



NORFOLK STATE UNIVERSITY INSTITUTIONAL REVIEW BOARD

Policy Title: Norfolk State University Institutional Review Board (IRB)

Policy Type: Administrative

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Responsible Office: Graduate Studies and Research

Responsible Executive: Provost and Vice President for Academic Affairs

Applies to: Full-time instructional and administrative/professional faculty, students, and staff

POLICY STATEMENT

The NSU Institutional Review Board (IRB) is a committee established in accordance with Federal Policy for the Protection of Human Subjects (45 CFR 46). The purpose of the IRB is to help protect the rights and welfare of human participants in research conducted under the auspices of Norfolk State University.

The guiding ethical principles of the IRB are respect for persons, beneficence and justice. These principles are embodied in the *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Vol 2. The Commission, 1978).

The policies and procedures presented herein govern human subjects research and the requirements for the review and approval of research by the Norfolk State University Institutional Review Board.

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DEFINITIONS¹

Word/Term:

Certification means the official notification by the institution to the supporting Federal department or agency component, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

Clinical trial means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Department or agency head means the head of any Federal department or agency, for example, the Secretary of HHS, and any other officer or employee of any Federal department or agency to whom the authority provided by those regulations found at Title 45, Part 46 of the Code of Federal Regulations to the department or agency head has been delegated.

Federal department or agency refers to a federal department or agency (the department or agency itself rather than its bureaus, offices or divisions) that takes appropriate administrative action to make this policy applicable to the research involving human subjects it conducts, supports, or otherwise regulates (*e.g.*, the U.S. Department of Health and Human Services, the U.S. Department of Defense, or the Central Intelligence Agency).

Human subject means a living individual about whom an investigator (whether professional or student) conducting research:

- (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Intervention includes both physical procedures by which information or biospecimens are gathered (*e.g.*, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (*e.g.*, a medical record).

Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.



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An identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Institution means any public or private entity, or department or agency (including federal, state, and other agencies).

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

IRB approval means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, *legally authorized representative* means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

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.

Public health authority means an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research:

- (1) Scholarly and journalistic activities (*e.g.*, oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- (2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health



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

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

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

Written, or in writing, for purposes of this part, refers to writing on a tangible medium (e.g., paper) or in an electronic format.

¹(DHHS regulations, at 45 CFR Part 46.102 Subpart A) [45 CFR 46 of the July 19, 2018 edition of the e-Code of Federal Regulations](#)

CONTACT(S)

The Provost and Vice President for Academic Affairs is responsible for the implementation of this policy, and obtaining approval for any revisions as required by BOV Policy # 01 (2014) Creating and Maintaining Policies through the appropriate governance structures. Questions regarding this policy should be directed to the Dean of the School of Graduate Studies and Research.

STAKEHOLDER(S)

Full-time Teaching and Research Faculty, Administrative & Professional Faculty/Staff, Students, and Administrators

INSTITUTIONAL REVIEW BOARD POLICY UNDER SPONSORED PROGRAM ACTIVITY

Institutional Review Board Responsibilities. The NSU IRB is a committee created by the University for the review, approval and monitoring of research involving human subjects, in accordance with the Belmont Report, Common Rule, DHHS regulations, and FDA regulations. It is the entity formally charged with protecting the rights and welfare of the research subjects and providing oversight and monitoring of these protections. The IRB ensures full compliance with Federal regulations for the protection of human subjects in research at Norfolk State University.



