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Biobanking Research and Human Subjects Protections: Perspectives of IRB Leaders

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Although biobanks in the United States are a significant resource for genetic and other health-related research in collecting, storing, and sharing human biospecimens and associated data for systematic access and use (herein referred to as “biobanking”), they raise unique ethical and policy challenges on a wide range of issues.[1] Conflicting guidance from government agencies, research organizations, and professional bodies on issues related to informed consent, privacy and confidentiality, and the return of individual genetic research results to biobank participants has often left investigators and institutional review boards (IRBs) unclear about how to develop biobanking policies in a way that protects biobank participants while advancing research. Differences in institutions’ biobanking policies and procedures may impede biobanks’ efforts to share biospecimens and associated data with researchers at other institutions, which is crucial for the genetic research enterprise.

Tables

The two tables for this article are available on the *IRB: Ethics & Human Research* website.

Disclosure

Gregory E. Kaebnick, the editor of the *Hastings Center Report*, managed the review process for this manuscript in place of Karen Maschke, the editor of *IRB: Ethics & Human Research*.

For this study, we sought to learn about IRBs' policies and procedures for collecting, storing, and sharing biospecimens and associated data, how they were developed, and how they are revised. We also wanted to obtain the perspectives of IRB leaders about their IRBs' policies and human subjects protection practices. We targeted IRBs at institutions that are members of the National Institutes of Health's (NIH's) Clinical and Translational Science Awards (CTSA) consortium. There are more than 60 medical research institutions in the CTSA consortium, including leading academic medical centers, institutions with a diverse population of adult and pediatric patients, and institutions with investigators that conduct genetic research.[2] The goal of the CTSA program is to speed the translation of research discoveries into improved health.[3] Understanding how these institutions' IRBs address protections for human subjects of biobank-related research may help in the development of ethically sound policies that permit and encourage biospecimen and data sharing within and across all institutions where human subjects research is conducted, not only those in the CTSA consortium.

Study Methods

Data for this paper are drawn from a larger multi-method study of biobanking at a representative sample of IRBs at CTSA member institutions. As part of this NIH-funded project, we collected both quantitative and qualitative data about biobanking policies and practices from the IRBs at these institutions. This paper focuses on the qualitative data from in-depth telephone interviews with 22 IRB leaders (directors and administrators) from 17 CTSA-affiliated institutions (five of the interviews had two respondents). IRB leaders for these interviews were recruited from institutions selected because of the leaders' responses to our study's quantitative survey of 51 IRBs at CTSA member institutions. This survey asked a number of questions regarding IRB policies related to collecting, storing, and sharing human biospecimens. From these quantitative survey results, we identified 31 IRBs that tended to provide divergent responses on eight key survey questions (Table 1, available, along with Table 2, on the *IRB: Ethics & Human Research* website). "Divergent responses" represent more extreme responses to these eight questions (i.e., selecting "always" or "never" on selected policy options). By choosing IRBs with divergent responses, we sought to identify IRBs that have clear policies reflecting differences of opinions in the field about the most appropriate human subjects protections. Once the institutions were identified, the same IRB leaders who completed the previous quantitative survey were sent an email inviting them to participate in an in-depth interview. All respondents were emailed a minimum of two times, and then a research assistant initiated three follow-up phone calls. Out of the 31 IRBs, 17 agreed to participate. Reasons for not participating were not collected due to the lack of response to emails or telephone calls.

The interviews took place between January 2013 and March 2013. After a respondent(s) gave verbal informed consent, an investigator on our project with experience in qualitative research conducted a semi-structured interview to obtain information about 1) the given IRB's biobanking policies, 2) how the IRB's biobanking policies were developed and by whom, 3) the IRB's process for revising human protection polices related to biobanking, and 4) how flexible the IRB was about revising biobanking policies. We also asked questions about the history and/or ongoing discussions at the IRB of specific procedures relevant to

biobanking such as consent approaches, sharing biospecimens, and biobank participants' withdrawing their materials from research. The interview questions were tailored to include the responses provided in the previous quantitative survey. Interview questions are listed in Table 2.

