WINSTON-SALEM STATE UNIVERSITY

INSTITUTIONAL REVIEW BOARD

MANUAL
FOR RESEARCH INVOLVING HUMAN SUBJECTS

INTRODUCTION

I. POLICIES AND RESPONSIBILITIES

A. Federal Legislation

By Federal legislation signed into law on July 12, 1974, all behavioral or biomedical research involving human subjects conducted at or sponsored by an agency of the Federal government must be approved by an Institutional Review Board (IRB). The regulations governing Institutional Review Boards are contained in the Code of Federal Regulations; 45 CFR 46, Revised June 18, 1991.

https://www.hhs.gov/ohrp/
https://grants.nih.gov/policy/humansubjects.htm

B. WSSU Policy

It is the policy of Winston-Salem State University (WSSU) that all research conducted by faculty, staff or students of Winston-Salem State University, which involves human subjects, be reviewed and approved or declared exempt by the Institutional Review Board (IRB). This Board, appointed by the chancellor, is charged with protecting the rights and welfare of and minimizing risks to human subjects who are involved in biomedical or behavioral research. **Research** is defined by applicable Federal regulations (45 CFR 46.102(d), revised June 18, 1991) as a "systematic investigation, including research development, testing and evaluation, designed to develop or contribute to general knowledge." **A human subject** is defined as "a living individual about whom an investigator…conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information" (45 CFR 46.102(f)); and **minimal risk** means "that the probability and magnitude of harm or discomfort anticipated in research are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests" (45 CFR 46.102(i)).

C. Class Projects

Class projects involving human subjects done solely for educational purposes and not for research purposes need not be reviewed by the IRB. However, it is recommended that these projects be reviewed by departmental or college/school human subjects committees. If there are questions, the IRB is available for consultation. If class projects involve data collection beyond the scope of usual educational purposes and are off-campus, then all IRB procedures must be followed. (For example, a usual educational purpose would be collecting blood pressure data on patients in a clinic and then discussing the data in a class session; or collecting observations of students in an elementary school and then using it for class discussion.) If data are to be published by the student or the faculty member, then all IRB procedures must be followed.

D. Faculty Using Students as Subjects in Research Projects

Student Non-coercion Statement

This notice is to be attached to the human subjects consent form for any research project where a faculty member is using their students as subjects.

Students:

Please be informed that you do not have to consent to be in a research project. You may also initially consent and then decide to withdraw. The faculty member will not use your refusal to participate in any way to affect your grade or the way you are treated in your courses, the department, or the university.

Furthermore, research data should not be collected during class time except when those data would have been collected as part of the regular teaching and assessment of your learning. If data is collected on all students as part of the regular class, then you have the right to refuse to have your data included in subsequent research from those data.

Should you feel that you have been coerced or forced into participating in this research or that data being collected during class time is solely for the purpose of research, please contact the Institutional Review Board through the Compliance Officer at (336) 750-2982.

E. Cooperative/Collaborative Research Projects 45 CFR PART 46.114

Cooperative research projects are those projects covered by this policy, which involve researchers from more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. For Federal grants, upon the approval of the Department or Agency head, an institution may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort. Institutions should bear in mind several considerations when contemplating the use of another institution's IRB to review its protocols. Specifically, local laws, institutional policies, and constraints, professional and community standards, and population differences are all relevant factors to IRB deliberations. Review by an institution in another geographical, cultural, or professional setting may not take into account pertinent local factors defined by the research setting.

F. Institutional Review Board's Responsibility

1. Review and approve, require modifications, or disapprove all covered research.

2. Require that informed consent is in accordance with regulations.

3. Require documentation of informed consent or may waive documentation in accordance with regulations.

4. Notify investigators in writing of decisions.

5. Conduct continuing review of approved research no less than once per year.

G. Researcher's Responsibility NEW *PROCESS FOR IRB SUBMISSION*

The Office of Sponsored Programs will only accept IRB submissions through the CAYUSE Human Ethics, the on-line system.

The researcher must complete Winston-Salem State University Institutional Review Board Application for Approval of Research Involving Human Subjects through the CAYUSE Human Ethics.

Department Chairperson's (or his/her designee) approval is no longer required for routing the IRB applications IF the Principal Investigator holds the rank of a faculty. However, if the PI is a student, Department and College/School must approve a proposal CAYUSE Human Ethics before it is forwarded to the IRB for exemption or approval.

The Winston-Salem State University Informed Consent Form template and the items on the Informed Consent Checklist, must be attached in the electronic portal CAYUSE Human Ethics for IRB review. The Informed Consent form should have a statement directing research subjects to contact the IRB at (336) 750-2982) if they have any questions, comments, complaints or concerns regarding their rights as a research subject.

The researcher must submit the required items through CAYUSE Human Ethics at least 14 days prior to a scheduled IRB meeting.

IMPORTANT: It is the responsibility of each researcher who proposes research involving human subjects to define the risks to which human subjects will be exposed during the proposed research. ***Please complete all question in the CAYUSE Human Ethics modules. The researcher must consider the following when completing the application in CAYUSE Human Ethics.***

1. Show that the significance of the proposed research warrants exposing the subjects to the defined risk;

2. Describe the safeguards and procedures that will be employed to minimize the risk to the human subjects;

3. Describe how the human subjects will be informed of the research risk;

4. Explain the procedures for obtaining and documenting informed consent;

5. Explain the procedures for maintaining confidentiality;

6. Submit all information to the Institutional Review Board (IRB) through CAYUSE Human Ethics to obtain approval of the proposed research before it is conducted.

7. Obtain a Certificate of Completion for training in Ethical Conduct of Research and Protection of Human Subjects located via the internet through CITI Training.

   What does CITI stand for?
   CITI stands for Collaborative IRB Training Initiative (web based training program in human research subjects' protections)

   University policy, responding to NIH requirements, requires all persons engaged in research involving human subjects to complete training in ethical conduct of research (RCR) and protection of subjects (Human Subject Training). ***Please include certificate of completion as an attachment in the CAYUSE Human Ethics.*** This includes faculty, staff, students, collaborators, subcontractors, and non-subject volunteers, regardless of funding. The policy includes people who have **ANY** contact with human subject participants, direct or indirect, including mailing or analyzing of questionnaires and conducting phone interviews, or contact/handling of data or human tissue samples.

