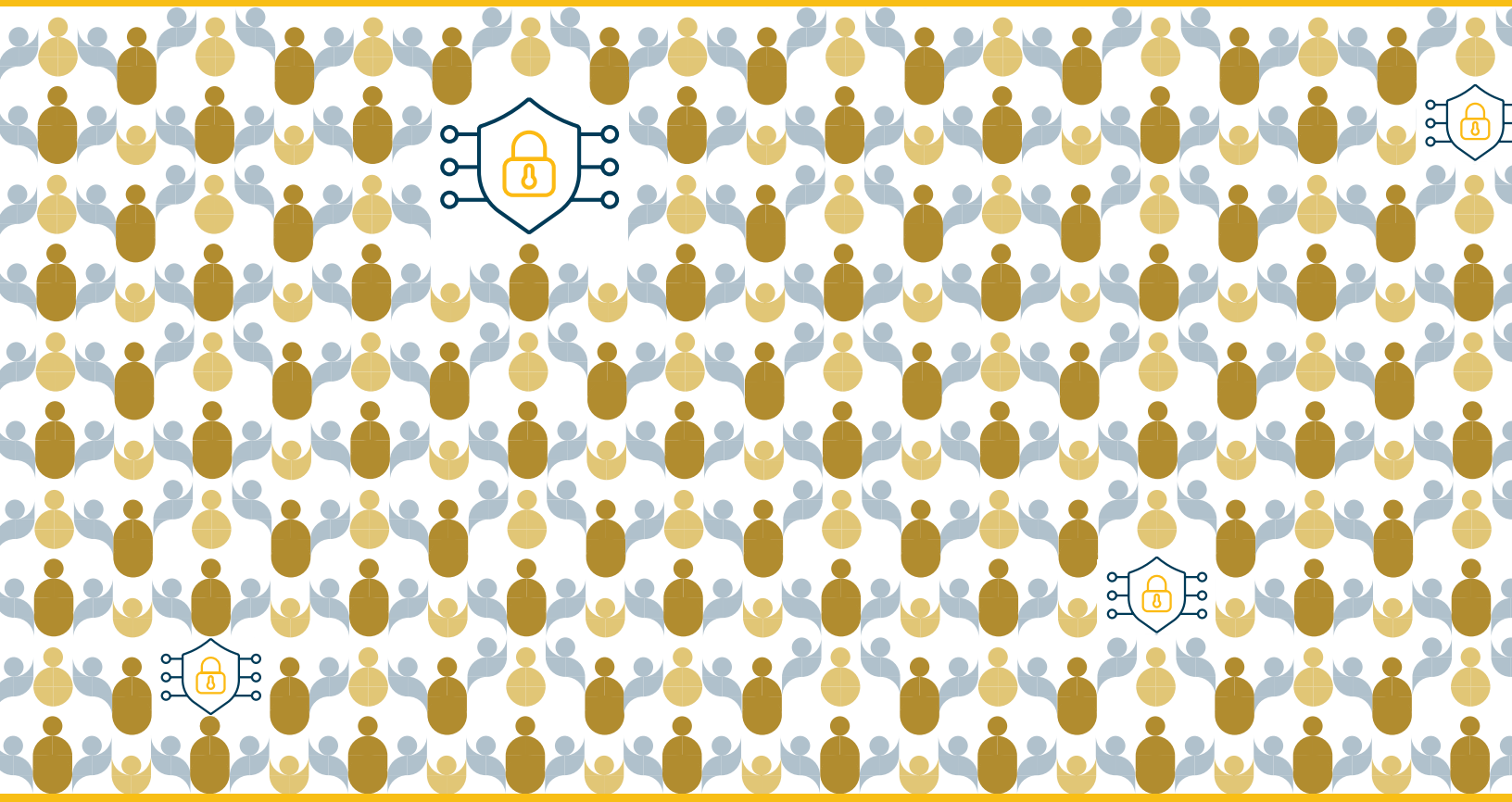
Pregnancy Privacy Protections
for Participants (P4)

MRCT CENTER
THE MULTI-REGIONAL
CLINICAL TRIALS CENTER OF
BRIGHAM AND WOMEN'S HOSPITAL
AND HARVARD

Privacy Protections:

Considerations for Pregnant Participants



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Introduction

The complete **Pregnancy Privacy Protections for Participants Toolkit (P4 Toolkit)** is meant to inform the research study team, IRBs, and participants about possible data privacy risks if the participant were to become pregnant during a research study. The P4 Toolkit contains two types of tools: **1) those directed to the clinical research teams and IRBs and 2) those for research staff to adapt and share with participants.**

The MRCT Center created the "Privacy Protections: Considerations for Pregnant Participants" handout as a template for research teams to adapt and use when providing information to potential participants. It is intended to be provided at the earliest point at which potential pregnancy or data privacy will be discussed (e.g., screening, informed consent), and **before** any pregnancy testing occurs. Please note, this tool is intended to be adapted to the specific study, local legislative context, and site policies. When adapting, keep to our Creative Commons license. Use your institution's own design template and branding, do not display the MRCT Center logo, and include the following attribution:

> **Adapted from: Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center). Privacy Protections: Considerations for Pregnant Participants. Boston, MA: MRCT Center; 2026. Available from: https://mrctcenter.org/resource/pregnancy-privacy-protections-for-participants-p4-toolkit/.**

In addition, we have formatted some words or phrases in **gold font** to alert you that these words or phrases are defined in the MRCT Center Clinical Research Glossary. When adapting, if you are editing the text into more simplified (i.e., plain) language, you welcome to create hyperlinks from these words or phrases to the appropriate term in the Clinical Research Glossary. Otherwise, you may choose to remove the gold font.

