

Institutional Review Board News

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UT Department for Human Research Protections

Investigator Responsibilities

Conducting research on human subjects imposes many very important responsibilities upon investigators. The DHRP would like to remind investigators of some of the most important responsibilities related to the protection of human research subjects. These guidelines are consistent with Good Clinical Practice guidelines, Department of Health and Human Services regulations and FDA regulations.

- (1) Obtain and document informed consent from the subject, or if appropriate and approved by the IRB, the subject's authorized representative, using the most current and approved consent form(s). Sign and date the consent form at the time the consent is obtained. **Do not** use expired consent forms. Check the validation dates on the consent form before obtaining consent.
- (2) Keep the signed consent form with the original subject's signature in the patient's chart if the subject is a patient or in your study records if the subject is not a patient. Give a copy to the subject.
- (3) Develop an eligibility checklist with specific inclusion and exclusion criteria to determine that all eligibility criteria are met.
- (4) Promptly notify the IRB in writing of all protocol deviations or violations when they are discovered.
- (5) Request changes to the protocol or consent form by submitting a Request for Amendment/Modification form prior to initiation of changes. Implement changes only **after** written notification of approval from the IRB.
- (6) Complete and submit continuing review applications in plenty of time to fulfill the federal requirement for IRB review at least once every 12 months or more frequently based on the degree of risk (review frequency is determined by the IRB). Federal regulations do **not** permit extensions of time to conduct continuing review.
- (7) If IRB approval of the study lapses, the research **must stop**, unless the IRB finds that it is in the best interest of individual subjects to continue participation in the research interventions or interactions. **Do not** use outdated consent forms or continue to enroll subjects in the study until the study is re-approved.
- (8) Report adverse events to the IRB regardless of the relationship to the study within the required timeframe for adverse event reporting. Refer to the Adverse Event Reporting instructions on the research website for the required reporting timeframes.
- (9) If a Data Safety Monitoring Board (DSMB) has been established for the trial, submit a written summary of the DSMB's periodic review to the IRB for review. Include the DSMB's written summary with your continuing review application.
- (10) **Keep good records!** You should have a study file that contains all study-related information, e.g. all correspondence and protocol information from the sponsor and all IRB correspondence. In general, each subject enrolled or screened for a study should have a file in which documents are placed including a copy of the signed consent form, copies of case report forms, etc. After the study is completed, retain records as required by the University, the sponsor and other record keeping requirements. Federal regulations require retention of records relating to research for three years after the completion of the research. Check the sponsor's record keeping requirements. Keep records for the longest applicable requirement. Remember, if it's not documented, you cannot prove that it happened.

(Adapted From The University of Florida's IRB InvestiGATOR Newsletter)

Recruitment and Advertising for Research Studies

All advertising to recruit study subjects must be reviewed and approved by the IRB. Any advertisement that is not approved may not be used to recruit subjects. Investigators should follow these guidelines when planning advertising to recruit subjects:

- (1) Submit all advertisements in final form to the IRB for review. Do not submit drafts. Transcripts must be submitted for audio and video advertising.
- (2) Print ads must be stamped by the IRB before use.
- (3) Recruitment conducted via the Internet or e-mail must include the IRB number and approval date.
- (4) Any modifications to advertisements must be reviewed and approved by the IRB.

University of Toledo
Department for Human Research Protections
Center for Creative Education, Room 0106
3025 Arlington Avenue
Toledo, OH 43614-2598
Ph. 419-383-6796
Fax: 419-383-3248
Federalwide Assurance #: 00010686

New Addition to the DHRP Staff

Debra Kuron, Secretary 1, has joined the Department for Human Research Protections. Debra will provide secretarial support to the DHRP staff. She will assist with processing research applications, Research and Sponsored Programs data entry, and the coordination of IRB meetings. As Deb becomes acclimated to the department's operation, her responsibilities will expand to include providing back up support for the Social, Behavioral and Educational IRB.

IRB Websites and IRB E-mail Update

The DHRP continues to work on updating the websites for each IRB. As part of this process, the forms for each IRB have been updated and each IRB was assigned a new email address (listed below).

Biomedical IRB:

The Biomedical IRB forms are updated and will be posted on the new web site page when it becomes available. Investigators will be required to use the new forms after they become available online.

E-mail address: IRB.Biomed@utoledo.edu

Social, Behavioral and Educational IRB:

Revised forms for the SBE IRB were posted in February (<http://research.utoledo.edu/forms.htm#itsforms>) and are required for all research applications submitted after March 1, 2007.

E-mail address: IRB.SBE@utoledo.edu

Submitting Research Applications to the Biomedical IRB or the Social, Behavioral and Educational IRB

Although located on different campuses, each IRB serves the entire University. Thus, the SBE IRB generally should review all Social, Behavioral or Educational research and the Biomedical IRB should review all Biomedical research.

Any UT human subject research application, regardless of the type of research, may be submitted to the DHRP office on either campus. The staff will route the application to the proper IRB.

Questions regarding which IRB to use may be directed to Samara Wisniewski, DHRP Director of Regulatory Compliance, at samara.wisniewski@utoledo.edu.

DHRP/IRB Office Locations

Health Science Campus
CCE Building, Room 0106
419-383-6796

Main Campus
University Hall, Room 2300
419-530-6167

Request from the Biomedical IRB Regarding Late Application Submissions

The DHRP and IRB staff would like thank all of the investigators who get their completed applications in to the IRB office by the monthly deadline, and remind everyone of the importance of those submission deadlines. Because there are many steps that an application goes through before the IRB meeting, the staff needs to have all Biomedical IRB applications by 12:00 PM three weeks prior to the scheduled IRB meeting.

At the request of the Biomedical IRB Chair, Dr. Skeel, the DHRP will be enforcing submission deadlines so that they are able to complete all required tasks and provide applications to IRB members in a timely manner. Late application submissions will be considered only if the principal investigator submits a formal written request the IRB Chair or Director of Operations before the submission deadline. The request must be (1) in writing and signed by the primary investigator, (2) addressed to the IRB Chair and Director of Operations, (3) state the reason that the investigator is requesting more time, and (4) received by the regular submission deadline. Requests made via e-mail will only be considered if they are sent directly from the primary investigator to the IRB (IRB.Biomed@utoledo.edu).

Extensions will not automatically be granted and will be made only for exceptional circumstances. Incomplete applications (including lack of signatures) are considered late and must follow the above process. Please review your applications carefully and use the IRB checklist provided on the application to avoid having to make a request for a late submission.

The Convened IRB Review Process

The strict adherence to our deadline for submissions is necessary because there are several steps that an IRB application must go through before the IRB meeting. After applications are logged into the IRB system and assigned an IRB number, they are pre-reviewed by DHRP staff. The pre-review process is designed to identify issues with clarity and grammar as well as non-substantive issues such as typos in the consent form. Pre-reviews are also used to identify any regulatory issues. Most applications submitted to the IRB require some type of revision in the pre-review process. Resolving non-substantive issues before the applications go to the IRB primary and secondary reviewers allows members to focus on scientific, ethical and regulatory issues.

Applications are then sent to the primary and secondary reviewers, who complete a thorough review of all materials submitted to the IRB and contact investigators with requests for modifications before the full IRB review. Additionally, application materials must be available to the IRB members for review prior to the meeting date.

The IRB and the DHRP appreciate your understanding.