   Before the IRB can **review and approve** any protocol, the principal investigator must provide the IRB with names of any such people as identified above. There is a section in IRBIS that you can provide the names of individuals engaged in research involving human subjects if there are collaborators who are at a non-WSSU organization that is under governance of an IRB, certification from that IRB can substitute for WSSU certification. If such certification is not available, individuals may become certified according to NIH procedures, even though they may not be affiliated with WSSU. Before you can begin your r**esearch** study, ***all persons associated with the research must submit their certificates to the IRB as an attachment in the CAYUSE Human Ethics. If it is found that this procedure is not followed, then IRB approval is immediately withdrawn.*** Certificates should also be included with modification and renewal applications if certificates have not been provided earlier, including certificates for any new people added to the project since the last application. IRB Human Participant Protections training is located at

   https://www.citiprogram.org/default.asp

   https://www.cancer.gov/about-cancer/treatment/clinical-trials/patient-safety

   http://grants1.nih.gov/grants/policy/hs_educ_faq.htm;

II. IRB MEMBERSHIP, SCHEDULED MEETINGS AND REVIEW PROCESSES

The composition of the IRB is governed by Federal Regulations. The Board must have at least five members of varying backgrounds and expertise, including at least one person not affiliated with the University and at least one person whose primary concerns are in a nonscientific area. The IRB must not be homogeneous with respect to gender or profession. Current membership can be found on the IRB website.

The IRB cannot convene without a quorum. Also, they may not take actions if they lose a quorum during a meeting. A quorum is defined as a majority of the voting members (fifty percent plus one) including **at least one member whose primary concerns are in non-scientific areas.** Every effort will be made to schedule meetings to accommodate as many members as possible. Each member of the committee was chosen because of their expertise in

their particular field. *It is the members' professional responsibility to attend meetings and participate. Tentative meetings for the IRB committee will be held monthly. Failure to attend at least 25% of these meetings will result in removal and replacement of the committee member.*

Tentative meetings of the IRB are scheduled for the third **Friday** of each month. If no proposals have been received by **fourteen days** prior to this time, the meeting may be cancelled. If proposals have been received, then the chair determines whether or not the proposal meets the Exempted Criteria or may be reviewed under the Expedited Criteria. If a proposal meets either of these criteria and is approved, the members will be informed at the next meeting. If the proposal is not approved under these criteria or requires a full review, it is placed on the agenda of the next regularly scheduled meeting. *Proposals requiring full review are transmitted electronically through CAYUSE Human Ethics 14 business days before the scheduled meeting. All applications will be reviewed in the CAYUSE Human Ethics and all stipulations will be posted in CAYUSE Human Ethics for review by Human Subjects IRB.*

IRB members may not participate in an IRB's initial or continuing review of any protocol in which they have a real or apparent conflict of interest, except to provide information requested by the IRB. This includes the Principal Investigator (PI) and all Associate Investigators (AI). When a motion is made to take a vote, all such persons must leave the room. In fact, they may be asked to leave sooner if the chair or a member thinks that more objective discussion and decision making will take place in their absence.

An IRB may invite individuals with competence in special areas to assist in the review of issues, which require expertise beyond or in addition to that available on the IRB. These individuals may not vote.

A. Approval/Disapproval of a Research Protocol

Most protocols are approved by the IRB with stipulations. The requested changes must be made and *submitted through CAYUSE Human Ethics as a response to a stipulation* before final approval is given. The IRB may table a protocol about which it has substantive concerns and criticisms. This gives the PI an opportunity to address fully the IRB's concerns and resubmit the modified protocol *through CAYUSE Human Ethics* for review at a subsequent meeting.

When a vote is not unanimous, the minority opinion must be recorded in or attached to the minutes. The IRB considers documentation of dissenting opinions an important part of the review process. *At each convened meeting, the IRB must approve the minutes of the previous meeting after a careful review by the members.* Therefore, before a vote is taken, there is an opportunity to correct or improve the minutes.

IRB disapproval of protocols occurs rarely but it is a final decision. No person, including the chancellor, has the authority to override the disapproval of a protocol.

Each investigator is notified in writing of the findings of the IRB Committee *within five days of the committee meeting.* Research activities cannot begin until an investigator receives written notification of the committee's decision.

B. Suspension or Termination of IRB Approval of Research

The IRB has authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination or approval shall include a statement of the reasons for the action and shall be reported promptly to the investigator, appropriate institutional officials, and, if funded research, the Department or Agency head.

III. CRITERIA FOR APPROVAL OF RESEARCH. 45 CFR PART 46.111

In general, the proposed research should:

A. Comply with all the ethical principles endorsed by the investigator, faculty member, Department, College/School, and University; and

B. Comply with the IRB criteria listed below.

To approve research an IRB should determine that all of the following conditions exist:

1. Risks to subjects are minimized.
2. Risks are reasonable in relation to anticipated benefits, if any, to subject and to advancement of knowledge.
3. Selection of subjects is equitable.
4. Informed consent will be sought.
5. Informed consent will be documented.
6. Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure safety of subjects.
7. There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
8. Where any of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study to protect subjects.

A. IRB Review - Points To Consider When Reviewing Proposals

1. Does the study involve reviews of records, observation, surveys, or interviews?
   If so, does it qualify for exemption or expedited review under the federal regulations and institutional policy?

2. Is the scientific design adequate to answer the questions posed?
   Is the sample size (number of subjects) adequate?
   Is the method proposed for selecting and assigning subjects to treatment groups unbiased?

3. Does the investigator serve a dual role that may pose a conflict of interest?

4. Is any of the information to be collected sensitive (*e.g.*, related to sexual practices, substance abuse, or illegal behavior)?

5. Are there adequate plans to protect participants from the risks of breach of confidentiality and invasion of privacy?

6. Are there plans for approaching subjects in a way that will respect their privacy and their right to refuse? If the protocol involves an epidemiological study, will subjects or their relatives be protected from learning inappropriate information?

7. Does the recruitment process protect subjects from being coerced or unduly influenced to participate? Are any payments to subjects reasonable in relation to the risks, discomfort, or inconvenience to which subjects will be exposed?

8. Are there adequate plans to exclude subjects who are vulnerable to injury during the period of withdrawal of active and effective therapy, if that is part of the research design?

9. Have the rights and interests of vulnerable subjects (*e.g.*, desperately ill persons) been adequately considered?

10. Are all appropriate elements of informed consent clearly provided for [Federal Policy §46.116], including:

    a. Do the consent documents describe the study design (including plans for randomization, use of placebos, and the probability that the subject will receive a given treatment) and conditions for breaking the code (if the study is masked)?

    b. Do the consent documents describe the risks and benefits of each of the proposed interventions and of alternative courses or actions available to the participants?

    c. Do the consent documents clearly describe the extent to which participation in the study precludes other therapeutic interventions?

    d. Are provisions made for supplying new information to subjects during the course of the study and for obtaining continuing consent, where appropriate?

    e. Must investigators obtain consent before reviewing records?

