



**UIC** UNIVERSITY OF ILLINOIS  
AT CHICAGO

## Office for the Protection of Research Subjects

July 2007 Newsletter

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*Eric A. Gislason*

### A Message from the Vice Chancellor for Research:

It is the mission of my office to facilitate and support research of superior quality at UIC. In keeping with that mission, I am pleased to announce that UIC will submit its application for accreditation to the Association for the Accreditation of Human Research Protection Programs (AAHRPP) in the fall of 2007. This monthly newsletter is designed to enhance communication between the Office for the Protection of Research Subjects (OPRS) and investigators as we prepare for our accreditation submission and site visit. The newsletter will focus on the new policies, forms, tools, and procedures affecting investigators as well as communicating the roles and responsibilities of researchers in the AAHRPP process.



## UIC AAHRPP accreditation - what investigators need to know

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Check back monthly for more AAHRPP news and information. Also visit the AAHRPP website at <http://www.aahrpp.org>

### What is AAHRPP?

The Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) is an independent agency that includes and partners with research participants and their organizations to promote ethically sound research by setting effective, reasonable standards and encouraging the use of best practices.

127 universities, hospitals, and independent research organizations have achieved accreditation with over 400 other institutions in the accreditation process.

Jesse Brown VAMC, in affiliation with UIC and Northwestern, has applied for accreditation. In 2008, UIC will apply for sole accreditation. AAHRPP's gold seal of accreditation will signify that UIC is committed to the most comprehensive protections for research participants and the highest quality research.

The AAHRPP team will visit UIC September 26-28, 2007 to review records and conduct interviews of IRB members, staff, and chairs, as well as investigators and research staff for the Jesse Brown VAMC accreditation. The site visit team also interviews coordinators, co-investigators, students, and other research staff, as well as key organizational officials.

### Why is this good for UIC?

The first step toward accreditation is a comprehensive self-evaluation of the institution's human subjects protection program. Gaps are identified, problems recognized, revisions to policies and forms go into effect, and the overall goal is improvement in the institution's Human Subject Protection (HSP) program.

With full accreditation, UIC moves into the top level of research institutions, proving our commitment to the welfare of individuals and the highest standards of ethical research.

This process becomes ongoing, and as the research world changes, we change with it, yet always with the subjects welfare at the forefront.

### What does this mean to you?

Accreditation and the high standard that this accreditation imposes signal to potential sponsors, potential researchers and potential research participants that UIC believes in and conducts reliable and respectable research. Accreditation may mean more opportunities for the research community at UIC.

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### New **POLICIES** affecting investigators

OPRS has posted new policies and guidance to the web site. To see the listing of all posted polices and guidance, visit the OPRS website at <http://tiger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/index.shtml>.

### **NEW!** Human Subjects Protection Program Manual v8.0:

[Weblink to manual](#)

The complete UIC Human Subjects Protection Program Manual is now available to investigators on-line. The manual is organized into five sections, including one for investigators. Need to know when you should apply for a certificate of confidentiality? Or, how do you close a study when you have completed your research? The table of contents is easy to read and is bookmarked for ease of use. And, the manual is a searchable .pdf document -- just type in a keyword to find the sections you need.

### **NEW!** Determining Whether Research or Other Activities Represent Human Subjects Research

[Weblink to policy](#)

[Weblink to form](#)

This new policy, "Determining Whether Research or Other Activities Represent Human Subject Research" replaces the guidance, "Definition of Human Research Subjects". To summarize, the policy takes the responsibility of determining whether or not an activity represents human subjects away from the investigator or department and gives the responsibility of the determination to the IRB and OPRS staff. Investigators who intend to conduct activities that might represent human subjects research must submit an application describing the proposed activities to the UIC OPRS for a human subject determination, except in limited circumstances in which the OPRS has waived this requirement. If an investigator believes the activity represents human subjects research, the investigator must submit the appropriate application in the usual manner.

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### **NEW!** Guidance - Data and Safety Monitoring Plans (DSMPs), Data and Safety Monitoring Boards (DSMBs), and Data Monitoring Committees (DMCs)

[Weblink to guidance](#)

This new, guidance document defines a data and safety monitoring plan, a data and safety monitoring board (DSMB) or data safety monitoring committee (DMC) and outlines when these might be necessary or required for a research protocol. Investigators can use this guidance document to understand the NIH and FDA requirements and the decision process the UIC IRB's may use in determining whether independent data safety monitoring may be required or recommended for their research.

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**New TOOLS for investigators**

OPRS has developed new tools to enhance communication with investigators.

