OPRS Newsletter

December, 2016

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Message from the Director

At the beginning of this year (January 2016 OPRS Newsletter), I wrote the following, "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." Change did occur, and as we rapidly approach 2017, I am confident more change is on the way.

First, the National Institutes of Health (NIH) published a new policy for NIH-funded, multi-site studies involving non-exempt human subject research. Effective May 25, 2017, most NIH-funded, multi-site research studies will be eligible for single IRB review. The goal of the initiative is to allow research to proceed as effectively and expeditiously as possible. To achieve this goal, significant "behind the scenes" effort has been made to develop UIC's policies and procedures for complying with this initiative. Please see Charles Hoehne's and Brandi Drumgole's article in this newsletter for additional information.

Next, electronic submissions became a reality for all UIC investigators conducting human subject research in 2016. The rollout of OPRS Live (beta) was completed in early fall. During planning consultations with other institutions and commercial developers, we were told the rollout would take at least two years. We did it in one. In homage to our current political climate, the development and rollout effort, led by Bhavin Patel, Shreyas Chandrakant and the OVCR Tech Team, was HUGE! While still a work in progress, investigators have submitted approximately 3600 applications electronically through the new system. Make no mistake- The learning curve has been significant for investigators, OPRS staff, IRB members and other users, which initially slowed down the submission and review process. We are now, however, starting to see the benefits of electronic submissions. Turnaround times are decreasing and OPRS Live (beta) enhancements are being implemented to make the system as user friendly as possible. For a brief overview of OPRS Live (beta), along with a sneak peek at future enhancements, please see Charles Hoehne's article in this newsletter.

In other news regarding efforts to streamline the IRB review and approval process. I am pleased to announce that UIC will be implementing in Spring 2017 a new flexibility policy which will allow the IRB to grant three-year approval periods for minimal risk, non-federally funded research studies. Please see the article entitled, "Important HSPP Policy Change -

Extension of Approval Periods for Minimal Risk Non-Federally Funded IRB-Approved Research" included in this newsletter for additional information about this exciting initiative.

Finally, 2016 marks the end of an era at OPRS with the retirement of Dr. Clyde Wheeler, OPRS Associate Director. Dr. Wheeler was an integral part of OPRS since 1997. During this time, OPRS grew from a small office to a fully accredited Human Subject Protection Program. We thank Dr. Wheeler for his service and wish him well in retirement.

To the entire UIC research community, thank you for your patience and cooperation during the past year. 2017 promises to be another year of change. In particular, Department of Health and Human Services (DHHS) revisions of the Common Rule are still pending. At the 2016 Advancing Ethical Research Conference held in Anaheim in November, the message was very clear: Change is coming, but no one knows what those changes will be. In the meantime, stay tuned. We will let you know what the changes are and how we will adapt to them as they emerge.

Happy Holidays and good luck with your research endeavors in 2017!

Jim Fischer
OPRS Director

New Policy for NIH-Funded, Multi-Site Research

CONTRIBUTED BY CHARLES HOEHNE AND BRANDI DRUMGOLE

The National Institutes of Health (NIH) published a **new policy** for NIH-funded, multi-site studies involving non-exempt human subject research. Effective May 25, 2017, a single Institutional Review Board (sIRB) will be used to conduct the ethical review required by the Department of Health and Human Services (DHHS) regulations for the protection of human subjects.In response to the new NIH policy, OPRS has developed internal policies and procedures ("Registration of a Protocol, Continuing Review, Amendment, and Study Closure by an External IRB or Central IRB"). Highlights of the OPRS policy include:

- Investigators participating in a **NIH-funded, multi-site study** are expected to rely on a Single Institutional Review Board (sIRB) to carry out the functions that are required for institutional compliance with IRB review set forth in the HHS regulations at 45 CFR 46. Additional information can be found at: http://osp.od.nih.gov/sites/default/files/NIH_sIRB_Policy_Multi_site_Research_UPDATED2016.pdf
- Principal Investigators (PIs) who wish to use an External IRB or a Central IRB as the IRB of record for the overall study must register the study with UIC OPRS.
- A Reliance Agreement or Memorandum of Understanding must be signed and executed before the study may be initiated at UIC as the role of the IRB of record, the role of UIC, and the role of the UIC Principal Investigator must be clearly explained.
- A Coverage Analysis must be completed by the OVCR Clinical Trials Office for all clinical trials requesting use of an external IRB prior to the initiation of research at UIC so that the Principal Investigator and subject understand their responsibility regarding the costs of the research procedures and appropriate local context language is inserted in the consent document.
- The External IRB or Central IRB will be the IRB of record and, therefore, responsible for ensuring that the research satisfies the federal regulations.

