

# 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

### AAHRPP Special Edition

This special September edition of the OPRS Newsletter is devoted to preparing the UIC Research Community for the upcoming site visit of the Association for the Accreditation of Human Research Protection Programs (AAHRPP). The AAHRPP site visit encompasses a thorough review of the UIC human subjects protection program, including the OVCR, the OPRS, UIC policies and procedures, and UIC forms, review guides, tip sheets, and applications. IRB members from each IRB, OPRS Staff, and UIC Investigators will be interviewed as part of the accreditation process.



James H. Fischer  
Director, OPRS

The OPRS is offering special continuing education credits for those who wish to be prepared for the site visit. Please see the Education section of this issue for more information. OPRS will also launch an AAHRPP web page with up-to-date training materials.

UIC OPRS is here to help you with any questions you may have concerning the AAHRPP interviews, IRB processes, or policies and procedures. Please contact Andra Popa (312-413-1632, [apopa@uic.edu](mailto:apopa@uic.edu)) or Chuck Hoehne (312-355-2908, [choehne@uic.edu](mailto:choehne@uic.edu)) anytime from Monday - Friday, 9am-5pm for a brief training session or an informal question and answer period.

Jim Fischer

WATCH FOR MORE INFORMATION ON THE UPCOMING SITE VISIT BY AAHRPP.



## TIPS FOR INVESTIGATORS

### PREPARING FOR THE AAHRPP INTERVIEW: BASICS FOR A SUCCESSFUL INTERVIEW

#### **Know what resources are available for your use.**

The AAHRPP interviewers will not expect you to have the answers to every question. They will however want to see that you are familiar with the resources available to you, and that you know where you can find information when needed.

The UIC IRB site ( <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/index.shtml> ) provides access to IRB policies and procedures, application forms, frequently asked questions, and access to federal regulations and guidance (OHRP, FDA). There is also a separate section providing guidance and directions to those conducting research at the JBVAMC. Similar resources are available on the NU OPRS website. Also, the UIC OPRS, NU OPRS and JBVAMC R&D staffs encourage your questions.

#### **Know your study.**

The investigators chosen by AAHRPP to be interviewed are selected relative to a specific protocol. The OPRS will inform you which of your protocols led to your selection. You can expect the AAHRPP interviewers to have reviewed your protocol and to ask questions that will assist them in assessing whether your conduct of the study is in compliance with the IRB approved protocol.

You should review the specific protocol prior to the interview and make sure you have a clear understanding of all aspects of the study. For example, who composes your research staff and what are their responsibilities, how do you communicate with the research staff, what is your informed consent process, how is the research data collected, have there been any amendments and how were they handled, have any serious adverse events occurred and how were they reported?

#### **Know your responsibilities.**

The principal investigator is required to provide continuous and appropriate oversight of their research protocols and staff and assume ultimate responsibility for all study related activities and are directly responsible for the protection of human subjects. Responsibilities are included in the **Investigator Responsibilities Poster** from OPRS, which is included with the study approval letter. Responsibilities include, but are not limited to:

- Oversight of staff
- Delegation of responsibilities
- Creating a protocol
- Initial IRB Review
- Continuing IRB Review
- Submitting Amendments
- Submitting a Final Report

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

PREPARING FOR THE AAHRPP INTERVIEW:  
BASICS FOR A SUCCESSFUL INTERVIEW  
CONTINUED FROM PAGE 2

- Maintaining VA-mandated and other education current
- Reporting to the IRB
- Creating a system of essential documents
- Proper Tissue Banking
- Adequate Resources
- Sound Research Study Design
- Minimizing Risk
- Equitable Selection
- Informed Consent Process (recruitment, payment, advertisements)

**Know which policies apply to your research:**

Principal Investigators should be aware of which policies apply to their research and have a fundamental understanding of how these policies impact their research. While the policies do not need to be memorized, investigators should be able to consult the pertinent policies while conducting their research.

