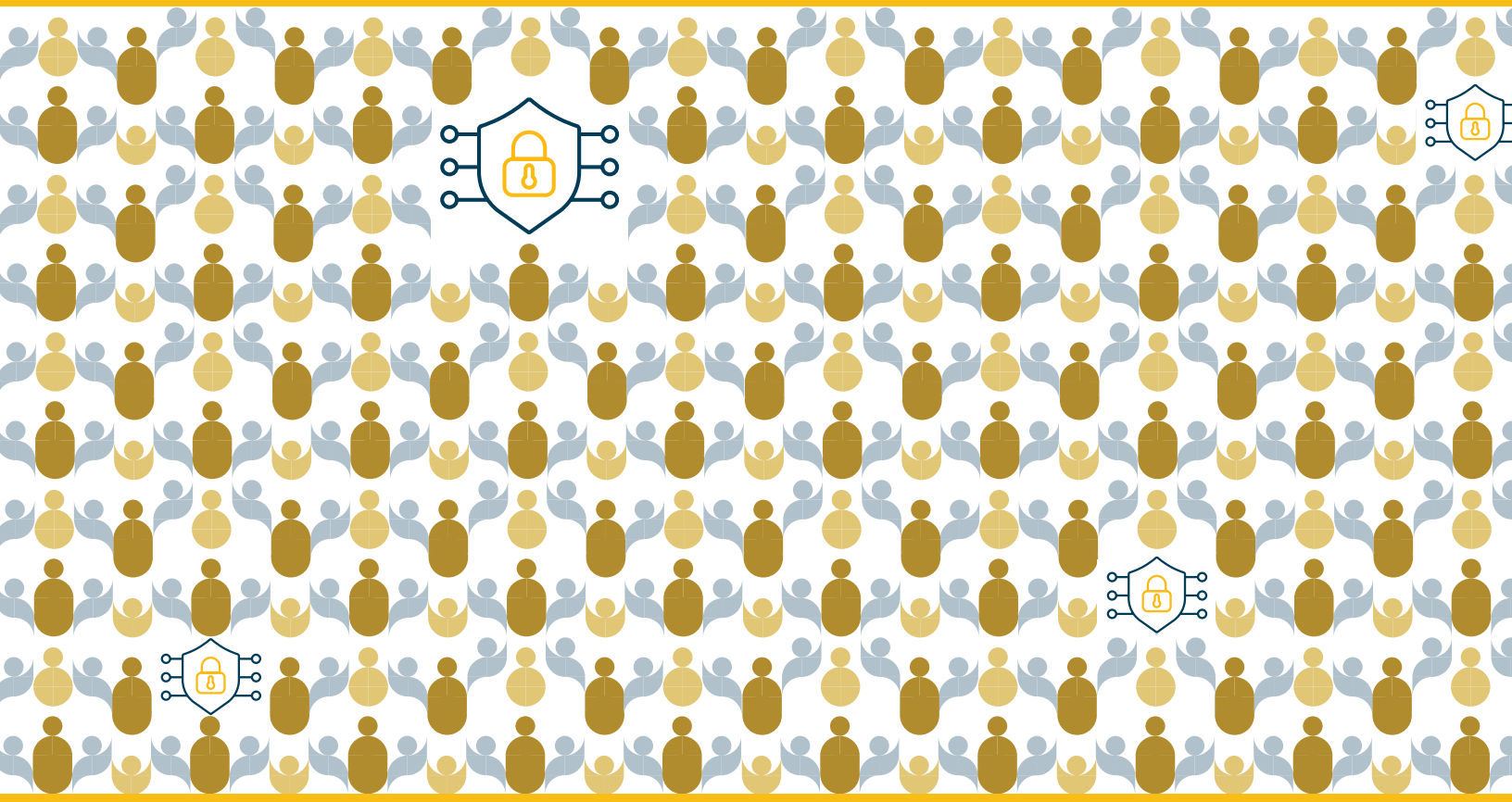
Pregnancy Privacy Protections
for Participants (P4)

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

Local Context:

Reproductive Health Information for the Research Team and the IRB



APRIL 2026

v 1.0

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 team and IRBs**, and **2) those for research staff to adapt and share with participants**.

The MRCT Center created the "Local Context: Reproductive Health Information for the Research Team and the IRB" tool to support research teams in refining the local context information they provide to the reviewing IRB, specifically about information regarding pregnancy privacy risks. This tool is intended to be used in combination with the other tools in this P4 Toolkit. For example, while the "Privacy Protections: Considerations for Pregnant Participants" handout is written for participants as the primary audience, the key privacy concerns outlined in that document can inform thinking about the questions that may be important in a local context form.

