# Public Attitudes toward Consent and Data Sharing in Biobank Research: A Large Multi-site Experimental Survey in the US

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Individuals participating in biobanks and other large research projects are increasingly asked to provide broad consent for open-ended research use and widespread sharing of their biosamples and data. We assessed willingness to participate in a biobank using different consent and data sharing models, hypothesizing that willingness would be higher under more restrictive scenarios. Perceived benefits, concerns, and information needs were also assessed. In this experimental survey, individuals from 11 US healthcare systems in the Electronic Medical Records and Genomics (eMERGE) Network were randomly allocated to one of three hypothetical scenarios: tiered consent and controlled data sharing; broad consent and controlled data sharing; or broad consent and open data sharing. Of 82,328 eligible individuals, exactly 13,000 (15.8%) completed the survey. Overall, 66% (95% CI: 63%–69%) of population-weighted respondents stated they would be willing to participate in a biobank; willingness and attitudes did not differ between respondents in the three scenarios. Willingness to participate was associated with self-identified white race, higher educational attainment, lower religiosity, perceiving more research benefits, fewer concerns, and fewer information needs. Most (86%, CI: 84%–87%) participants would want to know what would happen if a researcher misused their health information; fewer (51%, CI: 47%–55%) would worry about their privacy. The concern that the use of broad consent and open data sharing could adversely affect participant recruitment is not supported by these findings. Addressing potential participants' concerns and information needs and building trust and relationships with communities may increase acceptance of broad consent and wide data sharing in biobank research.

# Introduction

Health research increasingly requires very large numbers of participants to be willing to share their biological samples, genomic data, and clinical information with researchers.<sup>1</sup> The proposed Precision Medicine Initiative (PMI) is one prominent example of a very large biobank created to improve understanding of human health and disease.<sup>2,3</sup> In this type of biobank, participants are asked to share their data not only with the institutions making the request but also with other investigators at diverse sites, often for pro-

jects not yet conceived.<sup>4</sup> The National Institutes of Health (NIH) Genomic Data Sharing Policy already requires that NIH-funded researchers proposing to generate genomic data obtain broad consent from participants, that is, consent that permits wide data sharing.<sup>5</sup>

Obtaining broad consent has also been proposed by the Department of Health and Human Services and the White House Office of Science and Technology Policy as the preferred approach. Their 2015 *Notice of Proposed Rulemaking (NPRM)* required that informed consent be obtained for all research using tissue samples and most clinical data and

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\*Correspondence: saskia.sanderson@ucl.ac.uk (S.C.S.), kyle.brothers@louisville.edu (K.B.B.) http://dx.doi.org/10.1016/j.ajhg.2017.01.021. © 2017 American Society of Human Genetics. stated that such consent can be obtained in a one-time, open-ended or "broad" fashion.<sup>6</sup>

Obtaining broad consent from participants in biobanks reduces administrative burdens and may accelerate discovery.<sup>5</sup> However, broad consent and wide data sharing reduces participants' control over how their data is used.<sup>7,8</sup> Individuals who object to decreased control may be less willing to take part in the research.<sup>9–13</sup>

Decreased willingness to participate in research is of particular concern for populations who are already underrepresented in medical research. Most genomics research to date has used data predominantly from individuals of Northern European ancestry, limiting the insights gained for individuals of other ancestries.<sup>14–18</sup> Ancestry is only imperfectly correlated with the social constructs of race and ethnicity, but this association does mean that perspectives on research participation within underserved groups can influence inclusion from underrepresented ancestry groups. Some racial and ethnic groups, including African Americans, have less trust in medical researchers than others,<sup>19,20</sup> so the move toward broad consent could undermine much-needed efforts to increase participation in medical research among underrepresented groups.

Members of the public are key stakeholders in this discussion.<sup>21</sup> A recent systematic literature review<sup>22</sup> reported that, when presented with different consent models and asked to choose among them, individuals often favor greater levels of control and select more specific types of consent over broad consent.<sup>23–25</sup> These findings could have serious implications for large-scale research efforts. Asking respondents to choose from among several consent or data sharing options is quite different, however, from asking them to enroll in a particular biobank with a defined data sharing policy. In addition, it is unclear whether respondents to these previous surveys truly understood the trade-offs involved, or whether they were simply endorsing the idea of greater choice more generally. As noted in the same review, previous studies have also tended to be small and local and to underrepresent key demographic groups.<sup>22</sup>

We therefore conducted a large survey of attitudes toward consent and data sharing in biobank research among diverse participants recruited at multiple healthcare systems participating in the Electronic Medical Records and Genomics (eMERGE) Network.<sup>26</sup> The eMERGE Network is ideal for this type of research, as it has the necessary infrastructure and access to a large diverse population of individuals who are among those most likely to be invited to participate in a biobank. The overarching aim of the present study was to examine patients' attitudes toward participating in biobank research using an experimental study design that randomly assigned participants to different consent and data sharing conditions.

We hypothesized that participants randomly assigned to a hypothetical biobank with broad consent and open data sharing would express less willingness to participate in, and have more negative attitudes toward, the biobank than those assigned to a biobank with tiered consent and controlled data sharing. We also hypothesized that willingness would be lower among participants of lower socioeconomic status and from underserved racial and ethnic groups. In addition, we examined participants' perceived benefits, concerns, and information needs regarding participating in biobank research.

## Subjects and Methods

#### **Study Design and Procedures**

This was an experimental survey study. Individuals were randomly assigned to one of three conditions and completed self-report questionnaires. Participants were patients who had: (1) sought care for themselves or their minor child at one of 11 eMERGE Network sites<sup>26</sup> between October 1, 2013 and September 1, 2014; (2) a valid address that could be geocoded; and (3) age and sex available in the electronic health record. To maximize diversity of the sample, and specifically to enrich the observed sample with demographic groups that have been underrepresented in previous studies, we utilized a disproportionate stratified sampling scheme. Strata were defined by the cross-classification of patient age group (at adult centers:  $\leq$  35 years and > 35 years; pediatric centers:  $\leq$ 12 years and > 12 years), sex, race (white, black, Asian, Native American/Alaska Native, Hawaiian/Pacific Islander, other), ethnicity (Hispanic/Latino or not), education group (< 12 years, 12-15 years, 16+ years), and residence in a rural versus urban/suburban census block group. To be able to execute this complex study design, values for each stratification variable needed to be known (or estimated) prior to randomization. Many of these items, as well as home address, were readily available in the EHR. Others were incomplete or were inaccurate. Home addresses were geocoded and linked to unique census block groups. Information from the 2010 census and 2008-2012 American Community Survey were used to impute missing stratification information, using the mode of the participant's census block group value, in order to define the "approximate" sampling frame. Further details on the sampling frame and the stratified sampling strategy are provided in Tables S1 and S2. A thorough exposition of the sampling scheme, including how census data were utilized for the purpose of sampling, will be provided in a separate article. The sampling frame was approximately 2.4 million patients, of whom 90,000 were selected.

