

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

The Office for the Protection of Research Subjects updates and revises its policies and forms on a regular schedule to aid investigators and provide safe research practices for research subjects. A goal in revising the forms is to ensure the IRB receives from the investigator the information needed to quickly and efficiently review and approve the research. By reducing the requests for clarifications, delays in the approval process should be avoided. Please see the list of forms revisions in this month's newsletter.



James H. Fischer
Director, OPRS

UIC's submission for application for accreditation by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) is under review. AAHRPP's feedback thus far has been more positive than imagined. The AAHRPP site visit is projected to occur between mid to late September.

In order to aid investigators and coordinators who may be interviewed by the AAHRPP site team, OPRS will provide education on the key human subject protection regulations and IRB processes.

By the end of August, our AAHRPP web page will be posted, providing information on forms and policy revisions, a schedule of education opportunities and daily tips geared to help you through the AAHRPP process.

This issue includes the first of our AARPP tips and reviews.

RiSC Web, our electronic submissions process, is currently live with a test group of investigators at the College of Medicine. The feedback has been positive, and electronic submissions of IRB applications are in the very near future across the entire UIC research community.

As always, your comments and feedback are appreciated.

Jim Fischer
Director OPRS

WATCH FOR A SPECIAL AAHRPP EDITION OF THE OPRS NEWSLETTER COMING SEPTEMBER 5, 2009.



NEWS FOR INVESTIGATORS

AAHRPP SITE VISIT: SEPTEMBER 2009

The Association for the Accreditation of Human Research Protection Programs (AAHRPP) site visit this September encompasses more than the OPRS IRB staff. AAHRPP is interested in what you, the investigator and study coordinator, know about Human Subjects Protection.

The AAHRPP site survey team will question OPRS staff, IRB members, investigators and study coordinators on aspects of UIC's Human Subjects Protection Program. The survey team will cover areas such as Study Design, Conflict of Interest, Informed Consent, Risk Evaluation, Subject Questions and Complaints, Study Personnel Training, among others.

The following are sample questions derived from an AAHRPP evaluation:

Investigator Oversight

- How do you oversee the activities of research staff?
- What are the qualifications required to be a study coordinator for this study?
- Is working with the IRB cumbersome?
- How do you see your relationship with the IRB?
- What is the role of your co-investigator?
- How does communication occur between the PI and the co-investigator?

Study coordinator

- How does the investigator have oversight of the studies?

Conflict of Interest

- What are your institution's requirements for financial disclosure before or during the conduct of a human research proposal?
- What is the importance of disclosing financial conflicts of interest in the conduct of human research?

Study Design

- Give an example of how you design your research proposal to detect harm promptly.
- What is a sound study design?
- What type of research design characterizes the majority of your studies?
- What are your IRB reporting requirements for reporting deaths that may be related to study participation?

Risk Evaluation

- Is there anything different about risks that research subjects undertake compared to risks that patients undertake when receiving care?
- Can you implement a change in your study without having IRB approval?
- Where would I look in your research protocol if I was looking for how you minimize risk in your studies?
- What do you do if your protocol lapses in IRB approval?

AAHRPP will interview select institutional review board members, OPRS staff, investigators and research coordinators.

AAHRPP SITE VISIT: SEPTEMBER 2009 CONTINUED FROM PAGE 2

Recruitment

- How do you determine if a subject is decisionally-impaired?
- What is an example of a recruitment procedure that you employ that maintains equitable selection of subjects in your study(ies)?

Informed Consent

- Who obtains informed consent of potential subjects in your studies?
- How do you determine whether an individual that you delegate authority to conduct the informed consent process is qualified?
- How do you assess decision-making capacity in potential subjects whose decision-making capacity is in question?
- What are your institution's policies on obtained informed consent for human research subjects?

For more information, please visit the AAHRPP web page, coming in August.

ANNOUNCING THE CLINICAL RESEARCH FORUM

The **Clinical Research Forum (CRF)** was created by a group of UIC research personnel in an effort to facilitate the activities of clinical research here at the University. The group meets on the third Wednesday of each month at 10:00 a.m., on the 3rd floor of the Neuropsychiatric Institute (NPI), North Tower, located at 912 S Wood St.

