

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

As the OPRS newsletter passes its first anniversary date, I look back over the improvements (I hope) in our policies and forms. As an investigator, cumbersome forms and processes were an unwelcome frustration. For example, when I joined OPRS as Interim Director in late January 2007, the process for reporting adverse events and unanticipated problems involved safety reports and other reporting for the investigator. No matter when an adverse event or unanticipated problem occurred, or whether or not it was study related, a safety report had to be submitted. Last August, OPRS streamlined the process. This fall, we have streamlined the process even further. (Please see the article on Prompt Reporting in this issue.)



James H. Fischer
Director, OPRS

Other articles this month include a brief note on exemptions, a revised definition of when researchers engage UIC in their research and a timely discussion on managing Conflict of Interest when conducting human subjects research by Dr. Rebecca Lind.

As always, we welcome your feedback and comments.

Jim Fischer
Director OPRS

AAHRPP SITE VISIT

The AAHRPP site visit for JBVAMC has been scheduled to occur at the end of October. Educational sessions for JBVAMC investigators will be scheduled and announcements sent in the next week.

OPRS Newsletter Publication Schedule:

Dec/Jan Feb/March April/May



NEWS FOR INVESTIGATORS

RULES OF ENGAGEMENT OR WHO IS REQUIRED TO SUBMIT AN IRB APPLICATION?

The OVCR has revised the UIC policy on when researchers engage UIC in research to make it less burdensome for adjunct faculty. Currently, the OPRS policy on *Who is Required to Submit an IRB Application* reads as follows:

The UIC Human Subject Protection Program (HSPP) has jurisdiction over the following categories of research when that research involves the use of human subjects, or identifiable private data or tissues derived from human subjects, and the institution is “engaged” in the research by the nature of the research activities:

- Research conducted by UIC faculty and staff.
- **Research conducted by adjunct faculty, such as non-salaried faculty, in their role as an adjunct faculty member and when there is intention of utilizing his/her faculty appointment to the University in a publication resulting from the research, or when his/her appointment is listed among the investigator’s credentials in study documents.**
- Research conducted by students, including research to satisfy a requirement imposed by UIC for the award of a degree or the completion of a course of study.
- Research performed on the premises of UIC, or using equipment belonging to UIC.
- Research involving the use or disclosure of protected health information or other identifiable private information.
- Research funded by or supported through UIC.

The second bullet concerning adjunct faculty has recently been revised to:

- **Research conducted by adjunct faculty, such as non-salaried faculty, in their role as an adjunct faculty member.**

By eliminating the need for adjunct (nonsalaried) faculty to submit non-UIC research to the UIC IRB, this change reduces duplicative human subject review, inadvertent noncompliance with UIC policies and confusion on whether adjunct faculty may refer to their UIC credentials in publications.

“The OVCR has revised the UIC policy on when researchers engage UIC in research to make it less burdensome for adjunct faculty.”

MANAGING CONFLICTS OF INTEREST IN HUMAN SUBJECTS RESEARCH

You may have seen stories about Conflict of Interest (COI) in the media – both research-related and in other realms. The federal government and the general public is increasingly concerned about proper disclosure and management of COIs in research. The NIH, Office of the Inspector General, and Congressional representatives are all increasing their scrutiny. The American Association of Medical Colleges and other organizations – always sensitive to COI – are speaking out more about COI.

Another major force influencing the further development of our conflict management processes is the Association for the Accreditation of Human Research Protection Programs (AAHRPP), an IRB accrediting organization. UIC is in the process of submitting an application to AAHRPP, and the evaluation standards that the institution will be held to are high. As a result, the COI office, OPRS, and ORS are working together more closely than ever before. We're refining our processes to satisfy not only the AAHRPP guidelines but also increasing scrutiny on multiple levels.

One of the obvious refinements is the protocol-specific form, the **COI-SEAM (Statement of Explanation And Management)**. The SEAM form, and guidance for preparing the form, is available under the "Managing Conflicts" section of the COI website (www.research.uic.edu/conflict). For each protocol on which a COI is disclosed, a SEAM is now required. A COI subcommittee on Human Subjects Research evaluates the situation, including the disclosure and management mechanisms presented in the SEAM. This subcommittee mechanism allows rapid response to disclosed COIs. The subcommittee makes a recommendation to the IRB.

The IRB has final authority for approving research protocols, which includes evaluating the conflict management techniques. In upholding its charge to protect the rights and welfare of the subjects, the IRB can require revisions to the SEAM, which may involve changing the conflict management mechanisms. Barring exceptional circumstances, **the IRB requires the disclosure of COIs in the informed consent documents.** Template language for disclosing a variety of common COIs is available online; it can be accessed from the page providing guidance on preparing SEAMs.

The COI office works with investigators to review drafts of SEAMs, and is available for any of your conflict of interest questions. Many investigators find that after they create a SEAM, much of the information is applicable to other protocols, and the SEAM can be modified to efficiently produce subsequent individual protocol-specific SEAMs. Contact coi@uic.edu or (312) 996-4070.

Dr. Rebecca Lind

"The IRB has final authority for approving research protocols, which includes evaluating the conflict management techniques."

