

**From:** Academic Affairs  
**Sent:** Thursday, November 19, 2015 1:48 PM  
**To:** Faculty; Subscribers; 'AASTAFF@lists.mtsu.edu' (AASTAFF@lists.mtsu.edu)  
**Cc:** irb\_information  
**Subject:** IRB Procedures notification

## **IRB**

### **INSTITUTIONAL REVIEW BOARD**

Office of Research Compliance  
010A Sam Ingram Building  
Murfreesboro, TN 37132



**TO:** MTSU Research Community – Faculty, Staff and Students  
**FROM:** The Office of Compliance and the MTSU IRB  
**RE:** IRB Procedures

Assuring due diligence and proper administration of the University's federally-mandated obligations to protect the subjects of Research Involving Human Subjects is essential to the reputation and integrity of the institution and individual researchers. Errors in our protection effort - errors of process, policy, judgement, misinformation, omission, negligence, etc. – can result in ethical, legal and financial consequences for individual researchers, IRB members, and the University.

Protection of human subjects is the primary objective of the IRB which is a committee of peers. The IRB is the responsible entity for assuring protection of human subjects at MTSU. The Office of Compliance staff provides policy, administrative and clerical support to the IRB and researchers. IRB activity and Office of Compliance functions are overseen by the Institutional Official, in our case the Vice Provost for Research.

This notification is intended to summarize and clarify IRB processes and terminology. The information here does not replace the information found in the IRB's MTSU web pages. Active and prospective researchers are responsible for understanding the contents of the IRB web pages.

- **EXEMPT Protocol**–
  - This review does not require a full IRB committee approval and it does not require continuing review as long as the protocol is in good standing.
  - Review is conducted by Compliance staff or IRB Chair.
  - NOTE that most of the documents required for exempt and expedited procedures are the same.
  - **To avoid delays**, please review Exempt protocol requirements thoroughly at <http://www.mtsu.edu/irb/ExemptPaperWork.php>
- **EXPEDITED Protocol**
  - Expedited status does not equate to an accelerated review.
  - Protocols that do not qualify for exemption, or the ones that require continuing review will be reviewed as expedited.
  - Reviews will be conducted via a Designated IRB Member review.
  - **To avoid delays**, please review Expedited protocol requirements thoroughly at <http://www.mtsu.edu/irb/ExemptPaperWork.php>

- SUBMISSION –
  - NOTE: each application is a new instance and therefore treated with the same rigor as any other.
  - Note also that student protocols must be sent via the faculty advisor.
  - All IRB petitions -- new protocol applications, continuing review requests, addendum to existing protocols and other types of documentation -- must be sent via email to [irb\\_submissions@mtsu.edu](mailto:irb_submissions@mtsu.edu).
  - General questions and inquiries should be sent to [irb\\_information@mtsu.edu](mailto:irb_information@mtsu.edu).
  - NOTE: if documents are sent to the information address rather than to submissions, they will neither be saved nor processed.
  - The researchers should receive an email within FOUR business days after they submit their documents, if sent to the submissions address.
  - Contacting us prior to the four-day waiting period is not useful for either of us as we will not likely have any kind of answer. Please wait.
  - Visit the following links to learn more about document submission for IRB review:
    - <http://www.mtsu.edu/irb/PreparingIRBApplications.php>
    - <http://www.mtsu.edu/irb/FAQ/SubmissionProcess.php>

## THE APPLICATION EVALUATION

- PRE-SCREENING –
  - The compliance staff will receive the documents and check for completeness before sending them for review.
  - Once all necessary documents have been submitted and the compliance staff has determined that application to be complete, an email confirming the commencement of the review process will be sent to the researchers. Please note that our review work and your timeline will not start until an application is deemed to be complete.
  - For a list of all necessary documents to be sent with each type of petition, visit our website [www.mtsu.edu/irb](http://www.mtsu.edu/irb) and click the appropriate links. Please submit only one protocol and attached documentation per email.
- REVIEW –
  - The review process is different for each mechanism of choice. Please visit <http://www.mtsu.edu/irb/FAQ/TypesOfIRBReviews.php> to know more about the various IRB review processes
  - This review does not begin until the application is complete and it has passed the pre-screening process
  - **Exempt** - The studies that qualify for exemption will be reviewed by the Office of Compliance. They will be sent to an IRB member only if additional review is required
  - **Expedited** - The studies that qualify for this mechanism should fall within one of the categories listed in the OHRP's classification. The completed application will be sent to an IRB reviewer. Certain types of studies have specific reviewer requirements. The reviewers will be in direct contact with the researchers.
  - **Full Review** – The process is similar to the expedited mechanism, but the researchers will be contacted by the Chair of IRB after the prescreening is complete. The decision to approve/modify or defer is made by a majority of IRB members at a convened IRB meeting whose membership meets the quorum requirement.
  - Please visit <http://www.mtsu.edu/irb/FAQ/ReviewerNotes.php> to know more about what the reviewers are looking for in your application.
- IRB REVIEWERS

