### Revision to UC Irvine’s Human Research Education Program

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As part of our efforts to promote the highest ethical standards in the conduct of research, UCI is revising the education requirements for investigators who engage in research involving human subjects. The new education requirement applies to all faculty, staff, and students who serve as lead researchers, co-researchers, research personnel or faculty sponsors at UCI.

- **UCI’s Human Research Protections unit in the Office of Research is adopting the Collaborative Institutional Training Initiative (CITI) modules as our new web-based human research protections education program.**
  
  Two Basic Human Research Training courses are offered, one for Biomedical Investigators and one for Social & Behavioral Investigators. Individuals choose the course that best matches their research activities.

- **Investigators are now required to complete a CITI refresher course every five years in order to conduct research involving human subjects. There are two Refresher Human Research Training courses, a biomedical version and a social & behavioral version. Again, individuals choose the course that best matches their research activities.**

The CITI program is available at [https://www.citiprogram.org/default.asp](https://www.citiprogram.org/default.asp).

**When do these new changes take effect?**

**Effective October 15, 2011** individuals who have not previously completed the UCI Human Research Tutorial are required to complete either the CITI Basic Human Research Training course for Biomedical Investigators or for Social & Behavioral Investigators before they can be listed on a new IRB Application or added to an active, ongoing IRB-approved study.

**Effective January 15, 2012** individuals who completed the Human Research Tutorial more than five years ago are required to complete either the CITI Refresher course for Biomedical Investigators or for Social & Behavioral Investigators before they can be listed on a new IRB submission or added to an active, ongoing IRB-approved study. Failure to complete a CITI Refresher course may delay review and approval of modification requests, continuing review applications, and new IRB Applications.

**NOTE:** Completing the existing Human Research Tutorial again is not sufficient to meet this requirement.

You can review when you last completed the Human Research Tutorial at [http://apps.research.uci.edu/tutorialcheck/](http://apps.research.uci.edu/tutorialcheck/). Individuals who completed the Human Research tutorial more than five years ago will also be sent courtesy reminder notices.

A [Frequently Asked Questions](#) web page has been developed to provide individuals with further details about the CITI courses.

If there are additional questions regarding the new policy or the CITI courses, please contact the Human Research Protections staff.
The Association for Accreditation of Human Research Protection Programs, Inc. (AAHRPP) has confirmed that UCI’s Human Research Protection Program has received full AAHRPP accreditation for five years!!!

Thank you for your involvement and support!!

CHANGES TO OTHER COMMITTEE REVIEWS

COIOC

EFFECTIVE IMMEDIATELY there are changes to the Conflict of Interest Oversight Committee (COIOC) and the Institutional Review Board (IRB) review process.

NEW STUDIES: In order to facilitate the review process, for new studies only, IRB review may run concurrent with COIOC review. A new study will not be granted a conditional approval however until the IRB has reviewed the COIOC report and suggested language for the consent form as accepted by the Associate Vice Chancellor for Research. If this report is not available at the time of IRB review, the study will be tabled pending receipt of the COIOC report, documenting the COIOC recommendations. Once the COIOC report is received, the study (along with the COIOC report) will be re-presented to the IRB for review. The IRB has final authority to determine whether the management plan related to the disclosable financial interest is sufficient to prevent financial interests from adversely affecting the rights and welfare of human research subjects.

MODIFICATIONS (e-MODs) AND CONTINUING PROTOCOL APPLICATIONS (e-CPAs): For e-MODs and e-CPAs, IRB review will continue to be on hold pending COIOC review and acceptance of the COIOC recommendations by the Associate Vice Chancellor for Research. This process continues to be the most facilitative for researchers. The IRB has final authority to determine whether the management plan related to the disclosable financial interest is sufficient to prevent financial interests from adversely affecting the rights and welfare of human research subjects.

