OPRS Newsletter

January, 2016

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Message from the Director

We have closed the book on 2015 and can look forward to an interesting and challenging new year. Change is coming as the UIC Human Subject Protection Program progresses. While change can be unsettling, 2016 will be rewarding as several advances in human subject research protections move forward.

> *"The art of progress is to preserve order amid change and to preserve change amid order."*
> **Alfred North Whitehead**

First, electronic submission of research applications will become a reality at UIC in 2016. Pilot testing and training for investigators, IRB members and OPRS staff is on-going and feedback from the UIC research community has been positive. Conversion from paper to electronic submissions is a large undertaking. We know there will be a learning curve and speed bumps along the way; however, we also know that electronic submissions will be easier to submit, quicker to review and enhance human subject protections at UIC.

In 2015, the Department of Health and Human Services announced proposed revisions to the regulations that govern research on individuals who participate in research. While not finalized, as per HHS, the proposed rule changes include:

- Strengthened informed consent provisions to ensure that individuals have a clearer understanding of the study's scope, including its risks and benefits, as well as alternatives to participating in the study.

- Requirements for administrative or IRB review that would align better with the risks of the proposed research, thus increasing efficiency.
- New data security and information protection standards that would reduce the potential for violations of privacy and confidentiality.
- Requirements for written consent for use of an individual's biological samples, for example, blood or urine, for research with the option to consent to their future use for unspecified studies.
- Requirement, in most cases, to use a single institutional review board for multisite research studies.
- The proposed rule would apply to all clinical trials, regardless of funding source, if they are conducted in a U.S. institution that receives funding for research involving human participants from a Common Rule agency.

Once the rules are finalized, it is anticipated that institutions will have a specified period of time to implement them. Clearly, significant change in human subject protections is coming, and we all must prepare for the changes. Link to HHS September 2, 2015 announcement: http://www.hhs.gov/about/news/2015/09/02/hhs-announces-proposal-to-update-rules-governing-research-on-study-participants.html#

UIC will begin the process of obtaining Association for the Accreditation of Human Research Protection Programs (AAHRPP) reaccreditation in 2016. The reaccreditation application will be submitted to AAHRPP in early 2017. It is anticipated that revision of institutional policies and procedures will be required in 2016 to meet current AAHRPP standards.

The goal of these initiatives is to further promote the ethical conduct of excellent research. The key to successfully achieving this goal at UIC will be building upon our many strengths through innovation, cooperation and hard work. Please stay tuned for announcements and additional OPRS newsletters detailing change in 2016.

The following topics are addressed in this issue of the newsletter:

- When to submit a Final Report to the IRB;
- Registration information for the Community Engaged Research Boot Camp 2016; and
- How the purposes of the "Determination of Whether an Activity Represents Human Subject Research" and "Development/Center/Training Grant" applications differ.
- Did you know?

"The speed at which progress rolls is not determined by the number of people who started pushing it, but by the number of people who are passionate to hold on doing so."
Israelmore Ayivor, Leaders' Ladder

To all UIC faculty, staff and students- Happy New Year and much academic and research success in 2016!

Jim Fischer
OPRS Director

When to submit a Final Report to the IRB

CONTRIBUTED BY BARBRA CORPUS AND CHARLES HOEHNE

Investigators frequently contact OPRS staff to determine when they should submit a Final Report closing out a study.

As per institutional policy: Final reports must be submitted upon completion of the study.

A study would be considered eligible for closure if it meets **all** of the following criteria:

- The other study sites have closed the study (applicable for multi-center studies where UIC is the lead or coordinating site);
- The Principal Investigator (PI) has completed enrollment and data collection;
- The PI and his or her research personnel no longer have any contacts or interactions with the subjects, including long-term follow up; and
- One of the following:
  a. All data collection is complete and the only remaining activity is analysis of the data, the data are de-identified (including video/audio files), and there are no identifying links or codes to the de-identified data; OR
  b. All data collection and analysis of identifiable data is complete. ***Once the Final Report is submitted under this option, the identifiable data cannot be used for this or any other research purposes without obtaining a new IRB approval.***
  c. If a study is sponsored, the PI may follow the sponsor's guidance regarding the ability to close the study with the IRB while continuing to address data queries.

