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Broad Consent for Research on Biospecimens: The Views of Actual Donors at Four U.S. Medical Centers

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Abstract

Commentators are concerned that broad consent may not provide biospecimen donors with sufficient information regarding possible future research uses of their tissue. We surveyed with interviews 302 cancer patients who had recently provided broad consent at 4 diverse academic medical centers. The majority of donors believed that the consent form provided them with sufficient information regarding future possible uses of their biospecimens. Donors expressed very positive views regarding tissue donation in general and endorsed the use of their biospecimens in future research across a wide range of contexts. Concerns regarding future uses were limited to for-profit research and research by investigators in other countries. These results support the use of broad consent to store and use biological samples in future research.

Keywords

broad consent; biobanking; biospecimen donor; informed consent; ethical issues; survey

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INTRODUCTION

The collection, storage and distribution of human biological specimens contributes significantly to precision medicine and expedites important research (Loe, Robertson, & Winkelman, 2015; Vaught, 2016; Wendler, 2011). However, the collection and storage of remnant clinical tissues, blood and other biospecimens raises important ethical issues, including whether and when donor permission should be sought for use of biospecimens in future research studies (De Souza & Greenspan, 2013; Garrison et al., 2016; Grady et al., 2015; Wendler, 2006). As yet, no consensus exists regarding how much information should be provided to donors to facilitate autonomous choice regarding their donation decisions (Grady et al., 2015; Master, Nelson, Murdoch, & Caulfield, 2012; Steinsbekk, Myskja, & Solberg, 2013).

Multiple models of consent have been endorsed (Weiner, 2014), including: (a) *specific consent*, which requires patients to be re-contacted for each future study; (b) *tiered consent*, for which donors check the kinds of research for which their biospecimens may be used in the future; (c) *dynamic consent*, which engages donors on an iterative basis (D'Abramo, Schildmann, & Vollmann, 2015; Steinsbekk et al., 2013; Thiel et al., 2014); (d) *blanket consent*; which involves no restrictions at all for future use of donated biospecimens (Tomlinson, 2013); and (e) *broad consent*, which combines general consent for future research at the time of sample collection with the possibility of imposing some limits on research scope after review by a governance group (Grady et al., 2015). Of note, the recently revised federal *Common Rule* protecting human research subjects in the United States, to be implemented in 2018, provides an express regulatory pathway for obtaining broad consent for unspecified future research use of information and identifiable biospecimens (Registry, 2017). In addition, the *All of Us Research Program* of the *Precision Medicine Initiative* of the National Institutes of Health will use broad consent procedures (National Institutes of Health, All of Us Research Program).

A majority of individuals surveyed, as well as many ethicists and researchers, support the use of broad consent models (Brown et al., 2016; Chen et al., 2005; De Vries, Tomlinson, Kim, Krenz, Haggerty, et al., 2016; Garrison et al., 2016; Grady et al., 2015; Kern, 2010; Simon et al., 2011; Tomlinson et al., 2015; Wang, Fridinger, Sheedy, & Khoury, 2001). However, some have objected that broad consent does not provide sufficient information nor sufficient protection for donors' values (Loe et al., 2015; Ploug & Holm, 2015), such as possible donor objections to stem cell research (Dasgupta et al., 2014; Lowenthal, Lipnick, Rao, & Hull, 2012), or to research done by for-profit companies or international researchers (Helft, Champion, Eckles, Johnson, & Meslin, 2007; Pentz, Billot, & Wendler, 2006; Trinidad et al., 2012; Valle-Mansilla, Ruiz-Canela, & Sulmasy, 2010). Further, most empirical studies have used *hypothetical scenarios* rather than *actual donors* (De Vries, Tomlinson, Kim, Krenz, Haggerty, et al., 2016; De Vries, Tomlinson, Kim, Krenz, Ryan, et al., 2016; Ewing et al., 2015; Hill, Turner, Martin, & Donovan, 2013; Kaufman, Murphy-Bollinger, Scott, & Hudson, 2009; Schwartz, Rothenberg, Joseph, Benkendorf, & Lerman, 2001; Stegmayr & Asplund, 2002; Wendler & Emanuel, 2002). The few studies that surveyed actual donors focused on genomic research (Garrison et al., 2016; Hull et al., 2008; Kaphingst, Janoff, Harris, & Emmons, 2006; Valle-Mansilla et al., 2010; Vermeulen,

Schmidt, Aaronson, Kuenen, & van Leeuwen, 2009), especially giving attention to the risk of breaches of confidentiality (Siminoff et al., 2017). One study at a single institution found a majority of cancer patients expressed no concerns about unspecified future research (Helft et al., 2007).