To ensure that IRB submissions are reviewed in a timely manner, it is strongly recommended that Lead Researchers (when reporting disclosable financial interests for themselves or other research personnel) submit their IRB documentation including the COI disclosure information to the Office of Research Administration by the COIOC deadline. COIOC and IRB deadlines are posted on the ORA Calendar.

RSC

EFFECTIVE OCTOBER 1, 2011 you will note changes to the Radiation and Safety Committee as it relates to the IRB review process.

NEW STUDIES AND e-MODs: New IRB applications that include research procedures involving radioactive materials or radiation-producing machines and modification requests that add research procedures involving radiation must obtain Radiation Safety Committee (RSC) approval before IRB review. The IRB will review the results of the RSC before granting approval.

For more information on this topic, as well as important reminders about other required committees, visit the HRP website and refer to the subsection titled, “Other Required UCI Reviews”.

FALL 2011
Does Your Project Require Prospective IRB Approval?

The UCI Institutional Review Board (IRB) is a committee of scientists and non-scientists, responsible for the prospective review and approval of all human subject research at UCI. This includes all interventions and interactions with human subjects for research, including advertising, recruitment and/or screening of potential subjects.

**Example:**

An undergraduate psychology major decides to investigate students’ perspectives on their own ethnic and gender identity. The student hopes to present her findings at the Undergraduate Research Opportunities Program (UROP) and possibly have a publication to list on her application to graduate school. The undergraduate investigator designs an experiment. She posts recruitment flyers around campus, conducts face to face interviews with about 20 student volunteers, analyzes the data, and writes a summary.

This activity constitutes human subjects research. The student is conducting a systematic investigation (e.g., interviews), designed to contribute to generalizable knowledge (e.g., presenting at UROP, possible future publications). The student will obtain data through communication and interaction with human subjects (e.g., interviews) for research purposes. Prior IRB review and approval is required.

The UCI IRB prospectively reviews all study materials, including recruitment flyers, informed consent documents including consent scripts, online web surveys, interview questions, and questionnaires. All members of the study team who are conducting human subject research must be listed on the UCI IRB approved version of the Protocol Narrative, PRIOR to engaging in human subject research.

**What Types of Approval does the IRB Issue?**

- Exempt registration is granted if a study meets one of the six exempt categories. Exempt research involves the lowest level of risk to subjects (e.g., anonymous survey).

- Expedited approval is generally granted if a study involves no more than minimal risk to subjects and meets one of the seven expedited categories of research for new studies (i.e. face-to-face interviews, studies involving auditory or visual stimuli).

**How Long Does IRB Approval Last?**

Human research studies granted Exempt registration are registered for 3 years. Human research studies granted Expedited approval require at least annual IRB review.

To continue an Expedited research project, an application for continuing review must be submitted to the UCI IRB in advance of the study expiration. If a researcher fails to submit an electronic Continuing Protocol Application (e-CPA) to the IRB or the IRB does not approve continuation of the research before the date of expiration, the research, including all research activities must stop.

**On Line Resources:**

For more information, including examples of educational activities that do not involve Human Subject Research, please see the definition of human subjects research.

For more information about the continuing review process, please review the following page:

http://www.research.uci.edu/ora/hrpp/continuingprotocolapproval.htm

We also encourage you to contact the HRP Staff if you have questions.
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### Education & Reminders:  
**Tips from HRP Staff**

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**DRUG LOGS**

HRP Staff Member Valerie Sanchez wants to remind the research community to submit their Drug Logs when the research project involves investigational drugs.

**WHY?**

Research involving the use of investigational test articles (i.e., investigational drugs, biologics or devices) requires that the Investigator or other appropriate individual or entity (e.g., hospital pharmacy), provide appropriate control of test articles.

The Drug Log meets this requirement for documentation purposes and is required if the study includes an investigational drug or biologic.

**SAMPLE: Drug/Biologic Accountability Log**

For more information on this topic, as well as important reminders related to the use of investigational devices, visit the HRP Website and refer to the subsection titled, “Drugs, Biologics and Devices”.

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**Human Research Protections**

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**We’re on the Web!**  