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Contrasting the Ethical Perspectives of Biospecimen Research Among Individuals with Familial Risk for Hereditary Cancer and Biomedical Researchers: Implications for Researcher Training

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While ethical concerns about participating in biospecimen research have been previously identified, few studies have reported the concerns among individuals with familial risk for hereditary cancer (IFRs). At the same time, biomedical researchers often lack training in discussing such concerns to potential donors. This study explores IFRs' and biomedical researchers' perceptions of ethical concerns about participating in biobanking research. In separate focus groups, IFRs and biomedical researchers participated in 90-min telephone focus groups. Focus group questions centered on knowledge about laws that protect the confidentiality of biospecimen donors, understanding of informed consent and study procedures, and preferences for being recontacted about potential incidental discovery and also study results. A total of 40 IFRs and 32 biomedical researchers participated in the focus groups. Results demonstrated discrepancies between the perceptions of IFRs and researchers. IFRs' concerns centered on health information protection; potential discrimination by insurers and employers; and preferences for being recontacted upon discovery of gene mutations or to communicate study results. Researchers perceived that participants understood laws protecting donors' privacy and (detailed study information outlined in the informed consent process), study outcomes were used to create a training tool kit to increase researchers' understanding of IFRs' concerns about biobanking.

Introduction

Large population-based biobanks are repositories of blood, tissue, and other biospecimens used for research aimed at identifying links between genetic and environmental influences of diseases such as cancer (Bauer *et al.,* 2004; Hewitt, 2011). The scientific community is hopeful that research using biospecimens will lead to new cancer cures; however, the general public is often unaware or skeptical about the purpose of biospecimen research (Jack and Womack, 2003; Compton, 2007; O'Doherty and Hawkins, 2010). Studies have reported that fear of confidentiality breaches, exploitation, and privacy management are main reasons why the general public has been reluctant to participate in biospecimen donation (Melas *et al.,* 2010; Erwin *et al.,* 2012; Luque *et al.,* 2012). To protect individuals from such privacy and confidentiality breaches, the Genetic Information Nondiscrimination Act (GINA) was passed into law in 2008, prohibiting medical insurance companies from refusing to issue both individual and group health plans based on the outcomes of genetic tests (U.S. Equal Employment Opportunity Commission, 2008). GINA also prohibits employers from discriminating against current and future employees based on the health information derived from DNA research (U.S. Equal Employment Opportunity Commission, 2008). Little is known about the extent to which potential biospecimen donors, particularly those at genetic risk for cancer, are aware or understand these laws and how this may impact donation.

Although past studies have reported the general public's perceptions of donating biospecimens (Compton, 2007; O'Doherty and Hawkins, 2010; Ormond *et al.,* 2010; Erwin *et al.,* 2012; Luque *et al.,* 2012), less is known about concerns of individuals with familial risk for hereditary cancer (IFRs). Recent research suggests that there may be unique concerns about biospecimen donation among IFRs, specifically

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unaffected carriers (Hewitt, 2011). At the same time, biomedical researchers often lack training in discussing such concerns to potential donors, moreover, IFR potential donors. The purpose of this study was to explore ethical concerns about biobanking among IFRs and compare biomedical researchers' perceptions of patients' concerns about donating biospecimens. Together, the information was used to create a curriculum that trains researchers about how to best address such concerns.

Materials and Methods

Participants

Researchers sent letters to IFRs registered with the National Cancer Institute (NCI) Cancer Genetics Network (http://epi.grants.cancer.gov/CGN/) inviting them to participate in a telephone focus group to provide opinions about biospecimen research initiatives. All IFR subjects met the following criteria: (1) self-described as high risk for developing cancer due to a familial history of hereditary cancer as determined by answering yes to ''have you or an immediate family member ever had a blood test to identify if there was a mutation''; (2) between 18–65 years of age; (3) fluent in English; and (4) willing to participate and provide informed consent. Subjects participating in the researcher focus groups were nominated by an advisory panel from 12 cancer centers and academic institutions. Researchers met the following criteria: (1) fluent in English; (2) held a position related to cancer research in a professional capacity (biomedical/behavioral: faculty, postdocs, fellows, clinical researchers); and (3) willing to participate and provide informed consent.

Data collection, management, and analysis

All focus groups were conducted with a focus group guide (Table 4), using telephone conferencing and moderated by the principal investigators and a study coordinator. Focus groups lasted between 60 to 90 min, and participants received a $30 gift card as remuneration for their time and effort.