11. Will the consent process take place under conditions most likely to provide potential subjects an opportunity to make a decision about participation without undue pressure? (Need to carefully consider if research is connected to class.)

12. If the study is a clinical trial, how will the trial be monitored? What will be done with preliminary data? Should an independent data and safety monitoring board be established? How will decisions about stopping the trial be made? By whom? On what basis?

13. At what interval should the IRB perform continuing review of this project?

B. Categories of Research

Research involving human subject falls into three categories under the Federal Regulations.

Exempt. Federal Regulations declare that there are some types of research that may be exempt. See **next section** for the definitions.

Expeditable. Federal Regulations list ten types of research which may be reviewed by the IRB using an expedited procedure. See **next section** for the definitions.

All Other Research. All other research must be reviewed by the IRB.

C. Federal Criteria for Studies Exempt from IRB Review 45 CFR 46.101(b) Rev. 8/19/91

The following are considered as exempt from review. However, such exemptions must be determined by the IRB after application by the principal investigator.

EXEMPT RESEARCH UNDER THE REVISED COMMON RULE

As of January 19, 2018 the federal government will change the types of human subjects' research that are considered "exempt." These projects will be exempt from annual IRB review and exempt from the informed consent requirements that apply to other types of research. However, some of the new categories will require prospective participant agreement and a limited form of IRB review.

Even when research is exempt from further requirements of federal regulations, basic ethical standards still apply.

- Except in the case of chart reviews or database research, potential subjects must be provided enough information to be able to choose whether or not to participate. The information would typically include the voluntariness of their participation, the purpose of the research, the nature of the subject's involvement, time commitments, and contact information for the investigator.
- Research data must be handled and stored securely, in compliance with university policy.
- Access to research data must be limited to study team members and other authorized personnel.
- All members of the research team must be current on human subjects training and must have a current conflict of interest disclosure.

Each exempt category is described below. The regulatory text is in blue, and clarifications follow.

EXEMPT CATEGORY 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.

Most educational research on regular and special educational instructional strategies, and research on the effectiveness of, or comparison among, instructional techniques, curricula, or classroom management methods may be exempt under this category.

Changes to this exempt category include the caveat that there must not be any impact of subject's opportunity to learn or any negative impact if the research involves an evaluation of the instructors. If the research involves significant time and attention away from the delivery of regular curriculum or withholding of standard educational content, this exemption would not apply. Also, there must be protection against negative impact on employment if instructors are being evaluated. Research involving randomization to an unproven educational technique, or research conducted by supervisors involved in employment decisions may not be approvable under this exemption.

Applicability to vulnerable populations:

- Pregnant women may be included in this type of research.
- Research that targets a prisoner population is *not* eligible for this exemption. The exemption is allowable if the research is aimed at a broader population and only incidentally includes prisoners.
- Research involving children is eligible for this exemption.

EXEMPT CATEGORY 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:

(i) 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;

(ii) 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

(iii) 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*.

This exemption category involves several changes from pre-2018 rules. The wording of this exemption was changed to clarify that the category applies to research that *only*

involves interactions. Additionally, the use of potentially sensitive information might be allowable if appropriate protections are in place and the IRB conducts a new process called 'limited IRB review.'

This category involves interactions (verbal and written responses) and data collection only. The data collection can include audio or video recordings. Research involving "interventions" would not be approvable under this category. Interventions include manipulation of the environment or physical procedures to collection information, such as a cheek swab.

Applicability to vulnerable populations

- Pregnant women may be included in this type of research.
- Research that targets a prisoner population is *not* eligible for this exemption. The exemption is allowable if the research is aimed at a broader population and only incidentally includes prisoners.
- Research involving children is eligible for this exemption only when it related to educational tests or observations in which the investigators don't participate in the activities being observed. Additionally, children are not eligible for this exemption if the project requires limited IRB review.

EXEMPT CATEGORY 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:

(i) 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;

(ii) 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

(iii) 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*.

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.

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.

This exempt category is completely new in the 2018 revisions to the federal regulations. There are limits on the interventions that are considered 'benign' and requirements on IRB review of this type of research

Applicability to vulnerable populations:

- Pregnant women who are adults *may* be included in this type of research
- Research that targets a prisoner population is *not* eligible for this exemption.
- Research that could include children is not eligible for this exemption. The exemption is allowable if the research is aimed at a broader population and only incidentally includes prisoners.
- Research involving decisionally-impaired persons is *not* eligible for this exemption.

EXEMPT CATEGORY 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:

(i) The identifiable private information or identifiable biospecimens are publicly available;
(ii) 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;
(iii) 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" as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research 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 applicable federal privacy standards found in the E-Government Act, Privacy Act and the Paperwork Reduction Act. The 2018 changes significantly broaden the type of secondary research that can be done under this exemption category:

- The requirement that all study data be existing at the time of IRB submission has been eliminated. Data under this exemption may be both retrospective and prospective.
- The requirement that the study involves data only has been eliminated. The research may also involve the use of specimens.
- Creating a de-identified dataset for analysis is still an approvable option and continues to be the most straight-forward approach.
- If investigators need to retain data that contains any HIPAA elements or need to retain a linking list, then appropriate HIPAA protections could make the project approvable. Depending on the circumstances of the data, the HIPAA protections might include a Business Associate Agreement, a Data Use Agreement or a waiver of HIPAA authorization with accounting of disclosures.

- Certain sources of publicly available data require the recipient to sign an agreement outlining restrictions on access, use, security and transfer. Most often, those agreements will need review by the university's general counsel.

It is important to note the Exemption Category 4 only applies to the *re-use* of data and specimens that were or will be collected for non-research purposes or from research studies other than the proposed research study. The research materials typically will be publicly available materials, medical records or existing repositories of clinical specimens. No contact between investigator and subject is allowed. If an investigator wants to collect information/specimens directly from research subjects, then another approval path would be required.

Applicability to vulnerable populations:

- Data/specimens from pregnant women would be allowed
- Data/specimens from prisoners could be allowed as long as the research wasn't designed to recruit prisoners and prisoners were only incidental subjects of the research.
- Data/specimens from children would be allowed
- Data/specimens from persons with decisional impairment would be allowed

EXEMPT CATEGORY 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. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website 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 the research involving human subjects.

The scope of this category has been broadened. Prior rules required that the Federal demonstration projects be conducted by the Federal agency. This category has been updated to allow projects that are simply funded by a Federal agency. The scope has been expanded to include purposes not only to study and evaluate but also to improve these programs. Note that projects eligible for this exemption will be posted on a Federal website.