UIC policies can be accessed at the following web-site: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/index.shtml>

JBVAMC policies can be accessed at the following web-site: <http://www.chicago.va.gov/services/research.asp>

**Keep answers short**

During the AAHRPP interview process, please keep answers short and do not volunteer additional information. Please take a moment to think about and formulate your answer before responding.

**When asked a question, answer only the question. Do not meander onto other topics.**

AAHRPP site-reviewers have a small block of time to conduct the interview. Only provide information relevant to the question, and try not to elaborate too much unless asked for more details.

**Do not use your time in the interview to complain about the IRB/OPRS System.**

The UIC OPRS has a system in place for researchers, IRB members and subjects to submit suggestions, concerns or complaints about the IRB/R&D Administrative Process or human research. Please relay constructive feedback to the AAHRPP site reviewers, and utilize the Office for the Protection of Research Subjects (OPRS) Suggestion Box/Complaints for initiating communication about issues you feel need attention. For details see the OPRS webpage: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/contact.shtml>.



## REVIEW FOR INVESTIGATORS

### BASIC INFORMATION FOR HUMAN SUBJECT RESEARCH SUBMISSIONS

#### When is an activity considered human subject research?

Not all activities with human subjects represent human subjects research. At UIC, only research activities meeting the common rule (i.e., DHHS, VA) or FDA definition of research involving human subjects require submission to the IRB for review and approval or a claim of exemption. When the research is not a clinical investigation under FDA purview, the research is not considered to involve human subjects if investigators are not obtaining either: (1) data about living individuals through intervention or interaction with those living individuals, or (2) identifiable private information about living individuals.

Examples of activities not generally considered human subject research are research involving cadavers, data or specimens when investigators have no access to code or link that could allow identification of the individual, classroom exercises solely to fulfill course requirements or to train students in the use of particular methods, access to specified public use datasets, case reports of a single patient, biography or oral history research, or quality improvement or assurance activities.

#### Who determines whether an activity is research involving human subjects?

To assist in determining whether or not an activity is human subject research, see the decision tree on the Getting Started page ([http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/getting\\_started.shtml](http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/getting_started.shtml)) on the UIC OPRS website. However, investigators at UIC **are not authorized to decide independently that an activity does not represent human subjects research**, except in limited circumstances. Investigators who intend to conduct activities with human subjects must submit an application to the UIC OPRS for a human subjects research determination.

#### What review process is required for the collection of information from medical records?

The type of review process (convened, expedited, exempt or a not human subject determination) depends on several factors, including whether identifiable information will be accessed and/or recorded, whether the data to be collected is retrospective or prospective, and the level of risk. The Getting Started page on the UIC OPRS website contains a decision tree ([http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/getting\\_started.shtml](http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/getting_started.shtml)) to assist investigators in making this decision.



## TEST YOURSELF!

### HOW MUCH DO YOU KNOW ABOUT HUMAN SUBJECTS PROTECTION?

#### Case Study #1

The clinicians in General Medicine Clinic instituted a new treatment regimen for community acquired pneumonia. After 6 months, the impression is that this regimen is working very well. The staff decides to review their patients' records to verify its effectiveness. Does this activity require IRB review and approval?

*Maybe not.* Quality assurance projects are not considered human subjects research, provided the data will not be presented outside the Department or Institution. However, if there are plans to present the data at a regional or national meeting, or publish the outcome, the activity may now represent human subjects research as the results are contributing to generalizable knowledge and IRB review and approval may be needed.

#### Case Study #2

A researcher in Physiology plans to use hippocampal tissue from human cadavers to determine the effect of head trauma on propagation of ictal discharges. Does this activity require IRB review and approval?

No. The research does not involve living individuals.

#### Case Study #3

An investigator wished to understand patient reactions to patient education materials provided by the Neurology Clinic. A colleague had performed a telephone survey collecting this information two years ago under an approved IRB protocol. The colleague plans to remove all identifying information from the surveys prior to providing them to the investigator. The key to the code on the data will also not be shared and the investigator will not be sharing the research results with the colleague in a manner in which it could be linked to individual subjects. Does this activity represent human subject research?

