Public attitudes towards consent and data sharing in biobank research: a large multi-site experimental survey in the US

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ABSTRACT

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; 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.[1] The proposed Precision Medicine Initiative (PMI) is one prominent example of a very large biobank created to improve understanding of human health and disease.[2; 3] 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 projects not yet conceived.[4] 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.[5]

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 stated that such consent can be obtained in a one-time, open-ended or 'broad' fashion.[6]

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

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.[14-18] 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,[19; 20] so that the move towards 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.[21] A recent systematic literature review[22] 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.[23-25] 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 underrepresent key demographic groups.[22]

We therefore conducted a large survey of attitudes towards 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.[26] 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 towards 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 towards, 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[26] 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: ≤35 years and >35 years; pediatric centers: ≤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 vs. 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 **Table S1** and **Table S2**. A thorough exposition of the sampling scheme, including how census data were utilized for the purpose of sampling, are provided in an upcoming journal 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.[27] 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.[28]

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.[22] A complete draft of the survey instrument content was tested and refined using cognitive interviews with 40 patients across six 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 1500 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.[29; 30] 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.[31] Self-rated health, an indicator of quality of life, was assessed using the widely-used single item from the SF-12.[32]

Trust and privacy Concern about privacy was assessed using two items.[33] Trust was assessed with two items.[34; 35]

Willingness to participate Willingness to participate in the hypothetical biobank described was assessed using a single item adapted from previous research.[25; 36]

Attitudes towards participating

Attitude items were either generated specifically for this study, or adapted from previous research.[24; 25; 37-40] 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[22] 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. Likert-style scales were used with 5 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.[41] To determine if 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 90th percentile of weights, or (2) the median+6*IQR, whichever was higher.[42; 43] 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 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.[44] Ten complete imputation data sets were created for each site. Survey weighted regression analyses were performed on each complete data set and combined using the standard 'Rubin's rules'.[45] For every analysis, site-specific estimates were then combined to summarize characteristics of the entire eMERGE Network using multivariate random-effect, meta-analytic methods.[46] 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% vs. 66%, χ^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% vs. 65% respectively, χ^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 .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 self-reported 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 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, 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%), 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%); 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%); 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 towards 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.[23-25] 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 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 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,[47; 48] 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,[49] but other investigations have shown religiosity is associated with negative perceptions of the value of science and technology.[50-

[53] 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 that plan to rely on recruitment of volunteers, such as the PMI, 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,[23; 37] 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 engagement strategies. We also found, however, that these associations between privacy, trust and willingness were no longer statistically significant after attitudes towards 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 which 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 includes three tables and supplemental references.

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Table 1. Sociodemographic and health characteristics of survey respondents by consent and data sharing model and across models

	Broad-controlled		Broad-open		Tiered-controlled		Overall	
	N	%	N	%	N	%	N	%
Total	4405	34%	4371	34%	4224	32%	13,000	100%
Sex								
Female	2734	63%	2739	64%	2601	63%	8074	63%
Male	1583	37%	1561	36%	1557	37%	4701	37%
Age								
18-35 years	1058	25%	1023	24%	1030	25%	3111	25%
36-50 years	1364	32%	1339	32%	1317	32%	4020	32%
51-64 years	1019	24%	1042	25%	942	23%	3003	24%
65+ years	823	19%	822	19%	790	19%	2435	19%
Race								
White	2197	51%	2202	52%	2122	52%	6521	51%
Asian	746	17%	718	17%	742	18%	2206	17%
Black or African American	506	12%	501	12%	476	12%	1483	12%
Other	438	10%	405	9%	385	9%	1228	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 Islander	45	1%	49	1%	47	1%	141	1%
Ethnicity								
Latino	785	18%	758	18%	725	18%	2268	18%
Not Hispanic/Latino	3507	82%	3476	82%	3365	82%	10348	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%	1395	11%
Some college	1026	24%	1060	25%	965	24%	3051	24%
Bachelors degree or equivalent	1180	28%	1166	28%	1132	28%	3478	28%
Masters degree or equivalent	767	18%	778	19%	772	19%	2317	19%
PhD / MD / JD or equivalent	452	11%	438	10%	443	11%	1333	11%
Annual household income								
Less than $30,000	902	22%	915	23%	889	23%	2706	23%
$30,000 - $60,000	838	21%	847	21%	778	20%	2463	21%
$60,000 - $90,000	599	15%	644	16%	650	17%	1893	16%
$90,000 to $150,000	852	21%	781	19%	785	20%	2418	20%
More than $150,000	864	21%	866	21%	804	21%	2534	21%
Total number of people in household								
1	551	13%	584	14%	498	12%	1633	13%
2	1281	30%	1316	31%	1260	31%	3857	30%
3	826	19%	805	19%	758	18%	2389	19%
4 or more	1623	38%	1550	36%	1604	39%	4777	38%
Poverty[a]								
Below the poverty line	586	15%	615	15%	590	15%	1791	15%
Not below the poverty line	3422	85%	3391	85%	3273	85%	10086	85%
Work situation								
Working	2313	53%	2288	53%	2233	54%	6834	53%
Retired	796	18%	805	19%	785	19%	2386	19%
Disabled / Unemployed	496	11%	493	11%	471	11%	1460	11%
Other	741	17%	725	17%	679	16%	2145	17%

