

Determine whether project meets the following three criteria; OHRP's or FDA definitions of both involving "research" and "human subjects" and determine TXST level of engagement.

Once application is complete submit for an administrative review by RIC.

The RIC will decide which level of review the application will be processed.

Exempt/ Exempt Limited Review

Must involve no more than minimal risk to participants and falls into one or more of the eight exempt categories defined by federal regulations.

Requires RIC administrative review. Exempt Limited Review will also undergo review by the IRB chair or designated voting member.

Expedited

Must involve minimal risk to participants and falls into one or more of the nine expedited categories defined by the federal regulations.

Requires RIC administrative review and review by at least one voting IRB member.

Full Board

Must involve greater than minimal risk to participants, intentional deception, or vulnerable populations.

Requires RIC administrative review and review by voting members at a convened Full Board IRB meeting.

If clarifications are needed, the application may be returned to the researcher to make required revisions to meet ethical guidelines and compliance standards.

Application should be resubmitted within 30 days or RIC has the right to abandon the application.

Resubmit revised application to continue IRB review process.

Contact the RIC office at OSRP-IRB@txstate.edu or 512-245-1423 with questions.

Decision letters are automatically generated in the online application system and can be found under "Correspondence Generated" in the activity log.

Research **cannot** commence until IRB has provide its official approval letter and stamped consent forms are uploaded under "Admin Notes & Files" in the application.

Any changes to the research protocol must be submitted to RIC as an amendment before they are implemented into the project.

Changes include but are not limited to; population, procedures, personnel and CITI training certification.

There is not a limit on the number of amendments that can be submitted.

Annual Continuations of Expedited or Full Board projects must be submitted before the documented renewal date.

Protocols have a two renewal limit. A new protocol must be resubmitted every three years.

All studies need to submit a close request once all data is collected and the analysis of identifiable information is complete.