Now that the *Common Rule* expressly endorses broad consent as a mechanism for biospecimen collection, more data are needed to determine if actual donors regard broad consent as appropriate, if broad consent provides sufficient information regarding potential future research uses (De Vries, Tomlinson, Kim, Krenz, Haggerty, et al., 2016), and if donors express concerns about future research uses. Donors providing broad consent cannot know at the time of consent what specific research will be conducted with their biospecimens, and thus future studies using their biospecimens may violate their autonomous values (Bardill & Garrison, 2015; De Vries, Tomlinson, Kim, Krenz, Haggerty, et al., 2016; Ploug & Holm, 2015).

The present study addresses these gaps in the literature by surveying broad consent donors at four cancer centers to determine: (1) whether they support use of their biospecimens across a range of research types, (2) whether they regard broad consent as providing them with sufficient information, and (3) whether they have concerns regarding specific potential future research uses of their biospecimens. Such data are needed to design evidence-based practices for obtaining informed consent for biobanking and to inform Institutional Review Board (IRB) assessment of biobanking protocols based on the preferences of actual donors.

METHODS

This study was a sub-study of The National Cancer Institute *Biospecimen Pre-analytical Variables (BPV) Program* (Lipworth, Morrell, Irvine, & Kerridge, 2009) which investigated the effects of different biospecimen collection, processing, and storage procedures on molecular analysis data utilized in cancer research at 4 academic medical centers. The BPV study used broad informed consent for future research use of specimens. At one center, to increase enrollment, we supplemented the BPV sample with patients who signed the same broad consent for biobanking in the clinic. We surveyed 302 cancer patient donors from June 2013 through March 2015 by approaching all donors for the BPV Program at all sites.

A Steering Committee guided the BPV-ELSI Study and developed survey questions based on ethical issues about biobanking taken from the published literature regarding biobanking. The committee included bioethicists, survey researchers, biobank scientists and policy experts from the National Cancer Institute (NCI), the National Institutes of Health Department of Bioethics, the Office for Human Research Protections, and Leidos Biomedical Research, Inc. (NCI contractor for this study), as well as the ELSI study investigators at the University of New Mexico (UNM), Emory University Winship Cancer Institute (WCI), Boston Medical Center (BMC), and the University of Pittsburgh (UPitt).

Twenty-four rating-scaled survey questions (see Table 2) were developed, based on the extant related ethics literature that asked donors to provide responses on 0 to 10-point rating scales with variable scale point labels that modeled latent continuums of importance,

acceptability, desire to know, or concern as appropriate. In addition, we asked 4 open-ended questions about donors' reasons for donating and their concerns related to use of their biospecimens. We also obtained information about participants' backgrounds and personal characteristics and administered one standard *Trust in Researcher* scale (Hall et al., 2006) (see Table 1).

Respondents were surveyed by trained research staff and were supervised by site PI's and the overall study PI. Respondents completed surveys from one hour to 63 days (mean=16.1; median=12.0; sd=14.2) after reading the BPV donor consent form, and they were not allowed to refer back to the BPV consent form. All survey questions were written at an average of 7th grade level (Flesch-Kincaid reading level in WORD) and were pilot tested using standard cognitive testing procedures. Interviewers provided participants with a written copy of the questions and read all questions and response options verbatim either face-to-face (12% of interviews) or over the phone (83%), as preferred by the participant, with 5% beginning as face-to-face interviews that concluded over the phone. Interviews took about 30 minutes on average to complete.

Participants were compensated for time and effort with a $50 merchandise card. All centers entered de-identified data into a secure NCI web-portal, and data were verified for accuracy of entry. IRBs at each institution approved the study, and survey respondents provided oral informed consent for the survey.

