WAKE TECH INSTITUTIONAL REVIEW BOARD

Guidelines - Operational Procedures

Institutional Effectiveness and Research

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SECTION 1 INTRODUCTION

A. Purpose of Institutional Review Board

The National Research Act, passed by Congress in 1974, directs all institutions receiving federal support for research and evaluation studies, including universities, public schools, hospitals, and nonprofit organizations, to establish Institutional Review Boards (IRBs). The purpose of the IRB is to review research requests conducted by Wake Technical Community College (Wake Tech) employees or researchers from other institutions on its premises or under its sponsorship to ensure that they protect research participants, meet commonly accepted ethical standards, adequately comply with applicable regulations, and follow institutional polices. With that consideration, the IRB will approve and regulate proposed research protocols involving human subjects, including all behavioral or social research studies, which includes evaluation and educational research.

B. Research Ethics

Wake Technical Community College supports the ethical principles found in the Nuremberg Code and the Belmont Report. Below are highlights of these guidelines:

1. Basic Principles of the Nuremberg Code

- The voluntary consent of the human subjects is essential.
- The research should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
- The research should be conducted to avoid all unnecessary physical and mental suffering and injury.
- No research should be conducted where there is a priori reason to believe that death or disabling injury will occur.
- The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
- Proper preparations should be made, and adequate facilities provided to protect the research subject against even remote possibilities of injury, disability, or death.
- The research should be conducted only by scientifically qualified persons.
- During the research, the human participant should be able to end the experiment.
- During the study, the researcher in charge must be prepared to terminate the research at any stage.

2. Basic Principles of the Belmont Report

- **Respect for Persons:** This principle incorporates at least two ethical convictions. The first is that individuals should be treated as autonomous agents, and second that persons with diminished autonomy are entitled to protection. The role of the IRB seeks to ensure respect for persons by requiring an informed consent from research participants. In addition, a Data Sharing Agreement is completed, if applicable.
- **Beneficence:** The principle of beneficence incorporates the ethical treatment of persons not only by respecting their decisions and protecting them from harm, but also making efforts to secure their well-being. The role of the IRB assesses the risks and benefits of human research.

- **Justice:** The principle of justice incorporates the "fairness in distribution" in terms of the selection of participants for research. The role of the IRB is to review all applications and ensure that the inclusion and exclusion of people in the research is fair and equitable.

C. IRB Definitions

- **Adverse Events**: Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign, 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.
- **Anonymized**: Refers to information or data where identifiers (and codes that are linked to identifiers) have been removed, as well as other values that would enable individuals to be identified through inference. **U.S Department of Health and Human Services** (hhs.gov)
- **Coded**: Data that is identified to enable a researcher to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced by a letter, number, symbol or combination of the aforementioned. A key to deciphering the code is created, thereby enabling the linkage of the individual's identity to the private information/specimen.
- **Common Rule**: a "Federal Policy for the Protection of Human Subjects" that was adopted by several federal departments and agencies that specifies how research that involves human subjects is to be conducted and reviewed. Up-to-date Common Rule (new window) Plain text link: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html
- **Confidentiality Agreement**: The manner of treating private information, which has been disclosed by the individual subject of the information to a particular person or persons for a specific purpose, such that further disclosure of the information will not be allowed to occur without authorization.
- **Data Privacy**: Informational privacy especially when the information in question is stored in a database.
- **Deception:** the research subject is not fully informed of the research's nature and purpose at the time of the data collection to prevent biased behaviors or responses from the subject/respondent.
- **De-Identified:** Refers to information or data where direct identifiers such as names and addresses were removed. In common use, the term refers to data where it may still be possible to identify individuals by inference or through codes held by the investigator or a third party.
- **Educational Research**: Wake Tech defines educational research as a scientific field of study that examines education and learning processes and the human attributes, interactions, organizations, and institutions that shape educational outcomes. It is conducted by asking questions and/or identifying hypotheses to be tested, collecting data according to a formal design or protocol, and drawing generalizable conclusions based on the results (Wake Tech Survey Policy).

