**Do not** alter the language within this biorepository informed consent template, except to supply project-specific information in passages enclosed in brackets.

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.

Replace the brackets in the line below with the title of your project.

You have the option of contributing to a research biorepository called [ ] which takes part in the University of Michigan Medical School Central Biorepository (“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.
* 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 payments from scientific discoveries made using the information or samples you donate.
* An oversight committee will review and approve requests to use your biospecimens or information, and to make sure the uses are in line with what you have agreed to in this document and the information pamphlet.

**Leaving the Central 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 [Name, 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 Central Biorepository.** You should also understand that:

Replace the brackets in the line below with a brief list of the specimens you plan to collect from subjects (e.g., blood, cells, tissue).

* **Sample donation.** You will be asked to provide [ ].

If subjects will complete a survey, remove the brackets from the line below. If your project does not involve a survey, remove the entire line.

* [**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 “Privacy and Confidentiality” 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 for 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; to tell you something they have learned about you or your sample, or to ask you to participate in another research study, based on your enrollment in the biorepository. 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. *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 “Privacy and Confidentiality” for details.* But once your information has been shared with others, it may no longer be protected by HIPAA.

**Privacy and Confidentiality**

Do not delete any of the bullets below when using this form for the CBR.

**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 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 computer security will be perfect.
* No published scientific reports will identify you directly.
* The CBR has obtained a Certificate of Confidentiality from the National Institutes of Health.

This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or lawsuit unless you say it is okay. They also cannot provide them as evidence unless you have agreed.  This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate does not stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others.  The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate does not stop disclosures required by the federal Food and Drug Administration (FDA).  The Certificate also does not prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research.  The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

**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 a University of Michigan 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**; 734-763-4768.*

*By signing below, I agree to participate in the [ ] repository.*

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 Participant Name Printed Participant Signature Date

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 Investigator or Designee Name Printed Investigator of Designee Signature Date