INSTITUTIONAL REVIEW BOARD

Standard Operating Procedures for Research Involving Human Subjects
2013-14

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North Carolina Agricultural and Technical State University

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1. **INTRODUCTION**

North Carolina Agricultural and Technical State University (N.C. A&T) faculty and students engage in significant research involving human subjects. The U.S. Department of Human Services (DHHS) Office of Human Research Protections (OHRP) requires under the Code of Federal Regulations Title 45, Part 46, that a local Institutional Review Board (IRB) be “established to protect the rights and welfare of human subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated.”

N.C. A&T has established the IRB according to OHRP requirements to serve as a catalyst in establishing a culture of research compliance of the highest ethical standards. The IRB operates as a fair and impartial board, immune from pressure by the institution's administration, the investigators whose protocols are reviewed, or other sources.
2. Policy

It is the policy of North Carolina A&T State University that all research involving human subjects must be reviewed and approved by the IRB.

This policy applies to all research involving human subjects if the research:

- Is sponsored by the University;
- Is conducted by or under the direction of any employee or agent of the University in connection with his or her University responsibilities;
- Is conducted by or under the direction of any employee or agent of the University using any property or facilities of the University; or
- Involves the use of the University's non-public information to identify or contact human research subjects or prospective subjects.

Important examples include research:

- Funded by federal or local government agencies;
- Funded by foundations;
- Not funded by any agency or foundation;
- Conducted in collaboration with other institutions or organizations;
- For dissertations, theses, and certain class projects; and/or
- Involving the use of data or specimens obtained from outside resources (businesses, schools, data banks, etc.)
3. IRB Structure and Membership

Members of the N.C. A&T IRB are designated by the Chancellor. Recommendations for appointment of its membership are submitted by the Vice Chancellor of the Division of Research and Economic Development (DORED), who serves as the Institutional Official (IO) named in the University's Federalwide Assurance.

As required by federal law, the IRB is composed of a diverse group of scientists and non-scientists with experience and expertise relating to the research regularly conducted at the University. Title 45 CFR 46 details other minimal requirements for the structure of the Board.

The leadership team for the IRB consists of three executive officers: the Chair, the Co-Chair, and the Research Compliance Officer.

3.1 IRB Members

Members are nominated to the Chancellor by the Institutional Official, in collaboration with the Compliance Officer, and are eligible for appointment for two-year terms.

Members are responsible for ensuring that the rights and welfare of research subjects are protected. Members vote to approve, require modifications in, disapprove, or defer research submitted to the IRB. Members are expected to attend IRB meetings on a
regular basis, serve as general reviewers for research within their areas of expertise, and serve as primary or secondary reviewers for research discussed at convened meetings. Members are expected to conduct expedited reviews on behalf of the IRB when so designated by the IRB Chair or the Compliance Officer (as the Chair’s designee). Members also may be asked to participate on other subcommittees and assist with education, as long as there is no conflict of interest with their IRB responsibilities. Established members in good standing who have fulfilled their terms have the option of serving an additional term. All members except community members and consultants must be employed by the University.

In accordance with DHHS requirements, the IRB membership is appointed such that it possesses “the professional competence necessary to review specific research activities.”

**Non-Scientific Members**

Nonscientific members provide input on areas germane to their knowledge, expertise, and experience, professional and otherwise. For example, members who are lawyers should present the legal views of specific areas that may be discussed, such as exculpatory language or state requirements regarding consent. Non-scientific members should advise the IRB if additional expertise in a non-scientific area is required to assess whether the protocol adequately protects the rights and welfare of participants.

**Scientific Members**

Scientific members contribute to the evaluation of a study on its scientific and statistical merits and standards of practice. These members also advise the IRB if additional expertise in a scientific area is required to assess whether the protocol adequately protects the rights and welfare of participants.

These disciplines are generally representative of the University’s most common areas of human subjects research:

- Agriculture,
- Business Administration,
- Education (human development and services, human performance and leisure studies, teaching, school administration, counseling),
- Engineering (computer, mechanical, industrial and systems),
• Leadership Studies,
• Nursing,
• Psychology, and
• Sociology.

Training
All persons serving on the N.C. A&T IRB must complete the Collaborative Institutional Training Initiative (CITI) online training course for IRB members before conducting IRB business. CITI training is required every three years; additional education is provided during IRB meetings. Members are provided with the following to read and have available for protocol reviews:

• This manual,
• Chapter 3 of OHRP’s IRB Guidebook,
• The Belmont Report,
• Institutional Review Board Member Handbook (Amdur and Bankert), and
• Periodic material provided at IRB meetings, attendance at seminars or external meetings.

Members actively participate in ongoing education provided during convened meetings. The Compliance Officer and Chair provide orientation and mentoring for protocol review and operating procedures. New members initially attend IRB meetings as observers to learn about IRB deliberations. They also shadow other members during review meetings to learn how to conduct IRB reviews of protocols.

Active Membership Required
To remove a member from the IRB, there must be just cause shown of that member’s inability or unfitness to serve on the Board. Just cause for removal may be lack of minimum attendance, lack of participation at meetings as judged by the IRB Chair, misconduct, excessive delays in completing protocol review, or unresolved conflict of interest. If an IRB member fails to attend two out of the three convened meetings per semester, he or she would be considered inactive and may be removed from active membership. The Institutional Official may appoint replacements.

IRB Member and Chair Performance Evaluations
IRB members are responsible for completing a self-evaluation annually. The evaluation includes a self-assessment of:
• Knowledge and application of the federal regulations,
• Knowledge and application of IRB policies and procedures,
• Participation in IRB meeting discussions,
• Timeliness in completing reviews, and
• Interaction with investigators and IRB support staff.

The Compliance Officer also performs an ongoing assessment of members and chairs based on the same assessment areas and provide feedback to the IO. The Compliance Officer presents feedback to individual members to enhance and promote growth in their performance as IRB members. The Compliance Officer is responsible for submitting the performance reports to the Institutional Official at the end of each fiscal year.

**Membership Compensation**

Community members are volunteers and are not compensated except to pay for parking on campus. (A space near the meeting location is reserved for each community member when possible. These spaces should be utilized before parking at a metered space or in the parking deck.) Faculty members are also volunteers, who serve on the IRB with the approval of their department chairs. At the end of each fiscal year, each member receives a letter of appreciation acknowledging their contribution to the Board.

**Resources**

DORED provides each IRB member with a handbook, other applicable texts, educational opportunities, and meeting space.

**Conflicts of Interest**

Each IRB member is required to complete and sign the Conflict of Interest form at the beginning of every fiscal year. The form defines what constitutes a conflict of interest and ensures that members adequately manage any conflicts by reporting those to the IRB Chair or Compliance Officer during protocol reviews and full board meeting voting processes. The IRB will not have a member participating in initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. Members are reminded at the beginning of each meeting to recuse themselves at the time of discussion of any protocol with which they have a conflict of interest. The recusal is noted in the minutes.
3.2 IRB Chair

Persons appointed to serve as Chair must be employees of N.C. A&T and have served on the IRB for at least two years. Chairs serve four-year terms and may be reappointed one fiscal year after their terms have ended. In addition to the responsibilities of IRB membership, the Chair has primary responsibility for conducting IRB meetings and ensuring operation of the IRB within all applicable regulatory requirements. The IRB Chair works with the Compliance Officer, IRB members, the Institutional Official, and investigators to ensure that the rights and welfare of research subjects are adequately protected. As a fair and impartial committee head, the Chair functions as a role model for how IRB business should be conducted. This role has shared authority over all IRB policy and procedures in collaboration with the Vice Chancellor of DORED and the Compliance Officer.

