INSERT LOCAL SITE NAME
GLOBAL ALLIANCE TO PREVENT PREMATURITY AND STILLBIRTH (GAPPS) REPOSITORY:
PROSPECTIVE/ANTEPARTUM ENROLLMENT

Investigators:

RESEARCHERS' STATEMENT

We are asking you to be part of a repository. A repository is a research resource that collects, stores, and distributes biological samples and related information from people who agree to participate. The Global Alliance to Prevent Prematurity and Stillbirth (GAPPS) Repository was designed to help research normal and abnormal pregnancies, including how pregnancy affects maternal and child health after delivery. The purpose of this form is to give you the information you will need to help you decide whether or not to be a part of the GAPPS repository. Please read this form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When all your questions have been answered, you can decide if you want to be involved in this repository or not. This process is called informed consent. We will give you a copy of this form.

PURPOSE

The purpose of this research is to establish a data and specimen storage system called the Global Alliance to Prevent Prematurity and Stillbirth (GAPPS) Repository. The GAPPS Repository is a network of hospitals and women working together to gather these clinical and biological materials to be used to research normal and abnormal pregnancy outcomes.

The GAPPS repository stores health information (through questionnaires and a 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 in the GAPPS Repository at Seattle Children's Research Institute. Coded clinical information and samples will be available to researchers who wish to study factors (including proteins, immune responses and genes) that may be involved in normal and abnormal pregnancies. Researchers must first get permission from their institutional review board and the GAPPS Data and Specimen Utilization Committee, before getting material from the GAPPS Repository. Research studies on material collected from pregnant women may increase our understanding of normal and abnormal pregnancies, including how pregnancy affects maternal and child health after delivery.

We are asking for permission to collect and store data and samples during your pregnancy and after delivery. The specimens will include blood, urine, rectal swabs, cheek swabs, vaginal and cervical swabs, vaginal pH, amniotic fluid, and diaper samples from your baby. These samples may be used to obtain genetic material called DNA. Placenta and cord blood that are typically discarded after delivery will also be collected. 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 the *INSERT LOCAL SITE NAME*.

REPOSITORY PROCEDURES

Your doctor or obstetrical provider 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:

- We will collect about five blood draws from you. 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 it as part of your clinical care, but if we can't, we would still like to collect it 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, during delivery and after delivery. Your provider may recommend that you have other blood draws for additional tests. If this occurs, we will collect additional blood during these draws.

- We will collect fluid from your cervix and vagina using no more than three swabs (similar to a pap smear) during speculum exams by the obstetrical care provider.

- We will collect fluid from up to five swabs from your vagina with the help of your care provider (during a pelvic exam) or yourself (self collection) once in each trimester, and also at delivery and after discharge. 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. They are minimally invasive and will take only a few seconds to collect each time.

- We will use a soft swab to collect and record your vaginal pH (acidity) with the help of your care provider (during a pelvic exam) or yourself (self-collection) once in each trimester, and also at delivery and after discharge. 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. They are minimally invasive and will take only a few seconds to collect each time.

- We will collect swab samples from the rectum. This collection will be performed by you or your provider at your first OB visit, 3rd Trimester, and at delivery.

- We will ask you to self collect cheek swabs at first, second, and third trimesters, at delivery, and post-delivery.

- We will collect a small amount of urine. 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.

- If your provider recommends that you undergo a procedure called amniocentesis for special testing of the amniotic fluid, we will collect the discarded amniotic fluid for research.

- If your provider performs a cesarean delivery we will collect a small amount of amniotic fluid by inserting a needle into the amniotic fluid sac once the c-section incision is made.

- After delivery, we will collect the placenta and any cord blood remaining in the placenta or cord. The placenta is usually thrown away. If you choose to bank cord blood privately or provide your cord blood to a public bank, you could still provide cord blood for research.

- We will collect a small amount of urine and meconium from your baby's first diaper changes while you are at the hospital.

- We will collect samples of secretions from the airway if your baby has a tube placed to aid in breathing.