New Forms and Policies for Researchers



FOR INVESTIGATORS WHO ARE CONDUCTING A PROTOCOL UNDER AN APPROVED CLAIM OF EXEMPTION

OPRS has recently modified the Exemption Policy and through this revision, Exemptions are approved for a 3 year period. Investigators who intend to continue research beyond the 3 year approval period will need to re-submit the research for a new exemption determination.

At this time, OPRS has grandfathered Protocol Exemptions that are greater than three years old and granted an extension which will allow Investigators to continue conducting their research under the currently approved Exemption until April 30, 2009.

An email from OPRS will request the following certification from the investigator:

1. the research continues to be active and;
2. there have been no changes to the approved research plan.

If the research is to be continued after April 2009, the protocol must be re-submitted using the updated Exemption Application (www.research.uic.edu/protocolreview/irb/forms/0280.doc) by March 15, 2009 to ensure there is no lapse in an approval.

If there is no response from the investigator within two weeks of the email, the research protocol will be closed and no research activities, including data analysis, may be conducted under the closed protocol. Except in this special circumstance, please note that OPRS policy requires a Final Report when research has been completed.

CHANGES TO THE INVESTIGATOR'S REPORTING POLICY TO THE IRB

The policy regarding investigator reporting responsibilities to the IRB for unanticipated problems involving risk to subjects or others (UPIRSOs) has been revised. The revised policy will also be accompanied by an updated submission form entitled "Prompt Reporting to the IRB"

The revised policy incorporates a more complete list of items that require prompt reporting to the IRB and changes the criteria for determining whether an internal adverse event requires reporting to the IRB. Investigators are only required to decide that the adverse event is unanticipated and related to the research to determine the need for prompt reporting. The term "UPIRSOs" will be replaced by the more generic and simpler term "unanticipated problems."

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CHANGES TO THE INVESTIGATOR'S REPORTING POLICY TO THE IRB CONTINUED FROM PAGE 4

In accordance with the revised policy, the following events/incidents require prompt reporting to the IRB:

- A. Internal adverse events determined by the investigator to be unanticipated and related to the research;
- B. External adverse events determined by the investigator, sponsor, coordinating center or DSMB/DMC to represent an unanticipated problem (i.e., unanticipated, related, and increased risk of harm);
- C. Publication, interim analysis, safety monitoring report, or updated investigator's brochure that indicates an unexpected change to the risks or benefits of the research;
- D. Change in FDA labeling or withdrawal from marketing of a drug, biologic or device used in the research;
- E. Subject complaints that indicate an unanticipated problem or event which cannot be resolved by the research staff;
- F. Changes to the protocol made without IRB approval to eliminate apparent immediate harm to subjects;
- G. Protocol violations that cause harm to subjects or others, place them at increased risk of harm, impact the scientific integrity, have the potential to recur or represent possible serious or continuing noncompliance;
- H. Unanticipated adverse device effects;
- I. Breach in confidentiality;
- J. Incarceration of a subject in a protocol not approved to enroll prisoners;
- K. Administrative hold by investigator or sponsor (sponsor imposed suspension);
- L. Events requiring prompt reporting by the protocol or sponsor;
- M. Observed or apparent noncompliance (refer to UIC policy, "*Handling Complaints and Allegations of Potential Non-Compliance with Human Subject Protection Regulations*", for definitions).

To assure compliance with the federal regulations, the revised policy also shortens the reporting time to the IRB from 7 working days to 5 working days for the following:

- Internal adverse events considered serious as defined above (e.g., death, life threatening injury);
- Changes to the protocol made without IRB approval to eliminate apparent immediate harm to subjects.

The other incidents list above must be reported within 10 working days of discovering or being notified of the event.

The principal investigator is responsible for reporting adverse events and problems to the sponsor and any other agencies as specified in the protocol, data safety monitoring plan or other agreements.

The revised IRB policy and reporting form will be posted shortly on the OPRS web site. The implementation of the new policy and form will become effective on October 15, 2008.

JBVAMC STANDARD OPERATING PROCEDURES LINKED TO WEB SITE

Principle Investigators and research staff performing VA Research should note that the OPRS website has a link to the main JBVAMC home page and JBVAMC standard operating procedures for its human subjects protection program.

From the OPRS home page, click on the **Research at JBVAMC** tab in the left side menu.

On the **JBVAMC page**, click on **Services** in the left side menu.

On the **Services** page, in the pale blue menu on the right, click on **Research**.

On the **Research Page**, the 6th item in the pale blue menu on the right is the link for the **JBVAMC SOPs**.

To access the JBVAMC website directly, click on the following link:

<http://www.chicago.med.va.gov/research/research.htm>

and then proceed as outlined above.

Investigators and their research staff should become familiar with the JBVAMC standard operating procedures. UIC OPRS will provide training in the upcoming month to discuss when an investigator should follow the JBVAMC policies and procedures and when UIC OPRS policies and procedures should be followed.



CONTINUING EDUCATION OPPORTUNITIES

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

Tuesday, November 18, 2008 1:00 PM - 4:00 PM MBRB Auditorium

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