It is understood that there are several nuances that may complicate the decision whether or not to submit a Final Report. OPRS is therefore developing a "Final Report of IRB Activities for Study Closure" which will soon be available on-line: http://research.uic.edu/compliance/human-subjects-irb/policies

Basic principles of the policy include:

- Principal Investigators, or other responsible parties as applicable, must file a UIC OPRS ***Final Report*** form to request study closure with OPRS for IRB approved and exempt studies upon the completion

of the study but prior to the expiration date of IRB approval. Investigators are sent reminders at 90, 60, and 30 days before the expiration
date. It is, however, the PI's responsibility to avoid a lapse of IRB approval.

- A ***Final Report*** form must be submitted even if the research was never initiated, no subjects were enrolled, or the PI is terminating the research earlier than originally planned.

- Once a study has been closed via a ***Final Report*** form, it cannot be re-opened. If a later use for the research data is identified, then the PI must submit a new research application for the use of the previously collected data. The later use of the data may qualify for an exemption or meet the definition of research not involving human subjects, if the existing data is recorded without identifiers (de-identified).

- Department Heads, Unit Heads, and Faculty Sponsors are responsible for ensuring that PIs leaving UIC submit a ***Final Report*** form for each of their active protocols or transfer the responsibility to another qualified investigator to serve as PI by submitting an amendment form. Refer to the UIC HSPP policy ***Managing Research Prior to Departure, Sabbatical, Medical Leave, or Other Absence*** for additional information.

- PIs who do not file a ***Final Report*** form may be subject to sanctions, including but not limited to, the classification of the applicable protocol as "lapse in IRB approval," determination of research non-compliance, additional education and training, research termination and reporting to appropriate agencies, and/or a restriction of research privileges.

- Lapse in IRB approval represents a failure to obtain approval of a continuing review or final report by the expiration date assigned by the IRB. After expiration of IRB approval, all research activities must stop, including any recruitment, research related interventions or interactions, data collection, data sharing/reporting, analysis of data, and no new subjects may be enrolled. Refer to the UIC HSPP policy and procedure ***Lapse in IRB Approval*** for additional information.

- Studies granted exemptions from IRB review are issued an expiration date of three years. Investigators must either re-submit a new Claim of Exemption application to continue the research or submit a Final Report to close the protocol.

Registration information for the Community Engaged Research Boot Camp 2016

CONTRIBUTED BY LYNN PODRAZA AND CHARLES HOEHNE

Community Engaged Research (CER) Boot Camp is an intensive, three-day, hands-on, interactive, program that provides the knowledge and tools Community Engaged Research Staff needs to carry out successful research studies.

Who Should Attend? Community Engaged Research Staff

When? 3 Fridays, February 5, 12 and 19, 2016 Time: 9am-4:30pm
Where? UIC College of Nursing; 845 S Damen Ave, Chicago, IL 60612, Events Center Room 306
Why Participate? So you will be able to:

1. Define core components of community engaged research
2. Articulate the roles and responsibilities of the research team and community partners
3. Identify aspects of professional and ethical behavior related to researcher, community partner and research participant interactions.
4. Examine best practices for study preparation, implementation, dissemination and sustainability
5. Ensure your study meets Federal, State and University regulatory requirements

> ***"I did then what I knew how to do. Now that I know better, I do better."***
> ***Maya Angelou***

What is the Cost? $275 (UIC) or $300 (non-UIC). Includes course materials, UIC IRB continuing education (2hours), breakfast and lunch. If using a FOAPAL number, have it ready you when you register.

Registration: Enroll online at www.go.uic.edu/CR_BootCamp

Registration is limited and closes January 22, 2016

***For more information contact*:** Lynn Podraza at podrazal@uic.edu or 312-996-2102

How the purposes of the "Determination of Whether an Activity Represents Human Subject Research" and "Development/Center/Training Grant" applications differ

CONTRIBUTED BY CHARLES HOEHNE

Investigators occasionally confuse the "Determination of Whether an Activity Represents Human Subject Research" ("Determination") and "Development/Center/Training Grant" applications.The purpose of this article is to briefly explain the different purposes of the applications and thus avoid unnecessary delays due to the submission of the incorrect application to OPRS.

In short:

The "Determination" application should be submitted to OPRS when an activity will NEVER represent human subject research.

