Glad you asked: Participants' Opinions of Re-Consent for dbGaP Data Submission

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Abstract

No consensus exists about when researchers need additional participant consent (re-consent) to submit existing data to the federal database of Genotypes and Phenotypes (dbGaP). Reconsent for submission of their data to dbGaP was sought from 1,340 study participants, 1,159 (86%) of whom agreed. We invited the first 400 of those who agreed to complete a telephone survey about their reasoning for their consent decision and their satisfaction with the re-consent process; 365 participants completed the survey. Respondents reported that it was very (69%) or somewhat (21%) important that they were asked for their permission. Many respondents considered alternatives to consent, such as notification-only or opt-out, to be unacceptable (67% and 40%, respectively). These results suggest that re-consent for dbGaP deposition may be advisable in certain cases to anticipate and honor participant preferences.

Keywords

informed consent; data sharing; dbGaP

By matching health histories with DNA sequences, genetic epidemiological studies can detect new associations between genetic variants and disease risks. But to achieve sufficient statistical power, such studies require large, well-characterized datasets. One way to reach
such sample sizes is to combine information from existing datasets and participant cohorts. To facilitate research collaboration and access to existing datasets, the National Institutes of Health (NIH) in 2006 established the database of Genotypes and Phenotypes (dbGaP), a centralized clearinghouse for coded, de-identified study data (Mailman et al., 2007). Since January 2008, NIH has required that all investigators who receive NIH support to conduct genome-wide association studies (GWAS) and other high-throughput genomic research submit their de-identified study data to dbGaP, with exceptions granted on a case-by-case basis.

For studies that will enroll participants prospectively, the informed consent procedure can — and should — address data sharing through dbGaP (Caulfield et al., 2008; Lunshof, Chadwick, Vorhaus, & Church, 2008; McGuire, Hamilton, Lunstroth, McCullough, & Goldman, 2008). But data from many cohorts for which the NIH is now encouraging data sharing were collected long before dbGaP was established; in most cases, informed consent did not contemplate the wide sharing now being done. Under current policy, prior to dbGaP submission, institutional review boards (IRBs) that oversee a project must certify that submission to dbGaP and subsequent sharing for research purposes “are consistent with” the informed consent of study participants from whom the data were obtained. (The NIH itself does no independent review of the consents and their scope. If a local IRB determines that dbGaP submission is outside the scope of the original study consent, it can require investigators to seek additional consent from participants, or refuse to certify (and thus allow) the submission. Local IRBs can and do differ in their determinations.

Whether and under what circumstances additional participant consent (re-consent) should be required prior to submitting research data into dbGaP is unresolved. Ethical arguments can be marshaled for a range of possible approaches (Tasse, Budin-Ljosne, Knoppers, & Harris, 2010). At one extreme, one could argue that the public good of unrestricted biorepository research outweighs the rights of individual participants to choose whether to participate when the research presents a minimal risk to participants (Bathe & McGuire, 2009; Helgesson, Dillner, Carlson, Bartram, & Hansson, 2007). At the other extreme, one could argue that the autonomy interests of the research participants requires obtaining express permission or some other precautions for additional procedures that the original consent process did not specify, including submission of data to dbGaP (Greely, 2007). For researchers, practicability is a key consideration, as approaching research participants for additional permission can be time consuming and expensive (Colditz, 2009).

Lack of policy consensus on when re-consent is appropriate has been compounded by an absence of data on research participants’ attitudes toward data sharing through dbGaP. Where studies have investigated participant attitudes, most have used hypothetical scenarios to examine participant and potential participant concerns and preferences, particularly regarding the nature and/or necessity of consent to address data sharing (Kaufman, Murphy-Bollinger, Scott, & Hudson, 2009; Wendler & Emanuel, 2002; Willison et al., 2007). In these studies, the proportion of participants preferring consent prior to each research use ranged from 12% to more than 50%, depending on factors such as the source of samples (clinical versus research) and anonymization. We know of no other investigations in which research participants have been asked their opinions on the need for consent (or re-consent) for sharing their data in any manner, let alone through a federal data repository.

