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**Changes to Conflict of Interest Regulations for PHS Funded Research**

Last summer, the U.S. Department of Health and Human Services issued revisions to the Public Health Service (PHS) regulations regarding the disclosure, review, reporting and management of personal financial conflicts of interest. **Institutions such as UCI that apply for and receive research support from PHS agencies (i.e., NIH, CDC, HRSA, SAMHSA, AHRQ, and FDA) must follow and comply with the revised regulations starting August 24, 2012.**

The revised regulations entitled, “Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought,” differ in many ways from the existing rules for disclosure and review of personal financial interests related to PHS funded research. [NIH Guide Notice Number NOT-OD-11-109](http://www.nih.gov) includes a chart that highlights the major changes between the 1995 regulations and those that take effect on August 24, 2012.

UCI is currently working on several initiatives designed to make compliance as efficient as possible including development of a campus implementation policy that aligns as closely as possible to the regulatory requirements. The procedures for disclosing personal financial interest will undergo change as well and the Office of Research is currently updating and revising its conflict of interest disclosure forms to satisfy the revised regulations. The lowering of disclosure thresholds and expanding the disclosure requirement to financial interests related to one’s institutional responsibilities coupled with the addition of mandatory training, public accessibility and new management plan reporting and monitoring requirements will place new burdens on the campus and its research community. Complete information about the 2011 revised regulations including a very useful set of FAQs prepared by the NIH is available from the [NIH Financial Conflict of Interest webpage](http://www.nih.gov).

**IRB 101—A Workshop for the New Submitter**

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**Remember that Conflict of Interest Oversight Committee (COIOC) clearance is required for IRB approval— so researchers must be sure to follow these revised regulations or possibly face delay in the IRB review and approval of their protocols.** If you have any questions please do not hesitate to contact Administrator Grace Park at parkgj@uci.edu or at x47218.

**IRB 101— A Workshop for the New Submitter**

Human Research Protections (HRP) staff are conducting a hands-on workshop for individuals new to the IRB submission process (or those who need a refresher). The purpose of this 90-minute workshop is to provide researchers and research staff with the resources they need to submit a complete IRB application package. For more information on this monthly course and to sign up for the workshop, visit the [UC Learning Center](http://www.uclearningcenter.org).
They are Vulnerable: Pregnant women and human fetuses are considered a “vulnerable” research population. As such, additional protections are in place for all human subjects research involving this population. Research involving the human fetus raises special concerns. The fetus has a unique and inextricable relationship to the mother. Obviously, assent cannot be obtained from the research subject. Further, pregnant women have traditionally been excluded from research, including research that may directly benefit the woman or her fetus. Given the potential significance of obtaining biomedical knowledge through the inclusion of this special population, researchers and the IRB must consider whether it is appropriate to include this population and the additional measures of protection needed.

Regulatory Considerations: Federal Regulations regarding pregnant women and fetuses (45 CFR Part, Subpart B) specify under what conditions pregnant women and their fetuses may be enrolled in human subject research conducted or supported by the Department of Health and Human Services (DHHS). At UCI, commiserate protections are in place for non-DHHS supported research. Although the FDA does not specifically address the inclusion of pregnant women and fetuses in a clinical investigation, if the proposed research involves FDA-regulated products, the FDA’s regulations at 21 CFR 50 Subparts A, B and 21 CFR 312, 812 apply.

Per 45 CFR 46.204 (b) – Any non-exempt research specifically involving pregnant women without the prospect of direct benefit to the pregnant woman or fetus may only be approved when:

⇒ the risk to the fetus is no greater than minimal

AND

⇒ the purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means

For minimal risk research, the IRB will not review a protocol under Subpart B, unless the protocol specifically states that pregnant women will be included. For those studies, should a research team wish to add pregnant women as a subject population, submission of a modification request to the IRB is required. The IRB will then review the request per the regulations under Subpart B.

