

**General IRB Procedures\***  
Tennessee Technological University  
per DHHS - 45 CFR 46.103(b)(4) and (5)  
July 2010

**1. Procedures which the IRB will follow for conducting its initial review of research:**

Three (3) levels of review are utilized for approval of research with human subjects: exempt, expedited and full board. In each case, the initial review of the application materials takes place within the Principal Investigator's (PI) department after which the requisite number of copies of all IRB application materials are submitted to the Office of Research and Graduate Studies (ORGS) and further disseminated as necessary based on the required level of review as detailed below. The initial departmental-level review addresses potentially problematic issues, and a signed endorsement from a representative from within the department indicates agreement with the level of review that is marked on the Form A cover page.

Projects deemed eligible for **exempt** review (using exempt categories found at 45CFR 46.101b) are reviewed and approved by a departmental designee and then one copy is forwarded to the ORGS for verification of all required items. If the project is externally funded or funding pending, the ORGS staff will further review the application upon receipt to check for any potential compliance risks. While continuing review is not required in this category, any changes in the approved project must be submitted and approved through the departmental designee.

Projects requiring **expedited** review must be further reviewed and approved by a primary reviewer (who is a member of the IRB) and two other IRB members. After initial review within the PI's department as discussed above, one copy of all IRB application materials are submitted to the ORGS. The copy is scanned and the e-copy forwarded to the IRB committee chair who identifies a primary and two other IRB members to review the application materials. The paper copy is filed in the ORGS. The IRB committee chair prepares a memo (example included in Appendix A) and forwards the memo along with the e-copy of the IRB application to each of the three reviewers. ORGS staff are also copied on this email. If an IRB member on the email has indicated that he/she would prefer a paper copy of the application materials, one is sent from the ORGS. The procedures for how this review is conducted is detailed in Appendix B.

Any application, not meeting either the exempt or expedited review requirements, will be referred for Full Board review in which case 14 copies of the application materials are submitted to the ORGS where staff will disseminate a copy to each member of the IRB. **Full Board Review** is review of proposed research at a convened meeting at which a majority of the membership of the IRB is present, including at least one member whose primary concerns are in non-scientific areas. Each committee member will be able to discuss the IRB application at the convened meeting once the IRB chair opens the item to discussion. For the research to be approved, it must receive the approval of a majority of those members present at the meeting.

The IRB may only approve an application when its decision is based on consideration of the following:

- Risks to subjects are minimized:
  - (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
  - (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
- Selection of subjects is equitable. In making this assessment, the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
- Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by federal regulation.
- Informed consent will be appropriately documented, in accordance with, and to the extent required, by federal regulation.
- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

## **2. Procedures which the IRB will follow for conducting its continuing review of research:**

With the exception of projects approved under exempt review criteria (see item #1), the IRB is required to reevaluate research projects at intervals appropriate to the degree of risk but not less than once a year. When a project is approved through the IRB, that approval is for a maximum period of 12 months. If the project has also been or will be submitted for consideration of external funding, the effective start date for the 12-month approval is the date indicated on the approved IRB application or on the grant/contract award notification, whichever date is later. For research involving no more than minimal risk, the approval period is generally one year. For research involving greater than minimal risk as determined at the time of approval, the IRB will determine the appropriate approval period. The approval letter from the ORGS will indicate the expiration date.

Current TTU policy states as follows:

For projects that continue for more than 12 months, the PI/project director must submit a statement of compliance to the Office of Research for review and approval of project continuation. The compliance statement must be submitted not later than one week prior to the expiration of the previous 12 month approval. It should provide reference to the earlier approved project along with the project title and PI and indicate continued compliance by the investigators with procedures outlined in their approved IRB application. In addition, details should be provided as applicable on:

1. Total number of subjects involved in the project to date or, if existing data study, number of individuals whose records have been obtained.
2. Listing of any adverse events or unanticipated problems.
3. Number of subjects who withdrew and the reason(s) (if known) for withdrawal.
4. Listing of any complaints regarding the project.
5. Discussion of any new information (such as recent literature, interim findings, etc.) since the last IRB approval that may affect the assessment of the risks or benefits or possibly impact any participant's willingness to continue to take part in the research.
6. Describe all amendments or modifications made to the project since the last IRB review.
7. Discuss any changes to the project that have been implemented without being approved by the IRB.
8. Indicate whether any approvals of changes or additions are being requested. If so, identify which type(s) of modifications and attach the appropriate details.
9. Address whether data is still being collected. If yes, attach a copy of the most recently approved consent document.
10. Provide information about any remaining activities to be completed. If activities are confined to data analysis, indicate if the data include direct identifiers, codes, demographic information, or any other information that could be used to link the participants to the data.
11. Provide a projected end date for the project.