All focus groups were audiotaped and transcribed verbatim for qualitative analysis. Transcripts were hand coded using a constant comparative and content analysis approach (Patton, 1990). A priori codes were determined based on the focus group guide, (Patton, 1990). Two researchers coded transcripts independently, discussed findings, resolved differences, and came to consensus on the final codebook. The remaining transcripts were entered into the ATLAS.ti® qualitative analysis program. The study team members met to discuss findings and to confirm saturation of content (Sandelowski, 1995). A larger panel of experts comprised bioethicists, behavioral and clinical researchers and trainees, and a medical geneticist discussed and reviewed results to identify domains for the future curriculum for researchers.

Results

A total of 12 telephone focus groups with IFRs ($n=40$, range of 4–8 IFRs per focus group, demographics listed in Table 1) and 5 with biomedical researchers ($n=32$, range of 3–8 researchers per focus group, demographics listed in Table 2) were conducted. Overall, focus group responses revealed discordances between researchers' and IFRs' knowledge and attitudes regarding biobanking research (Table 3). Four main domains of IFR concerns were identified: (1) confidentiality and privacy concerns; (2) understanding of the informed consent; (3) communication preferences for medical incidental discovery; and (4) preferences for learning overall biospecimen results. Researchers acknowledged many of these concerns, but they differed in that they believed biospecimen donors understood laws protecting donors' privacy and rights and also detailed study information outlined in informed consent. We present the combined research findings below with notation of the participant type (IFR or researcher) and report researcher preferences for a biobanking ethics curriculum.

Table 1. Demographics of Individuals with Familial Risk for Hereditary Cancer ($N=40$)

Variable	n *(%)*
Gender	
Male	3 (7.5)
Female	37 (92.5)
Age	
18–24	0 (0)
25–34	3 (7.5)
35–44	9 (22.5)
45–54	15 (37.5)
55+	13 (32.5)
Race	
Asian	0 (0)
Black or African American	0 (0)
White	40 (100)
Other	0 (0)
More than one race	0 (0)
Ethnicity	
Hispanic or Latino	0 (0)
Not Hispanic or Latino	40 (100)
Marital status	
Married	35 (87.5)
Separated/divorced	3 (7.5)
Widowed	1 (2.5)
Single	1 (2.5)
Highest level of education	
High school graduate/GED	2 (5.0)
College 1–5 years/technical school	4 (10.0)
College graduate	13 (32.5)
Graduate or professional school	21 (52.5)
Health insurance	
Yes	39 (97.5)
No	1 (2.5)
Employment status	
Employed for wages	27 (67.5)
Self-employed	4 (10.0)
Homemaker	3 (7.5)
Retired	5 (12.5)
Out of work	1 (2.5)
Total annual household income	
Less than $10,000	0 (0)
$10,000–$25,000	0 (0)
$25,000–$35,000	3 (7.5)
$35,000–$50,000	4 (10.0)
$50,000–$75,000	6 (15.0)
$75,000–$100,000	5 (12.5)
$100,000+	19 (47.5)
Do not know	3 (7.5)
Total	40 (100.0)

GED, Graduate Equivalent Diploma.

Table 2. Demographics of Biomedical and Behavioral Researchers ($N=32$)

Variable	n *(%)*[a]
Gender	
Male	2 (6.3)
Female	30 (93.7)
Race	
Asian	2 (6.3)
Black or African American	9 (28.1)
White	18 (56.3)
Other/more than one race/not specified	3 (9.3)
Education status	
Master's degree	1 (3.1)
Doctoral (MD/DO/PhD)	31 (96.9)
Years of experience in area of expertise	
1–5	5 (15.6)
6–10	12 (37.5)
11+	14 (46.9)
Participated in/conducted biobanking research	
Yes	13 (40.6)
No	19 (59.4)
Interested in using ethics and biobanking training	
Yes	29 (90.6)
No	2 (6.3)
Not sure	1 (3.1)

[a]Percentages may not add up to 100% due to rounding.

