

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 year winds down, OPRS looks forward to 2008. I hope that many departments will take advantage of Brown Bag Lunch Training. Initiated to address specific concerns expressed by investigators, these training sessions are customized to address departmental concerns and focus on “how to” information sharing. Please see Charles Hoehne’s article on Continuing Education to learn more.



James H. Fischer
Director, OPRS

On the issue of the decisionally impaired in research, OPRS has formed a committee from the UIC community to help develop policies and procedures in this area. Members include the interested investigators, IRB members and others who participated in the Town Halls this fall.

The newsletter will take a break with the January edition and resume again in February. And from OPRS, we hope you have a healthy and happy New Year.

OFFICE FOR THE PROTECTION OF RESEARCH SUBJECTS (OPRS) 2007 HOLIDAY SCHEDULE

Office for the Protection of Research Subjects (OPRS) will observe the reduced service schedule for non-essential services for the holidays. Therefore, the OPRS will be closed from **5:00 PM on Friday, December 21, 2007**, and will reopen at **8:30 AM on Wednesday, January 2, 2008**.

In addition, the east side OPRS satellite office will be closed beginning December 17th. Protocol submissions should be dropped off at the main office, 1737 West Polk Street, Suite 203, during that week.

The OPRS Newsletter will celebrate the holiday season by taking a vacation in January. We will resume publication in February 2008.

New Forms and Policies for Researchers

OPRS ANNOUNCES AN UPDATED CONTINUING REVIEW OF RESEARCH FORM AND INSTRUCTIONS

FORM – Continuing Review of Research

Version 2.7 08/06/07

OPRS has revised the Continuing Review Form (http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/forms/irb_continuing_review.doc) and Instructions (http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/forms/irb_continuing_review_instructions_V2.1.doc) which are currently available for use. Investigators are required to use the revised forms as the older versions of the Continuing Review Form will no longer be accepted.

The revisions provide a more straightforward Form to ease the administrative burden on principal investigators and their staff. The following is a list of the most significant changes to the Form:

SUMMARY OF CHANGES TO THE CONTINUING REVIEW FORM AND INSTRUCTIONS:

- **Amendments.** This section has been expanded to better capture information regarding the different types of changes that could be made at the time of Continuing Review.
- **Review Process Determination.** Additional questions avoid some of the past confusion regarding the review process and whether it qualified for expedited review.
- **Findings from This Research.** Extra Yes/No questions help make a better assessment as to how to answer questions a, b, and c or whether they require a response.
- **Summary of Recent Literature, Others' Findings, or Relevant Information.** Yes/No questions enable the investigator to assess whether an evaluation is required as to how current information impacts the study.
- **Informed Consent in Other Languages.** Specific questions have been added to evaluate the language of the informed consent process, how it was conducted, the number of subjects enrolled, and the specific language the written information provided to subjects.
- **Withdrawal.** This section now asks for the total number of subjects who have dropped out, been lost to follow up or who have been withdrawn. A question asking if there have been any subjects lost to follow up has been added. The expanded list of questions will provide the IRB with an overview of those who have withdrawn.
- **Safety.** This section has been completely restructured to include the needs related to the updated UPIRSO Policy (<http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0279.pdf>). The section has been separated to account for information related to Data Safety Monitoring Board or Data Monitoring Committee Reports, and Reportable Events (unanticipated problems, study related serious adverse events, VA related adverse events, major and minor protocol violations).

“Always make sure you are using the most current version of a form.”

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OPRS ANNOUNCES AN UPDATED CONTINUING REVIEW OF RESEARCH FORM AND INSTRUCTIONS CONTINUED FROM PAGE 2

- **Protocol Exceptions During the Current Reporting Period.** This is a new section to capture any exceptions that were granted for the research.
- **Review by Other IRBs.** This section has been expanded to include the names and FWA numbers of the other institutions providing reviews, as well as to remind the investigator that documentation of recent IRB approval from the other institutions is required.
- **Expanded Sections.** The Instructions have been broadly expanded to provide detailed guidance as to how to complete the Form, provide additional explanations and definitions, and includes instructions for submission to the IRB for review.



TOOLS FOR INVESTIGATORS

PROCEDURES FOR SUBMITTING CANCER-RELATED RESEARCH FOR INSTITUTIONAL REVIEW BOARD REVIEW

The Office for the Protection of Research Subjects in collaboration with the UIC Cancer Center has developed procedures for the submission of cancer-related research for Institutional Review Board (IRB) review. Except as noted below, this process requires that all cancer-related research be approved by the Cancer Center's Protocol Review Committee (CC-PRC) prior to final IRB approval, and in some cases, prior to submission for IRB review.

