Published in final edited form as:

J Empir Res Hum Res Ethics. 2010 March ; 5(1): 83–91. doi:10.1525/jer.2010.5.1.83.

Attitudes toward Genetic Research Review: Results from a National Survey of Professionals involved in Human Subjects Protection

Amy A. Lemke,
Northwestern University

Susan B. Trinidad,
University of Washington

Karen L. Edwards,
University of Washington

Helene Starks,
University of Washington

Georgia L. Wiesner, and
Case Western Reserve University

GRRIP Consortium¹

Abstract

The recent expansion of human genetics research has raised complex ethical and regulatory issues. However, few published reports describe the views of professionals involved in human subjects protection (HSP) regarding the risks and benefits of genetic research. This anonymous, web-based study elicited the opinions of 208 HSP professionals about review of genetic research. The majority of respondents felt that different guidance is needed for various aspects of genetic protocol review compared with other types of human subjects research. Importantly, opinions were divided on specific genetic research issues such as what constitutes human subjects research, when to re-consent, and the likelihood and risks of research participant identification. Findings from this study illustrate the need for a collaborative approach to ethics oversight in the conduct and review of genetic research.

Keywords

Institutional review board; research ethics committee; genetics; genetic research; human subjects protection

Genetic research is a rapidly changing, quickly growing field of inquiry. Current research uses a wide variety of approaches, ranging from family linkage analyses to genome-wide association studies that require tens of thousands of participants, and from medical sequencing studies to

¹This investigation involved multiple collaborators including the University of Washington Center for Genomics and Healthcare Equality, the Case Western Reserve University Center for Genetics Research Ethics and Law, Public Responsibility in Medicine and Research, the American Society of Human Genetics, and the Genetic Research Review and Issues Project (GRRIP) investigators. Additional GRRIP project investigators include (in alphabetical order) Joann Boughman, Wylie Burke, Lynn Dressler, William Freeman, Nancy Gerson, Eric Juengst, Susan Lewis, Patricia Marshall, P. Pearl O'Rourke, Roselle Ponsaran, Nancy Press, and Mary Quinn Griffin.

Address correspondence to: Amy A. Lemke, MS, PhD, Center for Genetic Medicine, Northwestern University, 676 N. St. Clair Street, Suite 1260, Chicago, Illinois, USA 60611. a-lemke@northwestern.edu or aalemke@tds.net.

gene expression studies. In addition, local research review entities, such as institutional review boards (IRBs) and research ethics committees, are reviewing multi-site genetic studies with large participant enrollment and data repositories that seek to follow participants over time. While anecdotal reports suggest that the regulatory review of human genetic studies is more time consuming and complicated compared with other types of human subjects research, there is little empirical evidence documenting such differences.

Genetic research falls under the same regulatory umbrella as other biomedical research where the rights and safety of human volunteers in health research are protected under federal law. In the U.S., Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46) includes the required IRB oversight of human subjects research. Local IRBs and research ethics committees, rather than a national body, are empowered to approve, require modifications, or disapprove research within their jurisdictions.

In recent years, an increasing number of researchers and ethicists have questioned the efficacy of existing regulatory frameworks and institutional mechanisms for human subjects protections (Kim et al., 2009; Begley, 2008; Bonetta et al., 2003; Fost, Levine, 2007; Giles, 2005; Levine 2001). While the rules and standards originally designed to protect research volunteers were an appropriate and necessary response to past abuses in clinical research, important changes have since taken place with regard to both the perceptions of the general public toward research protections (Satel, 2009; Dressler, 2001) and the workings of the research enterprise (Galison, Hevly, 1992; Collins et al., 2003). Whereas the development of early participant protection regimes was rooted in a concern to protect human subjects from the harms that could occur as a result of research participation, the relatively recent rise of research advocacy groups has often pressed for greater inclusion and less paternalistic oversight. At the same time, the evolution of the research enterprise into a system that favors “Big Science” – large projects, often involving multiple complex scientific aims and inter-institutional collaboration – presents new challenges to a human subjects protection system designed to maintain accountability at the local level. Few published reports exist about whether or how these changes have affected the views or practices of professionals involved in human subjects protection.

