







# GETTING STARTED




Click the arrow boxes in this document for more information/links.

Note: If you are unsure whether your proposed activity is human subjects research, complete a Form 129 and submit to the IRB before completing the following steps. 

1. Complete human subjects training (unless you have completed within the last 3 years).    
Instructions   CITI
2. Studies being submitted for requested exempt and expedited status may be submitted at any time. Studies being reviewed by the full board must follow the deadlines for submission.    
categories   deadlines
3. Plan ahead as the IRB process has several steps. From the time of **complete** submission, you can expect results of an exempt review in one week, and expedited or full reviews within 4 - 6 weeks. Your submission must be complete before the review process can be accomplished.
4. Complete the IRB forms. See question 9 on form 103 for an itemized list. If you need help with these forms, or the submission process, please call the IRB Office at 439-6053. We'll be happy to assist you. 
5. Attach all required documents (i.e., questionnaires, advertisements, etc.)
6. Obtain appropriate signatures.
7. Submit the appropriate number of copies of the entire submission packet (**collated**) to the IRB.
  - Exempt: 1 original
  - Expedited: 1 original + 2 copies = 3 total
  - Full: 1 original + 35 copies = 36 total (only 3 copies of protocol and 2 copies of investigator brochure) (suggestion: contact the IRB for a pre-review before making copies)

8. The IRB office will review your submission for completeness and will either request revisions/missing information or, if complete, will forward to the IRB Chair or Vice-Chair.
9. Submissions that require full board review will be placed on the next scheduled meeting as determined by the submission deadline. Exempt studies are reviewed by the IRB Chair/Vice Chair, and expedited studies are reviewed by assigned IRB reviewers.
10. You may be required to revise your submission once more if required by the IRB (called "approved pending requested changes").
11. If your study is approved pending requested changes, submit your revisions to the IRB office. Those changes will then be reviewed by the IRB Chair/ Vice-Chair before final approval is issued.
12. Do not begin your research study until you have a final, formal approval letter from the ETSU or ETSU/VA IRB, as well as other required institutional approvals (i.e, VA R&D approval if VA study, etc).

This is a quick-start guide only. See IRB Policy and Procedures for detailed information. 



## **Contact the IRB.**

**Janine Richardson, OPHRS Director**

423-439-6054

richardf@etsu.edu

**Teresa Doty, IRB Coordinator (Medical)**

423-439-6055

doty@etsu.edu

**Aracelis Vasquez, IRB Coordinator (Campus)**

423-439-6002

vasqueza@etsu.edu

**Beth Aimee Every, IRB Secretary**

423-439-6053

every@etsu.edu