

## The Research Centre for Women's and Infants' Health BioBank at Mount Sinai Hospital

You are being asked to contribute to research studies that are supported by the Research Centre for Women's and Infants' Health (RCWIH) BioBank. The RCWIH BioBank is a not-for-profit program that collects human tissue samples (such as placenta and umbilical cord blood) and clinical data for research studies at Mount Sinai Hospital and other research institutes. Please read this explanation about the BioBank program and the risks and benefits involved before you decide if you would like to participate. You should take as much time as you need to make your decision. You should ask the BioBank staff or physicians affiliated with the program to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to discuss the RCWIH BioBank program with anyone you wish. Your participation is voluntary and will not affect your care while at Mount Sinai Hospital.

### Why study the placenta?

As a baby develops inside the mother's womb it is absolutely dependent upon the placenta that acts as its life support system. This important organ connects the growing baby (via its umbilical cord) to the lining of the womb (uterus). The placenta acts as a transport system bringing oxygen and nutrients from the mother and removing waste products from the baby. In addition, the placenta produces hormones and growth factors that help the baby grow and develop. Without the placenta the baby cannot survive inside the mother's womb.

### Advancing women's and infants' health research

It is becoming clear from research studies that many problems of pregnancy are related to how the placenta grows and functions. These problems include:

- Premature birth
- Intrauterine growth restriction (IUGR) (slow growth of the baby)
- Pre-eclampsia (high blood pressure in the mother potentially compromising the baby)
- Pregnancy-induced diabetes

Babies born after these complications have a higher risk of developing health problems before or after birth.

Clinicians and scientists within the Research Centre for Women's and Infants' Health and others in the wider research community would like to learn more about how the placenta grows and develops during pregnancy, and how nutrients and other substances pass across the placenta to the developing baby. We hope that the data obtained from these research studies will help develop new treatment options.

### How you can help

Once your baby is born, the umbilical cord is clamped and the baby is separated from the placenta. The placenta is then delivered and discarded. Sometimes, at the request of you or your doctor, umbilical cord blood may be collected for stem cell banking or for clinically indicated blood tests.

As a participant in the RCWIH BioBank program, after all previously requested or clinically indicated umbilical blood collection has occurred, your placenta will be collected, along with the umbilical cord and remaining umbilical cord blood to further the research efforts focused on improving outcomes of pregnancy. The placenta will be obtained at the time of your delivery at no inconvenience to you. These tissues will be studied either immediately after birth, or in some cases they will be frozen or preserved, stored and studied at a later date. The placenta will also undergo routine examination in the pathology laboratory at Mount Sinai Hospital.

In addition to the placenta, we may also request a small sample of blood (10 cc or 2 teaspoons) or saliva or buccal cells from you and your partner around the time of your delivery (buccal cells are cells from the inner lining of the mouth or cheek; they are routinely shed and replaced by new cells, and can be collected by gently swabbing the inside of the mouth with a brush). Sometimes, it is important to be able to compare a baby's test result from the placenta to one or both parents' samples. As well, maternal blood samples will allow researchers to compare mother and baby blood levels of hormones, proteins and nutrients that enable the baby to grow. In most cases, blood samples are collected at the same time as routine blood tests and carry no risk to you or your baby.

### Confidentiality

As part of the research to improve outcomes of pregnancy, the RCWIH BioBank will require access to your medical records to gain background personal health information for clinicians and scientists.

Personal health information is any information that could be used to identify you and includes your name, address, date of birth, new or existing medical records, and results of medical tests or procedures. In addition, some information about your baby, such as birth weight, length, and head circumference, will be collected from your baby's health records. This information is from the routine physical examination of the baby, which is performed by the hospital's neonatal team after all deliveries. Only RCWIH BioBank staff members approved by the Research Ethics Board of Mount Sinai Hospital will be allowed to look at your or your baby's records and they will collect only the information that is needed for research.

The information that is collected by the BioBank will be kept in a locked and secure area and may be retained for an indefinite period of time. Representatives of the Mount Sinai Hospital Research Ethics Board may look at the BioBank's records and at your personal health information to check that the information collected for the purpose of research is correct and to ensure all proper laws and guidelines are followed.

All information collected for research will be kept confidential, and no personal health information will be shared with anyone outside of the BioBank program unless required by law. No names will appear in any reports, publications, or presentations that may come from this research. If you decide to withdraw from the BioBank program, the information about you and your baby that was collected before you left will still be used, but no new information will be collected without your permission.

