family members, citing that it was a "sensitive subject" that may make them feel "uncomfortable". A woman in the South Asian group cited religious reasons for not wanting to donate organs. Others didn't like the idea of their body being "chopped up like on a butcher's board" and preferred "to remain whole" and "untouched". A few participants erroneously believed that their organs would not be useful to researchers because they were old or unhealthy. When focusing on particular organs, eyes were found to be most contentious and made participants feel "funny" or "squeamish". They also had concerns that eyes were "identifiable".

When asked whether they would be willing to donate whole organs not suitable for transplant for research purposes instead, 68% of survey responders said they would, 11% would prefer they were not used at all if they couldn't be used for transplant, 9% would not agree to donate an organ for transplant and 12% didn't know.

Uses of HBS

The most controversial types of research were research involving HBS in combination with animals (only 34% of survey participants would donate for this purpose), research conducted outside the UK (35%), and research involving 'cells from embryos' (41%) (Figure 3). Research into understanding how our body fights disease was the least controversial (85%).

Figure 3: Would you be willing to donate samples for the following type of samples for research?



Note: percentages may not add up to 100% due to rounding.
Chi-square was conducted to examine effects of participant characteristics on willingness to donate samples for research outside the UK and research involving animals as these two research types had least support. Those participants who were less willing to donate samples for research outside the UK were significantly more likely to be: over 55 years (67.8% vs. 53.8% , $X^2=17.2(1)$, P=0.001); from a low socio-economic group (E) (72.8% vs. 56.6%, $X^2=11.92(1)$, p=0.001); non-white ethnicity (78% vs. 58%, $X^2=5.7(1)$, p=0.017); have a religious affiliation (63.4% vs. 49.8%, $X^2=14.83(1)$, p=0.001); have a lower education level (GCSE or equivalent or lower) (65.9% vs. 55.5%, $X^2=8.18(1)$, p=0.004); and had not had tissue removed during a medical procedure (62.5% vs. 55%, $X^2=4.57(1)$, p=0.033). Those participants who were less willingness to donate samples for research involving animals were significantly more likely to be: female (69.5% vs. 51.8%, $X^2=30.74(1)$, p<0.001); from a low socio-economic group (E) (78% vs. 58.4%, $X^2=19.9(1)$, p<0.001); non-white ethnicity (80% vs. 60.5%, $X^2=6.09(1)$, p=0.014); have a religious affiliation (63.6% vs. 56.7%, $X^2=4.02(1)$, p=0.045); be very religious whereby they did have a religious affiliation (78.7% vs. 61.9%, $X^2=5.99(1)$, p=0.014); have no knowledge of the medical research process (67.6% vs. 57.1%, $X^2=10.4(1)$; p=0.001) and had not agreed to donate leftover tissue for medical research (81% vs. 49.3%, $X^2=6.12(1)$, p=0.013).

Research involving animals was cited as a cause for concern by a number of focus group participants, particularly if the research caused the animals "excessive pain". Others had concerns about the way animals were cared for in research settings. Nevertheless, a view held by a significant number of people was that research and drugs tested on animals was "not a nice thought...but in the long run the best option" and that "the information gained from watching [an animal used in research] might help thousands of people".

Research conducted outside the UK was a concern for some focus group participants because other countries might not have similarly strict governance arrangements as those that exist in the UK, or because HBS might be sold. Other types of research cited as being controversial included cloning, stem cell research, genetic engineering and "designer babies".

Access to HBS

Most survey responders were willing to donate HBS to NHS hospitals (84%), medical research charities (79%), universities (68%), diagnostic companies (63%) and pharmaceutical companies (56%) (Figure 4).