It is noted that the applicant must receive written notification of approval from the IRB to continue this research beyond the current expiration date. After the expiration date, per Federal Regulations, all research on the project must halt until the necessary IRB approval has been secured. Reminders will be sent to the Primary Investigator sixty (60) days prior to the expiration date. Also, note that all changes in the project that deviate from the original submission must be approved by the IRB prior to implementation, except when necessary to eliminate apparent immediate hazards to the subjects.

### **3. Procedures which the IRB will follow for reporting its findings and actions to investigators and the institution:**

The Principal Investigator will be notified in writing (by the ORGS) of IRB approval or disapproval. Any departmental or center IRB liaison or advisor will be copied. The approval documents will contain the relevant federal regulation citation, the approval date, the expiration date and the IRB file number. If disapproved, the reasons for the action will be detailed in the written correspondence.

**Conditions of Approval**

Approval of a project by the IRB only signifies that the procedures adequately protect the rights and welfare of the subjects and should not be taken to indicate University approval to conduct research. Approval of a project by the IRB applies only to the procedures submitted in the application. The investigator must secure prior approval from the IRB for any changes in the procedures that will affect the use of human subjects. The investigator must also report to the IRB any problems that arise in connection with the use of human subjects. If an approval is granted with contingencies, those contingencies must be satisfied (reviewed and approved) prior to beginning the project. Approval for projects is valid only until the expiration date. The Associate Vice President for Research and Graduate Studies and the IRB members receive a monthly report detailing all new IRB submissions.

**4. Procedures which the IRB will follow in determining which projects require review more than annually:**

The IRB must conduct continuing reviews of protocols at intervals appropriate to the degree of risk, but not less than once per year. "Not less than once per year" means that the research must be reviewed on or before the one-year anniversary date of the previous IRB review, even though the research activity may not begin until some time after the IRB has given approval. All human subjects research activities are subject to audit at anytime by the IRB. In determining the appropriate interval for the continuing review of a protocol, the IRB shall take into consideration the level of risk involved in the study, as well as the risk/benefit ratio. If the application requires full board review, this recommendation will be reviewed during the review. The terms of the protocol approval include the interval for continuing review and will be communicated to the investigator in writing in the study approval letter.

During a continuing review, the IRB considers the information provided by the researcher in the Continuing Review Request (see item 2), the report of findings to date, and the current informed consent document (if applicable), as well as any other requested information, to determine whether to extend approval for another 365 days (or any other stipulated time period up to 365 days in length).

**5. Procedures which the IRB will follow in determining which projects require verification from sources other than the investigators that no material changes have occurred since previous IRB review:**

The IRB may, at its discretion, determine that information is needed from sources other than the investigator to verify that no material changes have occurred since the previous IRB review. The IRB may request verification from sources other than the researcher that no material changes have occurred since the initial or previous continuing review if:

- (i) the study is complex, involving unusual levels or types of risk to the subjects,
- (ii) the researcher has failed previously to comply with the IRB's requirements or 45 CFR 46, or
- (iii) there exist reasons to have concerns about possible material changes occurring without IRB approval.

- 6. Procedures which the IRB will follow in ensuring prompt reporting to the IRB of proposed changes in research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject:**

All changes in the project that deviate from the original submission must be approved by the IRB prior to implementation, except when necessary to eliminate apparent immediate hazards to the subjects.

This approval is sought by submitting all appropriate documentation (including the approved consent form). The amendments may not be implemented by the investigator prior to review and approval by the IRB. The investigator will be contacted in writing once the modification has been approved.

