Northwestern State University of Louisiana

Institutional Review Board

Policies & Procedures Manual

2024-25

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Table of Contents

Mission Statement

The mission of the Northwestern State University (NSU) Institutional Review Board (IRB) 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* (1979), which has informed U.S. federal law and public policy on research with human subjects for more than four decades.

The IRB bases its requirements and actions regarding the approval of any research study (or "protocol") on the principles of *The Belmont Report* (1979), the National Research Act of 1974 (1974), and the regulations developed by the U.S. Department of Health and Human Services (HHS) for the protection of human subjects of research (2018). These guidelines require that research with human beings must "maximize potential benefits and minimize possible harms" (*The Belmont Report*, p. 6, 1979).

Policy and Procedure Manual Purpose

The primary purpose of the Policies & Procedures Manual is to inform IRB members, IRB Office staff, and NSU administrators of the current operational standards concerning Board membership, eligibility, and general responsibilities; procedures for protocol review and approval; post-approval monitoring of protocols; the reporting of decisions and related actions; IRB Office responsibilities; and records management policies. These standards are informed by the IRB Mission Statement and the HHS regulations (Protection of Human Subjects, 2018).

A secondary purpose is to acknowledge publicly the work of the NSU IRB and to contribute to institutional transparency by making this manual available on the IRB website free of charge. We welcome feedback through the free exchange of ideas, a central goal of the university community.

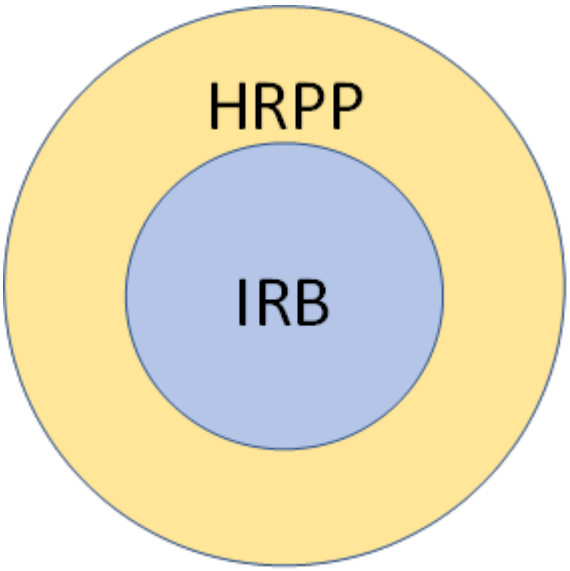
Human Subject Research Protections

Human Research Protection Program

The Human Research Protection Program (HRPP, 2022) concept was instituted by the federal Office of Human Research Protections (OHRP, 2016), which oversees all U.S.-based IRBs 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 IRB in its mission to protect human subjects in research protocols (see Figure). This section of the Manual identifies those specific units, groups, and individuals at Northwestern State University of Louisiana.

Figure

HRPP and IRB Relationship Model



Through the HRPP, the OHRP and the university acknowledge that the NSU IRB 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 IRB in making effective decisions regarding the welfare and rights of human participants in a particular research protocol.

HRPP Director and IRB Chairperson

The complete duties and responsibilities of the HRPP Director and IRB Chair are listed in Appendix A.

Faculty Status

The HRPP Director and IRB Chair should be tenured faculty; however, the Dean of the Graduate School may appoint any full-time NSU faculty member to either position.

Reporting Relationship

The HRPP Director will report directly to the Dean of the Graduate School. The IRB 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. However, other NSU offices, groups, and individuals can be involved in the HRPP when needed. For example, the University Registrar has been consulted in the past concerning the effects of data privacy procedures and the university's responsibilities under the Family Educational Rights and Privacy Act (FERPA, 1988).

1. Institutional Official (Dean of the Graduate School)
2. NSU HRPP Director
3. University Offices/Groups/Individuals
    a. Academic Affairs Office
    b. IRB Office
    c. Administrators - Deans/Academic Unit Heads/Directors
    d. University Research Coordinators
    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, individuals as needed.

IRB Membership

Membership in the IRB is comprised of members of the HRPP and are guided by the HHS regulations (Protection of Human Subjects, 2018, § 46.107).

The IRB members must represent a variety of backgrounds, including area of expertise, experience, gender, race, and age (Protection of Human Subjects, 2018, § 46.107.a). The IRB membership shall be sufficiently qualified through the experience and expertise of its members to provide effective review of research protocols commonly conducted at Northwestern State University.