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In accordance with the guidelines set forth by applicable federal regulatory agencies and University IRB policy, the responsibilities and authority of the IRB are as follows:

- Review, approve, require modifications to secure approval, or disapprove all University human research activity or clinical investigations;
- Review proposed changes in previously approved research or clinical investigation and approve, require modifications to secure approval, or disapprove proposed changes;
- Conduct continuing review of previously approved research or clinical investigation at intervals appropriate to the degree of risk, but not less than once per year;
- Monitor, when appropriate, the informed consent process and the conduct of the research or clinical investigation;
- Suspend or terminate approval of research or clinical investigation that is not conducted in accordance with IRB requirements or that has resulted in unexpected serious harm to subjects;
- Handle reports of unanticipated problems and allegations of noncompliance with human subjects' regulations, and in cases where corrective action is needed, issue appropriate sanctions, including but not limited to:
 - requesting minor changes to the protocols,
 - re-consenting volunteers,
 - inform journal editors of the lack of appropriate consent for data collection,
 - disapproving the use of the collected data,
 - disqualify the investigators from conducting research involving human subjects or clinical investigation at the University, and
 - recommending further administrative action to University administration.

IRB Standard Operating Policies and Procedures

MEMBERSHIP OF THE IRB

In accordance with membership requirements of the Code of Federal Regulations (45 CFR 46.107 and 21 CFR 56.107), the IRB is comprised of persons from various disciplines and departments, including a scientist member, nonscientist member, and a representative not otherwise affiliated with NSU (community representative).



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Appointment of IRB Chairperson, Length of Service, and Duties. The Chairperson of the IRB is appointed by the Dean of the School of Graduate Studies and Research in accordance with DHHS and FDA regulatory requirements. There are no term limits placed on length of service as IRB Chairperson. The IRB Chairperson has the following duties:

- Conduct each meeting in an orderly manner. The Chairperson is responsible for chairing the meeting, conducting business so that each proposal is fairly and completely reviewed, seeing that the IRB reaches a decision on the disposition of each proposal and ensuring that these decisions are communicated to the individuals who submitted the proposal.
- Review and approve research utilizing expedited review procedures in accordance with DHHS and FDA regulations.
- Review, as needed and as delegated by the IRB in appropriate circumstances, responses from investigators to determine if investigators responded sufficiently to the IRB's concern to allow approval under expedited review procedures and without being returned to the fully convened IRB.
- Appoint qualified IRB members to review and approve research utilizing expedited procedures in accordance with DHHS and FDA regulations.
- Sign correspondence on behalf of the IRB.
- Designate a senior IRB member to assume the responsibilities of the Chairperson during any period of the Chairperson's absence.
- Review IRB policies and procedures at least annually to confirm current compliance with all Federal, State, and local requirements for the protection of human subjects.

Appointment of Members, Length of Service, and Duties. IRB Committee members are appointed by the Dean of the School of Graduate Studies and Research in accordance with DHHS and FDA regulatory requirements. Members serve a three-year term limit and may be reappointed for a second term.

The IRB complies with the membership requirements of DHHS regulations at 45 CFR 46.107 and FDA regulations at 21 CFR 56.107 as follows:

- IRB will have at least five members;
- Members will possess varying backgrounds to promote complete and adequate review of research activities commonly conducted at NSU;
- IRB members will be sufficiently diverse relative to race, gender, cultural background, and sensitivity to community attitudes;
- Members will include persons able to ascertain the acceptability of proposed research in terms of institutional commitments, regulations, applicable law, and standards of professional conduct and practice;



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- The IRB will consist of qualified persons of both sexes;
- The IRB will not consist entirely of members of one profession or discipline;
- The IRB will include at least one member whose expertise is in a scientific area;
- The IRB will have at least one member whose expertise is in a non-scientific area;
- The IRB will include at least one member who is not otherwise affiliated with NSU and who is not part of the immediate family of a person who is affiliated with NSU.

Members vote to approve, require modifications in (conditionally approve), disapprove, or defer research submitted to the IRB. Members may be asked to conduct expedited reviews on behalf of the IRB. Members are expected to attend IRB meetings on a regular basis, serve as primary reviewers for research within their areas of expertise, and serve as general reviewers on all research discussed at convened meetings. Attendance of all present members is recorded in the meeting minutes.

All IRB members will be evaluated on an ongoing basis to ensure appropriate participation and performance in the conduct of their research reviews. Criteria by which IRB members may be evaluated include the following:

- Attendance at meetings
- Completion of IRB member orientation and human subject protection training
- Knowledge of regulatory guidance
- Demonstrated expertise or interest

No member will be allowed to participate in the initial or continuing review of any project in which the member has a conflicting interest or the perception of a conflict of interest, except to provide information requested by the IRB.