- We will collect some cheek swab samples from your baby using soft swabs at delivery and before you leave the hospital.

- We will ask you to complete up to five brief questionnaires about your health before, during and after pregnancy: a health history questionnaire and dietary assessment early in your pregnancy, review of systems questionnaire in mid-pregnancy, one questionnaire before discharge after delivery and a follow up questionnaire about six weeks after you deliver. The initial and follow up questionnaire may take 25-30 minutes to complete. The other questionnaires could take about 5-10 minutes to complete.

- We will 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. If you deliver at a hospital other than the study hospital, we will request copies of your

medical record and your baby's medical record from that hospital. Additionally, future researchers may request your child's medical records for their first 24 months of life.

- If you agree, we may ask other members of your family (father of the baby, your mother, sister, sister's children, or any other children you may have) if they would like to be in our repository. Once they agree, we will ask each of them to sign a consent form and give us a cheek swab or blood sample. This will help us investigate genes that may be involved in abnormal pregnancy outcomes. We will also ask members of your family to complete a health questionnaire that will take about 5 minutes to complete.

- 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 traditional identifying information, with the exception of 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 this repository.

- Samples and information from you and your baby will be used for research on the types of microorganisms present in the human body. Information from your baby's and your microbial DNA/RNA will be made available to other researchers through an open-access database on the internet. The information will be coded, meaning your name and other traditional identifying information will be removed before it is deposited and precautions will be taken to protect your privacy.

- Your baby's and your human DNA may have all or part of your DNA analyzed and the data may be made available to other researchers through the National Institute of Health database of Genotypes and Phenotypes (dbGaP) repository, a controlled-access database. dbGaP allows researchers to collect and share information with each other, which may result in learning new and important things more quickly. The information in this database will be stored permanently. Information from your baby's or your human genetic material may be linked together and to genetic information about your baby's microbes or your microbes and other information you have provided for the study. But we will not include your name, medical record number, or contact information in dbGaP. Other researchers must get permission from a special committee at NIH to be able to use your data in the dbGaP database.

Database	Type of database	Level of access	Institution in control of data in database	Kind of data being housed
Global Alliance to Prevent Prematurity and Stillbirth (GAPPS) Database	Data and tissue bio-bank used to research normal and abnormal pregnancies, maternal, newborn and child health outcomes	Qualified researchers with IRB approval must apply to the GAPPS Utilization Committee and be approved in order to access the samples and information	Global Alliance to Prevent Prematurity and Stillbirth (GAPPS), an initiative of Seattle Children's Hospital	Data and tissue samples without traditionally identifying information, with the exception of date of birth and dates of medical service
Database for Genotypes and Phenotypes (dbGaP)	A national database for genetic information	Qualified researchers must apply to a special committee at the National Institutes of Health (NIH) and be approved in order to access the samples and information	National Institutes of Health (NIH)	Data and tissue samples, without traditionally identifying information such as name or date of birth

Other databases	The type of information being stored and shared may vary	Varying access ranging from closed access (committee approval necessary) to open access (available to anyone on the internet)	Various institutions	Data and tissue samples, without traditionally identifying information such as name or date of birth

At the end of this consent form there is a flowchart showing when providers normally request a blood draw or perform a pelvic exam for routine prenatal care. The flowchart includes special visits, such as for an amniocentesis procedure that may occur for you. The flowchart also shows when specimen collections may occur for the GAPPS Repository, or when we may ask you to fill out a questionnaire. One of the Study Coordinators named above will be in contact with you throughout your pregnancy so she can meet you at these visits.

We may use some of your blood or placental tissues and some of your child's cord blood to establish cell lines. Cell lines allow cells to be grown outside of the body, perhaps indefinitely.

We do not plan to provide you with the results of any research tests or evaluations. This is because the tests done on your samples are research tests and not meant to test the medical status of you or your child.

We will transfer your study information and specimens to the GAPPS Repository at Seattle Children's Hospital Research Institute for long-term storage and future research on normal and abnormal pregnancies, including how pregnancy affects maternal and child health after delivery.