No. The data will not be recorded by the investigator in such a manner that individual subjects can be identified and no direct interaction or intervention with participants is occurring.

#### Case Study #4

Review of publicly available transcripts of public hearings about treatment of epilepsy and risk of suicide. Is this "research" per the UIC policy and procedure?

No. Private individually identifiable information is not obtained and no direct interaction or intervention with participants.

#### Case Study #5

An investigator receives only coded information on the treatment outcomes of patients treated for arthritis with Drug A versus Drug B from the patients treating physician. The only involvement of the treating physician is to provide coded information to the investigator. The investigator and the treating physician enter into an agreement prohibiting the release of the key to decipher the code to the investigator under any circumstances, until the individuals are deceased. What level of IRB review is needed for this proposal?

This proposal is **not** human subject research as no identifying information is being obtained by the investigator and no interactions or interventions with individuals are occurring. If this research was being conducted at UIC, the investigator should submit a *Determination of Whether an Activity Represents Human Subjects Research* form to the UIC OPRS to verify this determination.



## POLICY SPOTLIGHT!

### PROMPT REPORTING POLICY

Please note that the Prompt Reporting policy has recently been revised. Please see the OPRS website for the complete policy: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/index.shtml>

In the meantime, here is a short **Who, What, When, Where, and How** of the policy.

#### WHAT requires reporting to the IRB?

- Unanticipated and related internal adverse events;
- External adverse event that represents an unanticipated problems;
- Unexpected change to the risks or benefits as stated in publication, interim analysis, safety monitoring report, or updated investigator's brochure;
- Change in FDA labeling or withdrawal from marketing of a drug, biologic or device used in the research;
- Subject complaints that indicate an unanticipated problem or event which cannot be resolved by the research staff;
- Changes to the protocol made without IRB approval to eliminate apparent immediate harm to subjects;
- 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;
- Unanticipated adverse device effects;
- Breach in confidentiality;
- Incarceration of a subject in a protocol not approved to enroll prisoners;
- Administrative hold by investigator or sponsor (sponsor imposed suspension);
- Events requiring prompt reporting by the protocol or sponsor;
- Observed or apparent noncompliance.

#### WHEN does it need to be reported to the IRB?

- Within 5 working days of becoming aware of the event:
  - For internal adverse events considered serious as defined above (e.g., death, life threatening injury);
  - For other protocol changes made without IRB approval to eliminate apparent immediate harm to subjects
  - Within 10 working days of discovering or being notified:  
Other items listed above

**PROMPT REPORTING POLICY CONTINUED FROM PAGE 6****WHO is responsible?**

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

**HOW is the event reported?**

- UIC - the investigator informs the IRB on the *Prompt Report to the IRB* form in the appropriate timeframe
- NU study reviewed by the Collaborative IRB - the investigator informs the NU IRB in the appropriate timeframe; the event is then forwarded to the Collaborative IRB.

**WHAT is different with research conducted at the JBVAMC?**

- Only unexpected deaths are required to be reported. An unexpected death is defined by the following criteria:
  - Death of a subject in which a high risk of death is not projected as indicated by the protocol, informed consent form or the investigator's brochure
  - Unexpected deaths do not include deaths associated with a terminal condition, unless the research intervention clearly hastened it; and
  - Deaths determined not to be clearly associated with the research also do not qualify as unexpected deaths,
  - Deaths meeting the definition of an "unexpected death" are synonymous with deaths meeting the criteria of an unexpected problem.
- Both the UIC or NU investigator and the JBVAMC investigator should sign the prompt reporting form before submitting the event to the IRB.
- The event is to be reported directly to the IRB. After the IRB makes a determination, the IRB will forward the event to the R&D.

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

**AAHRPP WEB PAGE**

A new website has been developed by OPRS focusing on AAHRPP. The AAHRPP web page will provide you with information on forms and policy revisions, a schedule of education opportunities and daily tips and training materials geared to help you through the AAHRPP process. The site can be accessed at [http://  
www.research.uic.edu/protocolreview/irb/aahrpp.html](http://www.research.uic.edu/protocolreview/irb/aahrpp.html).