Confidentiality and privacy concerns

IFRs suggested that willingness to donate biospecimens was contingent upon trusting research institutions to maintain privacy. The majority of IFRs felt comfortable with providing health or family history if they believed the research institute would protect their information and not share it with insurers or employers. Other factors impacting biobanking participation included trust in the institution, researcher, or organization conducting biospecimen research. One participant noted,

> *If I were contacted by some random person or at some place I had never heard of, I wouldn't just say, ''Okay.'' I would definitely want to look into the details and the background of the researcher, the study, and the organization and make sure it was something that I felt was legitimate and worthwhile to me.* (IFR)

Almost all researchers agreed that IFRs' privacy concerns (e.g., fear of discrimination or lack of information protection), are the primary risk associated with biospecimen donation. While biomedical researchers are aware that the GINA law legally prohibits the release of personal information to insurance companies or employers, they acknowledged that IFRs may not be familiar with the law or distrust the law to protect their privacy. For example, one researcher reported, ''*The maximum risk is that information is made public…and maybe the insurance companies will treat them differently than if they were healthy or not with-risk patients.*''

GINA laws

Despite inclusion of this language within informed consent documents, roughly half of the IFRs were unaware of GINA laws.

> *Actually I had never heard of it* (GINA). *Laws are broken all the time. It's good to have it, and we are probably better off having it than not. But it's not a complete guarantee of anything.* (IFR)

After receiving details about the law, a majority of IFRs still did not trust the law to protect them from insurance or employer prejudice.

> *I think with any anti-discriminatory law, you don't really know what's going on in the head of the person's who's sitting across from you at the desk who knows that information…who isn't supposed to discriminate against you.* (IFR)

Researchers, however, felt that the description of GINA in the informed consent documents reassured potential donors that they would not be discriminated against, regardless of biospecimen research outcomes.

> *We made sure to put the GINA language in our consent form so that would be something that study coordinator would be commenting on. Hopefully, there could be a discussion if the person had some kind of mistrust about what was going to happen with their information.* (Researcher)

Informed consent

Many IFRs reported being unaware of the specific details of biobanking described in the informed consent document. For example, nearly all IFRs were unaware of study withdrawal terms. Specifically, they were unclear about details such as the terms of withdrawal, who to contact, and how the withdrawal would be executed. One IFR asked,

> *''Theoretically, if it is set up so that the tissue samples cannot be identified with any individual person, then they shouldn't be able to be identified for the sake of being withdrawn?''*

On the other hand, researchers believed that the language in the informed consent document used to describe their institution's policy on study withdrawal was clearly stated and understood.

> *On our Institutional Review Board (IRB) consent form, it's a separate section where subjects designate if they want to be involved in biobanking.* (Researcher)

Informed consent documents. A topic that was discussed by researchers, but given less attention among IFR focus group participants, was the preference for the type of informed consent document used with potential biospecimen donors. More researchers believed that the use of blanket consent forms, that is, a statement of consent to allow for unlimited future use of specimens collected for other studies, was unethical. They agreed that while the blanket consent was more convenient, this consent approach was not consistent with the main tenets of the protection of human subjects that emphasize research participants' autonomy to make an informed decision to participate in research studies.

> *Well, I think the blanket consent definitely makes it easier for the researcher in terms of doing what they need to do. But*

Table 3. Comparing Biobanking Perceptions of Individuals with Familial Risk for Hereditary Cancer with Biomedical Researchers

Domain	*Individuals with familial risk for hereditary cancer*	*Biomedical researchers*
Confidentiality and privacy	GINA laws: not known, not understood, untrustworthy, not properly implemented Ethical concerns: privacy/confidentiality, anonymity of samples, access to samples by others, researcher profits from discoveries, use of samples in areas of research other than cancer	GINA laws: included in consent forms, researchers unaware that participants unfamiliar with law Perceived donor risks: lack of information protection, comprehension of consent forms, prejudice Researchers need guidance on how much information to provide and still retain donor's trust.
Incidental discovery	Incidental discovery: some wanted to be updated and notified if something is found in their sample that could affect themselves or their offspring, even if untreatable; others preferred never to be recontacted after donating biospecimens Communicating incidental discovery: preferred to be contacted by a researcher affiliated with the study, a physician in the specialty of the disease, or a genetic counselor	Incidental discovery: participants should be notified only if clinical finding can be treated or is medically actionable Donor notification of incidental discovery: participants should be notified of incidental discovery. Logistic concerns of how to notify donors in question
Overall biospecimen research results	Interested in knowing biospecimen research results in a way that is useful and comprehendible	Believe it is important to share biospecimen research results with donors. Annual newsletter released, but difficult to tailor this newsletter to each separate, smaller study with a low number of participants
Informed consent	Participants often do not keep their consent form or remember the information Unaware they may withdraw from study at any time; unfamiliar with withdrawal process Want to be reassured verbally and receive explanations about biospecimen research in addition to the consent form	Researchers were unaware participants are unfamiliar with the biospecimen withdrawal process Depending on the type of study, blanket consent forms may be OK Impossible to contact donors to reconsent for each new study, especially in larger studies Consenting process should be critical component of curriculum

GINA, Genetic Information Nondiscrimination Act.

ethically speaking, it's probably not in the best interest of the donor…, the donor is not, totally informed about all the potential uses of their specimens. (Researcher)

Researchers were also divided over the issue of whether or not time limitations should be created to regulate when researchers are able to use donated biospecimens. One group believed time limits should be implemented in biobanking consents as they are for any other IRB approved research study.