RISKS, STRESS OR DISCOMFORT

When taking a blood sample, there may be brief discomfort, and a bruise may form where the needle poke occurs.

Collecting swabs from the cervix and vagina may cause mild discomfort, similar to a pap smear. Rectal swab collections may also cause mild discomfort. These samples will be collected by the obstetrical care provider or by a self collection. The frequency of these swabs could be during the first trimester, at second trimester, at third trimester, at delivery, and at post-delivery. The vaginal swab represents an "extra" procedure for you but is minimally invasive and takes only a few seconds to collect.

Only placental tissue or cord blood that would otherwise be discarded will be used, so there are no additional risks to the pregnancy or fetus from collecting these samples.

The risks or discomforts associated with providing a sample of your amniotic fluid for clinical testing will be explained to you by your doctor.

The research questionnaires ask about medical history, family history and behaviors such as smoking and drinking alcohol. Some people may feel uncomfortable answering some questions. You can choose not to answer specific questions.

We do not plan to share with you research findings about you/your child's genetics except in rare circumstances. If this happens, we will contact [LOCAL SITE 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.

Some genetic information may predict health problems you or your relatives could have in the future. This information might be of interest to health providers, life insurance companies and others. There are state and federal laws that protect against genetic discrimination. There is a federal law called the Genetic Information Nondiscrimination Act (GINA). This law makes it illegal for health insurance companies, group health plans and most employers to discriminate against you based on your genetic information. However, the law does not completely protect you from discrimination.

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

Your samples could be used to make new products, tests, or findings. These may have value and may be developed and owned by the research team and/or others. If this happens, there are no plans to provide any money to you.

BENEFITS

You will not directly benefit from this repository. 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.

MEDICAL RECORD INFORMATION

We are required by Federal regulations and some hospital policies to put information about your participation in research into your hospital medical record. The information in your medical record will include:

- The name of this research project - *Global Alliance to Prevent Prematurity and Stillbirth (GAPPS) Repository*
- Name of the group or company that is paying for the research: Seattle Children's
- The number the group or company assigned to this study
- The name of the researcher(s)
- The name of the study coordinator
- Contact phone number for the study
- Emergency phone number for the study
- Expected start and end dates for your time in the study
- Whether this study includes healthy volunteers

Information about your research procedures may also be put into your medical record. This will include:

- The samples collected from you as part of this research

Your medical record will NOT contain results of any tests done on your samples.

People who have access to your medical record may be able to find out that you are in this repository. They will also be able to see that research tests have been done, but the research results will not be available. In the future, if you give permission to any person or group to look at your medical record (such as an insurance company or employer), they could receive this research information.

If you have already given permission to anyone (such as your health insurance company) to look at your medical record, they may receive this research information if they ask for a copy of your medical record.

OTHER INFORMATION

Taking part in this research is voluntary. You can refuse to provide any samples or data at any time during your participation. You can withdraw from this research repository at any time. Withdrawing from this repository will not change the health care you receive. If you withdraw, we will destroy the information and samples we have collected from you. However, we would not be able to destroy or get data back if it has already been released from databases to other researchers. Any remaining samples will be destroyed. If you want to withdraw from this research, please contact *INSERT LOCAL PIs NAME* at (xxx) xxx-xxxx.

Your medical information, questionnaire and specimen information will be coded and your identity will remain strictly confidential. We will keep the link between your name and your research information/samples in a locked file at the *INSERT SITE NAME*. The GAPPS repository will include you and your child's date of birth and dates of medical service. Under certain circumstances this information can be used by the researchers who use samples and information from the GAPPS repository. Any publication resulting from this repository will not reveal you or your child's identity. Although we will make every effort to keep your information confidential, no system for protecting your confidentiality can be completely secure. It is possible that unauthorized persons might discover that you are in this repository, or might obtain information about you. Hospital and government offices sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this research takes place, your records may be examined. The reviewers will protect your privacy. The research records will not be used to put you at legal risk of harm.