Cancer-related research

When completing the Application form for Initial IRB Review for Social and Behavioral Sciences or Health and Biological Sciences, the box for "Additional Review Required – Cancer Center" should be checked "Yes" for research in any cancer-related research dealing with human subjects that will be performed at UIC or the JBVAMC in the following categories:

1. Any clinical cancer research performed at the University of Illinois at Chicago (UIC) or the Jesse Brown VA Medical Center (JBVAMC) involving UIC faculty and dealing with human cancer patients treated with these modalities:
 - Transplants
 - Immunotherapy
 - Chemotherapy
 - Gene therapy
 - Surgery
 - Radiotherapy

"All cancer-related research must be approved by the Cancer Center's Protocol Review Committee."

CANCER RELATED RESEARCH CONTINUED FROM PAGE 3

2. All clinical research at UIC or the JBVAMC involving UIC faculty researching chemoprevention of cancer using either synthetic or naturally occurring products; or prevention of cancer involving currently accepted methods of treatment (e.g., prophylactic mastectomies in high-risk breast cancer patients).
3. Any clinical trial dealing with pain control or prevention, infection control and/or prevention, or nutrition support for cancer patients.
4. All protocols requiring the use of human tumor specimens, or blood or serum specimens from cancer patients.
5. All retrospective chart reviews of UIC or Jesse Brown VAMC patients with endpoints related to cancer.

New Cancer-Related Research Protocols requiring review and approval by the CC-PRC prior to submission for Convened IRB review:

All new cancer-related studies *initiated* at UIC or by UIC faculty *that have not already been peer reviewed and supported* by NIH mechanisms or the NCI Cancer Therapy Evaluation Program (CTEP) or Cancer Control Protocol Review Committee involving cancer patients, or involving individuals at increased risk of cancer, who are diagnosed and/or treated at the UIC or the JBVAMC will require a full review (scientific and feasibility) by the CC-PRC prior to submission for convened IRB review.

The IRB will not review such protocols without documentation of CC-PRC review and approval. **Note:** The IRB accepts CC-PRC review in lieu of Departmental Review (Appendix F) for cancer-related protocols submitted for convened IRB review.

New Research Protocols that may be submitted to the CC-PRC and IRB concurrently:

CC-PRC approval is not required prior to IRB submission for the categories of research listed below. However, the investigator must submit the protocol to the CC-PRC office and obtain a CC-PRC Investigator Initial Review Submission Form documenting CC-PRC permission for concurrent submission prior to IRB submission. This form must be initialed and dated by CC-PRC staff and copies must be included with the investigator's IRB submission. The IRB will review the submission, but will require documentation of CC-PRC approval before granting final IRB approval.

“Note: The IRB will not review cancer-related protocols without documentation of CC-PRC review and approval.”

CANCER RELATED RESEARCH CONTINUED FROM PAGE 4

The following categories of research may be submitted to the CC-PRC and IRB concurrently:

1. All new cancer clinical trial protocols for convened review that *have already been peer reviewed* and supported by NIH mechanisms (RO1, UO1, PO1, and P50), and clinical research protocols approved by NCI's CTEP or Cancer Control Protocol Review Committee.
2. All new cancer-related protocols that qualify for submission for expedited IRB review. (**Note** that if the IRB determines that the research does not qualify for expedited review and requires convened review, then the requirements for prior review and approval by the CC-PRC as outlined above for convened review will apply.)
3. All new cancer clinical trials that have *already been reviewed* by a National Cancer Institute Central IRB and are being submitted for facilitated IRB review by expedited review procedures. UIC has designated the National Cancer Institute Central IRBs (CIRBs - IRB#1 Adult and IRB#2 Pediatric) as IRBs authorized to provide oversight for cancer research conducted at the University. (**Note: The use of facilitated review at UIC is currently limited to Pilot, Phase II and Phase III pediatric oncology group studies only.**)

New Cancer-Related Protocols not requiring review by the CC-PRC that may be submitted to the IRB without submission to the CC-PRC:

The following may be submitted directly to the IRB and do not require CC-PRC review:

- 1) Single case emergency use protocols.
- 2) Treatment/management guidelines not asking a research question.
- 3) Surveys of healthy subjects and the general population and population-based studies that do not involve UIC patients, patient tests, drugs or procedures, and/or do not have endpoints related to cancer.
- 4) Secondary analysis of registry data.
- 5) Protocols that deal exclusively with established cell lines available in the public domain.

