

Latest information from the Fred Hutch Institutional Review Office

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IRB

New Requirement for Fred Hutch-Led Studies Engaging University of Washington

As introduced in UW Human Subject's Division's (HSD) <u>May 2, 2023 newsletter</u>, beginning July 1, 2023, all new studies that are:

- 1. Led by a Fred Hutch PI, and
- 2. Reviewed by the Fred Hutch IRB, and
- 3. Which engage UW in the research activities

must obtain authorization from HSD by submitting a request in Zipline prior to the Fred Hutch IRB issuing its approval for the portion of the research engaging UW.

After HSD has reviewed the <u>request in Zipline</u>, they will issue a letter to the study team to document this authorization. The Fred Hutch IRB will proceed with our review of the overall study but will hold final approval until we receive a copy of this letter from the study team.

Note: For studies led by a UW PI that have already been following this process, the Fred Hutch IRB will hold screening and review of the overall study until after we receive HSD's authorization. There is no change to that process.

Why is UW HSD authorization required?

Due to the single IRB mandates, there is an increased need for UW to track its engagement as an institution to ensure UW is complying with federal regulations. Additionally, Fred Hutch and UW recently renegotiated their longstanding cooperative agreement, and this is a term of the agreement.

What is UW HSD doing to assist study teams?

Fred Hutch employees can now obtain a UW NetID and gain access to Zipline by:

- following the instructions at <u>Identity.UW</u> to login via their Fred Hutch account to obtain a UW NetID, then
- self-registering in <u>Zipline</u> by logging in with the new UW NetID and selecting "Fred Hutchinson Cancer Center" as their department.

Detailed instructions for this process are now on the <u>Account Creation for Fred</u> <u>Hutch Employees</u> webpage.

In consultation with the IRO and Clinical Research Support, HSD has developed enhanced <u>webpage guidance for cancer-related research</u> along with:

- A <u>two-page worksheet</u> tailored to Fred Hutch-led research to assist study teams with identifying UW engagement
- A <u>quick reference guide</u> with specific instructions for and FAQs about Zipline submissions for Fred Hutch-led studies

For questions about this new requirement, contact hsdrely@uw.edu.



Hutch IRB Updates

New Online Training Module! Creating and Managing Participating Sites in Hutch IRB

A new online module helps study teams manage Fred Hutch IRB submissions related to a multi-site study when the study includes participating sites (pSites) outside the Cancer Consortium.

When Fred Hutch has been selected as the single IRB, the local Fred Hutch/ Cancer Consortium study team is responsible for making IRB submissions on behalf of the participating sites outside the Cancer Consortium (who do not have access to the system).

Navigate to the new pSite training module in Hutch Learning via one of the links below:

- Fred Hutch
- Legacy SCCA

See the <u>Hutch IRB Training page</u> for links to all currently available training modules.

We continue to offer optional 1:1 coaching sessions for the new system, in addition to weekly office hours on Wednesday mornings from 10:00 AM to 11:00 AM (except holiday weeks). Contact IRO@fredhutch.org with questions about training.

Final Data Migration to Hutch IRB is Now Complete

On June 12, the IRO conducted the third data migration to Hutch IRB. All active human subject research projects overseen by the Fred Hutch IRB now have a presence in the new system. Thank you to study teams for your partnership in this process.

Reminder: Migrated Studies in Hutch IRB

If you haven't done so already, be aware that you will need to take several actions on any study that was migrated into Hutch IRB:

- Only the PI and Primary Contact will have access to a migrated study in the system (assuming they completed their System Access training). If you wish to update who can view, edit, or submit on your studies, please access the written instructions available <u>here</u>.
- Only data has migrated, not documents. You will need to "complete the record" by adding approved documents. Instructions are available <u>here</u>.
 - UPDATE: Previously, we recommended you complete the record at the same time as your first submission in Hutch IRB on a migrated study.
 Based on your feedback, we now instead recommend that you turn in a separate Modification to complete the record, if time allows prior to your first standard submission.
- For migrated studies relying on an External IRB, you "complete the record" at the time you are informing the IRO of the next continuing review having been completed with the IRB of record. Instructions are available <u>here</u>.

Staff Updates

Now Hiring: IRB Analyst 1

CONTACT US

INSTITUTIONAL REVIEW OFFICE PHONE: 206.667.5900 EMAIL: IRO@FREDHUTCH.ORG WEB: <u>HTTPS://EXTRANET.FREDHUTCH.ORG/EN/U/IRO.HTML</u>

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