The "Development/Center/Training Grant" application is generally tied to funding and should be submitted to OPRS when an activity will AT SOME point represent human subject research but specific plans for human subject research have not been defined or fully developed.

More specifically:

OPRS developed the "Determination" application for three key reasons:

1. To minimize the risk of investigators inadvertently conducting human subject research without prospective IRB approval or an exemption;
2. To reduce the number of Initial Review applications and Claim of Exemption submissions that do not represent human subject research; and
3. To provide formal documentation to investigators indicating whether or not their activity represents human subject research at UIC.

"Determination" applications must be submitted to OPRS when an activity MAY represent human subject research, but any of the following conditions apply:

1. The activity does not appear to represent "research" as defined under 45 CFR 46.102(d): Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
2. The activity does not appear to involve "human Subjects" as defined under 45 CFR 46.102(f): Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains: (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.
3. UIC does not appear to be engaged in the human subject research. For additional information regarding research engagement, please refer to the "Engagement of UIC in Human Subject Research" policy: https://research.uic.edu/sites/default/files/0912.pdf

Important note: UIC faculty, staff, and students who intend to conduct activities that may in part represent research with human subjects are not authorized to determine independently whether the project is subject to the Human Subject Protection Program, except in limited circumstances. Full details regarding this requirement are available on-line: https://research.uic.edu/sites/default/files/0273.pdf

"Development/Center/Training Grant" applications: In accordance with 45 CFR 46.118, UIC recognizes that there are some applications for grants, cooperative agreements, or other applications that are funded by federal departments or agencies with the knowledge that subjects may be involved

within the period of support, but these applications do not include specific plans for human subjects research in order to accomplish the aims of the application. The Development/Center/Training grant application should be submitted by investigators whose application falls into one or more of the following categories:

1. "Core" or "Center" grants—these are institutional grants that will support individual research projects that are "yet to be determined" at the time of submission of the grant application, when the Core or Center grant will not enroll subjects directly, but supports separate protocols involving human subjects.
2. Training grants—these applications request funding for research fellows or others who will be supported for the purpose of implementing human subject research, but the specific studies on which they participate are not part of the training grant application.
3. Development only applications—these applications include plans for the development of specific human subjects research studies, but those studies will only be initiated after some preliminary projects are completed (e.g., development of instruments or compounds, or prior animal studies).

Regardless of the category above, under NO circumstances may an investigator initiate human subjects research by the grant/contract, including pilot studies, prior to the review and approval of a separate IRB application or a Claim of Exemption (through OPRS).

Important notes:

- Development only applications are not a short cut to IRB approval of human subject research. The IRB can on ly approve research for development only (45 CFR 46.118) if the grant, contract or sub-contract specifically details the development phase (e.g. "Months 1-2: Development of Study Instruments").
- Once plans for human subjects have been finalized, the research is no longer eligible for a Development only designation under 45 CFR 46.118, and IRB approval must be obtained prior to conducting any human subject research.

If you have any questions, please contact OPRS at 312-996-1711 or uicirb@uic.edu.

Did you Know?

CONTRIBUTED BY CHARLES HOEHNE

- As per the UIC Information Technology Security Program (http://security.uic.edu/policies/), "The Workforce, including select student e mployees as identified by a Unit in Policy ***PER.2 Job***

Descriptions, Responsibilities, and Training, **must** use university administered messaging systems (e.g. email, instant messaging, document sharing) to conduct university business." Consistent with this campus-wide policy, OPRS strongly encourages investigators to ONLY use their UIC email address for conducting human subject research, including completion of investigator training, submission of research applications, communications with OPRS and ALL conduct of human subject research.

- OPRS received 1328 new applications for initial review in 2015, an increase from 1230 in 2014 (approximately 8%).
- There are no deadline days for applications submitted for EXEMPT or EXPEDITED review. Applications submitted for CONVENED review have deadline days that are listed on the OPRS website (http://research.uic.edu/compliance/irb/irb-members-oprs-staff/general-information/irb-meeting-deadlines). The sooner a Claim of Exemption or expedited Initial Review application is submitted, the sooner it will be reviewed (i.e., first in, first reviewed). If possible, you should avoid deadline days because many investigators submit exempt and expedited applications on deadline days and the volume of submissions may impact timeliness.