Northwestern State University of Louisiana

Research Ethics Board

Policies & Procedures Manual

2026-27

Approved: March 16, 2026

Effective: September 1, 2026

New in the 2026-27 Edition

Title	Brief Description	Page #
REB Member Training Policy	Revised requirements for completing the REB Member certificate (CITI Program)	Moved to the new publication: The NSU HRPP Guidebook
REB Chair: Responsibilities	Oversight for preparing the official REB convened meeting minutes.	Appendix A

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Mission Statement

The mission of the Northwestern State University (NSU) Research Ethics Board (REB) is to ensure the rights and welfare of every person who may be involved in NSU-sponsored research that employs human subjects. Our guiding values are "respect for persons," "benevolence," and "justice," the ethical principles first described in *The Belmont Report* (1978), which has informed U.S. federal law and public policy on research with human subjects for more than four decades.

The REB bases its requirements and actions regarding the approval of any research study (or "protocol") on the principles of *The Belmont Report* (1978), the National Research Act of 1974 (1974), and the current regulations developed by the U.S. Department of Health and Human Services (HHS) for the protection of human subjects of research (updated 2018). These guidelines require that research with human beings must "maximize potential benefits and minimize possible harms" (*The Belmont Report*, p. 6, 1978).

Policy and Procedures Manual Purpose

The primary purpose of the Policies & Procedures Manual is to inform REB members, REB Office staff, NSU administrators, and federal oversight agencies of the current operational standards concerning Board membership, eligibility, and general responsibilities; procedures for protocol review and approval; monitoring of approved protocols, including Continuing Review, Amendments, and Adverse Events; the reporting procedures for all decisions and related actions; REB Office staff responsibilities; and, REB records management policies. These standards are informed by the REB Mission Statement and the HHS regulations (45 CFR 46). A secondary purpose is to acknowledge publicly the work of the NSU REB and to contribute to institutional transparency by making this manual available on the REB website free of charge. We welcome feedback through the free exchange of ideas, a central goal of the university community.

Human Subject Research Protections Program (HRPP)

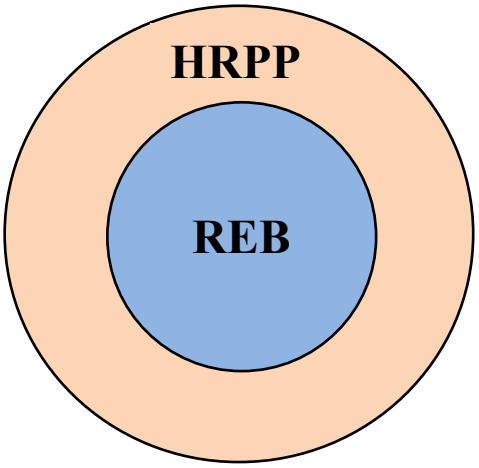
Background

The Human Research Protection Program (HRPP, 2022) concept was instituted by the federal Office of Human Research Protections (OHRP, 2003), which oversees all U.S.-based REBs on behalf of HHS. The central idea behind the HRPP model is that, at any research institution, there are multiple administrative units, groups, and individuals that support the REB in its mission to protect human subjects in research protocols (see Figure 1). This section of the Manual identifies

those specific units, groups, and individuals at Northwestern State University of Louisiana.

Figure 1

HRPP and REB Relationship Model



Through the HRPP, the OHRP and the university acknowledge that the NSU REB is not solely responsible to protect human participants in research. Other university offices and personnel, as well as external consultants and experts, can be called upon whenever necessary to aid the NSU REB in making effective decisions regarding the welfare and rights of human participants in a particular research protocol.

HRPP Director and REB Chair

Duties

The complete qualifications and responsibilities of the HRPP Director and REB Chair are listed in Appendix A.

Faculty Status

The HRPP Director and REB Chair should be tenured faculty; however, the Institutional Official (IO) may appoint any full-time NSU faculty member to either position.

Reporting Relationship

The HRPP Director will report directly to the university Institutional Official. The REB Chair works with the HRPP Director to administer the convened meetings and protocol reviews.

HRPP Membership

Membership in the HRPP is made up of the following university offices, groups, or individuals:

1. Institutional Official (NSU Executive Vice President and Provost)
2. NSU HRPP Director
3. University Offices/Groups/Individuals

a. REB Office: REB Chair and staff
b. Academic Affairs Office
c. Administrators - Deans/Academic Unit Heads/Directors
d. University Research Coordinators (URCs)
e. Researchers - including faculty sponsors and their students.
f. Office of Institutional Research (OIR)
g. Sponsored Programs Office (SPO)
h. Institutional Animal Care and Use Committee (IACUC)
i. University General Counsel
j. Other offices, groups, and individuals as needed.

Research Ethics Board (REB) Membership

Membership in the REB is guided by the HHS regulations (Protection of Human Subjects, 2018, § 46.107).

The REB members must represent a variety of backgrounds, including appropriate areas of expertise, experience, gender, race, and age (Code of Federal Regulations, 45 § 46.107.a). The REB membership should be sufficiently qualified through the experience and expertise of its members to provide effective review of the types of research protocols commonly conducted at Northwestern State University.

Required Member Categories

The REB membership shall consist of, at minimum, personnel from the following university academic units, offices, groups, and external stakeholders. One member from each College or unit unless otherwise indicated (does not include any members designated as Alternates).

Voting Members

A complete list of the qualifications and responsibilities of REB voting members is listed in Appendix B.

> NOTE: Under the NSU REB charter (see the NSU Faculty Handbook), the number of members for each unit shown below is the *minimum* number required; The REB reserves the right to appoint additional voting members in various areas of expertise as needed, with approval from the Institutional Official

1. College of Arts and Sciences: three members (to include one member from the Louisiana Scholars' College)
2. College of Business and Technology; one member
3. College of Education and Human Development: two members
4. College of Nursing and School of Allied Health; two members
5. Student Affairs Representative (Dean of Students or designee)

6. Graduate Student Representative; one member.
7. Community Representative ("Unaffiliated")

NOTE: Unaffiliated here means "in any capacity": The REB Community Representative does not have any relationship--formal or informal--with NSU. For example, a university employee, an outside contractor, a member of an unpaid university board or group, as well as the candidate's immediate family members who serve as an employee, outside contractor, or a member of an unpaid university board or group, make the candidate ineligible to serve as a Community Representative; see "IRB Membership" in 45 CFR §46.107(c).