“Please be sure to contact OPRS with any questions.”

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.



CONTINUING EDUCATION: UIC INVESTIGATOR EDUCATION PROGRAM

An important component of UIC's Human Subjects Protection Program (HSPP) is Investigator Education. It is well recognized that the researcher, as the primary contact with the subject, has the most important role in protecting the rights, welfare, and safety of the research subject. One way to help ensure that research subjects are protected is to require that the researcher complete educational courses in human subjects protections that empower them with the knowledge to conduct the research in compliance with federal regulations and ethically. The educational program at UIC helps to ensure the primacy of protecting the human subjects who participate in health science/biomedical and social/behavioral science research.

All UIC Investigators and other key research personnel are required to complete Initial Education, HIPAA Research Training (if the research involves the use or disclosure of Protected Health Information), and a minimum of two contact hours of Continuing Education every two years.

In order to help investigators complete the required training, the UIC Office for the Protection of Research Subjects (OPRS) offers several offers several ways for investigators to complete the required training:

Initial Education Requirements: UIC's initial education requirement for key research personnel involved in human subject research can be met in two ways.

1. Attend UIC's Investigator 101 - What Researchers Need to Know Before Research Can Start: This live workshop is offered throughout the year and covers the history of research ethics, ethical principles and The Belmont Report, development and application of the federal regulations for human subjects 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. In addition, the workshop instructs researchers regarding their responsibilities post-approval (i.e., amendment admissions, continuing review, unanticipated problem reporting, etc.). Investigators must attend the three hour presentation including the question and answer session, take a quiz at the end of the session, and complete an optional evaluation of the session; or
2. Complete the Collaborative IRB Training Initiative (CITI) "Core" Course Online: The CITI web-based course hosted by the University of Miami will take three to six hours to complete depending on an individual's prior knowledge and experience with research, ethical principles and regulations about human subjects protections and CITI course requirements. Links to the Belmont Report, the Declaration of Helsinki and OHRP Human Subjects Document Library, as well as the UIC Human Subjects Protection web site can be found on the Institutional Page.

Please note that on November 15, 2007 the CITI Course site released a new multi-language platform that permits CITI to display courses in Spanish and Portuguese

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“All UIC investigators and other key research personnel are required to complete IRB 101”

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languages for international participants. Plans are also being made to offer courses in Chinese, Japanese, French and Russian.

Complete information regarding the initial training requirements can be found at: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/education/initial.shtml>.

HIPAA Research Training: Investigators must satisfy this requirement by taking online training. Investigators who are unable to access the online training can access the training program at OPRS. To set up an appointment, please contact OPRS at 312-996-1711.

Instructions for completing the UIC HIPAA Research 101 Online Training can be found at: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/education/hipaa.shtml>.

Continuing Education (CE) Requirements: CE should be obtained by investigators and key research personnel for ongoing participation in the conduct of human subject research at UIC. All investigators and other key research personnel involved in the conduct of human subject research are required to seek a minimum of two contact hours of CE every two years and provide OPRS with documentation of CE fulfillment of non-UIC offerings. This standard should be sought for as long as the researchers are involved in the conduct of human subject research. The CE requirement is not extended to non-UIC research personnel; however, CE for these persons is also highly recommended.

OPRS offers investigators several ways to satisfy CE requirements. Complete information regarding the continuing education requirements can be found at: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/education/continuing.shtml#resources>.

Additionally, to address specific concerns expressed by investigators, OPRS has initiated a **“Brown Bag Lunch Training”** program. These training sessions are scheduled upon request. The training sessions are particularly popular because they are customized to address departmental concerns, and focus on “how to” information sharing. All requests for such training are assessed on a case-by-case basis and must be open to the UIC research community.

The goal of the UIC Investigator Training Program is to provide researchers with the tools necessary to ensure human subjects protections. If you have thoughts or ideas about investigator educational programs that would be helpful to investigators – be it a formal CE program or a Brown Bag Lunch Training session – please contact Charles Hoehne at OPRS: 312-355-2908 or choehne@uic.edu.

“Continuing education opportunities are listed on the OPRS website.”

DECEMBER FAQ: WHAT IS THE DIFFERENCE BETWEEN AN ENGAGED AND NON-ENGAGED RESEARCH SITE?