Please adapt this "local context" form as necessary for 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). Local Context: Reproductive Health Information for the Research Team and the IRB. Boston, MA: MRCT Center; 2026. Available from: https://mrctcenter.org/resource/pregnancy-privacy-protections-for-participants-p4-toolkit/.**

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Local Context

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 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. Often, clinical research is conducted at multiple sites, and one IRB may serve as the reviewing IRB of record on behalf of more than one or all of the participating sites. Given the requirement for compliance with local and national regulations, a single ethical review becomes complicated when there are different state laws and different institutional policies in different geographical settings.

In the U.S., a single IRB (sIRB) review is a requirement for research conducted or supported by the federal government: one IRB reviews on behalf of all participating sites with very limited exceptions. While that one review applies to all the relying sites (and their parent institutions), each participating site may have specific local regulations, site- or institution-specific policies, and/or required consent language that must be taken into account. These elements are collectively referred to as "local context" and must be addressed as part of the overall review process.

Generally, in advance of the review, each relying site or institution provides local context information (i.e., site-specific considerations that could impact the conduct of the study) to the reviewing IRB to ensure that those elements are appropriately reflected in the study materials, such as the informed consent form. Additionally, local context review helps the relying site comply with its responsibilities, ensuring that local requirements are met and that the research will be conducted consistent with all applicable policies and regulations.

There are no standardized requirements for local context forms. In the context of privacy concerns regarding reproductive risks post-Dobbs, the tool below provides a list of prompts and questions that sites, institutions, and investigators, can include in the local context information they provide to the reviewing IRB. These questions help to assess the reproductive privacy risk profile with respect to the participant, the investigator, the provider, and the relying site/institution in the location where the research will be conducted.

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

1. PREGNANT PARTICIPANTS, FETUSES, AND NEONATES

A principal responsibility of ethics committees is to ensure the protection of the rights and welfare of research participants; this responsibility is largely borne by the investigators and their research staff. Potential participants must be fully informed about the reasonably foreseeable risks associated with the research. Whenever a participant is or becomes pregnant, potential risks to the pregnant person, fetus, and neonate must be considered. In the U.S., for research supported or conducted by federal agencies, or if the institution has elected to apply federal regulations to all research, there are specific federal regulations that apply to protocols involving pregnant participants, human fetuses, and neonates.

1A. Are there specific state laws, regulations, local ordinances, or site/institutional policies for the enrollment of pregnant participants or participants who may become pregnant in research applicable to this site/institution(s)?

○ Yes ○ No ○ N/A

1B. Are there specific state laws, regulations, local ordinances, or site/institutional policies that apply to pregnant participants, human fetuses, or neonates in research?

○ Yes ○ No ○ N/A

If **Yes** for **1A** or **2A**, please describe and attach or reference relevant documents:

2. PARTICIPANTS OF REPRODUCTIVE POTENTIAL

This section helps identify site-specific reproductive healthcare restrictions, reporting requirements, and data privacy considerations that could affect participant welfare or introduce legal complexities to the research protocol.

2A. Are there state-specific laws, regulations, local ordinances, or site/institutional policies on reproductive health or healthcare that could affect study participants?

○ Yes ○ No ○ N/A

If **Yes** for **2A**, please describe and attach or reference relevant documents:

2. PARTICIPANTS OF REPRODUCTIVE POTENTIAL

2B. **Does the site have mandatory reporting requirements for pregnancy testing results?**

○ Yes ○ No ○ N/A

2C. **Does the site have mandatory reporting requirements for pregnancy outcomes (birth, miscarriage, or termination)?**

○ Yes ○ No ○ N/A

If **Yes** for **2B** or **2C**, please describe and attach or reference relevant documents:

2D. **Are there data privacy laws that protect personal reproductive health information in this jurisdiction?**

○ Yes ○ No ○ N/A

2E. **Does the institution or site have specific policies regarding the collection, storage, or sharing of reproductive health data?**

○ Yes ○ No ○ N/A

If **Yes** for **2D**, describe whether and how these laws will impact the research protocol, the participant, research staff, and care provider:

If **Yes** for **2E**, please describe these policies:

2F. **Please provide any consent form language (for any participant, and if applicable, specifically for minors) for pregnancy testing, pregnancy, or disclosure that is required by the institution, site, or state law:**