**INSTRUCTIONS FOR HIPAA AUTHORIZATION TEMPLATE FOR PREGNANT PARTICIPANTS OR PREGNANT PARTNERS OF PARTICIPANTS**

**[Delete information on this first page before presenting to participants.]**

**The purpose of this template** is to create the HIPAA Authorization form that participants, parents, and/or legally-authorized representatives of participants sign to give you permission to obtain and use protected health information (PHI) of participants for research purposes. You must not change the content of the form; you may only update the protocol number, study title, and PI name on page 1 to reflect the individual study.

**This stand-alone HIPAA Authorization has been approved for use by both UW Medicine and Fred Hutch.**

* For UW Studies: HIPAA language included in the research informed consent form may not be used to obtain authorization for UW Medicine**.**
* For Fred Hutch Studies: Fred Hutch prefers investigators use this stand-alone HIPAA authorization.  Review and approval to include HIPAA language within the research informed consent form is facilitated by the Institutional Review Office (iro@fredhutch.org) upon submission to the IRB.

A single HIPAA Authorization form signed at the start of the study can be used for sub-studies and additional optional parts of the study in addition to the main study so long as all of the applicable information is included in the form and the sub-studies are under the same IRB application as the main study.

**Authorization to Use and/or Disclose Protected Health Information**

**for Research Purposes**

Fred Hutchinson Cancer Center

UW Medicine

**Protocol or Reviewing IRB #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Protocol or Study Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

The federal Health Insurance Portability & Accountability Act (HIPAA) Privacy Rule and Washington state privacy laws protect the use and disclosure of individually identifiable health information, known as protected health information (PHI). You have the right to decide who may receive your PHI for research purposes. This authorization states how your/your baby’s PHI may be used and with whom it may be shared as part of the research study. Along with this form you will be given an informed consent document that describes the research.

**What information will be used for research purposes?**

To participate in the research study, you must give permission for your/your baby’s health care providers to release your/your baby’s health information to the research team. Such health information includes information in your/your baby’s medical records that could personally identify you. This may include:

* Demographic information such as name, date of birth, address, and phone number
* Medical information such as medical history, progress notes, operative reports, laboratory and imaging results
* Past and present medical records related to the study, including records of external providers that are available via your electronic health record at Fred Hutchinson Cancer Center & authorized affiliates

In the event of an adverse event, such as injury related to the research, other records may be accessed for the purposes of your/your baby’s treatment and/or for reporting purposes. This may include records from other health care providers from which you/your baby have received medical care, but who are not specifically listed in this Authorization. The HIPAA Privacy Rule requires the information requested be limited to the minimum necessary to accomplish the purpose of this research.

**Who will be allowed to release this information?**

If you provide your permission and sign this form, you are allowing every health care provider who provides services to you/your baby in connection with this study or from which you have received medical care, to provide the information described in this authorization to the research team. These providers include, but are

not limited to Fred Hutchinson Cancer Center and UW Medicine and affiliated clinics.

**Who can access your/your baby’s PHI for the study?**

Efforts will be made to ensure that your/your baby’s PHI will not be shared with other people outside of the research study. If you give permission, the research team will receive and use your/your baby’s PHI for the research study as described in the informed consent. The research team may also share your information with other researchers, the study sponsor (including any persons working on behalf of the sponsor) or other staff involved during the conduct of the study. Your/your baby’s health information may also be shared at any time with federal and state agencies (e.g., U.S. Food & Drug Administration (FDA) and the Washington State Department of Health) and others as required by law and/or to individuals or organizations that oversee the conduct of research studies, and these individuals or organizations may not be held to the same legal privacy standards as are doctors and hospitals. Thus, the research team cannot guarantee absolute confidentiality and privacy.

**Expiration date of the authorization**:

This permission to release your PHI expires when the research ends and all required study monitoring is complete, except as provided in this document.

**You have the right:**

1. To refuse to sign this form. Not signing the form will not affect your/your baby’s regular health care including treatment, payment, or enrollment in a health plan or eligibility for health care benefits. However, not signing the form may prevent you/your baby from participating in the research study described in the informed consent.
2. To review and obtain a copy of your personal health information collected and maintained in your respective medical record during the study. However, it may be important to the success and integrity of the study that persons who participate in the study not be given access until the study is complete. The Principal Investigator has discretion to refuse to grant access to this information if it will affect the integrity of the study data during the course of the study. Therefore, your request for information may be delayed until the study is complete.
3. To cancel this authorization at any time. If you choose to cancel this authorization, you must notify the Principal Investigator listed on the informed consent. However, even if you cancel this authorization, the research team, research sponsor(s) and/or the research organizations may still use information about you/your baby that was collected as part of the research study between the date you signed this authorization and the date you cancel the authorization. This is to protect the quality of the research results. You understand that canceling this authorization may end your participation in this study.
4. To receive a copy of this form.

**Specific authorizations**:

You understand that this release also pertains to records concerning hospitalization or treatment that may include the categories listed below. According to federal and state laws, you have the right to specifically request these records notbe released to the research team. However, you understand that if you limit access to any of the records listed below, you/your baby may not be able to participate in this research study.

Check below to **INCLUDE** and release any of the following to the research team:

[ ]  Behavioral or Mental health records

[ ]  Alcohol/Substance use disorder records

[ ]  Sexually transmitted disease information

[ ]  HIV (AIDS) records

I have had the opportunity to review and ask questions regarding this authorization form. By signing this authorization, I am confirming that it reflects my wishes.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Printed name of Individual/Legal Representative**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature of Individual/Legal Representative Date Signed**

If signed by a legal representative, state the relationship and identify below the authority to act on the individual’s behalf:

Individual is: [ ]  a Minor [ ]  Incompetent [ ]  Disabled [ ]  Deceased

Legal Authority:

[ ]  Custodial Parent

[ ]  Legal Guardian

[ ]  Executor of Estate of the deceased

[ ]  Power of Attorney Healthcare

[ ]  Authorized Legal Representative

[ ]  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_