Any member of the IRB may be removed by the NSU designated official or the IRB Chair for failure to perform the duties of an IRB member, including failure to attend at least two-thirds of the IRB meetings held within any 12-month period; or for scientific misconduct, conflict of interest, or behavior such that review of research by the IRB is made difficult or impossible.

Consultants to the IRB. At its discretion, the IRB may recruit (non-voting) consultants (sometimes referred to as “non-voting or ex officio” members) whose presence at the meetings would aid the IRB in conducting its duties.

- *Continuing Consultants.* serve a fixed term and generally attend all meetings. They may have access to all documents submitted to the IRB, may participate in IRB deliberations, and make recommendations to influence IRB determinations. However, Continuing Consultants may not vote on IRB determinations. Continuing Consultants will not be included in determining or establishing quorum at IRB meetings.



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- Ad Hoc Consultants. The IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of research which requires their expertise. These individuals will not have voting privileges on the IRB. These individuals will be contacted by the IRB Chair or the Primary Reviewer of the protocol, as appropriate. The Ad Hoc Consultant will be asked to disclose in writing (e.g., via email) whether he or she has any conflicts of interest with the research. If any conflicts exist another Ad Hoc Consultant will be identified.

Ad Hoc Consultants serve on an as-needed basis and generally attend IRB meetings only when their special expertise is needed. Ad Hoc Consultants may have access to all documents submitted to the IRB that are pertinent to the research under review, may participate in IRB deliberations, and make recommendations to influence IRB determinations. If the Ad Hoc Consultant submits a written review, all members of the IRB will be provided a copy. In the alternative, the Ad Hoc Consultant may attend the IRB meeting and present his/her review verbally; in such instances the key points of the review will be documented in the IRB meeting minutes. However, Ad Hoc Consultants may not vote on IRB determinations. Ad Hoc Consultants will not be included in determining or establishing quorum at IRB meetings.

- Legal Counsel. The IRB may include an Attorney appointed by the NSU General Counsel to serve as a Continuing Consultant (i.e., non-voting member) to the IRB. In this capacity, the attorney will advise the IRB as to fulfilling its function to protect the rights and welfare of human subjects.

Conflict of Interest Requirements. Federal regulations at Title 21, Part 56, and Title 42, Part 50 of the Code of Federal Regulations require the disclosure and management of financial Conflicts of Interest in research. Federal human subject protection regulations at 21 CFR 56.107(e) and 45 CFR 46.107(d) require IRB members to be free of any conflict.

Conflicts of Interest may be interpreted to include any situation in which financial, professional, or personal obligations may compromise or present the appearance of compromising an individual's or group's professional judgment in conducting, reviewing, or reporting research.

IRB members are prohibited from participating in the deliberative discussion or vote relative to any research in which they have, or may appear to have, a financial, personal, or professional conflict.

IRB Meeting Procedures

The IRB convenes monthly meetings of the full board to review research requiring full review and to address other agenda items. The IRB may utilize electronic technology (e.g., teleconference or videoconferencing) to facilitate the participation of the members in regular meetings. The planned meeting agenda and meeting notice are provided to members in advance of the meeting.



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Quorum. A simple majority of the committee members constitutes a quorum for the NSU IRB. The IRB must review proposed research, including proposed changes to previously approved research, at convened meetings at which a majority of the members of the IRB are present. This includes at least one member whose primary concerns are in nonscientific areas, except when expedited review is authorized (45 CFR 46.108(b) and 46.103(b)(4)). In order for research to be approved, it must receive the approval of a majority of those members present at the meeting (45 CFR 46.108(b)).

