



# Universal Consent for Biological Samples

## Frequently Asked Questions

**Welcome to NewYork-Presbyterian and Weill Cornell Medicine! We're excited to welcome you and want to congratulate you on your pregnancy and/or the birth of your baby. We want to invite you to join a project to help researchers learn more about the health of birthing parents and babies. You can help by volunteering for the Perinatal Intergenerational Research Institute Sample Biorepository.**

### What is the PIRI Sample Biorepository and why is it important?

PIRI is a group of people who want to make it easier for future scientists to study the health of parents giving birth and their babies. Sometimes, medical research about pregnant individuals, new parents, and their babies is limited because there aren't enough samples to study, and it's challenging to connect samples from both the parent and the baby. PIRI aims to help by collecting many samples from parents and their babies over time and storing them in a special place called a biorepository. This biorepository is like a big storage facility where biological samples are kept for research purposes. Our goal is to use these linked samples to learn more about how pregnancy and childbirth are connected to the parent's and baby's health. With this knowledge, we hope to improve the health of birthing parents and their babies.

### What is a biological sample?

A biological sample is something taken from your body, such as blood, urine, other fluids, or tissue. These samples have important information about your health, so doctors often collect them during regular checkups or as part of your care at the doctor's office or hospital. Doctors use these samples to figure out the right treatment for you. However, they usually only use a small amount of these samples for tests, and the rest are thrown away.

### Who will give samples to the PIRI biorepository?

All birthing parents and their babies who are getting care at NewYork-Presbyterian/Weill Cornell Medicine will be asked to join the study. Each year, about 7500 birthing parents get prenatal care and deliver their babies here.

### What are you asking me to do?

We're asking if you'd be okay with us keeping your and your baby's samples and medical records for future research. If you choose to do so, we will also ask you to collect a few samples yourself and give it to the nurse or research staff.

### Do I have to join? If I say no, will it affect my care?

**No.** Joining is totally up to you, and it won't change how the doctors, the nurses, or the staff at NewYork-Presbyterian/Weill Cornell Medicine will treat you or your baby.

### What samples will be collected from me?

During your prenatal care or when you give birth, there will be some samples left over from regular tests or procedures. These samples might include, but are not limited to, urine, stool, spinal fluid, umbilical cord blood, placental tissue, and breastmilk (but only if you have more milk than your baby needs).

We are also asking for a few extra samples, like a small amount of extra blood (no more than 2 tablespoons). This extra blood may be collected during your prenatal visits and delivery, at the same time as when you're getting blood drawn for your regular checkups. We will also ask you to collect vaginal swabs or provide a saliva sample at home. If you choose to donate these extra samples, don't worry! We will give you clear instructions on how to do it.

### Why do you want extra tubes of blood?

One of PIRI's main goals is to find out things during pregnancy that may predict health risks for both moms and babies. The blood we collect during regular care is stored in a way that makes it hard to use for research. The extra tube will help us store enough blood for future research.

### What samples will you collect from my baby?

When your baby is born, cord blood will be taken for routine testing, and we will save the any unused blood for research. In the newborn nurse, we'll collect stool and urine from their dirty diapers and saliva using gentle suction or a swab. If your baby needs blood work at the hospital, we'll also collect any leftover blood after that testing. If your baby is in the NICU, we'll take samples from any regular care or testing. These samples may include stool and urine from dirty diapers, leftover blood, saliva and other body fluids, their diet, and tissues leftover if they had surgery.

### Are there any risks?

Taking part won't cause you or your baby any discomfort or harm. Most samples are leftovers from routine medical tests that would have been thrown away. If we need extra samples, we'll collect them in a gentle and painless way. There is a minimal risk of loss of confidentiality, but we will do everything possible to keep your information private.

### How will my information be kept private?

You and your baby or babies will get **anonymous ID** numbers for the study. These numbers will be used to label your samples, and your baby's number will be connected to yours. Your personal identifying information will be kept in a safe place away from the samples. No one will publish things like your name, medical record number, or birthdates. Only the people directly involved in research will see your identifying information and they will keep it private.



### How long will the samples be kept?

The samples may be kept indefinitely so that future researchers can learn from them.