- **Exempt:** The Department of Health and Human Services 45 CFR 46.101(b) (new window) specifies that research activities may be exempt from IRB oversight if human subjects' involvement is limited to one of the listed scenarios, including studies involving the collection or study of existing data when those data either are publicly available or are not personally identifiable. Please note that majority of the research requests submitted to Wake Tech's IRB fall under exempt categories. IRB requires individuals to submit an IRB Intake Form and, if needed, a Data Sharing Agreement regardless of if the researcher feels the study is exempt. Wake Tech's

IRB has the final determination regarding IRB research categories. Plain text link: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.101

- **Expedited:** The Department of Health and Human Services 446.110 (new window) specifies that research activities may be eligible for expedited review if the protocol involves only minimal risk, or a previously reviewed protocol is receiving minor modifications. Expedited review is carried out by the IRB Chair. Expedited reviews have the force of full reviews, except that if the protocol is found not acceptable, it must be reviewed by the full committee, as the chair or designee alone cannot reject a proposal. Plain text link: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html
- **FERPA:** the Family Educational Rights and Privacy Act (FERPA) (new window) is a federal law that protects the privacy of student education records. Plain text link: https://studentprivacy.ed.gov/ferpa
- **Generalizable knowledge:** Knowledge expressed in theories, principles, and statements of Knowledge: relationships that can be widely applied to other experiences. Typically statements about a population are made based on a sample. The term is often used when disseminating research results beyond an individual or internal group.
- **Human subject:** a living person. A researcher typically obtains the following information regarding human subjects: (a) data through an intervention or interaction with the participant and/or (b) identifiable participant information. According to 45 CFR 46102(d) (new window), examples of participant data collection include but are not limited to: (a) questionnaires/surveys, (b) interviews and (c) behavioral and/or classroom observations. **If your research involves human subjects or identifiable data on human participants, you must gain IRB approval to conduct your research.** Plain text link: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.102
- **Informed consent:** An ongoing process of communication between the participant and the study team. Informed consent is a continuing process through which a participant, after having been informed, voluntarily confirms their willingness to participate in a research project and can demonstrate understanding of all aspects of the research project that are relevant to the participant's decision to participate.
- **IRB:** an institutional review board established to review, approve, disapprove, or require modifications to submitted research proposals that involve human subjects. Institutions that receive federal funding for research must have their research approved by an IRB.
- **IRB approval**: the determination of 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.
- **Office for Human Research Protection (OHRP):** The office under the Department of Health and Human Services (HHS) is responsible for implementing HHS regulations (45 CFR 46) governing biomedical and behavioral or social science research involving human subjects.
- **Personal Identifiable Information (PII):** Any representation of information that permits the identify of an individual to whom the information **applies to be reasonably inferred.** Some information gathered by researchers contains data that can be used to confirm an individual's identity. Additional information on 18 personal identifiers of human subjects (new window) which are considered protected health information. Plain text link: https://privacyruleandresearch.nih.gov/pr_08.asp

- **Principal Investigator (PI):** Primary individual responsible for the preparation, conduct and administration of a: (a) research grant, (b) cooperative agreement, (c) training or public service project, (d) contract or (e) other sponsored project. The PI adheres to federal regulations, state and local laws, institutional policies, IRB policies, and procedures regarding the safety and protection of human subjects, and good clinical practice (GCP) guidelines. The principal investigator ensures adherence by:
    - Supervising the research process.
    - Taking responsibility for ensuring that key study personnel are properly trained and qualified and have appropriate facilities and resources to conduct the research.
    - Ensuring adherence to the study protocol.
    - Monitoring the informed consent process.
    - Communicating regularly and effectively with the research staff.
    - Taking responsibility for protecting the safety and welfare of research subjects.
- **Research:** a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.
- **Unanticipated Problem**: 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; and (b) the characteristics of the subject population being studied; related or possibly related to 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) than was previously known or recognized. (hhs.gov)
- **Wake Tech Sponsor:** A Wake Tech employee who manages the interactions between an external researcher and the college, to balance the college's support of research that serves its mission with the potential resource requirements for such support. (see Section 2, A)

D. Authority of the IRB

Wake Technical Community College holds a Federal Wide Assurance (FWA 0005155) through the Office for Human Research Protections (OHRP). As part of this assurance, Wake Tech agrees to consider research involving the use of humans as research as being subject to federal regulation as it falls under the Wake Tech Research Policy.
The IRB has the authority to:

- determine the human subject research protocols that may be conducted at Wake Tech.
- approve, deny, modify, suspend or terminate studies based on the consideration of any issue it deems relevant to human subject protection.
- deny research request that does not involve Wake Tech students, faculty and/or staff and/or does not fulfill the mission and vision of Wake Tech.
- require progress reports from the investigators and oversee the conduct of the study.
- access and make copies of records related to any research approved by the IRB (or another institution under an IRB Authorization Agreement), regardless of location of those reviews, for

any reason. Using the least disruptive method, a notice will be given pertaining to the need to review, copy, or duplicate records outside routine recording keeping.
- provide continuous advice and counsel to personnel engaged in research activities that involve human subjects.