Persons appointed to this role are expected to have characteristics that render the IRB review process as effective and efficient as possible. Those include interpersonal skills, leadership skills, experience with human subjects research, and a reputation that encourages respect (i.e., expertise in research involving human subjects, tenured status). A willingness to devote the time and effort to perform the duties required is essential. The IRB Chair is empowered, pending IRB review, to suspend the conduct of a study if he/she determines that an investigator is not following IRB requirements.

Chair Responsibilities

- Keep apprised of OHRP and FDA regulations and changes and apply them to the IRB policies and procedures;
- Represent the IRB in discussions with University representatives;
- Represent the IRB in discussions with federal authorities;
- Deem protocols as exempt, eligible for expedited review or requiring full committee approval;
- Direct IRB proceedings;
- Assist in the development of meeting agendas;
- Review all protocols submitted to the full committee;
- Vote on protocols submitted for full committee review in the event of a tie among members;
- Maintain an in-depth understanding of ethical issues, state law, institutional policy, and federal research regulations applicable to studies reviewed by the IRB;
• Assist the Compliance Officer in drafting letters from the IRB to researchers regarding IRB decisions;
• Represent the IRB in defending or discussing IRB decisions with researchers; and
• Identify and assist the University in managing issues of non-compliance.

3.3 IRB Co-Chair
IRB Co-Chair(s) are appointed to serve for four years and is/are eligible for reappointment. They are appointed to ensure that IRB business continues in the absence of the Chair and to provide a Chair-in-training for a smooth transition at the end of the Chair’s term. Persons appointed to these positions should have experience in human subjects’ research and demonstrate the same characteristics and skills as the IRB Chair. Co-Chairs possess shared authority with the IRB Chair and act in the Chair’s absence. In addition to their authorities and responsibilities, such individuals serve as members of the IRB and are counted for the quorum. They have voting privileges and other authorities and responsibilities of members, including the responsibility to review, make motions, participate in discussions, and vote on approval/disapproval of studies.

During the appointment period, an IRB Chair or Co-Chair may be removed at the discretion of the Vice Chancellor for Research and Economic Development.

3.4 Non-Voting Ad Hoc Reviewers and Ex-Officio Members
In addition to possessing the professional competence necessary to review specific research activities, the IRB requires members who are able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB, therefore, includes persons knowledgeable in these areas as ad hoc or ex-officio members.

The Vice Chancellor for Research and Economic Development, Associate Vice Chancellor for Research, the University Legal Counsel, and the Director of the Office of Research Compliance and Ethics are appointed to serve as ex-officio members on the IRB. They may attend meetings as consultants; only the Director of the Office of Research Compliance has voting privileges.

The IRB may also utilize ad hoc reviewers in cases where additional or specialized expertise in protocol review would be of value to the Board in its deliberations. Ad hoc reviewers are not IRB members and do not vote on protocols. For example, the N.C.
A&T IRB does not regularly review protocols involving prisoners. Therefore, the committee must act to include a prisoner or prisoner representative with expertise in prisoner research in order to review and/or approve the research in accordance with 45 CFR 46.304.

**3.5 Alternate IRB Members**

One or more alternate members may be appointed to fill in for regular IRB members who are, on occasion, unable to attend convened IRB meetings. Alternate members must be listed on the IRB’s official membership list, which must specify which member (or members) the alternate is qualified to replace. The backgrounds of alternate members should be similar to the member they are replacing or they should be able to represent similar interests. Although an alternate may be qualified to replace more than one regular member, only one such member may be represented by the alternate at any convened meeting. Terms of appointment, length of service, and member obligations are the same as for regular IRB members.

A list of current IRB members is posted on the IRB website of the Office of Research Compliance and Ethics.

**3.6 IRB Compliance Officer**

The Compliance Officer’s duties are:

- Keep apprised of OHRP and FDA regulations and changes and apply them to IRB policies and procedures;
- Conduct administrative reviews of all IRB protocols and related materials;
- Provide researchers with feedback on administrative errors on protocols and about missing documents before IRB member review;
- Act as a liaison between the IRB and the researchers;
- Communicate the actions and findings of the IRB to the Institutional Official;
- Make determinations for exemptions;
- Approve amendments for minor changes to exempt protocols;
- Sign official correspondence related to IRB decisions on behalf of the IRB;
- Organize protocols for and reports dispositions to the IRB;
- Provide education to IRB members, administrators, faculty, students, and staff;
- Provide information to researchers outside of N.C. A&T about the policies and procedures for conducting research at this institution;
- Provides regulatory updates to the IRB;
• Assist in the development of policies and procedures
• Assist the Chair in scheduling IRB functions to include (but not limited to) IRB meetings, review meetings, and meetings with researchers to resolve concerns
• Handle the filing of IRB documents; and
• Direct the electronic collection of protocols and related documents.

3.7 Compliance Officer for Animals, Biosafety, and Radiation

The Compliance Officer for non-human subjects serves as a backup for the Compliance Officer for human subjects in the event of absence due to illness, vacation, professional development activities, or travel.
4. **Scope of the IRB’s Authority**

The involvement of human subjects in any research project is not be permitted until the IRB reviews and approves the research protocol, generates the letter of approval, and stamps the informed consent form (and other supplemental documents), if appropriate, for such research to be conducted.

The IRB has the authority to:

- Review and approve, require modification in, disapprove, or table any research activity, including proposed changes in previously approved human subject research;
- Require progress reports from investigators, including continuing review at intervals appropriate to the degree of risk, but not less than once per year, and to observe or have a third party observe the consent process and the research;
• Suspend or terminate approval of research not being conducted in accordance with applicable federal regulations and/or IRB requirements, or that has been associated with unexpected serious harm to subjects; and
• Place restrictions on a study and/or certify that investigators are qualified to conduct the research.

4.1 Observation of Consent Process or Research Activities
The IRB has authority to observe or have a third party observe the consent process and the research. This observation might be prompted by subject complaints, concerns about the conduct of a particular research study, the performance of a particular research team, or because the study was selected for random review. Observation may be conducted by IRB members or staff or by others designated to conduct audits as a part of their responsibilities (e.g., the Protocol Review and Education Program committee). Such observation would typically be initiated by the IRB Chair or Compliance Officer.

4.2 Institutional Accountability
N.C. A&T follows OHRP guidelines for maintaining a Federalwide Assurance and appointing an institutional official to oversee the University’s human protections program. The University provides the resources needed to maintain staffing and office space through DORED. The institution ensures that the IRB’s authority is maintained as an independent entity.

4.3 The Limits of IRB Authority
The IRB does not:

• Provide editorial services,
• Act as a risk management department,
• Provide data safety monitoring services, or
• Provide data storage.