Required Expertise: Voting Members

Among the voting members, the REB must have at least one member whose primary expertise is in a scientific area and at least one member whose primary expertise is in a non-scientific area (Code of Federal Regulations, 45 CFR § 46.107.b) [8]. At least one non-scientific REB member must be present at any NSU REB Convened Meeting when a formal vote of the REB membership will be taken. For further guidance concerning "scientific and "non-scientific" REB members, see https://www.hhs.gov/ohrp/sachrp- committee/recommendations/2011-january-24-letter-attachment-b/index.html

Non-Voting Members

1. REB Chair (votes only in case of a tie)
2. REB Institutional Official (currently held by the Vice President for Academic Affairs)
3. Sponsored Programs Office Representative
4. Consultants

Alternate Members

The REB may have alternate members whose role is to attend REB meetings to replace the designated voting member. The alternate may substitute for the designated member for an entire meeting or at any time during the meeting.[9] When not serving as a replacement for a voting member at a convened meeting, an alternate is not counted in the establishment of quorum and does not vote. However, an alternate is counted for attendance and may participate in meeting discussions if eligible to do so. For more information on Alternate members, see https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/irb-registration-process/index.html

Membership Term

Membership in the REB is for three consecutive academic years (August through May), except for Graduate Student Representatives, who serve for one academic year. When the member's term is about to expire, the REB Chair will contact the member about continuance for a new three-year term. If the member declines, the Director will contact the appropriate department

head or Dean to request a replacement or to renew a current member's REB term.

Membership in the NSU REB is subject to approval by the Institutional Official.

Member Training Requirements

Each member of the REB (except Consultants; see below) must successfully complete the required REB Member training before beginning service and must maintain certification for the entire term of service.

All required REB training is offered exclusively through CITI Program. Training certificates received from other vendors will not be accepted. For more information on training requirements, see the HRPP Guidebook.

Other REB Personnel

Outside Consultants

The REB may, at its discretion, invite consultants with competence in special areas to assist in the review of protocol applications and other issues that require expertise beyond, or in addition to, that available among the REB membership (Code of Federal Regulations, 45 CFR § 46.107.e).

NOTE: Outside consultants do not receive REB voting privileges.

REB Voting Member Responsibilities

General responsibilities of REB Members possessing voting privileges are described below.

Current Knowledge

Review regularly required training courses and current NSU REB policies and procedures.

Confidentiality

Keep confidential all content, both spoken and written, of NSU REB meetings and protocol reviews and share such information only with current members of the REB.

Protocol Reviews

Review and have authority to approve, require modifications (to secure approval), or disapprove any university-sponsored research protocol that employs human subjects.

Protocol Status

Have the authority to suspend or to terminate any approved research protocol that is not being conducted in accordance with the REB's requirements or that has been associated with unexpected serious harm to study participants. Any suspension or termination of approval shall include a statement of the reasons for the REB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the agency head.

Informed Consent

Require that information given to subjects as part of informed consent is in accordance with HHS regulations (Code of Federal Regulations 45 CFR § 46.111.a.4). The REB may require that information, in addition to that specifically mentioned in § 46.111, be given to the subjects when,

in the REB's judgment, the information would meaningfully add to the protection of the rights and welfare of subjects.

Informed Consent Documents Review

Require review of the informed consent granted by the human participants, when appropriate, including each signed and dated consent form.

In-progress Observation

Require observation by REB members or have a third party do so for the informed consent process and any research activities—while these activities are in progress—for any approved protocol.

Researcher Responsibilities

All researchers, including co-investigators, are required to register with and submit all REB-related materials to the electronic REB application portal. The NSU REB uses Single Sign-on (SSO) to manage user access. First, log in to the NSU computer network (such as MyNSU) using your NSU email credentials. More detailed information concerning researchers (eligibility and qualifications, training requirements, and the REB application process, can be found in the NSU REB Researcher Handbook.

Unaffiliated Researcher Requirements

Researchers not affiliated with NSU as a faculty, staff, or students, seeking to use NSU students and/or personnel for human subject research study, must obtain approval from the NSU REB. Researchers not affiliated with any institution as a faculty, staff, or student are required to complete an Individual Investigator Agreement; see the HRPP Guidebook for details.

Non-human Subjects Research (NHSR) Protocol [13]

At NSU, the NHSR Determination Questionnaire is often the first step to apply for study approval from the NSU REB. Many studies conducted by NSU faculty and students are approved for NHSR Determination status, due to the minimal risk and local-only focus of the study. *For this reason, NHSR applications do not require a full REB protocol review.*

The Questionnaire is reviewed by the HRPP director, REB chair, or designated REB Voting Member(s) to verify NHSR status. For a designated reviewer, the member eligibility rules apply (Code of Federal Regulations, 45 CFR § 46.107). The assigned reviewer completes the NHSR Questionnaire Reviewer Checklist via the electronic REB portal to determine if the proposed protocol qualifies for NHSR Determination. If so, the researcher may begin the study after the official approval letter is received. Records will be maintained of all activities regarding actions on the application.

Protocol Review Categories

Exempt Protocol

Reviewed by the HRPP Director or delegated to the REB Chair or designated REB voting member(s) to verify status. For a designated reviewer, the member eligibility rules apply (Code of Federal Regulations, 45 CFR § 46.107). If the reviewer(s) cannot serve as a reviewer, the HRPP Director, or designee, will select another voting member. The reviewer completes the Protocol Review Checklist via the electronic REB portal. If accepted as an Exempt protocol, the HRPP Director, or designee, may approve the application, set forth conditions of approval, or may elect to have the entire REB committee or an REB sub-committee review the application. Records will be maintained of all activities regarding actions on the application.