SECTION 2 Guidelines for Researchers

A. Researchers Responsibilities

Individuals conducting research as students of external institutions or as employees of external research centers are responsible for the quality of their own research. They are responsible for the design, methodology, and writing of their own research, either solely or with the advice of their professors or fellow researchers. Wake Tech's IRB process does not require the college's internal sponsor to evaluate a researcher's design, methodology, or writing. It does not require the sponsor to make judgements about the quality of the research.

Wake Tech employees acting on behalf of the college conducting research that would have limited scope within the college and with limited distribution are responsible to their supervisors and departments.

Wake Tech employees acting on behalf of the college conducting research to be disseminated broadly within the college and beyond the college must consult with the chair of the IRB Committee.

1. General Investigator Responsibilities

a. Principal Investigators

The role/responsibilities of the PI are as follows:

- Primary communicator with the IRB; especially, when there is more than one researcher.
- Completes the appropriate IRB form located on the Wake Tech IER-IRB webpage while ensuring all materials are accurate and complete.
- Communicates all IRB matters to other researchers and oversees that all research conducted is according to the IRB protocols, guidelines and Wake Tech research policies such as Data Sharing Agreements, Research Policy E0104 and Survey Policy E1500
- Reporting any changes and/or adverse events to the IRB. In addition, cooperating in continuous IRB reviews.
- See **Section 1, C** for detailed information.
- Collaborates with Wake Tech Sponsor to track the start and end times for approved IRB Exemptions for timely renewals, if applicable.

2. Role of Internal Sponsor

The *internal sponsor's* role is to manage the interactions between the researcher and the college, to balance the college's support of research that serves its mission with the potential resource requirements for such support. For example:

- If a researcher requests directory information on a group of our students, the sponsor can direct them to the Registrar's Office for its review (including FERPA review) and consideration.

- If a researcher interested in career and technical education has identified a cohort that includes only college transfer students, the sponsor can explain the mismatch.
- If a researcher asks for 15 minutes at the beginning of 30 seated classes, the sponsor can suggest that the researcher find a less intrusive approach and suggest such an approach.
- If a researcher suggests actions that would commit an unreasonable level of college time, resources, or finances, the sponsor can make clear that the requested resources are not available.
- Supports the PI with tracking the start and end times for approved IRB Exemptions for timely renewals
- Reviews Wake Tech Research Policy
- Reviews Wake Tech Survey Policy, if applicable.

3. Criteria for Submitting an Internal Reports and/or Data Eagle Assist Ticket:

External Researcher:
If the researcher is outside of Wake Tech, it is their responsibility to request that the Wake Tech sponsor submit an Internal Reports and Data Eagle Assist Ticket located in the Wake Tech Portal on behalf of the PI.

Internal Researcher:
When completing the ticket, the Internal Researcher and/or Wake Tech Sponsor will provide the following information:

- the name of the researcher
- an alternative contact info for the researcher
- adequate details pertaining to the data request
- a date that the data is needed by (requested dates are not guaranteed either internally or externally)

Attachments are strongly encouraged that highlight the following information:

- data dictionary discussing the exact data fields they are requesting
- specify their intended scope (population of interest and timeframe for data)
- identify required format
- template for requested data, such as an Excel spreadsheet with pre-filled headings

4. Recruitment and Screening:

The researcher is responsible for including any documents and procedures used in recruiting and identifying participants with the application and these documents will be reviewed by the IRB before conducting any research. Participant recruitment materials such as social media posts, email messages, advertisements, posters, etc. are considered part of the informed consent process when they provide information about the study to potential participants. The IRB will review such materials to ensure that the appeal is not coercive, and that the information provided is consistent with additional information described in the IRB application.

5. Grant Applications

The IRB application will be submitted within 30 days of grant submission. According to federal regulations, (45CFR 46.118), no human subjects may be involved in any project supported by agency grants until the project has been reviewed and approved by the IRB. In cases when an external agency requires research that will need an IRB approval at the time of the grant application deadline, the PI can request a high priority review on the IRB Intake Form Protocol Form. If the IRB has the capacity to conduct a high priority review, it will proceed.

