

NORFOLK STATE UNIVERSITY



INSTITUTIONAL REVIEW BOARD

MANUAL

FOR RESEARCH INVOLVING HUMAN SUBJECTS

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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. NSU Policy

It is the policy of Norfolk State University (NSU) that all research conducted by faculty, staff or students of Norfolk State University, which involves human subjects, be reviewed and approved or declared exempt by the Institutional Review Board (IRB). This board 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, Cynthia Duhe-Harris at (757) 823 2602.

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

The Office of Research and Innovation will only accept IRB submissions through the IRBNET.ORG, the on-line system.

The Principal Investigator (PI) must be from NSU. The PI (NSU faculty or staff) is the **ONLY** person that can submit to IRBNET. No students or external individuals can submit.

The PI **AND** student or external individual must **UPLOAD** the CITI required training

REQUIRED CITI Training documents: Conflict of Interest, Social and Behavioral Responsible, and Conduct of Research. Additional training may be needed based on your major. Please email the administrator if you have any questions at irb@nsu.edu

The researcher must submit the required items through IRBNET by the 1st Monday of EACH month.

Required Documents:

CITI Training Certificates

Application

Survey(s)

Additional Pertinent Information

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 on the application. The researcher must consider the following when completing the application:

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 IRBNET 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 IRBNET. 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-NSU organization that is under governance of an IRB, certification from that IRB can substitute for NSU certification. If such certification is not available, individuals may become certified according to NIH procedures, even though they may not be affiliated with NSU. Before you can begin your research study, all persons associated with the research must submit their certificates to the IRB as an attachment on IRBNET. 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.

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 nonscientific 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.

The meetings for IRB are scheduled for the third Thursday of each month. If no proposals have been received the meeting may be cancelled. If proposals have been received, they will be reviewed under the Expedited Criteria.

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.

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 IRBNET 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 IRBNET 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 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.

Expedited. 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. 3/08/21

§46.104 Exempt research.

(a) Unless otherwise required by law or by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the categories in paragraph (d) of this section are exempt from the requirements of this policy, except that such activities must comply with the requirements of this section and as specified in each category.

(b) *Use of the exemption categories for research subject to the requirements of subparts B, C, and D.* Application of the exemption categories to research subject to the requirements of 45 CFR part 46, subparts B, C, and D, is as follows:

(1) *Subpart B.* Each of the exemptions at this section may be applied to research subject to subpart B if the conditions of the exemption are met.

(2) *Subpart C.* The exemptions at this section do not apply to research subject to subpart C, except for research aimed at involving a broader subject population that only incidentally includes prisoners.

(3) *Subpart D*. The exemptions at paragraphs [\(d\)\(1\)](#), [\(4\)](#), [\(5\)](#), [\(6\)](#), [\(7\)](#), and [\(8\)](#) of this section may be applied to research subject to subpart D if the conditions of the exemption are met. Paragraphs [\(d\)\(2\)\(i\)](#) and [\(ii\)](#) of this section only may apply to research subject to subpart D involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Paragraph [\(d\)\(2\)\(iii\)](#) of this section may not be applied to research subject to subpart D.

(c) [Reserved.]

(d) Except as described in paragraph [\(a\)](#) of this section, the following categories of human subjects research are exempt from this policy:

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.

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:

1. (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.
2. (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
3. (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 to make the determination required by [§46.111\(a\)\(7\)](#).

EXEMPT CATEGORY (3) (i) 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;

(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 [§46.111\(a\)\(7\)](#).

(ii) 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.

(iii) 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.

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:

1. (i) The identifiable private information or identifiable biospecimens are publicly available;
2. (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;
3. (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
4. (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch 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, 44 U.S.C. 3501 note, 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, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

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.

1. (i) 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 the research involving human subjects.
2. (ii) [Reserved]

EXEMPT CATEGORY (6) Taste and food quality evaluation and consumer acceptance studies:

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

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 [§46.111\(a\)\(8\)](#).

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 [§46.116\(a\)\(1\)](#) through [\(4\)](#), [\(a\)\(6\)](#), and [\(d\)](#);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with [§46.117](#);

(iii) An IRB conducts a limited IRB review and makes the determination required by [§46.111\(a\)\(7\)](#) 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

(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 abiding by 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, 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 gum 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 xrays 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.

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:**

IV. HUMAN SUBJECT REGULATIONS DECISION CHARTS

- [Chart 01](#): Is an Activity Human Subjects Research Covered by 45 CFR Part 46?
- [Chart 02](#): Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.104(d)?
- [Chart 03](#): Does Exemption 45 CFR 46.104(d)(1) for Educational Practices Apply?
- [Chart 04](#): Does Exemption 45 CFR 46.104(d)(2) for Educational Tests, Surveys, Interviews, or Observation of Public Behavior Apply?
- [Chart 05](#): Does Exemption 45 CFR 46.104(d)(3) for Benign Behavioral Interventions Apply?
- [Chart 06](#): Does Exemption 45 CFR 46.104(d)(4) for Secondary Research that Does Not Require Consent Apply?
- [Chart 07](#): Does Exemption 45 CFR 46.104(d)(5) for Public Benefit or Service Programs Apply?
- [Chart 08](#): Does Exemption 45 CFR 46.104(d)(6) for Food Taste and Acceptance Studies Apply?
- [Chart 09](#): Does Exemption 45 CFR 46.104(d)(7), Storage for Secondary Research for Which Broad Consent Is Required, Apply?
- [Chart 10](#): Does Exemption 45 CFR 46.104(d)(8) for Secondary Research for Which Broad Consent Is Required Apply?
- [Chart 11](#): Is Continuing Review Required Under 45 CFR 46.109(f)?
- [Chart 12](#): Waiver or Alteration of Informed Consent in Research Involving Public Benefit and Service Programs Conducted by or Subject to the Approval of State or Local Government Officials (45 CFR 46.116(e))
- [Chart 13](#): When Can Informed Consent Be Waived or Altered Under 45 CFR 46.116(f)?
- [Chart 14](#): Can Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?

