

Human Subjects Research Policy

Shenandoah University's policy requires review and approval of all activities that involve using human subjects in research. The Institutional Review Board (IRB) is responsible to the Vice President for Academic Affairs. Approval of the IRB must be obtained prior to involvement of human subjects. Failure to have human subjects research reviewed by the IRB, including those protocols believed to be exempt, is a violation of University policy and will be reported to the Vice President for Academic Affairs for disciplinary action.

Selecting Your Review Category:

IF YOUR PROJECT MEETS ALL OF THE FOLLOWING CRITERIA, YOU SHOULD SELECT "EXEMPT" REVIEW:

- Research conducted in established or commonly accepted educational settings
- Research involving the use of educational tests if subjects cannot be identified
- Research involving surveys, interviews, or observations of public behavior that do not deal with sensitive or critical responses. All research using survey or interview procedures is exempt when the respondents are elected or appointed public officials or candidates for public office.
- The project will not involve subjects in high risk groups, including but not limited to minors, pregnant women, prisoners, individuals with physical or mental disabilities, and/or Shenandoah University students.
- Research involving the collection or study of existing data or specimens that are either publicly available or not individually identifiable.

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IF YOUR PROJECT MEETS ANY OF THE FOLLOWING CRITERIA, YOU SHOULD SELECT “EXPEDITED” REVIEW:

- Collection of hair, nail clippings, dental plaque and calculus, or teeth in a non-disfiguring manner, or secretions.
- Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice.
- Collection of small (≤ 550 ml per 8 weeks, and ≤ 2 samples per week) amounts of blood by venipuncture from healthy, non-pregnant subjects 18 years of age or older and weigh at least 110 pounds.
- Voice or video recordings made for research purposes such as investigations of speech defects.
- Moderate exercise by healthy volunteers.
- Study of existing data, documents, records, pathological specimens, or diagnostic specimens.
- Research on individual or group behavior where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.
- Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

NOTE: IF YOUR PROJECT DOES NOT MEET ALL OF THE CRITERIA FOR AN EXEMPT REVIEW OR ANY OF THE CRITERIA FOR EXPEDITED REVIEW, YOU MUST SELECT FULL REVIEW.

For additional assistance in selecting your review category, visit

<https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html> or contact the IRB Chairperson or IRB Compliance Coordinator.

Required Documents:**IF YOU SELECTED AN EXEMPT REVIEW, YOU MUST SUBMIT THE FOLLOWING ITEMS:**

- Application for Use of Human Subjects (Form B) online form
- Informed consent form (if applicable)
- Appendices (surveys, questionnaires, or tests) (if applicable)
- Letter of approval from each cooperating organization's institutional review board or administrative representative (if applicable)

IF YOU SELECTED EXPEDITED OR FULL REVIEW, YOU MUST SUBMIT THE FOLLOWING ITEMS:

- Application for Use of Human Subjects (Form B) online form
- Informed consent/minor assent forms (as applicable)
- Appendices (surveys, questionnaires, or tests) (if applicable)
- Letter of approval from each cooperating organization's institutional review board or administrative representative (if applicable)
- Electrical equipment safety check memo (if applicable)

Check for Completeness:**BEFORE YOU SUBMIT YOUR PROPOSAL, PLEASE CHECK THE FOLLOWING ITEMS FOR COMPLETENESS:**

- All researchers who will be active on the protocol have current CITI certificates of completion
- All corresponding documentation is included (required documents listed above within the appropriate category, surveys, research proposals, etc.)

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- Start date will allow sufficient time for review to be completed before involving subjects and end time
- Current forms are being used (the most current versions are located on the SU website and in the “Documentation” tab on Axiom Mentor)

NOTE: If there are missing documents, or information, your IRB application will be returned to you until all missing items are received. This will delay your approval Process.

Estimated Timeframe For Review:

- “Exempt” reviews *generally* take at least 2-4 weeks.
- “Expedited” reviews *generally* take 3-6 weeks.
- “Full Board” reviews will *generally* take anywhere from 6-8 weeks.

The time of review varies depending on the complexity of the research and if any revisions are requested. Please plan accordingly.

RESEARCH REVIEW PROCESS

All research involving living human subjects and/or their records must be reviewed and approved by the SU IRB PRIOR TO beginning research. Research is classified at three levels of review: exempt, expedited, and full. The final determination of exempt vs. non-exempt is determined by the IRB.

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