Exempt Limited Review Protocol

Reviewed by the HRPP Director or delegated to or designated REB voting member(s). The member eligibility rules apply (Code of Federal Regulations, 45 CFR § 46.107). If the reviewer(s) cannot serve as a reviewer, the REB Chair, or designee will select another voting member. The review is conducted to determine whether the protocol has met the requirements for Limited Review (Code of Federal Regulations, 45 CFR § 46.111.a). If accepted as a Limited Review protocol, the reviewer(s) may approve the application, set forth conditions of approval, or may elect to have the entire REB membership or an REB sub-committee review the application, with approval from the REB Chair. Records will be maintained for all activities regarding actions on the application."

Expedited Protocol

Reviewed by a subcommittee of two (2) REB voting members, determined by a pre-planned schedule of rotating reviewers, and notified via the electronic REB portal. A copy of each protocol application will be delivered to the subcommittee. The member eligibility rules apply (Code of Federal Regulations, 45 CFR § 46.107). If one or both of the appointed reviewers cannot serve, the REB Chair, or designee, will select another voting member. The members of the subcommittee will complete the Protocol Review Checklist via the electronic REB portal. Each reviewer will vote for Approval or Conditional Approval. The votes will be communicated to the REB Chair, including any conditions that must be fulfilled before the application is approved, if necessary. Conditional Approval requires a revised protocol application to address the required conditions and a discussion and vote to approve at a convened REB meeting. Records will be maintained of all activities regarding actions on proposals.

Full Board Protocol

Reviewed at a Convened Meeting of the full REB voting membership (see next section for details).

REB Convened Meeting Policies and Procedures

An official, convened meeting of the REB requires the following:

1. An official agenda
2. Minutes of the previous convened meeting
3. The required number and types of voting members to satisfy attendance and quorum requirements.
4. Copies of all documents required for formal votes (e.g., completed Protocol Review forms, Continuing Review forms, policy proposals, etc.)
5. After the meeting, official convened meeting minutes.

Voting Eligibility

There are two components governing the eligibility to vote at a convened meeting.

1. Completion of required training
2. Conflicts of Interest are not present

No member of the REB may participate in discussions of regular business items or vote on them where there is any form (or potential form) of conflict of interest. A member has the responsibility to recuse themselves from a convened REB meeting prior to the discussion of and formal vote on regular business items for which a known or potential conflict of interest exists (Code of Federal Regulations, 45 CFR § 46.107.e). The HRPP Director and/or REB Chair can also inform the Member of required recusal from a vote.

Meeting Organization

There are two components governing the organization of a convened meeting:

Parliamentary Procedure

All REB convened meetings will follow the general rules of parliamentary procedure; the REB Chair or designee will lead each convened meeting, introduce each agenda item, and administer all formal votes. All convened meetings will have a written agenda prepared and a copy given to each member (Voting, Non-voting, and Alternate) prior to the start of the meeting. NOTE: Under the federal rules, IRBs are not legally required to follow parliamentary procedure; for this reason, IRBs due not have a parliamentarian role.

Quorum Requirement

The REB members may discuss an agenda item and vote on it only if a quorum of the currently eligible voting members (present at the meeting) is established prior to the discussion and vote. At the beginning of and during the meeting, the REB Chair or designee will keep track of all current REB members, including those present, absent, recused, or otherwise currently ineligible. The existence of the quorum will be established before the discussion and vote of the

REB membership on each agenda item requiring a formal vote for both protocol applications and other REB business. If a quorum cannot be established, the vote on the agenda item must be tabled until the next convened meeting.

Meeting Procedures

Approval of Meeting Agenda

After a quorum is established, the REB chair will call for a motion to approve the official agenda for the current meeting. Once a voting member seconds the motion, a voice vote is taken, and the results are recorded in the minutes. Passing votes are Approve, Disapprove, or Abstain.

Approval of Minutes

Next, the REB chair will call for a motion to approve the minutes from the previously convened meeting. Once a voting member seconds the motion, a voice vote is taken, and the results are recorded in the minutes. Passing votes are Approve, Disapprove, or Abstain.

Discussion and Voting, Regular Business Items.

All REB convened meeting regular business items, except for protocol applications, follow the same voting procedure as the approval of the agenda and the previous meeting minutes.

Discussion and Voting, Protocol Applications

Before any formal vote, a quorum must be established. If a quorum is not established (e.g., a member must recuse themselves or leave the meeting), the vote on the current protocol application must be tabled until the next convened meeting.

Opening of Discussion

The REB Chair or designee will call for a motion to open discussion of the REB protocol application(s) currently under consideration, following the order listed in the meeting agenda.

Discussion

The discussion will proceed until all voting members have had the opportunity to speak to the viability of the application. The REB Chair then calls for a vote on the protocol.

Formal Vote

After a quorum is established, the REB chair will call for a motion to vote on the current protocol application. Once a voting member seconds the motion, a voice vote is taken, and the results are recorded in the minutes. The REB Chair, or designee, will call the roll of currently present and eligible voting members, established in the quorum procedure, and each voting member votes for one of five options: Approve, Approve with Conditions, Disapprove, Table, Abstain.

Passing Vote

A passing vote requires a simple majority vote of the established quorum for one of the five voting options. If the vote ends in a tie for at least two options, the REB Chair will vote to break the tie.

Vote Results Other Than Approval

Approved with Conditions. The conditions to receive approval must be recorded in detail in the meeting minutes. In addition, the primary investigator (PI) must submit a revised protocol application incorporating the required changes.

Exempt Applications. The REB Chair or designee will review all Exempt applications resubmitted with conditional approval. If all conditions are met, the Chair may grant approval. If all conditions are not met, the Chair may elect to have the entire REB membership, or a selected sub-committee review the application a second time to determine the final action.