B. Covered and Excluded Research Activities

1. Covered Types of Research

The IRB will review and consider approving human subjects research that is exempt and involves any Wake Tech employee, student, or agent who is engaged, either in their college's responsibilities or when using the college's name, symbols, property, or services in connection with the research. Engagement involves researcher's interactions with study participants or their data or biospecimens. Examples of activities include recruitment, obtaining informed consent, collecting data, and analyzing data. Prior approval is required for any research involving information from or about human participants, including external researchers. According to Federal Policy for the Protection of Human Subjects, research in this context is defined as systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

It should be noted that Wake Tech is not a research institution and most of the research conducted on Wake Tech subjects falls into the category of Educational Research and is therefore exempt from IRB Review per 45 CFR 46.101(b).

2. Research Conducted by Wake Tech Faculty and Staff

Covered Research

All Wake Tech faculty and staff who conduct educational research or research involving human subjects designed to contribute to generalizable knowledge must seek either exemption or approval by the Wake Tech IRB, even if the research does not receive funding from external sources.

Excluded Research

1. Assessment/Evaluation of Student Learning at Wake Tech: Faculty who are collecting information as part of their work in assessing student learning and performance for improvement of their courses, and who do not plan to use the data in educational research to make generalizable inferences that will be shared with others, are excluded from needing to gain exemption or approval from the Wake Tech IRB, including for the following activities:

- student evaluations of course instruction
- faculty-driven classroom surveys meant to assess teaching and learning
- simple feedback surveys conducted immediately following an event or point of service
- polling of faculty or staff in individual departments or divisions

- faculty and staff organizations surveying their membership.

2. **Research External to Wake Tech:** Faculty or staff who wish to conduct research independent of their roles and responsibilities at Wake Tech are not required to gain IRB approval or exemption if the:
   - researcher is their own private contractor.
   - research is conducted in their own time.
   - researcher is not reimbursed by any college accounts.
   - research is conducted without the use of college's students, personnel, space, materials, supplies or data.

3. Research by Investigators from Other Institutions

Investigators at other institutions who wish to collect research data at Wake Tech are directed to fill-out an IRB Intake Form on the Wake Tech IRB website to determine if the research will be exempt or subject to review by the Wake Tech IRB.

4. Excluded Types of Research

The federal definition 46.102 of research excludes the following types of research:

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

- Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during an event or crisis that threatens public health (including natural or man-made disasters).

- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

- Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

In addition, most of the research classified as Educational Research is exempt from IRB approval under 45 CFR 46.101(b). However, researchers must submit Wake Tech's IRB Intake Form and receive a confirmation letter affirming the exemption before research can be conducted on human subjects associated with the college.

6. Secondary Research (NIH, Office of Intramural Research)

Secondary research is the use of existing biospecimens and/or data for a purpose other than the original purpose(s) for which they were initially collected through interaction/intervention with living individuals, including those collected through clinical trials.

Secondary Research requiring IRB Approval:

- includes research with identifiable specimens and/or data or with coded specimens and/or data for which the investigator has a code key.
- identifiable specimens and/or data are used to conduct new research analyses (not explicitly described in current IRB approved protocol), the PI is required to write and submit a new IRB Intake Form
- an investigator conducts secondary research with coded/linked biospecimen or data and generates subject level results that are linked back to the research subjects.
- Collaborations with external researchers in which the investigators share coded/linked biospecimen or data for secondary research and receive coded/linked results that link back to subjects.

Secondary Research NOT requiring IRB Approval:

- the biospecimens and/or data are fully de-identified/anonymized by removing all identifiers and re-coding/disposing of code key and no one collaborating will have any way to re identify the materials.
- Investigator shares coded/linked biospecimens and/or data with a collaborator for secondary research and will only receive summary level results.

5. Research Activities Exempt from Committee Review

Research activities involving human subjects in the following categories may be exempt from review by Wake Tech's Institutional Review Board. In this case, the IRB Chair will review the IRB Intake Form for approval and consult the IRB members, if needed. The principal investigator is authorized to make the first determination based of eligibility for exemption; however, the College bears the responsibility for concurring in that determination based on notice provided by the principal investigator to the Institutional Review Board.

The following exemptions do NOT apply when:
a) deception of subjects may be an element of the research
b) subjects are under the age of eighteen.
c) the activity may expose the subject to discomfort or harassment beyond levels encountered in daily life; or
d) fetuses, pregnant women, human in vitro fertilization, children, or individuals involuntarily confined or detained in penal institutions are subjects of the activity.

