

Institutional Review Board News

December 2006



Volume 2, Issue 2

UT Department for Human Research Protections

Main Campus and Health Science Campus IRBs Join Forces Under One Department

Following the merger of UT and MUOT, the Institutional Review Board offices on the two campuses were reorganized in an effort to become a unified and comprehensive resource for those involved in research at The University of Toledo. The new department has been named The Department for Human Research Protections ("DHRP").

Due to the volume and variety of protocols resulting from an expanded research base, the new University will keep both IRBs with each dedicated to reviewing specific types of research. The DHRP main office and home of the Biomedical IRB, is located in Room 0106 of the Center for Creative Education on the Health Science Campus. The Social, Behavioral and Educational (SBE) IRB office is located in Room 2300 of University Hall on the Main Campus. Moving forward, studies will be routed to each IRB based on the specific type of research and not the campus of origin.

IRB Chairs and Vice Chairs

Barbara K. Chesney, Ph.D.: Dr. Chesney is the new SBE IRB Chair. She is the Chair of the Department of Sociology & Anthropology in the College of Arts & Sciences and an Associate Professor of Sociology. Dr. Chesney is also a member of the IRB serving the Washtenaw County Community Health Organization and The University of Michigan. Her research areas are medical sociology, social psychology, and public health.

Lee A. Pizzimenti, B.G.S., J.D.: Ms. Pizzimenti is continuing her service on the SBE IRB as the new Vice Chair. She is a Professor of Law at the University and has a special interest in the federal regulations protecting human subjects. Ms. Pizzimenti has been a member of the University of Toledo Human Subjects Committee since 1985.

Roland T. Skeel, M.D.: Dr. Skeel has served as the Chair of the IRB on the Health Science Campus, now designated the Biomedical IRB, for the past year and a half. He is a medical oncologist and has been on the faculty in the Department of Medicine for the past 30 years. Dr. Skeel's clinical and scholarly interests have been in cancer treatment, quality of life measurements of patients in clinical trials, and end-of-life care.

Deepak Malhotra, M.D., Ph.D.: Dr. Malhotra is the new Vice Chair of the Biomedical IRB. Dr. Malhotra is a Professor in the Department of Medicine and is Chief of Nephrology. He was Chief of Staff of the Hospital from 2004-2006. He was a

member of the IRB for several years prior to being Chief of Staff. He is active in both basic science as well clinical research endeavors.

IRB Staff – Here to Help Investigators Protect all Research Participants

For the past few months the DHRP has focused on increasing efficiency, supporting the quality research conducted at the university, assuring the highest level of ethical conduct and the adherence to all applicable laws and regulations pertaining to human subjects. Two full-time staff members recently joined the department to team with Susan Mates on the Health Science campus and the two part-time staff members located on the Main Campus.

Carolyn Pinkston, RN, BS, Director of Operations – A department administrator for several years, Carolyn managed operations for an academic department with an active clinical research division. Her initial focus in the new Department of Human Research Protections has been organizing the workflow associated with two IRBs, merging policies and procedures and developing a user friendly DHRP/IRB web site. Additional goals include implementing an electronic submission process, providing additional resources for student and primary investigators, and the preparations required for accreditation by the Association for the Accreditation of Human Research Protection Programs.

Samara Wisniewski, JD, Director of Regulatory Compliance – Samara joined the IRB office in August. She will serve as a resource to the IRB department, researchers, research staff and others involved in research regarding IRB review requirements, ethical guidelines and regulatory issues. Among other duties, Samara is currently pre-reviewing protocols in an effort to streamline the review process, working on updating and merging IRB policies and procedures for the two campuses, and reconciling informed consent forms.

Susan Mates, C.M.A-C., Biomedical IRB Coordinator Susan has worked in a support role for the IRB for approximately a year and a half. In addition to providing all administrative support to the IRB for several months, Susan acted as the sole office resource for the primary investigators and research coordinators during the recent restructuring phase. Her valuable contributions and significant knowledge base will continue to be an asset in her new assignment as the IRB coordinator on the Health Science Campus.