Expedited or Full Board Applications. These review types, when approved conditionally, must be reviewed at a convened REB meeting. The REB members will review these applications as new ones and will act on them accordingly.

Disapproval. If the vote is to Disapprove, the specific reasons for the result must be recorded in detail in the meeting minutes.

Vote Record

The REB Chair, or designee will record each vote and the result in the meeting minutes for each protocol application. In order to document the continued existence of a quorum, the votes will be recorded in the minutes using the REB Meeting Minutes Form Part B (see Appendices). The REB Meeting Minutes Form Part B is only used when voting on protocol applications.

Continuing Application Review Requirements

Time Frame

The REB members shall determine when a continuation review will be conducted for Expedited and Full Board application reviews (Code of Federal Regulations, 45 CFR § 46.109.e).

Stipulations

The REB members shall determine any special requirements for the review.

Reviewer Assignment

The REB members will vote to determine the REB member(s) who will conduct the review.

Waiver of Informed Consent or Waiver of Documentation of Consent

The REB will document the reasoning when approving a consent procedure which does not include, or which alters, some or all the required elements of informed consent, or when waiving the requirement to obtain informed consent (Code of Federal Regulations, 45 CFR § 46.117.c). This documentation requirement also applies when approving procedures that waive the requirement for obtaining a signed consent form for research involving the following:

1. Pregnant women, human fetuses, or neonates (45 CFR § 46.Subpart B)
2. Prisoners (45 CFR § 46.Subpart C)

3. Children (45 CFR § 46.Subpart D)
4. Cognitively impaired persons

Federal law does not require informed consent for Exempt protocols, but the NSU REB reserves the right to require informed consent whenever it deems it necessary. Informed consent is recommended for all REB-approved studies, except when doing so will adversely affect the protocol's risks, including privacy, to the study participants.

Meeting Minutes

The organization and layout of the convened meeting minutes will follow the NSU REB Meeting Minutes Form (see Appendix D). All meetings will record the following in the official minutes (Code of Federal Regulations, 45 CFR § 46.115.a).

1. Date, time, and location of the meeting
2. Time the meeting was called to order
3. Name of the person recording the minutes
4. The presence or absence of each REB member
5. Voting eligibility of each attending member for quorum and voting including
    a. Recusals from protocol application deliberations
    b. Those excused while the meeting is in progress
6. Voice vote for the approval of the current meeting's agenda
7. Voice vote for the approval of the previous meeting's minutes
8. A summary of the discussion of regular business, that that require a vote and those that do not require a vote, including but not limited to:
    a. Approval of changes to NSU REB policies*
    b. Announcements
    c. REB recent activity reports, including but not limited to:
        i. HRPP Director, REB Chair, or REB member or sub-committee reviews of Exempt, Limited Review, and Expedited protocols
        ii. Adverse Events
        iii. Continuing Review results
        iv. Changes in HRPP/REB Office policies
    d. Membership changes
    e. Upcoming meeting schedules
9. A summary of the discussion of each protocol application including
    f. Controverted Issues
        g. Those issues causing debate among the members.

ii. The resolution of the controverted issue

i. The establishment of a quorum before any formal vote

j. The final tally of the formal vote for each protocol application

k. Any other decision or action taken on protocol applications, including but not limited to:

i. Requirements for a continuing review

ii. Waivers/changes to informed consent

10. The signature of the meeting recorder and the date signed.

11. The time that the meeting was adjourned.

Continuing Review

Continuing Review is required under the federal rules for all protocols approved by the REB Full Board (and selected Expedited protocols). The REB members shall determine when a continuation review will be conducted. Research protocols approved under the 2018 Common Rule are eligible for continuing review (Code of Federal Regulations, 45 CFR § 46.109).

1. NHSR and Exempt Protocols
    a. For research review time frames of less than 12 months, continuing review is not required unless:
        i. Changes in the protocol are requested
        ii. Changes in the protocol occur, or
        iii. Adverse events occur.
2. Selected Expedited and all Full Board Approved Protocols:
    a. For research conduct time frames of greater than 12 months, a continuing review is required within 12 months of the REB approval date.
    b. Then, a continuing review will be conducted at least once every 12 months until the study is officially closed.
3. Continuing Review for Pre-2018 Common Rule-Approved Protocols:
    a. If the research was initially approved under the pre-2018 Common Rule requirements, then it is not eligible for continuing review. The researchers must re-apply under the 2018 Common Rule requirements.

Determination for Continuing Review

Assessment of Risk

All protocols approved by the NSU REB and deemed more than minimal risk require continuing review (Code of Federal Regulations, 45 CFR § 46.109.e).

High-risk Protocols. Require the PI to complete a Continuing Review Form (see Appendix

N). The REB reserves the right to set continuing review interval requirements less frequently than every 12 months for high-risk research protocols (e.g., every quarter, every month, etc.).

Complex Projects. The REB reserves the right to conduct continuing reviews at any time for projects that involve unusual levels or types of risk to subjects.

Exempt Protocols

A protocol approved as Exempt does not require continuing review, regardless of the study length, unless the protocol is changed or amended and/or is deemed to be more than minimal risk.

Stipulations

The REB members shall determine any special requirements for the review.

Unapproved Protocol Changes. Research projects where concerns have been raised about material changes to the protocol without REB approval, based upon information provided in other continuing review reports or from other sources.

Previous Non-compliance. Any PI or Co-PI who were previously found to have failed to comply with federal regulations and/or with the requirements or determinations of the REB.

Continuing Review Procedure

Reviewer Assignment

The HRPP Director will designate a current REB member with voting eligibility to conduct the continuing review of the protocol via the electronic REB portal.

The Continuing Review

The representative will review the research activities associated with the protocol as approved by the REB and will conclude whether the research follows the original proposal. The review will be recorded on the Continuing Review Form.

Outside Consultants

If the REB reviewer conducting the continuing review determines the need for verification from sources other than the PI and that no material changes have occurred since the previous REB review, the REB chair, or designee will appoint a person knowledgeable in that area to assist the REB reviewer in the continuing review (Code of Federal Regulations. 45 CFR § 46.109.g).