Data Analysis

Participants responded to the 24 main survey questions with ratings on 0 to 10-point rating scales as models of latent continuums. To compare conceptually related questions as within-subjects factors, responses were subjected to repeated measures factorial multivariate analyses of variance (MANOVA) models, using research site and respondent gender as between subjects factors in each model. Univariate factorial Site × Gender ANOVA models were conducted to analyze responses from two individual questions. Differences in respondent personal characteristics across sites were analyzed with chi-square or one-way ANOVA, as appropriate.

RESULTS

Ninety-three percent of donors asked to participate in this survey study agreed. The number of respondents varied by site: 38 at BMC, 61 at UNM, 77 at UPitt, and 126 at Winship, with differences due to the availability of patients with tissue types who qualified for the parent BPV tissue donation study. Table 1 describes characteristics of our survey respondents by research site. Results for all items and domains were generally consistent across the four academic medical centers, as well as across gender and other donor characteristics, with any differences across sites or donor characteristics invariably being small in magnitude (see Table S1 which shows question response means by site to illustrate consistency of responses by site).

Quantitative Survey Questions

Our quantitative questions covered four areas: (1) Ethical Safeguards; (2) Specific Uses of Biospecimens; (3) Concerns about Confidentiality of Data; and (4) Reporting Findings to Donors. Table 2 shows overall mean responses by question along with statistically significant effects found for item, site, respondent gender, and item by site plus effect sizes for each, which tended to be small in magnitude.

Ethical Safeguards—Donors reported receiving about the right amount of information from the broad consent form regarding their decision to donate (mean=5.51 [SD=1.24] on a scale from 1=not enough; 5=right amount; and 10=too much information). Donors considered it very important that a committee of experts decide what research can be done using their biospecimens (mean=8.03 [SD=2.54] with 1=not important at all; 5=moderately important; and 10=extremely important).

Specific Uses of Donated Biospecimens—Donors rated the use of their biospecimens for genetic research on cancer and on other diseases as extremely acceptable (means=9.50 [SD=1.30] and 9.53 [SD=1.35], respectively, on a scale of: 0=not all acceptable; 5=moderately acceptable; and 10=completely acceptable). Donors uniformly rated use of their biospecimens to study different types of illnesses (cancer, other medical illnesses, mental illness, genetic research, and fertility research) as extremely acceptable (means=9.67; 9.51; 9.39; 9.33, and 9.18, with SDs=1.04; 1.34; 1.69; 1.73, and 2.19, respectively). However, the use of donated tissues by for-profit companies to develop a new medicine that earns the company a lot of money was rated only moderately acceptable and with considerable variability of ratings among donors (mean=5.84 [SD=3.43]).

Donors also rated use of their specimens for research that “changes some cells,” “grows a cell line,” and “involves adult stem cell research” as extremely acceptable (means=9.07; 9.16; 9.54 with SDs = 2.03; 1.85: 1.37, respectively). Finally, donors rated use of their biospecimens by researchers at their own institution and at other U.S. research institutions as extremely acceptable (means=9.59; 9.28 with SDs=1.23; 1.86, respectively), but they considered use by researchers at for-profit companies and in other countries as only moderately acceptable (means=6.69; 6.09 with SDs=3.64; 3.91, indicating considerable variability in opinion).

Confidentiality—Biospecimen donors expressed fairly low levels of concern that someone outside the research team might learn that they had donated tissue or might learn what genes they have (means=3.15; 3.20 with SDs=3.60; 3.66, again indicating considerable variability in opinion).

Reporting Findings to Donors—Donors expressed a moderate interest in having general *scientific* results of studies using their specimens returned to them (mean=6.56 [SD=3.26]). They expressed “definitely wanting to know” *individual actionable* genetic results for either cancer or non-cancer diseases (means=8.97; 8.78 with SDs=2.01; 2.13, respectively on a scale from 0=definitely not want to know to 5=moderately want to know to 10=definitely want to know). In contrast, donors indicated only moderate desire to know

non-actionable results for cancer and non-cancer illnesses (means=4.81; 4.44 with SDs=3.96; 3.99, respectively, but with high levels of variability of views).