In accordance with 45 CFR 46.101 (b), the following categories of human subject's research is normally exempt from IRB approval:

(1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact

students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met: (a) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (b) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (c) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §.111(a)(7).

(3) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met: (a) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; and an IRB conducts a limited IRB review to make the determination required by §.111(a)(7). (b) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (c) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else. (d) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: ***(a)*** The identifiable private information or identifiable biospecimens are publicly available; ***(b)*** Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; ***(c)*** The research involves only information collection and analysis involving the investigator's use of

identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" ; or ***(d)*** The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearched activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002 if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974 and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995.

(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including 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. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(a) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing research involving human subjects.

(6) Taste and food quality evaluation and consumer acceptance studies: ***(a)*** If wholesome foods without additives are consumed, or ***(b)*** 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.

(7) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §.111(a)

(8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met: ***(a)*** Broad consent for the storage, maintenance, and secondary

research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §__.116(a)(1) through (4), (a)(6), and (d);

(b) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §__.117; *(c)* An IRB conducts a limited IRB review and makes the determination required by §__.111 (a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and *(d)* The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

Quick Reference Chart: Student Project vs Human Subject Research

At times, faculty may include research projects in courses and are unsure if IRB approval is needed. The chart below can help faculty determine if IRB approval is needed. If faculty are unsure, please contact the IRB Chair.

Student Project (no IRB approval needed)	Human Subject Research (IRB approval required)
✓ Results will not be generalizable outside of the context of the class project or assignment; the knowledge gained will not have an impact on a larger scale; small samples sized; very specific information applies to a specific program or activity at Wake Tech and cannot be applied at other academic institutions	✓ Intent is to use commonly accepted scientific methods to systematically collect data and information that will result in conclusions that have general applicability; there is a specific hypothesis or a question the researcher is trying to address; the impact of the research goes beyond the participants
✓ Required for a grade; project will not go beyond the scope of assignment and/or course	✓ Not required for a grade; going beyond the scope of the assignment; student and /or instructor plans/intends to analyze the results and contribute to the scientific literature in the field.
✓ Objective is to provide the student with experience in applying research methods	✓ Objective is to contribute to generalizable knowledge

SECTION 3 IRB Application Forms and Procedures

A. General Applications Guidelines

1. Applications Forms

Before beginning any research that involves human subjects, the research must be approved by the IRB. The Principal Investigator is required to thoroughly review and complete the IRB Intake Form or Extension/Modification form and include all required attachments. In the event of student research, a

supervising faculty member must approve the completed application, including attachments before submission to the IRB. These forms can be found on IER-IRB website.

a. IRB Intake Form: (online form)

- Used when a study meets the criteria for this level of review. (Section 2, B,5)
- A PDF of the IRB Intake Form is available within the online form for preview/preparation purposes.
- If the PI answers 'Yes" to the Data Sharing question, a draft of the Data Sharing Agreement must be attached to the form in Word Document format.
- If the research has been approved by an outside institution's IRB, the approval letter must be attached to the form. (**Attachment 1**)
- The PI is required to include a Summary of Abstract Guidelines (**Attachment 2**) and Research Design Description (**Attachment 3**).
- An individual member of the IRB reviews the research proposal to determine exemption.
- Allow 4-6 weeks for approval.

b. Extension/Modification Form: (online form)

- Studies can only be approved for one year at a time and renewed up to three years from the original project start date.
- After the third year, the IRB Intake Form will need to be resubmitted as a new protocol for review and approval.
- Required to be submitted 30 days before the project end date to ensure there is no lapse in IRB approval.
- Allow 3-4 weeks depending on whether full board approval is determined.

c. Data Sharing Agreement: (Word Document)

- Available on the IER-IRB website
- Required if the PI answers 'Yes' to the Data Sharing question on the IRB Intake Form
- If the PI answers, 'No' there may be a determination by the IRB that a DSA is required.
- Download in Word Document format and complete a draft.
- Attach the draft with a list of signees including their titles, and email addresses (Section VII, VIII)
- The draft will undergo a review by the IRB Chair and/or select IRB reviewers.
- Once the draft is finalized, the IRB Chair will procure signatures through DocuSign.
- Allow on average 2 weeks for review.

