



SPRING 2009

Preparing for a Routine Audit

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Tips from the Office of Research Oversight

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To ensure ongoing monitoring of human subject clinical and non-clinical research programs, the School of Medicine [SOM] established the Office of Research Oversight [ORO] to provide education and oversight services for its research programs. The ORO operates within the Health Affairs Compliance Program and is responsible for monitoring the research protocols conducted by School of Medicine faculty for compliance.

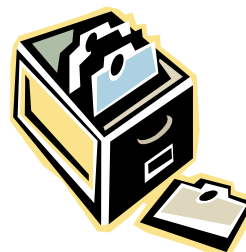
The ORO staff performs up to 50 routine audits of active UCI IRB approved research protocols annually. Protocol selection is generally a random process performed through periodic review of the IRB list of approved protocols. It is the goal of the ORO to review a sampling of studies from each department every 2 years. Additional assigned audits may also be performed as directed.

IRB-related findings identified in the ORO audit report are sent to Human Research Protections in the Office of Research Administration for follow up. Clinical and/or non-clinical-related issues are referred to the appropriate

SOM and/or Medical Center Department for follow-up. All research records are University property. Accordingly, researchers are required by University policy to keep their research records on site at all times for access by authorized agents of the Federal and State governments, the sponsor and the University.

Audit Readiness ... Things to Remember:

1. Have written policies and procedures for managing the protocol;
2. Create investigator and study staff signature and responsibility logs specific to each protocol;
3. Maintain protocol specific training logs for investigators and study staff;
4. Create checklists for assuring that all required documents and forms (IRB approved informed consent, protocol narrative, recruitment materials, research HIPAA Authorization, Surrogate Self Certification Form, Spon-



sored Projects approval, translated documents, ICTS Scientific Review, as required, etc.) are identified for the study, approved and on file prior to enrolling subjects;

5. Make sure documentation of the informed consenting process following UCI hospital guidelines is entered on the *Interdisciplinary or Faculty Practice Note* in the clinic/medical record, and copied to the research record; and
6. Document in the research, clinic and medical record each time a subject is seen for the study.

Thanks especially to Sherry Reece, Regulatory Affairs Specialist & Andrew Walton, Research Compliance Officer in the Office of Research Oversight for contributing this article.

In the next HRPP News Brief: stay tuned for more ORO tips on essential research documents...

UCI IRB Statistics for 2008

Did you know that the UCI Human Research Protections Program (HRPP) had **2112** active IRB research protocols during the 2008 calendar year? This is **3%** increase over 2007!

By Committee, IRB A (Biomedical) received **1229** total transactions, including new study reviews, modification requests, continuing reviews and adverse events / unanticipated problems reports. IRB B (Biomedical) received **1312** transactions and IRB C (Social –Behavioral) received **1068** transactions. This is a total of over **3600** transactions for 2008.

The average **turn around time** from submission to approval for new IRB applications requiring **Full Committee review** across all Committees was **32** working days. For new IRB applications requiring **exempt or expedited review**, the average **turn around time** from submission to approval was **24** working days. The IRBs and the HRP staff look forward to working with investigators in 2009 to facilitate the research goals of UCI!

Active IRB Protocols for 2008

Full Board	437
Expedited	1043
Exempt	632
<hr/>	
	2112



Request for Determination of Non-Human Subjects Research Form

Federal regulations and UC/UCI policies require IRB review of research involving human subjects.

If you are not sure if your research qualifies as human subject research, complete the Request for Determination of Non-Human Subjects Research Form,



available on the ORA website:
<http://www.research.uci.edu/ora/forms/hrpp/nonhsreview.doc>

Mail the completed form to the UCI IRB, Office of Research Administration, 300 University Tower, Zot Code 7600.

You may also scan the completed form and send by e-mail to irb@rgs.uci.edu.

The Human Research Protections staff will review this form and advise the Researcher via e-mail as to whether or not their research requires the submission of a New Study Application to the IRB.

Vulnerable Populations: Prisoners in Research

WHAT IS A "PRISONER"?	WHY ARE THEY CONSIDERED "VULNERABLE"?	WHAT TYPE OF PRISONERS MAY PARTICIPATE IN...
<ul style="list-style-type: none"> Any individual involuntarily confined or detained in a penal institution; Any individual sentenced to such an institution under a criminal or civil statute; Individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution; and Individuals detained pending arraignment, trial, or sentencing. Note if a subject becomes a prisoner at any time during a research study, submission of a modification request for inclusion of prisoners as a subject population is required unless the population included in the approved protocol. 	<ul style="list-style-type: none"> Prisoners have limited autonomy. They may be under constraints because of their incarceration, which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research. 	<ul style="list-style-type: none"> Research studies involving <i>minimal risk with</i> reference to physical or psychological harm, as opposed to harm or discomfort, to risks normally encountered in the daily lives, or routine medical, dental or psychological examination of healthy persons Studies of the possible causes, effects, and processes of incarceration, and of criminal behavior Studies of prisons as institutional structures or of prisoners as incarcerated persons Research on conditions particularly affecting prisoners as a class provided that the study may proceed only after consultation with, and approval by the HHS Secretary (through OHRP) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after consultation with, and approval by the HHS Secretary (through OHRP) Studies of epidemiologic research that describe the prevalence or incidence of a disease by identifying all cases or studies of the potential risk factor associations for a disease, where prisoners are not the particular focus of the research

Vulnerable Populations: Prisoners in Research...continued...