It has been argued that conventional mechanisms for protecting research participants, such as informed consent and de-identification of study data, may be less effective for genetic research in general and emerging high-throughput genomic analytic approaches in particular (Annas, 2001; Hunter, 2005; McGuire, 2006; O'Neill, 2001; Ellerin et al., 2005). Such research is relatively new and complex; moreover, the potential risks to research participants – such as breach of confidentiality of one's genetic information, or the possibility of discrimination on the basis of disease susceptibility – are difficult to define in comparison with risks in more traditional clinical studies.

Relatively few empirical studies have been conducted on how IRBs and research ethics committees function, and published research reports to assess these professionals' views regarding the risks and benefits of human genetic research are rare. One study of U.S. IRBs and international institutions receiving research funding revealed considerable variability in requirements for informed consent for research on stored biological samples (White & Gamm, 2002). In another study, investigators asked 55 IRB chairs to evaluate the ethical issues in a hypothetical study involving mental health-related genomic research; most respondents identified consent and confidentiality as important issues and expressed concern about the use of biological materials in new research (Wolf et al., 2008). Other reports describe the difficulties associated with managing human subjects review for large multi-center genetic studies with variable standards for evaluating risks (Sherwood et al., 2006; Greene et al., 2006; Greene & Geiger, 2006; McWilliams et al., 2003).

To develop policies and procedures that meet the goals of participant protection as well as scientific progress, it is important to understand how HSP professionals think about genetic research and what they perceive to be the risks and benefits that may accrue to participants. This research report presents the results of an anonymous, web-based survey aimed at understanding HSP professionals' attitudes, perceptions, and experiences in the review of genetic research proposals.

Method

Study Population and Recruitment

Public Responsibility in Medicine and Research (PRIM&R²) members who were identified as having a primary interest in human subjects research, general interest in all research, and those who declined to specify research interest, were invited to participate in this study. PRIM&R's members represent the many categories of people responsible for overseeing human subjects protections, including administrators, institutional officials, government representatives, and researchers. In April 2009, the PRIM&R executive director sent an introductory email inviting eligible members (n=2,777) to take the survey; a reminder was sent two weeks following the initial invitation. In addition, these individuals were invited to forward the survey invitation to other colleagues who were not current members of PRIM&R. An invitation to participate in the survey also was included in the June 2009 edition of the Northwest Association for Biomedical Research's (NWABR) e-newsletter, which has a circulation of 350 and reaches IRB members and staff in Washington, Oregon, and Idaho. NWABR is a non-profit organization that promotes public understanding of biomedical research and its ethical conduct.

This set of recruitment strategies was designed to maximize the response rate, distribution, and variety of potential participants. The use of multiple lists and the invitation to share the survey with other colleagues were intended to capture respondents outside the PRIM&R membership because of the likelihood that only a subset of committee chairs, members, and staff within any given review body will be PRIM&R members in a particular year. While the anonymous survey design may have encouraged participation, the trade-off was that it could not be ascertained who received multiple invitations nor the total number of people who were invited. Therefore an overall response rate could not be computed.

Survey Instrument

A 90-item, anonymous, web-based survey was developed to assess HSP professionals' attitudes toward genetic research review. The items covered five general topic areas: the application process (23 questions); the review process (10 questions); committee functions (21 questions); design-specific issues in genetic research (19 questions); and background/demographic information (17 questions). The types of response categories varied based on the question and included either "yes/no/not sure" options (20 items), 5-point Likert scales rating agreement, likelihood, or importance of the statement, with a sixth "don't know" option (53 items), or categorical responses (17 items), mostly for the background/demographic questions. The survey instrument is available as an online supplement.