Norfolk State University
The Office of Research and Innovation
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 Norfolk State University IRB. Although we serve a regulatory function, we take a collegial approach to consultation with researchers and their staff. Feel free to email us as you navigate the process. Please contact us at irb@nsu.edu as we are happy to respond to your questions.

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 Norfolk 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.

A. 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.

B. 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:
 - o blood sampling in minimal amounts
 - o review of records collected for non-research purposes (such as chart reviews)
 - o survey research

C. 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?

- Upload an Application for Approval of Research Involving Human Subjects through the IRB Information System called IRBNET (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 Norfolk 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 NSU have a process in place if the PI use incentives such as gift cards, money, or merchandise?

- Yes, if merchandise, gift cards, or money, etc are distributed you must provide the date given, a pseudo name, the type of incentive given (merchandise, gift card, or money) the amount, and how it was given. Appendix F is a template that should be used to accompany the annual **AND** closeout report.

Does NSU have a consent form template?

- Yes, a common consent form template is available. Please email the administrator at irb@nsu.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:

- (1) The research involves no more than minimal risk to the subjects;
 - (2) The waiver will not adversely affect the rights and welfare of the subjects;
 - (3) The research could not practicably be carried out without the waiver;
 - (4) 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.

Where do I send the application?

- The principal investigator (PI) MUST upload all documents on IRBNET. Please attach consent forms, advertisement flyers, etc. in IRBNET. The administrator will review the study's documentation in IRBNET 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 Norfolk 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.

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 submitted by the 1st Monday of the month will receive communication after the board meets on the 3rd Thursday of the month.
- If submissions are submitted after the 1st Monday of the month, they will be reviewed the next month.
- 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 IRBNET 45 days prior to it expiring.

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.

Appendix A

Norfolk State University IRB Authorization Agreement

This agreement authorizes to rely on the **Norfolk State University (NSU) Institutional Review Board (IRB)** for the review of the research noted below.

The Norfolk State University (Institution A)

OHRP Federal Wide Assurance (FWA) #:

OHRP Federal Wide Assurance (FWA) #:

(Institution B) Name:

OHRP Federal Wide Assurance (FWA) #: [Click here to enter text.](#)

Protocol IRB Number from Reviewing IRB: [Click here to enter text.](#)

Title of Study: [Click here to enter text.](#)

Principal Investigator at NSU: [Click here to enter text.](#)

Principal Investigator at Institution B: [Click here to enter text.](#)

The following terms are agreed upon by all parties and attested to by signature below:

Responsibilities of Reviewing IRB: NSU IRB, Office of Research and Innovation

1. Maintain an FWA with OHRP and maintain IRB registration with OHRP, as applicable.
2. Conduct initial review and continuing oversight in compliance with applicable federal regulations and state and local requirements to meet the human subject protection requirements of the FWA of Institution B.
3. Maintain membership of the IRB(s) that meets applicable federal regulations and human subject protection requirements of the FWA.
4. Make available to Institution B, the NSU policies and procedures.
5. Conduct reviews of initial, continuing, and amendment submissions; unanticipated problem reports; and any other documentation submitted by the Principal Investigator.
6. Maintain and upon request or provided through the principal investigator, make accessible to Institution B _____ the IRB application, protocol reviews, letters to Principal Investigators, approvals and disapprovals, and approved informed consent documents.
7. Investigate and manage any event that appears to rise to the level of an unanticipated problem involving risks to subjects or others and/or serious or continuing noncompliance.
8. Notify Institution B promptly if a determination of serious or continuing noncompliance is found, and the corrective actions deemed necessary by the NSU IRB. The NSU IRB may request that Institution B conduct its own investigation and report back to the NSU IRB.
9. If the NSU IRB determines that an event must be reported to oversight entities, such as ORHP, it will notify Institution B in advance and provide the opportunity for Institution B to review and comment on the report before it is sent. In addition, the NSU IRB will notify institution B of any correspondence it receives regarding this study from OHRP and /or other regulatory agency.
10. Notify Institution B promptly if it decides to suspend, disapprove, or terminate a study covered by this agreement.
11. Notify Institution B of any lapses of approval.
12. Maintain a post approval monitoring program to ensure compliance with IRB approved protocols and adherence to regulatory requirements.

Norfolk State University IRB Authorization Agreement

13. Provide a mechanism for research subjects enrolled at Institution B to address concerns or ask questions pertaining to the rights of research subjects.