Investigators interested in enrolling prisoners as research subjects must complete **Appendix C** when completing the electronic IRB Application or when requesting a modification to an IRB-approved study.

Research studies involving any interaction/intervention with prisoners requires initial full Committee review. **Note that the use of prisoners in biomedical research is prohibited. Biomedical research is defined by CA law as, "research relating to or involving biological, medical or physical science."**

For studies supported by the Department of Health and Human Services, the UCI must certify to the Secretary (through OHRP) that the IRB has made the seven findings required under 45 CFR 46.305(a), including the finding that the proposed research represents one of the permissible categories of research under 45 CFR 46.306(a)(2). For more information on this process, please refer to the following link: <http://www.hhs.gov/ohrp/special/prisoners/>

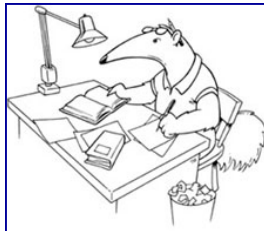
For more information on prisoner research, visit the Office for Human Research Protection's (OHRP) FAQ page: <http://www.hhs.gov/ohrp/prisonerfaq.html> or visit the Office of Research Administration at: <http://www.rgs.uci.edu/ora/rp/hrpp/vulnerablesubjectpopulations.htm#Prisoners>

The HRP Staff Pre-Review Process

WHAT IS IRB PRE-REVIEW?

HRP Staff conduct a thorough pre-review of all submissions submitted to the IRB.

The HRP Staff processes each submission and reviews each item for completeness. The HRP staff not only ensure that Federal and State



regulations for human subjects protections have been met but that all applicable UCI IRB policies and procedures have been addressed.

In addition the HRP staff, when necessary, assist investigators with formatting and updating the consent form for language, grammar and spelling to help ensure its readability.

The pre-review process is a collaborative process between the HRP Staff and the Lead Researchers and Administrative Contacts to help ensure that the submission is accurate and comprehensive prior to IRB review.

The goal is to help facilitate the review process by reducing the possibility that a protocol may be tabled by the Full Committee because substantial modifica-

tions and/or additional information (e.g., details, clarification, justifications) are required that are directly relevant to the Criteria for IRB approval (45 CFR 46.111 and 21 CFR 56.111).

IS AN INVESTIGATOR REQUIRED TO RESPOND TO A PRE-REVIEW MEMO?

No, investigators do not have to respond to the IRB Staff pre-review comments however it is strongly recommended. These comments, which are forwarded to the IRB, reflect issues noted by the IRB Staff, based on their experience and expertise. It is important to note, however, that the HRP Staff comments may not reflect the final determination of the Committee.

As such, Lead Researchers may receive additional comments from the IRB within 10 working days after the meeting.

DEADLINE TO RESPOND TO PRE-REVIEW COMMENTS

With the new IRB Full Committee deadlines now falling on Tuesdays in 2009, the HRP Staff will provide Lead Researchers and Administrative Contacts firm deadlines to respond to pre-review comments.

The Research Team must reply to Staff comments by the specified deadline for the response to be sent to the

full Committee.

This deadline will allow HRP Staff enough time to not only review the Research Team's response, but also allow sufficient time for the response to be sent to the entire committee for their consideration.

Per OHRP guidance, IRB members must be afforded sufficient time to review the IRB materials. The HRP Staff appreciates the research community's understanding in working within these deadlines to address any pre-review comments.

If you have any questions about HRP Staff pre-review comments, feel free to contact HRP Staff directly—they are not only here to protect human subjects—they want to help facilitate your research!

Contact information for all IRB Staff can be found on Page 4 of this News Brief.

"With the new IRB Full Committee deadlines now falling on Tuesdays in 2009, the HRP Staff will provide Lead Researchers and Administrative Contacts a firm deadline to respond to pre-review comments."



Friendly Reminders...

- **Effective February 1, 2009 -** new IRB applications must include the latest version of the protocol narrative

(December 2008).

- Applications submitted with an older narrative format will be held pending submission of the appropriate narrative.
- Don't forget to open, review and save all of your latest, IRB-approved documents which can be found in the IRB Document Depot @ <http://apps.research.uci.edu/irbdocs/>. Please make sure to save each version as part of your record-keeping responsibilities. Remember, only the LATEST version will be maintained in the Document Depot. Once a new modification or continuing application is approved, the previous approval letter and documents will be removed from the Document Depot.
- Use the working draft versions available on the IRB Document Depot when submitting modification requests and continuing review applications. Submission of incorrect versions will delay review and approval.



In the News...

A recent New York Times Article released on January 18, 2009, titled, "[*Test Subjects Who Call the Scientist Mom or Dad*](#)" raises some important ethical questions.

Is it appropriate for a researcher to enroll their own children in a research study? Is there an inherent conflict of interest? If so, can researcher bias possibly be avoided? Should researchers be required to disclose to the IRB that they will use their own children as research subjects?

What do you think?

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We're on the web!

<http://www.research.uci.edu/ora/hrpp/index.htm>

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The Office is Open:

Monday—Friday
8am—5pm

Note: ORA is now open from Noon -1:00pm