In 2008, the Group Health Research Institute had a unique opportunity to study current research participants’ views of re-consent for data sharing as part of the multi-institution electronic MEdical Records and GEnomics (eMERGE) Network. This collaborative study is exploring the feasibility of conducting GWAS using existing research cohorts and phenotypes derived from electronic medical record data. In keeping with NIH policy, all
sites are to submit de-identified study data to dbGaP. On the grounds that such data sharing was outside the scope of the original consent, the Group Health IRB required the investigators to seek the consent of living participants in the Adult Changes in Thought (ACT) Study, a longitudinal cohort study of aging and dementia funded by the National Institute on Aging. Thus the researchers attempted to re-consent ACT participants. This process let us explore the following questions with a subset of those approached for re-consent: (1) What reasons inform participant decisions about whether to let their data be deposited in dbGaP?; (2) What do participants think about the process used to ask for consent for data sharing in the Group Health eMERGE study?; and (3) Do they believe re-consent for this new research activity was necessary?

Methods

Setting and participants

The study was conducted at Group Health, a prepaid health plan serving approximately 600,000 members in Washington and Idaho. Group Health serves members insured by employers, individual coverage, Medicare, Medicaid, and state-subsidized insurance for low-income residents. Participants were members of the Adult Changes in Thought (ACT) Study, a longitudinal cohort study of aging and dementia funded by the National Institute on Aging.

In the ongoing ACT Study, randomly selected members age 65 and older in the greater Seattle area who show no evidence of dementia were invited to enroll. Cohort participants range in age from 65 to 102 and have been Group Health members for a median of 30 years prior to study enrollment (Kukull et al., 2002). The ACT Study enrolled 2,581 people between 1994 and 1996 and another 811 in 2000–2001. Since 2005, participants have been continuously enrolled to maintain a cohort size of approximately 2,000 persons. ACT Study participants receive biennial examinations to determine cognitive status.

Recruitment

The original consent for the ACT Study was fairly broad, covering “diseases associated with aging” and noting that de-identified data may be shared with researchers investigating dementia and other aging-related issues. The original consent form indicated that the study would be measuring genetic variables including ApoE4. However, the original ACT consent did not state that study data would be provided to a federally-administered data repository; for this reason, the Group Health IRB determined that eMERGE participation – which would include submitting existing and newly generated study data to dbGaP – required re-consent. While a waiver was granted for deceased participants, eMERGE researchers were required to seek re-consent from living ACT participants (or their surrogates, for those who had experienced significant cognitive decline since enrolling in the ACT Study). A waiver was granted for deceased participants because Washington state law considers DNA and sequenced base pairs to be personal health information, which is protected even for deceased individuals. Thus the Group Health IRB could have required the investigators to seek consent from legally qualified representatives.

The re-consent process for the eMERGE study took place between July 2008 and April 2009. Informed consent documents were mailed to ACT Study participants with a post-paid return envelope; those who did not return the documents within 2-3 weeks received a reminder telephone call from Group Health survey staff. ACT participants with scheduled biennial visits during the eMERGE re-consent period went through the informed consent process in person (n = 353). ACT participants who had been diagnosed with definite memory changes were not asked for consent; instead, their legally qualified surrogates were asked to
consent on their behalf. (Of 260 surrogates asked, 141, or 54%, consented.) Of 1,340
cognitively intact study participants contacted for re-consent, 1,159 (86%) agreed to
participate in eMERGE and have their data deposited in dbGaP; 152 (11%) declined; and 29
(2%) were determined to be ineligible (blind, too ill, difficulty with spoken English). Of
those asked for re-consent during biennial visits, 319 out of 353 agreed (90%).

Our original intent was to survey samples of both those who consented and those who
decided, in order to identify key drivers of decision making. However, only 13 (less than
10%) of those who declined re-consent agreed to participate in the telephone survey, and
their data are not presented here. The survey convenience sample therefore comprised the
first 400 cognitively intact ACT participants who had consented by mail to having their
genetic information submitted to dbGaP. They were sent a letter in advance of being
approached by telephone. The Group Health IRB approved all protocols for this study.

