HHS Public Access

Author manuscript

J Empir Res Hum Res Ethics. Author manuscript; available in PMC 2016 December 01.

Published in final edited form as:

J Empir Res Hum Res Ethics. 2015 December ; 10(5): 449–456. doi:10.1177/1556264615610199.

Investigator Experiences and Attitudes about Research with Biospecimens

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Abstract

To advance scientific knowledge about human diseases and effective therapeutic treatments, investigators need access to human biospecimens and associated data. However, regulatory and procedural requirements may impede investigators' efforts to share biospecimens and data within and across institutions. While a number of studies have explored experiences and attitudes of study participants and others about biospecimen and data sharing, less is known about investigators' perspectives. We conducted an electronic survey to learn about investigators' experiences and attitudes about research with biospecimens and associated data. A total of 114 practicing scientists from a pool of 60 university medical schools with Clinical and Translational

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Disclaimers: None

The authors have no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Science Awards (CTSAs) funded by the National Institutes of Health (NIH) participated. We found a high degree of variability in investigators' experiences with Institutional Review Boards (IRBs) when seeking approval to conduct biospecimen research, as well as differences in approaches to informed consent for the collection of specimens. Participants also expressed concerns that the risks of biospecimen research may be overestimated by IRBs. This research suggests that the current regulatory environment for human research protections may require reconsideration with regard to standards for collection, use and sharing of biospecimens and data.

Keywords

biospecimens; institutional review board; informed consent; researcher attitudes

Introduction

The regulations governing human research in the United States are more than thirty years old (http://www.hhs.gov/ohrp/humansubjects/commonrule/index.html). The architects of what would become the Common Rule could not have anticipated the degree to which, in today's environment, successful research often relies upon collaboration of investigators at different institutions, and sharing of both data and biospecimens (Portilla, Evans, Eng, & Fadem, 2010). The need to aggregate information and materials from different institutions can create unique challenges for investigators as well as regulators (Guterman, 2010; McGraw et al, 2012). Many of these challenges are relevant particularly for genetic research studies that use stored biospecimens and data, where the information and materials often were collected without the express intention of secondary uses by the primary or secondary investigators, or for research goals not anticipated at the time of collection (Javitt, 2013; Meslin & Quaid, 2004; Vaught & Lockhart, 2012; Wolf, Bouley, & McCulloch, 2010).

Because the Common Rule allows for significant flexibility with regard to how such secondary uses of existing data and biospecimens may occur, differences in institutional policies and procedures have evolved (Rothwell et al, 2015). These differences may affect investigators' efforts to share biospecimens and to collaborate on inter-institutional research projects. The success of collaborative research depends on finding practical and ethically sound ways to address these issues within the current regulatory framework. Yet, little is known about how differences in institutional practices with regard to collecting, using, and sharing data and specimens may affect investigators' research (Master, Campo-Engelstein, & Caulfield, 2014). Understanding investigators' experiences and attitudes about issues such as informed consent and IRB oversight is necessary in order to develop practical, feasible and ethically sound options to advance inter-institutional research.

To address this gap, we sought to learn about the perspectives of investigators who conduct biospecimen research across major Academic Health Centers (AHCs) within the largest network of research institutions in the United States, the Clinical and Translational Science Awards (CTSA) consortium. We focused on their experiences with regard to IRB practices and research regulations, and their attitudes about the regulatory framework within which they operate. This study was part of a larger NIH-funded project designed to better

understand the range and variation of IRB policies and practices regarding human subject protections in the context of the collection, storage and use of biospecimens and associated data.

Methods

Participants

For this study, we recruited investigators at institutions that belong to the National Institutes of Health's (NIH) Clinical and Translational Science Awards (CTSA) consortium (as of 2014). The 60 research institutions in the CTSA consortium are leading academic medical centers that serve diverse populations of adult and pediatric patients, and are known for having world-renowned investigators who conduct genetic research (https://www.ctsacentral.org/).

Institutions funded by the CTSA program are intended to function as a "network of exceptional collaboration" (Kon, 2008) to transform clinical and translational research, including coordinated linkages in resources, vision, and studies. The CTSA program is one of the key objectives of the NIH Roadmap for medical research, which calls for integrating research networks and recognizes the importance of harmonizing regulatory processes (Zerhouni, 2007). The CTSA consortium forms the backbone of publicly-funded translational research in the United States and is a key example of the growing trend toward promoting collaborative research within and across sites in order to move interventions from the laboratory bench to the bedside. We chose to recruit investigators from CTSA-member institutions because they operate in environments that are expected to collaborate within and across sites.