- UIC is responsible for ensuring that the research is feasible, appropriate for the University and Community, and investigators and research staff are qualified. UIC is also responsible for ensuring that the research is conducted according to the IRB approved protocol.
- The UIC OVCR will charge the Investigator's Department for research coordination and monitoring associated with the use of the External IRB or Central IRB according to the schedule provided in the policy. Investigators should account for these fees as direct costs when submitting a proposal to the NIH Funding Institute or Center (IC).

The new OPRS policy can be reviewed in its entirety at the following OPRS website: http://research.uic.edu/irb0936**.**

FAQ's regarding the new NIH policy

Does this new policy apply to all human subject research?

No. The new policies and procedures ONLY apply to NIH-funded, multi-site non-exempt human subject research.

What types of studies are expected to use a single IRB (sIRB) under the new NIH policy?

The sIRB policy applies to the domestic sites of NIH-funded multi-site studies where each site will conduct the same protocol involving non-exempt human subject research, whether supported through grants, cooperative agreements, contracts, or the NIH Intramural Research Program. It does not apply to career development, research training or fellowship awards. Under the policy, "multi-site" is defined as two or more sites. Foreign sites participating in NIH-funded, multi-site studies will not be expected to follow this policy. The policy recognizes that it may not always be possible to use a sIRB, and it provides for exceptions when review by the proposed sIRB would be prohibited by federal, tribal, or state law, regulations or policies.

Who is responsible for selecting the sIRB and when must this be done?

In the proposal for research funding, NIH expects the submitting investigator to include a plan describing the use of a sIRB. Where possible, the plan should include the registration number issued to the IRB by the HHS Office for Human Research Protections. For delayed-onset research, where the IRB cannot be identified, proposals should include a statement that awardees will follow the sIRB policy and communicate plans to use a registered IRB of record to the funding NIH Institute/Center prior to initiating a multi-site protocol. UIC generally expects that a UIC IRB will serve as the IRB when the lead site is UIC.

What will happen if the applicant is not able to identify the sIRB, for example, because the sites are in disagreement about the selection?

If the sIRB cannot be identified prior to award, NIH will place terms and conditions on the award restricting human subject research. If sites are unable to agree on the sIRB, the Funding Institute or Center (IC) funding the research will assist in resolving the matter. The sIRB will need to be identified before the release of funds under the award.

What is the difference between a central IRB and a sIRB?

Both are designed to help streamline IRB review, and the terms are sometimes used interchangeably. However, the term central IRB is generally used to refer to an IRB that reviews many different research protocols. Central IRBs are also sometimes referred to as independent IRBs. As used in the NIH policy, the term single IRB refers to the IRB (which may be a central IRB or an institution-based IRB) that is selected to serve as the one IRB of record for the review of one protocol that will be carried out at many sites.

Who can I contact if I have questions regarding this new policy?

Please contact Brandi Drumole, OPRS Assistant Director, at 312-996-0458 or bbrown1@uic.edu.

OPRS Live (beta) Update

CONTRIBUTED BY CHARLES HOEHNE

As the OPRS Director, Dr. Jim Fischer, noted in his newsletter introduction, electronic submission of all human subject research applications is now a reality at UIC. Approximately 3600 applications have been submitted through OPRS Live (beta).