Survey

A telephone survey combining open-ended and forced-choice questions was developed in
consultation with experts in ethics, law, social science, and research survey design.
Questions included whether participants had been part of research studies other than ACT;
whether they had discussed the decision to provide consent for deposition of their data into
dbGaP with anyone else, and if so who; and how easy or hard it was to make the decision.

An open-ended question asked: “What would you say is the main reason you decided to sign
this most recent consent form for the eMERGE study?” Following this, participants were
read “a list of things people might think about when they decide whether or not to give
general consent to release their information to a database,” (Table 1) and asked to indicate “how
important or unimportant each reason was to you in making your decision.” This list of pros
and cons was informed by results of a focus group study that included ACT Study
participants (Trinidad, Fullerton, Bares, Jarvik, Larson, & Burke, in press).

To assess participants' thoughts on the process used to obtain consent, they were asked to
rate how acceptable it would have been if: (1) “we had sent a letter that asked you to contact
us only if you did not want to agree to place your information in the database” (opt-out
approach); (2) “we had just let you know by letter that we had already sent your information
to the database (notification-only approach);” (3) “we had added your research information
to the national database without telling you or asking for your permission (no individual
permission or notification approach)?” To assess whether participants felt consent was
necessary, they were asked, “How important was it that we did ask you for your permission
to add your health and genetic information to a database?”

The survey was conducted by the Group Health Research Institute Survey Research program
using Sawtooth Ci3 and WinCATI computer-assisted telephone interviewing software. This
technology optimizes data quality and efficiency. Survey Research Program interviewers are
trained on general interviewing techniques, the use of the CATI system, and project-specific
procedures, including item-by-item specifications for each item in the questionnaire.
Responses to open-ended questions were entered verbatim. The survey took 13 minutes on
average to complete (range = 10-25 minutes). The average time between the return of
consent and completion of the telephone survey was 42 days.

Participant check

After survey data were collected and synthesized by the study team, we performed a
participant check(Miles & Huberman, 1994) by telephone with a small sample of survey
respondents. Participant checks allow researchers to assess the validity of the categories and
interpretations of the data developed by study investigators. Participants were asked a series
of open-ended questions that mirrored the forced-choice questions in the survey (e.g., “what were the main reasons you agreed to participate in the eMERGE research study?”) We randomly selected 15 participants who represented the spectrum of stated ease of decision to allow deposition of personal data into dbGaP (i.e., we included several who had found the decision somewhat difficult or who had found it neither easy nor difficult, as well as some who had found it easy to decide). Interviews were conducted by an experienced research interviewer who followed an interview guide and all interviews were digitally recorded and transcribed by Group Health Research Institute Survey Research Program. Participants in this × minute in-depth interview were paid $25.00 for their time.

Analysis

One-way tables of frequency counts were used for descriptive analyses. Respondents and non-respondents were compared using Pearson's chi square or Fisher’s exact tests for percents and F-tests for means. For open-ended items, the study team identified major categories and representative responses through qualitative thematic analysis. The categories and themes identified in the participant check interviews were compared to those obtained in the survey to see if they converged. This triangulation of data identified consistent themes, which strengthened our confidence in the findings.

Results

Participation

Of the 400 ACT Study participants eligible to participate in the survey, 91% (n=365) did so. Respondents had a mean age of 83 (range 67-100); 57% were female and most (85%) were white. Five participants actively refused to participate in the interview; others had difficulty with language, hearing, were disabled, or were not able to be contacted. There was no difference in gender (p=0.50) or race (p=0.23) between respondents and survey non-respondents. Respondents were younger (mean age=83) than non-respondents (mean age=87; p<0.01). Forty percent of respondents (n=146) had participated in medical research other than the ACT Study.

Reasoning around re-consent

It was very easy for 68% of the respondents (n=249) and somewhat easy for 21% (n=77) to decide to allow their ACT Study information to be added to a national databank. The majority, 72% (n=264), did not discuss the pros and cons of participation with anyone else. Of those who did, most spoke with a family member, usually their spouse; some spoke with their children.