Qualitative Response Results

When asked: "What are the main reasons why you decided to donate your tissue to be stored for use in future research?" over 90% of donors expressed altruistic reasons, either to help other people who might have cancer in the future or to help further research in general. Ten percent indicated a specific desire to help find a cure for *their own* cancer. When asked: "Do you have any concerns about donating your tissue and blood for use in future research?" fewer than 9% of respondents expressed any concern, and less than 1% said their concerns made them less likely to donate their biospecimens. Finally, when we asked donors: "Are there any specific types of research that would concern you or that you would not have wanted your donated biospecimens used for?" fewer than 19% specified any type of research for which they would not want their donated biospecimens to be used with 5% indicating that human cloning would be unacceptable.

DISCUSSION

Overall, our survey of 302 respondents from 4 medical centers shows that actual tissue donors who underwent broad consent express very positive views regarding its use to obtain tissue samples for future research. First, respondents indicate that the process of obtaining broad consent provided them with sufficient information regarding the future possible research uses of their samples. Second, donors on average express low concern about possible breaches in confidentiality that might result in someone outside the research team learning their genetic status. Third, consistent with the intent of broad consent, donors consider it highly acceptable for their biospecimens to be used to conduct research on a wide range of conditions including different types of cancer, other medical illnesses, mental illnesses, and research to help women become pregnant. Similarly, they find it acceptable that researchers at their institution and other institutions in the United States use their biospecimens for research. Fourth, respondents were very supportive of several types of research that, as it has been argued, might conflict with donors' preferences or values, including genetic research (McGuire & Gibbs, 2006), genetically "changing of cells," "growing cell lines," and "using adult stem cells" ("NPRM for Revisions to the Common Rule," 2015). In addition, the present findings are generally consistent across sites and respondent gender. These results, from actual donors who recently gave broad consent, provide strong support for the claim that broad consent is an ethically appropriate method of obtaining consent to store and use biospecimens for future research.

Our respondents expressed moderate concern with respect to two types of research. They regarded it as only moderately acceptable that researchers outside the U.S. and that researchers at for-profit companies use their biospecimens. Future research should assess these concerns further. In the meantime, broad consent forms might explicitly mention that these are possibilities.

Finally, whether future studies which propose to use stored samples for which broad consent was obtained need to undergo ethical review has been debated (Hoeyer, Olofsson, Mjörndal,

& Lynöe, 2004). Our survey is the only one of which we are aware that assessed this issue in actual donors who gave broad consent. These actual broad consent donors indicated that having expert committee review is very important, a finding which supports those who endorse review of proposed biospecimen uses by expert committees.

Our findings in support of broad consent are largely consistent with other studies of actual donors, with several caveats. One study found that 88% of 273 donors agreed with permitting research on any condition, but non-Caucasians, those with lower education and older patients were significantly less likely to approve various types of future research (Helft et al., 2007). Another study found that blacks, those with lower education and the very religious were less likely to participate in a biobank (Saskia C. Sanderson et al., 2017). However, other studies did not find statistically different views based on respondent characteristics (Valle-Mansilla et al., 2010; Vermuelen et al., 2009). Nor did we find differences based on our respondents' characteristics, including race, ethnicity, age, education, income and gender. Further, our results were generally consistent across our 4 diverse study sites. However, our study was not designed to have sufficient power to examine the effects of differences in respondent characteristics such as race and ethnicity.

Interestingly, the donors in Vermeulen's and Valle-Mansilla's studies supported "general informed consent" which may be akin to blanket consent, but they preferred certain kinds of control over future research, suggesting a broad consent model that allows some limitations on future research. Most (61%) of Vermeulen's 111 participants thought patients should be able to indicate the kind of future research for which their tissue may or may not be used, and 76% of Valle-Mansilla's 278 donors thought that "a research subject has the right to establish limits regarding the research that can be done with his or her tissue." The donors queried in these two studies may support the broad consent model as long as it allows limits on future research to be specified in the consent (Valle-Mansilla et al., 2010; Vermuelen et al., 2009).