The National Institutes of Health require that information regarding your race and ethnicity be collected. You will be given a form to complete; however, your response is strictly voluntary. The information will not be linked to your name or medical records.

We have obtained a Certificate of Confidentiality from the Department of Health and Human Services. The certificate is designed to prevent us from being forced to disclose identifying information for use in any federal, state, or local civil, criminal, administrative, legislative, or other court proceeding, even if faced with a court subpoena. You should understand, however, that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. We may not withhold information if you give your insurer or employer or a law enforcement agency permission to receive information about your participation in this project. This means that you and your family must also actively protect your privacy.

COSTS/COMPENSATION

You will receive a small thank you gift at time of enrollment. You may also receive $20 gift cards after completing interim questionnaires and self administered collections at two points throughout your pregnancy, typically second and third trimester ($40 total). A onesie and another $40 gift card will be given to you for completing the delivery and discharge questionnaire and your time taken in giving samples at delivery and immediate postpartum. If a 4-10 weeks postpartum visit is requested, another $20 gift card will be given for completion of follow up questionnaire and postpartum samples. ($100 in gift cards total). If you complete a questionnaire during a clinic visit, you will receive the thank-you gift or gift card at that visit. If you complete the questionnaire online, you will receive the thank-you gift or gift card in the mail or at your next appointment. If you complete a questionnaire while inpatient, you will receive the thank-you gift or gift card when the coordinator picks up the completed questionnaire.

Neither you nor your insurance company will be charged for taking part in this research. There will be no cost to you for any research procedure or exam. However, routine medical care for your condition will be charged to you or your insurance carrier

Qualified researchers who get permission to use information from the databases may not be from Seattle Children's. Some may be from other institutions, universities, or from commercial companies. It is possible that a commercial product could be developed by researchers. No compensation will be provided to you or your child if a commercial product results from this research.

COMPENSATION FOR INJURY

If you are injured or become ill as a result of participation in this research, immediately contact *INSERT LOCAL PIs NAME*, the doctor in charge of this repository at *INSERT LOCAL SITE NAME* at (xxx) xxx-xxxx. Your insurance will be billed for such treatment. The sponsor will pay any charges that your insurance does not cover. No other compensation is routinely available from the repository doctor or sponsor.

However, you will not be provided with reimbursement for medical care other than what your insurance carrier may provide, nor will you receive other compensation from *INSERT LOCAL SITE NAME* in connection with this research. Any such cost will be your responsibility, your insurance company, or the sponsor, as described above. By signing this consent form, you will not give up any legal rights. For more information concerning the research and research-related risks or injuries, you can contact *INSERT LOCAL PIs NAME* who can be reached at (xxx) xxx-xxxx.

An Institutional Review Board (IRB) has been established at *INSERT LOCAL SITE NAME*, composed of physicians, community representatives and members of the Hospital Administration. The purpose of this IRB is to protect the interests of human subjects participating in research. The IRB is an impartial third party not directly involved with the research. Any comments may be reported anonymously, and the IRB invites any comments, questions or complaints which you may have regarding: 1) treatment; 2) response to this treatment; and 3) subject's rights as an investigational research subject.
Comments may be addressed to:

Chair, Institutional Review Board
INSERT ADDRESS

or call: The IRB Coordinator
INSERT LOCAL SITE NAME at (xxx) xxx-xxxx
INSERT HOURS AVAILABLE

Printed name of study staff obtaining consent | Signature | Date

PARTICIPANT SIGNATURES AND INITIALS

By signing below, you state that the research has been explained to you and to your satisfaction and that you voluntarily consent to participate in this repository. You understand this study involves medical history review, surveys and collection of human and microbial genetic material. You have had an opportunity to ask questions. You understand that future questions you may have about this research will be answered by one of the investigators listed on the first page of the consent form. If you have questions about your rights as a research subject, you may call the *INSERT SITE NAME* IRB at (xxx) xxx-xxxx. You will receive a signed and dated copy of this consent form.

