The Department for Human Research Protections ("DHRP") updated its policies and procedures in compliance with federal regulations at 45 CFR 46 and Office for Human Research Protections ("OHRP") guidance. As part of the process, the DHRP Directors attended a seminar sponsored by OHRP focusing on writing procedures that comply with federal regulations.

Many of the policies and procedures remain unchanged, however, they are now conveniently located in one booklet with a table of contents. Key terms, documents and regulations are hyperlinked for those accessing the manual on the web. This new format should make it easier for everyone involved in UT related research to quickly find DHRP and IRB information. We hope that you take some time to look through the manual.

The manual will be available online at: www.utoledo.edu/research/RC/HumanSubs3/Policy.html when the Department’s website is launched on August 20th. You may also obtain a copy of the Policies and Procedures by sending an e-mail to: IRB.Biomed@utoledo.edu and typing “Procedure Request” in the subject line.

Questions related to the Policies and Procedures may be directed to Samara Wisniewski, J.D., DHRP Director of Regulatory Compliance.

Compliance Support Visits and Regulatory Audits

The DHRP has resumed its field operations activities consisting of Compliance Support Visits (“CSV”) and Regulatory Audits.

Compliance Support Visits are conducted on randomly selected studies with the intent of offering compliance education and support to investigators.

Regulatory Audits occur when there is a specific concern of non-compliance with either federal regulations or IRB procedures.

In both instances, the compliance team sends a letter at least two weeks in advance of the CSV or audit notifying the investigator of what records will be reviewed and what the team will look for.

Any serious problems found during a CSV or Audit are referred to the DHRP’s Compliance Oversight Review and Evaluation (CORE) Committee for further investigation. A CORE report is then presented to the convened IRB which decides whether appropriate corrective action is required.
DHRP Audit Results in Report to the Federal Office for Human Research Protections

The IRB recently audited a graduate student research study following a report from a faculty advisor that the student had implemented a significant change to the study protocol without IRB approval. The change involved removing certain exclusion criteria to enable people to participate in the study who should have been excluded.

The DHRP Compliance Oversight Review and Evaluation (CORE) Committee reviewed both the IRB and the investigator’s records, interviewed the faculty member who served as the advisor during the protocol violation, and then interviewed the student investigator.

The CORE Committee confirmed the protocol violation, and also found that there was no record of written consent for some subjects. Additionally, the investigation revealed that the student continued to analyze research data following expiration of IRB approval.

The IRB reviewed the Committee’s findings and then temporarily suspended the student’s research until the student completed remedial human subject protections education and obtained current IRB approval.

The IRB also temporarily suspended new approvals of the relevant faculty member serving as an advisor until the advisor completed training for research mentors (see story below for details on mentor training), and repeated the IRB training for researchers.

The IRB concluded that UT must report the compliance issues in this study to the federal Office for Human Research Protections (OHRP) under UT’s Federalwide Assurance and the Terms of The Assurance. A report was sent to OHRP on July 9, 2007 detailing the issues and remedial steps taken on both an institutional and institutional basis. The IRB expects to receive a response from OHRP within 60 days.

Part of the IRB’s responsibility for remedying the issues found in this study are to remind researchers of their responsibility to:

• Obtain written informed consent from every research subject prior to subject intervention;
• Implement changes to a protocol only after review and approval by the IRB; and
• Maintain IRB approval through continuing reviews until all data collection and analysis is complete.

Students, residents, and fellows at UT may only conduct research under the supervision of a UT faculty member at or above the level of instructor, or a qualified staff member of an equivalent level.

The recent compliance issues found in the audit of a graduate student study (see story above) highlight the need for active faculty mentoring of student researchers. The faculty advisor must be prepared to teach the student or resident how to conduct research responsibly under ethical, regulatory and institutional requirements.

The federal Office of Research Integrity (“ORI”), a division of the Department for Health and Human Services, provides a Mentor and Trainee Responsibilities Training Module on the web at http://ori.hhs.gov/education/products/niu_mentorship/index.html.