DELETE ABOVE THIS LINE

Privacy Protections

This "Privacy Protections: Considerations for Pregnant Participants" handout is designed to inform you, the **clinical research study participant**, about possible data privacy risks if you become pregnant during a research study. While research studies do have strict methods to protect participants' **data**, and it is very rare for a participant to become pregnant during a study, there is still a small chance that pregnancy will occur. It is important to know that the legal landscape for reproductive health is in flux, and your legal protection can depend on where you live and where you receive care (see this map of protections and restrictions).[1] For participants who test positive for pregnancy, these state laws may impact how well the research team can keep your data private (or **confidential**).

Not all types of research studies require that you take a pregnancy test to participate, but many do, and sometimes the test is done more than once. You may be asked to take a pregnancy test (at home or through a lab) during the **screening** stage, which is when the research team checks whether you are able to participate (that is, if you are **eligible** to take part in the study), or during or after you have been through the **informed consent** process, which is when the research team discusses the most important information about the study with you to help you decide if you want to sign up. If you sign up to participate, you may also be asked to take a pregnancy test at regular intervals during the study.

This tool first explains why it is important to report your pregnancy to the research team (if self-testing). We understand that you may have concerns about telling the research team about a positive test result that shows you are pregnant. However, we strongly encourage you to talk with the research team right away so that they can protect you and your developing baby to the best of their ability. This tool then explains the types of data that research teams will record related to your pregnancy, the actions that research teams take to keep your data private, potential limits to these privacy protections, and frequently asked questions.

The goal is to give you more information so that you can ask your study doctor and the clinical research team any questions you may have.

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[1] Guttmacher Institute. Interactive Map: US Abortion Policies and Access After Roe. Available from: https://states.guttmacher.org/policies/Accessed 23 October 2025

REMEMBER!

You have a right to ask the study staff any questions about the study before, during, or after you join.

Make sure you ask.
Make sure you understand the answers.
It is your right.

Reporting Your Pregnancy to the Research Team

In some trials, you will be tested for pregnancy only in a laboratory, and therefore the results of your pregnancy test will go immediately to the research team. In other trials, you could be asked to take a pregnancy test at home at one or more points during the trial, and you will be responsible for reporting a positive pregnancy test to the research team. In either case, it is important for the research team to know about your pregnancy to keep you, your developing baby, and future patients safe.

Could the study treatment hurt me or my developing baby?

- If the treatment has been studied in pregnancy before, the research team will tell you what is known.
- If the treatment has never been studied during pregnancy, no one can be certain whether it is safe for you (as your body changes during pregnancy) or for a developing baby.
- In either case, if you do not tell the research team about your pregnancy, they cannot help you, and you might keep getting treatments that could cause harm.
- If you become pregnant during a study that involves a research drug, you may need to stop taking the drug (and maybe even stop being in the trial). However, the study doctors may still ask to collect information about your health during the pregnancy and about your baby after birth.

How could my care (or the care of others) be affected if I delay reporting?

- Waiting to tell the research team about your pregnancy might make things riskier because vital chances could be missed to keep you and your developing baby safe.
- You might not get the right medical care for your condition. Pregnancy changes how your body processes and reacts to treatments. What's safe when you're not pregnant might be harmful when you are. The research team needs to know so they can monitor you and adjust your care if needed.
- You could miss out on the support and information that you need. The research team needs to know about your pregnancy so that they can help you find the right doctors and support services. They can also help you to learn about your options.
- The team would wrongly think that any health changes you experience are only due to the study treatment. When participants report pregnancies, it helps the research team learn about how the treatment affects both you and your developing baby, and it helps future patients and their babies.

Your Pregnancy Data When Participating in a Research Study

When you participate in a research study, the research staff keep detailed records of your health information, treatments, research data, and any changes in your condition. This includes pregnancy. All information usually becomes part of your permanent research file, even if you leave the study, and some information may be entered into your medical record as well.

What data might be recorded that is related to pregnancy?

Many types of data may be recorded, and those related to pregnancy include:

- Pregnancy test results.
- When the **positive test results** for pregnancy were known or reported to the study staff.
- Any changes to your study treatment because of the pregnancy.
- Information about the outcome of the pregnancy, such as a birth, miscarriage, or termination.
- Medical care related to your pregnancy.