Deliberations and Voting. At the convened meetings, scheduled submissions are presented and discussed. IRB members deliberate and then vote on these submissions according to the requirements of quorum and in accordance with policy. Approval is based on a majority vote by those members present at the meeting. Members may be present in person or audio (telephone) or audio-visual teleconference. Members present via teleconference will be noted as such in the meeting minutes.

IRB Minutes. All activities in IRB meetings will be documented in the IRB Minutes by the staff in the School of Graduate Studies and Research. Minutes will be disseminated for review and approval at the subsequent convened meeting.

IRB Review

The IRB has the responsibility to review all research projects involving human subjects before the research is initiated and provide ongoing oversight to research under the jurisdiction of Norfolk State University. In accordance with the Common Rule, codified at 45 CFR Part 46, DHHS regulations and FDA regulations, the IRB is required to conduct initial and continuing reviews of all non-exempt research at convened meetings at which a majority of the members are present, unless the research falls into one or more of the categories appropriate for an expedited review.

IRB Jurisdiction and Authority. The IRB has the authority to conduct initial reviews for exempt, expedited and full review studies; continuing reviews; amendments and revisions of approved research; suspensions and terminations of approved research; and investigations of noncompliance. The IRB has the authority to grant exemptions, approve, disapprove or require modifications to a study. It also has the authority to suspend, terminate or place restrictions on a study under its jurisdiction. Exemptions may be granted by the IRB Chair or designee, including the Dean of the School of Graduate Studies and Research.

Submission of IRB Applications and Reports

Any investigator planning a research study involving human subjects must submit an application for IRB review and approval or determination of exemption before initiating any interaction with subjects or their identifiable data.



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Timeline and Procedure. IRB Review (full review) is conducted by the members of the IRB at a full board meeting or by designated members of the Board in accordance with federal regulations. The Principal Investigator or designee completes an application for IRB review of a research protocol for initial full review and submits it to the IRBNET (a web-based tool that helps researchers and administrative offices better manage protocol submission, modification and tracking processes), in accordance with published submission deadlines. The designated staff screens the application to determine whether it is complete, whether additional expertise is necessary to conduct the review, or whether the research should be assigned for exempt or expedited review. The designated staff then schedules the IRB application on the agenda for the next available meeting or forwards it to the chair to be assigned for an exempt or expedited review.

Step 1: Complete the Required Human Subject Protection Training via Collaborative IRB Training Initiative (CITI) Program Principal Investigators and their co-investigators/study staff are required to take a human subjects protection training.

Step 2: Determine Type of Review/Submission

- Exempt Review
- Expedited Review
- Full Board Review
- Continuation Applications (Continuing Review)
- Other (Amendments: Revisions, Changes, or Modifications) to an Approved Study

Step 3: Obtain Appropriate Signatures & Approvals

Step 4: Assemble Study-Related Documents for IRB Review

Step 5: Prepare IRB Forms

- [Human Subjects IRB Form, External OSP Form 104](#)
- [Human Subjects IRB Form, Internal, OSP Form 103](#)
- [Revised 2018 Annual Report Form \(For Continuing Approval/or Close-out Report\)](#)

Step 6: Submit to the IRB

Approval times for studies that require full-board review may be affected by the timing of full-board meetings. Full board meetings are scheduled monthly. Study materials not received prior to the published submission deadline, will be scheduled for the IRB meeting that occurs in the following month. Expedited and exempt submissions are reviewed on a rolling basis. If the study qualifies for Full Board review, it will be reviewed at the succeeding Full Board meeting in accordance with the submission deadline dates. The IRBNET submission deadline for the initial review of exempt or expedited research, or requests for modifications is the first Monday of each month by 5 pm. Expedited annual review documents are due 30 days prior to the study expiration date.



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Review and Approval Actions

Under HHS regulations at 45 CFR 46.109(a), when conducting an initial or continuing review of a research study, or a review of proposed changes to a previously approved research study, an IRB can take any of the following actions:

- Approve the research study or proposed changes either (a) as submitted without any conditions, or (b) with conditions (note that when research is approved by the IRB with conditions at a convened meeting, further review by IRB at a subsequent convened meeting is not necessary)
- Require modifications to secure approval and defer or table the research study or proposed changes for further review at a future date after the required modifications are submitted by the investigator; or
- Disapprove the research study or proposed changes.

