



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

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## Appendix 1.

### Codebook

CODE	DEFINITIONS	EXAMPLES
<b>Importance of Trust</b>		
Trust of research/medical community	Expressing general distrust of the medical and research communities.	<p>“History has proven that we cannot trust the greater, you know, powers that be to do right by everybody [...] Because guess what? The same thing that can help you can hurt you.”</p> <p>“I think there is just a general, general mistrust between ... the medical community... I mean, personal relationships people have with doctors or nurses, I think sometimes it can be very good. But I think in general ... I just think it’s not that great.”</p>
Perceived contradictions in informed consent form	Perceived contradiction in the guarantee of confidentiality and the informed consent document stating researchers cannot protect data with absolute certainty.	<p>“I understood the part about the certificate of confidentiality part. But, then, above that part, it says there is still no guarantee of perfect security. So, why are y’all telling us about this certificate of confidentiality if there is no certain fact that we’re going to have good security of our information?”</p> <p>“It says, in this block here, ‘You can ask to leave the Bio Repository at any time by calling or writing to us. See the back panel for contact information.’ But, then in the smaller print, it says, ‘We will not be able to</p>

	Perceived contradictory information about being able to withdraw from research and underlying confusion about the process and duration of time it would take to have a specimen removed.	take your book back from the researchers after it has already been shared with them.’ So, 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 is nothing we can do.’ So, it’s kind of ... it’s very confusing when you look at this.”
Doctor-patient relationship	Importance of doctor building a relationship with the patient over time in order to develop trust and establish a safe environment.	<p>“I think that when you start talking to people about their DNA or some of the things you want to research, my thinking is that you have to have a relationship. Or some truthfulness about what you want to do. [...]</p> <p>Because the closer you get to people, the more comfortable they feel. [...]</p> <p>Let’s say we are representing the community, and we want to share this information with other people and how important research is, we would need more meetings; we would need more time.”</p> <p>“It’s the ‘trust’ word. It’s just got to be... It’s not the patient’s fault that they don’t understand. We don’t come with your understanding, your awareness, your knowledge. We’re trying to get that before we give anything away.”</p>
Time to process/ask questions	Concern about the time period given in order to make difficult, fully informed decisions and the general accessibility of understanding consent documents to all individuals participating.	<p>“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. Read through this and sign it... sometimes you can’t grasp it to sign it.”</p> <p>“At the time this is given, like you say, if you are presented with some shocking, some life-turning information like your child has this or you have this. Couldn’t it be like a time period? Well, we have some information, but we want you to process what we just told you and ingest it and then get back with us with this?”</p>
<b>Importance of Community</b>		
Community benefit from outcomes of research	Importance of community benefiting from outcomes of research, especially with regard to making treatment and medicine	“For the areas, or wherever the case may be, that need support, some of the profit should be returned back to those communities to do development to eliminate some of these issues that come from our genetic positions. [...] So, if you’re talking about somebody has the potential to make a profit, and you are doing so and you are receiving information from an area or community that does not have these resources or these

	more accessible for specific communities.	outs, it's almost a slap in the face."  "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. Absolutely. 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."
Cultural competence	Importance of tailoring the research experience directly towards the racial or cultural group participating.	"Not that I'm not for everybody, but, I've got to be for the ones who matters to me the most."  "And if we don't go as a community of Black women, there's almost no Black women there. And, and that was my point, is that the University has got to step up and not just in that area. [...] [W]ho dies from breast cancer more than anyone is Black women."
Community approval of research	Importance of community approval of what research is done and how it is being conducted, as well as direct involvement and accurate representation of individuals within the community.	"I represent all my culture, all my people, everybody that lives, breathes, and moves and eats and thinks like me. So, I could be subjecting other people in the future to something that's not positive by submitting my sample. Whether it be for personal growth or whatever. I'm just more so concerned about generations that follow me and the other people that live in my community that breathe and eat like me."  "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."
Community benefit from profits of research	Desire of community members to directly benefit from participating in research, especially through remuneration, as well as being externally compensated for research involvement more at the individual rather than community level.	"Say, I got diabetes and like she say, you find a cure, why, if I didn't make a profit or none of the payments, why should I have to pay for my own cure to my body? Because, at the end of the day, 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?"  "You know, it's like total disregard for [Henrietta Lacks] as a human being but more as a lab rat that you can just experiment off of. [...] 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 survivor's be paid? Who determines that they can't?"
<b>Suggestions to Improve Research</b>		

	Improve transparency about projects.	“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.”
	Improve transparency about findings.	“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 doing research, you should be able to find an aneurysm in my brain or whatever, you know, that they can’t find. You should be able to see or predict something that I ... You see in the future line before it actually hits my body and be able to tell me what I should be able to do to prevent it from happening.”

## Appendix 2. Document of Consent to Donate to a University of Michigan Biorepository and Authorization to Release Protected Health Information

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A biorepository contains samples of blood, tissue, and information from many different people. Researchers can take samples and information from the biorepository and use them in their own studies.

