FRED HUTCH
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The official newsletter of Fred Hutchinson Cancer Research Center's

Institutional Review Office

Volume 38
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In this issue:

As always, contact us anytime!

In person — Yale Building, J2-100

On the phone — 206.667.5900

Or online —

Email: iro@fredhutch.org

http://extranet.fhcrc.org/EN/sections/iro/index.html

1. Updated IRB Forms – Effective August 1, 2016

Effective August 1, 2016 the Institutional Review Office (IRO) has revised the majority of IRB submission forms.

What has changed?
All revised forms have undergone a facelift and now contain the current Fred Hutch logo. Updates have also been simplified to streamline and clarify the submission process. We anticipate the revisions will make forms easier to complete and cut down on the amount of follow-up required.

A full list of revised forms and a summary of changes may be found here:
http://extranet.fhcrc.org/EN/sections/iro/irb/forms/index.html

Can I still use the old IRB submission forms?
Old versions of the IRB submission forms will be accepted for three months, through October 31, 2016. As of **November 1, 2016**, all researchers are required to use the August 1, 2016 versions of the forms. Please visit the IRB Forms page above to obtain the most current form versions.

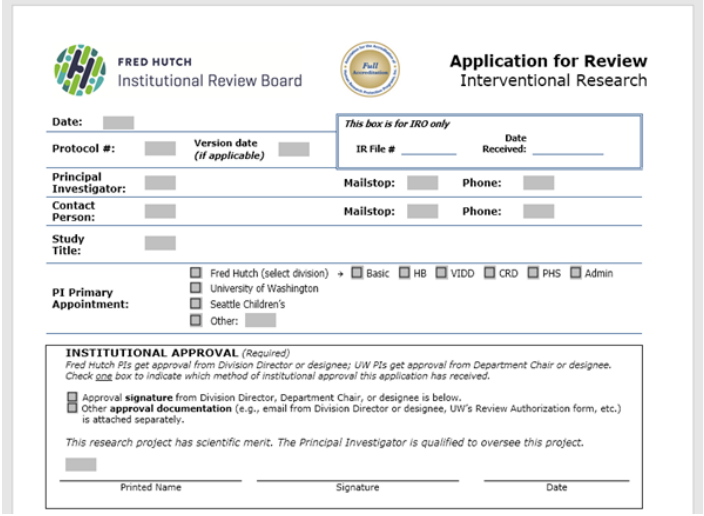
BONUS: Need your Division Director's signature on that New App? Good news:

Division Directors now have the option to provide sign-off for new IRB applications **via email!**

For this approval to be valid, please ensure the email includes the following:

- PI name
- Study title
- Confirmation that the research project has scientific merit
- Confirmation that the Principal Investigator is qualified to oversee the research project

Additional guidance on how to provide email approval is available here:
http://extranet.fhcrc.org/EN/sections/iro/irb/full.html



FRED HUTCH
Institutional Review Board

Application for Review
Interventional Research

Date:

Protocol #: Version date (if applicable)

This box is for IRO only
IR File # Date Received:

Principal Investigator: Mailstop: Phone:

Contact Person: Mailstop: Phone:

Study Title:

PI Primary Appointment: Fred Hutch (select division) → Basic HB VIDD CRD PHS Admin; University of Washington; Seattle Children's; Other:

INSTITUTIONAL APPROVAL *(Required)*
Fred Hutch PIs get approval from Division Director or designee; UW PIs get approval from Department Chair or designee. Check one box to indicate which method of institutional approval this application has received.

Approval **signature** from Division Director, Department Chair, or designee is below.
Other **approval documentation** (e.g., email from Division Director or designee, UW's Review Authorization form, etc.) is attached separately.

This research project has scientific merit. The Principal Investigator is qualified to oversee this project.

Printed Name Signature Date

IRB Forms: What has not changed?

A handful of forms are still under revision and will be released prior to the end of the year. These forms include:

- Continuation Review Report (CRR)
- HIPAA Supplement and Waiver of Authorization
- Waiver of Consent Supplement
- New Cooperative Review IRB Authorization Agreement Coversheet
- Cooperative Review Authorization Agreement CRR Coversheet

Stay tuned for the release of these forms!