- 7. Procedures which the IRB will follow in ensuring prompt reporting to the IRB, appropriate institutional officials, and the Department or Agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and (ii) any suspension or termination of IRB approval:**

Any unanticipated, serious, or continuing problems encountered regarding risks to subjects must be reported by the investigator immediately but not later than 10 days following the event.

Non-compliance: Deviation from the previously approved protocol, failure to fully disclose information relevant to the IRB review, or conducting human subjects research prior to IRB approval are examples of non-compliance. If non-compliance is suspected or reported, an investigation will be initiated by the IRB. At the conclusion of the investigation, the IRB will meet to examine the results of the investigation and define the allegations, if any. The researcher will be informed of the allegations and given ample time to respond. The IRB will then review the relevant information and make a determination regarding non-compliance. When non-compliance is found, the IRB and Tennessee Technological University will take appropriate action including, but not limited to, halting the research, assuring remedial action regarding any breach of regulatory or institutional human subject protection requirements, and addressing the question of the investigator's fitness to conduct human subject research. The IRB Executive Officer will report in writing within 10 working days to the IRB Chairperson, Associate Vice President for Research and Graduate Studies (if different from the IRB Executive Officer), relevant Department or Agency Head (sponsor), any applicable regulatory body, and the Office of Human Research Protections, any report of adverse events and/or determinations of suspensions, terminations and/or serious or continuing non-compliance as mandated in the Federal Regulations.

**APPENDIX A  
COVER MEMO TEMPLATE**

From: <Insert IRB Chair Name>, IRB Chair  
Re: Expedited Proposal for Your Review  
Date: <Insert today's date>

Enclosed is the following IRB proposal for your expedited review and consideration:  
<Insert PI's name (e-mail address)>: <"Insert Project Title">  
[if applicable] <Insert PI's name> faculty advisor for this project is <Insert advisor's name (adviser email)> in the Dept of <Insert advisor's dept>.

Lead Reviewer: <Insert Name (email)>  
Reviewer 2: <Insert Name (email)>  
Reviewer 3: <Insert Name (email)>

**Please reply to the Lead Reviewer by <Insert Date (usually 2 weeks from receipt)>.**

Send your responses to the Lead Reviewer designated above in a clearly labeled email note (Subject = IRB + name of PI). In your note, specifically articulate your concerns and suggestions.

In your email note, make certain that you provide the Lead Reviewer with a specific verdict:

- i. **Approved.** Proposal meets all IRB standards; no revision necessary; ready for reviewers' signatures:
  - *The lead reviewer will sign one copy of the Form B signature page and send it to the two other reviewers for signature, and that page will be forwarded to the Office of Research.*
  - *The lead reviewer will inform the PI that he/she may start the data collection immediately.*
- ii. **Approved, with minor revisions.** Proposal meets most IRB standards; some minor revising or editing is necessary for final approval. Before the lead reviewer solicits reviewers' signatures, the PI must send directly to the lead reviewer one copy of the pages of the proposal that include any revisions.
  - *If the revisions are acceptable, the lead reviewer will sign one copy of the Form B signature page and send that page along with the revised pages for the signatures of the other reviewers.*
  - *The lead reviewer will inform the PI that he/she may start the data collection immediately.*
  - *The last reviewer to sign will forward the approved documents to the Office of Research.*
- iii. **Not approved, Revise and resubmit.** Proposal requires significant revision and resubmission to IRB reviewers, according to reviewers' concerns and suggestions. The PI needs to submit one copy of the revised proposal to the Office of Research.
  - *The Office of Research staff will forward an electronic copy of the revised proposal to the IRB chair who will assign reviewers.*
  - *In most cases, the IRB chair will forward the revised proposal to the same committee members who conducted the earlier review.*
- iv. **Not approved, Address major flaws.** According to reviewers' concerns, proposal has serious design flaws regarding protection of human subjects. The proposed study may not proceed without serious reconsideration of how potential participants are treated.
  - *The lead reviewer will inform the PI that his/her proposal was not approved and will encourage the PI to contact the Office of Research staff for assistance.*

After sending your feedback to the Lead Reviewer, retain your copy (e-copy and/or paper copy) of the proposal until you're contacted by the Lead Reviewer with instructions.