Participants within each sampling stratum were randomized to receive a survey which included one of three hypothetical biobank scenarios. The scenarios were identical except for the details regarding consent type and data sharing approach.<sup>27</sup> In the first scenario, donated samples and data could be used for all kinds of medical research and data could be shared with approved investigators only ("broad-controlled"). The second and third scenarios contained an alternative consent approach or data sharing policy: in the "tiered-controlled" scenario, the consent process allowed participants to select the types of research for which their samples and data could be used, and in the "broad-open" scenario, the data sharing policy allowed de-identified data to be shared through an online database open to the public.

Pre-notification postcards were mailed, after which optical scan surveys were mailed along with a non-contingent pre-incentive \$2 bill, to potential participants in April 2015. Non-respondents received a reminder letter in May 2015 and a second survey in July 2015. Participants could complete the survey on paper and return it in a self-addressed stamped envelope or complete an identical survey through a secure, online survey interface on the REDCap database platform.<sup>28</sup> This project received IRB approval at all 11 participating sites.

#### **Development of the Survey Instrument**

The survey instrument, including the three hypothetical scenarios and the survey questions, was developed by a multidisciplinary expert working group, informed by the findings from a systematic review of the literature.<sup>22</sup> A complete draft of the survey instrument content was tested and refined using cognitive interviews with 40 patients across 6 sites. A pilot study to test the feasibility of the survey instrument and study procedures was then conducted across all 11 sites. In the pilot study, 166 respondents returned the survey, out of 1,500 patients who were sent the survey (response rate 11%). Analysis of pilot data suggested that planned study procedures were robust, and quality indicators including incomplete surveys and straight-lined responses necessitated only minor revisions to the survey. Respondents to the pilot survey were excluded from the main study, and responses to the pilot were not included in the main analysis.

#### **Survey Measures**

#### Demographics

Standard measures of demographic characteristics were used (see CDC Questionnaire in Web Resources).<sup>29</sup> Poverty was calculated from income and number of people in household. Rurality was assessed using census-level data. Religiosity was assessed using an item adapted from previous research.<sup>30</sup> Self-rated health, an indicator of quality of life, was assessed using the widely-used single item from the SF-12.<sup>31</sup>

#### **Trust and Privacy**

Concern about privacy was assessed using two items.<sup>32</sup> Trust was assessed with two items.<sup>33,34</sup>

#### Willingness to Participate

Willingness to participate in the hypothetical biobank described was assessed using a single item adapted from previous research.<sup>25,35</sup>

#### Attitudes toward Participating

Attitude items were either generated specifically for this study or adapted from previous research.<sup>24,25,36-39</sup> In order to generate these items, the multidisciplinary expert working group defined three relevant sub-domains to be assessed within the overarching domain of "attitudes towards participating in a biobank:" perceived benefits of participating in the described biobank, concerns about participating in the described biobank, and information needs about the governance of the described biobank (e.g., how decisions are made regarding the use of the samples and data). Initial lists of items to assess each of these sub-domains were compiled based on a review of the literature on these topics<sup>22</sup> and on expert input. The lists were culled in an iterative manner, in order to produce a manageable number of prioritized items that would not over-burden participants. The final list comprised five items assessing perceived benefits, six items assessing concerns, and eight items assessing information needs. Likertstyle scales were used with five responses ranging from "strongly disagree" to "strongly agree" for each item. Factor analysis confirmed that benefits, concerns, and information needs were distinct factors, with all items from each set loading on that factor with eigenvalues greater than 0.4. In order to describe responses to

these items, responses were dichotomized and proportions responding "agree" or "strongly agree" with each statement were reported. In addition, composite scale scores were created by calculating the mean of each set of items (possible range from 1 to 5). Mean scores were described for each attitudinal scale. In addition, for the purposes of the regression analysis (see below), participant's scale scores were categorized: scale scores ranging from 1.0 to 2.50 were categorized as "low," scale scores ranging from 2.51 to 3.50 were categorized as "intermediate," and scale scores ranging from 3.51 to 5.0 were categorized as "high." The three survey instruments are available online (see Web Resources).

#### **Data Analysis**

Response rates were calculated according to American Association for Public Opinion Research (AAPOR) criteria.40 To determine whether randomization was maintained within the subset of respondents, sample counts and percentages were calculated for socio-demographic variables. These summaries were computed within consent and data sharing models across all sites and compared using the Pearson's chi-square test. For all other analyses, each participant was assigned a post-stratified, sampling weight (i.e., the inverse of the probability of being sampled and answering the survey) to account for the stratified sampling design. Because understudied populations were intentionally oversampled, sampling weights varied dramatically within and across sites, and so we conducted site-specific weight trimming and redistribution combining two commonly used approaches: weights were trimmed at (1) the 90<sup>th</sup> percentile of weights, or (2)the median+6\*IQR, whichever was higher.<sup>41,42</sup> Recognizing that all trimming approaches are ad hoc, we conducted sensitivity analyses for the primary analysis using a number of approaches to trimming. Results from sensitivity analyses can be found in Table S3.

The impact of consent and data sharing models on willingness to participate in biobank research was estimated with a (survey weighted) three-level multinomial logistic regression (probably not/definitely not; not sure; yes probably/yes definitely) with linearized covariance estimates of uncertainty. For ease of exposition, all combined estimates (across multiply imputated datasets within a site and then across sites) were transformed and are reported as probabilities (or percentages). Comparisons among data sharing and consent models were performed via a Wald test from an ordinal logistic regression, proportional odds model. Similar methods were applied to estimate the impact of consent and data sharing models on each of the three attitudinal constructs (perceived benefits, concerns, and information needs).

To identify demographic and other characteristics associated with willingness to participate in biobank research, willingness was dichotomized (yes = agree/strongly agree; no = not sure/ disagree/strongly disagree) and was regressed on covariates using unadjusted (marginal) and adjusted logistic regression analyses. Adjusted models were fitted hierarchically using socio-demographic variables first; adding trust and privacy items second; and adding the attitudinal constructs third. Unadjusted estimates were summarized with percentages, and adjusted estimates of covariates associations with willingness to participate were summarized with odds ratios and associated 95% confidence intervals. Sub-domain analyses were performed to quantify the extent to which the relationship between survey type and willingness differed across socio-demographic variables. There was little to