**NEW! RiSC Web on-line information system for investigators**  
[Weblink to RiSCWeb](#)

**Use RiSCweb to:**

- Look up the status of your protocol
- View/Download OPRS correspondence
- Designate RiSCWeb protocol access to study coordinators or Co-Investigators by protocol
- View your training record
- Look up IRB meeting & deadline schedules

New users, create a login at <https://riscweb.ovcr.uic.edu/phase1/PasswordGenerator.aspx>.

**NEW! Study coordinator list serve**

OPRS has created two list serves for study coordinators: one for social & behavioral research (IRB 2) and one for biomedical research (IRB 1 & 3). OPRS will use these list serves to notify study coordinators of new policies, forms, updates and continuing education offerings.

To join the social & behavioral list serve, send an email to [listserv@uic.edu](mailto:listserv@uic.edu) with the text "subscribe irbcoordsb First\_name Last\_name" in the body of the email.

To join the biomedical list serve, send an email to [listserv@uic.edu](mailto:listserv@uic.edu) with the text "subscribe irbcoordbio First\_name Last\_name" in the body of the email.

Please note: Subscribers cannot post to this list serve; it is for OPRS/IRB information distribution only.

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**NEW! OPRS/IRB Suggestion Box**  
<mailto:uicirb@uic.edu>

OPRS would like your feedback! To send your feedback to OPRS, click on the email link above. OPRS will promptly respond to all emails. If you would like a response, make sure to include your email address. If you prefer your comments remain anonymous, the new suggestion box is now available on each page of the OPRS website.

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## Initial and continuing education **REQUIREMENTS** for investigators

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OPRS requires that investigators and key research personnel take initial training before conducting research. See this link for details:

<http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/education/index.shtml>.

Training also needs to be updated every two years with two Continuing Education credits. There are on-line courses on the OPRS website.

You can check your status anytime on RiSC Web (please make sure that you have created an account before logging in).

Over the next few months, OPRS will offer FDA audio conferences for CE credit. These conferences will be held in the OPRS conference room (AOB, suite 203) and will require a seating reservation. Call 312-996-1711 to reserve your spot.

**[August 16<sup>th</sup> from 12:00 - 2:00 pm \(2 CE credits\)](#)**

Adverse Event Compliance in Drug and Biologic Clinical Trials: *Know What to Report, When and How*

### **[Upcoming CE Opportunities](#)**

Check the OPRS website for dates/times

- Assure FDA Compliance: *Design and Execute Effective SOPs for Clinical Trials*
- Clinical Trial Quality Assurance: *Defining the Gold Standard.*
- Institutional Review Board Compliance: *Real-World Strategies for Sponsors, Investigators and IRBs*

### **Need CE Credit?**

- Does your department hold lectures that would be appropriate for Human Subjects Research Education credit?
- Have you heard of a program that you would like to see offered for Human Subjects Research Education credit?
- Will you be attending a conference that would apply to Human Subjects Research?

Please contact Laurie Kennard at 312-413-9175 to see if your program might apply.

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## *July FAQ*

**Q:** I want to make a change in my IRB-approved research study; what do I need to do?

**A: Complete an amendment form:** All changes in IRB approved research require the submission of an amendment form. Section 5 of the amendment form should not only list all proposed changes, but should provide the reason or justification for the changes.

**Revise study documents:** In addition to completing an amendment form, you should also modify all applicable study documents (research protocol, research application form, recruitment materials, consent and/or authorization forms as necessary) to reflect the changes being proposed in the amendment. When revising study documents, please follow the *Instructions for Amendments to Previously Approved Research*, available on the OPRS website at <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/forms/index.shtml>.

**Include sponsor's documents:** For sponsor-initiated amendments, you should also include any communication from the sponsor regarding the amendment, and a copy of the sponsor's amendment documents.

**Please note that a common cause of delay in approval of amendments is failure to include revised documents or sponsor's documents with the amendment form.**

Suzanne French

## **Top Ten Tips for Facilitating IRB Review of Your Research**

1. Be precise in your language
2. Pay attention to grammar and punctuation
3. Avoid deadline days
4. Obtain all of the necessary signatures
5. Include a research protocol with your application
6. Have someone independent of the research proof-read your documents
7. Ask OPRS for a pre-review
8. Allow adequate time for IRB review
9. Submit all appendices, recruitment and informed consent documents
10. Use the OPRS on-line resources

The full "Top Ten Tips" document, with explanations and hints for researchers, is available on the [Getting Started](#) page on the OPRS website.

Sophia Radlowski & Charles Hoehne

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