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Human Research Protections

News Brief

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UCI Researchers are busy…

UCI had over 2200 active studies in FY 2011!

Congratulations to our researcher community and best wishes for 2012!

The New Submitter's Workshop in 2012

Research Protections Staff have developed a workshop for those individuals new to the IRB submission process. The purpose of this 90-minute workshop is to provide researchers and staff with the resources they need to submit a complete IRB application package. The workshop will focus on three main objectives: "Where to go to find answers", "How to submit" and "What happens after you submit."

Attendees will learn how to access the most commonly used forms and documents on the Human Research Protections web site, how to draft a Protocol Narrative, how to complete the Application for IRB Review and, what happens after the Lead Researcher submits the application package. A general overview of the IRB review process is also provided. The training workshop will be held monthly at the Office of Research suite in the Research Park in Irvine. Other accommodations can be made for larger groups—either on campus or at the Medical Center in Orange.

Research Protections Staff hope that this workshop will provide the UCI research community with useful information and tips for submission of a complete IRB application package thereby facilitating the IRB review process. Stay tuned for email announcements regarding the launched of the NSW in early 2012!

A special thanks to the New Submitter's Workshop development group: Alicia Asgari, Christine Hegel-Cantarella, Joy Chu, Cheree DuBose, Beverley Esparza, Cathryn Lucas, Theresa Sanchez, and Valerie Sanchez.

New Deadline Day for IRB - Full Committee

Effective in 2012, the IRB deadlines to submit for full committee review are changing from Tuesday to Thursday.

WHY? Currently, researchers submitting for full committee IRB review receive administrative pre-review comments and have the option to provide a response along with revised documents for consideration by the committee. While many researchers take advantage of the pre-review process, others express concern they do not have sufficient time to respond. Now, researchers will have two additional days to respond to the pre-review comments. As always, while researchers are strongly encouraged to respond to the pre-review memo, a response is optional; either way the study will still be placed on the IRB agenda unless severely deficient or other regulatory committee approvals are required. Currently, the IRB members receive two versions of the agenda— the researchers' originally submissions and the researchers' pre-review responses with revised documents. This dual agenda process has caused some confusion. Now, IRB members will receive one agenda with the researchers' pre-review responses and revised documents. Having only one agenda streamlines the IRB review process for researchers, HRP staff and IRB members. See the new committee calendars and the Master IRB Calendar for deadline and meeting dates.

Human Subjects Application & Protocol Preparation Checklist

Researchers: Please review this checklist to ensure that your human subjects application packet is complete before you submit the application and protocol to the IRB for review.

You can access this checklist online as well.

- ☐ All applicable sections of the IRB application and Protocol Narrative should be completed.
- ☐ The Lead Researcher has either a paid UCI faculty appointment greater than or equal to 50%, or a Faculty Sponsor.
- ☐ The Lead Researcher must complete and sign the Disclosure of Investigators' Financial Interest, and Investigator's Assurance form.
- ☐ The Faculty Sponsor, if required, should sign the Investigator's Assurance form.
- ☐ All Departmental and/or Research Unit approvals must be secured.
- ☐ If using an experimental drug/device, the IND or IDE number and filing date are provided in Appendix J or Appendix K and listed on the Investigator's Brochure or Master Protocol.
- ☐ All potential co-investigators and research personnel have been listed as appropriate (in application and protocol narrative, on consent if involved in the informed consent process). Each research team member's role on the project is clearly defined in the narrative. Also, all have completed the required training (Human Research (CITI) and HIPAA, if applicable).
- ☐ The purpose of the research is explained adequately.
- ☐ The subject population and sample size is justified in the context of the proposed research (consider providing a power analysis, if appropriate).
- ☐ Equitable inclusion of women and minorities has been assured and/or addressed in the narrative.
- ☐ The proposed recruitment and consent methods guarantee voluntary participation. If the proposed subject population may be vulnerable to coercion, explain how this will be minimized.
- ☐ Subject inclusion/exclusion criteria explained in the narrative and consent in sufficient detail.
- ☐ Adverse event reporting and treatment is addressed.
- ☐ All research activities involving subjects are thoroughly explained.
- ☐ Probable risks to participants and potential benefits to participant and society are considered and adequately described in the narrative and consent.
- ☐ The consent form addresses all areas required by federal regulations and is written at an eighth-grade reading level.
- ☐ Data collection instruments and/or instrument citations are provided in the narrative.
- ☐ If research will take place off site, proper documentation (e.g., letter of cooperation, Federalwide Assurance number, off-site research agreement, etc.) has been obtained or is in progress.
- ☐ If research will be funded by an external sponsor (grant, contract, or gift), proposal paperwork has been filed with Sponsored Projects.
- ☐ All applicable approvals from other regulatory committee reviews have been obtained or are in process.
- ☐ Recommended Reading, "Top Ten Reasons Why Protocols are Deferred.".

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We're on the Web!:
http://www.research.uci.edu/ora/hrpp/index.htm

Education & Reminders:

Information Commonly Requested

A new section has been added to the "Applications and Forms" page of the Human Research Protections (HRP) webpage.

The new section is titled, "Documentation / Information Commonly Requested by Sponsors or Researchers" and contains template letters or documentation of various UCI policies and procedures related to HRP.

For instance, often, after an IRB meeting, we receive phone calls from researchers requesting confirmation that those IRB members who are also co-researchers on a protocol, were recused from the IRB meeting discussion and vote. Now, we have generated a template letter which addresses this issue.

Please take a moment to check out this new section. If you have suggestions for other documentation that is commonly requested by sponsors, please send your comments to Beverley Esparza at besparza@uci.edu.