

# OFFICE FOR THE PROTECTION OF RESEARCH SUBJECTS

## INSIDE THIS ISSUE:

### *New Forms and Policies for Researchers*

- *COI and the Initial Application Form* 2
- *Investigator COI Policy* 3
- *New Guidance for the Involvement of Non-English Speaking Subjects* 3
- *Determining Whether Research or Other Activities Represent Human Subjects Research* 4
- *Important Changes to the VA Submission Process* 5

### *Continuing Education Opportunities* 6

### *October FAQ* 7

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

The October issue of the newsletter covers several important topics, one of these being conflict of interest. There is a new Conflict of Interest policy for investigators, new Conflict of Interest sections in both Initial Applications as well as the Continuing Review form. A special article from Dr. Rebecca Lind, Assistant Vice Chancellor for Research and the Campus Conflict of Interest Officer, covers disclosing and managing potential Conflicts of Interest in Human Subjects research.

If you are a PI doing research at the VA, you should note the changes to VA submissions highlighted this month. These changes should help expedite the submission process between the R&D committee and the IRB. Please visit our new link on the OPRS web site, [Research at JBVAMC](#), for more information.



James H. Fischer  
Director, OPRS

In October I will be hosting, with Dr. Paul Heckerling, a Town Hall on **The Decisionally Impaired Subject in Research**. The Town Hall forum will be repeated with Dr. Timothy Johnson on the East Campus in November. The feedback from our research community is vital and OPRS encourages you to attend and be part of the decision making process.

## DISCLOSING AND MANAGING POTENTIAL CONFLICTS OF INTEREST IN HUMAN SUBJECTS RESEARCH



Rebecca Lind  
Assistant Vice  
Chancellor, OVCR

A conflict of interest is a function of the situation, and does not imply improper behavior. Potential and actual conflicts of interest must always be disclosed to the IRB.

Many researchers are involved in non-University income-producing activities such as consulting. In most situations, these activities are allowable with disclosure and management. Disclosure occurs when completing the IRB application, which contains a conflict of interest section. Personnel that are required to disclose include anyone who is responsible for the design, conduct, or reporting of the research. Academic staff are also required to disclose conflicts on the Report of Non-University Activities (RNUA) and the Office of Research Service's Proposal Approval Form (PAF).

Once disclosed, potential or actual conflicts of interest (COI) should be managed, reduced, or eliminated. For situations in which the reduction or management of the potential COI is desired, in addition to disclosure, the conflicted person should disclose and compose a COI statement. Guidelines for writing COI statements can be found at [http://tigger.uic.edu/depts/ovcr/research/conflict/COI\\_statements.shtml](http://tigger.uic.edu/depts/ovcr/research/conflict/COI_statements.shtml). The COI statement should include: a description of the nature of the conflict, a description of the conflicted person's role and function in the study, provide justification as to why the conflicted person should be involved in the study, and indicate what conflict management techniques are in place to minimize the possible impacts of potential or actual conflicts of interest.

CONTINUED FROM PAGE 1

Many protocols already include practices or mechanisms, which help reduce or manage conflicts of interest. In some cases, having some oversight of the sponsored research project can help ensure that the results are not biased toward the study sponsor. We recommend you contact the Conflict of Interest (COI) office for guidance before submitting a proposal disclosing a potential COI. Doing so is not necessary, but frequently facilitates the submission and review process.

For situations in which the elimination of the potential conflict of interest is desired (e.g., where reduction or management is insufficient to protect the objectivity of the research), several options are possible. For example, the conflicted individual may elect to cease consulting for the study sponsor or to divest his/her ownership interests in the company sponsoring the study. The conflicted individual may choose not to participate in the conduct of the study, and have the study conducted by an independent investigator.

In human subjects research, the IRB has final authority regarding whether the conflict management techniques are appropriate or if additional safeguards are needed to protect the rights and welfare of the subjects.

Rebecca Lind, Ph.D. – Assistant Vice Chancellor for Research  
Jacquelyn Jancius – Conflict of Interest Coordinator  
[coi@uic.edu](mailto:coi@uic.edu) or (312) 996-4070  
[www.research.uic.edu/conflict](http://www.research.uic.edu/conflict)

*“In some cases, having some oversight of the sponsored research project can help ensure that the results are not biased toward the study sponsor.”*

## New Forms and Policies for Researchers

### CONFLICT OF INTEREST AND THE INITIAL APPLICATION FORM

UIC faculty and staff regularly engage in work outside of the university, whether it is as developers of a new technology, authors of a standard evaluation instrument, or as independent evaluators and consultants. Engagement in outside work enriches the individual and is encouraged by UIC. In order to further enrich and preserve the integrity and reputation of faculty and staff and of the university as a whole, care must be taken to avoid both the substance and appearance of ethical or financial conflicts of interest.