For full committee research, the IRB will review each protocol under subpart B, if pregnant women are included. Should pregnant women be excluded, scientific justification must be provided to the IRB (e.g., the drug has known teratogenic effects, the risk to the fetus would involve greater than minimal risk, the target population includes subjects over the age of 70).

UCI IRB Documentation: Investigators interested in studying pregnant women and their fetuses are required to complete Appendix B when completing an IRB Application or when requesting to add the subject population by submitting a modification to the IRB-approved study. The IRB will complete a Supplemental Reviewer’s Checklist as part of their review, assessing the level of risk posed to the subjects and, if appropriate to include the subjects whether only the mother, or both the mother and father’s consent is required.
ATTENTION: The UC HIPAA Research Authorization form is not the same as the Notice of Privacy Practices Form that UCI Medical Center patients sign prior to receiving clinical care. UC patients sign the Notice of Privacy Practices Form. UC research subjects sign the UC HIPAA Research Authorization form.

When University of California (UC) HIPAA Research Authorization is required by the UCI IRB, the research team must obtain the required signatures on this specific UC form. The form includes the Heading, “University of California- Permission to Use Personal Health Information for Research.” UC is a HIPAA hybrid covered entity. UC is considered a Single Health Care Component (SHCC) for the purposes of complying with the HIPAA Rule. All UC entities covered by the HIPAA Privacy and Security Rules (i.e., medical centers, medical clinics, health care providers, health plans, student health centers) comprise the single entity. However, research is not covered under the single entity therefore a separate HIPAA Research Authorization is required.

Therefore, when a researcher conducting research pursuant to an IRB-approved protocol wants to obtain Protected Health Information (PHI) from records maintained by a SHCC (such as those found in a hospital’s medical records department) or collect information obtained during a clinical visit, the Privacy Rule requires that the SHCC receive assurances from the Privacy Board (at UCI the IRB serves as the Privacy Board), and/or researcher that either:

- the subject has authorized the use of PHI for research (by signing a study specific UC HIPAA Research Authorization form);
- the IRB has waived the research authorization based on specific waiver criteria; or
- the researcher is requesting only a limited or de-identified set of information.

MORE ABOUT UC HIPAA RESEARCH AUTHORIZATION ...

UCI takes subject privacy seriously.

Consider these important points about the UC HIPAA Research Authorization Form.

- The UCI IRB Approval Letter specifies whether or not UC HIPAA Research Authorization is required.

- The UC HIPAA Research Authorization Form cannot be altered. Except for the “fill in the blanks” as allowed by the template (e.g. study title, name of lead researcher, etc.), the UC HIPAA Research Authorization Form cannot be changed. This form was developed by the UC Office of the President for compliance with HIPAA and other applicable laws.

- REAL LIFE EXAMPLE: A UCI Researcher recently discovered that the research team was erroneously using the Notice of Privacy Practices Form to obtain HIPAA Research Authorization. As HIPAA Research Authorization was not obtained using the correct form, the IRB determined that it was necessary to secure HIPAA Research Authorization or the data collected could not be used for research purposes- including presentations, publications, and thesis work.
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Education & Reminders:  
IRB Member Rosters

Many Sponsors ask for a copy of the IRB Roster at the time of IRB review.

The IRB Roster is available on the Human Research Protections website.

The IRB Roster is updated as IRB membership changes.

Accordingly, be sure to print a copy of the IRB Roster at the time of review for your research team’s protocol.

Education & Reminders:  
Enrollment

Section 4 of the Protocol Narrative specifies the maximum number of subjects to be recruited as part of the study protocol. Please remember that the maximum number of potential subjects includes screen failures and early withdrawals.

Once an individual signs the Consent Form, they are considered “enrolled” in the research study, regardless if they later screen fail or withdraw.

Be mindful of this as the study continues, as the maximum number of subjects may need increase to accommodate screen failures or withdrawals.

To increase sample size, a modification must be prospectively submitted to the UCI IRB for approval.

Human Research Protections

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