4.4 IRB Meetings: Quorum
Decisions made by the IRB are made by a majority vote of the voting members in attendance at the IRB meeting. A majority of the IRB constitutes a quorum, which must include at least one member whose primary concerns are in nonscientific areas. Frequent absence of members is not acceptable. If quorum fails during a meeting (due
to lack of a majority of IRB members being present or the lack of a nonscientist member, for example), the IRB cannot take action or vote until the quorum is restored. A meeting also can lose its quorum when members with a conflict of interest leave the room for deliberation and voting.

4.5 Schedule of Meetings
The convened IRB is scheduled to meet three times each semester: an opening session, a mid-session, and a closing session. A list of IRB members available for review during summer months is established during the spring semester closing meeting. Whenever a full board review is required during months where no IRB meeting is scheduled, the convened IRB will be gathered by a called meeting.

4.6 Meetings via Telephone or Video Conference
IRB meetings are usually held face-to-face. However, they may be conducted completely or in part by telephone or videoconference, if necessary (for example, when an IRB member is unable to be present). In such cases, IRB members participating via telephone or video conference will receive a complete set of meeting materials to be reviewed at the meeting. The majority of the IRB must participate, and discussion must occur in real time. IRB members participating by telephone or videoconference are counted as part of the quorum and may vote.

4.7 Agenda
All members receive an agenda for the meeting that includes a list of protocols under review as well as the title, PI, and a brief summary of the studies that have been expedited since the last convened IRB meeting.

4.8 Minutes
All members receive copies of the minutes from each IRB meeting.

4.9 IRB Findings and Determinations
Findings and determinations must be noted in the minutes with reference to the appropriate federal regulations. Justification for these findings may be found in the IRB application or related correspondence with the investigator.

Determination of the level of risk for human subjects in the research study (no citation required). Determination of level of risk can be documented in the minutes by a single
entry if it is stated that all studies were determined to have a certain level of risk unless otherwise specifically noted.

The IRB will communicate justification for the following determinations in its correspondence to PIs:

- Waiver or alteration of informed consent [45 CFR 46.116(c) and (d)];
- Waiver of the requirement for written documentation of consent [45 CFR 46.117];
- Approval of research involving pregnant women, human fetuses and neonates [45 CFR 46.204-205];
- Approval of research involving prisoners [45 CFR 46.306];
- Approval of research involving children [45 CFR 46.404-407];
- Approval of research planned for an emergency setting [21 CFR 50.24]; and
- Special protections warranted in specific research projects for groups of subjects likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

**4.10 Resolving Disputes or Differences of Opinion**

When there is a difference of opinion among board members and/or consultants that cannot be resolved through discussion, additional expertise may be solicited. If more than two members are involved, a vote may be taken (IRB members only), and the majority will rule. If there is not a majority for any specific alternative, the IRB Chair will have the final say. If the IRB Chair is not available, the IRB Co-Chair will have the final say.
5. IRB Documentation

The IRB prepares and maintains adequate documentation of these IRB activities:

- Copies of all IRB application materials that have been reviewed by the IRB, including the initial application, funding proposals, master protocols, consent documents, and data collection and subject recruitment materials, as relevant.
- Approved consent documents, progress reports submitted by investigators, reports of injuries to subjects, and statements of significant new findings provided to human subjects.

5.1 Process for Communicating with Investigators

Investigators receive communication from the IRB in these ways:

- Letters
  - IRB findings, such as approvals, disapprovals, suspensions, exempt determinations, and determinations that a project does not involve human subjects research. Most are sent by email via the IRB Information System, IRBIS.

- Online Resources
  - IRB Standard Operating Procedures
o Forms and templates
o Principal Investigator’s Handbook
o Protocol application
o Training

- Phone
  o Inquiries on human subjects research
  o Appointments for protocol consultations

5.2 Process for Communicating with the Institutional Official

- Weekly highlights
- Directors’ meetings
- Quarterly reports
- Annual reports
6. UNIVERSITY RELATIONSHIPS

A. Vice Chancellor for Research and Economic Development
   The Vice Chancellor for Research and Economic Development, appointed by the
   Chancellor, serves as the Institutional Official (IO). The Institutional Official is
   responsible for the conducting of further review and approval or disapproval of
   research approved by the IRB.

B. University Legal Counsel
   The University Legal Counsel serves as an ex-officio member of the IRB.

C. The Graduate School
   The Graduate School requires that all theses and dissertations be cleared
   through the Office of Research Compliance and Ethics to ensure that research
   under the purview of compliance committees had been granted approval. If a
   thesis or dissertation includes data collection for human subjects research
   without IRB approval, the IRB will enforce consequences.

D. Director of Research Compliance and Ethics
   The Director of Research Compliance and Ethics is responsible for supervision of
   Compliance Officers and serves as a voting ex-officio member on research
   compliance committees. The director manages approvals for visiting researchers
   and authorization agreements with external institutions.
E. **Department Chairs**
Principal Investigators are responsible for obtaining the approval of their department chairs (or equivalent departmental authorities) on all new IRB applications. New applications are not reviewed without department chair approval. Department chairs do not have the authority to make exempt determinations or to authorize research data collection to begin without IRB approval.

F. **Institutional Animal Care and Use, Biosafety, and Radiation Safety Committees**
There are two Compliance Officers in DORED. One officer serves as the administrative support for the IRB; the other supports the Institutional Animal Care and Use, Biosafety, and Radiation Safety committees. Both Compliance Officers provide administrative support to any committee in the absence of the assigned Compliance Officer.

G. **Office of Sponsored Programs**
Proposals involving human subjects research are referred to the Office of Research Compliance and Ethics by grants administrators in Sponsored Programs. The IRB has the authority to review proposals to determine whether an IRB application is warranted. A PI cannot access research funds for a project involving human subject research until the project protocol receives IRB approval. Sponsored Programs has the authority to receive IRB communications concerning approval in order to determine the status of the IRB protocol and, consequently, the PI’s ability to access funds.

H. **Principal Investigators**
Principal investigators should contact the IRB through the Office of Research Compliance and Ethics or the IRB Chair concerning human subjects research. The IRB consults with PIs concerning protocol development and training in addition to its authority to approve, disapprove, suspend, terminate, or monitor human subjects research.

I. **Faculty Advisors for Student Researchers**
Faculty advisors are required to have a bio sketch on file with the Office of Research Compliance and Ethics and to have completed CITI training before student research being approved. In addition, the faculty advisor is responsible for guiding and reviewing the student researcher’s protocol and research. The faculty advisor has the overall responsibility for the student's project (i.e. if the
data is gathered before IRB approval, the advisor may face consequences for non-compliance as determined by the IRB).

J. Other Institutions
The IRB considers entering into agreements with outside institutions on a case-by-case basis. Researchers not affiliated with N.C. A&T are required to contact the N.C. A&T IRB through the Office of Research Compliance and Ethics to determine whether A&T IRB approval is required before solicitation of A&T faculty, staff, or students to participate in research activities. If it is determined that A&T is engaged with research conducted by a visiting researcher, an A&T faculty member must serve as a sponsor for the investigator.