What actions does the research team take to keep my data private?

- The research team will protect your privacy to the fullest extent that they can under the law.
- The team will store your data in computers and **databases** with strong passwords. Only the research staff will have the passwords. Only individuals with the necessary authorization to access the data will be permitted to do so, and they will be listed in the informed consent form.
- Typically, the team will keep your name, address, and other identifying information in a separate file from your study results file. For your study results file, you are only known by a **participant code** number.
- The team may have or request a Certificate of Confidentiality (when available). A Certificate of Confidentiality (CoC) is a document that says that research staff cannot share your research data with people who don't need it for the study, even if faced with legal demands such as court orders. But note that many studies do not have Certificates of Confidentiality. You should ask the study team if this study is protected by a CoC.
- Even if the study is protected by a CoC, there is some risk. A CoC only protects research data, but it does not protect data that is entered into your medical record in the same way. You should ask whether any information about your pregnancy will be entered into the medical record.

- The team may be able to give you information about where to find legal services (such as your local and state laws) when needed. The team cannot, however, give you legal advice.
- The team can also give you information about where to find additional medical services outside of the research study.

What are the potential limits to these privacy protections?

- Some pregnancy information may be required to be reported to pharmaceutical companies (which manufacture the medications) and government agencies, such as the U.S. Food and Drug Administration (FDA).
- The team cannot always protect your privacy from all legal demands, such as those from the US Congress, particularly if a Certificate of Confidentiality does not exist.
- You could face questions if your study records show that you were pregnant, but you are no longer pregnant, and there is no record of a birth.
- Rarely, people in the healthcare system may share data by accident. If you suspect that has happened, please inform your study team, who will look into the matter.
- If data is entered into your medical record, different protections are in place, but those are not as strong as Certificate of Confidentiality.
- You can always give permission to share your data.

Your Options if you Become Pregnant while Participating in a Research Study

If you become pregnant during a research study, you should talk with the research team right away. This is because the study treatment might affect the developing baby. You should have access to medical care and counselors to talk with you about your options as early as possible. You can also get more information about data privacy and what is, or will be, happening to your data.

What should I think about if I become pregnant while participating in a research study?

Everyone's situation is different, and the nature of the research studies—and risks and benefits—are different. Here are some questions you might want to ask:

- If I become pregnant, will I be able to stay in the study if I want to?

    - If the study involves a research **drug therapy**, you will likely need to stop taking the study drug. However, the study doctors may still request information about your health during pregnancy and its outcome.
    - If you are allowed to choose whether or not to stay in the study, the research team will discuss with you the risks, if any, of continuing to participate.
- How will staying in the study affect the pregnancy? Are there any health risks to the fetus? Are there any health risks to me from staying in the study while I'm pregnant (such as a higher risk of high blood pressure, pre-eclampsia, or diabetes during pregnancy)?
- What will be written down in my research record about my pregnancy and its outcome (birth, miscarriage, or termination)?
- Will the results of my pregnancy test or my pregnancy be reported in my medical record, and if so, why?
- What do the laws in my state say about ending a pregnancy (termination)?
- What are the laws where the research study is located (if different from the state where I live)?
- Who else should I talk to about my options, such as people on the medical or legal staff?
- Weighing both the possible **clinical benefits**/**research benefits** and possible **risks**, for myself and the fetus, how important is it to me to stay in the study?
- How important is it to my family (e.g., my partner, children) that I stay in the study?

What are the different paths I could take if I become pregnant?

- Review information about the risks and benefits of the study for you and the developing baby and discuss any new questions with the research staff.
- Seek counseling about the pregnancy options.
- Stay in the study with the **study intervention** or treatment modified, if necessary, and as permitted by the research study staff.
- Leave the study and receive medical care for the pregnancy.

Please note, the research team cannot and will not tell you what to do about your pregnancy.

Frequently Asked Questions

Q: If I tell you about my pregnancy, do I have to stay in the study?

A: No. You can leave the study at any time, whether or not you're pregnant.

Q: If I tell you about my pregnancy, can I stay in the study if I want to?

A: It depends on the study and its risks and potential benefits. Your study staff will discuss the options with you.

Q: Will the research team tell anyone outside the research about my pregnancy?

A: The study team will follow strict privacy rules, but sometimes some pregnancy data must be shared with study sponsors, pharmaceutical companies, and/or government groups, such as the Food and Drug Administration (FDA), as required.

Q: Can I get in legal trouble for participating in research while pregnant?

A: Taking part in research while pregnant is not illegal. It is also important to know the laws in your state.

Q: Can you say for sure that my information will not be shared with the police or others?

A: The study staff will use all methods to protect your privacy, but there is a small risk that data will be shared either by accident or in response to legal demands, particularly if a Certificate of Confidentiality is not in place.

Q: What if I don't want to tell you about my pregnancy?

A: Telling the research team about your pregnancy is strongly recommended, but no one can order you to tell, particularly if you have concerns. Please talk to the research team about your own situation and concerns.