Note: These timeframes are for planning purposes only. Some protocols may be completed sooner or take longer depending on the details.

d. Informed Consent Form

The Principal Investigator is asked to include their Informed Consent Form as part of their Summary of Abstract Guidelines (**Attachment 2**) when completing the IRB Intake Form. Under the HHS regulations 45 CFR46, it is required that the principal investigator obtain Informed Consent Forms from the subjects of research **unless**:

- The research is exempt under Federal Policy for the Protection of Humans Subjects (Section 2, B,4)
- The IRB finds and documents that the informed consent form can be waived 45 CFR 46.116 (c) or (d)
- The IRB finds and documents that the research meets the requirements of the HHS Secretarial waiver under 45 CFR 46.101 that permits a waiver of the general requirements for obtaining consent in a limited class of research in emergency settings.

It is Wake Tech's preference, for the PI to include the Informed Consent Form with Attachment 2.

2. IRB Application Attachments

a. Attachment 1- IRB Approval Letter from an outside institution, if applicable.

b. Attachment 2- Summary Abstract Guidelines

The following information below outlines the **Summary Abstract Guidelines** which are outlined in the IRB Intake Form:

1. Who is your Wake Tech Sponsor?
The research project is required to identify an internal Wake Tech sponsor.
This person can assist with any logistics and provide the college with a first line of review. S/he can also protect researchers from issues/policy matters of which they may not be aware.

2. Briefly describe the participants in the research project (researchers and subjects).

3. Briefly describe the location(s) where the research will take place.

4. Provide documentation that Wake Tech research subjects can review a disclosure statement and have the opportunity to opt out of the study.

5. Briefly describe the procedures to be used for data collection, privacy, and security.
Include: a) how the research project will assure that only the investigators identified above, or other approved researchers, will conduct the research and have access to the raw data;
b) how the research process will protect participant confidentiality through one or more appropriate strategies, including but not limited to:

- rather than using participant names, the research will use assigned codes;
- participant data will be aggregated, and no specific data or quotes will be attributed to a specific individual;
- participants will be advised of the risk of sharing information in group settings and asked to protect the confidentiality of others.

c) How files (paper or electronic) will be stored in a secure place and will be made available to others only if they demonstrate to Wake Tech compliance with these conditions; and d) how electronic and/or paper copies of the student surveys/interviews/responses/related will be maintained for a period only as long as necessary for this research project, unless the researcher provides assurances to the college that subsequent research is related to this project and will follow these same conditions.

c. Attachment 3 -Research Design

The PI will be responsible for attaching a Research Design document to the IRB Intake Form.
The Research Design needs to include: (if applicable)

- survey questionnaires
- tests
- Interview protocols/ questions.
- observations forms or protocols
- instructions to be given to participants for behavioral interventions, etc.

These are considered part of the application and undergo a review by the IRB before the research can begin. PI's may be asked for additional documents for review.

d. Data Sharing Agreement (DSA)

In the IRB Intake Form, the first question asks if data will be shared for this research project. If the answer is 'Yes', the next step is to attach a draft of the Data Sharing Agreement. Investigators can download a copy (Word Document) of the Data Sharing Agreement on the Wake Tech IER/IRB webpage.

Things to consider:

- Attachment is a DRAFT and will undergo review and possible revisions; do not procure signatures on the draft.
- Please provide specific details for Section IV DATA PARAMETERS especially for C (Storage of Data) and D (Transmission of Data). ***Ex. The evaluation team (teams name) will provide data via Google documents on (institution) secure Google Education Workspace Drive that is approved up to Highly Sensitive or Red Data.***
- Once the DSA is approved, the IRB Chair will procure signatures through DocuSign.
- Please allow on average 2 weeks for review

Once the IRB application including all attachments is approved and signatures are procured, an Approval Letter Packet will be sent to the PI. The Approval Letter Packet consists of the Approval Letter signed by the IRB Chair, IRB application, all attachments, and the signed DSA, if applicable. All documentation for the IRB will be housed on the Wake Tech IRB Teams Site through the secure Wake Tech Portal.

4. Changes to IRB

If there are any changes made in a study after initial approval, they must be submitted for approval to the IRB Chair before they are applied to the study. Minor changes such as changing a question can be submitted for approval as a written description. Major changes will require a revised application that

includes attachments. Upon approval, the researcher will be notified. Please reach out to the IRB Chair, if there are additional questions

5. Expedited Review Criteria and Categories

If the research does not qualify under the Exemption Research Activities in Section 2, B, it is eligible for Expedited Review. Wake Tech IRB's determination of eligibility takes into consideration the availability of resources, capacity and evaluation of benefits to Wake Tech as an institution. The Principal Investigator should send this request by email (attached letter) to the IRB Chair for determination. The IRB Chair and/or designated IRB member will determine if the specific circumstance of the proposed research is eligible for expeditated review. If determined to be greater than minimal risk, the proposal will be referred to a Full Board Review.