Name of Subject (printed) | Signature of Subject | Date

FUTURE CONTACT

You may contact me in the future about this study or other studies I might be eligible for. ❑ YES ❑ NO ____INITIALS

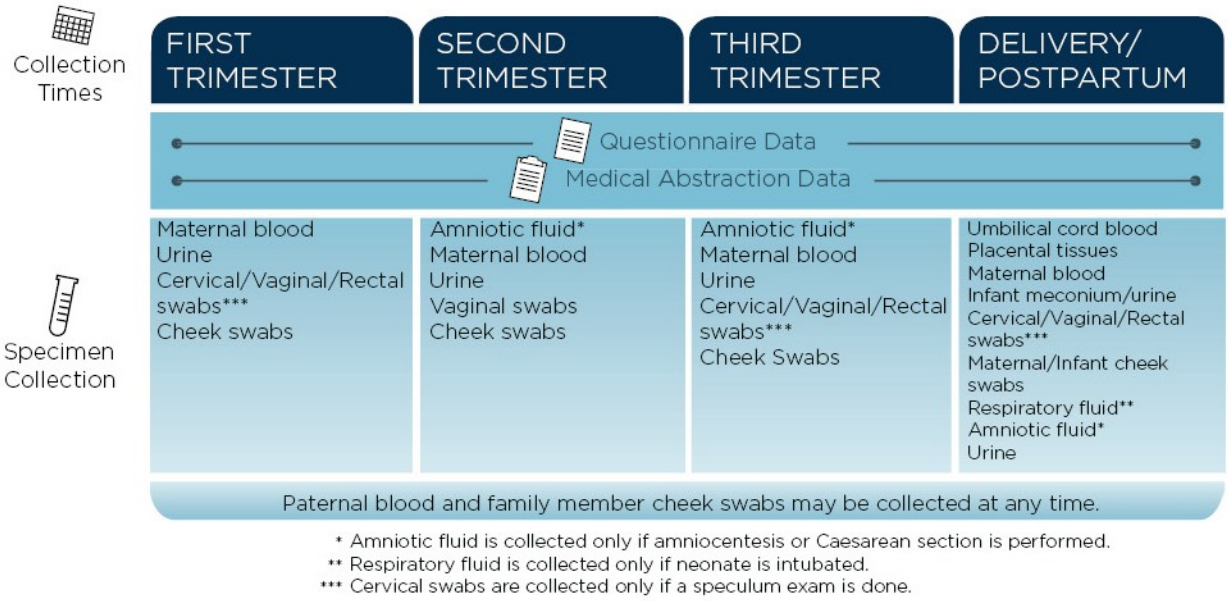
If you choose to allow the investigators to contact you in the future – after your participation in this research is completed, please provide contact information below. Please note that we cannot guarantee the confidentiality of email communication, but every effort will be made to protect your privacy where possible.

Email Address:

Address:

Telephone Numbers:_____

GAPPS Repository Collection Schedule



* Amniotic fluid is collected only if amniocentesis or Caesarean section is performed.
** Respiratory fluid is collected only if neonate is intubated.
*** Cervical swabs are collected only if a speculum exam is done.

MEDICAL RESEARCH SUBJECT'S BILL OF RIGHTS

The rights below are the rights of every person who is asked to participate in medical research. As a research subject, you have the following rights:

1. To be told the nature and purpose of the research.

2. To be told what will happen and whether any of the procedures, drugs or devices are different from what would be used in standard practice.

3. To be told about any significant risks, side effects or discomforts that can be reasonably expected from the research.

4. To be told of any expected benefits from participating in the research.

5. To be told the other available treatments that could be chosen instead, and how they may be better or worse than participating in the research.

6. To be allowed to ask any questions concerning the research both before agreeing to be involved and during the course of the study.

7. To be told what sort of medical treatment is available if any complications arise.

8. To refuse to participate at all or to withdraw consent to participate at any time, without jeopardizing the right to receive present or future care.

9. To receive a copy of the signed and dated consent form.

10. To be free of pressure when considering whether to agree to participate in the research.