Table 1. Sociodemograph	nic and Health Characteristics		-						
	Broad-Con	trolled	Broad-Op		Tiered-Cor	trolled	Overall		
	N	%	N	%	N	%	N	%	
Fotal	4,405	34%	4,371	34%	4,224	32%	13,000	100%	
Sex									
Female	2,734	63%	2,739	64%	2,601	63%	8,074	63%	
Male	1,583	37%	1,561	36%	1,557	37%	4,701	37%	
Age									
18-35 years	1,058	25%	1,023	24%	1,030	25%	3,111	25%	
36–50 years	1,364	32%	1,339	32%	1,317	32%	4,020	32%	
51–64 years	1,019	24%	1,042	25%	942	23%	3,003	24%	
65+ years	823	19%	822	19%	790	19%	2,435	19%	
Race									
White	2,197	51%	2,202	52%	2,122	52%	6,521	51%	
Asian	746	17%	718	17%	742	18%	2,206	17%	
Black or African American	506	12%	501	12%	476	12%	1,483	12%	
Other	438	10%	405	9%	385	9%	1,228	10%	
American Indian or Alaska Native	223	5%	245	6%	221	5%	689	5%	
More than one race	148	3%	155	4%	119	3%	422	3%	
Native Hawaiian or Pacific slander	45	1%	49	1%	47	1%	141	1%	
Ethnicity									
Latino	785	18%	758	18%	725	18%	2,268	18%	
Not Hispanic/Latino	3,507	82%	3,476	82%	3,365	82%	10,348	82%	
Educational Attainment									
Up to some high school (grades 9–12)	328	8%	279	7%	282	7%	889	7%	
High school graduate or GED	459	11%	465	11%	471	12%	1,395	11%	
Some college	1,026	24%	1,060	25%	965	24%	3,051	24%	
Bachelors degree or equivalent	1,180	28%	1,166	28%	1,132	28%	3,478	28%	
Masters degree or equivalent	767	18%	778	19%	772	19%	2,317	19%	
PhD, MD, JD, or equivalent	452	11%	438	10%	443	11%	1,333	11%	
Annual Household Incom	e								
Less than \$30,000	902	22%	915	23%	889	23%	2,706	23%	
\$30,000-\$60,000	838	21%	847	21%	778	20%	2,463	21%	
\$60,000-\$90,000	599	15%	644	16%	650	17%	1,893	16%	
\$90,000-\$150,000	852	21%	781	19%	785	20%	2,418	20%	
More than \$150,000	864	21%	866	21%	804	21%	2,534	21%	
Fotal Number of People in	n Household								
l	551	13%	584	14%	498	12%	1,633	13%	
2	1,281	30%	1,316	31%	1,260	31%	3,857	30%	

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	Broad-Controlled			Broad-Open		Tiered-Controlled		Querell	
							Overall		
	N	%	N	%	N	%	N	%	
3	826	19%	805	19%	758	18%	2,389	19%	
4 or more	1,623	38%	1,550	36%	1,604	39%	4,777	38%	
Poverty <sup>a</sup>									
Below the poverty line	586	15%	615	15%	590	15%	1,791	15%	
Not below the poverty ine	3,422	85%	3,391	85%	3,273	85%	10,086	85%	
Work Situation									
Working	2,313	53%	2,288	53%	2,233	54%	6,834	53%	
Retired	796	18%	805	19%	785	19%	2,386	19%	
Disabled or unemployed	496	11%	493	11%	471	11%	1,460	11%	
Other	741	17%	725	17%	679	16%	2,145	17%	
Healthcare Insurance									
Private insurance	3,061	71%	3,011	71%	2,948	71%	9,020	71%	
Public insurance	1,051	24%	1,065	25%	1,003	24%	3,119	25%	
Other type of insurance	102	2%	98	2%	91	2%	291	2%	
No insurance	87	2%	82	2%	94	2%	263	2%	
Rurality (from Census-lev	vel Data)								
Suburban or urban	2,549	58%	2,530	58%	2,427	57%	7,506	58%	
Rural	1,856	42%	1,841	42%	1,797	43%	5,494	42%	
Marital Status									
Married, living with someone	2,696	63%	2,701	64%	2,630	64%	8,027	64%	
Not married, living with someone	352	8%	333	8%	350	9%	1,035	8%	
Not married, not living with someone	1,201	28%	1,164	28%	1,112	27%	3,477	28%	
Number of Children									
No children	862	20%	850	20%	838	21%	2,550	20%	
One or more child	3,398	80%	3,384	80%	3,246	79%	10,028	80%	
Parent of Child Less than	18 yrs of Age								
No	2,508	57%	2,480	57%	2,344	55%	7,332	56%	
Yes	1,897	43%	1,891	43%	1,880	45%	5,668	44%	
Religiosity									
Not at all religious	615	14%	603	14%	591	14%	1,809	14%	
Not very religious	684	16%	660	15%	660	16%	2,004	16%	
omewhat religious	1,881	44%	1,836	43%	1,827	44%	5,544	44%	
/ery religious	1,131	26%	1,172	27%	1,057	26%	3,360	26%	
Self-Rated Health									
Excellent	544	13%	558	13%	501	12%	1,603	13%	
Very good	1,364	31%	1,345	31%	1,287	31%	3,996	31%	
Good	1,606		,		,		-,		

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	Broad-Con	Broad-Controlled		Broad-Open		Tiered-Controlled		
	N	%	N	%	N	%	N	%
Fair	659	15%	660	15%	660	16%	1,979	15%
Poor	168	4%	151	4%	133	3%	452	4%
Diagnosis of a G	enetic Disorder							
No	3,795	93%	3,783	95%	3,664	94%	11,242	94%
Yes	264	7%	218	5%	248	6%	730	6%

Note: Observed frequencies and percentages are reported ignoring sampling design. Pearson's chi-square tests were performed to assess differences between consent and data sharing models and each characteristic; no differences were detected and thus for brevity test summaries were omitted, but are available from the authors.

<sup>a</sup>Federal poverty level guidelines were used to assign poverty status and are a function of income and number of individuals within a household (below poverty line = 1 if income < number in household\*4,160+11,770) (Department of Health and Human Services).<sup>53</sup> Categorized income levels were collected in the survey and thus interval midpoints were used as a proxy for income in the threshold formula.

no evidence to suggest that such interactions existed (not shown). Responses to the individual attitudinal items were described, and 95% confidence intervals were computed.

Multiple imputation was conducted within each site to account for item non-response, which ranged from less than 1% to 5% for all key variables except income (8%). We used socio-demographic variables, biobank participation willingness, attitudinal constructs, and deciles of post-stratified weights to impute all missing data.<sup>43</sup> Ten complete imputation datasets were created for each site. Survey weighted regression analyses were performed on each complete dataset and combined using the standard "Rubin's rules."<sup>44</sup> For every analysis, site-specific estimates were then combined to summarize characteristics of the entire eMERGE Network using multivariate random-effect, meta-analytic methods.<sup>45</sup> All analyses were performed using R version 3.2.2 (R Project for Statistical Computing) and Stata Version 14 (StataCorp).

# Results

# **Participant Characteristics**

# Socio-demographics

Of 90,000 surveys mailed, 7,672 individuals were ineligible due to invalid address, death, or incapacity, and 681 refused to participate. Of the 82,328 eligible individuals, exactly 13,000 responded (AAPOR reponse rate 15.8%). Among responders, 11,712 completed the paper (91.9%) and 1,288 the online (9.9%) survey. Sixty-three percent of participants were female; 51% self-identified as white; 18% as Hispanic; 42% had less than a Bachelors degree; and 44% had an annual household income of \$60,000 or less (Table 1). There were no sociodemographic differences among participants receiving each of the three scenarios, indicating randomization was successful.