Required Member Categories

The IRB 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

The IRB reserves the right to appoint additional voting members in various areas of expertise as needed with approval from the Dean of the Graduate School. A complete list of the duties and responsibilities of IRB voting members is listed in Appendix B.

1. College of Arts and Sciences: three members (to include one member from the Louisiana Scholars' College)
2. College of Business and Technology
3. College of Education and Human Development: two members
4. College of Nursing and School of Allied Health
5. Student Affairs Representative (Dean or designee)
6. Graduate Student Representative
7. Community Representative
    a. The IRB Community Representative shall not have any relationship, formal or informal, with NSU. For example, a university employee, outside contractor, member of an unpaid university board or group. Additionally, immediate family members of a university employee, outside contractor, or member of an unpaid university board or group are ineligible to serve as the Community Representative

(Protection of Human Subjects, 2018, § 46.107.c).

Required Expertise

Among the voting members, the IRB must have at least one member whose primary expertise is in a scientific area and at least one member whose primary expertise is in non-scientific areas (Protection of Human Subjects, 2018, § 46.107.b). At least one non-scientific IRB member must be present at any NSU IRB Convened Meeting when a formal vote of the membership will be taken.

Non-Voting Members

1. IRB Chair
2. Dean of the Graduate School (or designee)
3. Sponsored Programs Office Representative

Alternate Members

The IRB may have alternate members whose role is to attend IRB 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.

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.

Membership Term

Membership in the IRB is for three consecutive academic years (August through May). When the member's term is about to expire, the HRPP Director 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 IRB term. Membership in the NSU IRB is subject to approval by the Dean of the Graduate School.

Member Training Requirements

Each member of the IRB must successfully complete the required IRB Member training before beginning service and must maintain certification for the entire term of service.

All required IRB training is offered exclusively through CITI Program. Training certificates received from other vendors will not be accepted (see Appendix C). Training certificates are

valid for five years after the award date for all members.

1. IRB Members: Stage 1 – Basic Course
2. Conflicts of Interest – Basic Course

Outside Consultants

The IRB 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 IRB membership (Protection of Human Subjects, 2018, § 46.107.e). Outside consultants do not receive voting privileges.

IRB Voting Member Responsibilities

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

Current Knowledge

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

Confidentiality

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

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 IRB'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 IRB'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 (Protection of Human Subjects, 2018, § 46.111.a.4). The IRB may require that information, in addition to that specifically mentioned in § 46.111, 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.

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 IRB 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 IRB-related materials to the electronic IRB portal. The NSU IRB uses Single Sign-on (SSO) to manage use access. First, log in to the NSU computer network using your NSU email credentials. Information for researchers prior to enrolling can be found on the NSU IRB website.

Data Use Policy

The collection and use of data from public data sets (PDS) is not considered human subject research if certain criteria are met (see Appendix D). Data from NSU-owned databases can be approved for use in an NSU IRB-approved research study if criteria listed in the Data Use Policy are met (see Appendix E).

Outside Researcher Requirements

Researchers not affiliated with NSU as a faculty, staff, or student seeking to use NSU students and/or personnel for human subject research study must obtain approval from the NSU IRB (see Appendix F).

Researchers not affiliated with NSU as a faculty, staff, or student are required to complete an Individual Investigator Agreement prior to beginning any research activity (see Appendix G).

Non-human Subjects Research (NHSR) Protocol

The NSU IRB NHSR Questionnaire is required for all planned research protocols conducted by NSU faculty or students (see Appendix H) and is reviewed by the HRPP Director or delegated to the IRB Chair or designated IRB voting member(s) to verify status. For a designated reviewer, the member eligibility rules apply (Protection of Human Subjects, 2018, § 46.107). The reviewer completes the NHSR Questionnaire Reviewer Checklist via the electronic IRB portal to determine if the proposed protocol qualifies as NHSR.

If accepted as an NHSR protocol, the HRPP Director, or designee, may approve the application, set forth conditions of approval, or may elect to have the entire IRB committee or an IRB sub-committee review the application. Records will be maintained of all activities regarding actions on the application.

Applications accepted as NHSR protocols will undergo review by the HRPP Director, delegated to the IRB Chair, or designated IRB voting member(s) to verify status using the Protocol Review Checklist (see Appendix I).