What limits on future research might be considered? Notably, our donors were not concerned with various types of genetic research, though commentators have suggested that genetic research raises unique concerns regarding consent (Caulfield et al., 2008; McGuire, Caulfield, & Cho, 2008; McGuire & Gibbs, 2006). Only 5% of our donors mentioned cloning as a concern in response to an open-ended question. Further exploration with broad consent donors is needed about research activities that should be described separately in a broad consent form.

Our donors on average did find it only moderately acceptable that researchers outside the U.S. (Helft et al., 2007; Pentz et al., 2006) or at for-profit companies (Helft et al., 2007; Trinidad et al., 2012; Valle-Mansilla et al., 2010) use their biospecimens. Donors and the general public may not be aware of the importance of collaborations with international researchers and the fact that NIH funds biomedical researchers around the world. Our donors and the public may also be unaware of the important contributions to biomedical science of research conducted by commercial entities. Educational outreach on these two issues may be appropriate in the future. However, respondents' views about international and commercial researchers were widely varied with some support and some opposition. And in contrast,

79% of Helft's donors thought that research outside the country was acceptable and 58% of Valle-Mansilla's donors were willing to provide general consent for research conducted by pharmaceutical companies (Valle-Mansilla et al., 2010). Most of Vermeulen's donors (59%) preferred to be consented specifically for research by commercial entities (Vermuelen et al., 2009). Given these differing views, as well as those that have been found in previous studies (Garrison et al., 2016; Grady et al., 2015; Helft et al., 2007), future research should consider how to address these two donor concerns.(Health and Human Services, 2017)

Donors strongly support the evolving consensus that general research findings and also individual research findings that might help prevent or treat cancer or some other disease should be offered to donors (Burke, Evans, & Jarvik, 2014; Christenhusz, Devriendt, & Dierickx, 2013; Jarvik et al., 2014; Knoppers, Ma'n, & Sénécal, 2015; Lolkema et al., 2013; Saskia C Sanderson et al., 2015; Siminoff et al., 2017). In contrast, our donors express divergent views regarding the return of findings that are not medically actionable (Helft et al., 2007; Murphy et al., 2008).

Our study is limited in some respects. The sample size (N=302) was not designed to provide adequate statistical power to examine differences across various personal characteristics of respondents such as race and ethnicity or other factors. Thus, null effects for possible donor characteristic moderator effects should be interpreted with caution. In addition, we only interviewed cancer patients, whose views may differ from other patients' views or from non-patients' views. We also did not assess the views of people who refused to donate their biospecimens, and opinions of such people might well contrast to those who agree to donate. However, studies indicate that a high percentage (typically, 60% to 99%) of patients agree to donate their biospecimens (Baer, Smith, & Bendell, 2011), as was the case in our parent BPV study (75% donor response rate).

BEST PRACTICES

To improve current and future scientific progress in treating people with serious illnesses by making the most efficient use of scarce biospecimens, biobanks and medical institutions should encourage biospecimen donation for future use in research using a broad informed consent model. Our findings show clearly that the vast majority of cancer patient donors are comfortable with a broad informed consent model that allows the donation of their biospecimens without providing donors specific knowledge of the future research studies in which their biospecimens will be used, so long as expert review of future studies is ensured. Finally, our findings also support the evolving practice of returning general research findings as well as potentially individually actionable findings.

RESEARCH AGENDA

Some researchers in the future may desire to contrast the views of actual donors of biospecimens to individuals who decline to donate. However, the vast majority of cancer patients asked to donate their excess tissues do so. Thus, understanding the potentially contrasting views of non-donors to donors such as ours may not prove to be very useful in efforts to increase the donor rate. As with all research, other researchers may also wish to

attempt to replicate our findings in different locales, both national and international. Attempts to replicate should also focus on specific sub-populations such as various types of vulnerable groups, including racial/ethnic minority populations.