	Broad-controlled		Broad-open		Tiered-controlled		Overall	
	N	%	N	%	N	%	N	%
Healthcare insurance								
Private insurance	3061	71%	3011	71%	2948	71%	9020	71%
Public insurance	1051	24%	1065	25%	1003	24%	3119	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-level data)								
Suburban / Urban	2549	58%	2530	58%	2427	57%	7506	58%
Rural	1856	42%	1841	42%	1797	43%	5494	42%
Marital status								
Married, living with someone	2696	63%	2701	64%	2630	64%	8027	64%
Not married, living with someone	352	8%	333	8%	350	9%	1035	8%
Not married, not living with someone	1201	28%	1164	28%	1112	27%	3477	28%
Number of children								
No children	862	20%	850	20%	838	21%	2550	20%
One or more child	3398	80%	3384	80%	3246	79%	10028	80%
Parent of child less than 18yrs of age								
No	2508	57%	2480	57%	2344	55%	7332	56%
Yes	1897	43%	1891	43%	1880	45%	5668	44%
Religiosity								
Not at all religious	615	14%	603	14%	591	14%	1809	14%
Not very religious	684	16%	660	15%	660	16%	2004	16%
Somewhat religious	1881	44%	1836	43%	1827	44%	5544	44%
Very religious	1131	26%	1172	27%	1057	26%	3360	26%
Self-rated health								
Excellent	544	13%	558	13%	501	12%	1603	13%
Very good	1364	31%	1345	31%	1287	31%	3996	31%
Good	1606	37%	1569	37%	1589	38%	4764	37%
Fair	659	15%	660	15%	660	16%	1979	15%
Poor	168	4%	151	4%	133	3%	452	4%
Diagnosis of a genetic disorder								
No	3795	93%	3783	95%	3664	94%	11242	94%
Yes	264	7%	218	5%	248	6%	730	6%

[a]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*4160+11770) (Department of Health and Human Services).[54] Categorized income levels were collected in the survey and thus interval midpoints were used as a proxy for income in the threshold formula.

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 available from the authors.

Table 2. Trust in the healthcare system, trust in medical researchers, and concerns about privacy of survey respondents by consent and data sharing model and across models