Survey Design

The project principal investigator (PI) and research team developed a quantitative survey to collect information about investigators' experiences with and attitudes about the collection, use, and sharing of biospecimens, and how the investigators' institutions address human subjects protections regarding biobanking-related research.

The 44-item survey addressed work history, experiences with informed consent, collection of biospecimens from adults and minors, research with existing biospecimens and data, sharing biospecimens and data with other researchers, and opinions about current rules and regulations regarding human research.

Survey Administration

The electronic survey was administered using the Research Data Electronic Data Capture Application (REDCap) software system, hosted at Case Western Reserve University (CWRU). REDCap is a secure, web-based application designed to support data capture for research studies, providing: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing

data from external sources (Harris et al, 2009). The survey was anonymous, and there were no attempts to collect the IP addresses of participants.

We used a multi-method approach to obtain the target sample (n=512). We contacted the IRB Administrators and Vice Presidents for Research at the 60 institutions within the CTSA consortium and asked them, via email and phone calls, to provide up to ten names of researchers engaged in research with biospecimens at their institutions. To supplement the names those informants provided, we also searched the NIH's Research Portfolio Online Reporting Tools (RePORT) system, using key search terms that included “specimen,” “biospecimen,” and “genetics,” to identify investigators who had been funded by federal grants for research involving biospecimens.

The PI then sent an introductory email with a link to the electronic survey to all the potential participants. Since we did not collect any identifying information from participants when they completed the survey, there was no way to send a reminder specifically to those people who did not participate. Therefore, reminders were sent by email to each potential participant two weeks following the initial invitation email.

Data Analysis

Data from the survey was transferred from REDCap to an SPSS v. 21 file. Descriptive statistics were used to describe frequencies of individual item responses. Open-ended items also were reviewed in SPSS to look for common themes that were illustrative of the quantitative data.

Protection of Human Subjects

This study was reviewed and confirmed as Exempt (IRB-2014-801) from the Common Rule requirements by the Case Western Reserve University IRB, and was performed in accordance with all ethical and other requirements in the United States and as specified by the sponsoring agency.

Written informed consent was not required light of the fact that the survey would be delivered electronically and returned anonymously, and posed no risk of harm to participants. The invitation email sent to each potential participant directly by the study PI contained specific language about the fact that the responses would be anonymous as respondents’ answers would not be linked to them or to their institutions.

Results

We received 114 responses, with 102 eligible for inclusion after confirming that the respondent had been a PI or Co-investigator for research that involved the collection, storage, or use of biospecimens. A total of 519 invitations were emailed with a response rate of 22%.

The majority of respondents (67%) said they have conducted research in which they collected, stored, or used biospecimens for >10 years. One-third had been the PI or Co-investigator on > 7 research studies that collected or used biospecimens. Eighty-one percent

had collected specimens prospectively from adults for research, while 47% had collected specimens from minors.

Informed Consent

We asked respondents to tell us what approaches to informed consent they have used most frequently when collecting biospecimens prospectively for research. As shown in Table 1, 24% said they most frequently/often used a study-specific consent approach that limits the use of biospecimens to a specific hypothesis-driven protocol; 24% most often used a "tiered consent" approach (i.e., study participants were offered multiple options for how their biospecimens could be used); and 25% said they most often used a "broad consent" approach in which study participants agree that their biospecimens can be used for future unspecified research.

Investigators who reported having used a tiered approach were then asked to elaborate on how frequently their consent forms contained particular types of options that allow donors to limit or direct future research uses of their specimens. Twenty-nine percent of these investigators reported that most or all of their consent forms gave donors the ability to limit the types of medical conditions that can be studied using their samples. Twenty-five percent of investigators allowed donors to limit which researchers may have access to their specimens in most or all of their consent forms. Forty-three percent of investigators indicated that most or all of their consents allow donors to choose whether they can be re-contacted for future consent for other studies. Lastly, 18% of investigators indicated that most or all of their consent forms allow donors to prohibit data generated from their specimens from being added to larger databases, such as the NIH's database of Genotypes and Phenotypes (dbGaP).

We asked, "Has your IRB raised objections or concerns to you about protocols in which you proposed a consent form stating that 'the biospecimens and associated data will be shared with researchers outside your institution?'" To that question, 20% answered "yes," 54% answered "no," and 26% had not proposed to do this.

