

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 OPRS revises policies to better serve the UIC research community, the October edition of the OPRS Newsletter offers an article focusing on lapses in IRB approval.

You may have noticed an increase in letters from the IRB concerning lapses in IRB approval and notifications of non-compliance related to lapses in IRB approval, typically non-serious and non-continuing but occasionally serious or continuing non-compliance.

Lapses in IRB approval were a major issue cited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) during their site visit to UIC during the JBVAMC accreditation. This raised concerns on the culture of our research community, and UIC self-reported to the Office of Human Research Protections (OHRP). As part of our corrective action plan, we assured OHRP that we would reduce the number of lapses of IRB approval and make certain research activity stops when IRB approval has expired.

Please take the time to read this article. The article and accompanying tip sheet describe what a lapse in IRB approval represents, what actions must be taken following expiration in IRB approval and what the consequences of a lapse are. Any questions or concerns, please feel free to call OPRS at 312 996 1711.

Also, this issue contains articles devoted to preparing the UIC Research Community for the upcoming site visit of the Association for the Accreditation of Human Research Protection Programs (AAHRPP) and further Test Yourself case studies.

The OPRS is offering special continuing education credits for those who wish to be prepared for the AAHRPP site visit and has launched 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) or Charles Hoehne (312-355-2908, choehne@uic.edu) anytime from Monday - Friday, 9am-5pm.

Jim Fischer
Director OPRS



James H. Fischer
Director, OPRS



TIPS FOR INVESTIGATORS

CONTINUING REVIEW AND EXPIRATION OF RESEARCH: CLARIFICATION!

The research expires at midnight the night of the expiration date stated on your approval notices and consent documents. For example, if your approval period is 10/16/07–10/15/08, the research is considered expired as of 12:01 am on 10/16/08.

Once the approval period has ended, the research is considered expired. Once the research is expired **all** research activities must come to a halt.

Continuing Reviews that are reviewed by expedited review are granted an approval period for 364 days from the date it was approved. For example, if a Continuing Review was approved by expedited review today, October 17, 2008, it would be granted an approval period of 10/17/08–10/16/09.

Continuing Reviews that are reviewed by the Convened IRB are granted an approval period that starts with the date it was approved and ends 364 days after the meeting date. For example if a Continuing Review is reviewed by the Convened IRB on 10/20/08 and is approved at the meeting, it will have an approval period of 10/20/08–10/19/09. However, if the Convened IRB requests modification to the research and it is not approved until 11/15/08, the approval period would be 11/15/08–10/19/09.

Approval periods can be granted for less than one year, but for no more than one year. The IRB has the authority to set the approval period for any amount of time it wishes dependent upon the risk and other issues with the research. For example, a research study that has had a compliance issue regarding a breach of confidentiality may only be granted an approval period of six months.

True or False:

If the approval period on the notice of approval and the consent document states 10/16/07–10/15/08, a subject can sign the consent document at 7:45 PM on 10/15/08.

True. The research does not expire until midnight on 10/15/08; therefore, the consent is valid at 7:45 PM.

True or False:

An investigator has a study that expires on 11/15/08. He submits his Continuing Review submission when he receives his 60-Day notice (9/15/08). His Continuing Review submission is granted approval by expedited review on 10/1/08. His approval notice and consent document should state 10/1/08–11/14/09.

False. The approval period cannot be granted for more than one year. His approval notice and consent documents should state 10/1/08–9/30/09.

CONTINUING REVIEW AND EXPIRATION OF RESEARCH: CLARIFICATION!

CONTINUED FROM PAGE 2

True or False:

An investigator has a study that expires on 10/15/08. He submits his Continuing Review submission for expedited review on 10/14/08. His Continuing Review submission is granted approval on 10/20/08. His approval notice and consent documents will state 10/15/08–10/14/09.

False. The approval period does not begin until the research is approved; therefore, the approval period should be 10/20/08–10/19/08. The research was expired from 10/15/08–10/20/08.