EXEMPT CATEGORY 6:

Taste and food quality evaluation and consumer acceptance studies: if wholesome foods without additives are consumed, or 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

This exemption category was not changed in the revised Common Rule. Note that it is the only exemption that is allowable for FDA-regulated research.

Applicability to vulnerable populations:

- Pregnant women may be included in this type of research.
- Research that targets a prisoner population is *not* eligible for this exemption. The exemption is allowable if the research is aimed at a broader population and only incidentally includes prisoners.
- Research involving children is eligible for this exemption.
- Research involving decisionally-impaired persons could be allowed if their inclusion was justified.
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EXEMPT CATEGORY 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).

This exemption is new with the 2018 Common Rule.

Research with vulnerable populations may be approvable with this exemption:

- Pregnant women may be included in this type of research.
- Research that targets a prisoner population is *not* eligible for this exemption. The exemption is allowable if the research is aimed at a broader population and only incidentally includes prisoners.
- Research involving children is eligible for this exemption.

EXEMPT CATEGORY 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:

(i) 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);
(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with § .117;
(iii) 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 479
(iv) 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 any legal requirements to return individual research results.

Research with vulnerable populations may be approvable with this exemption:

- Pregnant women may be included in this type of research.
- Research that targets a prisoner population is *not* eligible for this exemption. The exemption is allowable if the research is aimed at a broader population and only incidentally includes prisoners.
- Research involving children is eligible for this exemption.

NOTE: These exemptions do not apply to research involving prisoners, fetuses, pregnant women under the age of 18 or human in vitro fertilization.

[1] Children are defined in the HHS regulations as "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).

D. Federal Criteria for Studies That May Be Reviewed through an Expedited 46.110(b) Review Procedure

An IRB may use expedited review for:

- Research on list of eligible categories
- Minor changes in previously approved research.

The expedited review may be carried out by IRB chair or one or more experienced IRB members. The reviewers can exercise all of the authorities of the IRB except disapproval. All IRB members must be informed of research approved under expedited review [46.110(c)].

Applicability

(A) Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

(B) The categories in this list apply regardless of the age of subjects, except as noted.

(C) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be

implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

(D) The expedited review procedure may not be used for classified research involving human subjects.

(E) IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

(F) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

   (a) Research on drugs for which an investigational new drug application (21 CFR Part 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.)

   (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 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, heel stick, ear stick, or venipuncture as follows:

   (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

   (b) from other adults and children[1], considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means.

   Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and sub gingival dental plaque and calculus, provided the collection procedure is not more

invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where 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, including studies of cleared medical devices for new indications.)

   Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b) (2) and (b) (3). This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the convened IRB as follows:

   (a) Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

   (b) Where no subjects have been enrolled and no additional risks have been identified; or

   (c) Where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

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[1] Children are defined in the HHS regulations as "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).**INSTRUCTIONS FOR PREPARING THE RESEARCH PROPOSAL FOR EXEMPT, EXPEDITED & FULL REVIEW:**

Note: *You must submit the research proposal through CAYUSE Human Ethics following these guidelines.*

WELCOME TO CAYUSE Human Ethics,
The system is designed to be used for all of your interactions with the IRB. You can:

- Create new applications
- Modify or update approved studies
- View the status of pending submissions
- Close completed studies

You can select the relevant action from the column to the left. You will be prompted to provide the information needed to complete your submission, including consent forms, as relevant. Your application will be customized to fit the circumstances of your research, depending on your responses as you proceed. The questions are designed to be answered in a sequential order; however, you may use the links in the left column to revisit any portion of the application. Once you have provided the necessary information, your submission will be electronically certified by the principal investigator, routed for department level approvals (when indicated) and then received by the IRB. **TIP:** If you are having trouble using CAYUSE Human Ethics, you might want to try switching to a different browser. For example, if you are using Internet Explorer, try switching to Google Chrome or Firefox.

If you need assistance completing an application, please call or email **and** we will be happy to help you.

Click above to view a sample application with most questions available for review.
NOTE: Your old HARD COPY application QUESTION ARE DIFFERENT FROM IRBIS on-line system.

What about Modifications and Renewals?
As of July 1, 2018, all modifications and renewals must be submitted via the IRBIS online

system. Paper applications are no longer being accepted. Modification and renewal applications can be found on the investigator's IRBIS homepage under "Create a New Submission".

REWRITE- Any existing study (including those submitted on paper) that was previously entered into the IRBIS admin system has an electronic record in the online system. A PI wanting to renew online a study that previously existed on paper should login, click My Studies in the left navigation bar, and then select the relevant study number and initiate a renewal. Since only minimal electronic information exists for these studies (basic, identifying info), limited data is carried into this "new" online renewal application. Please note that nothing pre-populates beyond the General Information section and that data should be reviewed for accuracy by the PI at time of submission.

INFORMED CONSENT

§46.116 **General requirements for informed consent.**

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Informed Consent Checklist - Basic and Additional Elements

	A statement that the study involves research
	An explanation of the purposes of the research
	The expected duration of the subject's participation
	A description of the procedures to be followed
	Identification of any procedures which are experimental
	A description of any reasonably foreseeable risks or discomforts to the subject
	A description of any benefits to the subject or to others which may reasonably be expected from the research
	A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
	A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
	For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are

	available, if injury occurs and, if so, what they consist of, or where further information may be obtained
( ) Research Qs	An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject
( ) Rights Qs	
( ) Injury Qs	
	A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled
Additional elements, as appropriate	
	A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable
	Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
	Any additional costs to the subject that may result from participation in the research
	The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
	A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject
	The approximate number of subjects involved in the study
	A consent form should not contain exculpatory language. For example, if an informed consent document contains language by which a subject waives his or her right to be compensated for injuries arising from participation in the research, such language would meet the definition of exculpatory language because it has the general effect of freeing or appearing to free the investigator, sponsor, and/or the research institution from malpractice, negligence, blame, fault, or guilt

§46.117 Documentation of Informed Consent Checklist

a. Except as provided in paragraph "c" of this section, informed consent shall be documented by

the use of a written consent form approved by the IRB, and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.	
WRITTEN	The consent form may be either of the following: 1. A **written consent** document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator should give either the subject or the representative adequate opportunity to read it before it is signed.
DONE ORALLY	2. A **short form written consent** document, stating that the elements of informed consent required by §46.116 have been presented **orally** to the subject or the subject's legally authorized representative. When this method is used, there shall be a **witness** to the oral presentation. Also, the IRB shall approve a **written summary** of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.
WAIVER of req't for signed form	c. An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects, if it finds either: 1. That the only record linking the subject and the research would be the consent document and the **principal risk** would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or 2. That the research presents **no more than minimal risk** of harm to subjects, and involves no procedures, for which written consent is normally required outside of the research context. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