We asked, "Has your IRB raised objections or concerns to you about protocols in which you proposed a consent form stating that, 'the data from biospecimens will be deposited in a central repository, like DbGaP?'" Fifteen percent answered "yes," 37% answered "no," and 48% had not proposed to do this.

Stored Biospecimens: Identifiability, Risks, and Consent

We also wanted to learn about investigators' uses of biospecimens that could be linked to the individual donors, and those for which identifiers were removed. When asked "Which type of existing stored biospecimen is used most frequently in your research?," 28% of respondents said "anonymized[i]" biospecimen, 45% said "coded" biospecimen, and 17% said

[i]We defined *anonymized biospecimens* as having no identifiers or codes linked to identifying information about the donors and *coded/de-identified biospecimens* as being linked to identifying information about the donors, without the researcher having access to the key that links the code to identifying information.

"identified" biospecimen. Seven percent of the respondents said they have not used existing stored biospecimens.

Investigators' perceptions about how their IRB would assign a risk level to research based on the "identifiablity" of biospecimens are shown in Table 2. When asked, "If you proposed a new study involving human genetics using only stored biospecimens/data, what level of risk do you think your IRB would typically assign to this study when the biospecimens are *coded*?," 46% said they thought their IRB would classify the study as "no greater than minimal risk," 32% thought their IRB would view the study as "greater than minimal risk," and 22% were unsure about or didn't know how their IRB would classify the study. When asked the same question but about specimens that are *identified*, 18% thought their IRB would classify the study as "no greater than minimal risk," while 60% said their IRB would consider this "greater than minimal risk" and 22% did not know or were unsure.

We also were interested in understanding what investigators think about how their IRBs would handle the proposed use of stored biospecimens. We asked respondents whether their IRBs would classify a new study involving human genetics that used only stored, coded biospecimens/data as exempt from the Common Rule requirements for IRB oversight. Seventy-three percent said "yes," 9% said "no," and 18% were unsure/didn't know.

When asked whether investigators should be able to use "left-over" biospecimens collected in the clinical setting without informed consent for research as long as the subject's identity is never disclosed to the investigator, 64% of respondents said "yes," 28% said "no," and 8% didn't know. This question was further explored with the option to write comments explaining why use of "left-over" biospecimens collected in the clinical setting without informed consent should be permitted as long as the subject's identity is never disclosed to the investigator. One respondent wrote that this should be permitted because it "would enable research that is broadly representative" and another wrote, "risk is minimal when using unidentified samples."

We also asked whether it would it be desirable to implement a standardized general consent form to permit future unspecified research with biospecimens and data originally collected for research. Ninety-two percent chose "yes," 6% chose "no," and 2% didn't know. The same question was asked about biospecimens and data originally collected for clinical care. Seventy-five percent answered "yes," 11% answered "no," and 14% said they didn't know.

Sharing Biospecimens

We asked respondents to check all that apply to the question, "Under what conditions has your IRB allowed you to share biospecimens that you collected?" Fifty percent said sharing was permitted when the original informed consent document stated that such sharing could occur; 18% said they could share specimens after recontacting the donors and obtaining consent to do so; 39% said this would be permitted after de-identifying the biospecimens; 22% said they would have to anonymize the biospecimens; and 4% said their IRB doesn't allow sharing of biospecimens. Seventeen percent said they didn't know because the issue of sharing never came up (Table 3).

To learn about IRB requirements for cross-institutional sharing of biospecimens, we asked investigators about their experiences obtaining biospecimens from another institution and about giving biospecimens to another institution. Twenty-four percent of respondents said their institution would enter into an agreement to rely on another institution's IRB approve to *obtain* biospecimens, 17% said their institution would not do this, 29% were unsure/didn't know, and 30% had no experience with this scenario. When asked, "To share [*give*] biospecimens with [to] another institution for research, does your institution enter into an agreement to rely on the other institution's IRB approval?" Twenty-seven percent said "yes," 15% said "no," 35% were unsure/didn't know, and 23% had no experience with this scenario.

Opinions about Rules and Regulations

We asked respondents about their perspectives on the appropriateness of current rules and regulations regarding the collection, storage, use, and sharing of biospecimens. Respondents were asked to indicate whether they felt that policies were too restrictive, just right, or too permissive. As Table 4 shows, over two-thirds of respondents thought the policies were just right for the collection of biospecimens (69%), the storage of biospecimens (74%), the use of biospecimens (68%), and the sharing of biospecimens (63%). Almost no respondents judged the rules to be too permissive.

