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IRO News

Fred Hutch Cancer Center

Latest information from the Fred Hutch Institutional Review Office

In this issue:

IRB

New HIPAA Authorization Form Available

Effective 5/6/2025

A new protocol-specific HIPAA authorization form for research was recently established and approved for use at both Fred Hutch and the University of Washington. See HIPAA Authorization for the Use of Patient Information for Research for access to the new form.

- This form should be used for any **new** non-transplant studies conducted by Fred Hutch or UW investigators.
- This form does not replace the HIPAA authorization forms used for transplant research or for activities taking place at Seattle Children's Hospital.
- This form is intended to be used as a stand-alone document.
    - The Fred Hutch IRB will facilitate the review of any requests to include ("blend") HIPAA language in the research consent form upon submission to the IRB.
- Studies already using an approved authorization form do not need to switch to this form, nor do they need reauthorize participants.
- If a study team wishes to use the revised HIPAA authorization form for existing studies, they may do so at their discretion. Submission of a modification through the IRB is not necessary since the template is institutionally approved.
- The new HIPAA authorization form is being translated into the top 20 languages seen in the clinic. The translated forms will be coming soon. The IRO will send a separate notification once these are available.

See IRO's HIPAA Compliance in Research webpage and Compliance's HIPAA Authorization FAQs to learn more. You may contact the Privacy Office (privacy@fredhutch.org) for questions about the new protocol-specific HIPAA authorization form for research or IRO (IRO@fredhutch.org) for questions about IRB submission requirements.

Institutional Bridge Funding for Translations

Fred Hutch currently offers institutional bridge funding to help cover the costs of translating a consent form after use of the short form consent process. The bridge funding request process is described here. Fewer requests have been received than anticipated at this time, so below are a few clarifications:

1. Bridge funding is available to any Fred Hutch or UW study that does not have the funds to translate the full consent form after use of the short form consent process. Even if there is a study sponsor, if that sponsor only provides study drug or otherwise indicates it does not have the funds to cover translation costs, then you should submit a request for institutional bridge funding. There is no blanket restriction on which studies may request funds for translations, as long as you have first exhausted other potential sources of funding.
2. Lack of funding for translations is not a reason to exclude a potential non-English speaker from enrolling in a trial. This means PIs should continue to enroll non-English speakers when appropriate for the study. It is not appropriate to exclude this population purely based on funding for translations.

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Institutional Bridge Funding for Translations (continued)

As background, as of January 1, 2025, any use of the short form consent process to enroll non-English speakers must now be followed by translation of the full consent form (original announcement here). The purposes of this requirement are:

- To ensure regulatory compliance with FDA guidance and Washington state law requirements.
- To provide the individual with a consent form they can refer to throughout participation in the research.
- To actively stand by to our institutional value of *respect* and our mission to help "every person in every community."

Note that the short form process refers to "non-English speakers" and this should be understood to include individuals who either do not speak English or those with another language preference who are unable to understand English at a level of proficiency that would allow them to participate in meaningful informed consent.

An FAQ is available on this topic. Please contact IRO@fredhutch.org with any additional questions about the new requirements or the short form consent process. Questions about the bridge funding may be sent to Compliance at request@fredhutch.org.

Contact Us

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