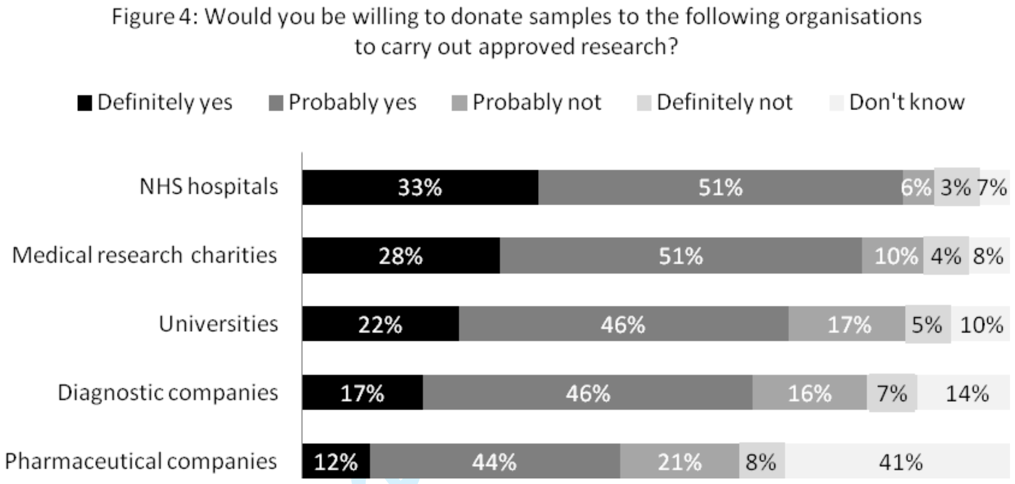


Figure 4: Would you be willing to donate samples to the following organisations to carry out approved research?

Note: percentages may not add up to 100% due to rounding.
Chi-square was conducted to examine effects of participant characteristics on willingness to donate samples for pharmaceutical companies as this organisation had the least support. Those participants who were less willing to donate samples to pharmaceutical companies were significantly more likely to be: over 55 years (39.4% vs. 31.3%, $X^2=6.16(1)$, $p=0.013$); from a low socio-economic group (E) (43.4% vs. 32.6%, $X^2=5.91(1)$; $p=0.015$), non-white ethnicity (60.9% vs. 32.9%, $X^2=14(1)$, $p=0.001$); live in London (45.1% vs. 31.7%, $X^2=11.02(1)$, $p=0.001$); have a religious affiliation (38.1% vs. 26.9%(1), $X^2=11.1(1)$, $p=0.001$); be very religious whereby they had a religious affiliation (54.5% vs. 36.7%, $X^2=6(1)$, $p=0.014$); have no knowledge of the medical research process (38.3% vs. 31.6%, $X^2=4.14(1)$, $p=0.042$); and had not had tissue removed during a medical procedure (38% vs. 29.8%, $X^2=6(1)$, $p=0.014$).

Focus group discussions highlighted that there was generally a high level of faith in the benefits of science, and trust towards the NHS, charities and universities, who were seen as contributing positively towards society. The role of ethics review boards and legal systems in providing oversight and control of medical research was considered important, nevertheless, it was acknowledged that most people are unaware of these safeguards.

"I do now know something about the process, and like the ethics side and presenting to a board, but before I wouldn't have known anything about the research process. So I guess I'm just thinking, how would I feel if I didn't know about those procedures?" Female – pilot group

Some initial negativity was found in relation to pharmaceutical companies conducting research because of their commercial, profit-making nature and concerns that they "exploit patients". However, such concerns were often addressed by other members of the group who acknowledged that commercialisation of research was "a fact of life" and that pharmaceutical companies "need to make money to keep their research going".

Medical records and lifestyle information

We asked participants whether they would be willing to have medical records and lifestyle information linked but de-identified (so that the sample is anonymous to the researcher but contains codes that would allow others to identify an individual from it) to their biosample. Sixty eight percent of survey responders would, 22% would not and 10% didn't know. Survey responders were more willing to have their de-identified lifestyle information linked to their biosample; 82% would, 12% would not, and 6% didn't know.