After this series of questions, respondents were asked to write their opinions about whether the current rules and regulations for collecting/using/sharing/storing biospecimens were too restrictive, about right, or too permissive. In the handful of written comments about current regulations being too restrictive, investigators raised several concerns.

As to privacy issues, one respondent wrote, "The concern for privacy and compliance has taken over the research environment based on the minuscule chance of data release, dramatically impacting the quantity and quality [of] research which is very likely to help those whose privacy is slightly at risk." Another said, "The theories about how privacy might be violated get extremely fanciful, and are not nearly as likely as getting your privacy violated in routine use of any computer."

Another comment reflects investigator frustration with the research oversight bureaucracy: "The bureaucracy is very frustrating and is very much of a disincentive to carrying out research on human subjects. I understand and completely agree with the need to protect individuals, and I understand abuses that have occurred with regard to human subjects. So I support rules and regulations. I just think the pendulum has swung too far towards unreasonable oversight and restriction."

When asked whether respondents think investigators should be able to use "left-over" biospecimens collected in the clinical setting without informed consent for research as long as the subject's identity is never disclosed to the investigator, 64% said "yes," 28% chose "no," and 8% didn't know.

This question was further explored with the option for participants to explain why use of "leftover" biospecimens collected in the clinical setting without informed consent should be

permitted as long as the subject's' identity is never disclosed to the investigator. Some representative quotes included: "Would enable research that is broadly representative" and, "Risk is minimal when using unidentified samples."

We also asked whether it would be desirable to implement a standardized general consent form to permit future unspecified research on biospecimens and data originally collected for research. Ninety-two percent chose "yes," 6% chose "no," and 2% didn't know. The same question was asked about biospecimens and data originally collected for clinical care. Seventy-five percent answered "yes," 11% answered "no," and 14% said they didn't know.

Discussion

Investigators who use biospecimens in their research encounter a wide variety of approaches to oversight, even among the nation's most respected academic medical centers. While sharing of biospecimens and data between investigators and institutions can be important for the conduct of research, we found variability in researchers' experiences and attitudes concerning the circumstances under which such sharing may occur.

We discovered that investigators conducting research with biospecimens have used a variety of consent approaches when obtaining biospecimens from donors. Of interest is that investigators have used study-specific consent, tiered consent, and broad consent in about the same proportions. Given the increasing endorsement and use of the broad consent approach (Hansson, Dillner, Bartram, Carlson, & Helgesson, 2006; Wendler, 2006), the fact that respondents did not use this approach to a much greater extent than other approaches may be due to certain research studies or contexts in which a broad consent approach is not appropriate or feasible (McGuire & Beskow, 2010). It's also possible that investigators used the tiered consent approach in the past and are now more likely to use the broad consent approach. Another possibility is that investigators or institutions simply have preferences in approaches to consent that become habits over time.

In addition to the finding that researchers encounter differences in approaches to informed consent for collection and use of specimens, we also found that some respondents reported feeling that regulatory entities and others may overestimate the risks of biospecimen research. That 92% of respondents support a standardized general consent form permitting future unspecified research with biospecimens and data suggests that investigators want to have the flexibility to pursue scientific research they might be constrained from conducting under a tiered consent approach. The need for flexibility, as well as for access to biospecimens, is likely also why nearly two-thirds of respondents (64%) agreed that conducting research with "left-over" biospecimens collected without consent from patients in the clinical setting should be permitted as long as investigators could never trace the biospecimen to the patient from whom it was obtained.

These data suggest there is work to be done in educating investigators. Specifically, it appears there is a need to provide investigators with ethical guidelines for use of biospecimens and to advise them about the risks associated with genetic research. The relatively high number of "I don't know" responses indicates a lack of knowledge about

ethical standards, regulations, and IRB practices. This raises concerns about potential risks to specimen donors' rights and welfare resulting from investigator errors, and is consistent with results from our previous study of IRB Administrators, who reported a perception that investigators are confused about the rules regarding use of biospecimens (Rothwell, et al, 2015).