EDUCATIONAL IMPLICATIONS

Our general findings showing considerable donor support for a broad informed consent model that does not provide donors' knowledge of specific research studies for which their biospecimens will be used. Our findings should be communicated directly to all stakeholder groups: biospecimen researchers, institutional review boards, research review committees, and biobank tissue use committees, as well as with biomedical researchers in general, including research trainees. Our general findings should also be shared with the media and the general public, with particular attention to the importance of collaborations with for-profit researchers and international partners.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Biographies

Teddy D. Warner, Ph.D., ELSI Study Principal Investigator and ELSI Study Site Principal Investigator, is Research Professor Emeritus of Family & Community Medicine at the University of New Mexico School of Medicine, where he has conducted a number of NIH funded studies of ethical issues in research. He taught research ethics for many years and served for years as an ethicist for his institution's NIH Clinical Translational Science Center. His research interests focus on ethical issues in research, education, and practice, on which he has published many papers. His expertise in survey methods, multivariate statistics, and psychometrics was central to this study. He worked on all aspects of this study as principal investigator.

Carol Weil, J.D., ELSI Study Investigator, chaired the Steering Committee for NCI Biospecimen Pre-analytical Variables ELSI study which generated the survey about broad consent that led to this publication. Since 2010 she has conducted policy analysis at NCI and provides advice to research teams on the ethical and regulatory issues involved in administering clinical trials and managing biorepositories, including consent strategies, data sharing plans, disclosure of research results, and community engagement. Previously, she served with the Office for Human Research Protections, where she oversaw compliance investigations of research institutions and developed human subject regulatory guidance. She worked on conceptualization, survey development, interpretation of study results and drafting and revising this manuscript.

Christopher Andry, Ph.D., ELSI Study and BPV Study Site Principal Investigator at Boston Medical Center (BMC), continues to partner with the NCI on biobanking processes and projects. He has an ongoing interest in biospecimen collection and analysis with a focus on the impacts of pre-analytic variables on biomarkers. Employed at BMC for over 30 years, he works there to ensure that an underserved patient population receives exceptional care, is treated respectfully and has opportunities to participate in translational research activities such as clinical trials and biobanking. He worked on conceptualization, survey development, interpretation of study results, manuscript revision, and overseeing the study conduct at BMC.

Howard Degenholtz, Ph.D., ELSI Study Site Principal Investigator at the University of Pittsburgh (UPitt), is Associate Professor of Health Policy and Management and faculty, Center for Bioethics and Health Law at the University of Pittsburgh. Dr. Degenholtz is a health services researcher with expertise in quantitative and qualitative methods. He has conducted empirical research on the informed process with a focus on the therapeutic misconception. He worked on conceptualization, survey development, interpretation of study results, manuscript revision, and overseeing the study conduct at UPitt.

Lisa Parker, Ph.D., ELSI Study Site Investigator at University of Pittsburgh, is a philosopher-bioethicist with expertise in ethics of informed consent for biobanking and return of results and incidental findings of genomic research. She has served on two NHGRI

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Latarsha Carithers, Ph.D., ELSI Study Investigator, is currently a Scientific Review Officer at the National Institute of Dental and Craniofacial Research. At the time of this project, she was a program director at the National Cancer Institute's Biorepositories and Biospecimen Research Branch. She worked on study conceptualization, developing contractual milestones and deliverables, developing the survey, providing logistical guidance and government oversight throughout the project.

Michelle Feige, **M.S.W**., ELSI Study Investigator, is now the Executive Vice-President of the Association for the Accreditation of Human Research Protection Programs (AAHRPP), where she provides strategic and substantive contributions to all aspects of AAHRPP's operations. Prior to joining AAHRPP, she worked in the education division of the US Office for Human Research Protections where she provided the medical research community with guidance on the federal regulations for the protection of human subjects, and spent 8 years at the National Institute of Mental Health where she started a novel program designed to protect research subjects with severe psychiatric illnesses. She co-chaired the steering committee for the NCI Biospecimen Pre-analytical Variables ELSI study which generated the broad consent survey that led to this publication. She worked on study conceptualization, survey development, interpretation of results, and manuscript revision.

David Wendler, Ph.D., ESLI Study Investigator, is a senior investigator and Head of the Section on Research Ethics in the Department of Bioethics at the NIH Clinical Center. He has been principal investigator on several empirical studies evaluating individuals' attitudes regarding research with biological specimens and broad consent. He worked on study conceptualization, survey development, interpretation of study results, and manuscript revision.