Summary Report

The findings of the designated representative will be brought before the REB at a convened meeting for a discussion and vote by the membership.

Records for the Review

Prior to the convened meeting listing the continuing review case on its agenda, all REB members will receive a copy of the original proposal and a summary report of the reviewer's findings. The

summary report should include:

1. The completed Continuing Review Form
2. A complete copy of the original REB application form including all supplemental documentation.
3. Any information related to currently associated protocol risks.
4. A summary of any relevant recent REB documentation, including but not limited to:
    a. Interim findings
    b. Amendments or other modifications to the protocol
    c. Any adverse event reports since the last review
    d. Any relevant multicenter trial reports
    e. Any proposed consent documents written after the initial protocol approval.
    f. Any written documentation of complaints or concerns about the protocol from study participants.

Continuing Review Membership Vote

Opening of Discussion

The REB Chair, or designee will call for a motion to open discussion of the Continuing Review currently under consideration, following the order listed in the meeting agenda.

Discussion

The discussion will proceed until all voting members have had the opportunity to speak to the merits of the Continuing Review. The REB Chair then calls for a vote on the Continuing Review.

Formal Vote

After a quorum is established, the REB chair will call for a motion to vote on the Continuing Review. Once a voting member seconds the motion, a voice vote is taken, and the results are recorded in the minutes. The REB Chair, or designee, will call the roll of currently present and eligible voting members, established in the quorum procedure, and each voting member votes for one of two: Approved or Further Action Required.

Vote Record

The REB Chair, or designee will record each vote and the result in the meeting minutes for each protocol application. In order to document the continued existence of a quorum, the votes will be recorded in the minutes.

Voting Results

Voting for Continuing Reviews will be recorded as either Approved or Further Action Required. The final decision requires a simple majority vote of the established quorum. If the voting members' vote ends in a tie, the REB Chair may vote to break the tie.

Review Approved. If the Summary Report states that no discrepancies were found in the way the protocol is being conducted, REB membership may vote to approve the review; the motion must include date of the next scheduled review. Both the approval and the next review date are recorded in the meeting minutes.

Further Action Required. If the Summary Report states that there are discrepancies in the way the approved protocol is being conducted, the membership may vote to require further action to resolve the discrepancies. The membership may also vote to suspend the research until the discrepancies are resolved, which requires a separate vote. The further action vote and the further action required, including a suspension of the protocol, must be recorded in detail in the meeting minutes.

Notification of Continuing Review Decision

The HRPP Director, or designee will notify the PI of the findings contained in the Summary Report, the REB membership decision status, including any further action required via the electronic REB portal. Notifications may be made to the Faculty Advisor, the Department Head, and the Institutional Official, as appropriate (Code of Federal Regulations, 45 CFR § 46.109.d).

Continuing Review Approved

The PI is directed to keep a copy of the approval letter in their research records for the required length of records maintenance (Code of Federal Regulations, 45 CFR § 46.115.a.4).

Further Action Required

The PI must complete and submit either an Amendment Request form (see Appendix O) or an Adverse Events (see Appendix P) form, whichever the REB determines to be applicable via the electronic REB portal. The research protocol may not be resumed until the PI has received written approval from the REB.The completed Amendment Request or Adverse Events form will be reviewed and discussed at the next convened REB meeting. The membership will vote to decide whether to continue, suspend, or terminate the research protocol at that time.

The result of the vote is recorded in the meeting minutes. If the vote decision is to approve the amendment request, the date of the next scheduled continuing review must be included in the decision and recorded in the meeting minutes.

Protocol Amendments

A protocol amendment is a change to any part of an REB-approved protocol. All protocol-related activities must be suspended while a Protocol Amendment request is in process. Protocol amendments include, but are not limited to:

1. Time Frame Changes
    a. Conversion of the protocol from a short-term project (less than 12 months) into a

longitudinal (multiyear) study.

2. Procedure Changes
    a. Protocol changes may include modification to any of the following:
        i. Subject population
        ii. Study methodology
        iii. Administration procedures
        iv. Data privacy or security procedures, or
        v. Any other part of the initially approved protocol.

Amendment Request Form

The PI submits the completed Amendment Request Form found on the NSU REB website via the electronic REB portal.

Protocol Amendment Approval Procedure

The completed Amendment Request or Adverse Events form will be reviewed and discussed at the next convened REB meeting.

Formal Vote

After a quorum is established, the REB chair will call for a motion to vote on the Continuing Review. Once a voting member seconds the motion, a voice vote is taken, and the results are recorded in the minutes. The REB Chair, or designee, will call the roll of currently present and eligible voting members, established in the quorum procedure, and each voting member votes for one of two: Amendment Approved or Terminate.

Vote Record

The REB Chair, or designee, will record each vote and the result in the meeting minutes for each protocol application. In order to document the continued existence of a quorum, the votes will be recorded in the minutes.

Voting Results

Voting for Protocol Amendment Approval will be recorded as either Amendment Approved – Recommence Protocol or Amendment not Approved – Protocol Termination. The final decision requires a simple majority vote of the established quorum. If the voting members' vote ends in a tie, the REB Chair may vote to break the tie.

If the amendment is approved, the research may be re-commenced with the revised protocol once official notification is received.

The result of the vote is recorded in the meeting minutes. If the vote decision is to approve the amendment request and the protocol will recommence, the date of the next scheduled continuing review must be included in the decision and recorded in the meeting minutes.

Notification of Protocol Amendment Request Decision

The HRPP Director, or designee will notify the PI of the result of the Protocol Amendment Request decision via the electronic REB portal. Notifications may be made to the Faculty Advisor, the Department Head, and the Institutional Official, as appropriate (Code of Federal Regulations, 45 CFR § 46.115.a.4).

If the amendment is approved, the research may be re-commenced with the revised protocol once official notification is received. The PI must keep the letter with the research records for the length of the records maintenance policy requirements.