# **Trust and Privacy**

Ninety percent of participants agreed health information privacy was important to them; 64% agreed that they worried about the privacy of their health information. Two thirds agreed that they trusted their healthcare system (64%) and medical researchers (61%). There were no differences in participants' trust and privacy among the three biobank scenario groups (Table 2).

# Willingness Compared between Scenario Groups

Overall, 66% (95% CI: 63%–69%) of participants stated that they would be willing to participate in the biobank described to them (Table 3). Willingness did not differ between broad and tiered consent models (68% versus 66%,  $\chi^2 = 1.07$ , p = 0.30). Willingness was slightly higher among participants presented with a controlled rather than an open data sharing model, although the difference was not large in absolute terms (68% versus 65%, respectively,  $\chi^2 = 4.48$ , p = 0.03).

## Attitudes Compared between Scenario Groups

Mean attitude scores (where 1 indicates low, 5 indicates high) were 3.85 for perceived benefits, 3.11 for concerns, and 3.95 for information needs overall. Mean scores did not differ between experimental conditions (see Table 3).

# Associations between Willingness and Participant Characteristics

Because patterns of associations between socio-demographic variables and willingness were the same within each of the consent and data sharing conditions separately, and because willingness did not differ at the 0.001 level between groups, all subsequent analyses were conducted on the sample as a whole.

The following participant characteristics were independently associated with willingness to participate before attitudes were entered into the model: race (as selfreported by the respondent in the survey), education, religiosity, and trust and privacy concerns (Table 4). Black or African American participants expressed the lowest levels (56%) and white participants the highest levels (70%) of willingness to participate (OR 0.59, 95% CI: 0.47 to 0.76). Participants who reported education "up to some high school" were less willing to participate (51%) than participants with doctoral training (76%) (OR 0.47, 95% CI: 0.33 to 0.67). "Very religious" participants were less willing to participate (63%) than "not at all religious" participants (73%) (OR 0.68, 95% CI: 0.54 to 0.85). Participants with lower levels of trust in medical researchers

	Broad-Con	trolled	Broad-O	Broad-Open		ntrolled	Overall	
	N	%	N	%	N	%	N	%
Privacy: Health Information	n Privacy Is I	mportant to N	Me					
Disagree or strongly disagree	117	3%	96	2%	100	2%	313	2%
Neither agree nor disagree	332	8%	327	8%	344	8%	1,003	8%
Agree or strongly agree	3,861	90%	3,850	90%	3,686	89%	11,397	90%
Privacy: I Worry about the	Privacy of My	y Health Infor	mation					
Disagree or strongly disagree	705	16%	671	16%	678	16%	2,054	16%
Neither agree nor disagree	856	20%	822	19%	838	20%	2,516	20%
Agree or strongly agree	2,745	64%	2,783	65%	2,607	63%	8,135	64%
Frust: I Trust my Healthcar	e System							
Disagree or strongly disagree	522	12%	499	12%	471	11%	1,492	12%
Neither agree nor disagree	1,018	24%	1,049	25%	1,021	25%	3,088	24%
Agree or strongly agree	2,778	64%	2,726	64%	2,637	64%	8,141	64%
Trust: I Trust Medical Resea	rchers							
Disagree or strongly disagree	301	7%	325	8%	279	7%	905	7%
Neither agree nor disagree	1,336	31%	1,362	32%	1,306	32%	4,004	32%
Agree or strongly agree	2,648	62%	2,565	60%	2,535	62%	7,748	61%

Observed frequencies and percentages are reported ignoring sampling design. Pearson's chi-square tests were performed to assess differences between consent and data sharing models and each characteristic; no differences were detected and thus for brevity test summaries were omitted, but are available from the authors.

and/or their healthcare system, those who felt more strongly that the privacy of their health information was important, and those more worried about the privacy of their health information were less willing to participate.

When attitudes toward the biobank were entered into the model, each of the three composite scale variables was independently associated with willingness: participants were more willing to participate if they perceived more benefits, had fewer concerns, and had fewer information needs (Table 4). In this model, education and religiosity remained associated with willingness, but race, trust, and privacy concerns did not.

### Benefits, Concerns, and Information Needs

The most endorsed benefit in the sample overall was "I would feel that I was helping future generations" (84%, 81%–87%) and the least endorsed benefit was "I would feel that taking part could help me personally" (44%, 40%–47%). The most endorsed concern was "I would worry about my privacy" (51%, 47%–55%) and the least endorsed concern was "I would worry that someone might make money using my health information" (36%, 33%–39%). The most endorsed information need about biobank governance was "I would want to know what would happen if a researcher misused the health information in the biobank" (86%, 84%–87%) and the least endorsed information need

about biobank governance was "I would want to know if my health information might be used by drug companies that make money" (59%, 56%–61%) (Table 5).

# Discussion

This is the largest survey of patients' attitudes toward participating in biobank research to date. In this study, we found no evidence to support the hypothesis that asking potential biobank participants to provide broad consent or permit open data sharing would lead to less willingness to participate than asking them to provide tiered consent or permit controlled data sharing. Models of consent and data sharing had limited relevance to participants' decision making when they were asked to make a decision about whether to participate in the single biobank scenario presented to them. These findings are consistent with previous research reporting that overall acceptance of broad consent is similar to that of specific or tiered consent, although a number of factors may influence this preference.<sup>23–25</sup> Our use of an experimental design and randomization means participants were presented with a decision that was closer to the real world than previous studies that have given participants choices and asked which consent model they preferred. Individuals may have pre-existing global views regarding

	Bioban	k Consent an	d Data S	haring Mod	el					
	Broad- (BC)	Controlled	Broad (BO)	Open	Tiered- (TC)	Controlled	All			
	N	%	N	%	N	%	N	%	BC versus BO	BC versus TC
Primary Outcome										
Willingness to Parti	cipate ir	n a Biobank								
No definitely not / Probably not	513	12 (10,14)	611	15 (13,18)	487	12 (9,15)	1,611	13 (12,15)	$X_1^2 = 4.48, p = 0.03$	$X_1^2 = 1.07,$ p = 0.30
Not sure	853	20 (17,22)	913	20 (17,23)	853	22 (19,25)	2,619	20 (19,22)		
Yes probably / Yes definitely	2,880	68 (65,72)	2,702	65 (61,69)	2,758	66 (62,71)	8,340	66 (63,69)		
Secondary Outcome	S									
Perceived Benefits										
Low (1.0–2.5)	143	4 (3,5)	147	4 (3,5)	146	3 (2,5)	436	4 (3,5)	$X_1^2 = 0.70,$	$X_1^2 = 1.42,$
Intermediate (2.5–3.5)	887	21 (18,23)	926	22 (19,25)	934	23 (20,27)	2,747	22 (20,24)	p = 0.79	p = 0.23
High (3.5–5.0)	3,164	75 (72,78)	3,063	75 (71,78)	2,952	73 (69,77)	9,179	74 (72,77)		
Concerns										
Low (1.0–2.5)	1,321	34 (30,38)	1,231	32 (28,37)	1,305	34 (29,39)	3,857	33 (30,37)	$X_1^2 = 1.23,$	$X_1^2 = 0.06,$
Intermediate (2.5–3.5)	1,263	30 (28,33)	1,243	30 (27,33)	1,175	30 (28,32)	3,681	30 (29,32)	p = 0.27	p = 0.80
High (3.5–5.0)	1,520	36 (32,40)	1,636	38 (34,42)	1,479	36 (32,40)	4,635	36 (33,40)		
Information Needs										
Low (1.0–2.5)	176	5 (3,6)	179	6 (5,8)	190	5 (3,6)	545	5 (4,6)	$X_1^2 = 0.08,$	$X_1^2 = 1.30,$ p = 0.25
Intermediate (2.5–3.5)	831	22 (19,24)	695	19 (17,21)	767	19 (17,22)	2,293	20 (18,22)	p = 0.77	
High (3.5–5.0)	3,161	74 (71,77)	3,267	75 (72,78)	3,087	76 (72,80)	9,506	75 (72,77)		