As familiarity with the electronic submission process has increased, turnaround times have decreased. It is fully expected that this trend will continue, especially as enhancements to the system are implemented. Here is a brief overview, notes and highlights of OPRS Live (beta):

- New users are encouraged to complete a brief tutorial prior to registering in OPRS Live (beta).
- If you are a new user, you will need to register by clicking on 'New User'. Enter your name and email address. You will then receive a temporary password in your email which you can use to login. The username should be the complete email address e.g. myemail@uic.edu. Please make sure you change your password, after you have logged in. In order to register for OPRS Live (beta), investigators must have a UIC Investigator Training record. UIC investigators should use their UIC email address when registering.
- The terms “full submission” and “quick submission” refer to the submission process, not the review process. Full submission means the application is routed electronically to the faculty sponsor (if needed), department head, and then to OPRS. Full submissions do not require “wet signatures.” Instead, electronic “signatures” are obtained when the principal investigator, faculty sponsor, and department head accepts the terms and conditions of the submission. Overwhelmingly, most applications are submitted to OPRS via full submission procedures. Quick submissions, on the other hand, are routed directly to OPRS. Since applications are not routed electronically to the faculty sponsor and/or the department head, “wet signatures” are required. Importantly, quick submissions are limited to: a) Applications submitted to the Western IRB or the NCI Central IRB; and b) Determination of Whether an Activity Represents Human Subject Research applications [Note: Neither wet signatures nor department head assurances are required for the Determination Application].
- Please keep the following basic information in mind when submitting an application electronically via the full submission process:
  a. Complete the short questionnaire. These questions will help determine the required review process (exempt, expedited or convened) and help the system keep track of required documents that need to be included with the application [e.g., If “yes” is answered to the inclusion of minors question, OPRS Live (beta) will prompt you to include Appendix B with the submission].
  b. Utilize the suggested list of documents to include with the submission. Note: Hyperlinks to specific OPRS documents (e.g., Initial Review Application and appendices) will be provided; however, you will need to develop your own study specific documents (e.g., research protocol, recruitment material, informed consent document, survey instrument, grant/contract/sub-contract).

c. Save all documents on your desktop, laptop or other device. Please utilize the document naming guidance when saving your documents.

d. Once all documents have been completed and saved, upload them into OPRS Live (beta).

e. The application is now ready to be submitted to the faculty sponsor (if required) and the department head.

- Please do not include multiple applications with one submission. For example, OPRS cannot accept an amendment submitted as an attachment to a Continuing Review Application. Instead, these documents must be submitted separately. Additionally, investigators should not submit two applications for the same study (e.g., Initial Review Application and Claim of Exemption; or Continuing Review Application and a Final Report). If you are unsure which application to submit, please contact OPRS (312-996-1711 or uicirb@uic.edu).
- OPRS no longer accepts paper applications or applications via email.

Examples of OPRS Live (beta) enhancements:

- Dashboards: At the request of many users, dashboards have been developed which enable users to navigate OPRS Live (beta) by clicking single buttons. For investigators, there are several (~15) dashboard buttons including Start New Submission, Submissions that need Modifications, My Active Protocols, My Completed Protocols, My Submitted Full Applications and My Submitted Quick Applications. Faculty Sponsors will have dashboard buttons indicating, Student Submissions Ready to Approve and Approved Student Submissions.
- Placeholders for Approved Documents: The OPRS Live Tech Support Team is developing a placeholder mechanism within the system for OPRS staff to place approved documents such as the research protocol, stamped recruitment documents and stamped informed consent documents. For this reason, it is important to submit such documents separately rather than embedding them into the research protocol or application. The placeholder enhancement will promote greater compliance when conducting research by making the currently approved documents available to the research team. It will also promote more efficient review of Continuing Review and Amendment applications. Most importantly, this enhancement will allow OPRS Live (beta) to be used not just for submitting applications, but also as a tool for conducting the research.
- Help and Training Videos and Documents: As enhancements are made to OPRS Live (beta), the embedded help and training videos and documents will be edited as needed. New videos and documents will be released as well.

OPRS Live (beta) users are encouraged to utilize the available assistance:

- For questions about technical OPRS Live (beta) issues Email: oprslivesupport@uic.edu
- For questions about the IRB process, policies, and submission requirements: oprslive-irbprocess@uic.edu OR 312-996-1711
- For updates to name, department, contact information and training: rwdataentry@uic.edu OR 312-996-1711
- For questions about specific protocols, including review status: Please directly contact the staff of the IRB to which your protocol was assigned.

