



FALL 2009

IRB Registration with the FDA

Inside this issue:



UCI's Institutional Review Boards (IRBs) have successfully registered with the Food and Drug Administration (FDA) in compliance with the new FDA rule issued on July 14, 2009. The rule requires all U.S. IRBs reviewing clinical investigations involving FDA-regulated products to register with the FDA.

IRB Registration with the FDA	1	<p>FDA's new requirement operates in coordination with the Office for Human Research Protections (OHRP), which already requires registration for IRBs reviewing federally-supported research. A single database of all U.S. IRBs, regardless of whether they review research regulated by FDA or other federal agencies, has been established.</p>
Incomplete IRB Submissions	1	<p>IRBs are required to renew registration every three years, or sooner if contact information changes. IRB registration does not represent accreditation or certification by FDA or OHRP. The agencies do not provide certificates confirming an IRB's registration.</p> <p>IRB Organization number (IORG):</p> <ul style="list-style-type: none"> ◆ UCI's IORG is 0000236 <p>IRB registration number:</p> <ul style="list-style-type: none"> ◆ IRB00000393 UCI IRB "A" Biomedical ◆ IRB00000394 UCI IRB "B" - Biomedical ◆ IRB00000395 UCI IRB "C" - Social Behavioral
Meet the IRB "C" Chair!	2	
The 7 Year De Novo Review	3	<p>Please note that these numbers are linked to both FDA and OHRP registrations.</p>
IRB Staff Contact Information	4	<p>For additional information, please view the Federal Register and FDA's FAQs Regarding IRB Registration, or contact the HRP staff.</p> <p>UC Irvine's Registration information can also be accessed via OHRP's online database.</p>
Incomplete IRB Submissions		
Limited Data Sets	4	<p>Incomplete protocol submissions will be held from IRB review pending submission of the required documentation. The following criteria will be used to determine when a submission is incomplete:</p> <ul style="list-style-type: none"> ◆ Two or more required appendices missing ◆ Incomplete Protocol Narrative (3 or more sections seriously incomplete) ◆ Missing Master Protocol or Investigator's Brochure ◆ Missing Consent Form or seriously incomplete document ◆ Missing Assent Form or seriously incomplete document
HIPAA Research Forms	4	

If an incomplete submission is submitted for full Committee review, the HRP staff -with the confirmation of the IRB Chair- will pull the submission from the full Committee agenda. The HRP staff will inform the researcher in writing of the incomplete submission.

As always, the HRP Staff are available to assist researchers and the study teams to help ensure that their submission is complete and ready for the IRB review.



Meet Dr. Mulnard – Chair of IRB C!

How did you become involved with IRB “C”? How were you appointed Chair?

I was a member of IRB A. Under previous IRB leadership, I was asked to be the temporary chair of IRB C. It is nine years later.

What is your expertise in social-behavioral research and the protection of human research subjects?

It comes from my background in nursing. Both the basic and advanced level of nursing education provides a very broad interdisciplinary range of coursework to support the nurse’s role in treating the whole patient from the bio-psycho-social perspective. My expertise in human research protections was initiated in 1992 when I joined the IRB here at UCI, and has been further developed during my 9 years as Chair of IRB C. In addition, I have taught courses for UNEX on human subjects safety, good clinical practices, and a clinical trials internship. I also consult for the Association for the Accreditation of Human Research Protection Programs (AAHRPP) as a site visitor and team leader for the accreditation of IRBs at other institutions.



What is your expertise in biomedical research, specifically the surrogate consenting process?

I spent two years (2001-2002), along with a colleague from UCSD, working with the UCOP and with the legislative process in Sacramento to write, invoke and implement the surrogate consent law that is currently in place for adults. Our interest in changing this law was inspired by our research and advocacy work with the community of individuals with cognitive impairment, particularly Alzheimer’s disease and related dementias.

What do you believe is the biggest misconception about the IRB?

I think the biggest conception is that investigators do not believe that the IRB is here to partner with them and facilitate their research, but instead see the IRB as an insurmountable barrier to their research.

Do you have any advice for new researchers at UCI?

Reach out to the office: chairs, staff, etc. to get some hands on assistance with your first protocol submission. Everything will be easier after the first positive experience.

What is the hardest part of being an IRB Chair?

Dealing with frustrations from the investigators can be challenging. Sometimes, investigators face difficulties with their submissions but we want them to know that the IRB Staff are here to facilitate.

What is the most rewarding part of being an IRB Chair?

Knowing that we help to facilitate a tremendous breadth of research here at UCI while still protecting all of the participants to the best of our ability.

Is there anything else you want the UCI Researchers to know about the IRB?

The message is that the IRB is here to work with researchers. We invite contact and interaction. By working together, it will reduce frustrations on both sides and investigators can be more successful.

Is IRB “C” looking for new members?

We always invite any individual who is interested in serving to contact us. At the present time, we have just filled our last crucial seat on the IRB, but always need new members as others complete their term of service.