These meetings are intended to disseminate information specific to procedures and polices, update on changes related to clinical research, inform about current practices, provide resources, and serve as a networking venue for all who attend.

Below is a list of upcoming meeting dates/times. For more information or to be added to the CRF listserv please, contact Nada Mlinarevich at nmlina1@uic.edu or 312.413.8128. We look forward to seeing you next month!

- Wednesday, August 19th at 10:00 a.m.
- Wednesday, September 16th at 10:00 a.m.
- Wednesday, October 21st at 10:00 a.m.
- Wednesday, November 18th at 10:00 a.m.
- Wednesday, December 16th at 10:00 a.m.

NEW AND REVISED DOCUMENTS

Rather than list each new and revised document in this newsletter, OPRS has created an on-line document that lists all of the revisions. This document is located at <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/updates.pdf>.

Included in the most recent batch of revisions are:

* Informed Consent Suite: New policy covering informed consent, new biomedical and social behavioral consent templates, new JBVAMC consent template, new tip sheets for informed consent and certificate of confidentiality language. Thank you to members of the Clinical Research Forum and the Center for Clinical and Translational Science for participating in the review of these documents.

* FDA-Regulated Research Suite: New policies and procedures covering Investigational New Drugs (IND), Investigational Device Exemption (IDE) & Humanitarian Use Device (HUD), new HUD consent form, new HUD application form.

* Policy revisions: The on-line listing is divided into significant and minor policy revisions. The minor revisions include simple administrative changes (i.e., fix typos, correct position titles, minor clarifications). Please check the revision logs on the listing to determine whether the changes affect the conduct of your research. If so, please click on the web address listed to review the policy.

UPDATED REVISED FORMS

As of September 1, 2009, OPRS will only accept the updated revised forms for the following:

Initial IRB Review Social and Behavioral Sciences* UPDATED!	v3.8, 6/1/09
Initial IRB Review Health and Biological Sciences* UPDATED!	v4.0, 6/1/09
Appendix A-1: Use of Drugs or Biologic Products in Research NEW (replaces Appendix A)	V4.0 6/29/09 Available 8/4/09
Appendix A-2: Use of Medical Devices NEW (replaces Appendix A)	V4.0 6/29/09 Available 8/4/09
Appendix B - Involving Children as Subjects in Research UPDATED!	v3.1, 4/1/09
Appendix G - Clinical Research Center (CRC) UPDATED!	
Appendix J - Debriefing for Research Involving the Use of Deception UPDATED!	v2.0, 6/22/09
Appendix L1 - IRB/IEC Authorization Agreement UPDATED!	v1.1, 5/29/09
Appendix V - Decisionally-Impaired Individuals as Subjects in Research UPDATED!	v1.1, 4/3/09
Biomedical Research Consent Form Template - English UPDATED!	6/16/09
Biomedical Research Consent Form Template - Spanish	Available 8/10/09
Behavioral Research Consent Form Template - English UPDATED!	6/29/09
Behavioral Research Consent Form Template - Spanish	Available 8/10/09



FREQUENTLY ASKED QUESTIONS

SUBJECT RECRUITMENT MATERIALS

In conducting the initial review of proposed research, IRBs must obtain information in sufficient detail to make the determinations required under HHS regulations at 45 CFR 46.111. This includes all recruitment material intended to be seen or heard by potential subjects (e.g., advertisements, flyers, phone scripts, newspaper ads, radio and television announcements, bulletin board tearoff's, Internet postings, and posters).

What content do I need to include in my recruitment material?

Consider each point of contact with the potential subjects. What information will be provided to them in writing? What will be said to them? Your submission for IRB review should include separate documents for each point of contact, whether written, verbal or both.

Recruitment material **MUST** include the following:

- Research project title or identifier (i.e., "Smoking Cessation").
- A description of the type of research and purpose of the research.
- The word "research" must be included in the description.
- A name of the person or office to contact and the number to call for further information.
- The UIC research protocol number, when available, and the fact that the research is being performed at UIC.
- The Principal Investigator's name, department, and address.
- The specific location of the research.
- Footer with version # and date.
- Space for the UIC IRB approval stamp (approximately 2.5 x 1.5 inches).