IRB Latitude to Approve a Consent Procedure that Alters or Waives some or all of the Elements of Consent

§ 46.116(d)- An IRB may approve a consent procedure, which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent, provided the IRB finds and documents that:

	C: 1. The research or demonstration project is to be conducted by, or subject to the approval of, state or local government officials, and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for

	obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and
	C: 2. The research could not practicably be carried out without the waiver or alteration.
	D: 1. The research involves no more than minimal risk to the subjects;
	D: 2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
	D: 3. The research could not practicably be carried out without the waiver or alteration; and
	D: 4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Special Requirements - 45 CFR 46 Subpart D - Additional DHHS Protections for Children Involved as Subjects in Research	
Assent/ Waiver	The IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted, or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children, and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances, in which consent may be waived in accord with §46.116 of Subpart A.
Parents	The IRB may find that the permission of **one** parent is sufficient for research to be conducted under §46.404 or §46.405.
	Where research is covered by §46.406 and §46.407, and permission is to be obtained from parents, **both parents must give their permission**, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
	If the IRB determines that a research protocol is designed for conditions or for a subject population, for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will

	participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, state or local law.

An **informed consent document** is typically used to provide subjects with the information they need to make a decision to volunteer for a research study. Federal regulations (45 CFR 46.116(link is external)) provide the framework for the type of information (i.e., the "elements") that must be included as part of the consent process. New with the revised 2018 Common Rule is the requirement that the consent document begin with a "concise and focused" presentation of **key information** that will help potential participants understand why they might or might not want to be a part of a research study.

The image below displays the five elements identified in the preamble to the revised Final Rule (link is external) as suggested key information.

Note: Element number 5 (alternative procedures) applies primarily to clinical research

WINSTON-SALEM STATE UNIVERSITY
INFORMED CONSENT FORM

Title of Study--required

Headings with (*) are required for all studies

IMPORTANT: BEFORE FINALIZING & PRINTING THIS DOCUMENT REMOVE THIS TEXT & ALL RED AND BLUE INSTRUCTIONAL TEXT (this document is ONLY a recommended template).

Preamble: include the following information.

- Statement that study involves research, .116(b)(1)
- Explanation of the purposes of the research and the expected duration of the subjects' participation, .116(b)(1)
- A description of the procedures to be followed, .116(b)(1) and
- Identification of any procedures that are experimental .116(b)(1) Description of any reasonably foreseeable risks or discomforts to the subject 116(b)(2)
- Description of any benefits to the subject or to others that may reasonably be expected from the research .116(b)(3)
- Disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject .116(b)(4) *If clinical research only*

Example: You are being asked to participate in a research study. Participation in this study is completely voluntary. The purpose of the study is ------. The duration of the study is -----. The procedures to be followed-------. The procedures that are experimental are none or there are no experimental procedures. The benefits to the subject that may be expected are-----.Please read the information below and ask questions about anything that you do not understand before deciding if you want to participate. A researcher listed below will be available to answer your questions.

RESEARCH TEAM*
Principal Investigator:
Name and Title
Department
Telephone Number

Faculty Sponsor:
Name and Title
Department

Other Co- Investigators or Researchers:
(List only those researchers qualified to be involved in the informed consent process)

Study Location(s):

Study Sponsor(s):

PURPOSE OF STUDY*
The purpose of this research study is to… *(Complete this sentence) Examples include "to explore attitudes of first-generation Americans regarding education; to understand how social support influences mental health."*

SUBJECTS*
Inclusion Requirements
You are eligible to participate in this study if you… *(Complete this sentence or use a bulleted list of inclusion criteria) Examples include, "are at least 18 years of age or older," "are right-handed," "live in Forsyth County"*

Exclusion Requirements *(Optional)*
You are not eligible to participate in this study if you... *(Complete this sentence or use a bulleted list of exclusion criteria) Examples include, "do not have corrected 20/20 vision," "are taking high blood pressure medications," "are not enrolled in at least 8 units at the institution."*

Number of Participants and Time Commitment*

This study will include approximately subjects and will involve approximately of your time.

PROCEDURES*
The following procedures will occur: *(Explain the research procedures in detail and in chronological order; include the expected duration of each procedure or each visit and the procedures to be completed at the visit.) Example:*
"You will complete a survey about your eating habits, then you will have your blood drawn (indicate amount) and your blood pressure taken".

RISKS AND DISCOMFORTS* *(Describe the risks and discomforts associated with the research study)*
[For minimal risk studies] This study involves no more than minimal risk. There are no known harms or discomforts associated with this study beyond those encountered in normal daily life.

OR

[For greater than minimal risk studies] The possible risks and/or discomforts associated with the procedures described in this study include: *(Complete this sentence. Categorize the risks by severity and include the likelihood of the risk/discomfort occurring. Make sure to consider all types of risks – psychological, social, economic, legal and physical.)*
Examples of risks/discomforts include: dizziness, nausea, embarrassment, social stigma (shame or disgrace), psychological distress, loss of employment, invasion of privacy and breach of confidentiality)

UNKNOWN RISKS *(Optional)*
There may be risks to being in this study that we don't know about now. You will be informed of any changes in the way the study will be done and any additional identified risks to which you may be exposed. *[This section is required if the research involves clinical procedures or risk profile of research intervention is not well known.]*

BENEFITS*
Subject Benefits
The possible benefits you may experience from the procedures described in this study include… *(Complete this sentence – the description of subject benefits should be clear and not overstated) Examples: increase reading comprehension, improved writing skills, learning about ways to improve my memory.*

OR

[If no direct benefit to the subject is anticipated, delete the above statement and insert – You will not directly benefit from participation in this study.]

Benefits to Others or Society*
[*Insert a statement about possible benefits to science or society here. Example: a decrease in the number of children injured in car accidents, greater understanding of how stress influences memory.*]

ALTERNATIVES TO PARTICIPATION* *(Describe the alternatives)*
[If no alternatives] The only alternative to participation in this study is not to participate.

[If subjects will be compensated with extra course credit] The course instructor offering extra course credit for participation in research must provide alternatives to earn extra course credit. The alternative assignment must require equal or less time and effort for the same amount of earned extra credit.

Students Participation *(if subjects are students of Principal Investigator)*

(Complete this section if applicable; please delete this section if this does not apply) Please be informed that you do not have to consent to be in a research project. You may also initially consent and then decide to withdraw. The faculty member will not use your refusal to participate in any way to affect your grade or the way you are treated in your courses, the department, or the university.