I know I'm going to need to upload genomic data to a resource such as dbGaP. What is the process?

1) Submit a Research Modification Form and Genomic Data Sharing Supplement to the IRB. Any Mod including a request to share or upload genetic data (e.g., to dbGaP) will need **full review** at a convened IRB meeting.
2) The IRB will examine the consent forms used to acquire the data to determine if the proposed data sharing is consistent with what was outlined in the consent.
3) Once the Modification is approved, the IRO will provide confirmation that it is appropriate for the Institutional Official (Office of Sponsored Research Director, Mark Boyer) to sign the Institutional Certification requested by the NIH.

The IRB review process takes time to complete correctly. Please plan accordingly.

2. Reaccreditation with Distinction Awarded to the Fred Hutch Human Research Protection Program (HRPP)

Fred Hutch has been accredited by the Council on Accreditation of the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) since 2008. On March 21, 2016, Fred Hutch was one of the first organizations to earn Reaccreditation with Distinction, a designation introduced by AAHRPP to acknowledge areas of excellence among organizations seeking reaccreditation.

The Fred Hutch HRPP was recognized for the following area of distinction:

- The Outreach, Diversity, and Inclusion Program, which ensured communities in Seattle understand the mission of Fred Hutch and increased the involvement of communities in research. The program was unique in its ability to build bridges between the researchers and the community and improve the diversity of the IRB and research staff.

The Fred Hutch HRPP was also recognized for the following strengths:

- Exceptionally trained and engaged personnel through the HRPP
- Extraordinarily constructed and comprehensive meeting minutes
- Individualized consultation by the IRB Office for new investigators
- Establishment of a Divisional Liaison to facilitate communication and operational issues surrounding clinical research
- A detailed and integrated Institutional Conflict of Interest Policy
- A comprehensive and robust auditing program that reviews 100% of the greater than minimal risk protocols at least once a year

Many thanks to the faculty, staff, and leadership for their involvement with this effort. Your contributions made reaccreditation of the Fred Hutch HRPP possible.

3. New IRB Policy on Genomic Data Sharing

The NIH implemented a new policy on January 25, 2015. At the time, the IRO and OSR worked together to communicate this change to the research community.

What did the 2015 change mean?
New or competing awards submitted to the NIH on or after January 25, 2015 are to address genomic data sharing plans, if applicable. Click on this link to see the NIH Policy in full: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html

What is changing now?
The IRB has updated its forms and released a new policy consistent with the NIH's requirements. The **Genomic Data Sharing Policy** is dated August 1, 2016. This information will be communicated to the IRB on the **Genomic Data Sharing Supplement** (formerly named the GWAS Supplement), which is included in the August 1, 2016 IRB Forms release.

Where can I get more information?
All PIs are encouraged to speak with their Project Officer at NIH when preparing new or competing grants. As always, please reach out to the IRO with any questions.

IACUC Meeting Schedule

The IACUC meets on the first Tuesday of each month.

To find out more about IACUC submission timelines, visit the IACUC site here:

https://centernet.fhcrc.org/CN/depts/iro/iacuc/meetings/index.html

Planning ahead for Vet Pre-Review

The veterinarians will need additional time to perform a thorough and appropriate pre-review. Please plan accordingly and allow one week for this review.

4. Upcoming Opportunities for IACUC and Human Subjects Protection Training

The next **IACUC** Basic Training Lecture will be held on October 13, 2016 at 10 am. This is a 2-hour, in-person lecture. Please contact iro@fredhutch.org to register.