Rebecca Pentz, Ph.D., ELSI Study Site Principal Investigator at Winship Cancer Institute, is Professor of Research Ethics at Winship Cancer Institute, Emory School of Medicine. She is the senior author of this manuscript and has done extensive empirical ethics research on biobanking issues. Her main interests include biobanking ethical issues, early drug development ethics and communication about new cancer therapies. She worked on study conceptualization, survey development, interpretation of study results, manuscript drafting and revision, and overseeing the study conduct at Winship Cancer Institute.

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Table 1

Characteristics of Respondents by 4 Research Sites

Characteristic	Univ. NM (n=61)	Winship (n=126)	Univ. Pitt. (n=77)	Boston MC (n=38)	Overall (N=302)
(% women) **Sex**	69%	45%	69%	50%	57%[a]
Mean (sd) **Age** years	55.61(12.8)	60.29 (12.69)	59.32 (12.40)	57.92 (13.15)	58.8 (12.59)
Education					
Less than high sch.	9.8%	7.2%	7.8%	15.8%	8.9%
HS graduate	34.4%	23.8%	35.1%	31.6%	29.8%
Some college	34.4%	33.3%	28.6%	21.1%	30.8%
4-yr degree	11.5%	16.7%	19.5%	18.4%	16.6%
Grad. degree	9.8%	18.3%	9.1%	13.2%	13.5%
Married/Partner	54.1%	69.8%	70.1%	42.1%	63.2%[a]
Living Biol. Child	88.7%	84.1%	81.8%%	71.1%	80.8%[a]
Employed	46.1%	34.0%	45.2%%	38.0%	40.1%
Ethnicity/race					
American Indian	18.0%	0.0%	0.0%	0.0%	3.6%
African American	0.0%	23.0%	7.8%	28.6%	14.9%
Asian American	0.0%	3.2%	0.0%	0.0%	1.3%
Hispanic, White	31.1%	0.0%	0.0%	11.4%	7.6%
White, non-Hisp.	47.5%	71.4%	89.6%	55.3%	69.2%
Multiple categories	3.3%	2.4%	2.6%	0.0%	2.3%[a]
Income Level					
< $20K	36.7%	13.5%	16.9%	23.7%	19.9%
$20,001K – $40K	24.6%	11.1%	24.7%	2.6%	16.2%
$40,001K – $60K	14.8%	12.7%	13.0%	10.5%	12.9%
$60,001K – $100K	9.8%	23.0%	22.1%	26.4%	20.5%
> $100K	9.8%	22.2%	20.7%	7.9%	15.2%
Not reported	6.6%	17.4%	11.7%	29.0%	15.2%[a]
Community Size					
City/large town	45.9%	40.5%	28.6%	81.6%	43.7%

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Characteristic	Univ. NM (n=61)	Winship (n=126)	Univ. Pitt. (n=77)	Boston MC (n=38)	Overall (N=302)
Small town	23.0%	32.5%	48.1%	18.4%	32.8%
Rural area	31.1%	27.0%	23.4%	0.0%	23.5%[a]
Have Research Exp	4.9%	18.3%	11.7%	21.6%	14.2%
Pre-cancer Health[b]	6.89 (2.57)	7.46 (1.77)	7.45 (2.05)	8.11 (1.54)	7.42 (2.02)[a]
Current Health[b]	6.21 (2.84)	6.77 (1.95)	7.45 (1.89)	6.42 (2.14)	6.79 (2.20)[a]
Social Issues[c]	5.52 (2.15)	5.13 (2.72)	5.19 (2.66)	6.29 (2.27)	5.37 (2.56)[a]
Religious Values[d]	5.52 (3.55)	7.54 (2.74)	6.77 (2.49)	5.68 (2.99)	6.73 (2.99)[a]
Trust in Researchers[e]	6.13 (0.85)	5.91 (0.93)	5.87 (0.94)	5.76 (0.89)	5.92 (0.91)

[a] $p < 0.05$; research site mean differences (ANOVA) *or* research site percentages (chi-square).