True or False:

An investigator has a research study that expires on 10/10/08. He submits his Continuing Review on 9/15/08 to be reviewed by the Convened IRB on 10/6/08. The Convened IRB requests modifications. The investigator responds to the modifications for expedited review and is granted approval on 10/15/08. His approval notice and consent documents will state 10/15/08–10/5/09.

True. The approval period for Convened reviews begins when the research is approved (10/15/08). The approval period for Convened reviews ends 364 days after the Convened meeting (10/5/09).



REVIEW FOR INVESTIGATORS

BASIC INFORMATION FOR HUMAN SUBJECT RESEARCH SUBMISSIONS

Privacy and Confidentiality – What's the Difference?

Privacy = People / Confidentiality = Data

Privacy can be thought of in terms of allowing others access to oneself. For example, a subject may not want it known that they use a particular clinic or that they have certain life experiences.

Confidentiality builds upon privacy and is based upon trust. From a research perspective, subjects trust that investigators will not divulge confidential information except in ways previously agreed upon. As AAHRPP states: Confidentiality refers to the agreement between the investigator and participant in how data will be managed and used.

AAHRPP also states: what is private depends on the individual and can vary according to gender, ethnicity, age, socio-economic class, education, ability level, social or verbal skill, health status, legal status, nationality, intelligence, personality, and the individuals relationship to the investigator. In other words, the investigator needs to individualize the plan for each study based on the expected study population.

BASIC INFORMATION FOR HUMAN SUBJECT RESEARCH SUBMISSIONS CONTINUED FROM PAGE 3

Investigators can address privacy concerns in their proposals including:

- When describing recruitment methods;
- The settings where interactions between an individual and investigator will occur; and
- Who will be present during the conduct of the research.

Investigators can address confidentiality concerns in their proposals including:

- When explaining how participants identities will be safeguarded;
- When describing short- and long-term plans for safeguarding the confidentiality of the research data;
- When describing provisions for de-identifying the data as soon as possible; and
- When describing confidentiality safeguards in the informed consent document/HIPAA authorization form.

Case Study

An investigator is conducting focus group discussions to learn more about how embarrassing skin rashes impact quality of life. Flyers will be posted in UIC clinics and hallways listing the specific date, time and location of the scheduled focus group discussions. Before the focus group discussion begins, there will be a group informed consent process, and once written informed consent has been obtained, the discussion will begin.

Question 1: Does this study design adequately protect privacy?

Answer: No. By listing the specific date, time and location of the focus group discussion, simply showing up at the meeting identifies the individuals as having a really embarrassing skin rash. To better protect the potential subjects privacy, the flyer should instead ask potential subjects to call the principal investigator to learn more about the research including the exact location of the focus group discussion. Additionally, informed consent should be obtained privately when possible.

Question 2: Does this study design adequately protect confidentiality?

Answer: It depends on how the investigator designs the research. The informed consent document will need to: a) clearly asks participants to respect the privacy and confidentiality of the participants; and b) clearly state that privacy and confidentiality cannot be guaranteed in a focus group setting. Additionally, the principal investigator will need to provide a clear plan for safeguarding the data (including where and how data will be stored and when the data will be de-identified).

Amendments and Protocol Exceptions: What's the Difference?

A protocol exception is a planned change to the research. Unlike an amendment, a protocol exception involves a single subject or, less commonly, a small group of subjects and is not a permanent revision to the research protocol. Similar to an amendment, IRB approval of a protocol exception must occur prior to its implementation. If the research involves an investigational agent (drug, device, or biologic), prior approval by the sponsor is also required. Additionally, when the research involves an investigational device and the changes or deviations may affect the scientific soundness of the plan or the rights, safety, or welfare of the subjects, FDA pre-approval is required.



TEST YOURSELF!

HOW MUCH DO YOU KNOW ABOUT HUMAN SUBJECTS PROTECTION?