More and more UIC investigators perform research involving organizations and entities outside of UIC. The relationships between UIC investigators and these outside entities can be confusing so when developing your research protocol and completing your IRB application it could be helpful to consider these commonly asked questions.

Should I consider UIC as a site engaged in my research?

Yes, if you are faculty, staff, or a student at UIC conducting research, you should consider UIC an engaged site. This would include all UIC academic and biomedical units; including training and research units, field offices, and clinics *even though they may not be physically situated on the UIC campus.*

Why does it matter if an outside (non-UIC) site is engaged or not engaged in my research?

All sites engaged in research conducted by UIC personnel (faculty, staff, and/or students) must be evaluated to determine the level of IRB oversight necessary to engage the outside site in the research. If an outside site does not have an IRB of its own, extra steps must be taken to determine if the UIC IRB will provide oversight of that outside site.

When is an outside (non-UIC) site considered to be engaged in research?

The simple answer can be expressed in terms of research activities. If UIC personnel (faculty, staff, and/or students) are *active* at an outside site, then that site is engaged for research purposes. *Active* involvement in research can include implementing and evaluating an intervention (e.g., an exercise program, an educational curriculum, a clinical trial) and/or gathering identifiable data (e.g., information from school or medical records, biomedical samples, personal information gathered during surveys, interviews, focus groups, or observations).

It is important to remember, however, that *active* can be broadly interpreted. A few common examples include:

- Obtaining identifiable data or gathering samples via non-UIC personnel who have routine access to data or subjects at non-UIC sites. For example, a nurse at a non-UIC site may gather data from medical records or draw biomedical samples that will be passed on to the UIC investigator as data. Although no UIC researcher may ever go to the non-UIC site to collect the data, that non-UIC site would generally be considered engaged.
- Obtaining data or gathering samples that are “de-identified” or “coded” from an outside site may still render the site engaged. Removing obvious identifiers, such as names and addresses, is not considered sufficient for the de-identification of data. Subject data may be considered *indirectly* identifiable if the cumulative characteristics being gathered could render a subject identifiable. For example, if there are only a few Asian, female, 30-40 year olds in a dataset of banking administrators, then those subjects might be considered identifiable. Likewise, coding

“The relationship between UIC investigators and outside entities can be confusing.”

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samples or data, particularly when a “master list” of identifiers exists – *even if the “master list” is only at the non-UIC site*, is not considered sufficient for the de-identification of data.

- Additional thought must always be taken regarding the collection of protected health information (PHI) from a site outside UIC. PHI is, by definition, considered identifiable data and guidelines regarding the collection, transmission, and use of PHI for research at UIC is governed by HIPAA.

For detailed guidance regarding the engagement of outside sites in UIC-based research, please refer to the US OHRP website at www.hhs.gov/ohrp/humansubjects/assurance/engage.htm

When is an outside (non-UIC) site *not* considered engaged in research?

Again, in terms of research activities, if UIC personnel only involve the outside site in *passive* research activities, then the outside site is probably not engaged. *Passive* involvement in research most commonly includes posting flyers or leaving contact information at an outside site or an outside site allowing UIC researchers to use its facilities (*not* its personnel) to interview, survey, or observe subjects.

When interpreting the meaning of *passive* activities at outside sites, it will be important to keep in mind the following:

Recruiting subjects at outside sites should not involve personnel at outside sites in obtaining consent from subjects or disclosing identifiable information about subjects (such as contact information). The recommended approach to recruiting subjects at a non-engaged outside site is to provide contact information for the UIC investigator via a flyer or information sheet posted at the outside site and to have potential subjects at the outside site contact the UIC researcher, not vice versa.

A “third party” outside site (with no ties to UIC or to the site where the data was originally collected) may gather de-identified and un-coded data or samples and transmit them to the UIC investigator, and remain a non-engaged site, only if the “third party” outside site has no access to the coded “master list” and/or is a commercial or professional entity (such as ICPSR or the US Census Bureau) that abides by recognized standards for maintaining privacy and confidentiality. Thus, for example, a “third party” laboratory, databank, or government entity may gather and send de-identified, un-coded data to the UIC investigator without being an engaged site.

For detailed guidance regarding when outside sites are not engaged in UIC-based research, please refer to the US OHRP website at www.hhs.gov/ohrp/humansubjects/assurance/engage.htm

As always, each protocol is different and the UIC OPRS encourages you to seek out specific guidance regarding your protocol after consulting these FAQs and the US OHRP website.

Contributed by Sandra Costello, IRB 2 coordinator

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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