K. Protocol Review and Education Program Committee
The Protocol Review and Education Program (PREP) provides principal investigators with education and quality improvement after IRB approval of their research protocols. Members are appointed by the Chancellor. The Compliance Officer will provide to the PREP committee a list of protocol numbers associated with studies approved within the fiscal year. The PREP committee will randomly choose protocol numbers for auditing. Once selected, the Compliance Officer will compile the files associated with the selected studies. If issues are found during an audit by the PREP committee, the Director of the Office of Research Compliance and Ethics will assist the IRB in determining whether further action is warranted. The PREP committee provides identifiable information only in the case of findings that are reportable to the Office for Human Research Protections. Findings that are non-reportable will be submitted to the Institutional Official and the IRB (through the Office of Research Compliance and Ethics) in aggregated format.
7. IRB FOUNDATIONS FOR REVIEW

7.1 Determining Human Subject Research

Only projects meeting both definitions – “research” and “human subjects” – come under the purview of the IRB. Researchers should contact the IRB for an appropriate determination.

Research — A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. (45 CFR 46.102(d))

- In general, studies do not need to be reviewed by the IRB if they involve data gathered solely for internal, ongoing campus use (e.g., course evaluation or institutional program development) or are part of classroom projects that will not be conducted or presented outside of the classroom. If results of these studies will be disseminated publicly in any way (e.g., conference presentation, publication), then the study is considered to constitute “research.” If no dissemination is planned at the time the data is gathered, but the possibility of future dissemination exists, the researcher is advised to submit the project for IRB review and approval before initiating the research. Approval is required only for prospective research; studies using only existing data do not require review by the IRB.
Human Subjects — A living individual about whom an investigator obtains (1) data through intervention or interaction with the individual or (2) identifiable private information. (45 CFR 46.102(f))

- Research on deceased individuals is not subject to IRB review.
- The definition of “intervention” includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment for research purposes.
- “Interaction” includes communication or personal contact between investigator and subject (e.g., telephone call, e-mail).
- “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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public.
- “Identifiable information” means the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

In cases where an IRB protocol has been submitted and is determined not to involve human subjects research, a letter reporting that determination will be issued to the investigator.

7.2 Determining Engagement of N.C. A&T in Human Subjects Research

Once it is determined that a project involves human subjects research, then a decision is made about whether N.C. A&T’s IRB must review the project and grant approval, whether an agreement will be made to rely on a collaborating institution’s IRB, or whether it is not N.C. A&T itself that is considered to be engaged in human subjects research.

The federal Office for Human Research Protections (OHRP) provides guidance that explains what activities constitute engagement and non-engagement in human subjects research. The scenarios below represent only a few examples of how a decision on engagement is made. Please refer the OHRP website to review all of the criteria: [http://www.hhs.gov/ohrp/policy/engage08.html](http://www.hhs.gov/ohrp/policy/engage08.html)

1. Collaborative research in which no human subjects will be recruited on the N.C. A&T campus
**Example:** An N.C. A&T faculty member is the lead PI and has received funding from the National Institutes of Health for a research project involving human subjects. The recruitment of participants and all study procedures will be conducted at UNC-Chapel Hill.

**Determination:** Even though the participants will not be recruited at N.C. A&T, the lead PI is covered under N.C. A&T's Federalwide Assurance. This meets the criteria for N.C. A&T being engaged in research. Therefore, the PI must submit a protocol following IRB review procedures or the University (through the Office of Research Compliance and Ethics) may choose to enter into a formal agreement with UNC-Chapel Hill, allowing their IRB to become the IRB of record for this study.

**N.C. A&T PI's Responsibilities:** Should an Authorization Agreement with an external IRB be considered, the N.C. A&T PI is responsible for providing the following items to the Director of the Office of Research Compliance and Ethics:

- External IRB Authorization Agreement Form (with FWA and IRB Registration numbers),
- Final study approval letter from the external institution's IRB, and
- A copy of the approved protocol

**In addition,** the PI must inform the N.C. A&T IRB of:

- Renewal approval notices,
- Modification approval notices,
- A report of any adverse events and/or unanticipated problems, and
- A study closure notice.

2. Researchers visiting N.C. A&T’s campus or contacting N.C. A&T students or faculty/staff

**Example:** A psychology student from Hampton University would like to recruit faculty to complete a telephone interview. The student plans to contact the faculty members in the Psychology Department using the online directory. No A&T faculty or staff will be conducting telephone interviews or obtaining consent from participants. The department chair may be asked to assist in contacting faculty members.
**Determination:** Since the N.C. A&T faculty will not be obtaining consent from the faculty contacted nor will they actually be conducting the procedures of the study (telephone interviews), the criteria for engagement are not met. Therefore, the Director of the Office of Research Compliance and Ethics will process the required documents and contact the student PI, granting permission to proceed or decline to allow access to participants on behalf of the IRB.

**Visiting PI’s Responsibilities:** The following documents must be submitted to the Director of the Office of Research Compliance and Ethics:

- IRB approval from the researcher’s home institution and
- Visiting Researcher Form

3. De-identified data about N.C. A&T faculty/staff/students given by N.C. A&T to a visiting researcher

**Example:** A researcher from the University of Alabama wants aggregated data about N.C. A&T’s student demographics. No student names or other identifying information will be included.

**Determination:** Because the data is de-identified, it technically does not involve humans. Therefore that investigator and institution are not considered to be engaged, and an authorization agreement or IRB approval is not necessary. Conversely, if the data is identifiable, the outside investigator is now engaged, therefore an authorization agreement is required for administrative approval.

### 7.3 The Three Principles Guiding IRB Review

*(from [The Belmont Report](#))*

**Respect for Persons**
- Individuals should be treated as autonomous agents.
- Persons with diminished autonomy are entitled to protection.

**Application:** Informed Consent
- Subjects, to the degree that they are capable, must be given the opportunity to choose what will or will not happen to them.
The consent process must include three elements: information, comprehension, and voluntariness.

**Beneficence**
- Human subjects should not be harmed.
- Research should maximize possible benefits and minimize possible harms.

**Application:** Assessment of Risks and Benefits
- The nature and scope of risks and benefits must be assessed in a systematic manner.

**Justice**
- The benefits and risks of research must be distributed fairly.

**Application:** Selection of Subjects
- There must be fair procedures and outcomes in the selection of research subjects.

### 7.4 Evaluation of Study Design and Quality

In reviewing research protocols, the IRB must determine that the study design justifies the risk/benefit determination and that study procedures are consistent with sound research design that minimizes the risks to subjects. While it may not be the authority of the IRB to resolve design merit issues, risk/benefit issues that arise as a result of the study design must be adequately addressed for the IRB to approve the protocol. The IRB asks these questions when reviewing study design and quality:

1. Is the design adequately described?
2. Does the design permit answering the research question(s) or achieving the research objectives?
3. Are the objectives feasible in the planned time frame?
4. Are the procedures adequately justified?

