

# IRB Institutional Protocol and Procedures

**Mission Statement and Overview:**

The Forsyth Technical Community College Institutional Review Board (IRB) exists to review and support ethical research involving human participants in order to ensure that the rights of all participants are protected. The IRB seeks to ensure that all research is ethical, confidential, voluntary, and poses minimal risk of harm to participants.

To assure the protection of human subjects and to comply with United States Federal law including the 45 CFR 46 statute, employee and student researchers at Forsyth Technical Community College must submit proposals for studies involving human subjects to the College’s Institutional Review Board for review and approval prior to initiating a proposed study. External researchers wishing to solicit participation from FTCC students, staff, or alumni must also submit proposals for studies involving human subjects to the College’s IRB for review and approval prior to initiating a proposed study. FT Policy 3.10 Institutional Research Board (IRB)

* The following principles apply to all research involving human subjects at Forsyth Technical Community College to ensure proper safeguards are provided:
  + The legal rights of all subjects will be respected based on federal and state regulations.
  + Risks to subjects must be reasonable relative to any anticipated benefits of results.
  + Research involving human subjects must be supervised by qualified persons, including qualified clinicians for all study-related healthcare decisions.
  + Participation of human subjects must be voluntary and the right to withdraw at any time must be provided. Information provided to subjects in order to gain consent must be adequate, appropriate, and presented in language that is suitable and fitting to the subject population.
  + All research programs that involve human subjects must be reviewed by the IRB and must receive approval prior to initiation.
* Duties and Obligations of Forsyth Technical Community College IRB:
  + To develop and revise IRB policies and/or procedures.
  + To distribute information to faculty, students, and other researchers regarding ethics, policies and/or procedures concerning research involving human subjects at FT.
  + To review human subject research requests submitted to the IRB involving FTCC staff or students including the review of informed consent and other documentation.
  + To keep records of, supervise, and track research involving human subjects at the college.
  + To suspend or terminate approval of a study, or to place restrictions on a study, when deemed to be in the best interest of the subjects in that study.

# Regulations and Ethics for Protection of Human Subjects in Research

While scientific research involving human subjects can produce substantial benefits, it also has the potential for troubling ethical questions. Past abuses of the violations of the rights and welfare of human subjects have resulted in various codes and regulations at the Federal level. State and local regulations, as well as institutional policies, provide additional protection for research subjects.

Regulations are built on three ethical principles: respect for persons, beneficence, and justice. The principles govern much of the research with human subjects in the United States, as well as all research involving these subjects at Forsyth Technical Community College. FTCC will voluntarily adhere to the Common Rule of 45 CFR 46, which is the federal regulation administering research falling under the regulation of Department of Health and Human Services (DHHS).

Institutions that receive federal funds in support of research on human subjects are required by the DHHS to comply with federal regulations that govern such research. As part of the compliance requirements, institutions must establish an IRB that maintains responsibility for reviewing all research activities involving human subjects within the given institution, and for ensuring proper training in research ethics. **Forsyth Technical Community College will voluntarily enforce 45 CFR 46 as the minimum standard for all studies across the entire institution, whether or not the study is receiving governmental or external funding.**

# Federal Regulations

Federal regulations are available online at [www.hhs.gov/ohrp/regulations-and-policy/regulations](http://www.hhs.gov/ohrp/regulations-and-policy/regulations) [45 CFR 46- The National Research Act](http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46)

The first federal regulation that became effective in 1974 and established the IRB system for work with human subjects.

[The Belmont Report](http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report)

The cornerstone statement of ethical principles for human subjects’ protection. The three ethical principles of the Belmont report are:

* Respect for persons- pragmatically expressed through informed consent and through establishing protections for those with diminished autonomy. This also includes the right to confidentiality and the right to withdraw consent without consequence.
* Beneficence- the act of securing the well-being of research subjects. The researcher must do no harm and maximize possible benefits while minimizing potential harm.
* Justice- fairness in the distribution of the burdens and benefits of research. This is reflected in the regulations through review criteria requiring equitable selection of subjects.

21 CFR 50 and 21 CFR 56

These regulations require researchers seek approval from an IRB for investigational use of drugs, devices, and biologics.

[The Common Rule](http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46)

Though it has now been integrated into 45 CFR 46, The Common Rule provides the basis for regulations covering the protection of human subjects in research. The Common Rule was revised effective January 21, 2019.

# Operations of the IRB

1. Decisions Available
   1. **Approval**: The activity may start as soon as approval is received if all other relevant FT requirements have been met.
   2. **Approval Pending with Required Modifications**: Approval of a protocol will be granted by the IRB Chair after addition or removal of contingencies or clarifications have been met.
   3. **Deferred**: The protocol requires extensive modifications and must be resubmitted to the IRB for reconsideration after modifications are made.
   4. **Denied:** The activity may not be conducted as proposed. The researcher will be provided with

written documentation of the reasons for the IRB’s decision. A new application may be submitted for consideration after being revised to address the reasons for denial.

*\*For academic research (thesis, dissertation, practicums, etc. Forsyth Tech will not lend approval of research or recruitment for research without documentation of prior approval or exempt status from the host institution.*

1. Documentation

The IRB prepares and maintains adequate documentation of IRB activities, including, but not limited to:

* 1. Copies of all research proposals reviewed, approved sample consent documents, and continuing reports submitted by investigators.
  2. Copies of all correspondence between the IRB and the investigators.
  3. Other correspondence or documents generated by the IRB.

1. Document Retention
   1. All documents and records required to be saved will be retained for a minimum of three (3) years after the completion of the research.
   2. The IRB Chair will maintain a list of the current IRB members and written procedures for the IRB.
2. Conflict of Interest

The IRB chair and IRB supporting staff are responsible for identifying and avoiding any situations in which they, either personally or by virtue of their position, might have a conflict of interest, or may be perceived as having a conflict of interest, in connection with a matter before an IRB of which they are a member.

A conflict of interest may arise if an IRB member, or an immediate family member/significant other, have a financial or intellectual interest in or are receiving compensation related to a research project under review by the FTCC IRB. A conflict may also occur if an IRB member has or anticipates a financial relationship (e.g. consulting, speaking, advisory boards, patents, equity, options) that could be perceived to overlap or present a conflict of interest with a proposal under review of the FT IRB.

1. Training

The IRB chair and supporting review faculty and staff will complete training regarding the protection of human research participants at least every four (4) years. Members will submit a copy of the completion certificate to the IRB Chair to be retained with IRB documents and records.

1. Non-Compliance

Any non-compliance with IRB policies and procedures will be investigated by the Chair of the IRB. Any actions against the researcher will be taken immediately and could result in a pause of all research activity as deemed necessary.