E&HR

Perspectives from a Predominantly African American Community about Biobank Research and a Biobank Consent Form

Laura K. Sedig, E. Hill De Loney, Sarah B. Bailey, Kayte Spector-Bagdady, Bianca Ghita, Lydia Koh Krienke, and Raymond Hutchinson

ABSTRACT Minority populations have been underrepresented in clinical trials, as well as in research biobanks that are created to conduct research with participants' biospecimens and related medical and research data. Biobank research raises issues about informed consent and privacy and the confidentiality of participants' personal data. Our study involved three focus groups of 10 adults each that were conducted in a medically underserved, predominantly African American community to elucidate questions and concerns regarding an institutional biobank. Transcripts from the discussion were qualitatively analyzed. Three main themes that arose from the focus groups included the importance of trust, the importance of the community in research, and suggestions to improve trust. The concerns identified in this study provide a starting point for future research to help research institutions become more trustworthy to the communities they serve.

KEYWORDS human subjects research, human research ethics, biobanks, biorepositories, informed consent, trust in research, trustworthy research, minority communities in research, benefit sharing

Sedig, L. K., E. H. De Loney, S. B. Bailey, K. Spector-Bagdady, B. Ghita, L. K. Krienke, and R. Hutchinson, "Perspectives from a Predominantly African American Community about Biobank Research and a Biobank Consent Form," *Ethics & Human Research* 44, no. 4 (2022): 26-33. DOI: 10.1002/eahr.500134

In the United States, minority populations such as Black, African American, and Latino populations have been underrepresented in clinical trials,[1] as well as in research biobanks that are created to conduct research with participants' biospecimens and related medical and research data.[2] As a result, research findings from studies involving therapeutic interventions and from genetic analyses of biospecimens may not be generalizable to patients from these populations. In the case of Black or African Americans, they may be reluctant to participate in clinical trials and biobank research due to mistrust of the medical and research communities resulting from research with Black participants in which consent was not obtained from the research participants (e.g., U.S. Public Health Service Syphilis Study at Tuskegee)[3] or from their surrogates (as with the use of Henrietta Lacks's cancer cells to create an immortal cell line for future research).[4] However, some studies suggest that the impact of the Tuskegee study and the research with Lacks's cell line on Black or African American people's willingness to participate in research may be more nuanced.[5]

To better understand the issues underlying the tenuous relationship between research institutions and some Black/African American populations, investigators from the University of Michigan collaborated with community organizers in Flint, Michigan, to conduct a focus-group study. Flint is a predominantly Black/African American and medically underserved community grappling with the effects of a 2014 water crisis in which drinking water that came from the Flint River was contaminated with lead.

We presented the consent form for the University of Michigan Medical School Central Biorepository (Central Biorepository) to focus-group participants for their feedback. The consent form was selected as the focus of the deliberative sessions due to previously described challenges related to achieving appropriately representative participation of Black/African Americans in biorepositories.[6] What type of consent for biobank-related research participants should provide has been the focus of prior research and commentary.[7] Some commentators contend that using a broad consent approach—providing consent for future unspecified research—needs to be critically analyzed before this approach is implemented.[8] The overall goal of the study was to inform future efforts to engage the Flint community, as well as other predominantly Black/African American and medically underserved communities, to help ensure a mutually beneficial relationship for their participation in research biobanks.

STUDY METHODS

Three community-led focus groups were held in Flint in August 2018. One of the investigators (RH) met with the Community-Based Organizations

Table 1.
Demographics

	Group 1	*Group 2*	*Group 3*	*Overall average*[1]
Age				
Average (years)	37	51	48	45
Range	18-70	29-79	18-75	18-79
Gender				
Male	60%	70%	10%	47%
Female	40%	20%	80%	47%
No response	0	10%	10%	6%
Race/ethnicity				
African American/Black	100%	100%	90%	97%
Caucasian/White	0	0	10%	3%
Highest level of school				
Some high school or less	10%	0	0	3%
Graduated high school	40%	20%	40%	33%
Some college	30%	30%	10%	23%
Associate's degree	10%	10%	0	7%
Bachelor's degree or higher	10%	40%	50%	33%
Reported knowledge of the Tuskegee syphilis study				
Yes	40%	60%	60%	53%
No	60%	40%	40%	47%
Reported having read the book or seen the movie about Henrietta Lacks				
Yes	10%	10%	40%	20%
No	90%	90%	60%	80%
Had previously participated in medical research				
Yes	10%	50%	40%	33%
No	90%	50%	60%	67%

[1] Totals may not add up to 100% due to rounding.