All faculty and staff are familiar with the annual declarations they must make to the university and the state regarding outside interests that may conflict or interfere with their professional duty to the university. Investigators and other research personnel may now notice that the IRB Initial Review Application forms have a new, expanded section regarding the reporting of conflicts of interest that parallel those in such grant and contract forms as the Proposal Approval Form (PAF). In addition to financial conflict of interest, the IRB initial application forms request information on any real or perceived nonfinancial (professional) or institutional conflicts of interest that may affect the conduct or integrity of human subjects research. A research protocol with an identified potential conflict of interest will not receive final approval from the IRB until a management plan is completed.

The OPRS staff welcomes any questions investigators may have regarding the new Conflict of Interest Disclosure section in the Initial Review Application forms. Improved coordination of conflict of interest information across UIC offices and departments will enable better management of real and perceived conflict situations, thereby enhancing the credibility and integrity of UIC researchers to funders, academic and professional organizations, and the community.

Contributed by Sandra Costello

## INVESTIGATOR CONFLICT OF INTEREST POLICY

**POLICY – Investigator Conflict of Interest Disclosure Policy for Human Subjects Research**

Version 1.0 4/17/07

Principal Investigators, Clinical Investigators, and others involved in the conduct of research are required by federal regulations and guidelines to disclose a wide range of real or potential conflicts. The Investigator Conflict of Interest Disclosure Policy for Human Subjects Research is provided by OPRS as a reference guide that applicable research personnel should consult before engaging in research as well as on an ongoing basis, particularly at key points such as continuing review. This policy provides (1) tools for identifying a variety of possible real or potential conflicts, (2) a description of the process of disclosure for each type of conflict, and (3) an overview of the conflict determination and management process.

Please carefully review the *Investigator Conflict of Interest Disclosure Policy for Human Subjects Research* while you have active research, available at <http://tiger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/O269.pdf>

## NEW GUIDANCE FOR THE INVOLVEMENT OF NON-ENGLISH SPEAKING SUBJECTS IN RESEARCH AT UIC

**GUIDANCE - for Involvement of Non-English Speaking Subjects in Research at the University of Illinois at Chicago (UIC)**

Version 2.5, 9-04-07

Principal investigators conducting biomedical, behavioral, and social science research that involves non-English speaking subjects must obtain a complete written translation of the English language IRB-approved informed consent document if one of the following elements is met:

1. the research targets a specific population that is non-English speaking;
2. a significant proportion of subjects are anticipated to be non-English speaking; or
3. the research is to be conducted at the College of Medicine.

If none of the elements listed above are met, including the research being located at other Colleges or Centers on the UIC campus, the UIC Hospital, or the UIC Outpatient Care Clinic, either a complete written translation of the English consent document or a “short form” consent with oral translation of the IRB-approved consent may be acceptable. The OPRS recommends that the investigator first obtain IRB approval for the English language written informed consent, and then submit the consent process to be used for non-English speaking subjects as an amendment. The IRB review in this situation can typically be carried out by the expedited process.

Guidance for the preparation and submission of materials for IRB review and approval for enrollment of non-English speaking subjects in research can be found at the following link: <http://tiger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/O281.pdf>.

Short form consent documents translated into several foreign languages can be found on the OPRS forms page.

**Source:** *Guidance for Involvement of Non-English Speaking Subjects in Research at the University of Illinois at Chicago (UIC)*, Version 2.5, 9-04-2007.

Contributed by Andra Popa

*NOTE: The short form will also be translated into Polish and Chinese in the near future.*

## NEW SUBMISSION PROCESS: DETERMINING WHETHER RESEARCH OR OTHER ACTIVITIES REPRESENT HUMAN SUBJECTS RESEARCH

### **POLICY – Determining Whether Research or Other Activities Represent Human Subject Research**

Version 1.0 04/23/2007

In an effort to help UIC students, faculty and staff quickly and accurately determine whether or not the activities they plan to conduct are subject to the IRB review and approval, OPRS has developed a new policy and submission process for *Determining Whether Research or Other Activities Represent Human Subject Research*.

UIC policy does not allow investigators to make an independent determination on whether an activity is human subjects research, except in limited circumstances. The OPRS makes this determination after receiving the *Determination of Whether an Activity Represents Human Subjects Research* application. This form takes only a few minutes to complete and is available on-line at: <http://tiger.uic.edu/depts/ovcr/research/protocolreview/irb/forms/index.shtml>.