Secondary outcomes were defined as the average of the recoded survey items (1 = No, definitely not, ..., 5 = Yes, definitely) that comprised the outcomes. Observed frequencies and survey-adjusted percentages (95% CI) are reported for all outcomes. Wald tests were performed to assess differences between data sharing models (broad-controlled [BC] versus broad-open [BO]) and between consent types (broad-controlled versus tiered-controlled).

participating in biobank research (i.e., they are generally open to, or generally against, participating), which are not swayed by the consent and data sharing models presented to them. It is also possible that many participants did not read the scenario carefully and were therefore responding to the general idea of participating in a biobank rather than the specific scenario presented to them. While this should certainly be considered a possible limitation of our findings, it is also possible that this lack of attention to detail simulates, in some ways, the attention that potential biobank participants give to analogous details in a real biobank consent document.

Our findings support the hypothesis that socio-demographic characteristics are associated with willingness to participate in biobank research. Consistent with previous research,<sup>46,47</sup> willingness to participate in a biobank was significantly lower among participants who self-identified as black or African American and those with lower levels of educational attainment. Although religiosity is difficult to assess, participants who self-identified as more religious on this simple measure were less willing to participate. Little research has previously explored associations between religiosity and attitudes regarding biobank participation,<sup>48</sup> but other investigations have shown religiosity is associated with negative perceptions of the value of science and technology.<sup>49–52</sup> Our findings support previous indications that certain socio-demographic groups will require greater efforts to ensure participation in large research initiatives going forward. Our results have implications particularly for biobanks such as the PMI that plan to rely on recruitment of volunteers rather than selection to represent the population. Unless there is an attempt to over-enroll underrepresented groups, as we did in our survey study, large studies like the PMI may end up with cohort samples that do not adequately represent the US population.

We also found that, consistent with previous research,<sup>23,36</sup> willingness to participate in biobank research was lower among respondents with more concerns about privacy and lower levels of trust. When designing recruitment strategies, researchers and institutions may be able to address these trust and privacy concerns at a local level by building relationships with their communities, and at a national level by implementing new policies and public education and

Table 4. Univariate and Multivariate Associations between Consent and Data Sharing Models, Socio-demographics, Trust and PrivacyItems, and Attitudinal Constructs and Willingness to Participate in a Biobank

			Multivariate Models, OR (95% CI)			
Independent Variable	Percent (95% CI)	Socio-demographics	Socio-demographics, Trust, and Privacy	Socio-demographics, Trust Privacy, and Attitudes		
Consent and Data Sharing Model						
Broad-controlled	68 (65, 71)	1	1	1		
Broad-open	65 (62, 68)	0.84 (0.68, 1.03)	0.81 (0.66, 1.00) <sup>a</sup>	0.80 (0.63, 1.02)		
Tiered-controlled	66 (61, 70)	0.94 (0.76, 1.17)	0.93 (0.69, 1.24)	0.90 (0.66, 1.22)		
Sex						
Female	66 (63, 69)	1	1	1		
Male	67 (63, 71)	0.92 (0.76, 1.11)	0.87 (0.72, 1.07)	0.91 (0.73, 1.13)		
Age						
18-35 years	65 (61,70)	1.05 (0.81, 1.35)	0.92 (0.65, 1.30)	0.97 (0.70, 1.34)		
36–50 years	65 (61,68)	1	1	1		
51–64 years	66 (62,70)	1.06 (0.76, 1.46)	0.99 (0.64, 1.53)	0.91 (0.59, 1.40)		
65+ years	70 (65,75)	1.01 (0.63, 1.62)	0.80 (0.43, 1.50)	0.79 (0.39, 1.58)		
Race						
White	70 (67,74)	1	1	1		
Black or African American	56 (51,60)	0.59 (0.47, 0.76) <sup>a</sup>	0.68 (0.52, 0.88) <sup>a</sup>	0.74 (0.53, 1.04)		
Asian	60 (54,66)	0.62 (0.49, 0.76) <sup>a</sup>	0.67 (0.53, 0.84) <sup>a</sup>	0.79 (0.59, 1.04)		
American Indian or Alaska Native	57 (49,65)	0.70 (0.51, 0.95) <sup>a</sup>	0.78 (0.57, 1.05)	0.81 (0.57, 1.15)		
Other <sup>b</sup>	56 (49,63)	0.67 (0.49, 0.94) <sup>a</sup>	0.82 (0.46, 1.46)	0.89 (0.61, 1.31)		
More than one race	65 (56,73)	0.83 (0.54, 1.27)	0.90 (0.60, 1.35)	1.10 (0.67, 1.81)		
Ethnicity						
Latino	67 (64, 70)	1	1	1		
Not Hispanic/Latino	61 (55, 66)	0.94 (0.71, 1.24)	0.91 (0.59, 1.40)	0.89 (0.66, 1.21)		
Educational Attainment						
Up to some high school (grades 9–12)	51 (44, 57)	0.47 (0.33, 0.67) <sup>a</sup>	0.40 (0.26, 0.59) <sup>a</sup>	0.34 (0.21, 0.54) <sup>a</sup>		
High school graduate or GED	58 (53, 64)	0.63 (0.43, 0.93) <sup>a</sup>	0.60 (0.39, 0.90) <sup>a</sup>	0.52 (0.33, 0.84) <sup>a</sup>		
Some college	64 (60, 68)	0.78 (0.58, 1.04)	0.79 (0.56, 1.12)	0.62 (0.44, 0.88) <sup>a</sup>		
Bachelors degree or equivalent	70 (67, 73)	0.83 (0.60, 1.14)	0.83 (0.58, 1.18)	0.75 (0.52, 1.08)		
Masters degree or equivalent	73 (68, 77)	0.96 (0.73, 1.28)	0.96 (0.73, 1.28)	0.91 (0.64, 1.29)		
PhD, MD, JD, or equivalent	76 (70, 81)	1	1	1		
Annual Household Income						
Less than \$30,000	56 (52,60)	0.58 (0.42, 0.79) <sup>a</sup>	0.67 (0.46, 0.97) <sup>a</sup>	0.74 (0.48, 1.13)		
\$30,000-\$60,000	63 (58,67)	0.66 (0.43, 0.93) <sup>a</sup>	0.71 (0.52, 0.96) <sup>a</sup>	0.81 (0.57, 1.13)		
\$60,000-\$90,000	68 (64,72)	0.84 (0.63, 1.13)	0.89 (0.63, 1.25)	0.99 (0.68, 1.43)		
\$90,000-\$150,000	74 (70,77)	1.12 (0.83, 1.50)	1.11 (0.85, 1.46)	1.15 (0.83, 1.61)		
More than \$150,000	73 (68,77)	1	1	1		
Total Number of People in Househo	old					
1	84 (66, 94)	2.23 (0.68, 7.32)	2.77 (0.29, 26.80)	2.08 (0.38, 11.48)		
2	68 (63, 72)	1.10 (0.87, 1.40)	1.10 (0.79, 1.53)	1.12 (0.79, 1.58)		
3	66 (62,69)	1.01 (0.81, 1.25)	1.09 (0.83, 1.43)	1.10 (0.85, 1.43)		

