



# RESEARCH USING HUMANS POLICY

Researchers conducting human subjects research are required to comply with:

## FEDERAL LEGISLATION

[Code of Federal Regulations Title 45 Part 46 \(45CFR46\)](#)

## STATE LEGISLATION

Federal regulations require researchers to conduct research in compliance with applicable state law. Investigators must comply with Georgia state laws as they pertain to human participant research.

## OVERALL SUMMARY OF TFC IRB

Toccoa Falls College (TFC) has established an Institutional Review Board (IRB) to review all proposed research involving human subjects to ensure that the subjects' rights and welfare are adequately protected. The IRB is composed primarily of faculty members from disciplines in which research involving human subjects is integral to that discipline's work. The human subjects review process is administered through the Office of Academic Affairs.

## APPLICATION PROCESS

All human subject research proposals must be submitted to the IRB. Researchers whose study is not federally regulated (i.e., is not federally funded and does not take place on federal property) and who believe their study is exempt from state law shall complete an application for exempt research. See the *Application Form for Exempt Research* [\[Appendix 1\]](#). Submit an electronic copy of the application and associated materials to the IRB Chair. All others must complete the *Human Subject Research Review Application Form* [\[Appendix 2\]](#). The responsible project investigator (RPI), or a member of the research team familiar with the project, should attend the Institutional Review Board (IRB) meetings regarding the project. The application and associated materials should be separated into the following different files:

- Application Form
- Human Subjects Training Documentation
- Informed Consent Documents
- Recruitment Documents
- Study Materials and/or Instruments
- Grant/Contract Information (if applicable)

Files should be saved with the investigator's last name followed by the information in the .PDF (ex – "Smith\_application"; "Smith\_trainingdoc").

## EXPEDITED REVIEWS

The Toccoa Falls College IRB conducts expedited reviews. According to this policy, expedited reviews are allowed in two instances:

- 1) The research protocol has undergone review at another institution and has obtained approval from that institution, or
- 2) Minor changes are being proposed to a previously approved research protocol.

If your protocol qualifies for expedited review, you may submit one copy of the research application to the IRB Chair. Protocols that have received approval at another institution should include the IRB application and approval letter from that institution.

## APPROVAL PERIOD

The approval period for a study is typically one year. Researchers must submit a Progress Report if a non-exempt project is to last longer than the approval period, which is typically one year. Researchers must submit the *Progress Report Form* [Appendix 3], to the Chair of the IRB two months prior to the study's expiration following the electronic submission procedure. The study must be reviewed and re-approved by the IRB for research to continue. Non-exempt studies are considered complete when data collection and data analysis are complete. Researchers must submit one copy of the *Close Out Report* [Appendix 4], to the Chair of the IRB one month after the study is complete.

## FORMS

All forms pertaining to research involving human subjects are available in electronic form from the Chair of the IRB and/or the Faculty Development portion of myTFC.

## REQUIRED TRAINING

All human subject researchers must obtain adequate training either through the CITI Program or the National Institutes of Health (NIH) Office of Extramural Research course "Protecting Human Research Participants" [<https://phrptraining.com>]. The NIH course is comprised of six training modules that are complete. Researchers must provide the IRB with the course completion certificate to be placed on file by the Chair of the IRB.

In addition, Investigators who propose studies with patient populations are required to document HIPAA (Health Insurance Portability and Accountability Act) training. Investigators must access the National Institutions of Health (NIH) booklet entitled "Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule" at [http://privacyruleandresearch.nih.gov/pr\\_02.asp](http://privacyruleandresearch.nih.gov/pr_02.asp)

Investigators must submit an attachment to the review application stating that the material has been read and will be adhered to in the proposed research. The attachment must include the date the material was read, which must be within the 12 months prior to the application.