Protocol Review Categories

Guidance for Exempt and Expedited Research Categories can be found in Appendices J and K.

Exempt Protocol

Reviewed by the HRPP Director or delegated to the IRB Chair or designated IRB voting member(s) to verify status. For a designated reviewer, the member eligibility rules apply (Protection of Human Subjects, 2018, § 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 IRB 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 IRB committee or an IRB sub-committee review the application. Records will be maintained of all activities regarding actions on the application.

Limited Review Protocol

Reviewed by the IRB Chair or designated IRB voting member(s). The member eligibility rules apply (Protection of Human Subjects, 2018, § 46.107). If the reviewer(s) cannot serve as a reviewer, the IRB Chair, or designee will select another voting member. The review is conducted to determine whether the protocol has met the requirements for Limited Review (Protection of Human Subjects, 2018, § 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 IRB membership or an IRB sub-committee review the application, with approval from the IRB Chair. Records will be maintained for all activities regarding actions on the application.

Expedited Protocol

Reviewed by a subcommittee of one or two (2) IRB voting members, assigned by the IRB Chair and notified via the electronic IRB portal. The member eligibility rules apply (Protection of Human Subjects, 2018, § 46.107). If one or both of the appointed reviewers cannot serve, the IRB Chair, or designee, will select another voting member. (NOTE: The IRB Chair may serve as one member of the subcommittee, if necessary, provided conflict of interest issues are addressed). A copy of each protocol application will be delivered to the subcommittee members. The members will review the protocol application and all supplementary documentation and then complete the Protocol Review Checklist (see Appendix I) via the electronic IRB portal. Each reviewer will vote for Approval or Conditional Approval. The votes will be communicated to the IRB Chair and include 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 IRB meeting. Written records will be recorded and maintained of all activities regarding actions on study protocols.

Full Board Protocol

Reviewed at a convened meeting of the full IRB voting membership (see next section).

IRB Convened Meeting Policies and Procedures

An official, convened meeting of the IRB 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. Official convened meeting minutes.

Voting Eligibility

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

Training

No member of the IRB may participate in discussions of regular business items or vote if the training requirements for IRB members have not been met or a required training certificate has expired.

Conflicts of Interest

No member of the IRB may participate in discussions of regular business items or vote on them where there is any form of conflict of interest. A member has the responsibility to recuse themselves from a convened IRB meeting prior to the discussion of and formal vote on regular business items for which a conflict of interest is known to exist (Protection of Human Subjects, 2018, § 46.107.e).

Meeting Organization

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

Parliamentary Procedure

All IRB convened meetings will follow the general rules of parliamentary procedure; the IRB 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.

Quorum Requirement

The IRB 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 IRB Chair, or designee will keep track of all

current IRB 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 membership on each agenda item requiring a formal vote for both protocol applications and other IRB 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 IRB chair will call for a motion to approve the official agenda for the current meeting. Once the motion is seconded by a voting member, a voice vote is taken, and the results are recorded in the minutes.

Approval of Minutes

Next, the IRB chair will call for a motion to approve the minutes from the previously convened meeting. Once the motion is seconded by a voting member, a voice vote is taken, and the results are recorded in the minutes.

Discussion and Voting, Regular Business Items.

All IRB 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 IRB Chair, or designee will call for a motion to open discussion of the IRB 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 IRB Chair then calls for a vote on the protocol.

Formal Vote

After a quorum is established, the IRB chair will call for a motion to vote on the current protocol application. Once the motion is seconded by a voting member, a voice vote is taken, and the results are recorded in the minutes. The IRB 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 three options: Approve, Approve with Conditions, or Disapprove.

Passing Vote

A passing vote (Approve, Approve with Condition, or Disapprove) requires a simple majority vote of the established quorum. If the voting members' vote ends in a tie, the IRB Chair may 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 IRB 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 IRB 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 IRB meeting. The IRB members will view these applications as new 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 IRB 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 IRB Meeting Minutes Form Part B (see Appendix M). The IRB Meeting Minutes Form Part B is only used when voting on protocol applications.

Continuing Application Review Requirements

Time Frame

The IRB members shall determine when a continuation review will be conducted for Expedited and Full Board application reviews (Protection of Human Subjects, 2018, § 46.109.e).

