

IRO Newsletter



Institutional Review Office (IRO)
<http://www.fhcrc.org/intranet/iro/>

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Research Community Forum

Save the Date – February 4, 2010 for “**Protecting Research Participants: Ethical Challenges within a Regulatory Framework**” a Research Community Forum presented by the **Office for Human Research Protections** and the **Northwest Association for Biomedical Research (NWABR)**. Dr. Jerry Menikoff, Director of OHRP, will be the plenary speaker. The Forum features basic and advanced IRB sessions, biomedical and social/behavioral/educational research topics, and a track for research teams. Agenda development and conference site selection (in Western Washington) are underway. Contact Laurie Hassell, Northwest Association for Biomedical Research, at 206-465-4691 or lhassell@nwabr.org if you have any questions

How Do I Notify the IRO of a No-Cost Extension or Update the Current Funding Dates for a Grant?

If an investigator receives a no-cost extension for a grant and none of the activity involving live vertebrate animals or human subjects has changed, then it is acceptable to send an email to the IRO indicating the new dates of support for the grant. This is considered an administrative clarification and can be updated by the IRO based on an e-mail from the Research Coordinator or the OSR Grant Specialist.

In the email, please include the following:

- name of the funding source/agency (e.g. NIH, NCI, Canary Foundation)
- dates of support that are changing (e.g. 9/1/04 - 8/31/09, no-cost extension from 9/1/09 - 8/31/10)
- title of the grant, the agency assigned grant number (e.g. R01 CA482080)
- 6 digit FHCRC Project ID/Budget number.

Please send emails to Amanda Egge aegge@fhcrc.org for no-cost extensions or corrections of any funding dates relating to IACUC files and send emails to Denelle Reilly dreilly@fhcrc.org for no-cost extensions or corrections of any funding dates relating to IRB files.

Purchasing Custom Antibodies from Off-Site Sources/Vendors:

Reminder to all investigators: Custom antibodies can only be purchased from vendors/sources that have approved Animal Welfare Assurance with the Office of Laboratory Animal Welfare (OLAW). The generation of custom antibodies is considered an activity involving vertebrate animals and is covered by Department of Health and Human Services PHS Policy. FHCRC receives federal funding and therefore, it is the policy of the Center that any custom antibodies must be purchased only from vendors/sources that have an approved Animal Welfare Assurance with OLAW.

- It is acceptable for an institution to rely on the IACUC of an assured, off-site location that is conducting the review of custom antibody production projects for vendors.
- Antibodies are considered customized if produced using antigen(s) provided by or at the request of the investigator (i.e., not purchased off-the-shelf).
- The location producing the antibody must have a current Assurance number with OLAW.
- Investigators can go to the Office of Laboratory Animal Welfare (OLAW) website: <http://grants.nih.gov/grants/olaw/olaw.htm> to determine the Institutions that hold approved assurances.
- Once the assurance status is verified and the vendor's IACUC has approved the project, FHCRC IACUC review is not required*.

*Note that if an NIH grant will be used to purchase custom antibodies, investigators can provide the FHCRC Assurance # A3226-01 on the appropriate SF424 or PHS398 (face page of the grant application) as the grantee

institution always retains primary responsibility for ensuring compliance with PHS Policy. For the IACUC approval date, investigators should put the date of the performance site's IACUC approval. In the 'Research Plan' section of the grant, section f. (Vertebrate Animals), the investigator should identify the performance site that will do the animal work and that vendor's Assurance number.

Please contact the IACUC Analyst at 667-5794 if you have any questions.

Is the IACUC Required to Review the Grant Application?

Yes. Regulations require the institution to verify, before award, that the IACUC has reviewed and approved those components of grant applications and contract proposals related to the care and use of animals. Please submit a protocol Revision Form, along with a copy of the funding source, to the IRO, mailstop J6-110, to add a new funding source to an existing IACUC file.

What is a Certification Letter and how do I get one from the IACUC?

A Certification Letter confirms that a specific grant application involves animal research, and the activities described in the grant have been reviewed and approved by this institution's IACUC. In particular, the NIH will request IACUC vertebrate animal certification (to include the OLAW Assurance number, verification of IACUC approval with date, and any IACUC-imposed changes. Pending or out-of-date approvals are not acceptable). Requests for certification letters need to come from the Principal Investigator, the IRO Contact of an IACUC file, or the Office of Sponsored Research. If you need a Certification letter, you will need to send an email to the IACUC Analyst, Amanda Egge, with this request. Please also include the following information in your request:

1. Name of Principal Investigator
2. IACUC file number(s) and title of IACUC file(s)
3. A name and address to address the letter to
4. The funding source (name of the funding agency), award number (grant number), and title of the award/grant

IRO Staff

IRO Director:

Karen Hansen (667-4867)
Jonathon Sargent, Admin Asst. (667-5949)

IRO Assistant Director:

James Riddle (667-6501)

IRB Operations Manager:

Denelle Reilly (667-6567)

IRB Committee A:

Sonja de Moya, IRB Analyst (667-1807)
Jeremiah Klashorst, Admin. Asst. (667 – 4981)

IRB Committee B:

Connie Nakano, IRB Analyst (667-2762)
Jason Tharpe, Admin Asst. (667-3120)

IRB Committee C:

Andrew McKelvey, IRB Analyst (667-7665)

IACUC:

Amanda Egge, IACUC Analyst (667-5794)
Lori Lodzinski, Admin Asst. (667-4976)

IRB Administrative Manager:

Lynell Bates, Admin Coordinator (667-4528)

SOP Administrator:

Cindy Hirano (667-4941)

IRB Certifications (310's):

Jeremiah Klashorst, Admin. Asst. (667-4981)

IRB Subcommittees

Jonathon Sargent, Admin Asst. (667-5949)

Contact for FHCRC/UW Cancer Consortium

Melody Anderson (667-4520)

General IRO Contact

(667 – 5900)

IRO eNewsletter

Please let us know if you have any information/topics that you would like to see covered in the IRO eNewsletter. Please email your suggestions to: jdiddle@fhcrc.org