As soon as a decision is made on a proposal, the lead reviewer will contact the PI and, if applicable, his/her faculty advisor by email to inform them of the reviewers' decision. If committee members agree in this review round to approve the proposal without revision (option 1 above), the PI will be informed that he/she may start the data collection immediately. If the PI needs to revise the proposal (options 2-4 above), the Lead Reviewer will contact him/her with committee members' suggestions. When a revision is submitted, it will be sent to you for your review or for your signature. Please wait until you hear from the Lead Reviewer regarding other reviewers' verdicts to sign the proposal. An official approval letter will also be sent from the Office of Research to the PI and the PI's Faculty Research Advisor, if applicable.

Please contact the IRB Committee Chairperson with any questions about interpreting or applying the standards and guidelines (available at <http://www.tnitech.edu/research/hs-guidelines>).

**APPENDIX B**  
**INSTRUCTIONS FOR LEAD REVIEWERS OF EXPEDITED PROPOSALS**

Because the IRB strives for procedural consistency, Lead Reviewers of expedited applications will follow the procedures outlined below. The IRB Chair will send applications via email with a cover memo to three reviewers, designating one as Lead Reviewer. For any IRB member who has indicated a preference for paper copies of the application materials, the Office of Research staff will send a paper copy upon receipt of the email from the IRB chair.

**1. Respond to the application.**

Within two weeks, reviewers send their overall assessment, concerns, and—if appropriate—revision recommendations to the Lead Reviewer via email. Each of the three reviewers independently evaluates the application according to IRB standards and guidelines (available at <http://www.tntech.edu/research/hs-guidelines>).

**2. The two reviewers' responses are combined with Lead Reviewer's response.**

The Lead Reviewer will prepare a summary of all three of the reviewers' responses. The response should clearly and specifically describe any concerns and suggested revisions. If a reviewer fails to contact the Lead Reviewer, the Lead Reviewer will send a friendly reminder to the sub-reviewer.

**3. Sending a response to the Principal Investigator.**

Within two weeks of receiving the application, the Lead Reviewer will send a summary of the reviewers' responses to the study's Principal Investigator. The lead reviewer will identify self as the representative of the IRB and relay reviewers' responses. The goal of the response should be to help the PI address human subjects-related concerns which frequently include lack of clarity, insufficient risk assessment or management, and/or insufficient procedures of informed consent. The response will be emailed to the PI, with a cc to the faculty advisor and a bcc to each of the two other co-reviewers. When sending a copy of the response as an email attachment, the document should be saved and sent as an RTF file (Rich Text Format), which is readable by all word-processing programs.

**4. If revisions are required, repeat steps 1-3.**

If the application requires only minimal revision, the Lead Reviewer will ask the PI to send the revised documents directly to the Lead Reviewer's mailbox, rather than sending the revised documents through the Office of Research. On the other hand, if the verdict is "revise and resubmit," the Lead Reviewer will advise the PI to submit one copy to the Office of Research, with the resubmitted documents clearly marked as "RESUBMISSION."

Should the application be rejected by the three reviewers, the Lead Reviewer will inform the Office of Research, and the Office of Research will inform the PI of the application's status.

**5. Secure signatures of approval from reviewers on one (1) copy of approved application.**

When the application is approved, one copy of the Form B signature page must be signed by the three reviewers. The cover memo will list the reviewers' campus mailbox addresses, department offices addresses, and email addresses. The lead reviewer will initiate the signature process.

**6. Submit one (1) approved, signed copy of the Form B signature page to the Office of Research.**

Once signatures are secured, the signed copy will be submitted to the Office of Research (DH 306, campus box 5036, campus telephone 3233). The Office of Research will send a letter of approval or disapproval to the PI and file a copy of the letter along with the original signed application.

**7. Submit a brief status report to the IRB Chair.**

The Lead Reviewer will send the IRB chair a brief email note informing the chair that the PI has been contacted with the reviewers' verdict, once the application has been reviewed and responded to, even if the application will be returned in revised form. Should the Lead Reviewer have any questions at any point, the IRB Chair should be contacted.