Furthermore, research data should not be collected during class time except when those data would have been collected as part of the regular teaching and assessment of your learning. If data are collected on all students as part of the regular class, then you have the right to refuse to have your data included in subsequent research from those data.

Should you feel that you have been coerced or forced into participating in this research or that data are being collected during class time solely for the purpose of research, please contact the Institutional Review Board through the Compliance Officer at 336-750-2982.

COMPENSATION, COSTS AND REIMBURSEMENT*
Compensation for Participation*
[CHOOSE ONE OPTION]
You will be paid $ [*enter type of payment and amount of compensation*]

OR
You will be paid $ [*enter type of payment and amount of compensation*] after each study visit. There are [*enter # of study visits if applicable*] visits. Total payment for participation in this study is $[*enter total compensation for completion of the study*]. If you decide to withdraw from the study or are withdrawn by the research team, you will receive compensation for the visits that you have completed.

OR
[If subjects will not be compensated, please insert - You will not be paid for your participation in this research study.*]*

Costs *(Optional)*
There is no cost to you for participation in this study.
OR
You will be responsible for the following costs… (*Complete this sentence).*

Reimbursement *(Optional)*
You will be refunded for the following expenses that you incur… *(Complete this sentence)*
Examples: parking fees, transportation fees

If no reimbursement will be provided, delete the above statement and insert – You will not be reimbursed for any out of pocket expenses, such as parking or transportation fees.

Compensation for Injury *– [Required if research involves greater than minimal risk]*
If you are injured as a direct result of your participation in this study, you will be referred to the necessary medical agency to treat the illness or the emergency 911 will be called. **Winston-Salem State University does not routinely provide any form of compensation or medical care for injury, other than a referral.** It is important that you report any suspected study-related illness or injury to the research team listed at the top of this form immediately.

WITHDRAWAL OR TERMINATION FROM THE STUDY AND CONSEQUENCES *(Optional) [Required if subjects may be terminated by researcher and/or if there are adverse consequences (physical, social, psychological, economic, or legal) of the subject's withdrawal from the study]*

You are free to withdraw from this study at any time. **If you decide to withdraw from this study you should notify the research team immediately**. The research team may also end your participation in this study if you do not follow instructions, miss scheduled visits, or if your safety and welfare are at risk.

CONFIDENTIALITY***
Subject Identifiable Data* *(Explain whether subject identifiers will be linked to the research data.)* Examples include:

- All identifiable information that will be collected about you will be removed at the end of data collection.
- All identifiable information that will be collected about you will be removed and replaced with a code. A list linking the code and your identifiable information will be kept separate from the research data.
- All identifiable information that will be collected about you will be kept with the research data.

Data Storage* *(Describe how the data will be maintained)*
Examples include:

- All research data will be maintained in a secure location at WSSU. Only authorized individuals will have access to it.
- All research data will be stored on a laptop computer that [is password protected or has encryption software.]

- All research data will be stored electronically on a secure [computer or network] with [encryption or password] protection.
  Other privacy options:
- The [audio/video recordings] will also be stored in a secure location; then transcribed and erased as soon as possible.
- The [audio/video recordings] will also be stored in a secure location; then transcribed and erased at the end of the study.
- The [audio/video recordings] will also be stored in a secure location and transcribed. The recordings will be retained with the other research data.

Data Access* *(Explain who will have access to the research data)*
The research team, authorized WSSU personnel, the study sponsor (if applicable), and regulatory entities such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP), may have access to your study records to protect your safety and welfare. Any information derived from this research project that personally identifies you will not be voluntarily released or disclosed by these entities without your separate consent, except as specifically required by law. Research records provided to authorized, non-WSSU entities will not contain identifiable information about you. Publications and/or presentations that result from this study will not include identifiable information about you.

Data Retention* *(Explain how long the research data will be maintained)*
- The researchers intend to keep the research data until analysis of the information is completed.
- The researchers intend to keep the research data until the research is published and/or presented.
- The researchers intend to keep the research data for approximately __ years.
- The researchers intend to keep the research data indefinitely.
- The researchers intend to keep the research data in a repository indefinitely. Other researchers will have access to the data for future research.

OTHER CONSIDERATIONS *(Optional)*
Use of Specimens
[If the study involves collection of specimens, one of the following statements is required]

Any specimen(s) (e.g., tissue, blood, urine) obtained for the purposes of this study will become the property of the Winston-Salem State University. Once you provide the specimens you will not have access to them. The specimen(s) will be discarded or destroyed once they have been used for the purposes described in the protocol.

OR

Any specimen(s) (e.g., tissue, blood, urine) obtained for the purposes of this study will become the property of the Winston-Salem State University. Once you provide the specimens you will not have access to them. The specimens will be used for research and such use may result in inventions or discoveries that could become the basis for new products or diagnostic or therapeutic agents. In some instances, these inventions and discoveries may be of potential commercial value and may be patented and licensed by the University. You will not receive any money or other benefits derived from any commercial or other products that may be developed from use of the specimens.

Investigator Financial Conflict of Interest
[If there could be the appearance of a conflict of interest, the following statement is required]
No one on the study team has a significant financial interest related to this research project.

NEW FINDINGS *(Optional)*

If, during the course of this study, significant new information becomes available that may relate to your willingness to continue to participate, this information will be provided to you by the researcher team listed at the top of the form.

IF YOU HAVE QUESTIONS*
If you have any comments, concerns, or questions regarding the conduct of this research please contact the research team listed at the top of this form.

If you are unable to reach a member of the research team listed at the top of the form and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research subject, please contact Winston-Salem State University Institutional Review Board (IRB) via the Compliance Officer in the Office of Sponsored Programs at khaniu@wssu.edu or in person at C125, Anderson Center, 601 Martin Luther King Jr. Drive, Winston-Salem, North Carolina 27110.

CONSENT STATEMENT*

You should not sign this form unless you have read and understand the attached Informed Consent Form. Participation in this study is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your future relationship with Winston-Salem State University. Your signature below indicates that you have read the information in this consent form and have had a chance to ask any questions that you have about the study.

I agree to participate in the study.