Informed Consent

The IRB will require that information given to subjects (or legally authorized representatives, when appropriate) as part of informed consent is in accordance with 45 CFR §46.116. The IRB may require that information, in addition to that specifically mentioned in 45 CFR §46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects. The NSU IRB shall require documentation of informed consent or may waive documentation in accordance with 45 CFR §46.117. Although not required by federal regulations, NSU institutional policy requires a consent process for exemptions when there are some kind of interactions with subjects, such as in most research exempt under Category 1 (educational practices), Category 2 (interviews, surveys, focus groups, observations of public behavior), and Category 3 (benign behavioral interventions).

Written Notification

The IRB will notify investigators in writing of its decision to approve or disapprove proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it will include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

Suspension or Termination of IRB Approval of Research

The IRB has the 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. According to IRB requirements, any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, and appropriate institutional officials. The NSU IRB operates in compliance with Post-2018: DHHS Regulations at 45 CFR 46.113.



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Cooperative Research

Cooperative research projects are projects that involve 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 Post-2018: DHHS Regulations at 45 CFR 46.114. Any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research. The NSU IRB operates in compliance with this requirement.

Amendments

The IRB must be informed in writing of any proposed changes to the study protocol and/or procedures, consent form, advertisement or study-related materials during the course of the research. Two copies of the revised materials must be submitted to the IRB for review, with changes highlighted on one copy. An expedited review may be utilized for minor changes. Significant changes may be submitted to the Full Board for review. IRB approval must be obtained prior to initiating any changes to an approved research protocol.

IRB Recordkeeping and Required Documentation

DHHS regulations at 45 CFR 46.108(a) (3-4) require that NSU implement written policies and procedures to govern the operations and direct the activities of the IRB (45 CFR 46.108(a) (3- 4). IRB records will include documentation of all IRB findings and determinations as required under DHHS and FDA human subject protection regulations and as recommended by the Office for Human Research Protections (OHRP) and FDA guidance.

IRB Records. At a minimum, IRB records must include all information required under DHHS and FDA regulations at 45 CFR 46.115 and 21 CFR 56.115, respectively and as recommended by official OHRP and FDA guidance.

Record Retention and Access

In accordance with Federal regulations at 21 CFR 56.115(b) and 45 CFR 46.115(b), IRB records will be retained for no less than three years, and research records will be retained by NSU for no less than three years after the completion of the research. This includes research protocols reviewed by the IRB for which no subjects were enrolled. All IRB records will be kept in a permission- restricted, protected electronic database. Ordinarily, access to IRB records is limited to the IRB Chairperson, IRB members, IRB staff, the University officials, and officials of Federal and State regulatory agencies, including OHRP and FDA. Research investigators and their staff will be provided reasonable access to the electronic files related to their research.



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Records maintained that document compliance or non-compliance with Department of Defense (DoD) required documentation shall be made accessible for inspection and copying by representatives of the DoD at reasonable times and in a reasonable manner as determined by the supporting DoD component. All other access to IRB records is limited to those who have legitimate need for them, as determined by the IRB Chairperson or the School of Graduate Studies and Research Dean.

EDUCATION AND COMPLIANCE

Education

The IRB requires IRB members and chairs, IRB staff, Principal Investigators, and all other research team members to complete CITI Training in the Protection of Human Subjects. Training must be completed once every 3 years, and each year thereafter, a refresher course must be completed.

- **Research Investigator Education**. At a minimum, all research investigators must complete the Collaborative IRB Training Initiative (CITI) educational program and the IRBNET training.
- **IRB Member Education**. Upon receiving an appointment to the IRB, a member receives comprehensive reference materials (including this Policy) necessary to review research from an ethical and regulatory perspective. All IRB members must also complete the CITI educational program. Members will periodically be provided with continuing education opportunities within this Institution or at neighboring institutions. Resources will be made available each fiscal year for one or more IRB members to attend national or regional human subject protection meetings.

