Document of Consent to Donate to a University of Michigan Biorepository and Authorization to Release Health Information

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 our research biorepository called **Critical Illness Biobank**. 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.

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 either of the following:

- **Dr. Michael Maile,** PI (734)-615-7679

Keep in mind that we will <u>**not**</u> 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. Your nurse will obtain a 14 mL blood sample from an existing catheter (a 10 mL tube and a 4 mL tube, about 3 teaspoons of blood). There is also an option to donate a blood sample on a second day, so researchers can study how your condition progresses over time. If you choose to take part in the second collection, your nurse will use the same procedure to obtain 10 mL of blood (about 2 teaspoons) once during the next 4 days. This will not occur if you are discharged from the ICU, do not have a catheter to draw the blood from, or choose not to take part.

- **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.
- **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 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. *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. 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.
    - 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.

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 Critical Illness Biobank.

______________________	______________________	__________
Participant Name Printed	Participant Signature	Date

Legally Authorized Representative Permission:

Patient Name: ____

Legally Authorized Representative Information:

Name: ____

Signature: ____

Address:____

Date of Signature (mm/dd/yy): ____________________

Relationship to subject: Parent Spouse Child Sibling Legal guardian Other

If "Other," explain: ____

Consent/Assent for Second Optional 10 mL Blood Sample Donation

Donation of optional 10 mL blood sample that will be added to the biorepository to be used in future research.

_____ Yes, I agree to donate the optional 10 mL of blood.

_____ No, I do not agree to donate the optional 10 mL of blood.

Legal Name:

____

Signature:

____

Date of Signature (mm/dd/yy): ______________________

_________________________ _________________________ ___________

Investigator or Designee Name Printed Investigator of Designee Signature Date