### Can I change my mind about my samples?

**Yes!** You can change your mind at any time, even if you already gave some samples. Once you sign the consent form, there will be ten days before any researcher can access your samples. If you want to leave the study, let the staff know, and they'll remove your samples and information. You can still change your mind after the ten days, but if we've already given your samples to other researchers, we might not be able to remove them. To leave the study, write a letter or send an email to the contact provided at the end of this information sheet.

### How will the samples be used and who will use them?

The samples might be used for different research goals to learn about diseases and to find new treatments. Only approved researchers and projects can use your samples. Most samples will go to researchers at NewYork-

Presbyterian/Weill Cornell Medicine. We might share samples with researchers from other places like other universities, private companies, or government agencies working on new tests or treatments. These researchers will need to get permission to use the samples from PIRI research team and a group called the Institutional Review Board. This group makes sure research is done fairly and safely. If they say it's ok, the researchers can use the samples, but they won't know your personal information.

Some samples have genes made of DNA, which tell our cells what to do. We don't plan to study the genes now, but we might in the future. Genetic research is an important part of studying the causes of diseases and response to treatments. Researchers may use methods, such as whole genome sequencing, to look at parts or all of your DNA code.

If we learn something from the samples, we might publish the findings in research papers, but we won't use your name or any other personal information.

### **Are there any risks associated with genetic testing?**

The risks of genetic (DNA) test and research are not known. In the future, results of genetic tests may be related to disease, illnesses, or addiction and allow researchers to predict the risk of getting an illness. There are unknown risks with genetic testing, including risks to relatives or other groups of people. It is possible that our genetic information could be used to identify you. Researchers will take steps to protect you from the risks of other people finding out about results of your genetic tests for future research, including insurance companies or future employers.

There are risks of loss of privacy and confidentiality, trouble getting insured or being employed, and being treated badly because of your results. There are some protections provided by law. For more information, please visit: <http://www.genome.gov/Pages/PolicyEthics/GeneticDiscrimination/GINAInfoDoc.pdf>.

Note, this Federal law does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Also, this Federal law does not protect against discrimination if you already have a genetic disease or disorder.

### **Will you share any results with me?**

You won't get any results back because researchers won't know whose samples they are studying. PIRI will share general information about any findings on our website <http://piri.weill.cornell.edu>.

### **How will I find out about new information that may change my decision to participate?**

During the study, we will let you know if there is any new information or changes that could affect your, your health, or your choice to study in the study. We will do this by giving updates on our website.

### **Who benefits from this biorepository?**

We will use your samples to help science progress and to learn more about diseases. Our goal is to find biological markers that can predict health risks for both moms and babies. This will help doctors take better care of everyone.

### **Does participating cost anything?**

No! It's free to take part. The staff will supply everything you need for sample collection, and you won't have to pay anything.

### **How can I participate?**

To join, sign the electronic consent form that has been provided to you. You can also click the link on our website or scan the QR code on the back of this sheet.

## Whom do I contact with questions?

If you have any questions, concerns, or complaints about the research, please contact:

**Neonatal PI: Dr. Camilia Martin**  
[NICUResearch@med.cornell.edu](mailto:NICUResearch@med.cornell.edu)  
646-697-NICU

**OBGYN PI: Dr. Lauren Osborne**  
[pippilab@med.cornell.edu](mailto:pippilab@med.cornell.edu)  
(212) 746-4031

Weill Cornell Medicine  
1300 York Avenue  
New York, NY 10065  
**PIRI**  
[piri@med.cornell.edu](mailto:piri@med.cornell.edu)

If you have any questions regarding your rights as a research participant, about what you should do in case of any injury or illness because of your study participation, or if you want to get information or give feedback, please contact the WCM Institutional Review Board (IRB) at:

WCM IRB, (646) 962-8200, [irb@med.cornell.edu](mailto:irb@med.cornell.edu)  
Website: <https://research.weill.cornell.edu/irb>

You may also submit questions or complaints without giving your name by calling (866) 293-3077 or visiting <https://www.hotline.cornell.edu/>.

Your permission for the use and disclosure of your health information for this project shall not expire unless you cancel it. Your health information will be used or disclosed as long as it is needed for this project; however, you can stop your permission at any time by notifying the WCM Privacy Office in writing. To do this, please send a letter to:

Privacy Office  
1300 York Avenue, Box 303  
New York, NY 10065  
Email: [privacy@med.cornell.edu](mailto:privacy@med.cornell.edu)

## Participate

### Electronic Consent Form