In response to an open-ended question soliciting the main reason for agreeing to dbGaP deposition, the predominant response was a desire to help others, especially as one is aging. Other reasons included appreciation of medical/scientific research in general and the hopes that research will translate into health benefits, appreciation of and trust in Group Health, appreciation of the ACT Study and its researchers and staff, and because giving consent was easy to do and required no in-person visit.

Table 1 presents survey responses in to the question, “How important or unimportant was each reason to you in making your decision?” The majority of survey participants endorsed the importance of contributing to research with the potential for improving patient care or contributing to knowledge in general. The role of Group Health researchers, and ACT Study researchers in particular, in leading the new research was cited as a strong and positive influence on the decision of many participants to re-consent. Despite their willingness to
have data submitted to dbGaP, however, many participants also noted concerns about data privacy and future research uses, including potential use of their data by for-profit entities.

**Opinion regarding options for consent for data sharing**

Acceptability of alternatives to consent (an opt-out approach, a notification-only approach, or no individual permission or notification approach) is presented in Table 2. It was very important or somewhat important to the majority (n=329, 90%) of respondents that they were asked for their permission to add their health and genetic information to the databank. An opt-out approach would have been completely or somewhat unacceptable to 40% (n=146) of respondents. A notification-only approach would have been completely or somewhat unacceptable to the majority of participants (n=244, 67%). A similar proportion (n=256, 70%) of respondents said it would have been completely or somewhat unacceptable if their research information had been sent to the databank without any communication from Group Health. Open-ended comments were few, but included a full range of responses, including: “I think it is important always to ask a subject for permission;” “I don't think I would be too upset if you had and didn’t tell me, but I think it is nice that you let people know;” and “I think you are going through an awful lot of trouble for very little.”

**Participant checks**

Of the 365 survey respondents, 83% (n=304) agreed to be contacted for further follow up. Participant checks were conducted with 15 randomly chosen survey participants who represented the spectrum of stated ease of decision to allow deposition of personal data into dbGaP. These interviews confirmed that among the most important drivers of the decision to consent were strong beliefs in the value of medical/scientific research and their trust and appreciation for Group Health, the University of Washington, and the ACT Study. Also in common with survey responses, the trust in Group Health and ACT investigators outweighed concerns regarding privacy, data security, or fear of discrimination.

The participant checks confirmed conclusions drawn from the survey responses. No major new themes or concerns were identified.

**Discussion**

A local IRB ruling requiring informed consent for deposition of previously collected research data into dbGaP allowed this real-time exploration of research participants' concerns and preferences regarding re-consent for such data sharing. The great majority (86%) of participants in this longitudinal study of aging and dementia provided consent to share their de-identified study data with the national data repository. Of course, that means 14%, nearly one in seven, did not consent. Notwithstanding the very high rate of re-consent, 90% of survey respondents all of whom had consented to sharing with dbGaP, reported that it was important that researchers had asked for their consent. Alternatives to consent were viewed as unacceptable by many survey respondents. This finding is noteworthy because it demonstrates the high value research participants place simultaneously on the benefits of health research and on personal autonomy. It also complicates the supposition that high rates of participant re-consent are equivalent to condoning open-ended use of previously collected research data without future need for individual consent.

Participants in this study described “reasons against” as well as “reasons for” consenting to dbGaP-mediated data sharing, although – as demonstrated by the high rate of re-consent in this population – the balance tipped in favor of “reasons for.” Some participants acknowledged concerns such as privacy, confidentiality, and potential commercialization of
research findings, but these concerns were outweighed by respondents' belief in the benefits of genomic research and trust in the ACT Study researchers and their respective institutions.