Compliance

The IRB monitors ongoing research for adherence to applicable regulations, policies and procedures, and tracking policy compliance.

Investigator Non-Compliance

Allegations of non-compliance may be addressed at convened meetings of the IRB and the IRB will determine the final required actions (suspending or terminating the research, reporting the non-compliance to federal oversight agencies and/or sponsors, etc.).

Unanticipated Problems (UP)/Adverse Events

Once the research has been approved by the IRB, the investigator responsibilities include reporting unanticipated problems involving risks to subjects or others. These are events that happen to subjects and may present an increased risk to the subject or others, that are not described (in type, severity, or frequency) in the protocol or other study materials and are possibly related to the subject's participation in the study.

If in the course of the research, there are any adverse events, the principal investigator must report the incidents via the IRBNET within five working days. The events must also be put in writing for official record and sent to the School of Graduate Studies and Research. Once an UP is verified upon review, the IRB may determine that the study protocol and/or consent forms need to be



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modified, and/or that currently enrolled subjects need to be informed of the new information, or that the study must be stopped. In accordance with federal policy, NSU will report all verified UP to OHRP (if applicable per their FWA) and/or FDA (when FDA has jurisdiction over the study).

Education and Training Records

NSU is required under its OHRP FWA to have a plan to provide education about human subject protections for research investigators and IRB members and staff. The School of Graduate Studies and Research will maintain accurate records listing research investigators, IRB members, IRB staff and research staff who have fulfilled the human subject protection training requirements. Such records will be available as a part of ongoing compliance monitoring activities.

PUBLICATION

This Policy shall be widely published and distributed to the University community. To ensure timely publication and distribution thereof, the Responsible Office will make every effort to:

- Communicate the policy in writing, electronic or otherwise, to the University community within 14 days of approval.
- Submit the policy for inclusion in the online Policy Library within 14 days of approval.
- Post the policy on the appropriate website; and
- Educate and train all stakeholders and appropriate audiences on the policy's content as necessary. Failure to meet publication requirements does not invalidate this policy.

REVIEW SCHEDULE

- Next Scheduled Review: 02/10/2025
- Approval by, date: Cabinet, 02/10/22
- Revision History: New
- Supersedes: N/A

RELATED DOCUMENTS

- Guidelines for Submitting Protocols to the Institutional Review Board (IRB) December 1999
- Policies & Procedures for the Protection of Human Subjects in Research, 2020

Historical Documents

[Nuremberg Code \(1949\)](#)

[Declaration of Helsinki \(1964-2002\)](#)



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[Belmont Report \(1979\)](#)

DHHS regulations at 45 CFR Part 46 Subpart A constitute the Federal Policy (Common Rule) for the protection of human subjects. This Common Rule applies to any human subject research supported by any of the agencies of the Federal government that support human subject research.

[Subpart A—Basic HHS Policy for Protection of Human Research Subjects](#)

The DHHS regulations presently include additional protections for pregnant women, human fetuses and neonates (Subpart B); prisoners (Subpart C); and children (Subpart D). These regulations are enforced by the DHHS, Office for Human Research Protections (OHRP), formerly known as the Office for the Protection from Research Risks (OPRR).

[Subpart B—Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research](#)

[Subpart C—Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects](#)

[Subpart D—Additional Protections for Children Involved as Subjects in Research](#)

FORMS

[Human Subjects IRB Form, External OSP Form 104](#)

[Human Subjects IRB Form, Internal, OSP Form 103 New name?](#)

[Revised 2018 Annual Report Form \(For Continuing Approval/or Close-out Report\) IRB](#)

Checklist for Submitting Protocols

IRB Cover Sheet

Department Chairperson and Dean Approval for Research Protocol

Assent of the Child Form

Employee/Student Consent Form Addendum

Addendum Consent Form

Sample Consent Form for Questionnaire Use

Norfolk State University Consent Form