

IRO Newsletter



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

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CHANGE TO IRO INVOLVEMENT IN ATTACHMENT A

Effective July 1, 2009 the Attachment A approval process will no longer incorporate a double check by the Institutional Review Office (IRO) before the grant is submitted to OSR. Where you would normally bring the grant to the IRO, it can now go straight to the next step in the process.

The Attachment A form has been shortened as a result of eliminating this additional review step!

Investigators and their research teams are still responsible for getting all necessary IRB or IACUC approval of their projects! Be sure your project has the right review to avoid any delay in funding!

A new decision support tool is available on the IRO web-site to help you determine how to fill out your grant, and what type of IRB or IACUC review your project needs. The tool can be found at <https://centernet.fhcr.org/CN/depts/iro/forms/Tool.doc>. A general overview of the requirements are below. This is not a comprehensive list, please use the decision support tool if you have any questions about what type of review you need.

DECISION 1 – Research Involving Human Subjects Yes or No?

1. **Involves interaction with humans = Yes.** If your project involves any interaction (direct or indirect) with human subjects as part of the research then you need an approved IRB file before OSR can set up your budget and research can begin.
2. **Involves only data and/or specimens originally derived from humans = Maybe.** If your project *only* involves the use of data and/or specimens originally derived from humans then you *might* need an IRB file; or, you might qualify for a “Not Human Subjects (NHS)” determination. Follow the NHS check list at the IRO web site https://centernet.fhcr.org/CN/depts/iro/irb/not_human_subjects_f/index.html to figure out if your research qualifies for NHS.

If after completing the NHS check list, your project appears to qualify for a NHS determination, submit the forms to the IRO office. The IRO will assign a NHS determination number which you must put on Attachment A BEFORE starting the grant through sign-off. If you qualify for a NHS determination number answer “**no**” on the grant and *no further IRB action is required*. If your project does not qualify for NHS answer “**yes**” on the grant and you need an approved IRB file before the grant is awarded..

3. **Nothing about or from humans = No.** If your project definitely does not involve interactions with or data derived from humans, then you *do not* need IRB review of your project.

DECISION 2 – Research Involving Vertebrate Animals Yes or No?

1. **Involves direct interaction with vertebrate animals = Yes.** If your project involves any interaction with vertebrate animals as part of the research then you need an approved IACUC file before OSR can set up your budget and research can begin.

2. **Involves only production of monoclonal antibodies = Yes.** See the decision support tool at <https://centernet.fhrc.org/CN/depts/iro/forms/Tool.doc> section 2.a for more information on IACUC requirements for production of monoclonal antibodies.
3. **Involves only tissues derived from vertebrate animals = Maybe.** See the decision support tool at <https://centernet.fhrc.org/CN/depts/iro/forms/Tool.doc> section 2.b for more information on IACUC requirements for transferring animal tissues.
4. **Nothing about or from vertebrate animals = No.** If your project definitely does not involve vertebrate animals, then you *do not* need IACUC review of your project.

REMEMBER – IT IS STILL UP TO THE INVESTIGATOR TO MAKE SURE ALL NECESSARY IRB/IACUC APPROVALS ARE IN PLACE. ACT EARLY SO YOUR FUNDING IS NOT DELAYED. THE IRO HAS TO REVIEW YOUR RESEARCH BEFORE YOU GET FUNDING FROM AN AWARD.

**ALLOW AT LEAST 60 DAYS TO GET ALL THE NECESSARY IRB/IACUC APPROVALS.
DO NOT WAIT UNTIL THE LAST MINUTE!**

CHANGE TO THE CONTINUATION REVIEW REPORT FORM

The Continuation Review Report (CRR) has been updated to reflect the recent policy changes for Unanticipated Problems Involving Risks to Subjects or Others (2.6), Reporting Obligations for Principal Investigators (1.11) and Noncompliance (1.9) as well as to incorporate users' feedback.

To incorporate the Unanticipated Problems and Noncompliance policy changes, Section 6.0 Data Collection and Monitoring, had the most significant changes. The two main changes were:

- Definitions and information regarding expedited reporting requirements were added to assist users; and
- Two new questions were added (Sections 6.1.f and 6.2)

In our continued effort to enhance the CRR, as well as other forms, the IRO incorporated changes based on users' feedback. Updating the centernet links to the extranet links and adding a comments box to Section 3.2.a are two such examples.

The latest version of the CRR form (version 4.0) is effective July 1, 2009. There will be a two-month grace period where either version will be accepted. Any CRR received by the IRO on or after September 1, 2009 must use this updated version (4.0).

Please contact James Riddle, IRO Assistant Director at 667-6501 or Denelle Reilly, IRB Operations Manager at 667-6567 with any questions/concerns regarding these changes.

UW will no longer provide IRB review for VA effective July 1, 2009

As of July 1, 2009, the UW IRB will no longer provide IRB review and oversight for research at VAPSHCS or the Boise VAMC. The VAPSHCS will have its own IRB, based on the existing UW IRB Committees V and V2. If you have any concerns about how this will affect your study, please contact the IRO Assistant Director, James Riddle at 667 – 6501, or at jriddle@fhrc.org.