Continued on page 2

IRB Staff, Continued from page 1

Jeff Busch, Ph.D., Social, Behavioral & Educational IRB Coordinator - Jeff joined UT's Research & Sponsored Programs in May 2006 as a Regulatory Compliance Officer. Since the merger Jeff's responsibilities have divided between the reorganization of the IACUC and Radiation programs and serving as the main campus contact for the SBE IRB. Jeff's regulatory experience will continue to benefit University research programs during the current transition and his responsibilities as the IRB coordinator for the Main Campus.

Michelle Shy, SBE IRB Administrative Support – Michelle has been providing support services on a part time basis for SBE IRB operations on the Main Campus for almost a year. She has primary responsibility for all protocol correspondence and data input, and attends to all the details of the monthly board meetings. Michelle's responsibilities also include administrative support for the Main Campus IACUC and radiation programs.

Highlights of Annual PRIM&R Meeting

The annual meeting of the organization for Public Responsibility in Medicine and Research (PRIM&R) held its annual meeting December 15-18 in Washington DC. DHRP and IRB leadership from both campuses attended this educational and idea-exchange meeting with 2700 other IRB professionals from around the US and many international sites. During the meeting, they were able to learn how many other human research protection programs from coast to coast operate their departments. Members of our DHRP also attended presentations by the national Office for Human Research Protections addressing the federal regulations on human subjects research. They learned a lot of valuable information that will allow them improve UT's human research protection program and provide better assistance to everyone involved in research at UT.

IRB Website Under Construction

The groundwork has been laid for a separate Web site for the DHRP and IRB. Utilizing the format provided by the UT Web Development group, the focus is to provide a singular, user-friendly site that is well designed, logical and easily navigated. Updated submission forms streamlined for investigator use and administrative processing are being drafted. In addition to the submission information and instructions, links to training information, FAQs, educational resources and government sites will be provided. The goal is to transition away from the RGA web page to the separate site by February. Advance notice of the new Web address and activation date will be included in an upcoming news article and via written notice to university departments. During this development phase if you have suggestions for items you would like to see added or valuable items you would like to remain, please write to HSCIRBoard@UToledo.Edu.



Compliance Notes

IRB Review: Federal regulations, University policy and ethical guidelines require IRB review prior to beginning any research on human subjects. Additionally, any changes to a research protocol must be reviewed and approved by the IRB (except for emergency situations).

Categories of Research for IRB Review:

Human subject research protocols and related documents are reviewed by the IRB under one of three categories: exempt, expedited or convened IRB review. In reviewing applications, the IRB first determines whether proposed research is "human subjects research" under the guidelines of 45 CFR 46.102. Next it determines which of the three categories of review is appropriate for the research. It is the prerogative of the IRB to determine whether research is *human subjects research* and which category the research falls under. Only research that receives an exemption letter from the IRB is exempt.

All research, regardless of category, must assure that (1) risks to subjects are minimized (sound research design; not unnecessarily expose subjects to risk; when possible, utilize procedures already being performed on subjects) and (2) that risks are reasonable in relation to any anticipated benefits.

Exempt Research: Exemption categories and guidelines are specified in the federal regulations (Title 45 CFR Part 46). Your research must fit into one or more of the listed categories in order to file a "Request for Designation as Exempt Research" with the IRB. The most common exempt research categories at UT are:

- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (unless one of the listed exceptions apply), and
- Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the researcher in such a manner that participants cannot be identified, directly or through identifiers linked to them.

None of the exemptions apply to research involving prisoners, fetuses, pregnant women or human in vitro fertilization.

Expedited Review: Research reviewed under the IRB's expedited process must be considered minimal risk (defined at [45 CFR 46.102\(i\)](#)) and involve only procedures listed in one or more of the categories listed in the Federal Register at [63 FR 60364-60367](#) (November 9, 1998). Those categories include (*list summarized*):

- Clinical studies when IND or IDE application is not required
- Blood sample collection – routine methods/small amounts
- Non-invasive prospective collection of biological samples
- Data collected through non-invasive means routinely practiced in clinical settings
- Materials (e.g. data, documents, specimens) that have been or will be collected for non-research purposes
- Voice, video or digital data collection for research purposes
- Individual or group behavior, surveys, interviews, oral histories
- Specified continuing reviews
- Minor changes or amendments to pre-approved research