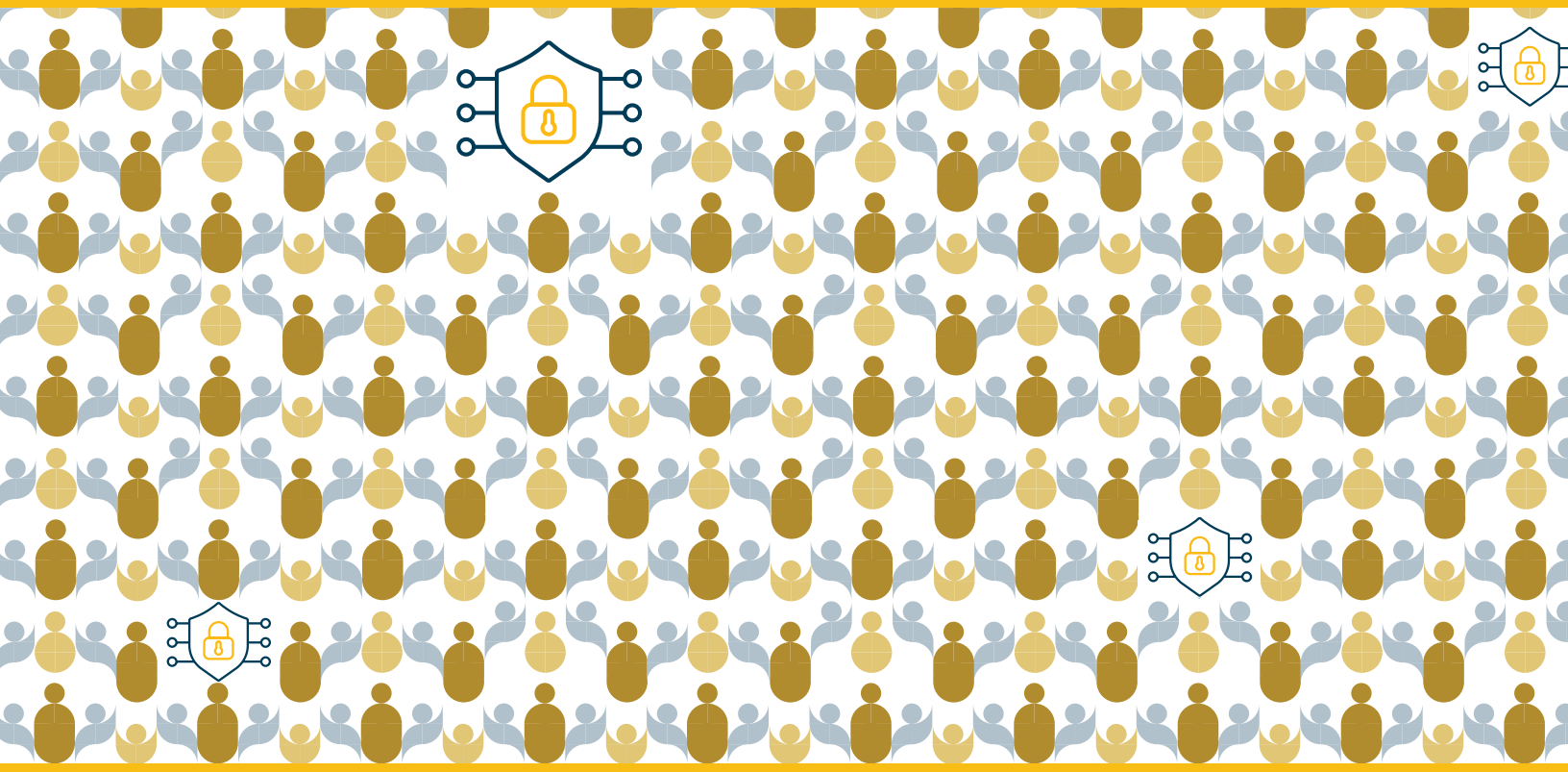
Pregnancy Privacy Protections
for Participants (P4)

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

Recommended Language for Informed Consent Forms:

Guidance for Researchers on Pregnancy Privacy Protections



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CLINICAL RESEARCH TEAMS | IRBs

Introduction

The complete **Pregnancy Privacy Protections for Participants Toolkit (P4 Toolkit)** is meant to inform the clinical research 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 team and IRBs**, and **2) those for research staff to adapt and share with participants**.