If revising the study design will meaningfully decrease the risk to subjects without a major compromise in the study results, then the IRB may require such revisions as a condition for approval.
8. TYPES OF INITIAL IRB REVIEW

8.1 Initial Administrative Review

All protocols undergo an initial administrative review. This review determines whether the protocol application has all sections appropriately completed and all necessary documents (consent forms, surveys, flyers, etc.). Should the protocol application be incorrect or incomplete, the Compliance Officer will return the application materials to the researcher along with a letter and comments for the researcher to use to correct the application. If the protocol application and all appropriate documents are correctly completed and included, the Compliance Officer has the authority to decide whether the protocol is exempt, or the officer can forward it to the full IRB for a decision.

8.2 Exempt Protocols

Exempt determinations (“exempt from further IRB oversight”) are made by the IRB or the Compliance Officer in accordance with federal regulations. Therefore, researchers cannot assume that their research meets exempt criteria and initiate research without IRB approval. All studies involving human subjects must be submitted to the IRB for review, and approval must be obtained before initiation of the study.
Studies that May Qualify for Exemption

- **Research conducted in established or commonly accepted education settings, involving normal education practices**, such as research on regular and special education instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

- **Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior**. However, such research does not qualify for exempt status if the study's information is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects, or if 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.

- **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 the immediately preceding item** if the human subjects are elected or appointed public officials or candidates for public office or if federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

- **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.

- **Research and demonstration projects** conducted by or subject to the approval of federal agency department heads and that are designed to study, evaluate, or otherwise examine public benefit or service programs, procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures or possible changes in methods or levels of payment for benefits or services under those programs.

- **Taste and food quality evaluation and consumer acceptance studies** if wholesome foods without additives are consumed or if a food is consumed that contains food ingredients at or below the level found to be safe and for a use found to be safe, or if a food is consumed that contains agricultural chemical or environmental contaminants 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.

Documentation Required for Exemption Consideration

Researchers need to provide the following (as applicable):
- Completed CITI training with affiliation to N.C. A&T;
- IRB Protocol Form;
- Consent Form(s), Assent Form, Parental Permission Form;
- Flyer(s) or other recruitment materials, including scripts;
- Survey(s);
- Interview questions;
- Bio sketch (faculty and advisors); and
- Grant application uploaded into RAMSES.

Determination of Exempt Studies

While a researcher may believe that his/her study is exempt, that determination is made by the IRB in the following manner. The Compliance Officer will review the protocol and associated materials and make a determination about exemption. If the protocol is not deemed exempt, it will be processed for expedited or full board review.

Outcome of an Exempt Determination

Researchers receive the following (as applicable):
- The IRB application with an assigned IRB identification number and
- All supporting documents (i.e. consent, survey, flyer, interview questions, etc.) with a stamp indicating the exemption date. Only stamped versions of these documents are to be distributed to research participants.

If more information is necessary for an exempt determination, the Compliance Officer will contact the principal investigator and require that the protocol application and/or supporting documents be re-submitted with more details or revisions. Re-submissions are not placed ahead of any new IRB protocol applications that may come into the Office of Research Compliance and Ethics before their arrival.

Reporting of Exempt Protocols to the IRB

The Compliance Officer reports at IRB meetings on all protocols reviewed under the exempt process.
See the PI Handbook for further guidance

8.3 Expedited Review of Protocols

Expedited review may be conducted by the IRB Chair or other IRB member designated by the Chair. Human subjects research may be eligible for expedited review if it involves no more than minimal risk, meeting the qualifications listed below, or if it constitutes only minor changes in previously approved research. In conducting expedited review, the IRB reviewers may exercise the full authority of the IRB except that they may not disapprove the research. A research activity may be disapproved only after review by the convened IRB in accordance with the non-expedited procedure set forth in 45 CFR 46.108(b).

Studies that May Qualify for Expedited Review

- Clinical studies of drugs and medical devices for which an investigational device exemption is not required or the device is cleared/approved for marketing and the medical device is being used in accordance with its approved labeling.
- Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture based upon the frequency and amount of blood as specified in federal regulations.
- Prospective collection of biological specimens for research purposes by non-invasive means (i.e. hair, nails, excreta, and so forth).
- Collection of data through non-invasive procedures routinely employed in clinical practice, including such procedures as physical sensors, testing sensory acuity, electrocardiography, and so forth, but excluding x-rays.
- Research involving materials that have been collected or will be collected solely for non-research purposes (i.e. leftover specimens that would not lead to identification of the human subject from which it was obtained).
- Collection of data from voice, video, digital or image recording made for research purposes.
- Research on group characteristics or group behavior (i.e. perception, cognition, motivation, and so forth).
- Research involving surveys, interviews, oral histories, or focus groups.
- Continuing review of research previously approved by a convened IRB if the research is permanently closed for enrollment of new subjects, all subjects have completed all research related interventions and the research is active only for long term follow-up, or no subjects have been enrolled, or remaining activities are limited to data analysis.
The continuing review of research not conducted under an investigational new drug application.

**Documentation Required for Expedited Review**

Researchers need to provide (as applicable):

- Completed CITI training with affiliation to N.C. A&T;
- IRB Protocol Form;
- Consent Form(s), Assent Form, Parental Permission Form;
- Flyer(s) or other recruitment materials, including scripts;
- Survey(s);
- Interview questions;
- Bio sketch (faculty and advisors); and
- Grant application uploaded into RAMSES (if applicable).

**For Minor Changes to an Existing Protocol Previously Approved Under Expedited Review**

Researchers need to provide (as applicable):

- Amendment Form;
- Current protocol with revisions incorporated;
- Current consent form with revisions highlighted;
- New consent form (clean copy); and
- Any other forms that the protocol changes would affect (i.e. flyer, survey).

**Determination of Expedited Review**

While a researcher may believe that his/her study is eligible to be expedited, that determination is made by the IRB. The Compliance Officer will either review the protocol and associated materials and determine the appropriate IRB member to review the protocol or refer the application to the Chair for a determination on whether the protocol can be expedited or needs a full board review.

**Outcome of an Expedited Review**

If the protocol is approved as expedited, a letter will be sent to the researcher. An approval packet will be returned to the researcher that includes:

- The IRB application with an assigned IRB identification number, and
All supporting documents (i.e. consent, survey, flyer, interview questions, etc.) with a stamp indicating the approval and expiration dates. Only stamped versions of these documents are to be distributed to research participants.

If more information is necessary, the Compliance Officer will contact the principal investigator and require that the protocol application and/or supporting documents be re-submitted with more details or revisions. Re-submissions are not placed ahead of any new IRB protocol applications that may have come into the Office of Research Compliance and Ethics.

**Reporting of Expedited Protocols to the IRB**

The Compliance Officer reports at IRB meetings on all protocols reviewed under the expedited process.

See the PI Handbook for further guidance.

### 8.4 Full Board Review of Protocols

This type of review may be conducted when an IRB member conducting the initial review deems the study to require a full board review. A full board review also may be required when there is more than minimal risk to the subjects, when the subject of the study is sensitive in nature, or when confidentially or privacy may be an issue.