_____ _____
Subject Signature* **Date**

_____
Printed Name of Subject *

_____ _____
Legally Authorized Representative/Guardian Signature ***Date***

_____
Printed Name of Legally Authorized Representative/Guardian's

_____ _____
Legally Authorized Representative/Guardian Signature ***Date***

_____
Printed Name of Legally Authorized Representative/Guardian's

_____ _____
Researcher Signature* **Date**

_____
Printed Name of Researcher*

Winston-Salem State University
The Office of Sponsored Programs and Research
Institutional Review Board (IRB)

A Guide to the IRB Process

We hope that this FAQ will orient you to basic policies and procedures for IRB review and approval. It is one of a number of resources available to researchers from the Winston-Salem State University IRB. Although we serve a regulatory function, we take a collegial approach to consultation with researchers and their staff. Feel free to call on us as you navigate the process. Please contact the Compliance Officer at (336) 750-2982. We are happy to respond to your questions.

A more in-depth **Winston-Salem State University Institutional Review Board Manual for Research Involving Human Subjects** is available as a separate WORD document.

What is the IRB?

- The Institutional Review Board (IRB) is a committee established to review and approve research involving human subjects.
- The primary purpose of the IRB is to protect the rights and welfare of human subjects.

What research has to be reviewed by the IRB?

It is the policy of Winston-Salem State University that all research conducted by faculty, staff or students, which involved human subjects, be reviewed and approved or declared exempt by the Institutional Review Board (IRB).

What is research?

- Research contributes to generalizable knowledge.
- Research is designed in advance.
- Research utilizes a systematic approach.

What is a human subject?

A human subject is defined by Federal Regulations as "a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information." (45 CFR 46.102(f))

What kinds of IRB review are there?

- There are three levels of IRB Review (full board review, expedited, and exempt), determined by the nature of the protocol, level of potential risk to human subjects, and the subject population.
- **The determination of level of review applicable to a particular study is made by the IRB.**
- Regardless of the kind of review, all applications use the same submission form.

Convened IRB review (full board review)

- Any study involving greater than minimal risk requires a review by the convened IRB. This includes studies with vulnerable populations and sensitive questions as well as studies with the possibility of physical risk.
- Studies assigned to full board review are reviewed by members ahead of time, and then discussed at the meeting. The Committee then votes on whether or not to approve the study.

Expedited IRB review

- Only research involving no more than minimal risk to subjects may be considered for expedited review.
- An expedited review is conducted by an individual reviewer, such as the IRB Chairperson, or a few reviewers, rather than going to the full board.
- Federal guidelines provide categories for expedited review. Examples of categories include:
    - blood sampling in minimal amounts
    - review of records collected for non-research purposes (such as chart reviews)
    - survey research

Exempt from IRB review

- Research with very minimal risk to human subjects as determined by regulatory guidelines may be exempted from continuing review at the discretion of the IRB.
- **An exemption is granted by the IRB upon review of the application.**

How do I apply?

- Submit an *Application for Approval of Research Involving Human Subjects through the IRB Information System called IRBIS (an on-line electronic portal) for submitting an application.* Instructions accompany the application.

What is the required ethics education?

- Human Subjects Protection Education is required of all faculty, staff and students who are engaged in the planning, conduct or analysis of research at Winston-Salem State University that involves human subjects.
- https://www.citiprogram.org/default.asp

Do I have to get consent from study participants?

- The standard expectation is that all subjects will sign a document containing all the elements of informed consent.
- The informed consent process gives potential subjects a description of the study that is clear and complete enough for the individual to judge whether she or he wants to participate.
- The consent form should provide readily understandable information in an amount appropriate to the level of risk in participating.
- Some or all of the elements of consent, including signatures, may be waived under certain circumstances.

Does WSSU have a consent form template?

- Yes, a common consent form template is available. Please contact the Compliance Officer at (336) 750-2982 or by email khaniu@wssu.edu.

What information must be included in a consent form?

- A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
- A description of any reasonably foreseeable risks or discomforts to the subject;
- A description of any benefits to the subject or to others that may be reasonably expected from the research;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- A statement describing the extent, if any, to which confidentiality of the records identifying the subject will be maintained;
- For research involving more than minimal risk, an explanation as to whether any compensation and/or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research related injury to the subject, if relevant. Typically, questions concerning a research project should be referred to the PI for that project, whereas questions concerning the rights of human subjects should be referred to the IRB.
- A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject

may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

- Other requirements may apply.

How do I obtain consent from Non-English speaking participants?

- Researchers should take great care when obtaining informed consent from individuals who do not speak English or whose understanding of the language is limited.
- Researchers should be fluent in the subject's language or an interpreter should be available during the consent process and throughout the subject's participation as needed.
- Consent forms should be prepared in the language understandable to potential subjects.

What are the exceptions to informed consent requirements?

- The IRB may waive consent if:
    - The research involves no more than minimal risk to the subjects;
    - The waiver will not adversely affect the rights and welfare of the subjects;
    - The research could not practicably be carried out without the waiver;
    - If appropriate, the subjects will be provided with additional information after participation.
- Consent may also be waived for some types of research regarding public service programs.

What about HIPAA?

- HIPAA stands for Health Insurance Portability and Accountability Act of 1996.
- HIPAA regulations are focused on privacy and security protections for individuals' health care information: "protected health information" (PHI).
- Protected Health Information (PHI) includes individually identifiable health and health care payment information, including the demographic data that is a potential identifier of the individual, maintained in the records of health care providers.
- If a research study either uses or creates protected health information, documentation of the subject's authorization to use such information is required.

What if I need to review medical records in order to identify subjects for recruitment?

- You need to answer the questions in CAYUSE Human Ethics that are similar to the questions below:

1. Will the information collected be limited only to that necessary to contact the subjects to ask if they are interested in participating in the study?

2. How will confidentiality/privacy be protected prior to ascertaining desire to participate?

3. When and how will you destroy the contact information if an individual declines participation?

Where do I send the application?

- The principal investigator (PI) develops a protocol through the CAYUSE Human Ethics, consulting with the Compliance Officer as needed. The PI should then electronically sign the application in IRBIS for electronic routing for approval. The Compliance Officer will review the study's documentation in CAYUSE Human Ethics and accepts the study for review by the Institutional Review Board. Committee members will be assigned to review the study.

What happens after submission?

- Your study will be assigned an IRB number that should be used on all correspondence relating to the study until the study is closed.
- The IRB will determine the level of review.
- The IRB will conduct the review and take one of the following actions:

Approval of research

- Research may proceed on receipt of written documentation of IRB approval.

Approval with Stipulations

- It is common for the IRB to request some changes to the consent form or protocol prior to approval. If there are stipulations, you will receive communication from the IRB and the Compliance Officer with details.
- The requested changes must be made in writing before final approval is given.
- The IRB may table a protocol about which it has substantive concerns and criticisms. This gives the PI an opportunity to address fully the IRB's concerns and resubmit the modified protocol for review at a subsequent meeting.
- If your response is acceptable, your project will be approved and you will receive an approval letter.

