Wilkes University Institutional Review Board (IRB) Policies, Regulations, and Rules

1. General

Federal law and University policy require that all research involving human subjects, conducted by Wilkes University researchers (faculty, staff, administrators, or students) must be reviewed and approved by the Wilkes University Institutional Review Board (IRB) for the Use of Human Subjects in Research. These rules are in place to protect the human subjects, the researchers, and the institution.

Purpose of the IRB

The purpose of the IRB is to review research that involves human subjects. The primary responsibility of this board is the protection of human subjects in such research.

The IRB’s function shall be to make certain that:

- The rights and welfare of any human subjects/participants/patients are adequately protected.
- When appropriate, informed consent will be obtained by adequate and appropriate methods in accordance with the provisions of applicable Federal regulations and/or professional ethical standards.
- Confidentiality of subject information is appropriately protected.
- The risks to the subjects/patients are outweighed by the potential benefits to the subjects/patients and the importance of the knowledge to be gained as to warrant a decision to allow the subject/patient to accept these risks.

Ongoing human subject research by University faculty is reviewed at yearly intervals.

2. Ethical Standards

All Wilkes University researchers (faculty, staff, administrators, and students) must adhere to strict ethical standards for the use of human subjects in their research. These standards are in place to protect the basic rights of their subjects. Any research that departs from the spirit of these standards violates University policy. Below are some guidelines that the IRB members consider during their reviews to maintain these standards.

1) All research procedures minimize the risks to subjects.
2) Any risk must be reasonable in relation to the potential benefits from the study.
3) Informed consent must be obtained from the subject before participation. This consent must be in writing unless exempted by the board.
4) Subject must be provided with adequate detail regarding the study to make an informed decision regarding their participation. This information should be included on the consent form and should be written in lay language, so that the subjects can make an informed decision regarding participation.
5) Subject's privacy must be maintained.
6) Subjects need to be made aware that they participate of their own choice and are free to withdraw from the study at any time.
3. Review Categories

There are three categories (or types of review) for projects that are submitted to the IRB. Determination of the type of review will be made by the IRB chair or a designee of the board upon consideration of the submitted materials.

The review categories are as follows:

3.1 Exempt from review,
3.2 Subject to expedited review,
3.3 Subject to full review.

3.1. Exempt from review.

Exempt research does not require IRB review or approval if the research is exempt from the federal regulations. The IRB chair or a designee, rather than the researcher, verifies whether or not research is exempt; therefore, an application must be filed with the IRB to confirm that the research is exempt from review. The IRB office will notify the principal investigator of the exempt status; however, should the IRB find otherwise, the principal investigator will be notified. Approval for exempt research does not expire, but any changes must be reported to the IRB office.

As stated in 45 CFR 46.101 (b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt:

1) Research conducted in established or commonly accepted educational settings, involving normal educational practices.

2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) Subjects can be identified either directly or through identifiers linked to the subjects; and
(ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, that is not exempt under paragraph (b)(2) of this section, if:

(i) the human subjects are elected or appointed public officials or candidates for public office; or
(ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens if these sources are publicly available or
if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

   (i) Public benefit or service programs;
   (ii) procedures for obtaining benefits or services under those programs;
   (iii) possible changes in or alternatives to those programs or procedures; or
   (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies,

   (i) if wholesome foods without additives are consumed or
   (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

For additional information on exempt research activities, refer to http://www.hhs.gov/ohrp/policy/exempt_res_det.html#FAQ1

Note that **Additional Protections** are in place for the following:
- Pregnant women, human fetuses, and neonates (refer to 45 CFR 46 Subpart B)
- Biomedical and Behavioral Research Involving Prisoners as Subjects (refer to 45 CFR 46 Subpart C)
- Children Involved as Subjects in Research (refer to 45 CFR 46 Subpart D)

For additional information on additional protections, refer to http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101

### 3.2. Subject to expedited review.

Expedited review will typically be conducted on those research applications that involve (1) no more than minimal risk to human subjects and involve only procedures listed in the categories appearing in 45 CFR 46.110 and 21 CFR 56.100, or for (2) minor changes in previously approved research during the period of one year or less for which approval is authorized.

Research activities subject to expedited review must meet specific criteria set by the federal government. The activities eligible for expedited review means that the IRB will review the specific circumstances of the proposed research to ensure minimal risk to human subjects. Should the IRB reviewers find otherwise, the principal investigator will be notified of that determination.