	Broad-controlled		Broad-open		Tiered-controlled		Overall	
	N	%	N	%	N	%	N	%
Privacy								
Health information privacy is important to me								
Disagree / Strongly disagree	117	3%	96	2%	100	2%	313	2%
Neither agree nor disagree	332	8%	327	8%	344	8%	1003	8%
Agree / Strongly agree	3861	90%	3850	90%	3686	89%	11397	90%
I worry about the privacy of my health information								
Disagree / Strongly disagree	705	16%	671	16%	678	16%	2054	16%
Neither agree nor disagree	856	20%	822	19%	838	20%	2516	20%
Agree / Strongly agree	2745	64%	2783	65%	2607	63%	8135	64%
Trust								
I trust my healthcare system								
Disagree / Strongly disagree	522	12%	499	12%	471	11%	1492	12%
Neither agree nor disagree	1018	24%	1049	25%	1021	25%	3088	24%
Agree / Strongly agree	2778	64%	2726	64%	2637	64%	8141	64%
I trust medical researchers								
Disagree / Strongly disagree	301	7%	325	8%	279	7%	905	7%
Neither agree nor disagree	1336	31%	1362	32%	1306	32%	4004	32%
Agree / Strongly agree	2648	62%	2565	60%	2535	62%	7748	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 available from the authors.

Table 3. Willingness and attitudes (composite perceived benefits, concerns, and information needs) towards participating in a biobank by consent and data sharing model and across models

	Biobank consent and data sharing model									
	Broad-controlled (BC)		**Broad-open (BO)**		**Tiered-controlled (TC)**		**All**		**BC vs BO**	**BC vs TC**
	N	%	N	%	N	%	N	%		
Primary Outcome										
Willingness to participate in a biobank										
No definitely not / Probably not	513	12 (10,14)	611	15 (13,18)	487	12 (9,15)	1611	13 (12,15)	X_1^2=4.48,	X_1^2=1.07,
Not sure	853	20 (17,22)	913	20 (17,23)	853	22 (19,25)	2619	20 (19,22)	p=0.03	p=0.30
Yes probably / Yes definitely	2880	68 (65,72)	2702	65 (61,69)	2758	66 (62,71)	8340	66 (63,69)		
Secondary Outcomes										
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)	2747	22 (20,24)	p=0.79	p=0.23
High (3.5-5.0)	3164	75 (72,78)	3063	75 (71,78)	2952	73 (69,77)	9179	74 (72,77)		
Concerns										
Low (1.0-2.5)	1321	34 (30,38)	1231	32 (28,37)	1305	34 (29,39)	3857	33 (30,37)	X_1^2=1.23,	X_1^2=0.06,
Intermediate (2.5-3.5)	1263	30 (28,33)	1243	30 (27,33)	1175	30 (28,32)	3681	30 (29,32)	p=0.27	p=0.80
High (3.5-5.0)	1520	36 (32,40)	1636	38 (34,42)	1479	36 (32,40)	4635	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,
Intermediate (2.5-3.5)	831	22 (19,24)	695	19 (17,21)	767	19 (17,22)	2293	20 (18,22)	p=0.77	p=0.25
High (3.5-5.0)	3161	74 (71,77)	3267	75 (72,78)	3087	76 (72,80)	9506	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, vs broad-open, BO) and between consent types (broad-controlled vs tiered-controlled).

Table 4. Univariate and multivariate associations between consent and data sharing models, socio-demographics, trust and privacy items, 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 & privacy**	**Socio-demographics, trust & privacy & attitudes**
Consent & 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)** [a]	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)**[a]	**0.68 (0.52, 0.88)** [a]	0.74 (0.53, 1.04)
Asian	60 (54,66)	**0.62 (0.49, 0.76)**[a]	**0.67 (0.53, 0.84)** [a]	0.79 (0.59, 1.04)
American Indian or Alaska Native	57 (49,65)	**0.70 (0.51, 0.95)**[a]	0.78 (0.57, 1.05)	0.81 (0.57, 1.15)
Other[b]	56 (49,63)	**0.67 (0.49, 0.94)**[a]	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)**[a]	**0.40 (0.26, 0.59)** [a]	**0.34 (0.21, 0.54)** [a]
High school graduate or GED	58 (53, 64)	**0.63 (0.43, 0.93)**[a]	**0.60 (0.39, 0.90)** [a]	**0.52 (0.33, 0.84)** [a]
Some college	64 (60, 68)	0.78 (0.58, 1.04)	0.79 (0.56, 1.12)	**0.62 (0.44, 0.88)** [a]
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)**[a]	**0.67 (0.46, 0.97)**[a]	0.74 (0.48, 1.13)
$30,000 - $60,000	63 (58,67)	**0.66 (0.43, 0.93)**[a]	**0.71 (0.52, 0.96)**[a]	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 to $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 household				
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)
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)**[a]	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)**[a]	**1.79 (1.00, 3.23)**[a]	1.65 (0.81, 3.35)
Rurality (from census-level data)				
Suburban / 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)**[a]
Somewhat religious	65 (61,69)	**0.74 (0.59, 0.93)**[a]	**0.73 (0.56, 0.96)** [a]	**0.62 (0.46, 0.83)** [a]
Very religious	63 (59,66)	**0.68 (0.54, 0.85)**[a]	**0.68 (0.53, 0.88)** [a]	**0.59 (0.44, 0.80)** [a]

