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NAME: \_\_\_\_\_  
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**Study: PRO00017015**

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**INFORMED CONSENT FOR USE OF CORD BLOOD, MATERNAL BLOOD AND DISCARD TISSUES FOR RESEARCH**

**WHAT IS A TISSUE BANK AND WHY AM I BEING ASKED?**

Froedtert Hospital and the Medical College of Wisconsin ("MCW") are asking your permission to save your Specimens in the MCW Tissue Bank for future research studies. The Specimens would come from your next clinical blood draw and the discard specimens after the baby is born. For purposes of this form, the term "Specimens" means cord blood, blood and birth related tissues such as placenta or umbilical cord. The MCW Tissue Bank also wants to collect and save clinical information related to your Specimens. This form tells you what we would like to do and possible risks. If there is anything you do not understand, please ask questions. Then you can decide if you want to give your permission or not.

You are being asked to take part in this bank because you have been seen at Froedtert Hospital or MCW. The MCW Tissue Bank is asking to collect cord blood and related tissues after delivery that are not needed or used by the doctor for diagnosis and would normally be discarded. You are free to say yes or no, and your decision will not change your current or future health care. This consent only refers to the current pregnancy/delivery. Any future pregnancies or donations will require separate consent.

**WHAT AM I BEING ASKED TO DO?**

If you agree to bank your Specimens, the umbilical cord blood and tissues will be collected after the birth of your child. The Specimens collected will be cryopreserved for possible research in the future that involves therapeutic use by stem cells. The Specimens will NOT be available for any subject for personal use.

The discard cord blood and tissues will be stored in the MCW Tissue Bank for future research, along with samples of many other people. MCW will also collect a one-time additional amount of your blood [no more than one (1) tablespoon] during your next routine blood draw and bank it. The amount of blood will be within safe limits. There are no costs to you or your insurance company for the collection or use of your Specimens in research.

Researchers may need to know more about your health and/or the status of your treatment in the future in order to do their research. As a result, the MCW Tissue Bank will also link collected Specimens to your health information through MCW's research database of clinical information which is maintained separately. Researchers who require this health information will need the approval of the Institutional Review Board (IRB) in order to view the information for their studies. The IRB is a committee of doctors, researchers and members of the community, responsible for protecting participants in research studies and making sure all research is done in a safe and ethical manner, and in compliance with applicable law. We will not allow anyone to do research with your Specimens or health information without the permission of the IRB.

**WHAT RISKS CAN I EXPECT?**

Your Specimens will be collected as part of a standard medical procedure so there is no extra physical risk to you or your child. The main risk of taking part in the Tissue Bank is the possible accidental release of your health information. While we make every effort to keep the information confidential, it is possible that an unauthorized person might see it. Accidental disclosure of your health information could cause psychological stress or insurance discrimination.

If your Specimens are banked, they may be used to study genetic material. Genetic material, or genes, are made up of DNA, and contain all the biological information which is passed on through families (inherited). Federal law prohibits health insurance companies from denying health insurance, or large employers from denying jobs, based on your genetic information. But the same law does not protect your ability to get disability, life, or long term care insurance.

**ARE THERE BENEFITS OF BANKING MY SPECIMENS?**

There is no direct benefit to you. Other people might benefit if researchers learn more by using your Specimens. You will not be paid for your Specimens. Other researchers or research companies may patent or sell products, discoveries and data that result from future research using your Specimens. You will not receive any payment or commercial rights if this happens.

**WHO WILL SEE MY HEALTH INFORMATION?**

MCW is required by law to protect your health information. We may record your research information, including results of tests and procedures done for research, in your Froedtert Hospital and/or Medical College of Wisconsin medical record. As a result, this research information may be seen by people allowed to see your medical records for healthcare operations or treatment, by those you allow to see your medical records by giving written permission, and by others when required by law. These include data coordinating centers; sponsors of research; Food and Drug Administration; Department of Health and Human Services; and/or Data Safety Monitoring Boards. MCW provides your health information to these groups only when required by law or approved by the IRB. Certain of these agencies or individuals may not be required to protect your health information in the same way that MCW does. If the results of research using your specimens are presented in talks or articles, no information will be presented that identifies you.

**CAN I REMOVE MY SPECIMENS ONCE THEY ARE BANKED?**

You can change your mind at any time, and ask that your Specimens be removed from the bank and destroyed, and that your associated health information no longer be used, by contacting the Tissue Bank Manager in writing at 8701 Watertown Plank Road, Milwaukee WI 53226. Research results that have already been obtained with your Specimens cannot be withdrawn. If you have more questions about the Tissue Bank, or think you were harmed because of this study, let the Tissue Bank Manager know right away by calling 414-805-9569. If you have questions about your rights in this study or want to report any problems, you can call a Research Subject Advocate at 414-955-8844.

**BY SIGNING THIS FORM YOU AGREE TO PARTICIPATE IN THE MCW RESEARCH CORD BLOOD BANK**

<b>Name of Subject (print) ▲</b>	<b>Signature of Subject</b>	<b>Date</b>
<b>Name of Witness (print if applicable) ▲</b>	<b>Signature of Witness</b>	<b>Date</b>
<b>Name of Person Obtaining Consent (print) ▲</b>	<b>Signature of Person Obtaining Consent</b>	<b>Date</b>

**IMPORTANT:** You will receive a signed and dated copy of this consent form to help you remember what we discussed.