

IRO Newsletter



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

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Updated IRB Policy 2.11 Informed Consent - Effective October 1, 2009

IRB Policy 2.11 Informed Consent has been updated to address the consent requirements for minors who reach the age of majority or become emancipated.

Section 6: Consent of children who reach the age of majority or become emancipated:

When a child participant reaches the age where they can provide consent for procedures involved in the research, informed consent must be obtained. A waiver of consent may be approved by the IRB as described in section 4 of this policy.

The language is very similar to the current policy language which reads: *“When a child participant in a research study becomes an adult, the participant’s informed consent must be obtained, even if there is no continuing interaction or intervention with the participant (for example, if specimens are stored for future research).”*

An emancipated minor is legally capable of providing informed consent.”

The current language was updated into “section 6” to reflect the practical reality that in some research situations it may not be appropriate, or practical, to

get consent from children when they reach the age of majority.

How does this impact my study?

No action is required for ongoing studies. For new studies, question 5.2.d of the IRB application already prompts the PI to inform the IRB how consent of children will take place when they become adults. If you will be requesting a waiver of consent please be sure to complete the Waiver of Consent questions in the application form and indicate the waiver is for purposes of children reaching the age of majority.

To review this policy, go to

<http://extranet.fhcr.org/EN/sections/iro/irb/policy/index.html>.

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/concerns regarding the revised policy.

Committee C Will Now Review Clinical Research Applications

IRB Committee C will now review applications for clinical trials. This will help with the large number of clinical research applications that are submitted for review and provide additional capacity to move new reviews through the IRB.

Model Consent Templates – *effective October 1, 2009*

In our continued effort to provide resources and guidance to Principal Investigators and Research Coordinators in the area of consent writing, the IRB recently developed two model consents specifically for the Public Health Sciences (PHS) Division and updated the three model consents geared toward clinical research. All of the five model consents provide sample language to help you develop consent documents that are simple, clear and short. The new and revised model consents can be found at <http://extranet.fhcrc.org/EN/sections/iro/irb/consent.html> <https://centernet.fhcrc.org/CN/depts/iro/irb/consent/index.html>

New Model Consents

- PHS Model Consent
- PHS Model for Minimal Risk Studies

Updated Model Consents

- Model Consent Clinical
- Model Consent for Minimal Risk
- Model Consent “R” (Consent to donate extra tissue samples for research during a planned clinical evaluation for blood or marrow stem cell transplantation)

The PHS Model Consents

The two new PHS model consents include the basic elements of consent as required by the Office for Human Research Protections (OHRP) described in 45 CFR 46.116 such as risks, alternatives and benefits but contain language uniquely designed for PHS related studies.

The Current Model Consents

The three model consents geared towards clinical research were updated in the following sections:

Section	Description of change
Will you pay me to be in this study?	Language added for compensation exceeding \$600 per calendar year.
What if I get sick or hurt in this study?	Instruction added: “If the sponsor has agreed to pay for study related injury, revise as necessary per the Clinical Trial Agreement.”
What if I get sick or hurt in this study?	For studies where UW is the funding recipient, entire section was updated.
What if I get sick or hurt in this study?	For studies that are more than minimal risk, the statement “You will not lose your legal right to seek payment for treatment if you sign this form.” must always be included at the end of this section.
Future Genetic Research	NEW Section related to potential future genetic testing and posting to GWAS databases such as dbGap.
Signature	Instructions regarding the use of witness were added.

Please contact James Riddle (jriddle@fhcrg.org), IRO Assistant Director at 667-6501 or Denelle Reilly (dreilly@fhcrg.org), IRB Operations Manager at 667-6567 with any questions/concerns regarding the model consents.

New Safety Information Regarding CellCept (mycophenolate mofetil - MMF)

The FDA recently announced that there have been cases of Pure Red Cell Aplasia (PRCA) in patients treated with CellCept (MMF). As a result, Roche has updated its Warning and Adverse Reactions sections of the CellCept Prescribing Information to describe this new safety information.

More details on the risk information can be found at <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm177397.htm>.

If your consent forms need to be updated to reflect this risk information, please go to <http://extranet.fhcrc.org/EN/sections/iro/irb/modification.html> to access the Protocol Modification Form. Please submit both a tracked change and clean versions of the consent form(s).

The Northwest Association for Biomedical Research (NWABR) invites you to attend!

2010 IACUC Regional Education Conference

Thursday - March 4th 7:00 am to 4:30 pm

Join your colleagues in Seattle for the 11th annual IACUC Regional Education Conference!

Conference Highlights

- **Outstanding local and national speakers**
- **Q&A with regulatory officials from NIH OLAW, USDA, and AAALAC International**
- **Problem-solving, scenario-based sessions covering common IACUC topics**
- **Tailored sessions for new IACUC members**
 - Regulatory Review
 - Protocol Review
 - Program & Facility Review
- **Opportunity to network with peers and colleagues**

Who Should Attend

- New and experienced IACUC members and administrative personnel
- Lab animal veterinarians and staff
- Researchers

Registration Date

Online registration available December 1st

Additional \$35 late fee after Feb 18th

- NWABR member \$250
- Member Group \$200
(10 or more registrants)
- Non-NWABR member \$350

For more information contact Reitha Weeks, NWABR Program Manager

rweeks@nwabr.org or (206) 957-3337 x305

www.nwabr.org

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