When you have a timeless commitment, you are allowing a fishing expedition. And when will you find what happens to the science? There is no hypothesis…, just to collect samples and see what comes out. (Researcher)

Others believed a time limit does not have to be given in every study, but should be reviewed on a case by case basis with options to renew the length of time biospecimens can be used.

A majority of IFRs felt researchers should be able to access their biospecimens with unspecified time limits under the condition that an IRB or governing body was monitoring the research to ensure their health information was protected.

Communication of personal results/incidental discovery

IFRs varied on their preferences of whether or not they would want to be notified if an incidental medical discovery was identified in their biospecimens, who should notify them, and the most appropriate time for this recontact. The responses were split evenly between three preferences. One group of IFRs preferred never to hear from the researchers after they donated biospecimens. Others wanted to be updated and notified if a genetic mutation or gene for disease that could affect them or their family's health was discovered in their sample. A few wanted to be contacted about the diagnosis or discovery only if it were treatable.

Absolutely (contact me), especially if there's something I could do about it other than just worry. (IFR)

Among those who preferred to be contacted if an incidental discovery was made, they preferred to be contacted by a researcher affiliated with the study, a physician in the specialty of the disease, or a genetic counselor who could provide information about the health implications of such findings.

Table 4. Focus Group Guides

IFR

1. Knowledge, attitudes, and experiences in health research.
2. Knowledge/experience with biospecimen donation.
3. Importance of trustworthiness of the biospecimen collector and of the donation process, previous research experience.
4. Ethical concerns regarding biospecimen storage, preferences for being recontacted if researchers identify a medical discovery (e.g., gene mutation, gene that predicts the future development of a disease) in the donated biospecimen(s), and religious or cultural concerns of donating.
5. Knowledge of GINA.
6. Suggestions for key points for researchers to remember when approaching IFRs to ask for a biospecimen donation.

Researchers

1. Ethical concerns related to biobanking.
2. Type of informed consent document (e.g., blanket, menu consent, study specific) believed most ethical in biobanking research studies.
3. Learning preferences (e.g., educational video, in-person discussion groups) and curriculum platforms to receive information about ethically conducting biobanking research.

IFRs, individuals with familial risk for hereditary cancer.

Researchers generally believed donors should be notified if a medical incidental discovery was made in the study. However, most believed that donors should be notified only if the findings were clinically actionable (e.g., a treatment was available for the patient). Researchers were divided on how incidental discovery should be communicated to the donor and by whom. They agreed on the need to revise current biobanking practices and informed consent documents to create a standardized procedure addressing incidental discovery. The dissenting researcher group felt that sharing incidental discovery information was not as simple as communicating results. Including this as an option in the informed consent documents, they believed, could lead to more confusion and participant dissatisfaction and a delay in the scientific research process.

> *I'm not sure of the logistics of that (re-contacting participants)…You have some people who want to be anonymous, no identifying information linked to their specimen—and then others who might want to be notified. So in terms of logistics, I'm not sure how that would work.* (Researcher)

Communication of overall study results

Approximately half of the IFRs expressed interest in receiving an update regarding the study results. They viewed their donation as an investment toward the prevention and cure of cancer and wanted to know that their contribution was meaningful. The other half expressed less interest in learning study outcomes unless the results directly affected their or their children's health.

> *Would I know the results ever? If it was information that would be beneficial to me or to my health, would that be shared with me?* (IFR)

A few participants stated that they would like to receive communication about the study and future studies in a way that is useful and comprehensible, as they previously received information that they deemed helpful for researchers but unhelpful for participants. They hoped that researchers would remember the ''face behind the sample.''