Stipulations

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

Reviewer Assignment

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

Waiver or Changes to Informed Consent Requirements

The IRB will document via the electronic IRB portal, 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 (Protection of Human Subjects, 2018, § 46.117.c). This 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 (Protection of Human Subjects, 2018, § 46.Subpart B)
2. Prisoners (Protection of Human Subjects, 2018, § 46.Subpart C)
3. Cognitively impaired persons
4. Children (Protection of Human Subjects, 2018, § 46.Subpart D)

Federal law does not require informed consent for Exempt protocols, but the NSU IRB reserves the right to require informed consent whenever it deems it necessary. Informed consent is recommended for all IRB-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 IRB Meeting Minutes Form (see Appendix L). All meetings will record the following in the official minutes (Protection of Human Subjects, 2018, § 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 IRB 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 IRB policies*
    b. Announcements
    c. IRB recent activity reports, including but not limited to:
        i. HRPP Director, IRB Chair, or IRB member or sub-committee reviews of Exempt, Limited Review, and Expedited protocols
        ii. Adverse Events
        iii. Continuing Review results
        iv. Changes in HRPP/IRB Office policies
    d. Membership changes
    e. Upcoming meeting schedules
9. A summary of the discussion of each protocol application including
    a. Controverted Issues
        i. Those issues causing debate among the members.
        ii. The resolution of the controverted issue
    b. The establishment of a quorum before any formal vote
    c. The final tally of the formal vote for each protocol application
    d. 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 time that the meeting was adjourned
11. The signature of the meeting recorder and the date signed.

Post-Approval Protocol Monitoring: Policies and Procedures

Continuing Review Time Requirements

The IRB members shall determine when a continuation review will be conducted for Expedited and Full Board approved protocols. Research protocols approved under the 2018 Common Rule are eligible for continuing review (Protection of Human Subjects, 2018, § 46.112).

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 review time frames of greater than 12 months, a continuing review is required within 12 months of the IRB 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 IRB and deemed more than minimal risk require continuing review (Protection of Human Subjects, 2018, § 46.109.e).

High-risk Protocols. Require the PI to complete a Continuing Review Form (see Appendix N). The IRB 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 IRB 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 IRB members shall determine any special requirements for the review.

Unapproved Protocol Changes. Research projects where concerns have been raised about possible material changes to the protocol without IRB 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 IRB.

Continuing Review Procedure

Reviewer Assignment

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

The Continuing Review

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

Outside Consultants

If the IRB 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 IRB review, the HRPP Director, or designee will appoint a person knowledgeable in that area to assist the IRB reviewer in the continuing review (Protection of Human Subjects, 2018, § 46.109.g).

Summary Report

The findings of the designated representative will be brought before the IRB 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 IRB 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 IRB application form including all supplemental documentation.
3. Any information related to currently associated protocol risks.
4. A summary of any relevant recent IRB 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 IRB 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 IRB Chair then calls for a vote on the Continuing Review.

Formal Vote

After a quorum is established, the IRB chair will call for a motion to vote on the Continuing Review. Once the motion is seconded by a voting member, a voice vote is taken, and the results are recorded in the minutes. The IRB 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 IRB 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 IRB 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, IRB 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 IRB membership decision status, including any further action required via the electronic IRB portal. Notifications may be made to the Faculty Advisor, the Department Head, and the Institutional Official, as appropriate (Protection of Human Subjects, 2018, § 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 (Protection of Human Subjects, 2018, § 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 IRB determines to be applicable via the electronic IRB portal. The research protocol may not be resumed until the PI has received written approval from the IRB.

The completed Amendment Request or Adverse Events form will be reviewed and discussed at the next convened IRB 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 IRB-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 IRB website via the electronic IRB portal.

Protocol Amendment Approval Procedure

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

Formal Vote

After a quorum is established, the IRB chair will call for a motion to vote on the Continuing Review. Once the motion is seconded by a voting member, a voice vote is taken, and the results are recorded in the minutes. The IRB 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 IRB 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 IRB 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 IRB portal. Notifications may be made to the Faculty Advisor, the Department Head, and the Institutional Official, as appropriate (Protection of Human Subjects, 2018, § 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, IRB members or other observers, etc. (Protection of Human Subjects, 2018, § 46.113).

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

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

Adverse Event Consideration

Opening of Discussion

The IRB 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 IRB 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 IRB.

Continuation

If the changes are approved, the PI is notified by the HRPP Director, or designee (Protection of Human Subjects, 2018, § 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 IRB 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/IRB Office policies) will be reported at the next convened meeting and recorded in the meeting minutes (Protection of Human Subjects, 2018, § 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

IRB-approved research. NOTE: Studies funded by external grants typically require reporting such incidents to the funding agency.