**Best Practices**

The judgments and attitudes of local IRBs differ with respect to the nature and/or necessity of re-consent for wide data sharing and the deposition of previously collected research data into dbGaP. In the eMERGE Network, only one of five involved IRBs ruled that active re-consent was needed. Besides considering potential risks to participants, the Group Health IRB's decision requiring consent was influenced by the fact that ACT was an ongoing study, meaning that investigators had current contact information for participants, and participants were used to hearing from investigators. For other kinds of studies, for example those for which recruitment was conducted a long time ago, re-consent may be less feasible. In addition to being consistent with participant wishes (and possibly expectations), re-consent is likely also to improve the research outcomes in longitudinal cohort studies, where demonstrating respect for participants' views may help promote ongoing participation and thus more valuable, higher quality research. For new prospective studies, researchers should gather explicit permission from participants for submission of their data into dbGaP or other repository, and include an option for participants to agree to a new study but refuse deposition of their data into dbGaP.

**Research Agenda**

While the unique characteristics of this cohort (e.g., older age, history of research participation and enrollment in a longitudinal study, longstanding health plan membership, strong trust in the research enterprise and specific institutions) may limit generalizability of the findings to other research cohorts, these same characteristics also make these respondents an informative “extreme case” (Gerring, 2007) for policy deliberation. ACT Study participants are elderly, have strong altruistic motives and extraordinary trust in the research team, and expressed relatively few concerns regarding privacy or other harms, yet they still wanted to be asked for permission to share their data. If a population with very high trust in both the researchers and the research institution prefers an individual re-consenting process, populations that do not have this kind of relationship with researchers may be even more likely to prefer active consent for deposition of their data in a federal repository. Further investigation of the opinions of other participant cohorts, including those for whom investigators have pursued related approaches such as notification or opt-out, will better inform biorepository research policy and practice.

Some of the limitations of the present study suggest further avenues for research. We did not assess ACT Study participants' understanding of what it means to consent to data sharing. Continued research aimed at finding the optimal way of communicating key information about data sharing, especially for less scientifically literate populations, will be important. We also did not assess how — or even if — the fact that dbGaP is maintained by the federal government may have influenced participants' decision-making. Future research should also explore more deeply why opt-out or notification-only consent options are not acceptable to a large proportion of study participants. Because respondents in the current study may have been biased because of the ordering of the questions, future studies should take care to randomly order questions, especially those focused on pros and cons related to decision-making. Since the people who are included in the convenience sample may have differed from those who provided re-consent later in the process by having reservations, it is conceivable that a smaller percent of the people would have had an easy time making the decision, a smaller percent might have reported the role of GH researchers as a positive influence, and a higher percent might have had more concerns. Finally, future research
should explore best practices for studies where consent was obtained long ago and make re-consent less practicable.

**Educational Implications**

The overall 86% consent rate of ACT Study participants contacted as part of the eMERGE project should be encouraging to researchers who fear that many participants will refuse to allow their data to be shared via dbGaP. At the same time, the 14% rate of non-consent is too great to be dismissed as insignificant or trivial. Nevertheless, our results suggest that re-consent may be advisable in certain cases to anticipate and honor participant preferences. The cost of seeking re-consent from ACT Study participants averaged approximately US $50.00 per participant. Researchers should be prepared for re-consenting study participants when feasible, and NIH should be prepared to provide researchers the time and money that this step requires.

**Acknowledgments**

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**References**


Tasse AM, Budin-Ljosne I, Knoppers BM, Harris JR. Retrospective access to data: the ENGAGE consent experience. European Journal of Human Genetics. 2010


Biographies

**Evette J. Ludman** is Senior Research Associate at Group Health Research Institute, Affiliate Associate Professor of Psychiatry and Behavioral Sciences at the University of Washington and Affiliate Investigator at the Fred Hutchinson Cancer Research Center. Trained as a psychologist, she has diverse research interests at the interface of behavioral science, the healthcare delivery system and the use of genetic information. She helped obtain funding for this study, provided overall oversight, and had primary responsibility for the design of the study and survey instrument, study implementation, data analysis and interpretation, and drafting of the manuscript.

**Stephanie M. Fullerton** is Assistant Professor of Bioethics & Humanities, and Adjunct Assistant Professor of Epidemiology and Genome Sciences, at the University of Washington. Her research focuses on the ethical and social implications of basic research practices in genetics, genomics, and microbiology, including researchers' use of racial and/or ethnic constructs in genetic epidemiology and participants' perspectives on result return and data-sharing in the context of GWAS and related forms of biorepository-based investigation. She consulted on study design and result interpretation, and assisted with preparation of the study manuscript.