**Studies that May Qualify for Full Board Review**

- Studies involving children where the topic is sensitive or involves physical interventions beyond normal physical education requirements.
- Studies involving adults where the topic is sensitive and/or the risk of a breach of confidentiality may cause psychological, physical, social, or legal harm.
- Studies involving procedures that may cause psychological or physical discomfort or harm to participants.
- Studies that may lead to stigmatization of a class of individuals.
- Clinical studies that involve drugs or medical devices.
- Studies involving bioengineered implants, food, or other products that are placed inside the subjects or are ingested by them.
- Studies involving DNA testing.
- Reviewing of medical records of HIV/AIDS patients or patients with diseases that carry a social or other stigma.
• Voice and audio recordings if there is a potential risk associated with confidentiality.

Documentation Required for Full Board Review

Researchers need to provide (as applicable):
• Completed CITI training with affiliation to N.C. A&T;
• IRB Protocol Form;
• Consent Form(s), Assent Form, Parental Permission Form;
• Flyer(s) or other recruitment materials, including scripts;
• Survey(s);
• Interview questions;
• Bio sketch (faculty and advisors); and
• Grant application uploaded into RAMSES (if applicable)

These documents constitute the materials that will be distributed to the assigned primary and secondary reviewers. They must be provided to the Office of Research Compliance and Ethics at least 14 days before the next scheduled IRB meeting. The Compliance Officer will forward the materials to the primary and secondary reviewers at least five days before the meeting. The materials will be posted in either Blackboard or IRBIS for all IRB members to view before the meeting.

Determination of Full Board Review

A protocol may be assigned a full board review by determination of:

• The assigned expedited reviewer;
• The Compliance Officer; or
• The IRB Chair.

Once a protocol is determined to need a full board review, the Compliance Officer will assign a primary reviewer and a secondary reviewer. If the determination was made by an expedited reviewer, he or she will serve as the primary reviewer. The protocol will be scheduled to be reviewed at the next board meeting. The researcher or researchers will be notified and are invited to attend. They may be asked to attend to address questions by the Board. Once the researcher or team has addressed the board’s questions, they will leave and the Board will discuss and vote on the protocol.
Outcome of a Full Board Review

- If approved, a letter will be sent to the researcher(s), and associated materials will receive an IRB identification number and an IRB approval stamp on the appropriate documents.
- If the protocol is disapproved or needs modifications to gain approval, the researcher(s) will be notified in writing. When a protocol is disapproved, the researcher(s) may appeal the decision in writing to the IRB Chair.

See the PI Handbook for further guidance on full board review of research.

Possible Findings and Actions of the IRB in a Full Board Review

IRB members’ voting options are:

1. **To approve:** The study is approved as submitted. Approval is valid for one year.
2. **To conditionally approve (minor revisions required):** The full committee does not need to review the study again when the minor revisions are made. The revisions necessary to secure approval are minor and will be communicated to the researcher(s) in a letter. This is NOT approval, and the study is NOT authorized to start until an approval letter is received. The needed revisions are reviewed by the IRB Chair or the Compliance Officer for completeness, and when the revisions are complete, an approval letter is sent to the researcher. The approval date is assigned based on the IRB meeting date when the protocol was initially reviewed by the Board and the determination was made.
3. **To defer (substantial revisions are required or more information should be provided):** The committee finds that the study is of sufficient concern in several areas and that minor revisions will NOT address those concerns. The IRB will defer further consideration of a study to a future meeting to allow the investigator to provide additional information and/or make substantive change(s). The resubmission of such studies must be reviewed by the full committee. The PI is notified via a deferral letter.
4. **To disapprove:** If the IRB determines that the research cannot be conducted at N.C. A&T or by employees or agents of the University or otherwise under the auspices of the University, the project, as proposed, is disapproved and may not go forward. Disapproval usually indicates that a protocol requires major changes not likely to be feasible without a complete reassessment by the investigator and/or sponsor. In some cases, the IRB may want to alert the Institutional Official of the disapproval.
5. **To abstain.** If an IRB member is helping to direct the study, is an investigator or co-investigator on the study, has any significant financial interest in the
outcome of the study, or has what he/she or the IRB considers to be an unacceptable conflict of interest for other reasons, the member will abstain from voting. This will be reflected in the minutes.

The IRB uses the primary and secondary reviewer model to review research projects reviewed by the convened IRB. The primary and secondary reviewer model is used for initial review for new research projects, continuing review for renewal of research projects, and review of modifications to research projects previously approved by a convened IRB. The IRB Chair is authorized to delegate the review to one primary and one secondary reviewer based upon the members’ expertise and experience.

**Primary Reviewer.** The primary reviewer (one member) presents his/her findings and provides an assessment of the soundness and safety of the protocol. He/she will make specific recommendations on clarifications required for approval and leads the IRB discussion of the study. The primary reviewer is required to conduct an in-depth review of all materials.

**Secondary Reviewer.** The secondary reviewer (one member) will add to the discussion as necessary. The secondary reviewer is required to conduct an in-depth review of all materials.

**Appeal of a Disapproved Full Board Protocol**

The researcher(s) must file any appeal to the IRB Chair in writing within seven working days of receipt of the Full Board decision.

Once the IRB Chair has received the appeal letter, he/she will contact the researcher(s) in writing with the areas of concern voiced by the board. The researcher(s) may address those concerns in a response sent to the Chair, and a new Full Board review is scheduled.

**8.5 Approval Time Frames**

Processing time for IRB approval is based on the review of completed protocol applications. Incomplete applications must be resubmitted and are reviewed in the order in which they are received back into the Office of Research Compliance and Ethics. Applications requiring minor changes or clarifications will be affected only by the amount of time the PI takes to make such changes.
Issues that could affect the time frame for approval are:

- Incomplete protocol application,
- Missing human subjects training (PI, advisor, research staff),
- No submission of advisor's bio sketch,
- No agency permission for soliciting human subjects (if applicable), and
- No agency agreement for data use (if applicable).

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<th>Initial Application Time Frames</th>
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<td>Exempt</td>
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<tr>
<td>Expedited</td>
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<td>Full Board Review</td>
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<th>Student Research</th>
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**Note:** These application time frames are not meant to indicate when researchers will receive final approval to start their projects. They are time frames for when researchers will get an initial response from the IRB. Minor corrections are requested on most protocols, and researchers should plan accordingly.

### 8.6 Renewal and Continuing Review of Protocols

Federal regulations require that all non-exempt research be reviewed at least annually. This review is conducted at specified intervals and must be as substantive as an initial review. The IRB determines the appropriate interval of review depending upon the level of risk to the subjects. However, continuing review must be conducted and approved at least once per year. All expedited and full board protocols expire at midnight one year after the original approval date. It is the Principal Investigator's responsibility to submit for renewal and obtain approval before the expiration date. The expiration date is included in the original approval letter, on all subsequent continuing review letters, and stamped on consent forms, surveys, etc.
Research activity may not continue beyond the expiration date without IRB approval. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval on the expiration date.

Renewal with **Minor Changes** in Previously Approved Research
The changes involve minimal risk to subjects and no significant alteration of the research design.

Renewal with **Major Revisions** in Previously Approved Research
The revisions increase risks to subjects, significantly affect the nature of the study, or involve a substantial change of personnel, such as the PI.