Questions were informed by key findings from 31 semi-structured, individual interviews conducted with HSP professionals working in six U.S. institutions. The Tailored Design

²PRIM&R is dedicated to advancing the highest ethical standards in the conduct of research. The organization provides educational programming and professional development services to individuals and organizations involved in biomedical, social science, behavioral, and educational research. Members include administrators from Human Research Protection Programs, Research Ethics Committees and Institutional Biosafety Programs, researchers and research staff, institutional officials, government representatives, subject advocates, ethicists, policy-makers, pharmaceutical and biotechnology personnel, and attorneys. www.primr.org

Method was used as a general guide in the survey development (Dillman, 2007). Pretesting was conducted through internal and expert review and eight cognitive interviews with HSP professionals (Willis, 2005). Pilot testing of the online version of the survey was also conducted to identify and correct any potential technical difficulties in using Catalyst WebQ, a proprietary survey software application developed at the University of Washington. This minimal-risk study was approved by the University of Washington IRB; all other study sites received IRB approval to share anonymized data.

Data Analysis

Data were downloaded from the web-based Catalyst tool and converted into a Stata (version 10.0) dataset for statistical analyses (StataCorp, 2005). Descriptive summary statistics were used to summarize responses to all questions. For the Likert scales, five categories were collapsed to three, combining the “strongly” and “somewhat” categories at either end of the scale (e.g., strongly agree, somewhat agree) to facilitate analysis and interpretation. Because respondents were allowed to skip individual items, the sample size varied by question. On average, the 90 items had missing data for 2.4% ($n \sim 5$) of the participants (range 0-10.6% for the items); percentages were computed based on the total sample of respondents ($N=208$), including the missing data.

Results

Participant Characteristics

A total of 208 individuals completed the web-based survey, including six individuals who were not current members of PRIM&R. There were no responses to the NWABR newsletter invitation. Among the respondents, 96% were PRIM&R members, 76% were female, and 57% had more than five years of experience serving on an IRB. Nearly all respondents (96%) were from the United States, and 28% indicated that they had played a role in genetic research as either research staff or investigators. Sixty-eight percent reported serving on an IRB with a biomedical focus. Tables 1 and 2 provide additional details about the participants and their research review experience.

The Application Process

Questions in this part of the survey asked about the types of guidance the IRB offers researchers when preparing applications – both in general and for genetic studies – and probed for respondents' beliefs about researcher-IRB concordance on a number of key issues. Nearly all respondents (93%) agreed that their IRB provides useful guidance for preparing applications in general, and half of respondents indicated that their IRB provides additional guidance to researchers who are preparing applications for human genetic studies. Most (89%) thought that researchers and their IRB generally agree about whether a given project involves human subjects, and 71% reported researcher-IRB agreement about the level of review required for a genetic project.

Respondents were asked whether genetic research studies require different guidance compared with other types of research. The majority felt that genetic studies do require special guidance for: (1) writing a consent form (74%); (2) planning for sharing of research data with other investigators (65%); (3) developing a data repository or biobank (64%); and (4) using large-scale data repositories (58%). Fewer than half indicated that different guidance is needed for designing recruitment procedures for genetic research (42%) or for developing a genetic research study design (36%), compared to other types of research.

The Review Process

Participants were asked about their involvement in the review of genetic research, which was defined as “family studies to determine the cause of a genetic disorder, or case control or other population studies to identify genetic contributors to health and disease, or studies of a particular condition(s) that include the collection of genetic data.” Sixty-one percent of participants were involved in the substantive review of genetic research studies, and 63% indicated that they communicate directly with genetic researchers about the IRB review of their studies.

The majority (70%) of participants reported that their IRB has access to genetics expertise when it is needed for the review of a protocol. For applications requiring full committee review, 46% agreed their IRB takes more time to review genetic research studies compared to other studies. The majority of respondents (64%) indicated that this is due to the need for additional clarification. In addition, 44% reported that the genetic component makes these applications more complex to review, and 38% endorsed the statement that extra time was needed because genetic protocols are not clearly written.