**Leslie Spangler** is a Research Associate at the Group Health Research Institute. Her research interests focus on chronic diseases in the matured adult population. She has been a research associate on numerous projects employing a variety of epidemiological methodologies, and has taken the lead in the design, conduct, interpretation, and presentation of statistical analysis of clinical trial, survey, and observational studies. She contributed to this study's design, data analysis, and manuscript revisions.

**Susan Brown Trinidad** is a Research Scientist in the Department of Bioethics and Humanities at the University of Washington School of Medicine; a co-investigator in the Center for Genomics and Healthcare Equality, a NHGRI-funded Center of Excellence in ELSI research; and a member of the University of Washington IRB. She has worked on a number of ELSI projects, with a particular focus on the views of research participants, the public, and IRB members and staff. She contributed to the design and analysis of this study and assisted in drafting the manuscript.

**Monica M. Fujii** is a Research Project Manager at Group Health Research Institute. Her current areas of research interest include the clinical utility of pharmacogenomic testing and the ethical, legal and social issues of biorepositories. She was the project manager for the study and contributed to the implementation and analysis of the results. She critiqued drafts of the manuscript.

**Gail Jarvik** is an Internist, Medical Geneticist, Head of Medical Genetics, Professor of Genome Sciences at the University of Washington, and the Director of the Northwest Institute for Genetic Medicine. She is a practicing physician board certified in both Internal
Medicine and Medical Genetics, and has a long-standing interest in the ethical implications of genetic research. She served on NHLBI committees related to the return of genetic results to research subjects and chairs the return of results advisory committee for the eMERGE consortium. She edited the instruments, critiqued the analyses, and assisted in drafting the manuscript for this study.

**Eric B. Larson** is Executive Director of the Group Health Research Institute and the Principal Investigator for both the grants which support the research and research subjects involved in the paper - the long standing Group Health, University of Washington Alzheimer’s disease patient registry, Adult changes in thought(ACT) study and the eMERGE project. He was involved in efforts to secure funding and to work with subjects, families and the Group Health leadership to facilitate conduct of the reconsent study. He assisted in the interpretation of results and review and revision of manuscript drafts.

**Wylie Burke** is Professor and Chair of the Department of Bioethics and Humanities at the University of Washington. Her work addresses the ethical and policy implications of genomic information in research and practice, and has commonly used qualitative methods to explore attitudes toward genomics. The present study occurred within the context of a large multi-site collaboration to advance understanding of the genetic contributors to common diseases. She contributed to this study’s design, data analysis, and manuscript preparation.
Table 1

Importance of reasons and concerns contributing to decision to allow consent of previously collected research data into dbGaP.

<table>
<thead>
<tr>
<th>Reason</th>
<th>Very important</th>
<th>Some-what important</th>
<th>Not too important</th>
<th>Not at all important</th>
<th>Don't know/refused</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research could improve patient care and prevent or treat illness</td>
<td>296 (81.1%)</td>
<td>63 (17.3%)</td>
<td>2 (0.6%)</td>
<td>1 (0.3%)</td>
<td>3 (0.8%)</td>
</tr>
<tr>
<td>Research could help increase knowledge for our society</td>
<td>274 (75.1%)</td>
<td>75 (20.6%)</td>
<td>6 (1.6%)</td>
<td>5 (1.4%)</td>
<td>5 (1.4%)</td>
</tr>
<tr>
<td>Research could help me or someone close to me in the future</td>
<td>223 (61.1%)</td>
<td>91 (24.9%)</td>
<td>28 (7.7%)</td>
<td>17 (4.7%)</td>
<td>6 (1.6%)</td>
</tr>
<tr>
<td>Concern that your privacy could be invaded or that your identity might be revealed somehow</td>
<td>69 (18.9%)</td>
<td>52 (14.0%)</td>
<td>112 (30.7%)</td>
<td>124 (34.0%)</td>
<td>8 (2.2%)</td>
</tr>
<tr>
<td>Concern about the kind of research this databank could be used for in the future</td>
<td>90 (24.6%)</td>
<td>100 (27.4%)</td>
<td>73 (20.0%)</td>
<td>91 (24.9%)</td>
<td>11 (3.3%)</td>
</tr>
<tr>
<td>Concern that your information could be used by others for their own profit</td>
<td>78 (21.4%)</td>
<td>73 (20.0%)</td>
<td>96 (26.3%)</td>
<td>100 (27.4%)</td>
<td>18 (4.9%)</td>
</tr>
<tr>
<td>Concern or confusion about the study itself / not sure what you would have to do for the study</td>
<td>41 (11.2%)</td>
<td>95 (26.0%)</td>
<td>99 (27.1%)</td>
<td>108 (29.6%)</td>
<td>22 (6.0%)</td>
</tr>
</tbody>
</table>