Case Study #1

An investigator obtains individually identifiable information on the treatment outcomes of patients treated for arthritis with either Drug A or Drug B by viewing patients existing individually identifiable medical records at the clinics where the patients were treated. The investigator records the patients' treatment outcomes in a coded manner that could permit the identification of the patients. What level of IRB review is needed for this proposal?

Answer:

Review is required at either the expedited or convened level depending on the level of risk. In this example, the investigator is conducting human subjects research because the investigator is obtaining and recording identifiable private information from patients (and now subjects) medical records. The study is not eligible for a claim of exemption, since the investigator is recording the information in a coded manner, thus allowing the subjects to be identified indirectly through a code linked to the subjects.

Case Study #2

An investigator obtains individually identifiable information on the treatment outcomes of patients treated for arthritis with either Drug A or Drug B by viewing patients existing individually identifiable medical records at the clinics where the patients were treated. The investigator records only patient age, sex, diagnosis, treatment, and health status at the end of 6 months of treatment so that the investigator cannot link the recorded information back to the patients. What level of IRB review is needed for this proposal?

Answer:

In this example, the investigator is conducting human subjects research because the investigator is obtaining (accessing) identifiable private information from patients (and now subjects) medical records. However, the study is eligible for a claim of exemption since the investigator is collecting existing data and does not record information in the research record that would allow the subjects to be identified either directly or indirectly through codes linked to the subjects.

Case Study #3

An investigator did not submit a continuing review application for their research study and the study has lapsed in IRB approval. The trial is a drug trial and the investigator would like to submit a request to the IRB to continue research interventions for some or all subjects. Should the investigator submit an amendment or a protocol exception to the IRB?

Answer:

Given these facts, the Investigator should fill out the Protocol Exception form. When a study is deemed lapsed in IRB approval, the investigator must submit a request to the IRB to continue research interventions or interactions for some or all subjects when it is in the best interest of the subjects to continue. The investigator requests a protocol exception for the continuation of certain aspects of the research on the UIC OPRS *Protocol Exception* Form. An investigator must clearly distinguish and explain what research activities from which

HOW MUCH DO YOU KNOW ABOUT HUMAN SUBJECTS PROTECTION? CONTINUED FROM PAGE 5

he or she will refrain as part of the lapse and what research activities require continuation. The investigator must also explain the underlying reasons for which the protocol exception is requested for each activity and each subject where an over-riding safety concern or ethical issue indicates that it is in the best interests of the individual to continue participating.

Case Study #4

An investigator obtains individually identifiable information on the treatment outcomes of patients treated for arthritis with either Drug A or Drug B by viewing patients existing individually identifiable medical records at the clinics where the patients were treated. The investigator records the patients' treatment outcomes in a coded manner that could permit the identification of the patients. What level of IRB review is needed for this proposal?

Answer:

Review is required at either the expedited or convened level depending on the level of risk. In this example, the investigator is conducting human subjects research because the investigator is obtaining and recording identifiable private information from patients (and now subjects) medical records. The study is not eligible for a claim of exemption, since the investigator is recording the information in a coded manner, thus allowing the subjects to be identified indirectly through a code linked to the subjects.



POLICY SPOTLIGHT!

LAPSES IN IRB APPROVAL INVESTIGATOR RESPONSIBILITY TO FILE A CONTINUING REVIEW OR FINAL REPORT

Investigators must file either a continuing review application or a final report well in advance of the expiration date of IRB approval.

Continuing Review Application. UIC OPRS strongly recommends submitting the continuing review application or final report application 30-45 calendar days prior to the date of expiration of IRB approval for expedited non-Jesse Brown VAMC submissions and 60 calendar days from the date of expiration for expedited JBVAMC submissions. For convened review protocols, investigators are strongly recommended to submit the continuing review or final report application 30-45 calendar days prior to the date of expiration for non-JBVAMC protocols and 60 calendar days for JBVAMC submissions. Submission deadlines for the appropriate board meeting (<http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/meetings.shtml>) should be kept in mind in planning the submission.