Responsibilities of Relying IRB: [Click here to enter Institution B name.](#) **(Institution B)**

1. Maintain a Federal Wide Assurance (FWA) and human research protection program as required by the DHHS OHRP.
2. Educate and train its investigators to perform research in compliance with human subjects' protection regulations.
3. Provide the **NSU IRB** with information pertaining to any specific requirements of local laws, regulations, policies, standards or other factors applicable to the review or conduct of research.
4. Ensure that the investigators and other personnel at Institution B who are involved in the study are appropriately qualified and meet the relying site's standards for eligibility to conduct research. This includes, but is not limited to, having the required professional staff appointments, credentialing, for their assigned role in the study.
5. Maintain policies and procedures at an institutional level to address Conflicts of Interest in research that comply with DHHS regulations. Ensure that Institution B investigators and study personnel disclose financial interests according to Institution B policy. Ensure that conflicts of interest are reviewed and a management plan is implemented, if required by Institution B policy. Provide all management plans to the **NSU IRB** for review. Ensure compliance of all management plans related to the study. If Institution B does not maintain policies and procedures compliant with DHHS requirements, ensure that all research personnel identified as Conflict of Interest Investigators complete UVA's financial interest disclosure requirements; cooperate with **NSU IRB** in the development of management plans, if applicable; and adhere to any associated management plans.
6. Perform local review by other local ancillary committee reviews as applicable per Institution B policies, such as radiation safety or pharmacy. Provide any relevant results of the reviews that may impact the conduct of this study as part of the information provided to the **NSU IRB**.
7. Assure that research activities at Institution B are not initiated until IRB approval is obtained.
8. Notify the **NSU IRB** within twenty-four hours of becoming aware of a suspension or restriction of an Institution B investigator or other personnel involved in research.
9. Maintain policies and procedures for dealing with injuries to human research subjects and share these policies and procedures with the **NSU IRB** as requested. To the extent of its own policies, Institution B will provide or arrange for treatment of injuries to human subjects, if any, that may result from study-related procedures that occur at Institution B. This agreement does not preclude the institutions from making other arrangements between or among them at the outset of a specific study to allocate differently the responsibility for costs associated with injuries to human subjects that might occur in the course of the study.
10. Ensure a mechanism exists by which complaints about research can be made by local study subjects or others. Promptly report such complaints to the UVA IRB-SBS if they meet the criteria of a potential unanticipated problem as defined by the **NSU IRB** policies.
11. Cooperate with and use all reasonable efforts to ensure Institution B investigators' cooperation with any inquiry by the UVA post approval monitors relating to the study.
12. Inform the **NSU IRB** if the site plans to no longer rely upon the UVA IRB-SBS for IRB review.

Norfolk State University IRB Authorization Agreement

13. Notify the **NSU IRB** of any correspondence regarding this study to or from OHRP and /or other regulatory agency.

Norfolk State University IRB Authorization Agreement

Institution A: NSU IRB Investigator Responsibilities

1. Ensure all Institution B research personnel designated as Conflict of Interest Investigators complete UVa's financial interest disclosure requirements unless the Institution B personnel will adhere to Institution B conflict of interest policies that are compliant with DHHS requirements.
2. Promptly provide Institution B PI with:
 - a. Current approved protocol and consent documents;
 - b. Approved modifications, amendments or changes to research protocols; and
 - c. Approval of continuing reviews and reviews of unanticipated problems;
3. Notify Institution B PI of standards and guidelines for reporting any post approval events such as adverse events, subject injuries, unanticipated problems, and protocol violations. Collect reports from Institution B of any unanticipated problems, deviations, suspensions and terminations, non-compliance, subject complaints, and submit such reports to the **NSU IRB** per reporting requirements.
4. Notify Institution B investigator promptly of any unanticipated problems involving risks to subjects or others as determined by the IRB of record.
5. Collect required information from Institution B necessary for completing continuing review submissions.
6. Notify Institution B investigator promptly about any lapses of approval. Forward to the **NSU IRB** any request from the Institution B investigator for continuation of a specific research subject on a protocol during a lapsed period of approval.

Institution B: Norfolk State University Investigator Responsibilities

1. Provide the **NSU IRB** with:
 - a. The list of research personnel engaged in the conduct of research;
 - b. Evidence of training for all engaged research personnel, including the investigator; and
 - c. Any other information required for IRB review.
2. Assure that all research activities at Institution B are not initiated until all IRB and funding-related requirements are completed.
3. Conduct protocols and obtain informed consent as approved by the IRB and in compliance with the UVa IRB-SBS policies and procedures and all relevant federal, state, and local regulations for human subjects research.
4. Provide any information requested by the **NSU IRB** that may be necessary for the continuing review process. This may include information regarding subject recruitment, summary of all enrolled subjects, screen failures, minor violations, and all other information needed for continuing review.
5. Notify the **NSU IRB** within five days of becoming aware of potential unanticipated problems involving risk to subjects or others or of serious or continuing non-compliance.
6. If at any time IRB approval lapses, cease all human subjects research work related to the expired protocol. Notify the **NSU IRB** of any subjects who are already enrolled who may be harmed if research ceases.
7. Promptly cooperate with any investigations of serious or continuing non-compliance or unanticipated problems.
8. Promptly cooperate with any post approval monitoring conducted by NSU. Such cooperation will include, but is not limited to, providing research records and related information and meeting with institutional research representatives upon request.

Norfolk State University IRB Authorization Agreement

9. Maintain records of all research and related activities for at least six years and longer if required by sponsor or law, following completion of research.
10. Cooperate with UVA in reporting and resolving any conflicts of interest reported by Institution B identified conflict of interest investigators, including but not limited to entering into management plans, as required by NSU.

The Officials signing below agree that [Click here to enter Institution B name](#). may rely on the Norfolk State University Institutional Review Board under the terms of this agreement.

