



PRAIRIE VIEW A&M UNIVERSITY

A Member of the Texas A&M University System

IRB Protocol Review Process

Updated: May 2, 2017

General Planning:

- At present, plan for at least 1 month to get your protocol through the IRB and at least 2 months if you know it is a Full Board protocol.
- Answer the IRB's questions promptly.
- Don't wait several weeks to answer the IRB's questions then expect the committee to turn the protocol around in a few days.
- There will be at least two and maybe three revision cycles (pre-reviews and committee reviews).
- In some circumstances, there could be more than three revision cycles.
- Protocols involving deception of human subjects will always require Full Board review.

Step #1: Submit your IRB Protocol

- Write a quality protocol.
- Really read the questions and answer them thoroughly
- Fill out the "Procedures" box on page #8. Explain everything from recruitment to publication.
- Include all attachments such as a consent form, the survey or the interview questions.
- If the protocol is for a thesis or dissertation, the IRB needs a copy of your proposal.
- Please check your grammar and spelling.
- List all procedures to be conducted. If it is not written in the protocol, you can't do it. There is no such thing as an unapproved pilot study.
- IRB Forms can be found on the IRB Webpage at:
<http://www.pvamu.edu/research/office-of-research-compliance/207-revision-v1/irb-forms/>

Step #2: The Office of Research Compliance (ORC) will conduct a Protocol Pre-Review

- ORC will send the protocol back if all the protocol questions are not answered.
- ORC will request that all the required attachments be submitted.
- This is a good time to complete the CITI *Social & Behavioral Researchers* IRB training course required for everyone listed on the protocol.

Step #3: IRB Review

- All protocols are sent to IRB members for screening.
 - 75% of the protocols submitted are declared “Not Research” or “Exempt” by the screener. This takes 1 – 3 weeks to process at the current turnover rates.
 - 20% of the protocols are approved as “Expedited” by the screener. This takes 1-3 weeks to process at the current turnover rates.
 - 5% of the protocols are approved as “Full Board.” Full Board protocols go to a convened IRB meeting for review. They take 1 – 2 months to approve.
- Your protocol may be returned to you for revisions more than once in any of these screening/review pathways.
- The IRB meets on the second Wednesday of the month.
- Please note that ORC places a protocol on the Full Board meeting agenda when the protocol is ready for review NOT when it is turned in.

Step #4: Protocol Declaration or Approval

- Protocol declaration as “Not Research or “Exempt” means you can start work.
- Protocol approval as “Expedited” or “Full Board” means you can start work.

IRB Review Cycles:

Protocol Review:

- A complete re-review of the protocol is required every 3 years.
- A continuing review form will be required annually for Expedited and Full Board protocols.
- For Expedited protocols, the continuing review is handled outside of an IRB meeting.
- For Full Board continuing reviews, the review must be taken back to a convened meeting of the IRB for re-approval until the committee downgrades its status to Expedited or Exempt.

CITI Social & Behavioral Researchers IRB training course:

- Training must be retaken every 3 years
- Training approval runs independently of protocol approval. It is dependent on the individual.