Partners Community Ethics Review Board, housed at the Healthy Flint Community Research Coordinating Center, to ensure community interest and engagement with the idea. The University of Michigan's institutional review board (IRB) determined that the study was exempt from the regulatory requirements of the Common Rule.

Each focus-group session began with an anonymous survey to collect demographic information. The three focus groups each consisted of 10 participants and lasted two hours. The participants were selected by Flint community leaders including two of the authors (EHDL and SB). The participants then individually read the Central Biorepository consent form and standard information guide (both of which are available in full text at the website referenced in endnote 9).[9] Next, they engaged in a group discussion about the consent form conducted by a community facilitator. Participants were also given surveys throughout the sessions to determine familiarity with clinical research topics. This manuscript focuses on the qualitative findings.

The same community facilitator led each group. The focus-group sessions were audio recorded and professionally transcribed by a community member trained in transcription who had not participated in the focus groups. Each participant received $50 for their time. Two members of the study team (BG and LKK) read the transcripts and inductively developed a coding schema. The coding schema was reviewed and revised by the entire team, and the transcripts were then coded (by BG and LKK). Discrepancies were discussed between the coders to come to a consensus.

STUDY RESULTS

There were 30 participants equally divided into three focus groups (see table 1). Their average age was 45 years, with a range from 18 to 79 years, and with an equal number of male and female participants. All but one identified as Black or African American. Nearly all (97%) of the participants graduated from high school, and 33% held a bachelor's degree or higher. Approximately half of the participants (53%) reported "knowing" about the Tuskegee syphilis experiments. The vast majority (80%) had neither read the book nor seen the movie about Henrietta Lacks. Thirty-three percent had previously participated in medical research.

Three main themes arose from the three focus groups: the importance of trust, the importance of the community in research, and improving trust. The role of trust was the most common theme identified among the three focus-group transcripts (the codebook is in appendix 1, available online, along with appendix 2; see the "Supporting Information" section below).

Many discussions centered around trust in the research and medical communities, perceived contradictions in the Central Biorepository's consent form, the importance of the doctor-patient relationship, and the importance of time to process information or to ask questions when recruited to enroll in a biobank. Some focus-group participants referenced historical events such as Tuskegee when discussing their lack of trust. One participant remarked, "I think there is just a general … mistrust between … the medical community," and also said, "I just think it's not that great. Just because of … the money. The history." Another commented, "You never know what happens when they get into the laboratory. … They are not sending that back to us."

Concern for contradictions in the consent form (available in appendix 2) centered around the lack of complete guarantee of confidentiality regarding the biobank's participants' medical and research data and around perceived discrepancies about whether biobank participants could withdraw from the biobank. The consent form stated that information about biobank participants would be deidentified, but that there was a risk that their personal information could be unintentionally shared with someone who should not have access to it. The consent form also informed prospective biobank participants that they could withdraw from the biobank, but that any data or biospecimens that were shared with researchers prior to their withdrawal may not be able to be retrieved since they would be deidentified. "So," a focus-group participant stated, "it's like, you tell me on one end that I can leave the program, but, on the other end, you're telling me, 'But, your stuff is out there now, so there's nothing we can do.' . . . It's very confusing when you look at this." Another focus-group participant summarized, "I feel like the paperwork gave you identity protection and then also took it away."

Focus-group participants also discussed the importance of the doctor-patient relationship when a patient is making a decision about research participation, with

one participant succinctly noting, "The problem is before you get to this: it's what relationship has been developed with the patient." They noted that, in the proposed biorepository research, there may not be an opportunity to have a discussion with their personal physician or even a member of the research team and that lack of interaction may influence their decision about whether to enroll.