Concerns about linking medical records with HBS were raised by focus group participants. Data protection and privacy were two key concerns, for example, participants were worried that their personal data might be "hacked or mislaid". Others cited concerns about data being accessed by the police or insurance companies. Some participants felt uncomfortable about sensitive medical details such as sexual diseases or illegal drug use being seen by people unconnected with their health. Nevertheless, most participants understood the importance of linking medical records and lifestyle information to HBS as long as they were not identifiable.

"You want the sample to be as useful as possible so you want to give them the most complete picture. You want to give them all the information that is available." Male – had operation in past two years.

DISCUSSION

Results from this study are consistent with the findings from other empirical research that there is a high level of public support for biomedical research and willingness to donate HBS for this purpose[3-5,7,16-18]. However, by presenting participants with scenarios consisting of a variety of HBS types across a number of settings, and by using both qualitative and quantitative methods, we have been able to build a richer understanding of public attitudes. Whilst it is important to bear in mind that the opinions expressed are hypothetical and therefore do not necessarily correspond with how people would actually behave in practice, they still offer an intriguing insight into public attitudes which can help inform policy and practice.

The general willingness of the UK public to donate residual HBS is consistent with findings from other studies conducted in the UK, USA and Scandinavia where willingness to donate varied from 67%-88%[3-5,7,16,17]. Interestingly, people who themselves had had tissue removed were significantly more likely to want to be asked to donate than those that hadn't (87% compared to 73%). A number of other studies conducted in the UK and elsewhere have found patient willingness to be high, between 83%-99%[19-24]. This is likely to be because donation of surplus tissue provides patients with an opportunity to reciprocate or demonstrate gratitude towards those involved in the therapeutic process[21] or because they have had the medical need explained to them and can relate to the experience more closely. Those responders who self-reported having some or good knowledge of the medical research process were also significantly more likely to want to be asked to donate. This finding supports the need for public education to improve understanding of the research process and the contribution HBS make to this. We identified that more people ~~Another striking finding was the apparent discrepancy between people who~~ saw biosample donation as important (87%) than~~and those who~~ wanted to be asked to donate (75%). It may be that although people see donation as important, other concerns e.g. around issues such as data privacy, or other ethical considerations such as commercial use of HBS may prevent some people from donating; concerns have been identified in this and other empirical studies[5,15,19,25].

Lower levels of support for HBS donation were identified amongst minority ethnic groups, a finding that has been seen elsewhere, particularly amongst African-Americans[18,26-28] and Asian-American women[29]. A study conducted in China also found that public and patient willingness to donate residual tissue was low compared to studies conducted in the UK, Scandinavia and the USA, at only 65%[30]. These differences may stem from different cultural attitudes towards donation, religious beliefs or low levels of trust in public institutions (which may stem from previous breaches of trust as highlighted by Ma et al.[30] amongst the 'Chinese' population). Mistrust of profit-making companies and the government were identified during focus group discussions with ethnic minority groups in this study, although not exclusively so. Information about the role of ethics review boards in safeguarding participants' interests is therefore vital for ensuring public trust.

A large proportion of people were unwilling to donate reproductive tissue. This type of HBS donation raised a number of unique moral, ethical and social concerns, as exemplified by focus group discussions. Interestingly, the survey showed that men were more likely to donate semen than women were excess eggs following an IVF procedure (58% v 48%), which may indicate egg donation is a more contentious issue or that women feel a greater attachment to eggs than men to sperm[31]. Another possible reason may be the limited number of eggs that a woman has, and the greater effort and risk required to make them available *ex vivo*, resulting in a more judicious approach to their use; for example, women may prefer to keep excess eggs following IVF for future uses rather than donate them for research. More controlled forms of consent (tiered or specific) may be one way of alleviating concerns people may have about donating sensitive HBS.

