User Guide for Completing the UC HIPAA Research Authorization Form

Top of Form Information

IRB# _____

University of California

Permission to Use Personal Health Information for Research

Study Title: _____

Principal Investigator's Name: _____

UC Location: _____

The study team completes the following fields before presenting the form to the study participant:

- **IRB #**: Enter the local IRB protocol number.
- **Study Title**: Use the full IRB-approved study title.
- **Principal Investigator's Name**: List the PI's name.
- **UC Location:** List the name of the UC Location releasing the PHI (e.g., UC Davis Health, UCI Health, UCLA Health, UC San Diego Health, UCSF Health). If there are multiple UC Locations releasing PHI, then each UC Location is responsible for completing this form for its location.

Sensitive Health Information Section

D. Will sensitive health information be used or shared?

If this study includes access to sensitive health information, the study team checks only those boxes that apply. The study team will only use this information if you give your permission by initialing on the line(s). (The study team checks only those boxes that apply.)

☐ HIV/AIDS testing information _____ (your initials)

☐ Genetic testing information _____ (your initials)

☐ Drug and alcohol abuse diagnosis or treatment _____ (your initials)

☐ Mental health diagnosis or treatment _____ (your initials)

Step 1: Study Team Checks Only Applicable Boxes

If the study involves access to any of the listed sensitive health information categories, the study team checks only the boxes that apply to the study. Leave non-applicable categories unchecked.

Step 2: Participant Initials Applicable Spaces

For each checked category, the prospective study participant must provide initials in the spaces that apply to the sensitive health information that will be released for research purposes. This step is required because California or federal law may prohibit disclosure of this information for research purposes without specific authorization.

Optional Research Section

F. Will my PHI be used for optional research?

☐ If this box is checked, the research includes optional research activities, as described in the Informed Consent Form. We may need to collect additional PHI for these activities. Sharing your PHI for optional research is your decision. Your decision to share your PHI will not affect your participation in the main research study. To give your permission to share your PHI for optional research activities, please initial here: _____.

Step 1: Study Team Checks if Applicable

If the study includes an optional research component that requires collecting ***additional PHI*** from the participant's medical record specifically for the optional research, the study team checks the optional research box. Ensure the Informed Consent Form clearly describes the optional research activities.

Do not check this box if the optional research only involves future use or re-use of data and/or specimens already collected for the main study and documented in the research record. For example, if the ICF states:

> *"Your data and/or specimens, including de-identified data and/or specimens, may be kept for use in future research."*

the box should remain **unchecked**, provided no additional PHI will be obtained from the participant's medical record for the optional research.

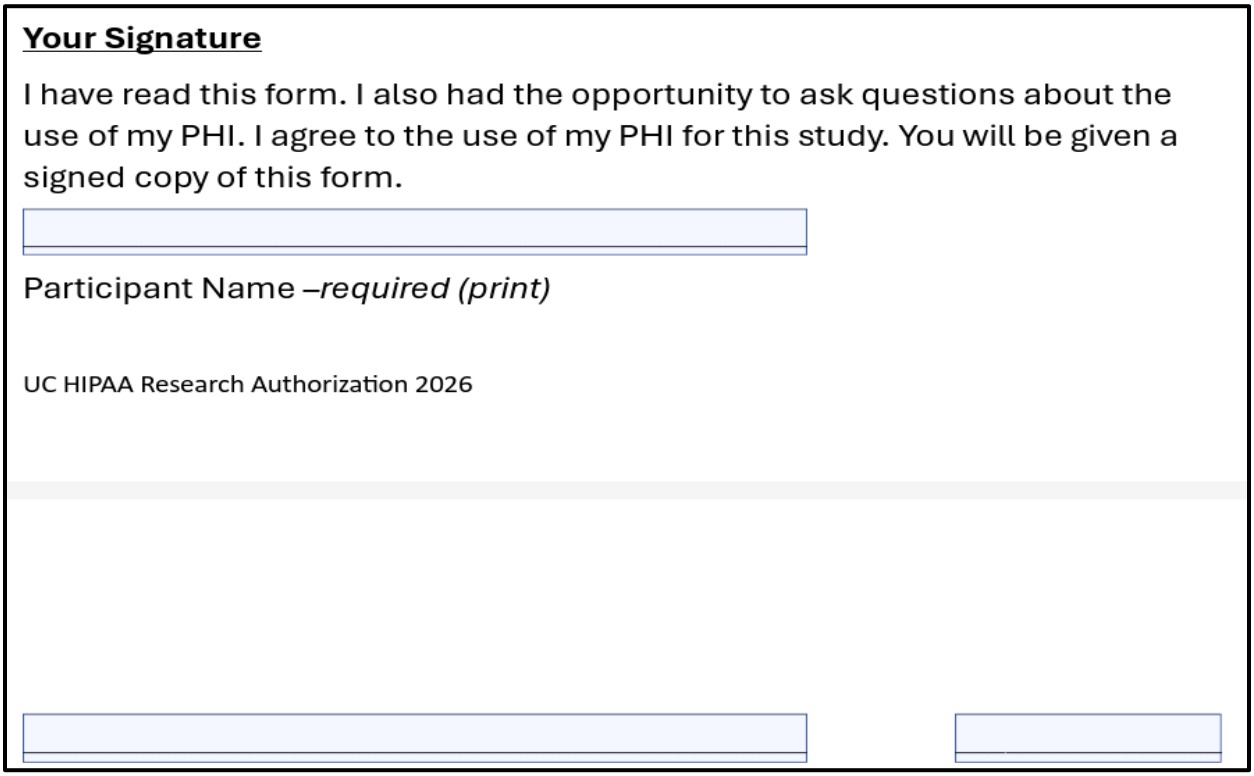
If there is no optional research, the study team leaves the box unchecked and does not request participant initials.