### 8.7 Documentation Required for Renewal

Researchers need to provide:
- A completed Annual/Continuing Review form,
- Copy of the current protocol,
- Copy of the current approved consent form,
- Copies of the supporting documents (i.e. flyer, survey, etc.),
- Revised protocol or consent with changes highlighted (if applicable), and
- Revised application with changes incorporated

### 8.8 Evaluation for Renewal

Initial processing for continuing reviews will begin with an administrative review to verify that required documents have been submitted and forms are complete. If the initial protocol was reviewed under the expedited procedure, then the continuing review may be expedited. However, should the protocol involve new procedures that require full board review, then the continuing review must be processed for full board review.

### 8.9 Outcome of an Approved Renewal

The researcher receives a letter approving the research for another year with all supporting documents and consent forms re-stamped. If the study was originally approved, for example, on March 2, the approval will expire the next year at midnight on March 1.
8.10 Reporting of Renewed Protocols to the IRB

The Compliance Officer reports at IRB meetings on all protocols reviewed under the continuing review process.

8.11 Studies that May Require Review More Often than Annually

The IRB may determine that a study must undergo protocol renewal procedures through continuing review within less than one year. This determination is usually based on:

- The nature, probability, or magnitude of anticipated risks to subjects;
- The likely medical or psychological condition of the proposed subjects;
- The overall qualifications of the PI and other members of the research team;
- The specific experience of the PI and other members of the research team in conducting similar research;
- The nature and frequency of adverse events observed in similar research at this and other facilities;
- The vulnerability of the population being studied (this includes unfamiliarity with the language used on consent forms and other printed matter);
- A previously suspended study;
- The PI has a past history of non-compliance;
- The study was found during an audit to have non-compliance issues; or
- Other factors the IRB deems relevant.

In specifying an approval period of less than one year, the IRB may define the period with either a time interval or a research milestone, e.g., number of subjects enrolled. The IRB minutes and/or a letter to the principal investigator should clearly reflect any determination requiring a review more frequently than annually.

See the PI Handbook for further guidance.

8.12 Renewal Reminders

The initial approval letter includes the expiration date of the protocol. When a research project is due for renewal, a written reminder is sent from the IRB to the PI approximately 60 days before the expiration date. Another reminder is sent approximately 30 days before the expiration date. If an application for renewal is not received from the PI by the expiration date, then the IRB will send an expiration notice to the PI. Copies of all reminders and expiration notices are kept in the IRB records.
It is ultimately the responsibility of the investigator to ensure that approval of the renewal has been requested, allowing adequate time before the protocol expiration date.

8.13 Lapsed Study

A lapsed study is one for which the approval period has expired before the renewal of approval by the IRB. Once a study has lapsed:

- All study-related measures must immediately cease.
- No new subjects may be enrolled.
- If the PI desires to continue a study that has lapsed for more than three months, then the PI must submit a new application for review by the IRB and must wait for IRB approval before resuming research under the protocol. If the PI submits the materials for continuing review within three months after the expiration date, the IRB may conduct continuing review and reactivate the protocol. This reactivation establishes a new approval period that is not retroactive to the prior date of expiration.
- For studies where subjects are receiving treatment or other intervention that may raise safety concerns if withdrawn, the investigator may request in writing that currently enrolled subjects continue with study activities. The IRB will consider the request in light of the medical condition of the subject (if any), the nature of the treatment or intervention, and the impact of withdrawal of the subject from the study. If the IRB finds that it is in the best interest of currently enrolled subjects to continue their involvement in the research, their participation may continue. Continuation of study activities in such circumstances should be considered by the IRB only if there is clear intent for the study to continue and an application for renewal is in progress.
9. REVISIONS TO APPROVED PROTOCOLS

Changes or modifications to previously exempted or approved protocols may not be initiated without IRB approval. To ensure that PIs are aware of this requirement, it is communicated in this document, the PI handbook, initial approval letters, during IRB presentations, and in the required CITI modules. In addition, the Protocol Review and Education Program (PREP) committee will assist in identifying revisions made without IRB approval.

9.1 Informational Changes in Previously Approved Research

Changes are considered informational only when there is no potential impact on the risk level for research participants. Informational changes may be approved by the Compliance Officer. Examples include:

- Changes in telephone numbers or contact information,
- Reduction in the number of research participants,
- Addition or deletion of research staff,
- Deletion of questions from the survey, or
- Correction of typographical errors.
9.2 Minor Changes in Previously Approved Research

Changes are considered minor only when there is no significant impact on the risk level to research participants. Minor changes to previously approved protocols may be approved by the Compliance Officer. Examples include:

- Minor increase (less than 25%) in the number of participants to be recruited,
- Minor change to the frequency or amount of blood drawn,
- Adding non-sensitive questions to the survey,
- Revising the format of the consent form,
- Changing contact information on the consent form, or
- Changing information on advertisements.

9.3 Major Changes in Previously Approved Research

Major changes to previously approved research must be approved by the IRB Chair or the Chair’s designee. Examples include:

- Major increase (more than 25%) in the number of participants to be recruited,
- Major change to the frequency or amount of blood drawn,
- Adding a standardized test or survey,
- Changing an intervention,
- Changing the recruitment plan,
- Extending the time period of the study,
- Adding a research site,
- Changing the PI,
- Revising eligibility or exclusion criteria, or
- Changing the consent to reflect new adverse event information.

9.4 Verification of Changes from Sources Other Than the PI

The IRB may determine that a source other than the PI would need to provide verification that no material changes in the protocol may have occurred. Examples of reasons why this may be necessary are:

- Random selection for not-for-cause review by the IRB or PREP committee,
- Complex projects involving unusual levels or types of risks to subjects,
- Projects conducted by PIs who previously have failed to comply with HHS regulations or the IRB, or
- Projects where concern about possible material changes occurring without IRB approval have been raised based upon information provided in continuing review reports or from other sources.
10. Study Completion, Closure, or Termination

10.1 Voluntary Closure

By submitting a protocol close-out form, the researcher confirms that the study is finished and that researchers have no further interaction with subjects or their data in ways that would require ongoing IRB approval. Once the IRB receives and accepts the notice of completion, the researcher is no longer required to submit for continuing review for renewal. If the investigator wishes to enroll new subjects for the study, or otherwise engage human subjects in research, he/she must reactivate the protocol with the IRB. Therefore, an investigator should only close a study when he/she is no longer enrolling new subjects, using research interventions on existing subjects, collecting data (including follow-up data), or performing any other tasks that were identified as part of the approved study. A study will not invariably be considered completed when it is closed to accrual, as research-related procedures may still be continuing. The IRB, in consultation with the PI, may consider closing a study when active data analysis and publication pursuant to the approved study has ceased, even if the investigator retains records that may identify individual subjects. Additional research projects using data acquired in the approved study may constitute new human subjects research studies subject to separate IRB review.
10.2 Administrative Closures

The Compliance Officer will administratively close any study for which the PI has not submitted a request to renew and approval has lapsed for more than 90 days. A study closure letter will be sent to the PI. Administrative closures also made be made if the PI has left the University and transfer of the study has not been pursued.