When asked to consider post-mortem donation, eyes and brains were considered the least desirable organs to donate for research purposes, a finding that has been reported elsewhere[7]. As the donation of eyes is crucial for vision research and drug testing, and with donated brains being essential for research into conditions such as multiple sclerosis, Alzheimer’s and Parkinson’s disease, different ways of raising awareness and motivating donation need to be considered. For example, completely transparent discussion with families on the day prior to forensic post-mortem examination, conducted in a sensitive manner, has led to research authorisation and donation in a very high proportion of cases to the Sudden Death Brain and Tissue Bank in Edinburgh[32]. It may also be worth considering incentives to donation for research, as have already been discussed in depth elsewhere, although with a greater emphasis on donation for transplant[33]. Our research highlights that a significant number of people (68%) would be willing to donate whole organs not suitable for transplant for research purposes instead. Such soft incentives are likely to be welcomed by families, a finding which has also been reported by Womack et al.[34] where over 70% of family members consented for the retrieval of blood and tissue at the time of post-mortem examination.

The finding that 67% of people were willing to undergo a local anaesthetic to donate tissue seems unusually high at first glance. Nevertheless, such a finding should not be dismissed; women have been known to undergo local aesthetic to donate healthy breast tissue for breast cancer research, as evidenced by the 2800 women who have donated to the Komen Tissue Bank in the United States[35]. The finding that a significant proportion of the public are willing to donate as ‘healthy volunteers’ also supports the premise that there is a strong altruistic desire to contribute to medical research and a high level of trust in and support for the research process[8].

Research involving animals and research conducted outside the UK were the least supported research types in this study. Animal research remains a controversial topic and much empirical and ethical debate has focused on this issue[36-38]. However, the finding that a large proportion of the public do not want their HBS used for research outside the UK is intriguing. Our qualitative data show that concerns exist around regulation and commodification of HBS, findings supported elsewhere in the literature[39,40]. To address these concerns, potential donors should be provided with information related to the specific issues that relate to those countries where HBS are likely to be sent.

Regarding access to donated HBS, overall findings indicate high levels of trust towards research organisations conducting biomedical research. Lowest trust was afforded to pharmaceutical companies, primarily because of their profit-making nature, a finding which concurs with other studies[5,10,11]. Greater transparency and education of the public by the research community about the role pharmaceutical companies play in research and drug development (as is currently being conducted through initiatives such as EUPATI; www.patientsacademy.eu), will help to highlight the collaborations that frequently exist between private and public enterprises. Emphasising the safeguards that exist in research through regulation and ethics review boards is also likely to alleviate some of these concerns.

Finally, our research reinforces the concerns held by the public regarding the linking of de-identified clinical data to HBS[19,25]. Discussion during the consent procedure around the value of associated clinical data, and the safeguards in place to ensure data security, may go some way to reducing these worries. Similarly, the strict governance arrangements around access to personal information by third parties including the police, insurance companies and employers should be made clear.

Strengths and Limitations

As with any qualitative research, the findings from this study rely on the researcher's interpretation of comments made by focus group participants. Nevertheless, we have used a methodology grounded in the data and ensured inter-rater reliability through cross-checking coding to ensure the interpretation was as close to the intended meaning as possible. Moreover, we have been able to verify focus group findings though the results from the survey. A major limitation of this study is its hypothetical nature; hence the results need to be interpreted with caution. Nevertheless, where possible, we presented questions as scenarios to try and make them as 'real' as possible. We also provided focus group participants with a background information sheet so that they had some knowledge about the subject matter before the discussion took place, and as such were likely to be more well informed than the general public. Survey participants were not given this information sheet and were only given selective background information that it was felt (by the authors) was necessary to enable them to make informed decision when answering the questions. This in itself, however, may have impacted the representativeness of the findings as they may have responded differently if no background information had been provided. A further limitation is that the dropout rate was relatively high; participants that did complete the survey may have done so because of a strong attachment to 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. Finally, the focus groups and survey were conducted in English which excluded those people who were not competent English speakers and/or readers. Our findings are therefore not necessarily representative of the non-English speaking community living in the UK.