- *This Agreement will become effective upon the date of the last signature below. The Agreement will remain in effect until such time that any institution provides a 30 day written notice of amendment or termination to the other institution.*
 - *This document must be kept on file at both institutions and provided to the Department of Health and Human Services Office of Human Research Protections, upon request.*
-

Signatory Official, The Rector and Visitors of the University of Virginia

I agree and accept the responsibilities under this agreement as outlined above:

FWA Institutional Official (or designee) Signature:

Date:

Name: Aixi Zhou, Ph.D., P.E.

Title: Vice Provost for Research and Innovation

Address: MCAR, Suite 602 | 700 Park Avenue, Norfolk, VA 23504

Phone: (757) 278-4112

Email: azhou@nsu.edu

University of Virginia Principal Investigator

I agree and accept the responsibilities under this agreement as outlined above:

PI Signature:

Date:

Name: [Click here to enter text.](#)

Title: [Click here to enter text.](#)

Email: [Click here to enter text.](#)

Norfolk State University IRB Authorization Agreement

Norfolk State University Signatory Official

I agree and accept the responsibilities under this agreement as outlined above:

Date:

FWA Institutional Official (or designee) Signature:

Name: [Click here to enter text.](#)

Title: [Click here to enter text.](#)

Address: [Click here to enter text.](#)

Phone: [Click here to enter text.](#)

Email: [Click here to enter text.](#)

Norfolk State University Principal Investigator

I agree and accept the responsibilities under this agreement as outlined above:

PI Signature:

Date:

Name: [Click here to enter text.](#)

Title: [Click here to enter text.](#)

Address: [Click here to enter text.](#)

Phone: [Click here to enter text.](#)

Email: [Click here to enter text.](#)

Appendix B



Institutional Review Board (IRB)

Human Subjects IRB Form-Internal OSP Form 103

Study Title

--

Principal Investigator (PI)

The PI must be an NSU faculty or staff member who will serve as the project supervisor and be held accountable for all aspects of the project. Students cannot be listed as PIs.

First Name:	Last Name:	
Telephone:	E-mail:	
Office Address:		
City:	State:	Zip:
Department:	Unit, School, or College:	
CITI Completion Date:		

Investigators

Investigator(s): Individuals who are directly responsible for any of the following: the project's design, implementation, consent process, data collection, and/or data analysis.
 Investigators must complete the CITI Basic Human Subjects Protection Training.

First Name:	Last Name:	
Telephone:	Email:	
Office Address:		
City:	State:	Zip:
Department:	College:	
Affiliation: <input type="checkbox"/> Faculty <input type="checkbox"/> Graduate Student <input type="checkbox"/> Undergraduate Student <input type="checkbox"/> Staff <input type="checkbox"/> Other:		
CITI Completion Date:		

First Name:	Last Name:	
Telephone:	Email:	
Office Address:		
City:	State:	Zip:
Department:	College:	
Affiliation: <input type="checkbox"/> Faculty <input type="checkbox"/> Graduate Student <input type="checkbox"/> Undergraduate Student <input type="checkbox"/> Staff <input type="checkbox"/> Other:		
CITI Completion Date:		

Upload a copy of the Additional Investigators form if more rows are needed.

1. Type of Research

1.a. This study is being conducted as part of (check all that apply):

- | | |
|--|--|
| <input type="checkbox"/> Faculty Research | <input type="checkbox"/> Non-Thesis Graduate Student Research |
| <input type="checkbox"/> Doctoral Dissertation | <input type="checkbox"/> Honors or Individual Problems Project |
| <input type="checkbox"/> Masters Thesis | <input type="checkbox"/> Other: |

2. Funding

2.a. Funding Status:

- Research is **not funded** (go to 3)
 Research is **funded** (go to 2b)
 Funding decision is pending (funding decision has not been made) (go to 2b)

2.b. Type of funding source: (Check all that apply)

- Federal Grant or Contract
 State or Municipal Grant or Contract
 Private Foundation
 Corporate contract
 Other (specify):

2.c. Agency & Funding Information

Funding Agency Name:

Agency Proposal Number:

Grant Start & End Date (MM/DD/YY):

2.d. List the point of contact at the funding source:

Name:

Mailing Address:

Telephone:

Email:

3. Research Dates

3.a. Date you wish to start research (MM/DD/YY):

3.b. Date you plan to end research (MM/DD/YY):
(End date for data collection and analysis)

4. Research Location

4.a. Where will the experiment be conducted? (Check all that apply)

- On Campus (Building and Room Number):

<input type="checkbox"/> Off-Campus	(Site Name and Street Address):
-------------------------------------	---------------------------------

5. Human Subjects Review

5.a. Has this project been reviewed by any other committee (university, governmental, private sector) for the protection of human research subjects?

Yes
 No **(If no, go to 6)**

5.b. List the other committee(s) that have reviewed this project and indicate which IRB is serving as the primary IRB

6. Study Purpose

6.a. Describe the rationale for the research project:

7. Subjects

7.a. What will be the maximum number of subjects in the study?			
7.b. Indicate the approximate number of:	Males:	Females:	
7.c. What is the age of subjects? (Check all that apply)			
<input type="checkbox"/> Children (Birth-17 years old)	<input type="checkbox"/> Adults (18-89 years old)	<input type="checkbox"/> Elderly (90+ years and older)	
7.d. Will students be enrolled in the study? (Check all that apply) <small>*If students are under 18 years old, parental consent must be obtained</small>			
<input type="checkbox"/> Undergraduate students	Department:	<input type="checkbox"/> Advanced students	Department:
7.e. Provide rationale for the choice of subjects. Enumerate any additional defining characteristics, including age, of the subject population. (e.g., symptomatology, history, socio-economic status).			