The research is eligible for Expedited review if it:

- presents no more than minimal risk to human participants.
- involves research listed in one or more of the seven categories listed below

Categories: (hhs.gov)

1. Clinical Studies: drugs and medical devices only when at least one of the following conditions is met:

- Research on drugs for which an investigational new drug application (21 CFRPart 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for Expedited Review); or
- Research on medical devices for which **(i)** an investigational device exemption application (21 CFR 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of Blood: samples by finger stick, ear stick, or venipuncture as follows:

- Healthy, nonpregnant adults who weigh at least 110 pounds, when the amounts drawn meet certain criteria; ***or***
- Other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected.

3. Noninvasive Collection of Biospecimens

- hair and nail clippings
- extracted teeth.
- excreta
- saliva
- dental plaque

4. Noninvasive Collection of Data

- Routinely employed in clinical practices, excluding procedures involving x-rays or microwaves
- If medical devices are employed, they must be cleared/approved for marketing.

- Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review.

5. Secondary Use of Data
   - Documents, records, or specimens that have been collected or will be collected solely for non-research purposes, such as medical treatment or diagnosis.

6. Data Recording Collection
   - Voice, video, digital, or image recordings made for research purposes.

- 7. Characteristics and/or Behavior Research (individual or group)
  - Research on perception, cognition, motivation, identity, language, communication, cultural beliefs, and/or social behavior.
  - Generalizable research employing survey, interview, focus group, program evaluation, human factors evaluation or quality assurance methodologies.

6. Full Board Review

This type of review does not require an additional application form. The Expedited Review will determine if the research requires a Full Board Review based on one of the following:

- Research shows greater than minimal risk to subjects.
- Research does not qualify under the Exemption Activities (Section 2, C,5)

The Principal Investigator (PI) will be notified by the IRB Chair if the research proposal requires a Full Board Review.
The below steps will be followed:

- The IRB Chair will schedule a meeting with the IRB members.
- The PI may be invited to answer any questions during a portion of the meeting but is not permitted to be present during the IRB's deliberations and/or vote.
- The IRB Chair will present the research proposal's summary, including an overview and identification of major concerns.
- The IRB Chair will call for a motion to either approve, provisionally approve, or disapprove.
- IRB members must be in attendance to vote, and the vote must represent the majority of the members present.

A Notification Letter will be sent to the PI detailing the IRB's decision following the Full Board Review.

- Approved: a notification letter will be attached to the approved application form with the termination date of current approval.
- Approved Provisionally: PI must submit the required changes to the IRB Chair before research may commence.
- Disapproved: letter will outline the IRB's rationale for disapproval and give the PI an opportunity to respond.
- All letters will be kept on file in the IER Division. (digital)

Please note that Wake Tech is not a research institution; therefore, does not typically have the capacity to review/approve non-exempt research request.

SECTION 4 IRB Meetings, Members and Review Procedures

The IRB reviews and approves research in accordance with federal regulations and institutional policies. The Common Rule at 45 CFR 46, subpart A requires that an IRB reviews and approves certain human subject research. It is not a requirement for institutions to have their own IRB and may rely on other IRBs for review of some, or even all their researcher's studies (OHRP)

Registration of Wake Tech IRB

The Wake Tech IRB is officially registered with the U.S Department of Health and Human Services office for Human Research (OHRP). The OHRB Chair is responsible for updating and renewing the IRB registration through the OHRP website (IORG0005155) Updates are required every three years and/or when changes occur with IRB membership or contact information.

IRB Members

The Wake Tech Chief Academic Officer appoints the IRB Chair, who then appoints IRB Members.
For the IRB to follow federal regulations (45 CFR 46.107), the IRB Chair will ensure that the following are met:

- At least five members will make up the IRB including one unaffiliated member and one alternate.
- Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
- Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
- Members have varying diverse backgrounds and discipline expertise.