Independent variable	Percent (95% CI)	Multivariate models, OR (95% CI)		
		Socio-demographics	Socio-demographics, trust & privacy	Socio-demographics, trust & privacy & attitudes
I trust my healthcare system				
Disagree	48 (43,54)	-	**0.73(0.55, 0.98)[a]**	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)[a]**	**0.52 (0.36, 0.75)[a]**
Neither	52 (49,55)	-	**0.38 (0.30, 0.49)[a]**	**0.61 (0.47, 0.80)[a]**
Agree	78 (75,80)	-	1	1
Health information privacy is important 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) [a]**	1.14 (0.80, 1.64)
Agree	65 (61,68)	-	1	1
I worry about the privacy of my health information				
Disagree	87 (85,89)	-	**3.64 (2.63, 5.02) [a]**	**1.44 (1.01, 2.07)[a]**
Neither	77 (74,80)	-	**2.15 (1.64, 2.83) [a]**	1.10 (0.81, 1.49)
Agree	57 (53,61)	-	1	1
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)[a]**
High (3.5-5.0)	80 (77,82)	-	-	**62.21 (28.72, 134.75)[a]**
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)[a]**
High (3.5-5.0)	40 (37,43)	-	-	**0.07 (0.05, 0.10)[a]**
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]**

[a]denotes significant differences at the 0.05 level.
[b]Due to small cell counts, Native Hawaiian/Pacific Islanders were grouped with the Other racial category.
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.

Table 5. Attitudes (specific perceived benefits, concerns, and information need) towards participating in a biobank

Attitudes	N	Agree / strongly agree Percent (95% CI)
Perceived benefits of participating in a biobank		
I would feel that I was helping future generations.	10773	84 (81, 87)
I would feel that taking part could lead to better medical treatments.	10564	83 (80, 85)
I would feel that taking part would help doctors where I get my medical care take better care of patients.	9957	78 (75, 80)
I would feel that taking part could help my family.	8139	65 (62, 67)
I would feel that taking part could help me personally.	5667	44 (40, 47)
Concerns about participating in a biobank		
I would worry about my privacy.	6578	51 (47, 55)
I would worry about my medical record being shared.	5903	45 (42, 49)
I would worry about how researchers would use my health information.	5404	41 (38, 45)
I would worry about my genetic information being shared.	4866	38 (34, 41)
I would worry that some research would be done that I did not want to take part in.	4713	37 (34, 40)
I would worry that someone might make money using my health information.	4856	36 (33, 39)
Information needs regarding governance of a biobank		
I would want to know what would happen if a researcher misused the health information in the biobank.	11055	86 (84, 87)
I would want to know what kind of knowledge would result from the use of my health information.	10827	84 (82, 86)
I would want to know who makes sure that my health information is used in the right way.	10752	84 (81, 86)
I would want to know if my health information might be used by insurance companies.	10160	79 (77, 81)
I would want to know the types of research my health information would be used for.	9748	74 (71, 77)
I would want to know who runs the biobank.	9500	73 (71, 75)
I would want to know how the biobank covers costs.	7716	60 (57, 62)
I would want to know if my health information might be used by drug companies that make money.	7625	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.

Web resources

The URL for the survey instruments used in this study can be found here:

https://emerge.mc.vanderbilt.edu/projects/emerge-cerc-survey-2/

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