			Multivariate Models, O	R (95% CI)
Independent Variable	Percent (95% CI)	Socio-demographics	Socio-demographics, Trust, and Privacy	Socio-demographics, Trust Privacy, and Attitudes
4 or more	65 (62,68)	1	1	1
Work Situation				
Working	67 (64,70)	1	1	1
Retired	69 (65,73)	1.24 (0.94, 1.64)	1.22 (0.90, 1.66)	1.10 (0.73, 1.66)
Disabled / Unemployed	60 (55,65)	0.90 (0.70, 1.16)	0.99 (0.77, 1.28)	0.98 (0.70, 1.37)
Other	64 (59,68)	0.97 (0.75, 1.26)	1.00 (0.65, 1.53)	0.95 (0.66, 1.37)
Healthcare Insurance				
Private insurance	67 (64,71)	1	1	1
Public insurance	64 (60,69)	1.45 (1.04, 2.03) <sup>a</sup>	1.33 (0.96, 1.84)	1.37 (0.89, 2.12)
Other type of insurance	59 (49,68)	1.05 (0.65, 1.68)	0.95 (0.57, 1.58)	1.09 (0.63, 1.87)
No insurance	63 (54,71)	1.79 (1.08, 2.96) <sup>a</sup>	1.79 (1.00, 3.23) <sup>a</sup>	1.65 (0.81, 3.35)
Rurality (from Census-level Data)				
Suburban or urban	66 (63,70)	1	1	1
Rural	67 (64,71)	0.94 (0.79, 1.11)	0.95 (0.80, 1.13)	0.99 (0.77, 1.27)
Marital Status				
Married, living with someone	69 (65,72)	1	1	1
Not married, living with someone	68 (63,72)	1.08 (0.79, 1.47)	1.08 (0.76, 1.54)	0.95 (0.67, 1.35)
Not married, not living with someone	61 (56,66)	0.91 (0.71, 1.17)	0.88 (0.66, 1.19)	0.86 (0.60, 1.25)
Religiosity				
Not at all religious	73 (69,77)	1	1	1
Not very religious	71 (67,74)	0.89 (0.68, 1.16)	0.85 (0.64, 1.13)	0.68 (0.48, 0.97) <sup>a</sup>
Somewhat religious	65 (61,69)	0.74 (0.59, 0.93) <sup>a</sup>	0.73 (0.56, 0.96) <sup>a</sup>	$0.62 (0.46, 0.83)^{a}$
Very religious	63 (59,66)	0.68 (0.54, 0.85) <sup>a</sup>	0.68 (0.53, 0.88) <sup>a</sup>	0.59 (0.44, 0.80) <sup>a</sup>
I Trust My Healthcare System				
Disagree	48 (43,54)	-	0.73(0.55, 0.98) <sup>a</sup>	1.02 (0.70, 1.47)
Neither	56 (53,60)	_	0.81 (0.60, 1.08)	0.95 (0.69, 1.29)
Agree	74 (71,77)	_	1	1
I Trust Medical Researchers				
Disagree	34 (29,41)	-	0.18 (0.13, 0.25) <sup>a</sup>	0.52 (0.36, 0.75) <sup>a</sup>
Neither	52 (49,55)	_	0.38 (0.30, 0.49) <sup>a</sup>	0.61 (0.47, 0.80) <sup>a</sup>
Agree	78 (75,80)	_	1	1
Health Information Privacy Is Imp	ortant to Me			
Disagree	76 (67,83)	-	1.10 (0.63, 1.94)	1.18 (0.80, 2.25)
Neither	80 (75,84)	-	1.47 (1.02, 2.13) <sup>a</sup>	1.14 (0.80, 1.64)
Agree	65 (61,68)	-	1	1
I Worry about the Privacy of My He	ealth Informat	tion		
Disagree	87 (85,89)	-	3.64 (2.63, 5.02) <sup>a</sup>	1.44 (1.01, 2.07) <sup>a</sup>
Neither	77 (74,80)	_	2.15 (1.64, 2.83) <sup>a</sup>	1.10 (0.81, 1.49)
Agree	57 (53,61)	_	1	1

(Continued on next page)

#### Table 4. Continued Multivariate Models, OR (95% CI) Socio-demographics, Trust, Percent Socio-demographics, Independent Variable (95% CI) Socio-demographics Trust, and Privacy Privacy, and Attitudes Perceived Benefits of Participating in a Biobank Low (1.0-2.5) 6 (3, 10) 1 Intermediate (2.5-3.5) 32 (29,36) \_ 8.10 (3.47, 18.90)<sup>a</sup> High (3.5-5.0) 80 (77,82) \_ 62.21 (28.72, 134.75)<sup>a</sup> **Concerns about Participating in a Biobank** Low (1.0-2.5) 91 (90,93) 1 \_ Intermediate (2.5-3.5) 76 (72,80) 0.32 (0.24, 0.43)<sup>a</sup> \_ $0.07 (0.05, 0.10)^{a}$ High (3.5-5.0) 40 (37.43) \_ **Information Needs about Participating in a Biobank** Low (1.0-2.5) 76 (68,82) \_ 1 Intermediate (2.5-3.5) 78 (73,82) 1.36 (0.88, 2.09) \_ \_ High (3.5-5.0) 62 (59.65) $1.62(1.02, 2.58)^{a}$

Survey-adjusted logistic regression estimates from the univariate models have been transformed to percentages (95% CI) while odds ratios (OR, 95% CI) summarize multivariate models.

<sup>a</sup>Significant differences at the 0.05 level.

<sup>b</sup>Due to small cell counts, Native Hawaiian/Pacific Islanders were grouped with the Other racial category.

engagement strategies. We also found, however, that these associations between privacy, trust, and willingness were no longer statistically significant after attitudes toward biobank research (benefits, concerns, information needs about governance) were added in to the model. This further suggests that outreach and engagement conveying the benefits of biobank research, and addressing concerns and information needs, may be important and achievable strategies to including more diverse populations in these research efforts.