Confusion on the part of investigators may also be the result of different IRBs' standards. While the Common Rule deliberately permits flexibility at the local level, investigators and research subjects may experience meaningful differences in informed consent practices and rules pertaining to secondary use of specimens because of the local variations in approaches to governance across institutions. Specific examples in federal guidance may help institutions to make more consistent decisions about individual research studies. Addressing these issues explicitly is a focus of the Office of Human Research Protections' (OHRP) proposed revisions to the Common Rule (http://www.hhs.gov/ohrp/humansubjects/anprm2011page.html). Specifically, the OHRP proposes to treat all biospecimens as if they are human subjects, regardless of whether they have been de-identified. Although this would provide greater consistency, there could be significant negative impact on the ability of researchers to share data and specimens under such a regime.

Less than half of respondents (42%) thought their IRBs would consider research with coded biospecimens to be "no greater than minimal risk" research while nearly a third (32%) thought their IRB would consider such research to be "greater than minimal risk." One possibility is that IRBs really are taking very different approaches. Another possibility is that investigators may not know their own IRBs' rules or may not understand the ways in which our current regulatory framework distinguishes between identifiable and de-identified specimens. That said, the current ease of gene sequencing and the proliferation of large genetic databases are changing perceptions of privacy risks and, accordingly, will place more responsibility on institutions and investigators to be precise and deliberate when explaining the limits of privacy protections to specimen donors.

Respondents also reported that their IRBs permit them to share biospecimens under several scenarios: when the original consent allows sharing, when new consent is obtained, and when samples are anonymized. When investigators obtain biospecimens from other institutions and when they share biospecimens with other institutions, IRBs may choose to rely on one another's approvals for the research. However, less than a third of investigators reported experience with this mechanism for facilitating collaboration. The willingness of IRBs to rely on another institution's IRB approval has important implications for multi-site research in general, as well as for research involving cross-institutional sharing of biospecimens and associated data. Other factors, such as study methodology and what information was collected from/about the research subject, may warrant inclusion as criteria for whether re-consent is obligatory.

The findings of this study are consistent with our previous work, in which we surveyed IRB directors to learn about institutional practices (Rothwell, et al, 2015). Both studies showed heterogeneity across institutions' and IRBs' practices with regard to collection of biospecimens, informed consent, secondary uses of existing stored biospecimens, and

sharing of research materials (data and biospecimens) between institutions. Procedural variations among institutions may impede investigators' efforts to share valuable biospecimens and data to answer questions that require large numbers of subjects to answer. Our results suggest that the current regulatory environment for human research protections may require reconsideration with regard to standards for collection, use and sharing of biospecimens and data.

Limitations

Given the relatively low response rate (22%) and sample size, it is possible that the respondents do not constitute a representative subset of investigators who collect, store, use, and share biospecimens. As a result, their perspectives and experiences may not be representative of the experiences and attitudes of other researchers.

In addition, our non-probability sampling methods may have introduced biases into the respondent pool. The purposive sampling techniques used in this study limit our ability to generalize the results more broadly. However, we chose to survey investigators at institutions in the CTSA consortium because these institutions are charged with promoting and engaging in collaborative research and thus their investigators who conduct research with biospecimens should be aware of biospecimen sharing even if they have not received biospecimens from or sent any to other institutions.

We did not independently assess investigators' knowledge and comprehension of the regulations (outside of their responses to the questionnaire) to compare levels of understanding with attitudes and practices. We also did not assess how federal legislation such as GINA affected investigators' attitudes.

Finally, respondents' reported experiences with their IRBs cannot be independently verified and may be influenced by potential sources of bias, such as selective memory and exaggeration.

For these reasons, we are deliberately cautious when we suggest that the variability of experiences may suggest a need to reconsider the regulatory framework for use of biospecimens and data.

Best Practices

Continued advances in medical research depend on the ongoing development of effective systems for the collection, storage and distribution of biospecimens and associated data.

Sharing of existing data and specimens is beneficial, and there are scientific and ethical imperatives for researchers and institutions to do so. The use of stored biospecimens and data maximizes scarce resources and may reduce the need to expose new participants to research risks or inconveniences. Practices that promote sharing of data and specimens while maintaining appropriate safeguards for the rights and welfare of research subjects should be encouraged. These may include public educational campaigns to inform potential donors about their rights, training and guidance for investigators, and technological solutions for

masking donor identities while preserving the value of specimens and associated clinical information.

The ideal future state of biomedical research is collaboration that includes and minimizes barriers to sharing of biospecimens and associated data, while ensuring that ethical norms for conducting research with human biospecimens and data are followed.