Each interview lasted an average of 50 minutes, and all of the interviews were audiorecorded. The recordings were transcribed verbatim, and one member of the research team verified the transcripts for accuracy. Content analysis was used to analyze the data. A distinguishing feature of content analytic approaches is the use of a consistent set of codes to designate data segments that contain similar material.[4] After the first three interviews, the transcripts of those interviews and the semistructured interview guide were reviewed to develop an initial coding template.[5] This template was then used to systematically code the first three transcripts, allowing for the addition of new codes that might have been missed with the initial development of the codebook.[6] All coded data were reviewed and verified by a second independent reviewer. No discrepancies emerged, and the remaining interviews were then conducted and coded using the same coding template. Additional information about study methods and coding can be obtained on request from the first author.

Study Results

Process for Developing Guidance for Biobanking

Interviews all started with asking the respondents to describe their IRB's process for the development of policies, guidance, or practices. For this study, policies were considered widely accepted procedures that are systematically applied to all studies and are developed and approved by institutional administrators. Guidances are sets of best practices that are supported by consensus. Most respondents reported that their institution distinguishes between guidance and policy and that they preferred to develop guidance for biobanking. Reasons for this approach included perceptions about how rapidly the biobanking landscape changes regarding issues related to consent and subtleties related to the identifiability of biospecimens and associated data. One respondent noted that biobanking is "a field that changes so quickly so we can be more flexible in developing guidance," as opposed to having to develop and change policies. Another respondent pointed out that "somebody's always coming up with some new twist that the policy might not have considered."

Several respondents noted that their institutions relied on workgroups as the primary mechanism for developing guidance for their investigators about biobanking. When asked what sources of information institutions used to develop biobanking guidance and policies, most respondents said their institution relied on guidance from the Office for Human Research Protections (OHRP), the Association for the Accreditation of Human Research Protection Programs (AAH-RPP), and their institution's office of legal counsel. Other sources of information included the National Cancer Institute's best practices recommendations for biorepositories,[7] guidance and policies at other research institutions, and feedback from their own investigators who conduct biobanking-related research. Respondents reported that guidance-development meetings involved an iterative process and included IRB members and administrators, experienced investigators, ethicists, and legal counsel. They acknowledged the importance of obtaining input from the community about

human subjects protections in biobanking but noted the difficulty of obtaining such input. One respondent admitted that “maybe we didn’t do a good enough job engaging them [the community].” Some respondents said they obtained community input by having individuals from the community serve on some of their IRB committees.

Biobanking versus Other Human Subjects Protection Policies

Most respondents reported that their institution’s process for developing guidance about biobanking encompassed additional considerations that are not typical for other human subjects protection policies. For example, the anticipated changes for biobanking within the federal landscape appeared to inhibit the development of consistent guidance (“Like all of us are waiting, waiting, waiting for changes in the Common Rule to come out,” one respondent said). Other factors considered were the increased need to involve more collaboration among stakeholders and the community, and limitations on the IRB’s ability to monitor all secondary uses of archived biospecimens.

When discussing ways in which guidance about biobanking differed from other types of guidance provided by IRBs, respondents spoke of the need to trust investigators. A number of respondents mentioned, for example, that they did not follow up on investigators to assess whether they complied with the details of the study as outlined in consent forms, such as destroying biospecimens of participants who withdrew from the biobank. (“We have to trust —we ask the investigator, and we have to trust them to do it,” a respondent said.). Additionally, several respondents mentioned that they had to trust researchers to conduct ethical research with deidentified biospecimens for which they may not be required to submit information to the IRB. (“What do you do in the case of nonhuman subjects research, biobanking protocol, and even though we don’t have technically a jurisdiction, what’s our role in reviewing those uses?” one respondent asked.)