Adverse Events

An adverse event is any event or effect of an active research protocol that negatively affects the health, welfare, or rights of any study participant or other persons involved, such as the PI, Co-PI, project staff members, students, REB members, or other observers, etc. The NSU REB has the right and the responsibility to suspend or terminate any protocol which harms in any way human subjects (Code of Federal Regulations, 45 CFR § 46.113).

When an adverse event occurs and is detected at any time by the PI, other involved research personnel, participants, or an REB member, the PI must:

1. Suspend all research activities
2. Contact the REB Office immediately and report the event
3. Complete and submit the Adverse Events Report detailing the issue to the REB.

Adverse Event Consideration

Opening of Discussion

The REB Chair, or designee will call for a motion to open discussion of the Adverse Event Report currently under consideration, following the order listed in the meeting agenda.

Discussion

The discussion will proceed until all members have had the opportunity to speak to the details of the Adverse Event. The REB chair will notify the PI of alternatives and/or other actions to assist in dealing with the adverse events/effects.

Submit Required Changes

The PI completes and submits the Continuation/Change in Protocol Application to REB.

Continuation

If the changes are approved, the PI is notified by the HRPP Director, or designee (Code of Federal Regulations, 45 CFR § 46.115.a.4). Once official notification of the approved changes and subsequent continuation is received, the PI may recommence the protocol with the revised procedures.

Reporting REB Findings and Actions

Formal Votes

All findings and actions determined by vote at a convened meeting will be documented in the meeting minutes. Actions or decisions taken outside of a convened meeting (e.g., reviews of NHSR, Exempt, Limited Review, and Expedited protocols, and changes in HRPP/REB Office policies) will be reported at the next convened meeting and recorded in the meeting minutes (Code of Federal Regulations, 45 CFR § 46.115.a.2).

Adverse Events/Researcher Non-compliance Determinations

The HRPP Director will report in writing in a timely manner to the university Institutional Official (IO) any adverse effects or researcher non-compliance determinations associated with REB-approved research. NOTE: Studies funded by external grants typically require reporting such incidents to the funding agency.

HRPP/REB Office Staff Responsibilities

Records Maintenance

The HRPP/REB Office staff will maintain an active database of all research, including but not limited to initial review dates, protocol review dates, other review dates (e.g., continuing reviews and adverse events), and all actions of the HRPP Director, REB Chair, REB members, convened meeting decisions for each protocol application, business agenda items, and policy additions, revisions, and/or changes (Code of Federal Regulations, 45 CFR § 46.115.b).

The Office staff will store securely and maintain all REB protocol applications and associated records for the length of time required by the NSU REB Records Maintenance policy and the HHS Regulations (Code of Federal Regulations, 45 CFR § 46.115.b).

Applicant Correspondence

The HRPP/REB Office staff will send correspondence in a timely manner to the applicant(s) concerning the status of the application for the following purposes in accordance with HHS Regulations (Code of Federal Regulations, 45 CFR § 46.115.a.4) via the electronic REB portal:

1. Acknowledgement of receipt by the REB Office.
2. Intake Review Results
    a. The determination of the completeness of protocol applications
    b. The identification of any missing required documentation
    c. Verification of all required training.
3. Official Decision Letter
    a. Approval or disapproval of any of the following, including any necessary details regarding the decision made.
        i. The initial protocol application

ii. Continuing review
iii. Protocol amendments
iv. Adverse events report, etc.

4. Other Information: Any other information deemed necessary to provide the applicant(s) with full accounting during and after the review process as well as the results of that process.

REB Records Maintenance Policies

Protocol Data

All data generated from all NSU REB-approved human participant protocols must be stored securely by PI, or the faculty advisor, as appropriate, for a minimum of three years after the study closes and remain accessible only to the PI, or faculty advisor, if applicable (Code of Federal Regulations, 45 CFR § 46.115.b).

HRPP/REB Office Data

All records generated/gathered, stored, and/or maintained by the Office, including REB applications and all related documentation, meeting agendas, and meeting minutes, must be stored securely for a minimum of five years and accessible only to HRPP/REB Office personnel.

Data Obsolescence

At regular intervals, at least once per year, records that contain personally identifiable information (PII) and deemed by the HRPP Director as obsolete or no longer needed will be destroyed so that the PII cannot be read or reconstructed.

References

Family Educational Rights and Privacy Act, 20 U.S.C. § 1232g (1988). https://www.ecfr.gov/current/title-34/subtitle-A/part-99

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (1979). *The Belmont report: Ethical principles and guidelines for the protection of human subjects of research*. U.S. Department of Health and Human Services. https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html

National Research Act of 1974, 42 U.S.C. § 289 (1974). https://www.govinfo.gov/content/pkg/STATUTE-88/pdf/STATUTE-88-Pg342.pdf

Office for Human Research Protections. (2016, February 12). *About OHRP*. U.S. Department of Health and Human Services. https://www.hhs.gov/ohrp/about-ohrp/index.html

Office for Human Research Protections. (2022, November 8). *Human Research Protection Program Resources*. U.S. Department of Health and Human Services. https://www.hhs.gov/ohrp/education-and-outreach/human-research-protection-program-fundamentals/index.html

Protection of Human Subjects, 45 C.F.R. § 46 *et seq*. (2018). https://www.ecfr.gov/on/2018-07-19/title-45/subtitle-A/subchapter-A/part-46

Appendices

Appendix A

REB Administrator Qualifications and Responsibilities

I. Administrator Qualifications

a. Employment

    a. Full-time NSU employee in good standing (required)

    b. Faculty status (required; tenured status is preferred)

b. Experience

    a. Previous experience as a researcher (required; human subjects research preferred)

    b. Previous experience as an REB member (preferred)

II. Responsibilities

a. HRPP Director

1. Coordinating the creation, dissemination, review, and revision of official HRPP/REB materials-forms, publications (including the official website), and policy statements.
2. Creating, maintaining, and updating the HRPP/REB administrative systems, including the REB protocol application submission/review system and HRPP/REB Office files.
3. Managing the daily operations of the HRPP/REB Office, including hiring, training, and supervising office staff.
4. Managing the REB membership roster, member eligibility, and member recruitment.
5. Designing and disseminating in-house educational programs for NSU faculty, staff, students, and REB members on the relevant federal regulations and HRPP/REB policies and procedures.
6. Conducting the initial review for all REB protocol applications and sending those protocols that require Expedited and Full Board review to the REB Chair for REB member reviewer assignment.
7. Overseeing the review of NHSR and Exempt protocol applications, including assigning REB members as reviewers as needed.
8. Notifying the principal investigator of the final approval decision for every protocol application (NSHR, Exempt, Expedited, and Full board).
9. Coordinating continuing review of all protocols deemed more than minimal risk and the investigation of noncompliance and adverse events for all approved protocols.
10. Coordinating review concerning the quality and effectiveness of the HRPP/REB.