Research Agenda

Given the limitations described above, the authors propose that a larger-scale study of investigators' experiences and attitudes regarding research with biospecimens should be conducted with researchers from a broader variety of institution types. Additionally, more in-depth investigation into investigators' experiences with institutional policies and practices governing human research protections is warranted. It would be beneficial to assess how knowledgeable investigators are about the Common Rule, their familiarity with regulatory distinctions between levels of risk, and how their understanding of these matters may influence their attitudes and behaviors.

Educational Implications

This research suggests that there is not a shared understanding of the regulations, standards or practices for collection, use and sharing of biospecimens. Institutional leaders and IRB members should thoughtfully review their policies and practices with regard to the collection, use, and sharing of biospecimens and data for research to identify and remediate approaches that are unnecessarily confusing or commonly misunderstood by investigators. Moreover, institutions and their IRBs are obligated to ensure that investigators are aware of the regulations, policies and practices governing the collection, use and sharing of biospecimens. In the opinion of the authors, when institutional leaders and IRBs develop and revise such policies and practices, they should solicit cooperation from investigators who conduct biospecimen-related research. Input from experienced investigators is itself an educational process (for IRBs and for investigators), and can help ensure that policies and practices adequately protect research participants without unduly impeding research with and sharing of biospecimens and associated data.

Acknowledgments

The authors received financial support for the research and authorship of this article from The National Human Genome Research Institute: NIH 5-R01-HG005691, Advancing Collaborative Genetic Research: Ethical and Policy Challenges. We thank the Clinical & Translational Science Collaborative (CTSC) at Case Western Reserve University for helping the authors to develop the electronic survey using the REDcap system. We also thank Dr. Tom Murray and Ms. Ann Nevar for their support of this project. Finally, we give a special acknowledgement and remembrance for Dr. Leona Cuttler, whose vision and guidance made this project possible.

Biography

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Karen J. Maschke is a Research Scholar at the Hastings Center and the editor of *IRB: Ethics and Human Research*. Her work focuses on the ethical, legal, and social implications of genetic research and genomic medicine.

Suzanne M. Rivera is Vice President for Research at Case Western Reserve University and a faculty member in the Departments of Bioethics and Pediatrics. Her research focuses on human research protection issues, including privacy concerns and secondary uses of existing data and specimens. She was the principal investigator of this study and was involved in all aspects of development and conduct of the research, and the writing of the article.

Beth Rosenthal was a project coordinator for the Center for Child Health and Policy at Rainbow Babies and Children's hospitals at Case Western Reserve University. In addition to her current work in bioethics, her research interests have focused on child health policy, the use of growth hormone in children, insurance coverage for growth hormone, and patient satisfaction.

Erin Rothwell is an Associate Professor in the College of Nursing and Division of Medical Ethics and Humanities at the University of Utah. Her research focuses on ethical issues with participant comprehension and informed consent with newborn screening, prenatal testing, and biobanking.

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Table 1

Most frequently utilized approaches to consent for collection of biospecimens

Type of Consent	% (n)
Study-specific consent for use limited to protocol hypothesis	24% (27)
Tiered consent (offering multiple options for future uses)	24% (27)
Broad consent for future unspecified uses	25% (28)
Waiver of consent	2% (3)
Did not collect biospecimens/Did not answer/Other	25% (29)

Table 2

Researchers' perceptions of level of risk IRBs would place on studies

	No greater than minimal risk % (n)	Greater than minimal risk % (n)	Unsure/don't know % (n)
Anonymized	72 (66)	10 (9)	18 (17)
Coded	46 (41)	32 (29)	22 (20)
Identified	18 (16)	60 (53)	22 (20)

Table 3

Conditions under which IRBs have allowed biospecimen sharing

Conditions for Sharing	% (n)
If the original consent allows for sharing	50 (57)
If a new consent is obtained prior to sharing	18 (20)
If samples are de-identified	39 (44)
If samples were anonymized	22 (25)
IRB does not allow sharing	4 (5)
Has not come up/Don't know	17 (19)

Table 4

Appropriateness of policies regarding biospecimens

	Too Restrictive % (n)	Just Right % (n)	Too Permissive % (n)
Collection of biospecimens	30 (26)	69 (60)	1 (1)
Storage of biospecimens	26 (22)	74 (62)	0 (0)
Use of biospecimens	29 (25)	68 (58)	2 (2)
Sharing of biospecimens	36 (30)	63 (53)	1 (1)