Many of the respondents noted that the issue of when a biospecimen is not considered human subjects research was a significant factor that influenced the process for IRB approval, but there was confusion about the point when the use does not qualify as human subjects research and how long this perspective would be relevant. For example, some respondents stated that the decision about whether a biospecimen-related research project was considered human subjects research comes at the time of collection, while other respondents stated that it is made at the time of the biospecimen’s storage, and others stated that it comes at the time when a biospecimen is released for research from a biobank. Furthermore, many respondents stated that biospecimens may eventually become reidentifiable, which raised concerns about whether biospecimens are ever really deidentified. Responses along these lines included one respondent’s question “Are they truly anonymous?” as well as these remarks from other respondents: “The *Nature* article recently demonstrated how easy it is identify deidentified specimens” and “It’s going to not be feasible to label tissues truly anonymous in about fifteen or twenty years.” Another issue respondents raised about deidentification was the matter of who deidentified the biospecimens. One respondent said, “Clearly anonymizing makes it not human subjects, but there’s some limitations around that: who’s anonymizing?,” and another asked, “Who holds the link?” Finally, several respondents stated that there was confusion within the research

community about biobanking, deidentification, and what is allowed with secondary uses of biospecimens. For example, one respondent pointed out that "[w]ithin the research community, there's not quite an understanding of what biobanking is and what is and is not allowed to [be done] with samples left over from a previous study." And another noted, "There's always the debate about what constitutes deidentified specimens."

Consent Forms and Participant Choice Regarding Future Research

When respondents were asked about the consent process, most of them stated that the consent approach for biobanking should offer participants a choice about whether their biospecimen and associated data can be used in the future. When respondents were asked what types of consent options should be included regarding how specimens are used in the future, their responses overall identified two general approaches. Some respondents supported a broad consent that would allow for future, unspecified research. Alternatively, several of the respondents stated that biobank participants should have the option to decide how specifically their specimens or data can be used. The primary reason stated for the preference to offer more choices was respect for persons (Respondents said, for example, "Respect for persons demand[s] that you give people the autonomy at least to make a myriad set of decisions about what to do with the sample," and, "There are certain people that would say, 'I don't care if my sample is de-identified. I don't want you using it for reproductive research. Even if my name's not on it, I don't support that type of research.'"). Respondents who supported a broad consent for future unspecified research provided these reasons: the inability to know or predict how specimens might be used in the future, the lack of practical mechanisms to enforce limitations on future use or to monitor all the future possibilities, and giving participants too many choices limits the potential value of the resource. One respondent said, "We try to discourage it [tiered consent] because unless you have written a 45-page consent form to describe the implication for each of these choices in a way that the average person can understand, my feeling is you are putting them in a position where you're just confusing them."

The review of consent forms concerning previously collected biospecimens was also explored during the interviews. Many respondents stated that they reviewed consent forms to ensure protection of human subjects and to assess whether the original consent form explicitly prohibited future uses of the biospecimens in general. If consent forms did not explicitly prohibit future uses, then studies typically were approved to use the biospecimens in a new approved research study. One respondent said, for example, "The key to not allowing research with anonymous biospecimens is when the consent form explicitly states that it will not be used for any future purposes. If [it] does not address future research, then according to the Common Rule, they can use them anonymously." Other responses along these lines included "As long as the informed consent form explains to the best of your ability at the time, the IRB can usually approve secondary use" and "It's important to make sure that the subjects were not informed that their specimens would never be shared with anybody ever under any circumstance." Several respondents noted situations when there are no consent forms for specimens collected years ago, at a time when future use was not a primary concern. "We're completely aware that over the last maybe ten years ago things changed, but 15 and 20 years ago investigators collected specimens and sometimes got

consent, sometimes didn't, under very different rules," a respondent stated, while another said, "The problem is if there is no consent to start with."

Challenges to Current and Retrospective Changes to Biobanking Guidance

Respondents raised concerns about the difficulty of developing consistent guidance and, consequently, the fact that many IRB decisions are made on a study-by-study basis. Respondents described making changes to a specific guidance or practice as relatively easy ("We take a study by study approach" one explained, and another said, "This would be vetted right now [on] an individual basis to make decisions."). In other words, changes to particular practices were prompted by individual investigators requesting these changes for a specific study. Some respondents indicated that in these cases, if the request did not conflict with federal regulations, changes were typically approved. Factors that influenced these exceptions to guidance included the age of the biospecimen (i.e., how long ago a biospecimen was collected) and where it was collected (a clinical or research setting). Exceptions to existing guidance that respondents mentioned in the interviews included the absence of an original consent form, the inability to contact participants again for a new consent, and when a new study is outside the scope of the original consent form but is minimal risk. One respondent's comment captured this complexity:

