CONSENT TO PARTICIPATE IN THE MOMI BIOBANK

TITLE: **MAGEE OBSTETRIC MATERNAL and INFANT (MOMI) BIOBANK**

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DESCRIPTION: We are asking you to be part of the MOMI Biobank. The MOMI Biobank is designed to help research normal and complicated pregnancies, including how pregnancy affects maternal and child health after delivery.

The MOMI Biobank, owned and operated by MWRI, stores health information (through medical records review) and samples (like blood and placenta) that are provided for research. These data and specimens will be given an identification number (not linked to participant name) and then stored at MWRI.

We are asking for permission to collect and store data and samples during your pregnancy and after delivery. The specimens may include: blood, urine, rectal swabs, cheek swabs, vaginal and cervical swabs, amniotic fluid, tissue biopsies if you have a Cesarean section (C-section) at delivery of your baby, and diaper samples from your baby. Placenta and cord blood from a live birth, which are typically discarded after delivery, will also be collected. Depending upon your clinical care during pregnancy it may not be possible to collect some samples, and you can also decline sample collections. Some samples are collected in addition to those collected clinically. We are asking you to take part in this study because you are pregnant and plan to deliver at Magee-Womens Hospital or at Magee-Womens, UPMC Hamot.

BIOBANK PROCEDURES

Your doctor will likely recommend that you have several blood draws and pelvic exams during your pregnancy as part of your regular prenatal care. If you choose to take part in this research, we will collect and store health information and samples throughout your pregnancy and after delivery. The detailed list of collections is below:

Specimens from Mother

- Blood: We may collect up to five blood draws from you over the course of your pregnancy. Each blood draw will contain about one to three tablespoons of blood from a vein in your arm. We will make every attempt to get this as part of your regular clinical care, but if we can't, we would still like to collect this at a time that is convenient for you. This will take a few more seconds during your blood draw and will usually occur once each trimester (1st, 2nd and 3rd trimesters), during delivery and after delivery. Your doctor may recommend that you have other blood draws for additional tests. If this occurs, we may collect additional blood during these draws.
- Urine: We may collect urine samples at the same time blood samples are collected during your pregnancy. This will be done when you are providing a sample as part of your regular care or separately if urine is not collected as part of your normal prenatal care.
- Placenta and Cord Blood: After delivery, we may collect the placenta, umbilical cord, and any

cord blood remaining in the placenta and cord from a live birth. The placenta and its umbilical cord are usually discarded after delivery. If you choose to bank cord blood privately or provide your cord blood to a public bank, you can still provide cord blood for research.

- Vaginal and Cervical Swabs: We may collect fluid from swabs from your vagina and cervix with the help of your doctor (during a pelvic exam) or yourself (self-collection) throughout your pregnancy. We will make every attempt to get these samples as part of your clinical care, but may ask for these as self-collections done by you. These collections are simple and minimally invasive and will take only a few seconds to collect each time.
- Rectal Swabs: We may collect swab samples from the rectum throughout your pregnancy. This collection will be performed by you or your doctor at each trimester like the vaginal swabs described above.
- Stool: We may collect stool samples throughout your pregnancy using a collection kit provided by the research team. This collection will be performed by you and can be submitted to a researcher at a future appointment.
- Amniotic Fluid: If your doctor recommends that you undergo a procedure called amniocentesis for special testing of the amniotic fluid, we may collect the residual or left-over amniotic fluid for research.
- Cheek Swab: We may collect a cheek swab sample from you using a soft swab. The collection technique will be explained and can be self-collected.

Specimens from Infant:

- Meconium: We may collect a small amount of meconium (your baby's first bowel movement) from your baby's first diaper changes while you are at the hospital.
- Cheek Swabs: We may collect cheek swab samples from your baby using soft swabs at the time of delivery and/or before you leave the hospital.

Specimens from Mother during Cesarean Delivery

In the event of a scheduled cesarean delivery, we may speak to you before delivery about specimens that can be collected during surgery. At this time, a physician investigator will review procedures, risks, and discomforts associated with specimen collection during cesarean delivery. If you would like to provide specimens obtained during cesarean delivery, you will be provided with an addendum consent form.

Medical Record Review: We may review your medical record and your baby's medical record and gather information such as medical history, lab results, images such as ultrasounds, and how you and your baby have done after the birth.

Father of baby involvement: If you agree, we may ask the father of the baby if he would like to be in the Biobank. Once he agrees, we will ask him to sign a consent form and provide a cheek swab and/or blood sample. This will help us investigate genes that may be involved in pregnancy complications.

Information that you provide for this study will be made available to other researchers through a controlled-access database. The information will be coded, meaning your name and your baby's name and other identifying information, except for dates of medical service and date of birth, will be removed before it is deposited and precautions will be taken to protect your baby's and your privacy. The data from this database will be shared with researchers using samples and data from the MOMI Biobank.