To learn more about HSP professionals' exchanges with researchers, respondents were asked to identify the issues that involve considerable discussion between researchers and their IRB in the review of genetic research applications. Considerable discussion was defined as “more than two or three back-and-forth rounds and/or more than a one-hour conversation.” Slightly more than half (53%) indicated that procedures for protecting participants' personal information or samples cause considerable discussion, followed by informed consent process and documentation (42%); return of genetic research results to participants (36%); re-consent from research participants for a new study or change in purpose (30%); plans, or lack of plans, to deal with community harms or benefits (24%); and study intent (20%).

Committee Functions

Respondents were asked whether various functions of their IRBs should differ for genetic research compared to other types of human subjects research. The vast majority felt that the following functions should not differ for genetic research: (1) ensuring that researchers have appropriate plans in place to protect human subjects (74%); (2) protecting the institution from potential liability (81%); (3) providing assessment of the scientific soundness of the study (81%); (4) ensuring compliance with applicable regulations (80%); (5) ensuring that appropriate safeguards are in place with regard to data in technology transfer efforts (68%); (6) ensuring that risks are commensurate with anticipated benefits or research (76%); and (7) facilitating and promoting research (82%).

Specific Genetic Research Issues with Limited Agreement

Respondents' views and experiences varied with regard to a number of study-specific issues, including what kinds of genetic research require human subjects review; data-sharing; and potential risk of harm to research participants (Table 3). Responses were nearly evenly split with respect to whether the use of coded human tissue specimens in genetic research constitutes human subjects research (45% agreed that it does vs. 43% disagreed). Asked whether it is ethically necessary to obtain re-consent from research participants if the researcher wants to share the participant's de-identified sample or data with an investigator at another institution, 44% agreed that re-consent is needed and 38% disagreed. Views also differed with regard to the risk of research participants' being personally identified in a study involving coded genetic data. When asked to indicate likelihood on a Likert rating scale, 34% of respondents indicated the belief that identification was a likely outcome, while 49% felt this would be unlikely. Respondents also disagreed about the likelihood of harm resulting from such identification, with 34% believing that harm would be likely and 45% believing harm would be unlikely.

Respondents were nearly evenly split (~35% each) with respect to their views on the likelihood that a federal agency (e.g., the Department of Homeland Security) or other law-enforcement agency might compel investigators to disclose information about genetic research participants.

Another area of disagreement was around the NIH data sharing policy regarding genome-wide association studies (NIH, 2007). Of note, nearly one-third answered “don't know,” suggesting they did not have sufficient knowledge or information to judge whether the policy is clear. Thirty-six percent of respondents agreed with the statement, “The NIH guidelines for sharing data from genome-wide association studies are clear,” while 16% disagreed.

Genetic Research Issues with Majority Agreement

For other genetic research issues, respondents' views were more in agreement (Table 4). In response to the question of whether researchers have an ethical obligation to return individual research results that would affect a participant's health or health care, 78% agreed that such a duty exists. Likewise, most respondents agreed that re-consent is ethically necessary in a number of scenarios: (1) if the researcher wants to add genetic measures to the study that did not originally include them (82% agree); (2) if the researcher wants to investigate a condition or clinical manifestation unrelated to the topic of the original study (81% agree); or (3) if the original consent was given by a minor subject's parents and the subject is now old enough to decide for him or herself (73% agree).

Discussion

This study offers empirical support that some HSP professionals view genetic research as raising new and unresolved questions in the area of participant protection, compared with other kinds of human subjects research. In particular, survey respondents considered genetic studies as posing special issues in terms of informed consent, data-sharing, and shared research resources (such as biobanks or data repositories).