The Seven-Year De Novo Review

Changes to the IRB Continuing Review Process

In order to ensure that research protocols continue to meet current regulatory and institutional standards, protocols will be required to undergo a “Seven-Year De Novo Review” every seven years effective **February 1, 2010**.

This will involve two changes:

First, Lead Researchers will still submit their annual continuing review as usual; however any protocol in its 6th year of approval or beyond for this first cycle (i.e., approved February 1, 2003 or earlier), will require submission of updated IRB documentation. This will include:

- ◆ Updating the protocol narrative to the most current version of the protocol narrative available at the [IRB Forms](#) page
- ◆ Ensuring that the consent form or study information sheet meets the most current consent/study information sheet requirements. The consent templates are available at the [IRB Forms](#) page and requirements are available at the [Informed Consent Preparation](#) website.
- ◆ Submitting all documentation for the protocol review such as any data collection instruments, recruitment materials, etc. This includes re-submission of any applicable IRB appendices.

This may involve providing new information that has not been previously requested and therefore, not previously reviewed by the Committee. As with any IRB review, studies are required to meet the current regulatory requirements, as well as UC/ UCI policies and procedures.

Second, in order to track the number of Seven-Year De Novo Review Cycles, the Human Subjects Protocol Number (HS#) for all protocols will be expanded. Protocols that have not yet undergone Seven-Year De Novo review will have a number such as HS# 2009-9999-0 to show that the protocol is in its first review cycle. Upon approval after the Seven-Year De Novo Review in seven years, the last digit will be updated to 2009-9999-1.

Exceptions to the Seven-Year De Novo Review Requirement—

- ◆ Expedited Category 8a: Continuing review of research *previously approved by the convened IRB* where
 - the research is permanently closed to the enrollment of new subjects;
 - all subjects have completed all research-related interventions; and
 - the research remains active only for long-term follow-up of subjects.
- ◆ Expedited Category 8c: Continuing review of research *previously approved by the convened IRB* where the remaining research activities are limited to data analysis
- ◆ Any other Expedited level research where the research activities are limited to long-term follow-up of subjects or data analysis of identifiable private information

Questions about the Seven-Year De Novo Review Process?

For questions about the Seven-Year De Novo IRB review process you may contact Karen Allen, Director of Human Research Protections at 949-824-1558 or karen.allen@uci.edu.

**Institutional Review Board "A"
Biomedical**

Matt Kinder
Administrator
949-824-9819
mkinder@uci.edu

OPEN POSITION
Analyst

Timothy Grigsby
Assistant
949-824-6068
Tim.grigsby@research.uci.edu

**Institutional Review Board "B"
Biomedical**

Valerie Sanchez
Administrator
949-824-7109
vmiran@uci.edu

Cheree DuBose
Analyst
949-824-5622
cheree.dubose@research.uci.edu

Theresa Sanchez
Assistant
949-824-2125
tmsanche@uci.edu

**Institutional Review Board "C"
Social - Behavioral**

Jessica Sheldon
Administrator
949-824-4779
jessica.sheldon@uci.edu

Alicia Asgari
Analyst
949-824-7114
ateiman@uci.edu

Matthew Alcala
Assistant
949-824-6662
Matthew.alcala@research.uci.edu

**IRB Team "D"
Biomedical Expedited
and Exempt Submissions**

Laverne Estanol
Administrator
949-824-3831
lestanol@uci.edu

Kristina Grimaldi
Analyst
949-824-5057
Kristina.grimaldi@research.uci.edu

Kin Hang
Assistant
949-824-0665
kkhang@uci.edu

Karen Allen
Director
Human Research Protections
949-824-1558
kallen@uci.edu

Beverley Esparza
Assistant Director
Human Research Protections
949-824-5746
besparza@uci.edu

**U.S. Mail:
Human Research
Protection Program**
Office of Research Administration
University of California, Irvine
300 University Tower
Irvine, CA 92697-7600

**The Office is Open:
Monday—Friday
8am—5pm**

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

What is a Limited Data Set?

A limited data set (LDS) may be used for research purposes. A LDS excludes 16 of the 18 Protected Health Information (PHI) identifiers. In particular, a LDS may include:

- Dates of birth
- Dates of death
- Dates of service
- Town or city
- State
- Zip code

A LDS is an exception to the Privacy Rule requirement for an authorization from the patient for research use of protected health information. For more information about HIPAA and PHI visit the HRP website:
<http://www.research.uci.edu/ora/hrpp/>



HIPAA and Research

Did you know...

Effective August 3, 2009, the IRB requires that for studies involving Protected Health Information (PHI), investigators must submit a completed **HIPAA Research Authorization Form with their IRB submission**, unless a waiver of HIPAA Authorization is being requested.

Once the study is approved, the HIPAA Research Authorization Form, along with other IRB approved documentation will be provided via the e-IRB Docs Depot.