You have the option of contributing to a research biorepository called [*name of collection*], which takes part in the University of Michigan Medical School Central Biorepository (“the CBR”). This document and a separate information sheet have details that you should consider before you decide to join. When this document is signed, it confirms *our promises to you and gives us your permission for the project team to obtain and use your samples and your protected health information.*

**Joining the Biorepository.** After reading both documents and asking us questions, you should understand that:

- The biorepository is a research project. It is not part of your health care and will not directly help you.
- It is designed to help us learn about health and disease for the benefit of all people. Any materials and information you donate will be available for any research projects approved by the [*name of collection*]'s Oversight Committee or the Central Biorepository Governance Committee.
- Participating in this project is completely up to you.
- If you decide not to participate in this project, it will not affect your health care treatment or payment, enrollment in your health plan, or your eligibility for health care benefits.
- You will not receive payment for participating in this project or receive any payments from scientific discoveries or profits made using the information or samples you donate.

**Leaving the Biorepository.** Even if you decide to take part now, you may end your permission and leave this project at any time without penalty. If you do decide to leave the project, contact [PI name and number] or Dr. Victoria Blanc, CBR Director at (734) 763-6423. Keep in mind that we will not be able to get back samples or your information if they have already been shared with other researchers or if we can no longer identify them as coming from you.

**Participating in the Biorepository.** You should also understand that:

- Sample donation.** You will be asked to provide [ ].
- [**Health survey.** You will be asked to complete a short survey about your health.]
- Health records.** You give the biorepository your permission to collect your protected health information from the University of Michigan and **any** other past, present, or future sources and link it to your donated sample. Your permission to let this project team do this has no expiration date. *See the back of this page for examples of what information can be used.*
- Sharing.** You give the biorepository your permission to share your samples and collected information with researchers **anywhere**, including those in other countries and those working in for-profit commercial companies. The biorepository will follow all regulatory standards before releasing samples or information.
- Research Uses.** You give your permission for researchers to use your samples and health information to study **any** disease or health condition. *The information sheet describes some ways researchers might use your samples and health information.*
- Recontact.** Researchers may contact you again to ask for more samples or information or to tell you something they have learned about your sample. You can always say no to the researcher.

**Risks and protections for you and your information.** You should also understand that:

- [There are minor physical risks involved with providing your sample(s). *See the information sheet.*]
- See the information sheet.*
- There is always a risk that you could be identified by your donation and health information.
- The project team will do its best to keep your information confidential, as required by a law called HIPAA. *See the back of this page for important details about privacy and confidentiality.* But once your information has been shared with others, it may no longer be protected by HIPAA.

## Privacy and Confidentiality

### What will researchers be able to see about me?

If you give them permission by signing this form, they will be able to take your health information from:

- Any health provider's records. This could include information such as:
  - What illnesses and treatments you have had, and how well the treatments have worked.
  - Results from x-rays or lab tests.
  - Mental health records.
  - Alcohol and substance abuse treatment records.
  - Whether you have HIV or AIDS.
  - Billing information.
  - When needed, identifiers like your name, address, or Social Security Number.
- Other health information from sources outside of our medical center with appropriate permissions.
- For more HIPAA information, go to: <http://www.uofmhealth.org/patient+and+visitor+guide/hipaa>.

To make sure this project is conducted safely and properly, University, Food and Drug Administration (FDA), government officials, and sponsors of the project might need to see your health information.

### How will my privacy be protected?

- Whenever possible, donated samples and your health information will be stored with a code instead of identifiers (such as name, date of birth, medical record number, social security number). However, the more coded information about you that is combined together, the more likely it is you could be identified.
- All information used by this project will be protected so that it can only be accessed by authorized people. Still, no one can guarantee that information security will be perfect.
- No published scientific reports will identify you directly.
- We will obtain a **Certificate of Confidentiality** from the National Institutes of Health, so we can keep your information private in a court or other legal proceeding. The Certificate will not allow us to withhold your information from the government if it is necessary for a federal audit or evaluation of federally funded research. Also, if you or a member of your family voluntarily discloses information about yourself or your participation in this repository, the Certificate will not prevent that information from being used in court.

### Can I be discriminated against based on genetic information that people learn about me?

Your biological samples contain genetic information about you. The Genetic Information Nondiscrimination Act (GINA) is a federal law that prohibits certain kinds of discrimination on the basis of genetic information. GINA applies to any genetic information obtained by this project, so you may want to know what protections GINA provides before you decide whether to donate.

- GINA prohibits health insurance companies and health plan administrators from asking for genetic information about you or your family members. It also prohibits them from using genetic information for decisions about coverage, rates, or pre-existing conditions. GINA prohibits employers with 15 or more employees from using genetic information for hiring, firing, or promotion decisions, or for any decisions regarding terms of employment.
- GINA does not apply to other kinds of insurance, like life, disability, or long-term care insurance.

For more information about GINA, go to: <http://www.genome.gov/10002328> or ask us for help.

*I have read this document and also reviewed the information sheet "Donating to the University of Michigan Medical School Central Biorepository." I have had a chance to ask questions and my questions so far have been answered. If I have questions about my rights as a participant I can contact the Institutional Review Board at: IRBMED, 2800 Plymouth Rd, Bldg. 520, Room 3214, Ann Arbor, MI 48109-2800; [irbmed@umich.edu](mailto:irbmed@umich.edu); 734-763-4768.*

*By signing below, I agree to participate in the University of Michigan Medical School Central Biorepository.*

\_\_\_\_\_  
Participant Name Printed

\_\_\_\_\_  
Participant Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Investigator or Designee Name Printed

\_\_\_\_\_  
Investigator or Designee Signature

\_\_\_\_\_  
Date