According to ORI, “The ultimate goal of this module is to promote responsible conduct of research and help those involved in research activities to become proactive and better prepared to deal with any issues that may arise during the course of a research project.”

Advisors are encouraged to complete some or all of the available modules.
A major concern for researchers is how quickly their protocols can be approved by the IRB so they can begin their research. While turn-around-time (TAT) can be impacted by many issues such as incomplete applications, lack of proper signatures, protocol or application omissions, absent or incomplete research training and the current workload in the IRB office, recent analysis of submission to approval dates has revealed average or better than average results from the UT IRB offices compared to national averages.

In an effort to improve IRB operational processes, the IRB developed a submission tracking program. The program logs several key factors - the submission date, scheduled date of review (IRB meeting), initial approval date, date the submission was returned to the PI for revision, submission return date and final approval date. By tracking each aspect of the process, the IRB was able to determine which interval in the process is responsible for delaying the final approval. This new tracking mechanism reveals that a significant amount of lag time occurs in the investigator’s department due to the need for corrections or revisions.

The new DHRP has been working diligently over the past year to improve not only the TAT but also the inter-departmental communication process and educational needs of the human research community on both campuses. This visible commitment to improve relationships has resulted in significant operational progress and a greater understanding of the partnership between researchers and the DHRP staff.

The numbers listed in the table below were compiled from the July 2006 – June 2007 tracking data. The DHRP encourages your questions and input as our department continues to grow and evolve. As many of you have heard during our recent presentations, “we are here to help, not hinder, institutional research.”

<table>
<thead>
<tr>
<th>IRB</th>
<th>Meeting Items Reviewed</th>
<th>Total Items Reviewed</th>
<th>Exempt Research TAT**</th>
<th>Expedited Review TAT**</th>
<th>Full Board Review TAT**</th>
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<tr>
<td>National Average</td>
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<td>N/A</td>
<td>14 days</td>
<td>14-21 days</td>
<td>21-35 days</td>
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<td>11 days</td>
<td>15 days</td>
<td>30 days</td>
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<td>185</td>
<td>Data not available for 2006–2007</td>
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TAT = mean submission to final approval

* Includes all amendments and modifications, PI withdrawals, Chair Approvals and Final Reports.

** Listed numbers are for “clean” submissions and exclude the various outliers noted in paragraph one, above.

Q & A of the Month: Why are researchers required to complete human research subject training?

Requiring educational training ensures researchers are aware of their federal and institutional responsibilities for protecting the welfare of human research subjects. As an institution holding an OHRP-approved Federalwide Assurance (FWA), UT is responsible for ensuring that investigators conducting UT-related human subject research understand and act in accordance with the requirements of the HHS regulations for the protection of human subjects. The Terms of the FWA state: “OHRP strongly recommends that the Institution and the designated IRB(s) establish educational training and oversight mechanisms (appropriate to the nature and volume of its research) to ensure that research investigators, IRB members and staff, and other appropriate personnel maintain continuing knowledge of, and comply with, the following: relevant ethical principles; relevant federal regulations; written IRB procedures; OHRP guidance; other applicable guidance; state and local laws; and institutional policies for the protection of human subjects.”

The UT IRB requires that all researchers complete educational training before it will accept an IRB application.

Educational training requirements for those using individually identifiable health information can be found online at: http://hsc.utoledo.edu/research/rga_frms/rga315.pdf.

Educational training requirements for all other researchers can be found online at: http://research.utoledo.edu/forms.htm#HSforms.
IRB Meeting Schedules 2007-2008

Biomedical Institutional Review Board

CONVENED REVIEW

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<tr>
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Social, Behavioral and Educational Institutional Review Board

CONVENED REVIEW

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All meetings are held at 2:00 PM

Biomedical IRB Email:
IRB.Biomed@utoledo.edu

Social, Behavioral and Educational IRB Email:
IRB.SBE@utoledo.edu

Carolyn Pinkston, R.N., B.S., Director of Operations
Samara Wisniewski, J.D., Director of Regulatory Compliance
Roland T. Skeel, M.D., Biomedical IRB Chair
Barbara K. Chesney, Ph.D., SBE IRB Chair