The IRB Members will receive comprehensive reference materials including educational information from the Office for Human Research Protections and this Guideline-Operational Procedures Document to support them through the review process.
At the minimum, IRB members will complete training available through the U.S Department of Health and Human Services:

- Training Checklist for IRB Members
- Human Research Protection Training (printable completion certificates)
- OHRP Webinars on 45 CFR 46

The Wake Tech IRB consists of 9 members in the following expertise:

Executive Director, Institutional Effectiveness and Research

- Ed.D, Adult and Community College Education, North Carolina State University
- MA, Geology, Rice University
- BS, Geoscience, Pennsylvania State University
- AS, State University of New York-Middletown

Executive Vice President and Chief Academic Officer

- Ed.D, Higher Education Administration, North Carolina State University
- MA, East Carolina University
- BS, Public Health, East Carolina University
- Chair, Chief Academic Officers Committee, Cooperating Raleigh Colleges
- Advisory Council Member, North Carolina Community College System Office

Vice President of Enrollment and Student Services

- MA, Higher Education Administration, University of Alabama
- BA, Communications, University of Alabama
- AA, Liberal Arts, Bevill State Community College, Alabama
- North Carolina Student Development Administrators Association, Executive Board Member

Vice President of Information Technology Services

- Ed. D, Educational Leadership, Community College and Higher Education, Western Carolina University
- MS Technology, Industry Training, Western Carolina University
- BS, Industrial Technology, Safety Northern Illinois University
- Certificate, College of Government Chief Information Officer (CGCIO) University of North Carolina.

Vice President of Workforce Development

- MBA- Southern Illinois University at Carbondale
- BA Radio-Television, Southern Illinois University at Carbondale
- North Carolina Community College Adult Educators Association
- NCCC Leadership Program
- National Council for Continuing Education and Training (NCCET) Leadership Program
- Pathways Leadership Initiative –Makle Mentoring
- NCCC Economic and Workforce Development Leadership Committee
- Wake County Economic Development –Board Member

Senior Director of Assessment, Research and Evaluation

- PhD, Social Policy and Sociology, Brandeis University
- MA, Social Policy, Brandeis University
- MA, Sociology, UNC Greensboro
- BA, Sociology, UNC Chapel Hill

Director of Data Analytics and Chief Data Officer

- MBA, Technology Management
- BA, International Relations and History
- NCCCS Data Governance Committee Member
- EDUCAUSE Program Committee Member

Senior Dean, Curriculum Registrar

- MA, Public History, North Carolina State University
- BA, History, North Carolina State University

Dean, Workforce Continuing Education Registrar

- Ed.D, North Carolina State University
- Dissertation: Perceptions of Effective Teaching Practices in Early College High Schools; A Juxtaposition of the Perceptions of Students and Their College Instructors
- MA, School Administration/Principal Licensure, North Carolina State University
- BA, Psychology, Meredith College Elementary Education Minor/Teacher Certification
- Superintendent Licensure
- Education Specialist II
- Kappa Delta Pi National Honor Society member

IRB Meetings, Communication Channel

The Wake Tech IRB is set up through Microsoft Teams on the Wake Tech Portal. The IRB Teams Site stores all documentation such as IRB reviews, resources, forms, educational and training information and the IRB Guidelines and Operational Procedures document. The Teams Site is also used for communication and meetings for all submitted IRB applications. IRB applications are initially completed through an online software application and are then downloaded as a PDF and stored in folders on the secure Wake Tech IRB Teams Site. At the discretion of the IRB Chair, a virtual meeting will be called to order for specific IRB reviews such as an Expeditated and/or Full Review. (Section 2, D, 1, 2).

Reporting Requirements to Office of Human Research Protection, OHRP

Wake Tech is not a research institution; therefore, has the capacity to only review research request which fall under an Exemption activity. As an OHRP requirement, IRB guidelines will include a procedure for reporting requirements that fall under **nonexempt** research.

The U.S. Department of Health and Human Services' (HHS) Federal Policy for the Protection of Human Subjects (the Common Rule), which is codified for HHS at 45 CFR part 46, subpart A, [1] requires that organizations engaged in or reviewing **nonexempt** HHS-conducted or -supported human subjects research establish and follow written procedures for ensuring prompt reporting to OHRP of the following:

1. any unanticipated problems involving risks to subjects or others;
2. any serious or continuing noncompliance with 45 CFR part 46 or the requirements or determinations of the institutional review board (IRB); and
3. any suspension or termination of IRB approval (pre-2018 Requirements at 45 CFR 46.103(b)(5) and 45 CFR 46.113, and the 2018 Requirements at 45 CFR 46.108(a)(4) and 45 CFR 46.113).

Please reach out to the IRB Chair in a timely manner, if you have a concern or question about reporting requirements for reviewing **nonexempt** HHS-conducted or -supported human subjects.

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