We found that participants were more concerned about some risks than others and wanted to know more about some aspects of governance than others. These findings may be of particular value to researchers, institutions, and organizations involved in developing public education and information materials about biobanks, as they shed valuable light on what potential participants want to know about research.

Limitations include a low response rate. Although this was not unexpected given our recruitment method and efforts to oversample populations typically less willing to participate in research, we cannot know how much opinions of nonresponders would differ. However, it seems unlikely that nonresponders would be *more* willing to enroll in biobanks. Our study also relied on participants' self-reported intentions and hypothetical scenarios, rather than actual behavior. It is also possible that participants did not read all of the hypothetical scenario, and so may not have appreciated the detail regarding the consent and data sharing model. They did, however, have opinions about other aspects of the proposal that suggests substantial engagement with the survey. The limitations need to be weighed against the study's strengths, which include broad geographical and diverse institutional coverage, a rigorous sampling strategy, and experimental design.

In conclusion, the results from this study suggest that biobanks using broad consent may not be less successful in recruiting participants than if they use more specific consent approaches. Open data sharing may be almost as acceptable to participants as controlled data sharing. Some socio-demographic groups differ in their willingness to participate in biobank research. Individuals discriminate between different positive and negative aspects of biobank participation and feel more strongly about knowing about some aspects of biobank governance than others. Targeted interventions designed to recruit underrepresented groups, to make biobank information easier to understand, and to address individuals' specific attitudes about participating in a biobank may help increase acceptance of broad consent and open data sharing in biobank research. These findings may be of use to biobank investigators concerned with how biobanks are governed and to policy makers working to revise regulations on the protection of human research subjects.

### Supplemental Data

Supplemental Data include three tables and can be found with this article online at http://dx.doi.org/10.1016/j.ajhg.2017.01.021.

#### Acknowledgments

We would like to acknowledge the work of the following: Melissa Basford, Meckenzie Behr, Jess Behrens, Laura Beskow, Ariel Chandler, Beth Chau, Rosetta Chiavacci, Kurt Christensen, Beth Cobb, Natalia Connolly, Stephanie Devaney, Joe DeWalle, Steve

Table 5. Attitudes toward Participating in a Biobank	Aanoo on Stananaka Arman	
	Agree or Strongly Agree	
Attitudes	N	Percent (95% Cl)
Perceived Benefits of Participating in a Biobank		
I would feel that I was helping future generations.	10,773	84 (81, 87)
would feel that taking part could lead to better medical treatments.	10,564	83 (80, 85)
would feel that taking part would help loctors where I get my medical care take better care of patients.	9,957	78 (75, 80)
would feel that taking part could help my amily.	8,139	65 (62, 67)
would feel that taking part could help me personally.	5,667	44 (40, 47)
Concerns about Participating in a Biobank		
would worry about my privacy.	6,578	51 (47, 55)
would worry about my medical record being hared.	5,903	45 (42, 49)
would worry about how researchers would use my health information.	5,404	41 (38, 45)
would worry about my genetic information being shared.	4,866	38 (34, 41)
would worry that some research would be lone that I did not want to take part in.	4,713	37 (34, 40)
would worry that someone might make noney using my health information.	4,856	36 (33, 39)
nformation Needs Regarding Governance of a Biobank		
would want to know what would happen if a researcher misused the health information n the biobank.	11,055	86 (84, 87)
would want to know what kind of xnowledge would result from the use of my nealth information.	10,827	84 (82, 86)
would want to know who makes sure that ny health information is used in the right way.	10,752	84 (81, 86)
would want to know if my health nformation might be used by insurance ompanies.	10,160	79 (77, 81)
would want to know the types of research ny health information would be used for.	9,748	74 (71, 77)
would want to know who runs the biobank.	9,500	73 (71, 75)
would want to know how the biobank overs costs.	7,716	60 (57, 62)
would want to know if my health nformation might be used by drug ompanies that make money.	7,625	59 (56, 61)

Each item was dichotomized (1 = agree or strongly agree, 0 = otherwise) and the observed frequencies and ordered survey-adjusted percentages (95% CI) are reported. Differences were not detected between data sharing and consent models on the construct level (Table 3) and thus only overall summaries are provided.

Ellis, Alexander Fiksdal, John Harley, Diana Harris, Paul Hitz, Yolanda Keppel, Nicole Lockhart, Keith Marsolo, Catherine MarxKate Nowakowski, Jen Pacheco, Josh Pankratz, Lisa Price, Michelle Ramos, Sarah Stallings, Allise Taran, Matt Verkemp, Gordon Willis, and Sonja Ziniel. The CERC Survey project within the eMERGE Network was initiated and funded by NHGRI with additional funding by the NIH Office of the Director through the following grants: U01HG006828 (Cincinnati Children's Hospital Medical Center/Boston Children's Hospital), U01HG006830 (Children's

Hospital of Philadelphia), UOIHG006389 (Essentia Institute of Rural Health, Marshfield Clinic Research Foundation, and Pennsylvania State University), U01HG006382 (Geisinger Clinic), U01HG006375 (Group Health Cooperative/University of Washington), 3U01HG006379 (Mayo Clinic), U01HG006380 (Icahn School of Medicine at Mount Sinai), 3U01-HG006388 (Northwestern University), U01HG006378 (Vanderbilt University Medical Center), and 3U01HG0006385 (Vanderbilt University Medical Center serving as the Coordinating Center).

Received: September 23, 2016 Accepted: January 11, 2017 Published: February 9, 2017

### Web Resources

- CDC, BRFSS Questionnaires, https://www.cdc.gov/brfss/ questionnaires/
- eMerge, https://emerge.mc.vanderbilt.edu/projects/emerge-cercsurvey-2/

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The American Journal of Human Genetics, Volume 100

# **Supplemental Data**

# Public Attitudes toward Consent and Data Sharing

# in Biobank Research: A Large Multi-site

# **Experimental Survey in the US**

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	N <sup>1</sup>	Sampled	Sampled + Checks <sup>2</sup>	Responded	Response Rate <sup>3</sup>
All					
	2,389,162	90,000	82,239	13,000	15.8
Population Type					
Adult	1,787,295	58,500	54,850	9,185	16.7
Pediatric	601,867	31,500	27,389	3,815	13.9
Centers					
Boston Children's Hospital	140,304	9,000	6,935	962	13.9
Cincinnati Children's Hospital	143,994	9,000	7,941	1,236	15.6
Children's Hospital of Philadelphia	209,755	9,000	8,439	1,039	12.3
Essentia Institute of Rural Health	243,092	4,500	4,129	680	16.5
Group Health Cooperative	217,959	9,000	8,973	1,429	15.9
Geisinger Health System	356,488	9,000	8,142	1,136	14.0
Mayo Clinic	136,391	9,000	8,443	1,983	23.5
Marshfield Clinic	134,212	4,500	4,280	811	18.9
Icahn School of Medicine at Mount Sinai	162,927	9,000	8,280	1,079	13.0
Northwestern University	206,554	9,000	8,521	1,380	16.2
Vanderbilt University	329,672	4,500	4,082	687	16.8
Vanderbilt Children's Hospital	107,814	4,500	4,074	578	14.2

**Table S1:** Population, sample and response frequencies across the eMERGE Network and by participating institution. Response rates were calculated as the proportion responding among sampled population meeting consistency checks.