If research qualifies for expedited review, a complete application from the IRB website should be submitted. This application will be screened by the IRB chair or a designee, and if subject to expedited review, the application will then be reviewed by one and no more than
two IRB members. This review can take from 2 to 3 weeks to complete. The IRB reviewers may request changes in the proposal. The IRB reviewers have the authority to approve, disapprove, or require a resubmission pending changes or additional information.

If the IRB reviewers determine that the research study should be disapproved, it must be taken to the full board for review. This may lengthen the review process.

Approval expires after one year. Studies undergoing expedited review must be re-reviewed every year, and any changes or adverse events must be reported to the IRB chair. (Refer to 6.4. Renewals and Extensions for Approved Research.)

For complete information on expedited research categories, refer to the following:
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.110
http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm

3.3. Subject to full review.

Full review requires that the all members of the IRB review the application packet. If a proposal must receive full board review, it is reviewed by the board at a convened meeting. The board can vote to either to approve, disapprove, or require resubmission pending changes or additional information.

After the meeting, the IRB office will notify the researcher of the board’s decision, and handle the rest of the approval process for the proposal. The IRB convenes every month. A proposal must be at the IRB office a few weeks before a meeting at which it is reviewed, and a study’s principal investigator may be requested to attend IRB meetings in order to answer questions.

Studies undergoing full board review must be re-reviewed every year, and any changes must be reported to the IRB office before they are implemented. Approval expires after one year. (Refer to 6.4. Renewals and Extensions for Approved Research.)

4. External IRB Approval

The IRB should be notified if research being conducted by a Wilkes researcher (faculty, staff, administrators, or students) has been approved by an outside IRB. In this situation, the principal investigator of the research has the responsibility to submit a completed application and any other pertinent documentation to the Wilkes IRB. A letter of approval from the outside IRB must be included. The Wilkes IRB office will notify, in writing, the receipt of such documentation but will NOT conduct a review of such research. Research cannot begin until such notification is received by the principal investigator.

5. Definitions

5.1. Research - A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program, which is considered research for other purposes. For example, some demonstration and service programs may include research activities.
5.2. Human Subject - Means a living individual, about whom an investigator (whether professional or student) conducting research obtains:

1) Data through intervention or interaction with the individual; or
2) Identifiable private information
3) Intervention includes both physical procedures, by which data are gathered (for example, venipuncture), and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject.
4) Private information includes information about behavior that occurs in a context, in which an individual can reasonably expect that no observation or recording is taking place, and information, which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information), in order for obtaining the information to constitute research involving human subjects.

5.3. IRB - an institutional review board established in accord with and for the purposes expressed in this policy.

5.4. IRB Approval - the determination of the IRB that the research has been reviewed and may be conducted at Wilkes University within the constraints set forth by the IRB, and by other institutional and federal requirements.

5.5. Minimal Risk - means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

For a complete list of definitions, refer to the ‘Definitions’ sections found at http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

6. Procedures

Described below is the process principal investigators are required to follow to seek approval from the Wilkes University IRB for the Use of Human Subjects in Research.

6.1. Responsibilities of the Principal Investigator

The principal investigator is responsible for completing the IRB application and submitting the required materials to the IRB office. For research whose principal investigator is a student, a Wilkes faculty member must sign designating that they have reviewed this application thoroughly and will oversee the research and acknowledge their role as the principal investigator of record.

While the principal investigator will designate the type of review sought (exempt, expedited, or full review), the IRB chair or a designated member of the IRB will verify the type of review the proposal will undergo and route the application materials through the proper review procedures.
It is essential that the principal investigator refer to this document and to the Code of Federal Regulations (CFR) Part 45 for the Protection of Human Subjects, referenced throughout this document, and available in its entirety at: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

6.2. Application - The application provides the IRB with the critical information regarding the proposed research under consideration. The application contains a cover page with general information followed by the application itself which contains the essential information that will allow the reviewers to evaluate the study.

The application contains the following sections for completion: Introduction, Summary, Subject Population, Procedures, Potential Risks, Potential Benefits, Compensation, Collaborators, Conflict of Interest, Additional Required Information, Protecting Human Subjects Training. Each of these sections needs to be completed, or if a section does not apply write "N/A". These sections need to be written in lay language, avoiding jargon and acronyms.

Failure to follow these procedures will cause delays in processing the application. Incomplete applications will be returned to the principal investigator without review.