Lastly, focus group participants reported that having time to carefully read the documents and have their questions answered could improve their trust in the biobank recruitment process. One participant suggested, "Maybe, if this was done in a two- or three-step process, so you've got time to hear what's being said, think about it, come back, and ask some more questions, think about it again, before you have to actually sign some sort of paper. But to just say, 'Sign this right here' … . Sometimes you can't grasp it to sign it." Another participant in a different focus group pointed out that these consent discussions often happen during stressful times: "A lot of time when you give these consents, the patient is already in trauma. So, they kinda don't understand, and they read this; they're really not gonna understand it…. You honestly have to give it to them in a different state of mind. They're going to just sign it."

Discussions touching on the theme of "community" centered around the desire for community approval of research, cultural and historical awareness by the research team of the frame of reference of potential biobank participants, and the need to have participation tailored to affected groups, with researchers specifically reaching out to those groups. Another major focus was on the desire for community benefit from the outcomes and profits derived from biobank-related research. Focus-group participants discussed the need for the community to receive improved access to health care based on the outcomes of the research.

The value in having the community engaged throughout the process, from determining what research is needed and how it is conducted to acting on the results, was also a theme that emerged from the focus groups. For example, one participant observed, "What's missing or what would make it even more attractive would be a community person, so our voice could be raised when some of these decisions are being made." A participant in a different focus group mentioned, "As far as being informed all the way from the beginning of the process to the end of the process … we are always in on the beginning, but we never get to the end."

The issue about the need for researchers to be aware of historical events and to consider how they may affect individuals when recruiting them to participate in biobanks also came up. One focus-group participant mentioned, "I was thinking … the physicians or the staff that's working with people that are soliciting, what their cultural competencies were…. So, I'm thinking their competency of relating the information may be lacking even before it gets to the patient."

Another focus-group participant emphasized the need to recruit affected individuals with the following information. "Every year we have the opportunity to go to the University of Michigan for the breast cancer conference that's held on campus. And if we don't go as a community of Black women, there's almost no Black women there…. The university has got to step up and not just in that area…. Who dies from breast cancer more than anyone is Black women. And only because of [name redacted] do we take a busload or two busloads of Black people down there."

> Many discussions centered around trust in the research and medical communities, perceived contradictions in the biorepository's consent form, the importance of the doctor-patient relationship, and the importance of time to process information or to ask questions when recruited to enroll in a biobank.

Much of the discussion focused on the desire that biobank participants and/or their communities will benefit from the research with their biospecimens, in terms of either profits or access to the medical advances that come from the research. One focus-group partici-

pant asserted, "Some of the profit should be returned back to those communities to eliminate some of these issues that come from our genetic positions. Because a lot of it stems from the food we intake and the water that we are subjected to and all these other things that develop [over] time and get based through our genes and genetic sequence anyway. So, if you're talking about somebody has the potential to make a profit … and you are receiving information from an area or community that does not have these resources or these outs, it's almost a slap in the face."

Some of the discussion was more focused on the benefits of the research. One focus-group participant had this to say: "You know, if there is something in my body that's going to help to prevent cancer, then, hey, everybody, let's get it out…. But don't be charging; you know what I'm saying? These crazy rates and my people still dying of cancer because they can't pay for it." A participant in another focus group echoed this sentiment, saying, "Once you find a cure, you're gonna obviously sell it to make a profit that no one is going to see besides the company. Why can't I get my cure?" Lastly, a participant summarized their frustration with this reference to Henrietta Lacks: "You know, it's like total disregard for her as a human being but more as a lab rat that you can just experiment off of…. I'm not saying that she needed profit. But these companies are profiting. So, why should her family live in poverty as a result? So, it makes me think when they say, 'Well, you can't be paid,' why not? Why can't I be paid? Why can't my family or my survivors be paid? Who determines that they can't?"

Suggestions about how to improve trust regarding research was the final major theme. Many participants voiced concerns about how biobank research would be conducted or the results would be used that made it clear that the nature of research was not adequately communicated in the informed consent form to begin with. Such concerns led one focus-group participant to suggest "twenty-four seven surveillance. We got access to cameras and Facebook live and everything else. So, while you are doing your research and everything, if I'm part of it, let me watch…. Because anything else showcases to me that you have something that you want to hide."