CONCLUSION

There is a high level of public support for, and willingness to contribute to biobanking and the research process. In particular, people appear keen to contribute to research above and beyond the donation of residual tissue. Nevertheless, underlying concerns exist regarding the use of certain types of HBS, the conditions under which they are used and data security, although these issues did not necessarily preclude willingness to participate. Improved public education in these areas, for example, through the development of a 'Frequently Asked Questions' document which includes information on the ethics infrastructure that exists in the UK may mitigate some of these concerns. More controlled forms of consent and focused communication for sensitive types of HBS ~~and donation incentives~~ may also positively impact public willingness to donate infrequently donated tissue types. More focused communication may also address the finding that certain sub-groups, such as particular minority ethnic groups, are less likely to donate. Finally, greater transparency in the biomedical research process and the fostering of trust in those organisations involved throughout that process is vital to ensure the process of donating tissue to biobanks is satisfactory to all parties involved. These suggestions should be considered by the research community and policy makers.

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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 I

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.

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

Appendix II

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 III

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 IV

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%
London	213	19%	144	13%

Appendix IV

Results of survey –unweighted and weighted

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%
GCE, A-level, Scottish Higher or similar	214	19%	214	19%
Vocational (BTEC/NVQ/Diploma)	230	21%	237	21%

Appendix IV

Results of survey –unweighted and weighted

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	
	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%

Appendix IV

Results of survey –unweighted and weighted

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%

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

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	%	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 IVF *	N	133	159	121	104	89	128	149	111	93	86
	%	22 %	26%	20%	17%	15%	23%	26%	20%	16%	15%
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	N	166	286	310	235	113	172	300	309	214	115

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requiring a general anaesthetic	%	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

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 additional procedure	N	154	336	298	204	118	164	348	301	180	118
	%	14 %	30%	27%	18%	11%	15%	31%	27%	16%	11%

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

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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%

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

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Results of survey –unweighted and 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%

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%

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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 license	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 procedure	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%
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

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	%	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?

		Generic		
Preferences	Unweighted		Weighted	
	N	%	N	%
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%
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%

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Results of survey –unweighted and weighted

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%
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%

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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%

Q39 Would you be willing to have your anonymised lifestyle information linked to your sample?)

	Unweighted		Weighted	
	N	%	N	%
It should be obtained at the same time as consent for organ transplantation and recorded on the organ donor register	580	52 %	579	52%
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%

Q40 Would you be willing to have your anonymised lifestyle information linked to your sample?)

	Unweighted		Weighted	
	N	%	N	%
Yes	174	16 %	166	15%
No	789	71 %	800	72%
Don't know	147	13 %	144	13%

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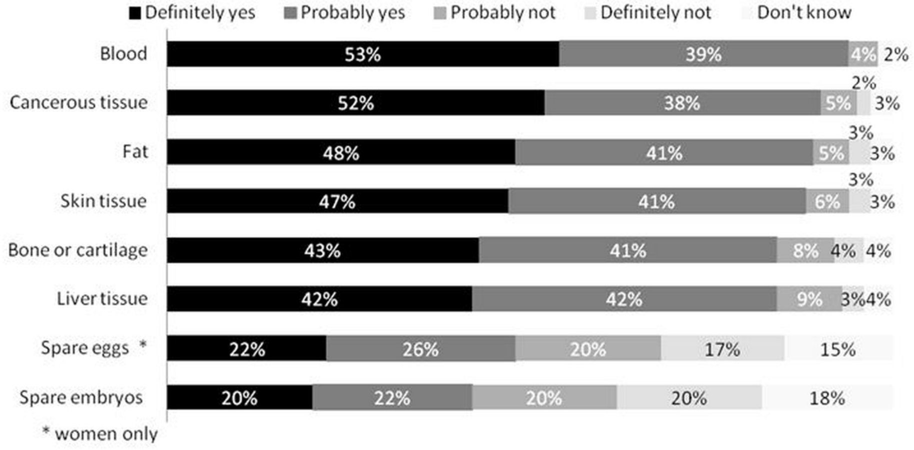
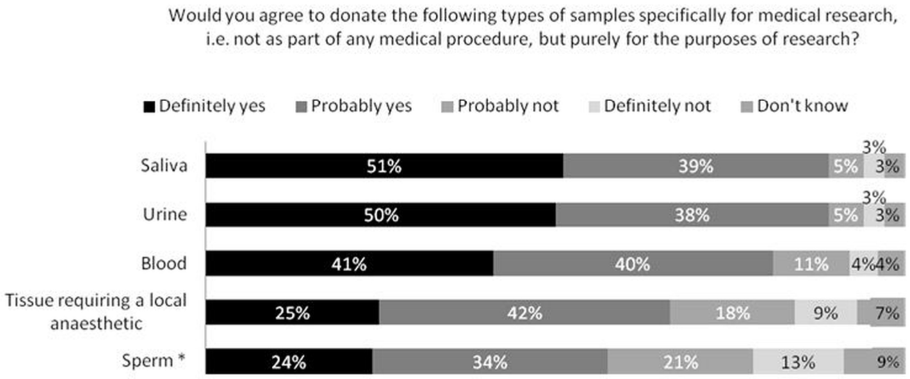
Note: percentages may not add up to 100% due to rounding.