11. Planning and preparing regular reports on HRPP/REB performance.
12. Coordinating HRPP/REB activities and areas of mutual interest with related university offices (e.g., Academic Affairs Office; Graduate Council; Institutional Animal Care and Use Committee (IACUC); Research Council; Sponsored Programs Office).
13. Collaborating with NSU administrators (e.g., Deans; Directors) and research coordinators on issues of mutual interest in research administration and HRPP/REB policies and procedures.
14. Providing required HRPP/REB regulatory documentation to and communicating with federal oversight agencies, including the U.S. Office of Human Research Protections (OHRP).
15. Monitoring changes in federal regulations and guidance and coordinating the update/revision of HRPP/REB policies.
16. Initiating and managing projects to raise funding for HRPP/REB operations and programs.
17. Administering contracts for HRPP/REB purposes, such as reliance, data use, and outside vendor agreements.
18. Reporting regularly to the NSU Institutional Official on HRPP/REB activities and current issues and needs.
19. Maintaining up-to-date knowledge of HRPP and REB laws, procedures, and practices through regular training via CITI Program, PRIM&R, and OHRP workshops.

b. REB Chair

1. Assigning REB members as reviewers for all Expedited review protocols.
2. Planning REB convened meetings, including meeting scheduling and distributing meeting materials, including all protocol reviews that require an REB official vote.
3. Facilitating REB convened meetings, including establishing quorum; leading discussions; enacting voting procedures for protocol reviews and policy questions; tabulating official vote results.
4. Reporting the results of the Expedited and Full Board protocol reviews to the HRPP/REB Office staff.
5. Overseeing the preparation of the final copy of the official REB convened meeting minutes in collaboration with the HRPP/REB Office staff.
6. Communicating regularly with the HRPP Director to coordinate activities and discuss current issues (e.g., HRPP/REB policies and procedures).
7. Maintaining up-to-date knowledge of REB procedures and practices through regular training via CITI Program.

Appendix B

REB Voting Members Qualifications and Responsibilities

I. Qualifications

a. NSU Faculty/Staff/Student Members

i. Full-time university employee or student in good standing.

ii. Assigned to an NSU academic or administrative unit.

iii. Does not currently serve as a full-time NSU administrator (except Student Affairs Rep.).

iv. Serves for three consecutive academic years on the NSU REB (except student members).

v. Must complete the required REB member training courses prior to service start.

vi. Community Members

a. Not employed in any capacity by NSU.

b. Not currently serving on an NSU body (unit, board, committee, etc.) **in** a paid or unpaid role.

c. Immediate family members do not currently serve NSU **in** B.**l** or B.2.

d. Serves for three consecutive years on the NSU REB.

e. Must complete the required REB member training courses prior to service start.

II. Responsibilities

a. Current Knowledge

i. Review regularly required training courses and current NSU REB policies and procedures.

b. Confidentiality

i. Keep confidential all NSU REB business (both spoken and written), including NSU REB meetings and protocol reviews, and only share such information with current members of the REB.

c. Attendance

i. Attend scheduled REB Convened Meetings and participate in member discussions of official votes on policy questions and Full Board protocol reviews.

d. Exempt and Expedited Reviews

i. As assigned, complete in a timely manner reviews of Exempt and Expedited research protocols.

e. Informed Consent Documents Reviews

    i. As assigned, review the informed consent granted by the human participant, including each signed and dated consent form.

Appendix C

Public Data Sets

Public Data Sets Policy Proposal

(Updated 2026.08.31)

The collection and use of data from public data sets (PDS) is not considered human subject research if the following three criteria are met:

1. The researcher will NOT merge any of the PDS so that individuals might be identified.
2. The research will NOT enhance any PDS with personally identifiable information (PII) or potentially identifiable data.
3. The data host does NOT require the researcher or the researcher's institution to sign a Data Use Agreement.

If the above criteria are met and the research will involve data collected from PDS pre-approved by the NSU REB (see the current PDS Approved List at https://www.nsula.edu/academics/colleges-and-schools/the-graduate-school/irb/), the study will qualify for NHSR designation.

Notes:

- The PDS Approved List is not comprehensive. For example, some universities provide certain public data sets. Check the website of the desired data archive for available data sets, restrictions on use, etc.
- The use of data from a PDS that is not on the Approved List must be approved by the NSU REB prior to the start of the study. Contact the NSU REB Office for more information.
- Some data archives charge fees for the use of their data. Consult the archive policies for more information.
- The NSU REB encourages university researchers to consider locating an appropriate data archive to store data collected in research work. If the list below does not include an appropriate archive, consult the Registry of Research Data Repositories, a global registry of research data archives from various academic disciplines. Web link: https://www.re3data.org/.