<sup>1</sup> N indicates the number of eligible subjects that met the inclusion criteria. Patients with at least one inpatient or outpatient clinic visit at one of the participating sites confirmed to be between October 1, 2013 and September 1, 2014 were originally eligible. However, as is well known, electronic health record (EHR) data have a number of challenges and so data cleaning measures were taken that included: removing patients missing or with an invalid medical record number, removing duplicate patient identifiers, removing those with missing a household identifier (a center-specific anonymized address), removing those with a household identifier in common with at least 20 other patients (likely a clinic address and possibly a homeless shelter), and removing those with an address that could not be geocoded. Further, patients known to have died or were on a 'do not contact' list were excluded. Patients with missing age or gender and those with an age conflict (e.g., <18 years at an adult center, or ≥18 years at a pediatric center) were removed. Finally, we randomly selected one patient per household to be eligible for inclusion.

<sup>2</sup> Multiple surveys/reminders were sent to initially sampled subjects (if needed) and subjects were excluded if they did not have a valid address, were not currently living or previously participated in the pilot phase of the survey.

<sup>3</sup> Response rate = Responded/Sampled+Checks.

	RS, %	<b>MES</b> <sup>1</sup> , %
Age Group		
<12, <35	34	48
>=12, >=35	66	52
Gender		
Female	56	52
Male	44	48
Race		
White	83	34
Black	9	20
Asian	2	16
American Indian/Alaska Native	1	5
Native Hawaiian/Pacific Islander	<1	4
Other	5	21
Ethnicity		
Not Hispanic/Latino	95	69
Hispanic/Latino	5	31
Education		
<hs< td=""><td>1</td><td>13</td></hs<>	1	13
HS + Some college	76	53
>= Bachelors	23	35
Rurality		
Rural	43	37
Suburban/Urban	57	63

**Table S2:** Marginal distributions of stratification variables under random (RS) and maximum entropy sampling (MES) of 90,000 participants.

<sup>1</sup> Maximum entropy sampling was performed separately within each center to identify the number of individuals to sample from each stratum such that the Shannon entropy in demographic characteristics in the sample was maximized.<sup>1; 2</sup> This corresponds to, to the extent possible, minimizing the stratum to stratum variation in the number of subjects sampled across the possible 288 strata. It is worth noting that there were strata that were empty. Within each stratum, we then randomly sampled patients for inclusion into the study with complete (or non-imputed) stratification information and augmented with those subjects with imputed data when necessary. We recognize that the precise definition of the population and the sampling frame are imperfect. There are a number of reasons that include but are not limited to: 1) incomplete demographic data EHR data that varied from site to site, 2) misclassified EHR data: the extent of the misclassification is observable for those who responded to the survey but are not observable for those who did not; and 3) at all pediatric sites, stratum defining demographic data correspond to children even though it was the parents who answered the survey. We must therefore describe respondents as the 'population' of parents of children at a participating site. We further recognize that mothers or female guardians tended to respond to the surveys far more often than fathers or male guardians. We are currently investigating the impact of misclassification of survey stratification variables on regression estimates and associated inferences.

**Table S3:** Weight Truncation Sensitivity Analysis. Five trimming and redistribution rules were applied to post-stratified weights and used in separate survey-weighted regression models between biobank willingness and data-sharing and consent model. Regression coefficients and 95% linearized confidence intervals were transformed to the probability (or percentage) scale. Wald tests were used to evaluate data-sharing (broad-controlled, BC vs broad-open, BO) and consent (BC vs tiered-controlled, TC) comparisons.<sup>1</sup>

	Broad-	Broad-	Tiered-	All	BC vs BO	BC vs TC
	controlled (BC)	open (BO)	controlled (TC)		X <sup>2</sup> <sub>1</sub> , p	X <sup>2</sup> <sub>1</sub> , p
No trimming						
	12 (9,15)	14 (11,18)	11 (8,16)	13 (11,15)	2.08, 0.150	0.83, 0.362
	19 (16,24)	19 (14,25)	22 (18,25)	20 (17,23)		
	69 (63,74)	67 (61,73)	67 (62,71)	68 (64,71)		
95 <sup>th</sup> Quantile						
	12 (10,14)	14 (12,17)	12 (9,15)	13 (11,15)	4.40, 0.036	1.63, 0.202
	19 (16,22)	20 (17,23)	22 (19,25)	20 (18,22)		
	69 (65,73)	66 (62,70)	66 (61,71)	67 (64,70)		
Maximum of median + 6*interguartile						
range and the 90 <sup>th</sup> quantile						
	12 (10,14)	15 (13,18)	12 (9,15)	13 (12,15)	4.48, 0.034	1.07, 0.202
	20 (17,22)	21 (17,23)	22 (19,25)	20 (19,22)		
	68 (65,72)	65 (61,69)	66 (62,71)	66 (63,69)		
Median + 6*interquartile range						
<u> </u>	13 (11,15)	15 (13,18)	12 (10,15)	13 (12,15)	7.07, 0.008	0.67, 0.413
	20 (18,22)	21 (19,24)	22 (19,24)	21 (19,23)		
	68 (64,71)	64 (59,68)	66 (61,70)	66 (62,69)		
Median + 4*interquartile range						
<u> </u>	13 (11,15)	15 (13,18)	12 (10,15)	14 (12,15)	7.93, 0.005	0.37,0.542
	20 (18,23)	21 (19,24)	22 (19,24)	21 (19,23)		
	67 (64,71)	63 (59,67)	66 (62,70)	65 (62,69)		

<sup>1</sup> To account for the complex sampling design and the effects of survey non-response, post-stratified survey weights were computed. Because the design sought to enrich the sample with minority populations, sampling probabilities differed dramatically, and therefore there was substantial sampling weight variability within and among sites. We therefore conducted a weight trimming and redistribution scheme that was partly described in the Methods section. Even though weight trimming, we conducted a sensitivity analysis to examine the impact of the trimming approach on the results from the primary analysis. Five trimming rules were considered: 1) no trimming, 2) trimming at the 95th quantile, 3) trimming at the maximum of a) the median + 6\*interquartile range (IQR) and b) the 90th quantile, 4) trimming at the median + 6\*IQR, and 5) trimming at the median + 4\*IQR.<sup>3; 4</sup> These rules are ordered by the extent of total trimming in our data. For example, the range of trimmed weights using rule 2 was 1 to 3100, while the range of weights using rule 5 was 18 to 870. This Table summarizes the results of the marginal analysis of willingness (3-level; not willing, not sure, willing) and data-sharing and consent model each trimming rule. As can be seen, the trimming rule can indeed impact the statistical testing results if the 0.05 significance level is used. However, this is primarily due to sample size. Overall, the clinical conclusions remain largely unchanged, i.e., neither consent model nor data sharing model had a large impact on inclination to participate in a biobank.

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