

# OFFICE FOR THE PROTECTION OF RESEARCH SUBJECTS

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## A MESSAGE FROM THE DIRECTOR OF THE OFFICE FOR THE PROTECTION OF RESEARCH SUBJECTS

Last February OPRS staff members, including myself, attended the AAHRPP conference in preparation for accreditation of UIC's Human Subjects Protection Program (HSPP). Although the focus of the AAHRPP conference was guiding HSPP's toward accreditation, the overall scope concentrated on making the IRB process simpler and more effective. As a UIC researcher I can appreciate the benefits of a simpler process and as director of OPRS, I continue to work toward making that process more effective.



James H. Fischer  
Director, OPRS

Several changes in OPRS that will be implemented in the coming months:

- UIC IRB 4 has been established to review protocols where the Jesse Brown Veterans Administration Medical Center (JBVAMC) is a performance site. This will reduce the workload of the two bio-medical boards, and serve to decrease turn around times.
- Policies and procedures manual update: an intuitive on-line index for quick access to investigator questions concerning IRB procedures and hyperlinks pinpointing topics of interest to researchers and coordinators.

Interim Vice Chancellor for Research Larry Danziger spoke at the *Bringing Administrators Together* Conference, held at the UIC Forum March 6<sup>th</sup> and 7<sup>th</sup>. In his address, Dr. Danziger reaffirmed OPRS's commitment to service to the UIC research community with the motto "Please call us anytime with questions."

OPRS is here to provide guidance for PIs in the following ways:

- OPRS Front Desk staff answer questions concerning submissions and deadlines, continuing education credits, and RiSC access.
- Coordinators are available to guide investigators through the submission process.
- The Assistant Directors deal with more complicated protocol-specific questions.
- The Associate Director and Director are available to meet with Investigators on questions concerning the IRB process and to assist in resolving problems .

OPRS looks forward to hearing from you.

**Beginning with this issue, the OPRS Newsletter will be bimonthly.**

**Apr/May    June/July    Aug/Sept    Oct/Nov    Dec/Jan    Feb/March**



## NEWS FOR INVESTIGATORS

Privacy=People / Confidentiality=Data

If something is private, then it must be confidential, and if something is confidential, then it must be private, right? From a human subject protections standpoint, the words are related but not interchangeable. The goal of this article is to explain how the terms differ and how these differences impact the review and conduct of research. In short, privacy pertains to people, while confidentiality pertains to data.

Privacy can be thought of in terms of allowing others access to oneself. For example, a subject may not want it known that they use a particular clinic or that they have certain life experiences. When privacy is violated, it can lead to an emotional reaction, particularly if the nature of the information disclosed is sensitive.

Confidentiality builds upon privacy and is based upon trust. From a research perspective, subjects trust that investigators will not divulge confidential information except in ways previously agreed upon. As the Association for Accreditation of Human Research Protection Programs (AAHRPP) states: “Confidentiality refers to the agreement between the investigator and participant in how data will be managed and used.”

When reviewing research proposals (protocols, applications, recruitment material, informed consent documents, and HIPAA authorizations), the IRB must assess the privacy/benefit ratio of the research with regards to privacy and confidentiality issues. Consequently, it is important for investigators to outline strategies to protect privacy and maintain confidentiality in their proposals.

There are multiple opportunities for investigators to address privacy concerns in their proposals including: when describing recruitment methods; the settings where interactions between an individual and investigator will occur; and who will be present during the conduct of the research. AAHRPP states: “what is private depends on the individual and can vary according to gender, ethnicity, age, socio-economic class, education, ability level, social or verbal skill, health status, legal status, nationality, intelligence, personality, and the individual’s relationship to the investigator.” In other words, the investigator needs to individualize the plan for each study based on the expected study population.

There are also multiple opportunities for investigators to address confidentiality concerns in their proposals including: when explaining how participants’ identities will be safeguarded; when describing short- and long-term plans for safeguarding the confidentiality of the research data; when describing provisions for de-identifying the data as soon as possible; and when describing confidentiality safeguards in the informed consent document/HIPAA Authorization form.

Lastly, it is important to note that complaints about violations of privacy and/or confidentiality frequently stem from an inconsistency between the expectations of the participant and the investigator. To minimize this risk of miscommunication, the burden is upon the investigator to carefully and clearly explain to potential subjects the “who, what, where, why, when, how” components of the data collection and data management plans.

Article by Charles Hoehne

Sections of this article adapted from the Association for the Accreditation of Human Research Protections (AAHRPP) Evaluation Instrument and University of Kentucky guidance.

*Privacy=People  
Confidentiality=Data*



## CONTINUING EDUCATION OPPORTUNITIES FOR INVESTIGATORS

OPRS requires that investigators and key research personnel take initial training before conducting research. Training also needs to be updated every two years with two Continuing Education credits.

### 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?

## INITIAL TRAINING IN HUMAN SUBJECTS PROTECTION

Offered throughout the year, Investigator 101 covers the history of research ethics, ethical principles and The Belmont Report, development and application of the federal regulations for human subject protections, UIC's Federal-wide assurance and policies, criteria for review of research, informed consent process, research protocol review processes, and the application of the ethical principles and regulatory requirements.

### UIC Investigator 101 Training Calendar

Wednesday, April 16, 2008	1:00 Pm—4:00 PM	SPHW, Room 119
Thursday, May 22, 2008	1:00 PM—4:00 PM	MBRB Auditorium
Friday, August 22, 2008	1:00 PM - 4:00 PM	SCE, Room 713
Tuesday, September 9, 2008	1:00 PM - 4:00 PM	MBRB Auditorium
Tuesday, November 18, 2008	1:00 PM - 4:00 PM	MBRB Auditorium

*All UIC investigators  
and other key research  
personnel are required to  
complete IRB 101.*

### Reminder:

**Expedited Reviews DO NOT have a deadline!**

## APRIL FAQ: *EXPIRATION DATE*

### ***What does the expiration date mean?***

The UIC Office for the Protection of Research Subjects policy and procedure defines the expiration date as the last date of approval for the protocol.

### ***Can I still perform research on the expiration date?***

Yes, the date of expiration stamped on the informed consent and indicated on correspondence from the UIC Office for the Protection of Research Subjects (OPRS) is the last date that the research is approved. For example, if the approval stamp states, "UIC IRB Approval Starts from January 1, 2009 to December 31, 2010," the informed consent form and research protocol is no longer valid as of **midnight December 31, 2010**.

### ***Can I have a grace period beyond the expiration date?***

No, federal regulations **do not allow for any period** extending the conduct of research beyond the last date that the protocol is approved (no greater than 364 days). Therefore, principal investigators and their staff should submit their continuing review application to OPRS with sufficient time to allow for corrections, modifications, or deferral determinations, as required by the IRB, and to receive approval **before** the date of IRB approval expiration.

### ***What happens if approval is not obtained by the expiration date?***

If the investigator has not obtained continuing review approval by the expiration date, all research activities must stop. If a continuing review or final report submission is not provided within 14 days, the research protocol is administratively closed. Following the lapse of approval, the investigator must provide the IRB with a list that specifies the number of currently enrolled subjects, an assessment of the risk to subjects of stopping study activities and the need to continue any research interventions, or a signed assurance that no subjects are currently enrolled in the research or at risk. Additionally, notification of the sponsor of any lapse of approval is typically required.

Office for the Protection of  
Research Subjects (OPRS)

Room 203 AOB, MC 672  
1737 West Polk Street  
Chicago, Illinois 60612

Phone: 312-996-1711  
Fax: 312-413-2929

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