The application asks you to provide basic information about the activity such as the principal investigator's name and contact information, the funding source and a brief summary of the activity. The application also asks you to answer the following questions:

1. Does the scope of the research extend beyond the four limited circumstances listed in the policy?
2. Does the activity meet the DHHS definition of "research"?
3. Does the activity involve "human subjects" according to the DHHS definition?
4. Is the activity subject to FDA human subject research regulations?
5. Does the activity involve human subjects according to FDA regulations?

Once you have submitted the application to OPRS, you will receive formal notification via email that OPRS has determined that:

1. the activity does not meet the definition of human subject research as defined by 45 CFR 46.102(f), and that you may conduct the activity without further submission to the IRB; or
2. the activity does meet the definition of human subject research as defined by 45 CFR 46.102(f) and further submission to the IRB is required.

Here are the Top Five Advantages of the *Determining Whether Research or Other Activities Represent Human Subject Research Policy*:

1. Fast and simple process. For fastest response (usually same day, frequently within 1-2 hours), you are strongly encouraged to email the completed application directly to OPRS at [uicirb@uic.edu](mailto:uicirb@uic.edu).
2. Minimizes the risk that you are inadvertently conducting human subject research without IRB approval.
3. No need to complete Initial Investigator Training prior to submitting this application (though the training will need to be completed if it is determined that you will be conducting human subject research).
4. Receive definitive, written documentation that you have consulted with OPRS and that IRB review of the activity is not required.
5. If it is determined that IRB review is required, you will receive OPRS guidance to get you started down the right path towards securing approval (exempt, expedited or full review).

If you have any questions about this policy, please do not hesitate to contact OPRS at 312-996-1711 or via email at [uicirb@uic.edu](mailto:uicirb@uic.edu)

Contributed by Charles Hoehne

*"How do you accurately determine whether or not your activities represent human subjects research?"*

## IMPORTANT CHANGES TO THE VA SUBMISSION PROCESS AND A NEW LINK “RESEARCH AT JBVAMC”

### Submission and Review Procedures for Human Subject Research Proposals to be conducted at the JBVAMC

**Step 1:** The investigator prepares both the UIC IRB and JBVAMC R&D Committee proposal applications. Please refer to the [JBVAMC R&D IRB Protocol Submission Checklist](#) to ensure that you have completed all required documents for submission. The investigator is responsible for ensuring the IRB application and implementation of research comply with the VHA Handbook 1200.5 and other applicable VA requirements.

**Step 2:** To ensure all applicable submission documents and requirements have been completed, a pre-review of the UIC IRB and JBVAMC R&D application materials is performed by the JBVAMC R&D office staff **before** submitting the IRB application to the UIC OPRS. Two (2) copies of the IRB and R&D applications, including all necessary forms, should be brought to the R&D office for the pre-review. Only after the pre-review is completed and the R&D Office staff sign-off on the [JBVAMC R&D IRB Protocol Submission Checklist](#) will the research project be accepted by UIC OPRS for IRB review.

**Step 3:** After obtaining the signed [JBVAMC R&D IRB Protocol Submission Checklist](#) from the R&D Office, the investigator is ready to submit the IRB application and applicable sections of the R&D application to the UIC OPRS. The following JBVAMC R&D application documents (as applicable) must be attached to each copy of the research protocol application for submission to the IRB:

- VA consent document (printed on form 10-1086),
- VA consent for use of picture and/or voice (form 10-3202),
- VA HIPAA Authorization form,
- VA Investigational Drug (form 10-9012),
- VA Tissue Banking application,
- Application for an Off-Site Tissue Banking Waiver (VA form 10-0436),
- PI Certification of Storage and Security of VA Research Information,
- Data Security Checklist, Radioactive Exposure Supplement,
- and VA Conflict of Interest Form or Statement of Disclosure.

Three (3) copies of the signed JBVAMC R&D IRB Protocol Submission Checklist must also be submitted with the initial application to the IRB.

**Step 4:** After UIC IRB review and approval of research, JBVAMC R&D committee review will occur. The UIC OPRS will provide the R&D committee with all IRB approved VA consent documents, HIPAA Authorizations and recruitment materials along with a copy of the IRB approval letter and approved IRB application submission (including revised protocol document, if applicable). On receiving these documents, the R&D office will schedule review of the research by the R&D committee and any relevant subcommittees. Although the research may begin at UIC once UIC IRB approval is granted, the research may not be initiated at JBVAMC until final R&D approval is obtained.

**Step 5:** Following JBVAMC R&D committee review, the investigator will be informed of the decision in writing and, if approved, all research related documents (consents, HIPAA authorizations, recruitment materials) approved and stamped for use at the JBVAMC will be distributed to the investigator.