Anecdotal reports of challenges, inconsistencies, and delays in review of human genetic research protocols are common. However, to our knowledge, this is the first study to systematically assess the range of views held by a group of HSP professionals toward genetic research review and related issues. An important finding from this study is that, among those surveyed, opinion is divided on some key issues, including what constitutes human subjects research and the perceived likelihood of research participant identification and harm. This heterogeneity of perspectives within the HSP community is contrary to the framing that accompanies many anecdotal reports, which assumes that these professionals have one shared view and researchers another.

Best Practices

This study provides a starting point for understanding the views of HSP professionals about genetic research. However, this study has several limitations that affect the generalizability of the findings. The first is the low response rate of approximately 7.5%, which is conservatively estimated based on the PRIM&R membership, since the vast majority of respondents (96%) were PRIM&R members. It is possible that many of those who received invitations did not reply because their IRB or research ethics committee does not review genetics studies. However, this could not be assessed as there was not a mechanism to compare respondent characteristics with those who did not respond. In addition, it is not known to what extent PRIM&R members are representative of the community of HSP professionals.

Notwithstanding these limitations, the findings of this study identify a few opportunities for practice improvement. Genetic research is a rapidly developing field, and as the science

changes, so do the regulations designed to provide oversight. As such it is especially important that HSP professionals and committees have access to needed expertise. While 70% of survey respondents indicated that they had such access, more than a quarter did not. Improving review committees' ability to obtain genetics expertise when necessary – whether through increasing the number of genetics researchers who serve on IRBs and research ethics committees, providing mechanisms for ad hoc consultation, or offering educational resources produced by scientific societies – could benefit both HSP professionals and investigators.

Parallel initiatives in the other direction could also be beneficial. For example, while about half of survey respondents reported that their IRB provides specific guidance for the completion of genetics research applications, half do not. Providing consultation to help investigators think through the possible harms to participants in genetic research – particularly harms that might not be immediately obvious, such as psychosocial, intra-familial, or community/group harms – early in the process, prior to submission of an application, may be a worthwhile investment of HSP professionals' time.

In genetic research, as in other dynamic fields of inquiry, regulatory guidance can become quickly outdated, frustrating HSPs and investigators alike. Efforts to identify shared goals and commitments (e.g., to conduct ethically sound, scientifically valuable research), foster common understanding, and develop mutual respect may help to ease the friction that can result from the challenges posed by a constantly shifting regulatory environment. Laying this groundwork is a prerequisite to the development of responsive policies and procedures.

Research Agenda

This study highlights the need to explore several issues in greater depth, including (1) the prospect of participant re-identification based on genomic data and its implications for participant protection procedures and policy (e.g., re: compelled disclosure); (2) what should be the threshold for offering genetic research findings to research participants; (3) when researchers should be allowed to use existing samples or data, for new questions without seeking additional consent, especially if the initial study did not involve genetics; and (4) implications of all these issues for informed consent procedures. Future empirical data collections ideally should involve all stakeholders, and consensus building should be considered to help develop guidelines for dealing with the complex issues identified.

Educational Implications

These study data, together with a parallel investigation of genetics researchers, will be used to inform a consensus development process involving PRIM&R, the American Society of Human Genetics, and the Genetic Alliance (a nonprofit health advocacy organization) in 2010. It is anticipated that this process will target key areas of disagreement or uncertainty within and between stakeholder groups. In addition, this study identified an area where further education may be needed in the HSP and researcher communities. Future education efforts aimed at HSP professionals and researchers could include information about the NIH policy for sharing data in genome-wide association studies. Furthermore, these findings offer an opportunity to provide feedback to the NIH about some HSP professionals' perceptions of the clarity of the policy.