> It's kind of tricky. If a new study is outside the scope [of the original consent form], but they're not getting new samples, I'm not exactly sure how all the chairs are handling this. I think it depends. I would think that in general, they might let them do it, but it might depend, too. I mean, we hate to say absolutely no, but we don't want to be so cavalier that we'd say, "Oh, absolutely yes," either. We don't know. This is a hard one. They could make the argument that it's impractical to get consent, that it's minimal risk, use all those arguments for a waiver. But then there's that ethical component that they said it was this and now it's that.

As exceptions to existing guidance occurred, some respondents stated that they were unsure how to retrospectively apply changes specifically to studies that are ongoing and in need of continuing review or to studies that use clinical samples collected years ago for secondary purposes. Representative quotations include the following:

- What you do is you review things as best you can, and then you change your policy at some point or your approach. You have everything coming back in for continuing review, and then what do you do? Do you retrospectively apply those changes? How strongly do you apply those? Do you say, this is a deal breaker, we can't continue to approve this study for you?
- Are samples that were collected 15 or 20 years ago allowed to be used today if there is no consent form? Are samples that were collected years ago from clinical procedures allowed to be used for secondary purposes now?

Discussion

Investigators conducting genetic research need access to biospecimens and associated data and may need to request those materials from biobanks at institutions other than their own.

Ensuring that investigators can obtain the biospecimens and data they need requires practical, ethically sound approaches within and across institutions to the complex issues of informed consent, storing and sharing of biospecimens and associated data, and protecting the interests and welfare of research participants. Our study was designed to learn about policies for biobanking at IRBs and about IRB leaders' perspectives regarding those policies. While we intentionally selected institutions with divergent responses to key items on a previous quantitative survey, we found that the IRBs at these institutions shared common uncertainties and challenges about human subjects protections for biobank-related research. In general, we found that IRBs preferred to develop guidance that was applied on a flexible, case-by-case basis rather than develop rigid policies. And we found that there were more similarities than differences across IRBs regarding their approach to human subjects protections for biobank-related research.

The findings of our study highlight several key challenges to developing consistent approaches for the collection, storage, and use of biospecimens for research. For example, some IRBs strongly encourage their investigators to use a tiered consent approach that gives biospecimen contributors a number of choices for how their biospecimens can be used in future research, while other IRBs strongly favor broad consent for future, unspecified research. That IRBs have divergent views about the consent approach for obtaining biospecimens for research reflects the ongoing debate about broad consent versus tiered consent.[8] Nonetheless, more participants in our sample supported broad consent to increase the utility of biospecimens collected and to minimize the logistical challenges of tracking the use of biospecimens obtained under a tiered consent approach. However, it is important to note that the main reason that some respondents said their IRB supported a tiered consent approach was to uphold the ethical principle of respect for persons by giving biospecimen contributors autonomy over deciding how their biospecimens can be used. Some commentators have pointed out that the autonomy argument can also be used to support a broad consent approach in that broad consent honors the individual's right to elect future unspecified uses rather than denying him or her that option.[9] Our findings also reveal an uncertainty about the important issue of what kinds of biospecimen use constitute human subjects research. Current debates surrounding the ability under certain circumstances to deidentify biospecimens—that is, to link a specific biospecimen to identifiable information about the person from whom it was obtained—complicate the development of guidance and policies for human subjects protections for biobank-related research. The concern about "reidentification" is reflected in the Department of Health and Human Services proposal to change the Common Rule[10] so that archived biospecimens are defined as inherently reidentifiable, thus requiring consent from the individuals from whom they were obtained before they can be used for research even when all personal identifiers are removed before the biospecimens are placed into storage. Additionally, state health departments are struggling with questions about how to create policies that would facilitate the use of residual dried bloodspots from newborn screening blood samples obtained without parental consent while at the same time protecting the rights of parents and newborns who may wish that their child's biospecimens not be used in research without their consent.[11] Finally, the findings reported here raise concerns about the impact of variation across IRBs regarding human subjects protections for biobank-related research. If IRBs make case-by-case

decisions about consent approaches and what constitutes human subjects research in the biobanking context, their decision-making could inhibit intra- and interinstitutional sharing of biospecimens and associated data.