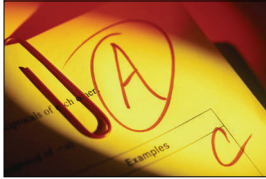
Protocol Review	Human (IRB)
Getting Started	
Meeting Deadlines	
Forms	
Education & Training	
Policies & Guidance	
Research at JBVAMC	←
FAQs	
Online Resources	
RISC Web	
Contact Us	

*Research at JBVAMC:*

[http://tigger.uic.edu/  
depts/ovcr/research/  
protocolreview/irb/  
jbvamc/index.shtml](http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/jbvamc/index.shtml)

## 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.



### Town Hall Discussion on the Issue of the Decisionally Impaired in Research

October 18th, 2007 12:00 - 1:00 PM

One Continuing Education Credit

UIC Hospital Conference Room #1130

OPRS would like input from the research community for the development of a campus-wide policy and guidance for recruitment and consent of decisionally impaired subjects in research. Please join Dr. James H. Fischer, OPRS director, and Dr. Paul Heckerling, Chair IRB 3, for a discussion on this important issue.

Be part of the decision making process!

### AUDIO CONFERENCE

The FDA audio conference held in August at OPRS (for 2 Continuing Education credits) was well received. The topic was [Adverse Event Compliance in Drug and Biologic Clinical Trials, especially appropriate with the roll-out of the new UPIRSO policy and the Event Requiring Prompt Reporting form.](#)

The audio conference will be presented again this fall for two Continuing Education credits on:

October 24<sup>th</sup>, 12:00 – 2:00pm

OPRS Conference room, 2<sup>nd</sup> floor

1737 West Polk St.

Space is limited. Call (312) 996-1711 to reserve a spot.

Julie Washington, Assistant Director in charge of Adverse Events and part of the committee that designed the new form, will be on hand to answer questions after the presentation.

[See what the FDA says about the presentation.](#)

*“OPRS would like input from the research community.”*

### 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.

## OCTOBER FAQ: HOW MANY COPIES DO I NEED TO SUBMIT

### Basic instructions for making copies for the OPRS

1. For ALL submissions, please follow these initial steps:
  - Put together the original packet: Print out one copy of all material prepared on the computer (IRB forms, consent documents, HIPAA Authorization, recruitment documents, etc.). Gather together all the other documents you need to include in the submission (research protocol, instruments, investigator's brochure, grant, CVs, outside approval letters, letters of support, etc.). The application's instructions include a list of the items you need to submit. The application form also prompts you to submit documents/forms when applicable to your research.
  - Get all signatures as instructed on the forms. You now have one entire packet ("original", "original packet" and/or "original copy").
  - Make one copy of this entire original packet. **KEEP THIS COPY FOR YOUR INVESTIGATOR RECORDS FILE.**

Note: If you will need any documents stamped (consent, recruitment, HIPAA authorization), make an additional copy of these items and set them aside. They will go back in with the original packet once you are done copying.

2. If you are submitting a Claim of Exemption or Initial Review Application or Continuing Review Form for expedited review, please complete the following additional steps:
  - Take the entire original packet and make one more copy.
  - The original packet and the photocopied packet should each be clipped/fastened separately, then submitted to the OPRS.
3. If you are submitting an Initial Review Application or Continuing Review Form for convened review, skip Step 2. Instead, please complete the following additional steps:
  - Take the entire original packet and make two more copies.
  - Set aside the two large copies.
  - Next remove (if part of the original packet) the research protocol, instruments, grant/grant sub-contract, product information, CV/biosketch, professional/medical license(s), and 1572. Put the remaining forms on the copier and make 22 more copies.
  - Each of these 22 copies should be clipped/fastened separately.
  - Take these 22 copies, add the 2 larger copies you had set aside, and the original copy and submit them all to the OPRS.
4. If you are submitting an Amendment or are responding to a request for Modifications or Deferral: These types of submissions often include revisions to previously-submitted documents. The original packet should include both a marked copy (with highlights and strikethroughs) and an updated "clean" copy.

Before making copies of the original packet to submit to the OPRS, the "clean" revised documents can be removed and set aside. (Note: You may choose to include the clean documents when making copies, but it is usually not necessary.)

- Make 1 copy if submitting for expedited review.
- Make 24 copies if submitting for convened review.

The original packet (with the "clean" documents returned, if applicable) and the photocopied packet(s) should each be clipped/fastened separately, then submitted to the OPRS.

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

[http://tigger.uic.edu/depts/  
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protocolreview/index.shtml](http://tigger.uic.edu/depts/ovcr/research/protocolreview/index.shtml)