Concluding Thoughts

This study demonstrates that consensus does not appear to exist within the surveyed HSP professional community about various genetic research issues. Comparison data from a parallel survey of genetic researchers will be forthcoming and, in combination with these findings, provide key points for discussion between these two professional groups. Genetic researchers, HSP professionals, and their respective professional organizations, will need to take

responsibility for understanding the risks inherent in genetic research and the human subjects protections needed. Because of the rapid changes in genetic technology, approaches, and research issues in this field, guidelines will require continual updating. Through a collaborative oversight approach, both genetic researchers and HSP professionals will need to provide the necessary education, guidelines and expert guidance for one another to effectively protect human subjects in genetic research.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

Support for this research comes from National Human Genome Research Institute grants P50 HG003374, P50 HG003390, and U01 HG004609. This work was presented in part at the American Society of Human Genetics Annual Meeting in Honolulu, Hawaii, in October 2009, and at the Public Responsibility in Medicine and Research Advancing Ethical Research Conference in Nashville, Tennessee, in November 2009.

References

- Annas GJ. Reforming informed consent to genetic research. *Journal of the American Medical Association* 2001;286(18):2326–2328. [PubMed: 11710901]
- Begley S. Coddling human guinea pigs. *Newsweek* 2008;152(7-8):14.
- Bonetta L, Dove A, Watanabe M. The road to research is paved with restrictions. *Nature Medicine* 2003;9(6):630.
- Collins FS, Morgan M, Patrinos A. The Human Genome Project: lessons learned from large-scale biology. *Science* 2003;300(5617):286–290. [PubMed: 12690187]
- Dillman, DA. *Mail and Internet Surveys: The Tailored Design Method 2007 Update with New Internet, Visual, and Mixed-Mode Guide*. 2nd. New York: John Wiley & Sons; 2007.
- Dressler, R. *When Science Offers Salvation: Patient Advocacy and Research Ethics*. New York: Oxford University Press, Inc.; 2001.
- Ellerin BE, Schneider RJ, Stern A, Tonolio PG, Formenti SC. Ethical, legal, and social issues related to genomics and cancer research: the impending crisis. *Journal of the American College of Radiology* 2005;2(11):919–926. [PubMed: 17411966]
- Fost N, Levine RJ. The dysregulation of human subjects research. *Journal of the American Medical Association* 2007;298(18):2196–2198. [PubMed: 18000206]
- Galison, PL.; Hevly, B., editors. *Big Science: The Growth of Large-Scale Research*. Stanford, CA: Stanford University Press; 1992.
- Giles J. Researchers break the rules in frustration at review boards. *Nature* 2005;438(7065):136–137. [PubMed: 16280994]
- Greene SM, Geiger AM, Harris EL, Altschuler A, Nekhlyudov L, Barton MB, Rolnick SJ, Elmore JG, Fletcher S. Impact of IRB requirements on a multicenter survey of prophylactic mastectomy outcomes. *Annals of Epidemiology* 2006;16(4):275–278. [PubMed: 16005245]
- Greene SM, Geiger AM. A review finds that multicenter studies face substantial challenges but strategies exist to achieve Institutional Review Board approval. *Journal of Clinical Epidemiology* 2006;59(8):784–790. [PubMed: 16828670]
- Hunter AGW. Is multicenter collaborative research in clinical genetics dead and, if so, what killed it? *American Journal of Medical Genetics Part A* 2005;134A(3):237–239.
- Kim S, Ubel P, De Vries R. Pruning the regulatory tree. *Nature* 2009;457(7229):534–535. [PubMed: 19177111]
- Levine RJ. Institutional review boards: a crisis in confidence. *Annals of Internal Medicine* 2002;134(2):161–3.
- McGuire AL, Gibbs RA. GENETICS: No Longer De-Identified. *Science* 2006;312(5772):370–371. [PubMed: 16627725]