8. Vulnerable Subjects

8.a. Are research subjects being used whose ability to give informed voluntary consent may be in question? (e.g., children, persons with AIDS, mentally disabled, psychiatric patients, prisoners.)

- Yes
 No

8.b. What type of vulnerable subjects are being enrolled? (Check all that apply)

- | | |
|--|--|
| <input type="checkbox"/> Critically Ill Patients | <input type="checkbox"/> Mentally Disabled or Cognitively Impaired Individuals |
| <input type="checkbox"/> Prisoners | <input type="checkbox"/> Physically Handicapped |
| <input type="checkbox"/> Pregnant Women | <input type="checkbox"/> Children |
| <input type="checkbox"/> Other (describe): | |

If yes, explain the procedures to be employed to enroll them and to ensure their protection:

9. Recruitment

Copies of all recruitment materials must be attached to this application.

9.a. Check all types of recruitment that will be utilized in the study.

- | | |
|---|--|
| <input type="checkbox"/> Internet | <input type="checkbox"/> Letters |
| <input type="checkbox"/> Newspaper/radio/television advertising | <input type="checkbox"/> Posters/brochures |
| <input type="checkbox"/> Other: Flyer | |

9.b. What methods will be used to identify and recruit prospective subjects? Specify the source of potential subjects. If an outside agency or organization will recruit subjects on the investigator's behalf, a support letter must be included.

10. Inclusion and Exclusion Criteria

10.a. Are subjects equitably chosen for participation in the study? (no one group is excluded without justification)

Yes

No (If no, specify criteria and justify in detail below.)

Comments:

10.b. Does the study require special evaluation and screening of potential subjects to determine their appropriateness for inclusion in the study?

Yes (If yes, elaborate on the screening process below and attach the screening questionnaire.)

No

Screening Criteria:

10.c. Outline the inclusion and exclusion criteria for the study:

Inclusion:

Exclusion:

11. Experimental Procedures

11.a. Describe the experimental procedures that will be followed. (Include a succinct, but comprehensive statement of the methodology relating to the human subjects. You are encouraged to include a discussion of statistical procedures used to determine the sample size.)

11.b. Will any aversive or painful procedures be employed (e.g., shock, the threat of shock or punishment, experimentally induced stress?)

- Yes **(If yes, specify and justify in detail below.)**
 No

Comments:

11.c. Will the deliberate deception of research participants be involved as part of the experimental procedure?

- Yes **(If yes, explain the nature of the deception, why it is necessary, any possible risks that may result from the deception, and the nature of the debriefing with specific reference to the deception.)**
 No

Comments:

12. Compensation

12.a. How much time will be required of each subject?

12.b. Will research subjects receive course credit for participating in the study?

- Yes **(If yes, please explain in comments section.)**
 No

Comments:

12.c. Are there any other forms of compensation that may be used? (e.g. Money, Gift Cards)

- Yes **(If yes, please explain in comments section.)**
 No

Comments:

13. Informed Consent

13.a. Do you intend to obtain informed consent from subjects?

- Yes **(If yes, please answer 13.b.)**
 No **(If no, complete Appendix F: Request for Waiver of Consent Form)**

13.b. Describe the procedures that will be used to obtain Informed Consent and attach the Informed Consent Document (follow the guidelines for preparation of the University Informed Consent Form).

Note: Subjects MUST be given a description of the procedures and rationale for the study to the extent possible. The benefits and ANY risks associated with participating in the study MUST be enumerated. The subjects MUST be informed of their right to terminate the experiment at any time. If there is no risk associated with the study and participants' signature on the informed consent sheet is the only identifying information about the name of the subject, then the subjects' signature may not be necessary.

14. Risks

14.a. What are potential risks of the research? (Check all that apply)

<input type="checkbox"/> Physical harm	<input type="checkbox"/> Psychological harm
<input type="checkbox"/> Release of confidential information	<input type="checkbox"/> Other:

According to 45 CFR 46.102 (i), Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

- What is the investigator's overall assessment of the risk classification of the study? (none, minimal, or more than minimal risk)?

Risk is:

14.b. Describe any potential risks to subjects for the activities proposed and describe the steps that will be taken to minimize the risks. Include any risks to the subject's physical well-being, privacy, dignity, emotions, employability, and criminal and legal status. A detailed, comparative statement of the risk (harm or likelihood) must also be described in the consent form.

15. Benefits

15.a. Assess the potential benefits that may accrue to the individual subject as well as to others as a result of the proposed study. Do the potential benefits justify the possible risks involved? Although you may mention general benefits to society, such speculative benefits should not be presented to a subject as a direct benefit for informed consent.

16. Protection of Anonymity

16.a. Describe in detail the procedures for protecting the anonymity (meaning that no one will ever be able to know the names) of the research subjects. If anonymity is impossible, then describe in detail the procedures for safeguarding data and confidential records. These procedures relate to how well you reduce the risk that a subject may be exposed or associated with the data.

17. Drugs or Devices

17.a. Will any drugs, devices, or chemical biological agents be used with the subjects?

- Yes (If yes, please attach Appendix G: Drugs, Agents, and Devices Form)
 No

18. Biological Materials

18.a. Will this research involve the collection, analysis, or banking of human biological materials (cells, tissues, fluids, DNA?)