It is important to note that there are several limitations to this study. There was a low response rate by IRB leaders to agree to be interviewed, and this response bias may influence the results. For example, the results may suggest more similarities across institutions than actually are present, and, if all of the individuals that were approached had agreed to participate, more differences might have emerged. Furthermore, IRB leaders who were interviewed were employed within a particular group of IRBs (those in the CTSA consortium), and this may not be representative of IRBs in general.

In summary, biobanks raise a unique set of issues for researchers and IRBs that can complicate the application of human subjects protections. These may include unclear and changing perspectives on the identifiability of stored specimens, a potential lack of control or knowledge about the consent process for biospecimen contributors, and, often, little to no connections to those individuals. Our data highlight that IRBs are struggling with the issues surrounding biobanking and with proposed changes from federal regulators about human subjects protections. There may be a need for more detailed guidance on study-specific issues such as when an original consent form is unavailable, use of samples outside the scope of the original consent form in a minimal risk study, or developing consistent terms to describe genetic data. It may be beneficial to seek examples of studies with unique and difficult circumstances from IRBs to provide more specific and practical guidance.

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References

1. McGraw SA, Wood-Nutter CA, Solomon MZ, Maschke K, Benson JT, Irwin DE. Clarity and appeal of a mulitmedia informed consent tool for biobanking. IRB: Ethics and Human Research. 2012; 34:9–19.
2. Kon AA. The Clinical and Translational Science Award (CTSA) Consortium and the translational research model. American Journal of Bioethics. 2008; 8:58–60.
3. Zerhouni EA. Translational research: Moving discovery to practice. Clinical Pharmacology and Therapeutics. 2007; 81:126–128. [PubMed: 17186011]
4. Elo S, Kyngas H. The qualitative content analysis process. Journal of Advanced Nursing. 2008; 62:107–115. [PubMed: 18352969]
5. Rothwell E, Anderson R, Goldenberg A, et al. Assessing public attitudes on the retention and use of residual newborn screening blood samples: A focus group study. Social Science & Medicine. 2012; 74:1305–1309. [PubMed: 22398141] Rothwell E, Anderson R, Swoboda KJ, Stark L, Botkin J. Public attitudes regarding a pilot study of newborn screening for spinal muscular atrophy. American Journal of Medical Genetics. 2012; 161A:679–686.
6. See ref. [4], Elo and Kyngas 2008.
7. National Cancer Institute. NCI Best Practices for Biospecimen Resources. http://biospecimens.cancer.gov/practices/2011bp.asp

8. Hansson M, Dilner J, Bartram C, Carlson J, Helgesson G. Should donors be allowed to give broad consent to future biobank research? Lancet Oncology. 2006; 7:266–269. [PubMed: 16510336] Hofmann B. Broadening consent and diluting ethics? Journal of Medical Ethics. 2009; 35:125–129. [PubMed: 19181887] Steinsbekk S, Myskja B, Solberg B. Broad consent versus dynamic consent in biobank research: Is passive participation an ethical problem? European Journal of Human Genetics. 2013; 21:897–902. [PubMed: 23299918]

9. See ref. [11], Hansson et al. 2006.

10. The Department of Health and Human Services and the Food and Drug Administration. Human subjects research protections: Enhancing protections for research subjects and reducing burden, delay, and ambiguity for investigators. Action: Advance notice of proposed rulemaking. Federal Register. 2011; 76(143):44512–44531. http://www.hhs.gov/ohrp/humansubjects/anprm2011page.html.

11. Botkin J, Goldenberg A, Rothwell E, Anderson R, Lewis M. Policy guidance for the retention and research use of residual newborn screening bloodspots. Pediatrics. 2013; 131:120–7. [PubMed: 23209103]

Table 1

Questions Used to Identify Extreme Scores for Interviews

7. Offering participants choices about how their biospecimens/data are used in future research (sometimes called "tiered consent"), our IRB would typically:

☐ *Prohibit this* ☐ *Discourage this* ☐ *Permit, but neither encourage/discourage* ☐ *Encourage this* ☐ *Require this*

15. When the IRB determines that a new proposed study is outside the scope of the future uses described in the original consent form, what approach would your IRB typically take with regard to the acceptability of each of the following?