## Risks

There are no health risks to you or your baby from taking the samples from the placenta and umbilical cord after delivery. Collection of these samples will not affect your labour or the delivery of your baby.

Samples collected by the RCWIH BioBank are not for the purpose of diagnosis, and results from tests on these samples will not be reviewed by a physician, or recorded in your medical history. However, a potential risk of participating in research is that investigators may discover an abnormality of uncertain significance that may have an impact on your or your baby's health. If warranted, a physician will meet with you to discuss the findings, and provide you with a letter to take to your family physician describing the circumstances of

the findings, and a recommended course of action. Your family physician may, in turn, recommend further diagnostic tests, which may then have an impact on your health and insurance.

## Benefits

Information from perinatal research will help doctors better understand the biological pathways that lead to complications of pregnancy. Most likely you will not receive any medical benefit from your participation in the BioBank program. However, if researchers note any findings that may be important for your baby's health, it may change the medical care provided and could positively influence or help to guide your baby's health management.

## Participation

Your participation in this program is voluntary. If you do not want to participate, or wish to withdraw at any time, you are free to do so and this will in no way affect your present or future care. Please be aware that your tissue samples can be removed from storage or destroyed at your request at any time in the future by contacting the Research Ethics Board of Mount Sinai Hospital.

## Development for Commercial Gain

Research carried out on the samples collected by the RCWIH BioBank may lead to the development of marketable treatments, devices, new drugs or patentable procedures. By donating your samples to the BioBank you will not benefit directly from any such commercial products. Any such benefits will remain with Mount Sinai Hospital and their research partners.

## Questions

If you have any questions about the RCWIH BioBank program, please call Dr S. Lee Adamson, BioBank Director at 416 586 8377. If you have any questions about your rights as a research subject, please call Dr Ron Heslegrave, Chair of the MSH Research Ethics Board at 416 586 4875. This person is not involved with this research in any way and calling him will not influence your participation in the BioBank program. If you wish to ask questions of an unbiased obstetrician not involved with the RCWIH BioBank, please call Dr Rory Windrim, a Staff Obstetrician and Maternal-Fetal Medicine Specialist, at 416 586 8660.

## Consent

I have had the opportunity to discuss the RCWIH BioBank program and all questions have been answered to my satisfaction. I consent to take part in the program with the understanding that I may withdraw at any time without affecting my medical care. I have received a signed copy of this consent form. I voluntarily consent to participate in the BioBank program. I understand that in no way does signing this consent waive my legal rights nor does it relieve the RCWIH BioBank, investigators, co-investigators, sponsors or involved institutions from their legal and professional responsibilities.

- I give the RCWIH BioBank permission to review *my medical records*, knowing that any person accessing my medical records will be approved by the Research Ethics Board of Mount Sinai Hospital and will have signed the Mount Sinai Hospital confidentiality agreement (PLEASE CHECK)
- I give the RCWIH BioBank permission to review *my baby's medical records*, knowing that any person accessing these records will be approved by the Research Ethics Board of Mount Sinai Hospital and will have signed the Mount Sinai Hospital confidentiality agreement (PLEASE CHECK)

I consent to have the following samples collected for research and tissue banking: (PLEASE CHECK ALL THAT APPLY)

- Placenta (*including placental membranes and umbilical cord*)
- Umbilical cord blood (*not for the purpose of stem cell research*)
- Umbilical cord blood (*for stem cell research - refer to the RCWIH BioBank Umbilical Cord Blood Consent Form, (Version 1; date: July 1 2010)*)
- Maternal samples:     Blood     Saliva     Buccal swab
- Paternal samples:     Blood     Saliva     Buccal swab

\_\_\_\_\_  
*Patient's Name (please print)*

\_\_\_\_\_  
*Patient's Signature*

\_\_\_\_\_  
*Date*

\_\_\_\_\_  
*Partner's Name (please print)*

\_\_\_\_\_  
*Partner's Signature*

\_\_\_\_\_  
*Date*

I confirm that I have explained the nature and purpose of the RCWIH BioBank program to the subject named above. I have answered all questions.

\_\_\_\_\_  
*Name of Person Obtaining Consent*

\_\_\_\_\_  
*Signature*

\_\_\_\_\_  
*Date*