Other focus-group participants were concerned about the transparency of research findings and return of individual research results. One participant remarked, "If I'm giving you my Social Security number for my stuff …, I should be able to go to a website, see the updating, what they found in my blood…. You should be able to see or predict something … before it actually hits my body and be able to tell me what I should be able to do to prevent it from happening."

DISCUSSION

The focus-group discussions identified significant areas of concern for members of the Flint community. One major concern was how the community would benefit from research conducted with the Central Biorepository's biospecimens and associated data. Community benefits could be achieved through access to treatments derived from the research or financial compensation, should researchers or an institution or company profit from the work. Focus-group participants were also interested in learning more about how the Central Biorepository would use the biospecimens and associated data. While the desire to monitor research projects in real time could prove difficult due to regulatory and practical concerns (e.g., maintaining security, maintaining research integrity, and the slow iterative process of individual projects that are difficult for observers to understand in the broader context), the sentiment of understanding the types of research conducted with the biospecimens and data is compelling.

Biobanks and the researchers to whom they provide biospecimens and data should consider how to engage biobank participants to inform them in a meaningful and comprehensible manner about how their biospecimens and information will be used. For example, an accessible website that lists the general purpose of current and previous research projects and how the research information impacted medical care would be useful. Novel means to share profits or knowledge of health improvements with research participants should also be considered, especially when the path from sample procurement to profitable treatment will likely be long and complex and include hundreds or thousands of participants from many communities.[10]

Focus-group participants noted that individuals recruited to participate in the Central Biorepository should have time to discuss their questions and concerns with their personal physician, demonstrating the need

for a trusted and knowledgeable individual to support potential biobank participants as they decide whether to enroll in the Central Biorepository. They also noted that recruiting individuals to enroll in the biobank at a time when they are dealing with medically difficult situations is not optimal. Clearly, a more open-ended approach with an extended timeline for decision-making would serve medically stressed individuals well and would perhaps result in more enrollment in the biobank.

The focus-group discussions also highlighted the need for an open dialogue with researchers and potential biobank participants to clarify the nuances of the consent and research processes. Some of the focus-group participants' concerns regard apparent contradictory statements in the informed consent document that derive from regulatory standards requiring disclosure that participant protective measures can fail. Examples of statements that raised concern include language indicating that confidentiality of personal information and data cannot be absolutely guaranteed or that one's ability to opt out of biobank research after biospecimens and data have been used and deidentified may not allow for removal of those data and/or biospecimens from the research. The standards referred to are established by federal mandate or local IRBs and are conditions of undertaking biorepository-based research. Without a meaningful opportunity to ask questions of research personnel, potential biobank participants might decline to enroll in the biobank if they don't receive the kind of information that might allay their concerns.

During the focus-group study, the investigators minimized directly guiding discussions or providing detailed explanations in response to confusion on the part of focus-group participants to avoid introducing investigator biases into the study. Thus, there was an absence of discussion about what information potential biobank participants would be provided in the recruitment and consent process about the Central Biorepository's privacy and confidentiality protections beyond what was described in the consent document. This approach served a purpose for our study because in many real-life research consent processes, potential participants are generally left to decide about enrolling in biobanks based only on information provided in the consent document.

It is important to note that the focus-group participants likely represent a narrow portion of the Flint community. The vast majority had a high school diploma (97%), and a sizeable minority had a bachelor's degree (33%), compared with the 85% and 12%, respectively, who have these in the community overall.[11] Furthermore, 33% of focus-group participants reported prior participation in medical research; this is a high percentage, once again reflective of the selection bias favoring well-educated and sophisticated community participants. The community leaders who assisted with recruitment are well-educated and well-connected individuals with access to others like themselves, that is, individuals with a commitment to enhancing the well-being of the community through participation in research. Thus, the sample population is biased toward those with a higher level of education and community engagement. The focus-group conversations may also have been biased by our initial survey asking participants whether they were aware of the Tuskegee syphilis and Henrietta Lacks cases. Additionally, the Flint community recently underwent a public health crisis, the Flint Water Crisis, which has heightened awareness of the citizens to be involved in discussions and decisions about public health and may consequently limit the study's applicability to other communities.