- Yes (If yes, please attach Appendix H: Biological Materials Form)
 No

19. Training

19.a. Briefly explain the nature of the training and supervision of anyone who is involved in the actual data collection, research design, or in conducting the research. This information should be sufficient for the IRB to determine that the PI and investigators possess the necessary skills or qualifications to conduct the study.

PLEASE NOTE:

- ◆ You may begin research when the University Institutional Review Board gives you final WRITTEN notice of its approval.
- ◆ You MUST inform the committee of ANY adverse event, changes in the method, personnel, funding, or procedure.
- ◆ At any time the committee reserves the right to re-review a research project, to request additional information, to monitor the research for compliance, to inspect the data and consent forms, to interview subjects that have participated in the research, and if necessary to terminate a research investigation.

Principal Investigator Signature

Date

Department Head/Dean Print Name

Department Head/Dean Signature

Date

Appendix C



Institutional Review Board (IRB) Form 104

Human Subjects IRB Application for External Investigator

Study Title

External Investigator (EI)

The EI who is directly responsible for the project's design, implementation, consent process, data collection, and/or data analysis, must complete the CITI Basic Human Subjects Protection Training. The EI cannot be listed as the PI and must have an NSU Representative too serve as the Project Supervisor/PI and be held accountable for all aspects of the project.

First Name:		Last Name:	
Work Phone:	Mobil Phone:	E-mail:	
University/Business /Organization:			
Title and Affiliation:		Department:	
Full Address:			
CITI Completion Date:			

NSU Principal Investigator (Internal Representative)

Principal Investigator(s): The PI must be an NSU Faculty or Staff member who will serve as the Project Supervisor and be held responsible for all aspects of the project, to include the IRB Proposal submission in IRBNet. Students cannot be listed as PI. All PIs must complete the CITI Basic Human Subjects Protection Training.

First Name:		Last Name:	
Telephone:		Email:	
Office Address:			
City:	State:	Zip:	
Department:		College:	
Affiliation: <input type="checkbox"/> Faculty <input type="checkbox"/> Graduate Student <input type="checkbox"/> Undergraduate Student <input type="checkbox"/> Staff <input type="checkbox"/> Other:			
CITI Completion Date:			

Additional Investigator

First Name:		Last Name:	
Telephone:		Email:	
Office Address:			
City:	State:	Zip:	
Department:		College:	
Affiliation: <input type="checkbox"/> Faculty <input type="checkbox"/> Graduate Student <input type="checkbox"/> Undergraduate Student <input type="checkbox"/> Staff <input type="checkbox"/> Other:			
CITI Completion Date:			

[Upload a copy of the Additional Investigators form if more rows are needed.](#)

1. Type of Research

1.a. This study is being conducted as part of (check all that apply):

- | | |
|--|--|
| <input type="checkbox"/> Faculty Research | <input type="checkbox"/> Non-Thesis Graduate Student Research |
| <input type="checkbox"/> Doctoral Dissertation | <input type="checkbox"/> Honors or Individual Problems Project |
| <input type="checkbox"/> Masters Thesis | <input type="checkbox"/> Other: |

2. Funding

2.a. Funding Status:

- Research is **not funded** (go to 3)
 Research is **funded** (go to 2a)
 Funding decision is pending (funding decision has not been made) (go to 2a)

2.b. Type of funding source: (Check all that apply)

- Federal Grant or Contract
 State or Municipal Grant or Contract
 Private Foundation
 Corporate contract
 Other (specify):

2. c. Funding Agency Information:

Funding Agency Name:

Agency Proposal Number

Grant Start & End Date (MM/DD/YY):

2.d. List the point of contact at the funding source:

Name:

Mailing Address:

Telephone:

Email:

3. Research Dates

3.a. Date you wish to start research (MM/DD/YY):

3.b. Date you plan to end research (MM/DD/YY):
(End date for data collection and analysis)

4. Research Location

4.a. Where will the experiment be conducted? (Check all that apply)

- On Campus (Building and Room Number):

<input type="checkbox"/> Off-Campus	(Site Name and Street Address):
-------------------------------------	---------------------------------

5. Human Subjects Review

5.a. Has this project been reviewed by any other committee (university, governmental, private sector) for the protection of human research subjects?

Yes
 No **(If no, go to 6)**

5.b. List the other committee(s) that have reviewed this project and indicate which IRB is serving as the primary IRB

6. Study Purpose

6.a. Describe the rationale for the research project:

7. Subjects

7.a. What will be the maximum number of subjects in the study?			
7.b. Indicate the approximate number of:	Males:	Females:	
7.c. What is the age of subjects? (Check all that apply)			
<input type="checkbox"/> Children (Birth-17 years old)	<input type="checkbox"/> Adults (18-89 years old)	<input type="checkbox"/> Elderly (90+ years and older)	
7.d. Will students be enrolled in the study? (Check all that apply) <small>*If students are under 18 years old, parental consent must be obtained</small>			
<input type="checkbox"/> Undergraduate students	Department:	<input type="checkbox"/> Advanced students	Department:
7.e. Provide rationale for the choice of subjects. Enumerate any additional defining characteristics, including age of the subject population. (e.g., symptomatology, history, socio-economic status).			

8. Vulnerable Subjects

8.a. Are research subjects being used whose ability to give informed voluntary consent may be in question?(e.g., children, persons with AIDS, mentally disabled, psychiatric patients, prisoners.)