The IRO also offers human subjects protection training **lectures** monthly, alternating between 2-hour basic lectures and 90-minute refresher lectures. All trainings begin at 10 am. Here is a schedule of upcoming training opportunities:

August 8, 2016 (refresher)
September 12, 2016 (basic)
October 10, 2016 (refresher)
November 7, 2016 (basic)
December 19, 2016 (refresher)

To register for any of these lectures, please contact iro@fredhutch.org

Can't make it to the in-person lecture? You can always complete the training **online** through CITI. To learn more about this convenient option, or to register with CITI, please visit the IRB training page here: http://extranet.fhcrc.org/EN/sections/iro/irb/training/citi.html

5. New Requirement for USDA-Regulated Research

Based on guidance from the USDA, veterinarian pre-review will now be required prior to IACUC review for all **USDA-regulated species**. This change is **effective September 1, 2016**. This requirement applies to new applications, 3-year de novo reviews, and protocol revisions requiring convened meeting review for studies which involve USDA-regulated species (e.g., canines).

80% of studies involving USDA-regulated species already seek vet pre-review, so the largest change is to ensure this process is documented. Documentation of vet pre-review may be in the form of an email. This documentation must be provided with submission materials to the IACUC.

Comparative Medicine (CM) veterinarians are available to help review IACUC protocols. The veterinarian may have suggested modifications that would help to facilitate the review of the protocol. Vet pre-review is already in place for studies undergoing Designated Member Review. These requirements have not changed.

Please contact CM at 667-4558 or cm@fredhutch.org to arrange for a veterinarian pre-review before submitting to the IACUC.

6. IRO Staffing Changes

The IRO would like to welcome **Meghan Scott** who joined the IRO Team in June 2016 as the IRO Assistant Director. Meghan joins Fred Hutch, bringing 12 years of IRB experience and over 10 years of management experience from her previous employer, Quorum Review IRB. Her most recent position prior to joining Fred Hutch was the Director of IRB Services, where she was responsible for administrative and management oversight of the Quorum Review IRB members, as well as the IRB Administrative Team. Meghan received her BA in Business with a minor of Psychology from the University of Puget Sound. She brings a tremendous amount of experience and expertise to the IRO.

The IRO also welcomes **Van Nguyen** as the Funding Administrative Assistant II. Van's role will primarily include IRO involvement in Attachment A, B , and C processing, 310 form certifications, Funding Verification and Activation Forms, Human Subjects training and general support to the IRO Director. Van is a recent UW graduate with a BA in Public Health. Van also previously worked in the Fred Hutch Cancer Epidemiology Research Cooperative (CERC) Department.

Additionally, **Dave Lowe**, who served the IRO as the Funding Administrative Assistant II for the better part of this last year has accepted the position of IACUC Administrative Assistant II. Congratulations, Dave!

Karen Hansen	Meghan Scott	Caroline Davis
IRO Director 667.4867	IRO Assistant Director 667.4372	IRB Operations Manager 667.5949

Senior IRB Analyst	
Esther Joneson	667.3051
IRB Committee A	
Sonja de Moya, IRB Analyst	667.1807
Dana Atkins, Admin. Assistant	667.4528
IRB Committee B	
Jean Rackley, IRB Analyst	667.2029
Fiona Henderson-Fuhr, Admin. Assistant	667.4981
IRB Committee C	
David Banjavic, IRB Analyst	667.7665
Koren Sanchez, Admin. Assistant	667.6567
IRB Committee D	
Noel Cebrian, IRB Analyst	667.5950
Vanessa Carlson, Admin. Coordinator	667.7075
IRB Expedited Reviews	
Tara Bauman, Expedited Analyst	667.2762

IACUC	
Amanda Egge, IACUC Analyst	667.5794
Dave Lowe, Admin. Assistant	667.6831
Multi-Center Assurances and Authorization Agreements	
Karen Hansen	667.4867
SOP Administration and IRO Website	
Jason Tharpe, SOP Administrator	667.4941
IRB/IACUC Subcommittees	
Jill Johnson, Admin. Assistant to Karen Hansen	667.3120
Grants and Training	
Van Nguyen, Admin. Assistant (IRB Certifications, 310s, human subjects training, and general questions)	667.4929
General Questions	
iro@fredhutch.org	667.5900

IRO eNewsletter

Let us know if you have any information to share or topics that you would like to see appear in the IRO eNewsletter.