- McWilliams R. Problematic variation in local institutional review of a multicenter genetic epidemiology study. *Journal of the American Medical Association* 2003;290(3):360–366. [PubMed: 12865377]
- National Institutes of Health. Policy for sharing of data obtained in NIH supported or conducted genome-wide association studies (GWAS); Federal Registry 2007. 2007. p. 49290-49297.[cited 2009 November 11]. Available from <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html>
- O'Neill O. Informed consent and genetic information. *Studies in History and Philosophy of Science Part C: Studies in History and Philosophy of Biological and Biomedical Sciences* 2001;32(4):689–704.
- Satel S. Clinical trials, wrapped in red tape. *The New York Times* 2009 August 8;:A19.
- Sherwood ML, Buchinsky FJ, Quigley MR, Donfack J, Choi SS, Conley SF, Derkay CS, Myer CM 3rd, Ehrlich GD, Post JC. Unique challenges of obtaining regulatory approval for a multicenter protocol to study the genetics of RRP and suggested remedies. *Otolaryngology Head and Neck Surgery* 2006;135(2):189–196. [PubMed: 16890066]
- StataCorp. Stata Statistical Software: Release 10. College Station, TX: StataCorp LP; 2005.
- White MT, Gamm J. Informed consent for research on stored blood and tissue samples: a survey of institutional review board practices. *Accountability in Research* 2002;9(1):1–16. [PubMed: 12705242]
- Willis, GB. *Cognitive Interviewing: A Tool for Improving Questionnaire Design*. Thousand Oaks, CA: SAGE Publications; 2005.
- Wolf LE, Catania JA, Dolcini MM, Pollack LM, Lo B. IRB chairs' perspectives on genomics research involving stored biological materials: ethical concerns and proposed solutions. *Journal of Empirical Research on Human Research Ethics* 2008;3(4):99–111. [PubMed: 19385758]

Biographies

Amy A. Lemke, MS, PhD, is a Research Assistant Professor in the Center for Genetic Medicine at Northwestern University Feinberg School of Medicine. She is a mixed-methods researcher and consultant for two NHGRI-funded Centers for Excellence in Ethical, Legal and Social Issues (ELSI), the Center for Genomics and Healthcare Equality and the Center for Genetic Research Ethics and Law. She is also a board certified genetic counselor.

Karen L. Edwards, MS, PhD, is an Associate Professor in the Department of Epidemiology and core faculty in the Institute for Public Health Genetics at the University of Washington. She is the Director of the CDC-funded University of Washington Center for Genomics and Public Health and is the Director of the Epidemiology and Biostatistics Core of the Pacific Northwest Udall Center, a NIH-funded Center of Excellence in Parkinson's Disease Research.

Susan B. Trinidad, MA, 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.

Helene Starks, PhD MPH, is an Assistant Professor in the Department of Bioethics and Humanities at the University of Washington. She is a mixed-methods researcher who teaches research ethics and is a co-investigator and the Director of Training for the Center for Genomics and Healthcare Equality, a NHGRI-funded Center of Excellence in ELSI research.

Georgia L. Wiesner, MD, is a board-certified medical geneticist and specialist in cancer genetics at the Case Western Reserve School of Medicine and University Hospitals Case Medical Center. She is an Associate Director of the Center for Genetic Research Ethics and Law, a NHGRI-funded Center for Excellence in ELSI Research.

Table 1
Participant Characteristics (n=208)

Characteristics	Responses	Percentage
Gender	Female	76%
	Male	22%
	Not answered	2%
Education (more than one answer allowed)	BA, BS, BSN	38%
	MA, MS, MSN, MBS, RN, MPH, MSW	42%
	PhD, ScD, EdD	18%
	MD, DDS, DMD, DO, DVM	12%
	Other	13%
	Not answered	5%
Position at Institution (more than one answer allowed)	IRB Administrator/Manager/Director/Staff	53%
	IRB Member	25%
	Regulation/Compliance Coordinator/Officer	20%
	IRB Chair	16%
	HRPP Administrator/Manager/Director/Staff	14%
	Other	71%
	Not answered	1%
Years served on an IRB	< 1 year	9%
	1-2 years	14%
	3-5 years	16%
	> 5 years	57%
	Not answered	5%
Research Area	N/A - Does not conduct research	53%
	Basic research (clinical or lab or mathematical)	17%
	Applied research (clinical or lab or mathematical)	26%
	Social sciences	18%
	Other health related	18%
	Other	5%
	Not answered	3%
Role with human genetic research (more than one answer allowed)	N/A - Does not conduct human genetics research	65%
	Principal Investigator	2%
	Co-investigator	8%
	Research staff	17%
	Consultant on study	4%
	Other	7%
	Not answered	2%

