Purpose

The Institutional Review Board (IRB) at Elizabeth City State University is responsible for reviewing research involving human participants to help ensure that their rights, safety, and welfare are protected.

The IRB supports ethical research practices in accordance with applicable federal regulations, institutional policies, and professional standards.

Faculty, staff, students, and external investigators conducting human subjects research under ECSU's oversight must obtain the appropriate IRB determination or approval before beginning activities requiring review.

Compliance Policy & Procedures – Human Subjects (link policy- 2 pages)

FWA and IRB Registration

FWA: 00018292

IRB Number: IRB00003640

IRB application and submission process

1. Determine whether IRB review is required
2. Prepare the research protocol and supporting documents
3. Submit IRB application through Cayuse. (Cayuse Human Ethics Instructions)
4. Certification Routing – Principal Investigator, Department, and the final IRB approval
5. Complete required human subjects protection training through CITI. (CITI Instructions)
6. Respond to IRB requests for clarification or revisions
7. Receive written approval of determination before beginning covered research

Types of IRB Review

Review category	Explanation
Exempt	Research meeting specific regulatory exemption criteria; institutional determination procedures apply
Expedited	Certain minimal-risk research eligible for review by an IRB chair or designated experienced reviewer

Full Board	Research requiring review by a convened IRB, including studies not eligible for exempt or expedited pathways

Not Sure If Your Project Requires IRB Review?

Faculty, staff, and students conducting surveys, interviews, classroom projects, program evaluations, quality improvement activities, or other research-related activities are encouraged to review the IRB Decision Tree before beginning their projects.

The decision tree is designed to help identify activities that may require IRB review or institutional determination.

Completion of the decision tree does not constitute IRB approval or an official determination. Researchers should contact the Office of Sponsored Programs when additional guidance is needed.

See Do I Need an IRB Review document...

Human Subjects Research Training

Human subjects research training requirements.

- CITI Program is the approved training provider.
- Principal Investigators, co-investigators, student researchers, faculty advisors, and other research personnel
- Complete Social Behavioral or Biomedical Research Investigators and Key Personnel or Social Behavioral or Biomedical Research Administrators
- Training completion certificates should be included with protocol documentation
- Refresher training and expiration periods every 4 years.
- Additional training for specialized research, when applicable.

Multi-site Research & Single IRB of Record (sIRB)

A Single IRB of Record (sIRB) may be required.

NIH**: Effective for multi-site grant applications with due dates January 25, 2018 and **beyond

***DHHS**: Effective as of January 20, 2020 – the single IRB-of-Record (sIRB) review requirement for all cooperative research projects sponsored by one of the federal Common Rule agencies*.

Federally-funded cooperative (i.e., multi-site) human subjects research studies are required per the Common Rule (45 CFR 46.114) to utilize a **single IRB-of-Record (sIRB)** to streamline the human subject/participant protections review process and avoid duplicate review by an institutional review board at each site.

Under the sIRB model, an Institutional Review Board (IRB) at one of the collaborating institutions agrees to provide IRB oversight for all participating institutions via an authorization agreement (a.k.a. "reliance" or "collaborative" agreement). This legal contract documents the respective authorities, roles, responsibilities, and communication plans among the IRB-of-Record (i.e., the "reviewing IRB") and the institutions relying on that IRB for project oversight. At UNCG, authorization agreements are signed by ECSUs Office of Sponsored Programs Director.

The reviewing IRB centrally handles the IRB review functions *only*. Related local functions, such as ancillary committee reviews (e.g., conflict of interest review, verification of completed human subjects protections training) remain with the individual participating institutions. The conduct and reporting of the research remain the study team's responsibility.

Federal Regulations Guidance

- The Common Rule (45 CFR 46) Protection of Human Subjects
- HHS Office for Human Research Protections (OHRP)
- The Belmont Report
- OHRP Guidance Resources
- OHRP FAQ – Use of Electronic Informed Consent
- NSF and the Common Rule of Research with Human Subjects
- OHRP International Compilation of Human Research Standards
- Human Research Volunteer Informational Videos | HHS.gov
- Checklist of Resources for Learning about Research and Research Participation
- HHS Office for Human Research Protections (OHRP)
- ORI Human Subjects Protection

Data Sharing

- NIH Data Sharing Policy