LAPSES IN IRB APPROVAL

INVESTIGATOR RESPONSIBILITY TO FILE A CONTINUING REVIEW OR FINAL REPORT CONTINUED FROM PAGE 6

Final Report Application. Investigators must file a UIC OPRS Final Research Report form to request study closure with OPRS for IRB approved and exempt studies within 30 days of the completion of the study.

Practical examples of when a final report application must be submitted to UIC OPRS include, but are not limited to, the following:

- If an investigator no longer has funding and cannot perform the study without funding, the investigator must submit a final report;
- If the investigator has not enrolled any subjects and does not plan to enroll subjects in the near future;
- If the sponsor has closed the study before the study is initiated at UIC;
- If an external event prevents the investigator from accessing the population needed to conduct the research;
- If the investigator determines that he or she does not have sufficient resources, including time, financing, space, and personnel, to devote to the research.

Department Heads, Unit Heads, and Faculty Sponsors are responsible for ensuring that PIs leaving UIC submit a UIC OPRS Final Research 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.

Lapses in IRB Approval. Lapse in IRB approval represents a failure to obtain continuing review approval by the expiration date assigned by the IRB or approval of a final report. After expiration of IRB approval, all research activities must stop, including any research related interventions, recruitment, data collection, data sharing/reporting and analysis of data, and no new subjects may be enrolled. If a continuing review or final report to the IRB is not received per the timeline outlined in the following link, the research is closed and a new submission is required to re-open it: <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0284.pdf>. For more information, please view the tip sheet at <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0876.pdf>.

Consequences of Lapse in IRB Approval. After the IRB approval for a study has lapsed, follow-up interventions or interactions with some or all subjects require the submission of a request to the IRB for a protocol exception. Interventions are allowed to continue only when it is in the best interest of the subjects. To request the continuation of certain aspects of the research during the lapse, the investigator must submit a UIC OPRS Protocol Exception form to clearly distinguish and explain what research activities from which he or she will refrain as part of the lapse and what research activities require continuation.



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.

UPCOMING TRAINING

DISCUSSION WITH DR. JEREMY SUGARMAN

October 27, 2009

10:45 - 11:30 AM

Student Center West, Chicago Room

1 credit

Jeremy Sugarman, MD, MPH, MA is the Harvey M. Meyerhoff Professor of Bioethics and Medicine, Professor of Medicine, Professor of Health Policy and Management, and Deputy Director for Medicine of the Berman Institute of Bioethics at the Johns Hopkins University. Dr. Sugarman conducts both theoretical and empirical research in medical ethics. His work concentrates on informed consent, research ethics, and the ethical issues associated with emerging technologies. He is the author of over 175 publications in peer-reviewed journals. He has also edited or co-edited four books (*Beyond Consent: Seeking Justice in Research*; *Ethics of Research with Human Subjects: Selected Policies and Resources*; *Ethics in Primary Care*; and *Methods in Medical Ethics*). Dr. Sugarman is an associate editor of *Clinical Trials*, a contributing editor for *IRB*, and is on the editorial boards of *Accountability in Research and Theoretical Medicine and Bioethics*. Dr. Sugarman serves on the Scientific and Research Advisory Board for the Canadian Blood Service and is a member of the Maryland Stem Cell Research Commission. He is currently Chair for the Ethics Working Group of the HIV Prevention Trials Network, the Ethics Officer for the Resuscitation Outcomes Consortium, and Co-Chair of the Johns Hopkins' Embryonic Stem Cell Research Oversight Committee. Dr. Sugarman is a member of the American Society of Clinical Investigation and a Fellow of the American Association for the Advancement of Science, the American College of Physicians, and the Hastings Center.

For additional information and to RSVP, please contact:
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ovcr/research/
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