In evaluating the themes that emerged from the focus groups and their relationship to each other, it seems obvious that those striving to enhance community trust in medical research and in biorepository research would be wise to heed the basic concerns expressed by the focus-group participants. These include assuring that biobank researchers are directly involved in a central biorepository's consent process to answer questions and allay concerns, allowing sufficient time for individuals to consider whether to enroll in the biorepository and to solicit input from trusted sources, providing an accessible website detailing the research objectives and progress of the studies that use the biorepository's data and biospecimens, and ultimately providing research outcomes to underserved communities with the intent of increasing awareness of medical advances relevant to community members.

This project was performed primarily to foster connections between researchers and the Flint community

to facilitate future, mutually beneficial research projects. The results have provided considerable food for thought and action as future research addressing how to increase research participation is planned. Future studies should be conducted in real time in a medically underserved community, such as Flint, when potential biobank participants are actually approached about enrolling in a research biorepository. For example, such an approach will allow for randomization between a group offered the consent form without opportunity for questions and a group offered the consent form in the presence of a biorepository researcher who can answer questions about protections offered and the nature of the research. This scenario would allow for assessment of what appears to be a vital need for participation by investigators in consent conversations to address participant concerns. In addition, expansion of the participant pool to be reflective of the Flint community at large will be informative regarding the impact of educational level and medical research familiarity on perspectives. Finally, with the rapid expansion of social media, it will be important to assess how perspectives change with time and with so many new platforms fostering communication about socially and medically relevant topics. Clearly, more research is needed to address concerns regarding participation in biorepository research in underserved communities such as Flint and simultaneously to enhance the cultural competence of the researchers engaged in that work. ♦

SUPPORTING INFORMATION

The appendices are available in the "Supporting Information" section for the online version of this article and via *Ethics & Human Research*'s "Supporting Information" page: https://www.thehastingscenter.org/supporting-information-ehr/.

Laura K. Sedig, MD, MSc, *is a clinical assistant professor of pediatrics at the University of Michigan Medical School;* **E. Hill De Loney, PhD,** *is a Michigan Institute for Clinical and Health Research Community Advisory Board member at the University of Michigan, the director of the Flint Odyssey House, Inc., and the Health Awareness Center, and the executive director of Community-Based Organization Partners;* **Sarah B. Bailey, PhD,** *is a community colead with the Michigan Institute for Clinical and Health Research at the University of Michigan, the chief executive officer of Bridges Into the Future, Inc., and the vice chairperson of the Community-Based Organization Partners;* **Kayte Spector-Bagdady, JD, MBioethics,** *is an assistant professor of obstetrics and gynecology and the associate director of the Center for Bioethics and Social Sciences in Medicine at the University of Michigan Medical School;* **Bianca Ghita, BS,** *is an MD candidate at Virginia Commonwealth University School of Medicine, class of 2025;* **Lydia Koh Krienke, MSN,** *is a public health nurse and researcher at Johns Hopkins University; and* **Raymond Hutchinson, MD, MS,** *is a professor emeritus of pediatrics at the University of Michigan Medical School.*

REFERENCES

1. Fisher, J. A., and C. A. Kalbaugh, "Challenging Assumptions about Minority Participation in US Clinical Research," *American Journal of Public Health* 101 (2011): 2217-22; Murthy, V. H., H. M. Krumholz, and C. P. Gross, "Participation in Cancer Clinical Trials: Race-, Sex-, Age-Based Disparities," *Journal of the American Medical Association* 291 (2004): 2720-72; NIH Revitalization Act. Subtitle B: §131-133;1993.

2. Ngui, E. M., T. D. Warner, and L. W. Roberts, "Perceptions of African American Health Professionals and Community Members on the Participation of Children and Pregnant Women in Genetic Research," *Public Health Genomics* 17, no. 1 (2014): 23-32; Davis, T. C., et al., "A Qualitative Study Exploring Barriers and Facilitators of Enrolling Underrepresented Populations in Clinical Trials and Biobanking," *Frontiers in Cell and Developmental Biology* 7, no. 74 (2019): doi:10.3389/fall.2019.00074; Sanderson, S. C., et al., "Public Attitudes toward Consent and Data Sharing in Biobank Research: A Large Multi-site Experimental Survey in the US," *American Journal of Human Genetics* 100, no. 3 (2017): 414-27.