Biological specimens placed in the MOMI Biobank will be used for research studies. The specific nature of these research studies will vary and are not fully known now, but may include studies of cells, biological markers, proteins and genes. If the specimens are being surgically removed or collected because of a disease, condition or pregnancy complication, it is likely that the research studies that use your specimens will be directed at the same disease or condition. However, it is possible that your specimens may be used in research studies directed at other diseases or conditions. All information and samples collected from you will be made available to other researchers who wish to study normal and complicated pregnancies. Researchers must first get permission from their institutional review board and the MOMI Biobank Oversight Committee, before getting material from the MOMI Biobank. Research studies on material collected from pregnant women may increase our understanding of normal and complicated pregnancies, including how pregnancy affects maternal and child health after delivery.

To use your biological specimens effectively for research, it is necessary that your and your baby's medical information is available for review. Therefore, if you agree to include specimens in the MOMI Biobank, you also agree to allow individuals responsible for the MOMI Biobank to review and collect past, current and future identifiable information from your and your baby's medical records about your pregnancy outcome, diagnosis, age, medical history, medical procedures and results of other tests done as part of your and your baby's standard medical care. This authorization to use medical records is valid for an indefinite period, and this information will be available in the MOMI Biobank for an indefinite period. Investigators may contact you in the future for other research projects.

These specimens may also be used to produce genetic material (like DNA and RNA) and this material will be stored for an indefinite period for future studies, including those that may be unrelated to your current condition. Some cells may be treated so that they can be studied for many years. These will be destroyed when they are no longer needed.

Your specimens will be stored in the MOMI Biobank in a way that will permit the people responsible for the MOMI Biobank to connect your identity with your sample. **However, when your specimens and medical information are made available for actual use in research studies, this information will be provided to researchers without personal identifiers so they cannot easily connect your identity with the specimens or medical information. Your specimens, genetic/medical data and genetic information may also be shared with other federally-funded tissue banks or data repositories**, which may also share specimens and medical information with other researchers. You will not be contacted when your specimens or information are sent to researchers. Biological specimens will only be released for research after careful review of the research proposal by oversight committees (e.g. MOMI Biobank Oversight Committee).

Other studies may collaborate with MOMI to retrieve the specimens, images, and information of participants who enroll in both their study and in the MOMI Biobank. If you participate in one of these studies, the study consent will explain the link to MOMI and you will consent for your specimens, images, and information collected by MOMI to be shared when you enroll. Under this arrangement, your identified information (name, medical record number) may be securely shared between MOMI and approved members of the applicable study teams.

Because it may not be possible to connect your identity with your tissue/ biological specimen when the sample is being used for research, **it may also not be possible to inform you of the results of such research**. If you agree to give samples of your biological specimens to the MOMI Biobank, they will become the property of MWRI and their use will be under the control of the MOMI Biobank. **Your medical information and sample(s) will be stored in the MOMI Biobank (and/or at other federal research repositories) until such time that the sample(s) are used up or are no longer felt to be appropriate for use in research studies**. Your voluntary decision to provide these specimens and identifiable medical information to the MOMI Biobank, or to later withdraw from it, will not affect your

current or future medical care at UPMC. Your signed consent or a note that you are enrolled in the MOMI Biobank may be placed on file as part of your medical record.

RISKS and BENEFITS:

You will receive no direct benefit by giving samples of your biological specimens to the MOMI Biobank. However, the availability of such samples for research use is important for understanding medical diseases and developing new treatments. We hope that women and babies in the future will benefit from this research. We will share what we learn from this research with other health professionals through medical publications. None of these publications will include information that could identify you in any way.

Specimens from Mother

- Blood: When taking a blood sample, there may be brief discomfort. Bruising, redness, and/or swelling may form where the needle stick occurs. Some people experience a feeling of lightheadedness. Rarely, an infection may occur at the site.
- Urine: There are no physical risks to urine collection.
- Placenta and Cord Blood: Only placental tissue, umbilical cord and cord blood that would otherwise be discarded will be used. There are no additional risks to you or your baby from collecting these samples.
- Vaginal and Cervical Swabs: Collecting swabs from the cervix and vagina may cause mild discomfort, like a pap smear. These samples may be collected by self-collection
- Rectal Swabs: Rectal swab collections may also cause mild, momentary discomfort. These samples may be collected by self-collection.
- Stool: There are no physical risks to stool collection.
- Amniotic Fluid: There are no additional risks to the collection of residual amniotic fluid from amniocentesis.
- Cheek Swab: The soft swab used in the mouth may cause momentary discomfort.

Specimens from Infant

- Meconium: Your infant's first diaper is typically discarded. The collection of meconium from your infant's first diaper poses no additional risk to you or your infant.
- Cheek swab: The soft swab used in the mouth may cause infant momentary discomfort.

We do not plan to share with you research findings about you or your child's genetics except in rare circumstances. If this happens, we will contact the University of Pittsburgh Institutional Review Board (IRB). The purpose of this IRB is to protect the interests of human subjects participating in research. In most cases, you will not receive results from research done on your or your baby's samples.
Some people feel that providing information for research is an invasion of privacy. Although we will make every effort to keep your information confidential, no system for protecting your confidentiality can be completely secure. We think it is very unlikely that you would ever be identified but it is possible that someone could:

- Break into the computer system(s). They could then find the code that links your genetic and medical information to you. This is very unlikely.
- Find a way to link your genetic or medical information in a database back to you. Your genetic information is unique to you. But you share some genetic information with your children, parents, brothers, sisters and other blood relatives. So, it might be possible for someone to use genetic information from your relatives to help figure out who you are. Again, it is unlikely this would happen.