Appendix D

REB Meeting Minutes Form

Meeting Information and Call to Order					
Meeting Date:		Location (Building/Room):			
Agenda Date:	Begin Time:	Minutes Recorder (Print Full Name):			
Attendance (REB Voting: Member)					
Full Name:	Non-scientist?	Attending?	Eligible to vote?	If not eligible to vote, state reason	Online Attendance
College of Arts & Sciences					
College of Business and Technology					
Community Members					
Gallaspy College of Education & Human Development					
Graduate Student Representatives					
College of Nursing and School of Allied Health					
Student Affairs Representative					
Total					
REB Chair					
				Votes only in case of a tie	

REB Non-voting Members & Outside Visitors		
Full Name:	Attending?	Reason for attendance

Current Meeting Agenda: Voice Vote				
Quorum and Discussion				
Quorum	# Of Voting Members Present/Total Members:			
	#Of Voting Members Who Arrived Late:			
	# Of attending members excused:			
	# Of Voting Members Eligible/Total Members:			
	Non-scientist present?	No	Yes	
	Quorum Established?	No	Yes	
Discussion (Summary):				
Motion for Approving Current Meeting Agenda				
Call for Motion (Voting Member Name):				
Motion Text:				
Amendment Text:				
Motion Seconded?	No	Yes	Voting Member Name:	
Vote (by voice):				
(If Member vote tied: the REB Chair or designee votes)				
Motion Passes?	No	Yes		
Explanatory Notes + any actions taken (Required if response above is "No"):				
Precious Meeting Minutes: Voice Vote				
Quorum and Discussion				
Quorum	# Of Voting Members **Present/Total** Members:			
	#Of Voting Members Who Arrived Late:			
	# Of attending members excused:			
	# Of Voting Members **Eligible/Total** Members:			
	Non-scientist present?	No	Yes	
	Quorum Established?	No	Yes	
Discussion (Summary):				
Motion for Approving Previous Minutes Vote				
Call for Motion (Voting Member Name):				
Motion Text:				
Amendment Text:				
Motion Seconded?	No	Yes	Voting Member Name:	
Vote	For (Tally#)=	Opposed (Tally#) =	Abstained (Tally#)=	

(If Member vote tied: the REB Chair or designee votes)			
Motion Passes?	No	Yes	Voting member Name:
Explanatory Notes+ any actions taken (Required if response above is "No"):			
Protocol Applications (See Part B: Agenda Items: Discussion and Formal Voting worksheet)			
Notes:			
Other Business: Formal Vote Required			
First Business Item: Quorum and Discussion			
Quorum	# Of Voting Members **Present/Total** Members:		
	# Of Voting Members Who Arrived Late:		
	# Of attending members excused:		
	# Of Voting Members **Eligible/Total** Members:		
	Non-scientist present?	No	Yes
	Quorum Established?	No	Yes
Discussion (Summary):			
Motion for Approving First Business Item			
Call for Motion (Voting Member Name):			
Motion Text:			
Amendment Text:			
Motion Seconded?	No	Yes	Voting Member Name:
Vote	For (Tally#)=	Opposed (Tally#) =	Abstained (Tally#) =
(If Member vote tied: the REB Chair or designee votes)			
Motion Passes?	No	Yes	
Explanatory Notes+ any actions taken (Required if response above is "No"):			
Second Business Item: Quorum and Discussion			
Quorum	# Of Voting Members **Present/Total** Members:		
	# Of Voting Members Who Arrived Late:		
	# Of attending members excused:		
	# Of Voting Members Eligible/Total Members:		
	Non-scientist present?	No	Yes
	Quorum Established?	No	Yes
Discussion (Summary):			
Motion for Approving Second Business Item			
Call for Motion (Voting Member Name):			
Motion Text:			
Motion Seconded?	No	Yes	Voting Member Name:
Vote	For (Tally#)=	Opposed (Tally#)=	Abstained (Tally #) =

(If Member vote tied: the REB Chair or designee votes)			
Motion Passes?	No	Yes	
Explanatory Notes+ any actions taken (Required if response above is "No"):			
Third Business Item: Quorum and Discussion			
Quorum	# Of Voting Members **Present/Total** Members:		
	# Of Voting Members Who Arrived Late:		
	# Of attending members excused:		
	# Of Voting Members Eligible/Total Members:		
	Non-scientist present?	No	Yes
	Quorum Established?	No	Yes
Discussion (Summary):			
Motion for Approving Third Business Item			
Call for Motion (Voting Member Name):			
Motion Text:			
Motion Seconded?	No	Yes	Voting Member Name:
Vote	For (Tally#)=	Opposed (Tally#)=	Abstained (Tally #) =
(If Member vote tied: the REB Chair or designee votes)			
Motion Passes?	No	Yes	
Explanatory Notes+ any actions taken (Required if response above is "No"):			
Other Business: Formal Vote Not Required			
A. Announcements & Progress Reports			
B. Recent NSU REB Activities			
C. Upcoming NSU REB Activities			
D. Convened Meetings: Upcoming Schedules			
Meeting Adjournment			
Voice Vote:			
Adjournment Time:		Adjournment Date:	
Minutes Recorder Signature:			

Appendix E

REB Meeting Minutes Form Part B

Part B: Agenda Items—Discussion & Formal Voting Worksheet

Directions: The Minutes Recorder completes ONE Worksheet for each protocol or business item scheduled for a formal vote that is listed on the IRB meeting agenda. Add additional sheets as needed.

Protocol Applications			
Protocol Applications: Quorum and Discussion			
Convened Meeting Date:			
Agenda Item #:			
Protocol # (if applicable):			
Quorum	# Of Voting Members **Present**/Total Members:		
	#Of Members Who Arrived Late:		
	# Of members in attendance excused:		
	# Of Voting Members **Eligible**/Total Members:		
	Non-scientist present?	No Yes	
	Quorum Established?	No Yes	
Discussion Summary:			
Motion for the Protocol Application			
Call for Motion (Voting Member Name):			
Motion Text:			
Amendment Text:			
Motion Seconded?	No Yes	Voting Member Name:	
Vote	Approve (Tally #) =		
	Approve Conditionally (Tally #) =		
	Disapprove (Tally #) =		
	Abstain (Tally #) =		
	Table (Tally #) =		
Vote Result:			
Explanatory Notes + any actions taken (Required if E. is "Approve Conditionally," "Disapprove," or "Table"):			