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The official newsletter of Fred Hutchinson Cancer Research Center's

Institutional Review Office

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In this issue:

De novo review of IRB files

At the time of continuing review, the IRB Committees and IRB Chairs will consider whether a de novo review of the study is necessary. This could be required for any IRB file, but the focus is primarily those that have been open for many years. This systematic review is designed to ensure that any changes in regulations since initial approval are incorporated and addressed appropriately. Generally, these studies will receive a **one-year approval** for the CRR, but are asked to submit a **New Application for review within six months**.

Please carefully review all correspondence from the IRB to see whether your study requires this action.

If you have any questions, please contact iro@fredhutch.org.

1. Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research

New versions of IRB policies, new IRB forms, and process changes for review of multi-site research have been implemented because a new NIH policy mandates the use of a single IRB (sIRB) of record for multi-site studies. All new or competing funding applications/ proposals received by NIH on or after **January 25, 2018** must describe a plan for the use of a sIRB, and all sites must agree to rely on the sIRB selected for that study. Fred Hutch IRB forms and procedures will apply to all multi-site research. Major changes include:

Policies

- *IRB Reliance Agreements Policy* (new)
- *Multi-Center Study Coordination – IRB Review and Oversight Policy* (revised)

Forms

- *Participating Site Application* (new, simpler form)
- *External IRB Cover Sheet* (new, concise form)
- *IRO Endorsement of External IRB Application* (new)

Flowcharts

- New flowcharts illustrating different IRB reliance agreement scenarios

All new versions of IRB forms must be utilized by September 1, 2017. They are simpler forms and were developed with stakeholders involved with multi-site studies.

For more information on new forms and procedures, and for details about how this impacts researchers, visit https://extranet.fredhutch.org/en/u/irb/sirb.html.

2. Revised Fred Hutch IRB Fee Schedule

A revised Fred Hutch IRB fee schedule is now available. The updated fee schedule changes the following:

- Effective **July 1, 2017**, IRB Fees have increased for Industry Sponsored studies.
- Effective **January 25, 2018**, new IRB fees will be charged as a direct cost for performance sites (outside the Cancer Consortium) that rely on Fred Hutch as the sIRB.

For more information on how these fees may impact your research budgets, visit https://extranet.fredhutch.org/en/u/irb/irb-fees.html.

Contact the IRO for assistance in preparing your research budgets:
email iro@fredhutch.org or by phone 206.667.5900.

3. Upcoming Revisions to the Common Rule (45 CFR 46)

On January 19, 2017, the Final Rule was published in the Federal Register. The effective date and compliance date for most changes is currently **January 19, 2018**.

Stay tuned for further information about the Final Rule in August!

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Association for the Accreditation of Human Research Protection Programs, Inc. Full Accreditation

4. Upcoming Opportunities for IACUC and Human Subjects Protection Training

The **IACUC** Basic Training Lectures are a 2-hour, in-person lecture. The next training lectures are:

- 7/21/17
- 10/20/17

The IRO also offers human subjects protection training **lectures** monthly, alternating between 2-hour basic lectures and 90-minute refresher lectures. Here is a schedule of upcoming training opportunities:

Basic
- 7/14/2017 (10:30-12:30 pm)
- 9/12/2017 (10:00-12:00 pm)
- 11/9/2017 (10:00-12:00 pm)

Refresher
- 8/14/2017 (10:00-12:00 pm)
- 10/9/2017 (10:00-12:00 pm)
- 12/11/2017 (10:00-12:00 pm)

Fred Hutch employees, please access Hutch Learning to register for any in-person session listed above. Other personnel, please email iro@fredhutch.org to register for any of these lectures. Visit IRB Training for other courses.

5. IRO Welcomes New Team Members

Katrina Nguyen joined the IRO in April 2017 as the QA Manager. Prior to this, Katrina was the Quality Systems Manager at Ambry Genetics in Aliso Viejo, CA and relocated from Mission Viejo, CA.

Alyssa McClure joined the IRO in April 2017 as the Committee D Admin. Asst. Alyssa joins the IRO most recently from Clinton Health Access Initiative in Boston where she served as a contracts analyst.

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Let us know if you have any information to share or topics that you would like to see appear in the IRO newsletter. Please email your suggestions to Meghan at mscott@fredhutch.org.