“GHC researchers are leading the study. Did that influence your decision?”

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Don't know/refused</th>
</tr>
</thead>
<tbody>
<tr>
<td>258 (70.7%)</td>
<td>100 (27.4%)</td>
<td>7 (1.9%)</td>
</tr>
</tbody>
</table>

“And that reason was...?”

<table>
<thead>
<tr>
<th>Very important</th>
<th>Some-what important</th>
<th>Not too important</th>
<th>Not at all important</th>
<th>Don't know/refused</th>
</tr>
</thead>
<tbody>
<tr>
<td>149 (57.8%)</td>
<td>103 (40.0%)</td>
<td>4 (1.5%)</td>
<td>1 (4%)</td>
<td>1 (4%)</td>
</tr>
</tbody>
</table>

“ACT study researchers are leading the study. Did that influence your decision?”

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Don't know/refused</th>
</tr>
</thead>
<tbody>
<tr>
<td>263 (72.0%)</td>
<td>96 (26.3%)</td>
<td>6 (1.7%)</td>
</tr>
</tbody>
</table>

“And that reason was...?”

<table>
<thead>
<tr>
<th>Very important</th>
<th>Some-what important</th>
<th>Not too important</th>
<th>Not at all important</th>
<th>Don't know/refused</th>
</tr>
</thead>
<tbody>
<tr>
<td>137 (52.1%)</td>
<td>112 (42.6%)</td>
<td>13 (4.9%)</td>
<td>0</td>
<td>1 (4%)</td>
</tr>
</tbody>
</table>

Footnote: All percents do not add up to 100% due to rounding.
Table 2

Acceptability of options for obtaining consent for deposition of previously collected research data into dbGaP.

<table>
<thead>
<tr>
<th>“How acceptable would it have been if we had...”</th>
<th>Completely acceptable</th>
<th>Somewhat acceptable</th>
<th>Somewhat unacceptable</th>
<th>Completely unacceptable</th>
<th>Don’t know/refused</th>
</tr>
</thead>
<tbody>
<tr>
<td>...sent a letter that asked you to contact us only if you did not want to agree to place your information in the databank?</td>
<td>98 (26.9%)</td>
<td>104 (28.5%)</td>
<td>76 (20.8%)</td>
<td>70 (19.2%)</td>
<td>17 (4.7%)</td>
</tr>
<tr>
<td>...just let you know by letter that we had already sent your information to the databank?</td>
<td>74 (20.3%)</td>
<td>38 (10.4%)</td>
<td>72 (19.7%)</td>
<td>172 (47.1%)</td>
<td>9 (2.5%)</td>
</tr>
<tr>
<td>...added your research information to the national databank without telling you or asking for your permission?</td>
<td>55 (15.1%)</td>
<td>41 (11.2%)</td>
<td>60 (16.4%)</td>
<td>196 (53.7%)</td>
<td>13 (3.6%)</td>
</tr>
<tr>
<td>“How important was it that we did ask you for your permission to add your health and genetic information to a databank?”</td>
<td>251 (68.8%)</td>
<td>78 (21.4%)</td>
<td>10 (2.7%)</td>
<td>17 (4.7%)</td>
<td>9 (2.5%)</td>
</tr>
</tbody>
</table>