6.3. Informed Consent Form - An important component to any submission to the board is the informed consent form. This form will be used by the researcher to document that the subjects are aware of the requirements of the study and that they are aware that they can refuse to participate or withdraw at anytime. It is important that this document contain adequate information so that subjects can make an informed decision regarding participation. This form should be written in lay language and avoid jargon and acronyms.

The basic elements of the informed consent, as identified in 45 CFR 46.116, include:

1) A statement that the study involves research, an explanation of the purpose of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental. The actual study hypothesis need not be stated.

2) A description of any reasonably foreseeable risks or discomforts to the subject. A description of any benefits to the subject or to others that may reasonably be expected from the research.

3) A disclosure of appropriate alternative procedures or course of treatment, if any, that might be advantageous to the subject.

4) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

5) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs, and, if so, what they consist of, or where further information may be obtained.

6) An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research-related injury to the subject.
7) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

For additional requirements related to informed consent, refer to http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116

6.4. Renewals and Extensions for Approved Research

For those projects that are multi-year studies or that require an extension beyond the one year limitation of the IRB approval, the principal investigator must submit a letter or email to the IRB chair.

- For a renewal of an approved multi-year study, the letter should contain a concise overview of the project to date (# of subjects, significant findings, etc.) and document any modifications to the original application.

- For an extension of an approved research project originally intended to be completed within one year, the letter should state the reason for the extension, provide a concise overview of the project to date, and document any modification to the original application.

Upon receipt of this letter, the IRB will revisit the original application and the request for renewal or extension using an expedited review process, unless otherwise warranted.

If the IRB review finds the research protocol acceptable, the principal investigator will receive a letter of approval. Approval expires after one year. Any changes must be reported to the IRB office.

7. Review and Approval Process

All materials will be sent electronically to the IRB. Upon receipt of an application package, the IRB office will check the materials for completeness and content. If the application is found to be complete, it will then be reviewed. If there are concerns or needed clarification, the board will correspond directly with the principal investigator to resolve these issues. The review process can take from 2-6 weeks depending on the clarity and complexity of the proposal and the type of review.

7.1. Criteria for IRB Approval of Research

The criteria for IRB approval is governed by federal regulation 45 FRC 46.111 which lists requirements that must be satisfied. These include:

1) Risks to subjects are minimized:
   (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
   (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
3) Selection of subjects is equitable.

4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.

5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.

6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

For complete information, refer to http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.111

7.2. Review Process: Full Board Review - The IRB may vote to approve, disapprove, or require resubmission of a research application. These actions require the vote of a majority of the members participating. The chair does not vote, except to break a tie.

1) In order for the research to be approved, the application must receive a favorable vote of a majority of the members voting.
2) If the vote is taken during a board meeting and the principal investigator or any board member at all associated with the protocol is present, they abstain from voting and/or leave the meeting room during the vote.
3) At the discretion of the chair, the vote may be taken via email, phone, or campus mail.
4) For an expedited review to be disapproved, the initial reviewers must inform the IRB chair who will convene a full board review of the application.

7.3. Review Outcomes - The review of the application materials will culminate in one of three outcomes:

1) Approve. This means no further action is necessary and the investigator may proceed with the research.

2) Resubmit. This means that the IRB reviewers or the full board has identified certain problems in either the application materials or the consent form. Following notification to the investigator, these applications are revised and returned for review by the IRB members or full board who may then grant approval.

3) Disapprove. This means the board does not approve the research as proposed. Written notification of reasons for the decision will be sent to the investigator and the investigator will be given an opportunity to respond in person or writing to the IRB.
7.4. Review Notification - The IRB shall notify investigators in writing of its decision to approve or disapprove a proposed research activity, or if resubmission is required pending modifications or additional information as required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, written notification with a statement of the reasons for this decision will be provided to the investigator with an opportunity to respond in person or in writing to the IRB.

8. Retention of Records

8.1. Principal Investigators - A copy of all records relating to the research project (original application, signed consent forms, correspondence with the IRB, etc.) should be retained for at least three years after the completion of the research.

8.2. IRB Records - The IRB shall prepare and maintain adequate documentation of activities including:

1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controversial issues and their resolution.

3) Records of continuing review activities.

4) Copies of all correspondence between the IRB and the investigators.

5) A list of IRB members.

6) Written procedures for the IRB.

7) Statements of significant new findings provided to subjects.