There could be other privacy risks we do not know about.

The risks associated with gene studies include the potential for a breach of confidentiality which could affect future insurability, employability, or reproduction plans, or have a negative impact on family relationships and/or result in paternity suits or stigmatization. It is possible that authorized officials from the University Research Conduct and Compliance Office, or UPMC hospitals may have access to your identifiable information, but only for monitoring the appropriate conduct of this biobank program. If the researchers learn that you or someone with whom you are involved is in serious danger of harm, they will need to inform the appropriate agencies as required by Pennsylvania law. Authorized representatives of UPMC hospitals or other affiliated health care providers may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study for the purpose of: (1) fulfilling orders, made by the investigators, for hospital and health care services associated with research study participation; (2) addressing correct payment for tests and procedures ordered by the investigators; and/or (3) for internal hospital operations (i.e. quality assurance).

The MOMI Biobank and all other federal repositories must follow federal rules and laws to protect your privacy. **A federal law called the Genetic Information Nondiscrimination Act (GINA) helps protect you from being treated unfairly because of your genes**. GINA generally makes it illegal for health insurance companies and group health plans to use genetic information in making decisions regarding your eligibility or premiums. This law will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information that we get from this research when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

This Federal law does not protect you against genetic discrimination by companies that sell life, disability, or long-term care insurance nor does it protect you against genetic discrimination by all employers.

COSTS and PAYMENTS: **There will be no additional costs to you or your insurance company** if you agree to include your biological specimens in the MOMI Biobank, nor will you receive any payment. Use of your specimens for research may lead to new inventions or products in the future. If researchers can develop new products from the use of the sample you give to the MOMI Biobank, you will not receive any money.

Research involving samples from the Biobank may result in the development of commercially valuable products or discoveries. The results of this research might be used for commercial and/or intellectual property and if that occurs no financial benefits will be passed along to donors. Others with whom the investigators work intend to claim sole ownership of the research results and of any use or development of the research records consistent with this consent. Other investigators, business associates or other research groups working using samples and data from the Biobank may use the research results, research records, and any development or inventions arising from their research for commercial and/or intellectual property purposes. MWRI may also charge companies and/or other researchers for use of this data in order to recover costs associated with collection, storage, analysis, or other activity associated with building and maintaining the Database and Biobank. No portion of those charges shall be passed on to donors.

Compensation for injury: If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. Currently, there is no plan for any additional financial compensation.

CONFIDENTIALITY: To protect your privacy, **your specimen(s) and information will be stored in the MOMI Biobank using a code number**, and only the individuals responsible for the MOMI Biobank will be able to connect this code number with your identity. The information linking this code number with your identity will be kept by these individuals in a secure manner. **Only approved researchers can use your specimens and information, and they will only know the code number; they will not be able to contact you or identify you personally**.

RIGHT to WITHDRAW: **You may refuse to allow us to include samples or information from the medical record of you/ and your baby in the MOMI Biobank**. Such a decision will not affect the current or future care you receive at this institution or any other benefits for which you might qualify. **If you agree to provide specimens to the MOMI Biobank, you may also withdraw your permission at any time** through a written request. Any identifiable research or medical information recorded for, or resulting from, your participation in the Biobank prior to the date that you formally withdrew your consent may continue to be used and disclosed for the purposes described above. Note that any specimens or data provided to investigators to analyze for research will continue to be used. It is not possible for us to guarantee that we will be able to destroy any samples that may have been previously provided for research use since your identity will not be connected with these samples.

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<u>VOLUNTARY CONSENT</u>: **The above information has been explained to me and all of my questions have been answered. I understand that any future questions I have can be answered by one of the individuals responsible for the MOMI Biobank (412-440-8515 [Pittsburgh, PA]; 814-303-2728 [Erie, PA]). The Human Research Subject Advocate of the Institutional Review Board, University of Pittsburgh (1-866-212-2668), will answer any questions I may have about my rights as a research subject.**

By signing this form, I agree to give samples of my biological specimens to the MOMI Biobank for use in research studies directed at any disease or condition and I agree to allow the use and disclosure of my medical record information as described above. I understand that I can always withdraw my authorization to allow the MOMI Biobank staff to review my medical records by contacting the MOMI Biobank directly.

I understand that, as a minor (age less than 18 years), my child (unborn at this time) is not permitted to participate in this research study without my consent. Therefore, by signing this form, I give my consent for his/her participation in this research study and authorize the use of his/her medical records for research purposes, as described in this consent form.

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Printed name of patient

_____ _____

Patient/ Subject Signature Date: Time:

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions, concerns or complaints as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____

Printed name of individual obtaining consent

_____ _____

Signature of individual obtaining consent Date: Time: