



The DHRP Newsletter

The University of Toledo
Department for Human Research Protections
Institutional Review Boards

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Sara L. Wisniewski, J.D., Editor

Upcoming IRB

Submission & Meeting Dates

Biomedical IRB

- March 19th: IRB Meeting, 2pm -5pm
- March 23rd, Noon: Application deadline for April 16th Meeting

Social, Behavioral & Educational IRB

- March 26th: IRB Meeting, 12:30pm-2:30pm
- April 16th: Application deadline for April 30th meeting

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Biomedical IRB Passes FDA Surveillance Inspection

An Investigator from the Food and Drug Administration (FDA) conducted a surveillance inspection of the Biomedical IRB operations from December 8 through December 16, 2008. Surveillance inspections are "not-for-cause" visits that are conducted approximately every five years.

The purpose of the inspections is to determine if the IRB is operating in compliance with applicable FDA regulations, and if it is following its own written procedures. Applicable regulations cover the protection of human subjects, IRB operations, investigational new drug applications, and investigational device exemptions.

IRB staff members are very mindful of the importance of following regulatory requirements, and have made several

improvements in its operations and procedural requirements over the last few years in an effort to maintain regulatory compliance. In addition to reorganizing and updating all IRB policies and procedures in 2007, the IRB issued an updated and revised adverse event policy in 2008 following new FDA guidance. Administratively, the department revised its standard operating procedures for recording IRB minutes and votes, as well as amended certain IRB forms. Each of these changes were made in an effort to allow the IRB to perform its duties in accordance with federal regulations.

Although investigators and coordinators sometimes question IRB staff following changes to policies, procedures or forms, such changes are generally

made to maintain compliance with regulatory requirements or to implement updated guidance from federal agencies.

The FDA inspector noted during the exit interview in December that he found no reason to issue a Form 483, which is issued when inspectors find operational issues that depart from the requirements of FDA regulations.

The seven day intense inspection was a little stressful for IRB staff members, even though they all believed that the IRB operates in accordance with all applicable regulatory and ethical standards. The positive remarks made by the FDA inspector during the exit interview regarding the operations and recordkeeping of the Biomedical IRB affirm that belief.

Expanded IRB Authorization To Facilitate UT Research Conducted at St. Vincent Mercy Medical Center

Effective October 1, 2008, the UT Biomedical IRB expanded its IRB Authorization Agreement with St. Vincent Mercy Medical Center (SVMCMC). The purpose of an IRB authorization agreement is to enable an institution with a Federalwide Assurance for The Protection of

Human Subjects to rely on an IRB of another federally assured institution to review all or certain designated research.

Prior to October 1, 2008, the agreement authorized SVMCMC to review all pediatric research conducted by UT

faculty, staff, students or volunteers performed at SVMCMC. The new agreement expands this authorization to cover research on adult subjects performed at SVMCMC. The primary purpose of expanding the scope of the agreement is to reduce the duplication of efforts

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Literature Reviews and Their Assessment: A Required Element of IRB Applications and Continuing Review

Contributed by Carolyn Pinkston, RN, BS, CIP



Investigators must understand that literature reviews are a two part process: (1) the search for the primary references, and (2) the intelligent and critical evaluation of the information found in the primary sources.

During a recent Biomedical IRB meeting, IRB members discussed the need to clarify with researchers the need for updated literature reviews during the continuing review process. Primary reviewers for the IRB raised the issue that researchers were only providing a list of current publications in the continuing review application and not a synopsis of the most current information on the research subject matter.

After a discussion, the board reached agreement on a statement to help clarify the requirement for updated literature reviews. The statement was subsequently added to the section of the Biomedical IRB continuing review application entitled "Progress Report Synopsis

(Section G, Part III):"

The purpose of the updated literature review is to assure the IRB that the Principal Investigator has reviewed pertinent literature regarding the study and any agents used therein, that there is no change in the risk–benefit ratio, and that the study continues to be relevant. The IRB is interested in an intelligent and critical review of the information contained in the primary sources. Please summarize relevant conclusions from the literature cited and provide your assessment of any change in the risk–benefit ratio and the value of continuing the study.

The principal investigator or a documented member of the

research team may conduct the relevant literature search, but the principal investigator must review the literature and personally draft a one or two paragraph synopsis detailing his or her assessment and its impact, if any, on the research being conducted.

Investigators should keep in mind that literature reviews are a two part process: (1) the search for the primary references, and (2) the intelligent and critical evaluation of the information found in the primary sources. IRB applications that are missing the latter component are considered incomplete because the IRB is unable to make adequate and informed assessments of risks and benefits without such information.



SBE Webinar: New Solutions to Ongoing Problems When Reviewing Social, Behavioral, and Educational Research

Contributed by Carolyn Pinkston, RN, BS, CIP

The Department for Human Research Protections recently sponsored a webinar promoted by the organization, Public Responsibility in Medicine & Research, PRIM&R. Several members of UT's Social, Behavioral and Educational IRB and DHRP administrative staff attended the webinar.

The featured speakers were J. Michael Oakes, Ph.D., Associate Professor, University of Minnesota and Mary Marshall Clark, Director, Oral History Research Office, Columbia University.

Dr. Oakes provided an overview of several timely issues including IRB mission creep, the definition of human subject research, the categories and qualifications for exempt and expedited research and student research activities. Dr. Oakes

also examined the expanding area of research conducted via internet surveys. The discussion included popular recruitment techniques, issues obtaining appropriate informed consent, sensitive questions and topics and the security of information gathered via the Web.

Ms. Marshall Clark's segment of the webinar was entitled, "Ethical Fieldwork: Oral History, Ethnography and IRBs." Ms. Marshall Clark examined the similarities and differences in which some oral historians and the federal Office for Human Research Protections (OHRP) define oral history, and the highly debated topic of their differences in approach for its review. Ms. Marshall Clark posed the question of whether all qualitative research requires IRB review.

She focused on the manner in which qualitative research differs in method and intent, in relation to 45 CFR 46, which defines research as "systematic investigation designed to contribute to generalizable knowledge". While there is great debate regarding IRB oversight of oral history projects, Ms. Marshall Clark did encourage IRB review when oral historians work with other researchers who intend to use open-ended qualitative interviews to draw systematic or generalizable conclusions in order to predict human behavior. To request a copy of the Webinar handout, please e-mail:

carolyn.pinkston@utoledo.edu.

For additional information about PRIM&R, go to: <http://www.primr.org>.

Expanded IRB Authorization

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of UTMC physicians and residents involved in human subject research at SVMMC. With this expanded agreement, UT researchers performing research at SVMMC will only have to submit one IRB application, and will be subject to the continuing oversight of one IRB.

Although the IRB review will rest solely with the SVMMC IRB, the UT IRB office will maintain close communication with the SVMMC IRB regarding all UT related research. All research conducted by UT faculty, students or other employees, regardless of whether the research is conducted at UT or at another institution is considered UT related research and

thus falls under the scope of UT oversight and compliance requirements. Copies of SVMMC IRB applications and approval documents listing UT individuals as part of the study team will be forwarded to the UT IRB office for review, and a summary of such information will be included with UT IRB reports to University administration.

Researchers should keep in mind that they must still obtain UT IRB approval for any research that is performed primarily at UTMC, even if they have SVMMC IRB approval.

Questions may be submitted to Sara Wisniewski at: Sara.wisniewski@utoledo.edu.

OHRP Research Community

Forum May 14, 2009

On May 14, 2009, the Office for Human Research Protections will hold a Research Community Forum in Ann Arbor entitled, "Reducing Regulatory Burden—Real Strategies for Change." The event is co-sponsored by the University of Michigan and is intended for researchers, research staff, IRB members and staff, and others involved in human subject research.

According to the event's website, "Invited speakers and panelists will share ideas from a wide range of public and private institutions. In addition, representatives from the Office for Human

Research Protections (OHRP), the National Institutes of Health (NIH), the Food and Drug Administration (FDA), the Veterans Administration (VA), the National Science Foundation (NSF), other federal agencies, the Secretary's Advisory Committee on Human Research Protections (SACHRP) and the Association for the Accreditations of Human Research Protection Programs (AAHRPP) will provide updates and participate in open forum discussions."

Information regarding the forum can be found at <http://www.research.umich.edu/hrpp/event.html>.

Compliance Q & A: >>>

What is an Investigator's Responsibility Regarding Continuing Review? What should an Investigator do if IRB study approval expires?

Investigators are responsible for fulfilling requirements associated with continuing review in time for the IRB to carry out review prior to the expiration date of the current IRB approval. Continuing review of research and approval of research studies is required so long as the research study is ongoing, that is, until research-related interactions and interventions with human subjects and the obtaining and analysis of identifiable private information described in the IRB-approved research plan have been completed.

Investigators are responsible for submitting sufficient materials and information for the IRB to meet its regulatory obligations, and should follow the IRB policies and procedures for continu-

ing IRB review of research. These policies and procedures are based on the HHS regulations at 45 CFR 46.103(b)(4).

If IRB approval of a specific study expires before continuing review and approval occur, investigators must stop all research activities involving human subjects related to that study ([45 CFR 46.103\(b\)](#)), except where they judge that it is in the best interests of already enrolled subjects to continue to participate. When investigators make this judgment, they must promptly notify the IRB ([45 CFR 46.103\(b\)\(5\)](#)). When the IRB reviews the investigator's decision, it may decide whether it is in the best interests of already

enrolled subjects to continue to participate in the research by considering the best interests of subjects either one at a time or as a group.

If an IRB determines that it is not in the best interests of already enrolled subjects to continue to participate, investigators must stop all research activities, including intervening or interacting with subjects, and obtaining or analyzing identifiable private information about human subjects ([45 CFR 46.103\(b\)](#)). Investigators may resume the human subjects research activity once continuing review and approval by the IRB has occurred.



Continuing Review Tip:

Calendar the IRB approval expiration date and submit the continuing review application at least 2 months in advance.

IRB Meeting Schedules

2009 Biomedical IRB Submission

Deadlines and Meeting Dates

<u>Submission</u> <u>Deadline is Noon on:</u>	<u>For the Meeting</u> <u>Held at 2pm On:</u>
February 23rd	March 19th
March 23rd	April 16th
April 27th	May 21st
May 26th	June 18th
June 22nd	July 16th
July 27th	August 20th
August 24th	September 17th
September 28th	October 15th
October 26th	November 19th
November 23rd	December 17th

2009 SBE IRB Submission

Deadlines and Meeting Dates

<u>Submission</u> <u>Deadline is 5pm on:</u>	<u>For the Meeting</u> <u>Held at 12:30 pm On:</u>
March 12th	March 26th
April 16th	April 30th
May 14th	May 28th
June 11th	June 25th
July 16th	July 30th

Additional dates will be set following the release of fall 2009 faculty schedules.

DHRP Website: <http://www.utoledo.edu/research/RCMain.html>

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