Table 2
Participant Research Review Experience (n=208)

Characteristics	Responses	Percentage
Primary Focus of IRB Panel	Biomedical	68%
	Social, behavioral, educational	20%
	Other	11%
	Not answered	2%
Areas represented on IRB	Staff/Admin personnel	67%
	Nursing/biomedical research	13%
	Social science research	11%
	Basic science research	4%
	Physician Nurse, Social Worker/Therapist, Pharmacist	23%
	Law/clergy	5%
	Patients/community	6%
	Other	9%
Areas represented on IRB	Not answered	1%
Number of protocols reviewed annually	<20	13%
	21-50	19%
	51-100	23%
	> 100	43%
	Not answered	3%
Percentage of genetics protocols reviewed annually	<5	54%
	5-20	36%
	21-50	6%
	>50	1%
	Not answered	4%

Table 3
Genetic Research Review: Areas with Limited Agreement (n=208)

Question	Strongly Agree	Somewhat Agree	Neither Agree Nor Disagree	Somewhat Disagree	Strongly Disagree	Don't Know	Not Answered
Use of coded human tissue specimens in genetics research constitutes human subjects research. (Assume researchers do not have access to the link between the original and coded data).	29%	16%	6%	20%	23%	4%	2%
I believe it is ethically necessary to obtain re-consent from research participants if the researcher wants to share the participant's de-identified sample or data (without a linkage file) with an investigator at another institution.	23%	21%	12%	18%	20%	2%	4%
The NIH has published a policy regarding the sharing of data from NIH-supported studies. The NIH guidelines for sharing data from GWAS are clear.	5%	31%	14%	14%	2%	32%	2%
Question	Very Likely	Somewhat Likely	Neutral	Somewhat Unlikely	Very Unlikely	Don't Know	Not Answered
How likely is it that a research participant would be personally identified in a study involving coded genetic data?	7%	27%	12%	19%	30%	2%	3%
How likely is it that a research participant would be harmed as a result of identification from coded genetic data?	4%	30%	14%	23%	22%	5%	2%
How likely is it that a federal agency (e.g., Homeland Security) or other law-enforcement agency might compel investigators to disclose information about genetic research participants?	14%	22%	16%	14%	21%	12%	2%

Table 4
Genetic Research Review: Areas with Majority Agreement (n=208)

Question	Strongly Agree	Somewhat Agree	Neither Agree Nor Disagree	Somewhat Disagree	Strongly Disagree	Don't Know	Not Answered
Researchers have an ethical obligation to return individual research results (genetic or non-genetic) that would affect a participant's health or health care. (Assume procedures were performed in a CLIA-certified laboratory.)	49%	29%	9%	6%	2%	4%	2%
I believe it is ethically necessary to obtain re-consent from research participants if:							
The researcher wants to look for a genetic variant or gene other than the one mentioned in the original consent form	39%	27%	7%	14%	5%	5%	3%
The researcher wants to investigate a different, but related, condition or clinical manifestation	30%	26%	6%	23%	7%	5%	4%
The researcher wants to investigate an unrelated condition or clinical manifestation	60%	21%	5%	4%	3%	4%	3%
The researcher wants to add genetic measures to a study that did not originally include them	63%	19%	5%	4%	2%	3%	4%
The original consent was given by a minor subject's parents and the subject is now old enough to decide for him or herself	51%	22%	9%	8%	4%	3%	3%