The MRCT Center created the "Recommended Language for Informed Consent Forms: Guidance for Researchers on Pregnancy Privacy Protections" tool as a template for research teams when drafting informed consent forms (ICFs) for potential participants. **Please adapt the example ICF form language as necessary for the specific study, local legislative context, and site policies.**

The ICF language was written in conjunction with the "Privacy Protections: Considerations for Pregnant Participants" handout, and we recommend that study teams and IRBs review, modify, and approve these materials early in study preparation. The Privacy Protections handout is intended to be given to potential participants at the earliest point at which potential pregnancy or data privacy will be discussed and **before** any pregnancy testing occurs (i.e., at eligibility screening, if pregnancy testing occurs before the informed consent process).

Please note that the P4 Toolkit is intended principally for a U.S. audience, in that there are significant differences in state law regarding reproductive health. Clinical trial leadership in other countries may benefit from reviewing these materials, but each will need to consider their own context. 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). Recommended Language for Informed Consent Forms: Guidance for Researchers on Pregnancy Privacy Protections. Boston, MA: MRCT Center; 2026. Available from: https://mrctcenter.org/resource/pregnancy-privacy-protections-for-participants-p4-toolkit/.**

DELETE ABOVE THIS LINE

Recommended Language for Informed Consent Forms

While clinical research studies 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 varies by state across the U.S.[1] Following the 2022 *Dobbs v. Jackson Women's Health Organization* decision, these changes may impact the privacy of participants. These new privacy risks for research participants warrant disclosure in informed consent forms.

Before deciding whether to participate, research participants have the right to understand how standard research practices could create legal exposure.[2] The Common Rule (45 C.F.R. 46) requires disclosure of serious risks about which reasonable participants would want to know, and potential criminal penalties in some jurisdictions meet this standard. Geographic variation in reproductive health laws, however, means that participants face fundamentally different risk profiles depending on their home state and/or location of the research (if different), making disclosure complex. While discussing these risks may be uncomfortable, clear and balanced language can convey necessary information without creating confusion or anxiety.

Below, we provide examples of language that could be added to informed consent forms (ICFs). For example, the ICF language may be modified to be more specific regarding the laws of the state of the site or participant. Alternatively, the informed consent document describing a research study testing a chemotherapeutic drug that is a known teratogen may be more descriptive (and prescriptive) than one that is unlikely to impact the course of a pregnancy.

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[1] The Guttmacher Institute. Available at: https://www.guttmacher.org. Accessed 21 April 2026

[2] We do not discount safety and other concerns that may be associated with pregnancy, but we focus on privacy protections here.

Example language:

OPTION 1:

We follow pregnancies as part of routine safety monitoring of this study. In states within the United States with restrictions related to pregnancy termination or loss, legal concerns may arise for you if you are or become pregnant, but do not have a record of the related birth. Please consider this risk when deciding whether to participate and speak to the study team if you have questions.

OPTION 2:

This study requires pregnancy testing and documentation of pregnancy outcomes. Your research data will be kept private to the best of our abilities. If you become pregnant during this study, this information will be recorded in your research record. You should be aware, however, that pregnancy-related documentation (including pregnancy followed by loss or termination) may carry different legal implications depending on your state's laws. We can provide more information and recommend that you speak with the study team if you have any questions.

OPTION 3:

In most states, the termination of a pregnancy is restricted to specific circumstances (e.g., only to save the life of the mother, only for ectopic pregnancies) or timeframes (e.g., the first six weeks of pregnancy in one state versus the first 24 weeks in another). In addition, there may be restrictions around pregnancy loss or miscarriage (e.g., immediate medical attention must be sought, the fetal remains must be buried or cremated). These restrictions vary significantly from state to state. Please ask your study team about the laws and regulations. It is important that you understand these terms.

This study requires testing for all participants who can become pregnant. The research team will enter the test results from the lab or from your report of a home test into your research record. Information about the pregnancy outcome (birth, miscarriage, or termination) will also be entered in your research record. **<<This information will be subject to the same privacy protections as the rest of your personal data.>> << Please note that results entered into the electronic medical record are not protected by the Certificate of Confidentiality that applies to the research record, as described here.>>**

While we protect personal information to the best of our abilities, we cannot guarantee that your data, including your pregnancy or pregnancy outcome data, will remain private.