Suspension or Termination of IRB approval (full board action only)

- If the IRB determines that the research cannot be conducted at Winston-Salem State University 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.

Exemption

- The IRB may determine that your study is not subject to continuing review.

How long does it take?

- An expedited or exempt review typically takes about 10 business days.
- Studies requiring full board review are scheduled for the first available meeting.
- Correspondence from the IRB is sent to the Principal Investigator within one week of full board review.
- The PI has a significant influence on length of time between submission and approval.
    - Well prepared applications result in fewer requests for stipulated changes.
    - Rapid response by the PI to requests for changes speeds the approval process.

What happens after I receive approval?

You may begin your research.

You have a responsibility to report problems or adverse events that may occur during the research to the IRB.

- "Adverse event" or "adverse experience" (AE) is an undesirable and unintended, though not necessarily unanticipated, injury or physical or emotional consequence to a human subject.
- Unanticipated Problems may or may not include specific events experienced by individual subjects, but are developments within the research activity that suggest a potential for increased risks to subjects or others.

All projects are subject to renewal, usually annually.

- If the research is continuing or data analysis is not yet completed, request renewal of approval through CAYUSE Human Ethics.

What if I want to modify the study?

- Once the project is submitted to the IRB, you may not make changes to the study until the IRB has completed the approval process for your original submission.
- Once your study is approved, you may submit modifications.
    - All protocol changes must be approved by the IRB prior to implementation.
    - All changes to documents used with subjects (consent forms, questionnaires, recruitment materials, etc.) must be approved by the IRB prior to use.

- The review of the amendment request may be expedited or may require full board review.

Where do I send the application?

- Your Application will be sent via CAYUSE Human Ethics. All signatures will be electronic signatures. Please attach consent forms, advertisement flyers, etc. in CAYUSE Human Ethics.

Where do I get more information?

- WSSU web site is a good source of additional information, providing links to many ethics, research, and regulatory sites. To access, go to Graduate Studies, Office of Sponsored Programs and Research, Research Compliance, Human Subjects.
- The **Winston-Salem State University Institutional Review Board Manual for Research Involving Human Subjects** (Investigator's Manual), a PDF document is available.
- Code of Federal Regulations: Protection of Human Subjects **45CFR46**.
- We are happy to respond to your questions. Feel free to call or email us. ~~Please contact the~~ IRB through the Compliance Officer at (336) 750-2982.

  https://www.wssu.edu/about/offices-and-departments/office-of-sponsored-programs/research-compliance/index.html

- For any questions related to Compliance please contact Dr. Islam Khan via 336-750-2982 or khaniu@wssu.edu. The Compliance office is located in the Office of Sponsored Programs on campus in the Anderson Center room C125. Research Involving Human Subjects (IRB) Web page link: https://www.wssu.edu/about/offices-and-departments/office-of-sponsored-programs/research-compliance/research-involving-human-subjects-irb.html

CAYUSE Human Ethics FREQUENTLY ASKED QUESTIONS

1. **How can I log into CAYUSE Human Ethics?**
   Student researchers need to be in the CAYUSE system in order to access the CAYUSE Human Ethics. WSSU students needs to fill out Student Access form and send it Compliance Officer at khaniu@wssu.edu to register in SP424. **Faculty are registered in the system as a default.**
   To get to the CAYUSE Human Ethics click here, login using your WSSU credentials, you will be on Cayuse Platform HOME, look for "Products" on the far right on top of the screen besides your Name. Once you are on Human Ethics page, click on +New Study, and start your application.

2. **How can I complete the IRB application in CAYUSE Human Ethics?**
   The training video is available for Human Ethics module on CAYUSE Resources page.

3. **Whom should I contact if I have questions?**
   For log in issues (user name and password) please contact the helpdesk at 336-334-7195 or the Compliance Officer @ 336-750-2982. For IRB assistance please email the Compliance Officer khaniu@wssu.edu or call 336-750-2982.

LINKS TO WINSTON-SALEM STATE UNIVERSITY IRB PROCESS

1. Review the WSSU IRB Manual and the Guide to the IRB Process.
2. Complete required CITI training and upload your certificate in CAYUSE.
3. Apply via electronic submission in CAYUSE Human Ethics. Please expect 7-10 business days to complete the review process.
4. Link to Winston-Salem State University RESEARCH COMPLIANCE web page for further info on FAQ, IRB process, attachments, and IRB Committee.

https://www.wssu.edu/about/offices-and-departments/office-of-sponsored-programs/research-compliance/research-involving-human-subjects-irb.html

IRB COMMITTEE MEETING

Teleconference meetings for fall and spring semesters are every 3rd Thursday of the month in Anderson G22. All IRB applications requiring a FULL BOARD must be submitted through IRBIS at least 14 days prior to scheduled IRB meeting. + IRB COMMITTEE

Islam Khan, Ph.D.
Compliance Officer
Office of Sponsored Programs
Room C125A, Anderson Center
336-750-2982
khaniu@wssu.edu

Appendix A

Regulations require each investigator to retain research data not only while the research is being conducted but also after the research is completed. How long do you have to keep the records after the completion of the research? Unfortunately, there are several different regulations each of which has different requirements. As a result, researchers must comply with the longest applicable standard according to current institutional policies.

Office for Human Research Protections (OHRP): Research records must be retained for at least 3 years after the completion of the research. Research is completed when all research related interventions/interactions with human subjects have been completed and all data collection and analysis of identifiable private information described in the IRB-approved research plan have been finished.

https://www.hhs.gov/ohrp/index.html

HIPAA Requirements: Health Insurance Portability and Accountability Act (HIPAA): Any research that involves collecting identifiable health information is subject to HIPAA requirements. These records must be retained for at least 6 years after the personal health information was disclosed.
https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/research/index.html

Food and Drug Administration (FDA): Research records must be retained for 2 years after either (1) the date a marketing application is approved or (2) the investigation is discontinued, and the FDA is notified.

http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312&showFR=1&subpartNode=21:5.`0.1.1.3.4

Department of Veterans Affairs (VA): Research Records must be retained indefinitely.

http://www.va.gov/ORO/Research_Information_Protection.asp

Sponsor Requirements: contract: If your study is sponsored you must insure that you comply with any terms for record retention detailed in the contract with the sponsor. For example, a sponsor may require you to retain your research related documents for 20 years. Prior to agreeing to a contract that specifies how long records will be maintained you should insure you will receive adequate funding to pay for the storage.

Questions of data validity: if there are questions or allegations about the validity of the data or appropriate conduct of the research, you must retain all of the original research data until such questions or allegations have been completely resolved.