Note: Re-use of information already collected into the research record for the main study, even if it will also be used for optional research, should be addressed in the ICF rather than the HIPAA Research Authorization. If optional research requires obtaining new PHI from the medical record, this must also be described in the ICF. If new PHI will be accessed for research activities not covered in the ICF (e.g., a separate future study), a separate HIPAA Research Authorization will most likely be required.

Step 2: Participant Initials if Box is Checked

Participation in optional research must be clearly voluntary and separate from participation in the main study. If the study team checked the optional research box, the participant must indicate whether they agree to the optional use of their PHI by placing their initials in the appropriate choice provided on the form. If the box is not checked, participant initials are not required for this section.

Participant Signature Section



The participant completes this section after the study team has reviewed the HIPAA Research Authorization with the participant.

Step 1: Verify the Form Before Signature

Before obtaining the participant's signature, double check that all required sections and any applicable initials have been completed.

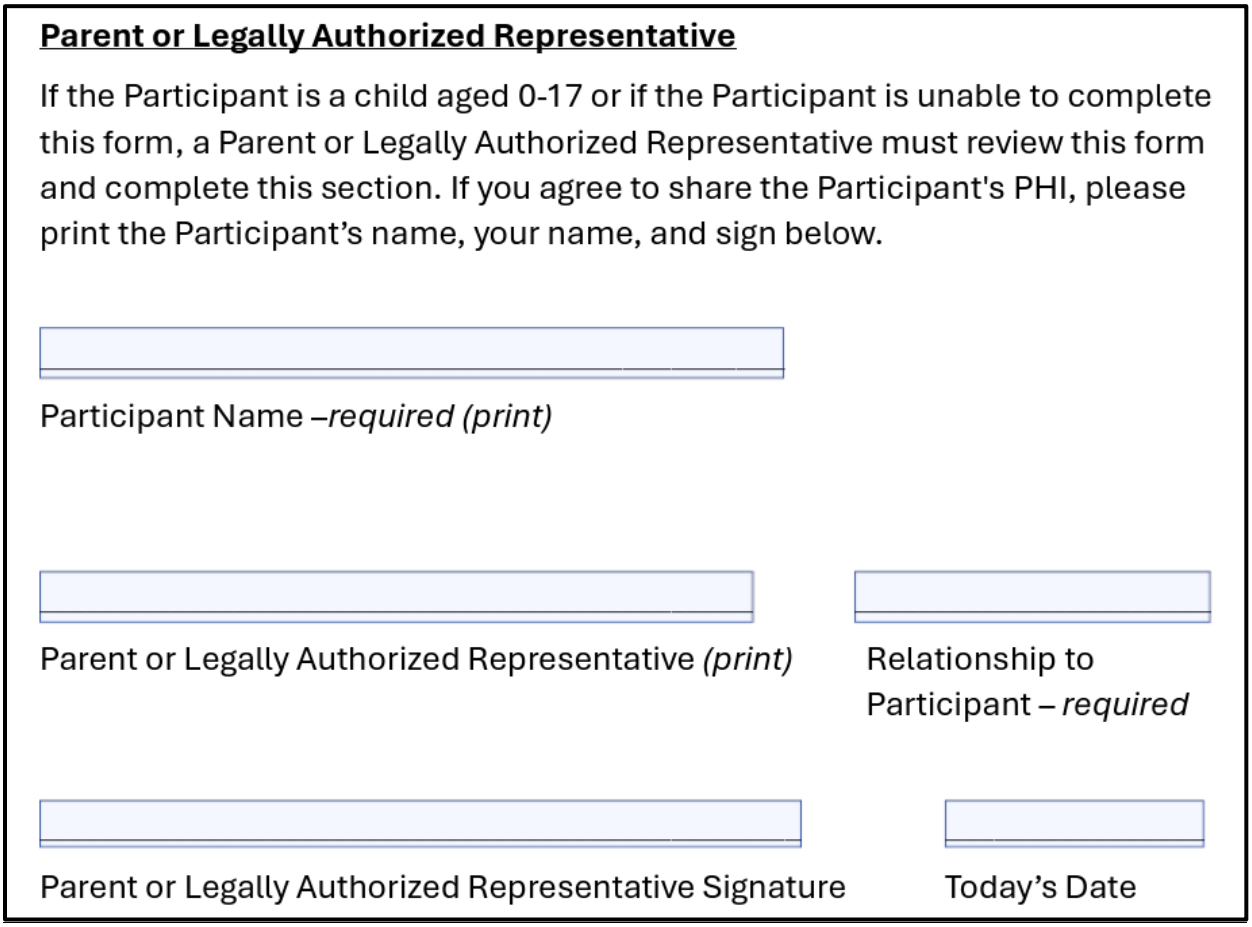
Step 2: Participant Completes the Signature Section

The participant must:

- Print their full legal name.
- Sign their name.
- Enter the date of signature. The date entered should reflect the actual date the authorization was signed.