Recruitment material **MAY** include the following:

- In summary form, the criteria that will be used to determine eligibility for participation in the research.
- A description of the time commitment and duration of the subjects' participation.
- A brief description of the study benefits of the research, if any (e.g., smoking cessation).

Do I really need to submit EVERYTHING for IRB review?

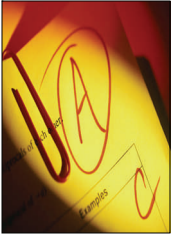
No, the following materials do not typically need to be reviewed by the IRB:

- Medical society newsletters.
- News stories (i.e. public service announcements) and publicity intended for other audiences.

Is there anything else I need to keep in mind when submitting recruitment material for IRB review?

Please include all recruitment materials with your Initial Review application. If you decide at a later date to add material or change the approved materials, the materials must be submitted as an amendment to the research protocol and must receive IRB approval before they are implemented.

For more detailed information, see the ["TIP SHEET - Recruitment Materials"](#) on the OPRS website.



CONTINUING EDUCATION OPPORTUNITIES FOR INVESTIGATORS

CONTINUING EDUCATION: 2 CREDITS
EVERY 2 YEARS

Do any of the following sound familiar?

- Your IRB approval is held up due to key research personnel with expired HSPP training. How can you track this?
- You need to get the required training done, but don't know what you have taken previously? What's your password? Why doesn't the system recognize you?
- You've done the training, passed the quiz, but still no certificate! What gives?

If you answered yes to any of the above, read on.

Keeping track of your training expiration dates:

By accessing RiSC, investigators who have received IRB approval to conduct research at UIC or the JBVAMC can track their education training status. As with any on-line site, there is a password/username retrieval system.

Go to: <https://riscweb.ovcr.uic.edu/phase1/> and log into RiSC. In the left side menu, go to Educational Status. Your completed educational courses will appear with the dates.

If you are not already listed as Key Research Personnel on an approved research protocol, you may send an email to lkennard@uic.edu to check your training status.

Keeping track of your staff's training expiration dates

What is the easiest and simplest way to do this? Send an email to Laurie at lkennard@uic.edu with the names of the personnel you wish to check. Laurie will respond within two business days. Please ensure that all names are spelled correctly.

The two on-line training systems: CITI and LMS

Collaborative Institutional Training Initiative (CITI) is provided by the University of Miami. Use CITI for your on-line *Initial Training* in Human Subjects Protections, and also for your 2 credit *Refresher* course. CITI courses are also required annually for PIs who do research at JBVAMC.

The Learning Management System (LMS) is an on-line course catalog based at UIC. LMS contains the *HIPAA On-line Training* course, HSPP 108 and 109 for JBVAMC investigators and their key research personnel, and the LMS catalog also provides two credit continuing education courses, *Good Clinical Practice* and *Protecting Human Subjects*. In the near future, an AAHRPP course will be added to the LMS catalog. As with any on-line site, there is a password/username retrieval system.

Live! Training

If you like training with a real live instructor, see the OPRS education page for dates when Assistant Director of Education, Charles Hoehne, presents his *Investigator 101* and *HIPAA* training courses. One of the benefits in attending a live session is the question and answer period.

For more information
see our Education page:

[www.research.uic.edu/
protocolreview/irb/
education/index.shtml](http://www.research.uic.edu/protocolreview/irb/education/index.shtml)

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.

ASK OPRS

Please submit any and all questions you might have to apopa@uic.edu with the Subject Line "Ask OPRS." Your name will be kept anonymous. Please submit by September 1st for inclusion in the October newsletter or by August 15th for inclusion in the special September edition of the newsletter.

OPRS will make sure that all questions are answered in a timely manner by email regardless of whether they are published. Policy writers, subject matter experts or OPRS staff will provide answers to your questions.

Please send any questions you may have at any time!

OPRS EAST SIDE SATELLITE OFFICE — NEW HOURS

As of June 18, 2009, the OPRS satellite office will no longer be open on Fridays. The new hours are:

- Mondays: 2:00 p.m. – 4:00 p.m.
- Wednesdays: 2:00 p.m. – 4:00 p.m.

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[http://tigger.uic.edu/depts/
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