Figure 1: Would you donate the following types of samples for medical research if they were left over (after any necessary medical tests had been done) following a medical procedure?



160x90mm (300 x 300 DPI)



211x90mm (300 x 300 DPI)

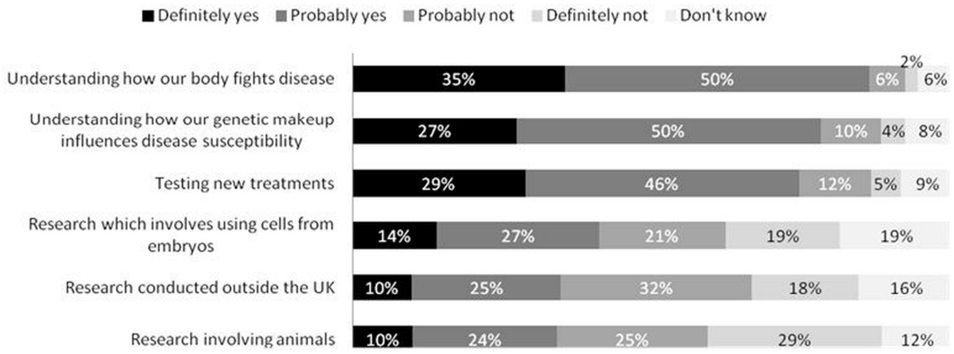
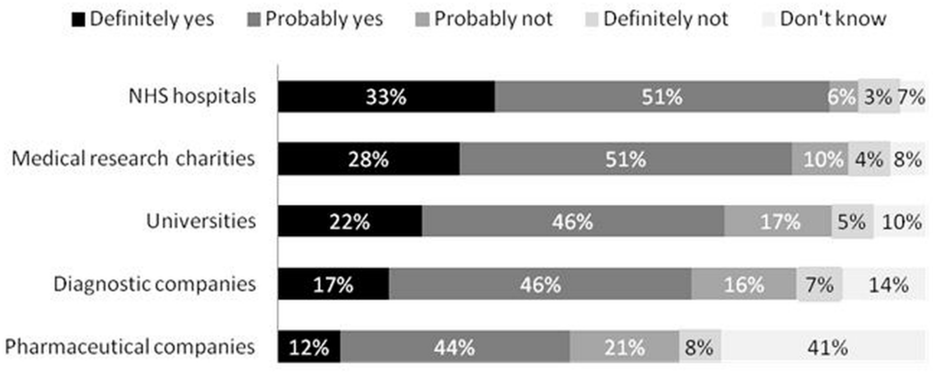


Figure 3: Would you be willing to donate samples for the following type of samples for research?

206x90mm (300 x 300 DPI)

Figure 4: Would you be willing to donate samples to the following organisations to carry out approved research?



182x90mm (300 x 300 DPI)