> *There's a name behind every sample and, if you learn something that could benefit the particular donor or add years to that donor's life, I think there's an onus to share that information with the donor.* (IFR)

When asked if they communicated the overall study results to participants and donors, some researchers mentioned distributing an annual newsletter that shared outcomes of the biospecimen research studies. However, they believed it was too difficult to tailor this newsletter to each separate study. Researchers stated it was difficult to balance protecting participants' anonymity while also effectively communicating results. Some researchers also found it difficult to update people who had moved. Most researchers agreed it was a good idea to create a regularly updated website with meaningful information for donors.

Researcher learning preferences for biobanking ethics curriculum

Researchers were interested in receiving training related to the bioethical concerns of biobanking, particularly through a web-based introductory course. They believed the best time to implement such a course is at the undergraduate level followed by the graduate level and higher. They recommended offering the training through an optional module by the Collaborative Institutional Training Initiative (CITI). However, fewer researchers preferred in-person training, believing CITI was an ineffective platform for teaching complex topics since information is often skipped or overlooked in a rush to complete ethics modules.

Discussion

Our results suggest that biomedical researchers did not fully understand IFRs' ethical concerns regarding confidentiality and privacy, informed consent, communication of incidental discovery in individuals' biospecimens, and recontact to discuss study outcomes. Researchers believed IFRs knew, understood, and trusted the GINA Discrimination laws. However, similar to past research with community members, IFRs had never heard of or did not fully understand GINA (Ormond *et al.,* 2010).

Researchers and IFRs differed in their perceptions related to the clarity of informed consent and the study withdrawal process. There is a large body of literature scrutinizing the medical

research consent process and associated documents as they relate to informed consent as a marker for proper understanding of their role and rights as a participant in medical research (Wirshing *et al.,* 1998; Flory and Emanuel, 2004; Dunn *et al.,* 2006). As such, to supplement informed consent documents, researchers should explore the use of novel interactive educational modalities to teach information about informed consent (Schillinger *et al.*, 2003; Rowbotham *et al.,* 2013).

In the case of incidental discovery, IFRs varied in their preferences to be notified if a genetic mutation or a gene is found in their sample. Currently, there is a debate as to which type of clinical information (e.g., actionable) should be shared with biospecimen donors. Actionable information is beneficial to the donor, whereas nonactionable findings (such as the genetics for Alzheimer's) may only create fear and emotional distress among the biospecimen donors (Yassin *et al.,* 2012). In a clinical setting, the American College of Medical Genetics and Genomics (ACMG) recommends that medical geneticists and other healthcare providers should report incidentally (secondary) variants regardless of the age of the patient. However, laboratories should seek and report only the types of variants within these genes that have been delineated by the ACMG (2013). In addition, the ordering clinician/team should be responsible for providing comprehensive pre- and post-test counseling to the patient (ACMG, 2013). While these guidelines only apply to a clinical setting, they may be useful to consult when creating guidelines for actionable and nonactionable findings in research studies.

Researchers were interested in receiving more information about how to ethically approach IFRs about biospecimen research, and they preferred the use of interactive tools as learning platforms, such as videos and webinars to teach specific components of the curriculum. Based on these findings, the development of a web-based curriculum aimed at increasing the biomedical and behavioral researchers' understanding of IFRs' and other vulnerable populations' perceptions about biobanking is under way.

Limitations

Several limitations should be noted when interpreting study findings. The definition for IFR in our sample was derived from a discussion with a cancer geneticist and the NCI Cancer Genetics Network. Due to their IRB regulations and concerns about confidentiality, we could not ask individuals to disclose the results of their test. However, they would not be in the network without a strong family history of hereditary cancer. We acknowledge that some IFR participants may be more concerned than others if they received a positive blood test. In addition, the study sample of IFRs was predominantly female, over age of 40 years old, more educated, and less ethnically diverse than the general public. However, respondents were representative of the Cancer Genetics Network. Many IFRs had previously participated in genetic research, which may have influenced their receptivity to participating in future studies, thus limiting the generalizability of findings to populations with no research experience. Future research should include more diverse populations (e.g., racially/ethnically diverse individuals, Spanish-speaking audiences, men). Biomedical researchers were also nominated and selected from partnering institutions, which may have influenced their responses.

Conclusion

Results from this study are being used to create a novel training tool kit that increases researchers' understanding of IFRs' perceptions about biobanking. To accomplish this, the research team used an interdisciplinary advisory group comprising bioethicists, behavioral and clinical researchers, and a medical geneticist. Based on previous recommendations, we are incorporating ethics language that addresses regulations governing research with human subjects, penalties for misuse of genetic information, economic factors of participants, and current knowledge of the population being recruited (Meslin and Quaid, 2004).

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Author Disclosure Statement

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