- The IRB members are appointed by the University's President as recommended by the Faculty Senate – their names are posted in our website
- They are committed to excellence in research and to the ethics and integrity of the human research program
- There is no monetary or other type of incentives to the IRB members – While each IRB member perseveres to meet the timely needs of the applicants, it needs to be emphasized that they also have their own commitments, such as, teaching, research and service.
- The applicants are therefore urged to exhibit their own due diligence in preparing their petition so the reviewers can concentrate only on the research.
- **TIMELINE –**
  - The review process for exempt and expedited protocols can take 2-3 weeks once the application is complete
  - The timeline for review does not start until the prescreening is over
  - The time requirement is also true for addendum requests and continuing reviews and the researchers have to plan in advance by not waiting till the date of expiration.
- **POST APPROVAL –**
  - Review <http://www.mtsu.edu/irb/FAQ/PostApprovalResponsibilities.php> to learn more about all the post approval procedures and investigator responsibilities
- **SPECIAL CONSIDERATIONS –**
  - **There are no special considerations** when it comes to the IRB process. All protocol applications will be given the same level of scrutiny whether the applicant is a student, faculty or administrator.
  - The University offers its fullest support to the MTSU IRB by not interfering or influencing the approval process.
  - As a condition for accreditation, the MTSU Officials will refrain from influencing the IRB decision – However, the OHRP guidelines allow the University's Institutional Official the authority to disapprove a protocol that has been approved by the IRB.
- **WORKFLOW**
  - Document receipt & acknowledgement
  - Prescreening and review notification
  - Review
  - Correspondence between the reviewer and the researchers
  - Approval – if the reviewer determines the protocol is compliant
  - Other IRB actions – if necessary
- **RESEARCH AT OFF CAMPUS SITES –**
  - Studies that would be conducted at other institutions will require permission letters in verifiable format – emails and text message will not be accepted.
  - In instances where an IRB approval is required in order to obtain permission letters, Rutherford County for instance, the MTSU IRB will issue a conditional approval to allow researchers to complete their formalities.
- **IMPORTANT DATES –**
  - Expect more processing time for prescreening and review when the University is closed for breaks and holidays, and applications will be prioritized per deadlines.
  - The IRB will review protocols over the summer break, but response may be slower especially if a full review is required.

- Full review applications must be completed at least 2 weeks prior to the date of a convened meeting in order for the Chair to bring the study to a vote.
- Approval for continuing review for expedited and full review protocols must be obtained prior to the date of expiration – it is the responsibility of the researchers to request for continuation well in advance
- During the months of October/November and March/April, expect additional delays because those are the busiest months of the year. In addition to the commitments to the IRB, our office also works with IACUC and FRCAC which have deadlines during the same months.

***Best practice for developing an ethics-oriented human subject research:***

Amidst all of the paperwork, documents and other formalities, the two main factors that often get forgotten while preparing for IRB approval are failure to protect the participant confidentiality and inadequate clarity in the informed consent process. Therefore, the researchers may first consider consent process; informed consent is not merely a form, but it is a conversation. It would be best if the researchers think through this process. Once a clear idea of consent has been conceived, the researcher has to demonstrate how he/she is going to protect the confidentiality of the subjects. Having completed these two essential components of the “Common Rule” filling other documents and satisfying the requirements would then be a mere formality because the investigator would have clearly demonstrated his/her commitment for ethical treatment of subjects.

It is important to remember that conducting your research with utmost ethical standards is not just the necessary condition to obtain IRB approval, but it is also the right thing. Although the main goal of the Office of Compliance is to protect the participants, we are also committed to develop a culture of compliance among the MTSU community. Therefore, we emphasize the necessity for researchers to demonstrate compliance.

NOTE: All necessary forms can be downloaded from [www.mtsu.edu/irb](http://www.mtsu.edu/irb) and answers to many questions may be found in <http://www.mtsu.edu/irb/faq.php>.