10.3 Adverse Events, Serious or Continuing Non-Compliance, and Unanticipated Problems

In cases of Serious Adverse Events (SAEs) or Unanticipated Problems (UPs), researcher noncompliance, or protocol violations, the IRB may decide to:

- Investigate via PI interviews, audits, and other resources;
- Suspend a study to ensure subject safety;
- Terminate a study;
- Initiate a report of research misconduct according to University policy;
- File a report with U.S. Office of Human Research Protections;
- Notify the Director of the Office of Research Compliance and Ethics;
- Deny the use of and seize data;
- Require additional education for PIs and research staff;
- Require frequent monitoring of the study; or
- Suspend access to funding (after consultation with the Institutional Official).

Whenever any of these processes are initiated, notices will be copied to the Office of Research Compliance and Ethics, Co-PI, department chairs, sponsor, and the Institutional Official. Once a study has been suspended, in whole or in part, an investigation of the problem prompting suspension of the study is initiated by the IRB and coordinated by the Compliance Officer. Upon completion of the investigation, the convened IRB may decide that a study should be terminated. Following the vote of the IRB to terminate a study and the evaluation of any appeals made by the PI, the study will be classified as inactive. Though the Chair may suspend a study, pending IRB review, only the convened IRB may vote to terminate a study. The Institutional Official is responsible for all required reporting of suspension or terminations by the IRB to the appropriate federal agencies. This reporting would generally be coordinated through the Office of Research Compliance and Ethics.
11. Categories of Principal Investigators, Co-Investigators, and Research Staff

Principal Investigator

The individual responsible for the conduct of the study. This responsibility includes the conduct of the study, all administrative aspects, and the study’s adherence to relevant policies and regulations (institutional, state and federal).

Students as Principal Investigators

A student submitting a study for IRB approval may be listed as the Principal Investigator. The student’s instructor or mentor on the project should be listed as the faculty advisor on the IRB application. Advisors are required to adhere to the “Supervision of Student-Conducted Research Involving Human Subjects” policy and are ultimately accountable for the study.

Co-Principal Investigator

Individuals who share the responsibility for the study with the Principal Investigator and who therefore require the same qualifications as the PI.
Project Coordinator/Research Assistant/Research Staff

Key personnel for a project who do not have the oversight responsibility of a Principal Investigator. Individuals do not need the qualifications of a PI to be named a Co-Investigator, but should be considered as key personnel on the project. In addition, faculty members may be listed as Co-Investigators if their role on the study is not that of PI or Co-PI.

Undergraduate Students

Undergraduate students working on a senior thesis or other class research project may list themselves as the Principal Investigator. The faculty member advising on the research should be listed as faculty advisor.
12. FREQUENTLY USED TERMINOLOGY

**Adverse event:** Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease temporally associated with the subject’s participation in the research, whether or not considered related to the subject’s participation in the research.

**Allegation of noncompliance:** An unproven assertion of noncompliance with federal regulations or University or IRB policies.

**Assent:** A child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent. [45 CFR 46.402(b)]

**Children:** Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. [45 CFR 46.402(a)] In North Carolina, the age of majority is 18 years.

**Clinical investigation (in the context of Food and Drug Administration regulations; not all clinical research is subject to FDA jurisdiction):** Any experiment that involves a test article and one or more human subjects and that is subject either to
requirements for prior submission to the Food and Drug Administration under sections 505, 507, or 520 of the Food, Drug and Cosmetic Act, or is not subject to requirements for prior submission to the FDA under these sections of the Act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions regarding nonclinical laboratory studies. [21 CFR 50.3(c)]

**Closure:** The ending of a study by anyone other than the IRB (e.g., sponsor or the PI).

**Continuing noncompliance:** A pattern of noncompliance that indicates an unwillingness to comply or a lack of knowledge that may adversely affect the rights and welfare of participants or may place participants at increased risk of harm. Examples of continuing noncompliance include: repeated instances of allowing a study to expire; repeated failure to respond to IRB inquiries or requests for documentation; repeated failure to respond to and resolve study contingencies; or repeated instances of failures to respond to IRB inquiries and contingencies.

**Covered entity:** The term that Health Insurance Portability and Accountability Act (HIPAA) regulations use to describe the businesses in the health care industry that are subject to HIPAA regulations. Specifically, covered entities are health plans, health care clearinghouses and health care providers who transmit health information in electronic form in connection with health care claims or encounter information, health care payment and remittance advice, coordination of benefits, health care claim status, enrollment or disenrollment.

**Engaged in research:** An institution becomes "engaged" in human subjects research when its employees or agents intervene or interact with living individuals for research purposes or obtain individually identifiable private information for research purposes [45 CFR 46.102(d),(f)]. For additional guidance and examples, see the Office for Human Research Protections website, [www.hhs.gov/ohrp](http://www.hhs.gov/ohrp).

**Guardian:** An individual authorized under applicable state or local law to consent on behalf of a child to general medical care. A guardian also means an individual who is authorized to consent on behalf of a child to participate in research [45 CFR 46.402(e)].

**IRB approval:** A determination by the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements [45 CFR 46.102(h)].
**Minimal risk** (for human subjects other than prisoners): 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. [45 CFR 46.102(j)]

**Minors:** Children who have not reached the age of majority (18 years of age in North Carolina).

**Noncompliance:** A failure to follow applicable federal regulations, the requirements or determinations of the IRB, or University policy.

**Office of Human Research Protections:** The Office for Human Research Protections provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services. The University is responsible for filing and updating its [Federalwide Assurance](https://www.hhs.gov) and IRB registration with OHRP annually.

**Parent:** A child’s biological or adoptive parent [45 CFR 46.402(d)].

**Permission:** The agreement of parent(s) or guardian(s) to the participation of their child or ward in research (also referred to as parental consent) [45 CFR 46.402(c)].

**Protected health information:** [HIPAA](https://www.hhs.gov) defines protected health information as individually identifiable health condition, health care and health care payment information, including demographic data, that is a potential identifier of the individual, maintained in the records of covered entities, as defined above, for treatment, payment and healthcare operations. PHI does not include individually identifiable health information in personnel records or education records covered by the [Family Educational Rights and Privacy Act](https://www.ferpa.ed.gov).

**Serious Adverse Event:** An event that is fatal or life threatening, results in significant or persistent disability, requires or prolongs hospitalization, results in a congenital anomaly or birth defect, or represents other significant hazards or potentially serious harm to research subjects or others. [See also: Adverse event]

**Serious noncompliance:** Noncompliance that adversely affects the rights and/or welfare of participants, places participants at increased risk of harm, or willfully violates policies and procedures.
**Sponsor:** An entity external to the University that provides support for a University research project pursuant to terms and conditions in an agreement between the sponsor and the University.

**Suspension:** The IRB’s temporary or permanent withdrawal of approval for some or all research activities. Suspended research remains under the jurisdiction of the IRB.

**Termination:** Permanent withdrawal of approval by the IRB for research activity. Terminated research no longer undergoes continuing review.

**Unanticipated problem:** Any incident, experience, or outcome that is unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; or (b) the characteristics of the subject population being studied; is related or possibly related to a subject’s participation in the research; and suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.