- Yes
 No

8.b. What type of vulnerable subjects are being enrolled? (Check all that apply)

- | | |
|--|--|
| <input type="checkbox"/> Critically Ill Patients | <input type="checkbox"/> Mentally Disabled or Cognitively Impaired Individuals |
| <input type="checkbox"/> Prisoners | <input type="checkbox"/> Physically Handicapped |
| <input type="checkbox"/> Pregnant Women | <input type="checkbox"/> Children |
| <input type="checkbox"/> Other (describe): | |

If yes, explain the procedures to be employed to enroll them and to ensure their protection:

9. Recruitment

Copies of all recruitment materials must be attached to this application.

9 a. Check all types of recruitment that will be utilized in the study.

- | | |
|---|--|
| <input type="checkbox"/> Internet | <input type="checkbox"/> Letters |
| <input type="checkbox"/> Newspaper/radio/television advertising | <input type="checkbox"/> Posters/brochures |
| <input type="checkbox"/> Other: Flyer | |

9.b. What methods will be used to identify and recruit prospective subjects? Specify the source of potential subjects. If an outside agency or organization will recruit subjects on the investigator's behalf, a support letter must be included.

10. Inclusion and Exclusion Criteria

10.a. Are subjects equitably chosen for participation in the study? (no one group is excluded without justification)

Yes

No (If no, specify criteria and justify in detail below.)

Comments:

10.b. Does the study require special evaluation and screening of potential subjects to determine their appropriateness for inclusion in the study?

Yes (If yes, elaborate on the screening process below and attach the screening questionnaire.)

No

Screening Criteria:

Outline the inclusion and exclusion criteria for the study:

Inclusion:

Exclusion:

11. Experimental Procedures

11.a. Describe the experimental procedures that will be followed. (Include a succinct, but comprehensive statement of the methodology relating to the human subjects. You are encouraged to include a discussion of statistical procedures used to determine the sample size.)

11.b. Will any aversive or painful procedures be employed (e.g., shock, the threat of shock or punishment, experimentally induced stress?)

Yes **(If yes, specify and justify in detail below.)**

No

Comments:

11.c. Will the deliberate deception of research participants be involved as part of the experimental procedure?

Yes **(If yes, explain the nature of the deception, why it is necessary, any possible risks that may result from the deception, and the nature of the debriefing with specific reference to the deception.)**

No

Comments:

12. Compensation

12.a. How much time will be required of each subject?

12.b. Will research subjects receive course credit for participating in the study?

Yes **(If yes, please explain in comments section.)**

No

Comments:

12.c. Are there any other forms of compensation that may be used? (e.g. Money, Gift Cards)

Yes **(If yes, please explain in comments section.)**

No

Comments:

13. Informed Consent

13.a. Do you intend to obtain informed consent from subjects?

Yes **(If yes, please answer question 13.b.)**

No **(If no, complete Appendix F: Request for Waiver of Consent Form)**

13.b. Describe the procedures that will be used to obtain Informed Consent and attach the Informed Consent Document (follow the guidelines for preparation of the University Informed Consent Form).

Note: Subjects MUST be given a description of the procedures and rationale for the study to the extent possible. The benefits and ANY risks associated with participating in the study MUST be enumerated. The subjects MUST be informed of their right to terminate the experiment at any time. If there is no risk associated with the study and participants' signature on the informed consent sheet is the only identifying information about the name of the subject, then the subjects' signature may not be necessary.

14. Risks

14.a. What are potential risks of the research? (Check all that apply)

- | | |
|--|---|
| <input type="checkbox"/> Physical harm | <input type="checkbox"/> Psychological harm |
| <input type="checkbox"/> Release of confidential information | <input type="checkbox"/> Other: |

According to 45 CFR 46.102 (i), Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

- What is the investigator's overall assessment of the risk classification of the study? (none, minimal, or more than minimal risk)?

Risk is:

14.b. Describe any potential risks to subjects for the activities proposed and describe the steps that will be taken to minimize the risks. Include any risks to the subject's physical well-being, privacy, dignity, emotions, employability, and criminal and legal status. A detailed, comparative statement of the risk (harm or likelihood) must also be described in the consent form.

15. Benefits

15.a. Assess the potential benefits that may accrue to the individual subject as well as to others as a result of the proposed study. Do the potential benefits justify the possible risks involved? Although you may mention general benefits to society, such speculative benefits should not be presented to a subject as a direct benefit for informed consent.

16. Protection of Anonymity

16.a. Describe in detail the procedures for protecting the anonymity (meaning that no one will ever be able to know the names) of the research subjects. If anonymity is impossible, then describe in detail the procedures for safeguarding data and confidential records. These procedures relate to how well you reduce the risk that a subject may be exposed or associated with the data.

17. Drugs or Devices

17.a. Will any drugs, devices, or chemical biological agents be used with the subjects?

- Yes **(If yes, please attach Appendix G: Drugs, Agents, and Devices Form)**
- No

18. Biological Materials

18.a. Will this research involve the collection, analysis, or banking of human biological materials (cells, tissues, fluids, DNA?)

- Yes **(If yes, please attach Appendix H: Biological Materials Form)**
- No

19. Training

19.a. Briefly explain the nature of the training and supervision of anyone who is involved in the actual data collection, research design, or in conducting the research. This information should be sufficient for the IRB to determine that the PI and investigators possess the necessary skills or qualifications to conduct the study.