[b] Health self rating scale: 0 = very poor to 10 = excellent.

[c] Social issues rating scale: 0 = very conservative to 5 = moderate to 10 = very liberal.

[d] Religious values rating scale: 0 = not at all traditionally religious to 5 = somewhat traditionally religious to 10 = very traditionally religious.

[e] *Trust in Researchers Scale* (7 statements each rated as: 0=strongly disagree to 5=disagree/agree to 10=strongly agree; sum of 7 items divided by 7 to put scores on 0 to 10 point scale where higher scores indicate higher trust).

Table 2

Biospecimen Donor Ratings of Issues Related to Research Use of Their Biospecimens (N = 302)

Survey Question Topic:	Mean (SD)	Item[f]	Site[f]	Sex[f]	Item × Site[f]
Donors' Ratings of Ethical Safeguards					
Amount of information provided in broad consent form[a]	5.51 (1.24)	–	<0.22	<0.87	–
Importance of expert review of studies using biospecimens[b]	8.03 (2.54)	–	<0.82	<0.85	–
Donors' Acceptability for Use of Donated Biospecimens[c]					
By for-profit companies	5.84 (3.43)	0.001	<0.95	<0.12	<0.86
For genetic research that might help prevent or treat cancer	9.50 (1.30)	η^2=.02[g]	η^2<.01	η^2<.01	η^2<.01
For genetic research that might help prevent/treat other diseases	9.53 (1.35)	–	–	–	–
For research about:					
Any type of cancer	9.67 (1.04)	0.001	0.001	<0.19	<0.02
Any medical illness other than cancer	9.51 (1.34)	η^2=.10	η^2=.02	η^2<.01	η^2=.01
Any type of mental illness	9.39 (1.69)	–	–	–	–
Any type of genetic research	9.33 (1.73)	–	–	–	–
Any type of research on fertility	9.18 (2.19)	–	–	–	–
For research that:					
Changes some cells	9.07 (2.03)	0.001	0.001	<0.01	<0.03
Grows a cell line	9.16 (1.85)	η^2<.10	η^2<.06	η^2<.03	η^2<.03
Involves adult stem cell research	9.54 (1.37)	–	–	–	–
For use of donated biospecimens by researchers:					
At your institution	9.59 (1.23)	0.001	0.17	<0.15	<0.43
At other U.S. research institutions	9.28 (1.86)	η^2<.42	η^2<.02	η^2<.01	η^2=.01
At for-profit companies	6.69 (3.64)	–	–	–	–
In other countries	6.09 (3.91)	–	–	–	–
Donors' Concern that[d]					
Your biospecimen donation might be disclosed to others	3.15 (3.60)	0.56	0.12	<0.57	<0.07
Others might learn about your genes	3.20 (3.66)	η^2<.01	η^2=.02	η^2<.01	η^2<.03

Survey Question Topic:	Mean (SD)	Item[f]	Site[f]	Sex[f]	Item × Site[f]
Donors' Desire for Findings to Be Reported to Donors [e]					
In reports of general scientific results on website/newsletter	6.56 (3.26)	0.001	0.10	<0.19	<0.01
Actionable genetic information regarding cancer	8.97 (2.01)	η^2<.55	η^2<.03	η^2<.01	η^2<.03
Actionable genetic information about other diseases	8.78 (2.13)	–	–	–	–
Non-actionable genetic information regarding cancer	4.81 (3.96)	–	–	–	–
Non-actionable genetic information about other diseases	4.44 (3.99)	–	–	–	–

Notes:

[a] 0 = far too little information; 5 = just right amount of information 10 = far too much information

[b] 0 = not at all important; 5 = moderately important; 10 = extremely important

[c] 0 = not at all acceptable; 5 = moderately acceptable; 10 = completely acceptable

[d] 0 = not concerned at all; 5 = moderately concerned; 10 = very concerned

[e] 0 = definitely not want to know; 5 moderately want to know; 10 = definitely want to know

[f] *p* value for this effect from an Item [repeated measures] × Site × Sex MANOVA (or Site × Sex ANOVA)

[g] η^2 = % of variance accounted for by the effect (a measure of effect size independent of sample size)