Note: If a Legally Authorized Representative (LAR) is signing on behalf of the participant, the participant/LAR should not complete this section. Instead, the LAR should complete the LAR section.

Parent or Legally Authorized Representative (LAR) Section



Complete this section only if the HIPAA Research Authorization is being signed by a Legally Authorized Representative (LAR) rather than the participant. An LAR must complete this section when:

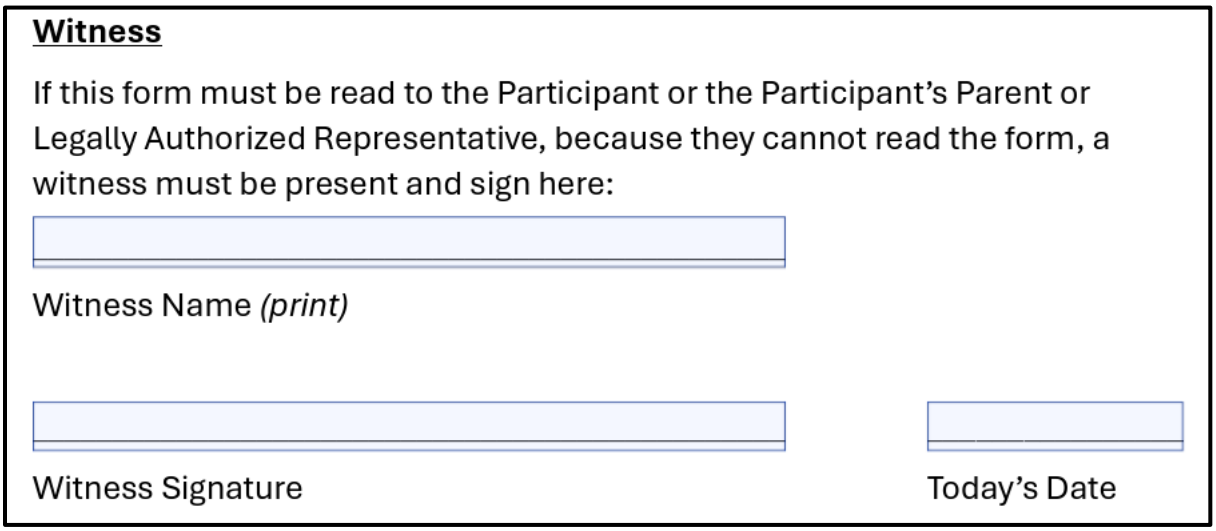
- The prospective study participant is a child (0–17 years of age). A parent or other LAR signs the HIPAA Research Authorization on the child's behalf. **Note:** Under California law, a minor may consent to certain healthcare services, including pregnancy-related care, sterilization, services related to rape or sexual assault, family planning, sexually transmitted infection (STI) prevention and treatment (including HIV testing), certain outpatient mental health services, substance use disorder treatment, communicable disease care, services related to intimate partner violence, and other legally authorized confidential services. Because a minor who has the legal authority to consent to these services also has the authority to authorize disclosure of the related records, the minor, not the parent or (LAR), must sign the HIPAA Research Authorization for the use and disclosure of those records, unless another legal exception applies. In many research studies, however, it is likely that the PHI to be disclosed extends beyond these confidential services and includes records for which parental authorization is also required. In those circumstances, both the minor and the parent/LAR may need to authorize the use and disclosure of the PHI. Consult your IRB or Privacy Office if you are unsure who should sign.
- The prospective study participant is unable to sign the authorization due to their health status or another legally valid reason. In these cases, the LAR may execute the HIPAA Research Authorization on the participant's behalf.

Note: If a participant enrolled as a minor reaches the age of majority during the study (18 years of age in California), the participant must sign a new HIPAA Research Authorization using the current version of the form and the current date. The parent or LAR does not sign the new authorization unless they continue to serve as the participant's legally authorized representative.

If required, the parent or LAR must:

- Print the name of the participant.
- Print the parent or LAR’s full legal name.
- Describe their relationship to the participant.
- Sign their name.
- Enter the date of signature.

Witness Section



A witness signature is not required unless the prospective study participant is unable to independently read and review the form. When a witness is required, the witness should be an impartial adult who is independent of the study. The witness should not be a member of the research team or anyone who could be unduly influenced by those conducting the study. The witness's role is to observe the authorization process and attest that:

- The authorization was accurately explained to the participant or LAR;
- The participant or LAR appeared to understand the information; and
- The authorization was signed or provided by the participant or LAR voluntarily.

If required, the witness must:

- Print their full name.
- Sign their name.
- Enter the date of signature.

Do not complete this section unless applicable.