



IRO NEWS

Latest information from the Fred Hutch IRO

In this issue:

- Rush IRB Items
- External IRB Coversheet
- Device Supplement and Assays
- CTMS Protocol Numbers
- DoD Documentation Updates
- Hutch IRB Project
- Hutch IACUC Conversion Final
- AAALAC Reaccreditation
- Staff Updates

Rush IRB Items

An Update & Some Reminders

Moving forward, COVID-related submissions will no longer automatically be classified as priority items by the IRO, with one exception: New Applications for *treatment-related* COVID studies will still be prioritized above other new studies. All other applications will be processed in the order received as usual.

The IRO will continue to accommodate rush requests if they meet one of the following criteria:

- Already enrolled participants with life-threatening issues
- Potential future participants with life-threatening issues *who have exhausted all other alternatives* (treatment studies only)
- Funding emergencies such as Just-in-Time submissions with a clear date indicated

For items that meet the above rush criteria, the process is:

1. Add “Rush” at the beginning of the subject line of your submission email.
2. In the body of the email, include a clear rationale for the rush request. If a specific timeline is requested, please indicate.
3. If the submission is a research modification, also provide the rationale in question 5 of the Modification form.

We request you be sensitive to the high workload of the IRO and IRB Committees—please plan ahead.

External IRB Coversheet

The IRO released a revised version of the [External IRB coversheet](#), effective March 15, 2021. This form is used when Fred Hutch is engaged in a research study but will be relying on an external IRB for review. This document was revised to (1) include better instructions on the steps involved

Continued... →



in this process, (2) better capture how the consortium institutions are engaged, and (3) address eConsent.

Please use the revised version of this form for new submissions. The IRO will no longer accept the prior version as of June 15, 2021.

Device Supplement and Assays

When does an in vitro diagnostic assay used in a research study require a device supplement?

It is important to know when an in vitro diagnostic (IVD) assay being used in research is an investigational device requiring submission of a [device supplement](#) to the IRB. The device supplement is critical for the IRB to make an assessment of risk (significant or non-significant) or exemption.

IVD assays are tests done on samples such as blood or tissue taken from the human body. They can detect diseases or other conditions and can be used to monitor a person's overall health to help cure, treat, or prevent diseases. IVD assays are increasingly used in precision medicine to identify patients who are likely to benefit from a specific targeted therapy.

An IVD assay is being used in an **investigational manner** when:

1. It has not been cleared or approved for the use described in the protocol, and
2. The investigational use is applied to human subjects.

IVD assays are regulated by FDA as devices. Therefore, when an assay is used in an investigational manner in a research protocol, a device supplement is required for the IRB to make a risk assessment:

- **Significant Risk** assays present a potential for serious risk to the health, safety, or welfare of the patient. An IVD assay is considered **significant risk** if:
 - ⇒ it involves invasive sampling solely for the purpose of testing, *or*
 - ⇒ the results will be used for patient management without confirmation by another procedure, *and* management of the patient according to results could result in harm, especially if test results are incorrect.

A significant risk IVD assay requires submission of a complete *Investigational Device Exemption (IDE)* application to FDA.

Continued... →



- **Non-significant Risk** assays do not present a potential for serious risk to patient. There is no invasive sampling performed solely for testing purposes (i.e., samples collected by an invasive procedure may be used only if the procedure was also required for the patient's clinical care).

Test results will be used for patient management, but are unlikely to result in harm, even if the result is incorrect.

A non-significant risk IVD assay does not require notification to FDA.

- **Exempt** assays do not present a potential for serious risk to patient. There is no invasive sampling performed solely for testing purposes, and test results will not be used for patient management without confirmation by another, medically established product or procedure.

An exempt IVD assay does not require notification to FDA.

For further FDA guidance see the links below:

[U.S. Code of Federal Regulations Title 21 Part 812](#)

[Investigational IVDs Used in Clinical Investigations of Therapeutic Products \(FDA Draft Guidance\)](#)

[FDA Overview of IVD Regulation](#)

[FDA In Vitro Diagnostics](#)

CTMS Protocol Numbers

A reminder from the Clinical Trials Management System (CTMS) group: For studies submitted through OnCore, the system automatically assigns a "protocol number" in the format RGxxxxxxx. You must use this number as the protocol number on your protocol document, consent form, etc. Please do not use the IR number as the protocol number on your documents because this causes downstream issues, including preventing the trial from being published on public websites.

Exceptions: This reminder does not apply to studies approved by the IRB before the launch of OnCore in 2018. It also does not apply to HVTN studies.



Department of Defense (DoD) Documentation Updates

Research supported by the Department of Defense has been required to have an independent research/medical monitor for studies involving more than minimal risk to the subjects. Revised DoD regulations removed this requirement.

The IRB may still require researchers to have a monitor or a Data and Safety Monitoring Board (DSMB) for any study for which the IRB thinks it is appropriate. Also, existing DoD-funded studies with a monitor or DSMB must continue to comply with the IRB-approved data and safety monitoring plan unless a modification is submitted to change the plan.

Related revisions to [IRB Policy 2.26 Research Involving Department of Defense Components](#) and related documentation, including the [DoD Supplement](#), will be effective May 10, 2021.

Hutch IRB Project Moving Forward

The Hutch IRB project is officially underway after a year-long pause. The goal of this project is to implement the [Huron Research Suite IRB module](#), an end-to-end, web-based, electronic IRB system, and to leverage the best practices of Huron while minimizing local technical customizations.

The Hutch IRB solution will tentatively launch in September 2022. For details about the project, and periodic updates, please visit our [project webpage](#).

Hutch IACUC Conversion Final

Congratulations! Study teams have transitioned 100% of Fred Hutch IACUC protocols to the Hutch IACUC electronic submission system. Hutch IACUC provides greater transparency into protocol status, improves review process efficiency, and aids in regulatory compliance. Another benefit to researchers is the system's functionality that allows for easy re-use of substances and procedures across protocols, and the ability to share these components across different labs.



AAALAC Reaccreditation

The Fred Hutch animal care program is currently undergoing reaccreditation. Fred Hutch was first accredited by AAALAC International in 1979, and the reaccreditation process occurs every three years. Site visitors will be on campus in July to review Comparative Medicine facilities and examine IACUC protocols.

AAALAC International is a private, nonprofit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs. Meeting AAALAC's standards means that Fred Hutch goes above and beyond the federal regulatory requirements in ensuring the wellbeing and importance of animals in research.

Staff Updates

Departures

Claire Chatel – Committee C Analyst departed in April.

Now Hiring

The IRO currently has an open IRB Analyst position. This position supports the comprehensive analysis of research submissions for compliance with regulations, guidelines, institutional policies, and ethical considerations. Review additional information on the Fred Hutch jobs site [here](#).

CONTACT US

INSTITUTIONAL REVIEW OFFICE

PHONE: 206.667.5900

EMAIL: IRO@FREDHUTCH.ORG

WEB: [HTTPS://EXTRANET.FREDHUTCH.ORG/EN/U/IRO.HTML](https://EXTRANET.FREDHUTCH.ORG/EN/U/IRO.HTML)

SUBSCRIBE OR MANAGE YOUR SUBSCRIPTION AT:

[HTTPS://LISTS.FHCRC.ORG/POSTORIUS/LISTS/IRO-NEWS.LISTS.FHCRC.ORG/](https://LISTS.FHCRC.ORG/POSTORIUS/LISTS/IRO-NEWS.LISTS.FHCRC.ORG/)