PLEASE NOTE:

- ◆ You may begin research when the University Institutional Review Board gives you final WRITTEN notice of its approval.
- ◆ You MUST inform the committee of ANY adverse event, changes in the method, personnel, funding, or procedure.
- ◆ At any time the committee reserves the right to re-review a research project, to request additional information, to monitor the research for compliance, to inspect the data and consent forms, to interview subjects that have participated in the research, and if necessary to terminate a research investigation.

External Investigator Signature

Date

NSU Principal Investigator (Internal Representative) Signature

Date

NSU Department Head/Dean Print Name

NSU Department Head/Dean Signature

Date

Save Form

Reset Form

Appendix D



Institutional Review Board (IRB) Annual and Closeout Report Form

NSU Researcher Information

Principal Investigator _____

Select One: Faculty Staff Student

School/Unit _____ Department/Center _____

Phone # _____ Email _____

Campus Address _____

External Investigator Information

Principal Investigator _____

Select One: Faculty Staff Student

School/Unit _____ Department/Center _____

Phone # _____ Email _____

Campus Address _____

1. Project Information

Title _____

Brief Description
Attach an additional sheet if necessary .

Funding Agency _____

Do you wish to continue this research? Yes Post the current consent form to this project in IRBNet.
No This will be considered the closeout report for the project (not for closure to patient entry).



Institutional Review Board (IRB) Annual and Closeout Report Form

II. Report Data

1. Report Period _____ to _____
MM/DD/YY (up to 1 year)

2. Is this research project ongoing at this site? Yes No Termination Date: _____

3. Did you actively enroll subjects or collect data during the report period? Yes No

4. Please provide the following information for this site:

Required Information	Totals for the Report Period
Number of Subjects Enrolled	
Number of Subjects Enrolled by Category (federal government reporting requirement)	
Males	
Females	
Black, Non-Hispanic	
American Indian/Alaskan Native	
Asian/Pacific Islander	
Hispanic	
White, Non-Hispanic	
Other or Unknown	
Number of Subjects Withdrawn from the Study	

Required Information	Totals
Total Number of Subjects Enrolled Since the Initiation of This Project	
Number of Subjects Engaged in the Study at the Present Time	
Number of Subjects Withdrawn from the Study Since Initiation	

5. Total Number of Subjects Enrolled Across All Sites to Date _____

6. Is the study closed to subject entry? Yes No

7. If yes, date of closure (day/month/year): _____

8. Is closure permanent? Yes No

9. Please describe any medical, legal or practical difficulties that were encountered during the reporting period of the study aside from adverse events. Difficulties may include complaints of subjects, logistic problems of performance, or any difficulties that may pertain to the rights of these subjects.
Attach an additional sheet if necessary.

10. Number of local adverse events: _____

11. Number of non-local adverse events: _____

12. Please provide a brief description of trends in adverse events. Adverse events must be reported to the NSU IRB within five days of the investigator being notified. If there are events that have not been reported to the IRB, submit notification with a brief explanation via IRBNet.
Attach an additional sheet if necessary.



Institutional Review Board (IRB) Annual and Closeout Report Form

	Response	
	Yes	No
13. Has the protocol or consent form changed in any way since the last approval? If yes, use IRBNet to submit to a copy of any amendment(s) not previously submitted.	<input type="checkbox"/>	<input type="checkbox"/>
14. Has any new information become available during the course of the research that may affect the subject's willingness to continue participation in the study?	<input type="checkbox"/>	<input type="checkbox"/>

If yes, explain:

	Response	
	Yes	No
15. Was new information provided to subjects? If yes, use IRBNet to submit documentation.	<input type="checkbox"/>	<input type="checkbox"/>
16. Is there recent information, especially regarding risks associated with the research, that the IRB should be aware of when conducting the continuing review? If yes, use IRBNet to submit the pertinent information.	<input type="checkbox"/>	<input type="checkbox"/>

Please use IRBNet to submit a brief overview of research results/observations obtained to date. If applicable, include local and multisite information and one copy of any publications that have resulted from this research.

NSU Principal Investigator/NSU Representative Signature Date

External Investigator Signature (if applicable) Date

NSU Department Head/Dean Print Name Signature Date

Reset Form

Save Form

Appendix E



Institutional Review Board (IRB) Form 105

Human Subjects IRB - Additional Investigators

Study Title

Additional Investigators			
Investigator(s): Individuals who are directly responsible for any of the following: the project's design, implementation, consent process, data collection, and/or data analysis. Investigators must complete the CITI Basic Human Subjects Protection Training.			
First Name:	Middle Initial:	Last Name:	
Email:		Telephone:	
Office Address:			
City:	State:	Zip:	
Department:		College, School or Unit:	
CITI Completion Date:			
First Name:	Middle Initial:	Last Name:	
Email:		Telephone:	
Office Address:			
City:	State:	Zip:	
Department:		College, School or Unit:	
Affiliation: <input type="checkbox"/> Faculty <input checked="" type="checkbox"/> Graduate Student <input type="checkbox"/> Undergraduate Student <input type="checkbox"/> Staff <input type="checkbox"/> Other:			
CITI Completion Date:			
First Name:	Middle Initial:	Last Name:	
Email:		Telephone:	
Office Address:			
City:	State:	Zip:	
Department:		College, School or Unit:	
Affiliation: <input type="checkbox"/> Faculty <input type="checkbox"/> Graduate Student <input type="checkbox"/> Undergraduate Student <input type="checkbox"/> Staff <input type="checkbox"/> Other:			
CITI Completion Date:			

Appendix F

