

IRO Newsletter



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

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Revised Application for Review Form, Protocol Disposition Form, and Supplement Forms

Over the last year, the IRO has collected feedback from investigators, coordinators, IRB members, and others on our IRB Application for Review form. For the past few months the IRO has been working to update the form and incorporate much of the feedback. The resulting updated IRB Application for Review form will be available on the IRO web-site November 16th, 2009. We would like to thank everyone who contributed feedback on the application questions.

There are no substantial new requirements or questions on the form, and we actually managed to not make the form any longer! Many of the questions are updated to provide clearer instruction on how to answer them.

Two new supplemental forms were created to accommodate the ever changing regulatory environment:

- Waiver of Consent
- Dataset Submission Supplement for NIH GWAS and Other Central Genetic Data Repositories.

The following supplemental forms were also updated with new simplified language and instructions:

- Protocol Disposition Form
- Coordinating Center / Operations Center Supplement
- Funding Source Supplement
- HIPAA Supplement – (*the HIPAA Waiver of Authorization for Use of Protected Health Information and HIPAA Supplement forms were merged into one*)
- International Research Performance Site Assessment Supplement
- Statistical Center Supplement

The effective date of the new form is November 16, 2009. The current version of the IRB Application for Review form will be accepted until January 15, 2010 to allow applications in progress to work through the system. New applications arriving in the IRO after January 15, 2010 will be required to be on the updated version of the form.

Please contact James Riddle (jriddle@fhcr.org), IRO Assistant Director at 667-6501 or Denelle Reilly (dreilly@fhcr.org), IRB Operations Manager at 667-6567 with any questions or concerns regarding the revised policies and forms.

Revised Model Consent Forms

The Model Consents and IRB Policy 2.11 Informed Consent – Effective November 1, 2009

The Model Consents were updated to clarify when a witness line and researcher's statement are needed.

Witness Line:

The revised instruction is: “Include a Witness signature line on your consent only if witness signature is required by regulations (e.g., incapacity, illiteracy or difficulty with language comprehension), IRB directive or agreement with study sponsor.” The instruction is now placed before the “witness/date” signature line.

If your study does not require a witness line, please remember to delete the “witness/date” signature line from your consent form before submitting it to the IRB for review.

Researcher’s Statement:

The revised instructions were updated to clearly state when a Researcher’s Statement is needed or what you need to do if you choose to include it in your consent form.

Revised statement: “The Researcher’s statement and signature is mandatory in the case of studies needing to comply with International Conference on Harmonization E6 (ICH) guidelines. Unless you need to comply with ICH, this statement and signature is not required. A pre-signed consent form is not acceptable.

If you have a research statement and signature line on your IRB approved consent form, you are required to have the person conducting the consent discussion sign the researcher statement.”

To review the model consents, please go to <http://extranet.fhrc.org/EN/sections/iro/irb/consent.html>.

IRB Policy 2.11 Informed Consent

The IRB Policy 2.11 Informed Consent has been updated to reflect the changes made to the model consents.

To review this policy, go to <http://extranet.fhrc.org/EN/sections/iro/irb/policy/index.html>.

Please contact James Riddle (jriddle@fhrc.org), IRO Assistant Director at 667-6501 or Denelle Reilly

(dreilly@fhrc.org), IRB Operations Manager at 667-6567 with any questions/concerns regarding the revised model consents and/or policy.

Updated Noncompliance Policy and Reporting Obligations for Principal Investigators Policy

The IRB Chair Liaison group in conjunction with General Counsel updated the definitions for Minor Noncompliance and Serious Noncompliance. The updated definitions provide more clarity to investigators and research coordinators when reporting events that “may” constitute an Unanticipated Problem, Serious Noncompliance and/or Continuing Noncompliance.

Please review the policies Noncompliance (1.9) and Reporting Obligations for Principal Investigators (1.11) at <http://extranet.fhrc.org/EN/sections/iro/irb/policy/index.html>.

To reflect the revised definitions, the Expedited Reporting Form for Unanticipated Problems or Noncompliance along with the Glossary of Terms and Acronyms were updated. The revised forms can be found at <http://extranet.fhrc.org/EN/sections/iro/irb/forms/index.html>.

The effective date for these revised documents is November 1, 2009. Please contact James Riddle (jriddle@fhrc.org), IRO Assistant Director at 667-6501 or Denelle Reilly (dreilly@fhrc.org), IRB Operations Manager at 667-6567 with any questions/concerns regarding the revised policies and forms.

OHRP Research Community

Forum: Protecting Research Participants: Ethical Challenges within a Regulatory Framework

February 4, 2010

*Bell Harbor International Conference Center
Seattle, Washington*

The Office for Human Research Protections, Northwest Association for Biomedical Research and the conference planning committee look forward to seeing you on February 4, 2010 for this event featuring tracks for the research team, and new and experienced IRB personnel with separate sessions for social/behavioral and biomedical settings. Plenary sessions by Dr. Jerry Menikoff, OHRP's Director and Dr. Pearl O'Rourke, Human Research Affairs Director at Partners Healthcare System, lead a distinguished roster of speakers representing human subjects protection programs in the United States and Canada.

Preliminary agenda and online registration are available at <http://www.nwabr.org/takepart/irb.html>. Fees for NWABR members are \$225, nonmembers pay \$295.

Please contact Laurie Hassell at 206-465-4691 or lhassell@nwabr.org for questions.

Co-presented by: Northwest Association for Biomedical Research (NWABR) and Office for Human Research Protection (OHRP)

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 Coordinator:

Lynell Bates (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)

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: jriddle@fhcrc.org