Important HSPP Policy Change - Extension of Approval Periods for Minimal Risk Non-Federally Funded IRB-Approved Research

CONTRIBUTED BY CHARLES HOEHNE

OPRS is pleased to announce that beginning in Spring 2017, IRB approval for minimal risk, non-federally funded research will be extended from a maximum of one year (365 days) to a maximum of three years (1095 days). UIC has chosen to limit the scope of its Federalwide Assurance (FWA) to federally funded research. "Unchecking the box" allows UIC to utilize greater flexibility for oversight of non-federally funded human subject research involving no greater than minimal risk to subjects. This exciting new Flexibility Policy will allow the IRB to focus more resources on greater than minimal risk studies while reducing regulatory burden on investigators, research personnel and OPRS staff.

Here is a sneak peek at the Flexibility Policy:

- This policy is limited to non-federally funded human subject research studies involving no greater than minimal risk to subjects.
- Should the funding status of a study reviewed under this policy change, it is the responsibility of the Principal Investigator to notify the IRB via amendment. If the amendment adds federal funding or increases the risk to subjects beyond minimal, the IRB approval period will be shortened to no more than one year.
- Under no circumstances will federally funded or FDA regulated research be reviewed under this policy.
- Inclusion/exclusion of any research study in this flexibility initiative will be at the discretion of the UIC IRB. That said, it is expected that the majority of eligible protocols will be granted three-year approval periods.
- For currently IRB-approved studies, the current one-year approval period will not be automatically extended, but the IRB will consider granting three-year approval at time of continuing review.
- This flexibility policy does not alter approval periods for exempt research, as UIC has already been granting three-year exemption periods for the past several years.

Mandatory Exclusions to the Flexibility Policy:

- Federal funding, including federal training and center grants
- No-cost extensions of federal funding
- Student projects for which the faculty sponsor receives federal funding
- Studies with FDA-regulated components
- Studies with clinical interventions

Please stay tuned in 2017 for additional information regarding the release of the finalized Flexibility Policy.

Did you Know?

CONTRIBUTED BY CHARLES HOEHNE

1. OPRS has begun the process of applying for American Association of Human Research Protection Programs (AAHRPP) reaccreditation. The application is due in the spring, and the site visit will be scheduled after the application process has been completed. The reaccreditation process will require analysis and modifications of

institutional policies and procedures. It will likely also require additional education and training for individuals involved in the UIC Human Subjects Protection Program (HSPP). The UIC HSPP was initially accredited in March 2010 and received reaccreditation for five years in September 2012. AAHRPP accreditation is important to the institution in part because it helps promote the ethical conduct of research benefiting everyone equally.

2. 2016 Holiday Schedule - The Office for the Protection of Research Subjects (OPRS) will observe the UIC reduced service schedule for non-essential services that begins on **Thursday, December 22nd**. OPRS will close at 5:00 PM on Thursday, December 22, 2016, and will reopen at 8:30 AM on Tuesday, January 3, 2017. OPRS Live submissions will not be accepted by the OPRS Front Desk during the reduced service period. OPRS will make every effort to process submissions that were received by December 1, 2016 prior to the December 22, 2016 closure; however, please note that our ability to do this depends on the volume of submissions received and staffing during this period. Convened submissions will be processed based on the current submission/meeting schedule. Please refer to the OPRS Web Site for the specific deadline and meeting dates. Please be mindful of your protocol expiration date. If your protocol expires before January 9, 2017, please have your Continuing Review in to OPRS at least four weeks ahead of the expiration date to prevent a lapse. Requests for emergency use of an investigational drug or device may continue to be submitted during this time.

3. Prior to his retirement from OPRS in November, Dr. Clyde Wheeler began his affiliation with UIC as a student in 1980. He began his career at UIC as an animal researcher; however, he changed career paths to human subject protections after developing severe allergies to animals. The rest, as they say, is history. Bon Voyage, Clyde! Thank you for a job well done!