3. "About the USPHS Syphilis Study," National Center for Bioethics in Research and Health Care, Tuskegee University, https://www.tuskegee.edu/about-us/centers-of-excellence/bioethics-center/about-the-usphs-syphilis-study.

4. Skloot, R., *The Immortal Life of Henrietta Lacks* (New York: Crown, 2011).

5. Dancy, B. L., et al., "Community-Based Research: Barriers to Recruitment of African Americans," *Nursing Outlook* 52, no. 5 (2004): 234-40; McCallum, J. M., et al., "Awareness and Knowledge of the U.S. Public Health Service Syphilis Study at Tuskegee: Implications for Biomedical Research," *Journal of Health Care for the Poor and Underserved* 17, no. 4 (2006): 716-33.

6. Sanderson et al., "Public Attitudes toward Consent and Data Sharing in Biobank Research"; Heredia, N. I., et al., "Community Perceptions of Biobanking Participation: A Qualitative Study among Mexican-Americans in Three Texas Cities," *Public Health Genomics* 20, no. 1 (2017): 46-57.

7. Thiel, D. B., et al., "Community Perspectives on Public Health Biobanking: An Analysis of Community Meetings on the Michigan BioTrust for Health," *Journal of Community Ge-*

netics 5, no. 2 (2014): 125-38.

8. Lorell, B. H., et al., "Informed Consent in Clinical Research: Consensus Recommendations for Reform Identified by an Expert Interview Panel," *Clinical Trials* 12, no. 6 (2015): 692-95.

9. The Central Biorepository Informed Consent Template and the Central Biorepository Informational Sheet are accessible, as of June 12, 2022, via the University of Michigan Medical School Office of Research's "Specialty Informed Consent Templates" page: https://az.research.umich.edu/medschool/templates/specialty-informed-consent-templates.

10. Bedeker, A., et al., "A Framework for the Promotion of Ethical Benefit Sharing in Health Research," *BMJ Global Health* 7, no. 2 (2022): doi:10.1136/bmjgh-2021-008096; Dauda, B., and K. Dierickx, "Viewing Benefit Sharing in Global Health Research through the Lens of Aristotelian Justice," *Journal of Medical Ethics* 43, no. 6 (2017): 417-21.

11. "Quick Facts: Flint City, Michigan," United States Census Bureau, accessed June 1, 2022, https://www.census.gov/quickfacts/flintcitymichigan. United States Census data from 2016 to 2020 is available via this page.

ADDENDUM

Since publication of our article "Evaluating the Ability to Consent to Research: A Twenty-Year Track Record" (by Mikaela Matera-Vatnick, Katherine W. Todman, Paul G. Wakim, Haley K. Sullivan, Carol Squires, Julie Brintnall-Karabelas, Samuel N. Doernberg, and Marion Danis, in *Ethics & Human Research* 44, no. 2 [2022]: 2-17, doi:10.1002/eahr.500119), it has come to my attention that there is a need to clarify how capacity assessments were performed when done as needed for a particular prospective research participant, as opposed to those routinely mandated by an institutional review board (IRB) for all protocol enrollees.

All capacity assessments that are reported in the study were guided by the same ethical principles and assessment criteria. For IRB-mandated capacity assessments, the assessment tools were protocol specific and used in the standardized way described in the article. For individual, as-needed assessments of the ability to consent and the ability to assign a surrogate, generic assessment tools were used to a variable extent as a guide to the discussion and assessment. Furthermore, the assessments were more informal than the reader might infer from the description in the manuscript and did not involve a formal rating process for all the domains entailed in full capacity. The process of assessing the capacity to consent often involved a conversation with the potential research participant, as a result of which the assessment team was able to ascertain whether the potential research participant had the capacity to understand their particular situation, the difference between research and clinical care, the fact that they would be enrolling in research, the risks entailed, and the voluntariness of enrollment.

In addition, because the Bioethics Consultation Service involves bioethics fellows in capacity assessments as part of their ethics consultation training, the assessment team for individual, as-needed assessments was most often comprised of an experienced consultation service member along with a trainee, rather than two experienced evaluators. Notwithstanding these clarifications about the process, we stand by the data.

—Marion Danis, MD
Department of Bioethics
National Institutes of Health Clinical Center
DOI: 10.1002/eahr.500131