	Prohibit this	*Discourage this*	*Permit, but neither encourage/discourage*	*Encourage this*	*Require this*
a. Anonymize the samples/data (when they were otherwise coded or identified)	☐	☐	☐	☐	☐

23. In situations where there is a substantive policy difference between institutions, what approach would your IRB typically take with regard to the acceptability of each of the following?

	Prohibit this	*Discourage this*	*Permit, but neither encourage/discourage*	*Encourage this*	*Require this*
a. Anonymize the samples/data (when they were otherwise coded or identified)	☐	☐	☐	☐	☐
b. Re-consent participants for the new use (when the samples/data are coded or identified)	☐	☐	☐	☐	☐
c. Consider an application for waiver of the requirement to obtain informed consent	☐	☐	☐	☐	☐

29. If a research participant who contributed biospecimens/data to a stored collection wants to withdraw consent, what approach would your IRB typically take with regard to the acceptability of each of the following?

For biospecimens and associated clinical data:

b. Anonymization and continued use use	☐	☐	☐	☐	☐
d. Destruction/permanent removal of all data from the individual in the dataset from collection	☐	☐	☐	☐	☐
e. Anonymization of data and continued use	☐	☐	☐	☐	☐

Table 2

List of Interview Questions

1	Please tell me about the process that was used to develop your institution's guidance that addresses human subjects' protections in biobanking. Again, this includes all written and unwritten documents, policies, standard operating procedures, etc.
2	Did the process you just described for how your biobanking guidance was developed differ from the way other human subjects guidance was developed at your institution?
3	If someone wanted to change the guidance at your IRB, how would that be approached? We are interested in regard to consent for the collection and storage of biospecimens for future research, sharing of biospecimens across institutions, and use of biospecimens/data beyond what was specified in the original consent.
4	In the phone survey, you indicated that 1) OHRP policies/guidance documents, 2) AAHRPP accreditation standards, and 3) advice and/or requirements of institutional legal counsel were most influential in the development of your IRB's policies and practices. Can you please tell me more about what role each of these had with regard to your biobanking policies and practices? These probes were used with questions 5 through 10: **a.** Was there anything distinctive or special about how the guidance came about compared to the general process you described above? **b.** Was there a lot of debate about what would be the appropriate guidance or what would be unacceptable? **c.** Is there continuing discussion or controversy about this issue?
5	On that survey, we asked about offering choices on consent forms when a researcher plans to collect biospecimens and associated data for a specific study but also wants to store them for future research. You told us your IRB would typically [interviewer described responses from the survey].
6	On the survey, we asked about IRB oversight when a researcher wants to conduct a new study using biospecimens/data that have already been collected and stored. You told us your IRB would typically [interviewer described responses from the survey].
7	On the survey, we also asked about IRB review of the original consent documents when a researcher wants to conduct a new study using biospecimens/data that have already been collected and stored. You told us your IRB would typically [interviewer described responses from the survey].
8	On the survey, you told us that when your IRB determines that a new proposed study is outside the scope of the future uses described in the original consent form, it would typically [interviewer described responses from the survey].
9	On the survey, we posed a situation where a researcher at your institution proposes a study that would involve biospecimens/data that she would obtain from an outside source. If the biospecimens/data were collected/stored under policies that differed substantively from those at your institution, you said your IRB would typically [interviewer described responses from the survey].
10	Finally, on the survey we asked about the situation of a research participant who contributed biospecimens/data to a stored collection but now wants to withdraw consent. You said your IRB would typically [interviewer described responses from the survey].
11	What role, if any, did the institutional experience with adverse events in genetic research have in influencing the development of your biobanking policies and practices?
12	Is there anything I have not asked you but you think is important regarding the bases for your (or other) IRB's guidance on human subject protection in biobanking?