HRPP/IRB Office Staff Responsibilities

Protocol Number Assignment

The HRPP/IRB Office staff will conduct "intake" for all new IRB protocol applications, record the receipt, and assign a unique Protocol Number to each separate application. The number format is XX-XXX, for Year-Sequence. Example: The first application received in the 2022-23 academic year (September through August) will be given Protocol Number 22-001.

Records Maintenance

The HRPP/IRB 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, IRB Chair, IRB members, convened meeting decisions for each protocol application, business agenda items, and policy additions, revisions, and/or changes (Protection of Human Subjects, 2018, § 46.115.b).

The Office staff will store securely and maintain all IRB protocol applications and associated records for the length of time required by the NSU IRB Records Maintenance policy and the HHS Regulations (Protection of Human Subjects, 2018, § 46.115.b).

Applicant Correspondence

The HRPP/IRB 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 (Protection of Human Subjects, 2018, § 46.115.a.4) via the electronic IRB portal:

1. Acknowledgement of receipt by the IRB 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 a full accounting during and after the review process as well as the results of that process.

IRB Records Maintenance Policies

Protocol Data

All data generated from all NSU IRB-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 (Protection of Human Subjects, 2018, § 46.115.b).

HRPP/IRB Office Data

All records generated/gathered, stored, and/or maintained by the Office, including IRB 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/IRB 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

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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

Appendix A

IRB Administrator Qualifications and Responsibilities

I. Administrator Qualifications
   a. Employment
      1. Full-time NSU employee in good standing (required)
      2. Faculty status (required; tenured status is preferred)
   b. Experience
      1. Previous experience as a researcher (required; human subjects research preferred)
      2. Previous experience as an IRB member (preferred)

II. Responsibilities
   a. HRPP Director
      1. Coordinating the creation, dissemination, review, and revision of official HRPP/IRB materials—forms, publications (including the official website), and policy statements.
      2. Creating, maintaining, and updating the HRPP/IRB administrative systems, including the IRB protocol application submission/review system and HRPP/IRB Office files.
      3. Managing the daily operations of the HRPP/IRB Office, including hiring, training, and supervising office staff.
      4. Managing the IRB membership roster, member eligibility, and member recruitment.
      5. Designing and disseminating in-house educational programs for NSU faculty, staff, students, and IRB members on the relevant federal regulations and HRPP/IRB policies and procedures.
      6. Conducting the initial review for all IRB protocol applications and sending those protocols that require Expedited and Full Board review to the IRB Chair for IRB member reviewer assignment.
      7. Overseeing the review of NHSR and Exempt protocol applications, including assigning IRB 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/IRB.
11. Planning and preparing regular reports on HRPP/IRB performance.
12. Coordinating HRPP/IRB 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/IRB policies and procedures.
14. Providing required HRPP/IRB 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/IRB policies.
16. Initiating and managing projects to raise funding for HRPP/IRB operations and programs.
17. Administering contracts for HRPP/IRB purposes, such as reliance, data use, and outside vendor agreements.
18. Reporting regularly to the NSU Institutional Official on HRPP/IRB activities and current issues and needs.
19. Maintaining up-to-date knowledge of HRPP and IRB laws, procedures, and practices through regular training via CITI Program, PRIM&R, and OHRP workshops.

IRB Chair

1. Assigning IRB members as reviewers for all Expedited review protocols.
2. Planning IRB convened meetings, including meeting scheduling and distributing meeting materials, including all protocol reviews that require an IRB official vote.
3. Facilitating IRB convened meetings, including establishing quorum; leading discussions; enacting voting procedures for protocol review and policy questions;

tabulating official vote results.

4. Reporting the results of the Expedited and Full Board protocol reviews to the HRPP/IRB Office staff.
5. Overseeing the preparation of the final copy of the official IRB convened meeting minutes in collaboration with the HRPP/IRB Office staff.
6. Communicating regularly with the HRPP Director to coordinate activities and discuss current issues (e.g., HRPP/IRB policies and procedures).
7. Maintaining up-to-date knowledge of IRB procedures and practices through regular training via CITI Program.

Appendix B

IRB 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 IRB (except student members).
      v. Must complete the required IRB member training courses prior to service start.
   b. Community Members
      i. Not employed in any capacity by NSU.
      ii. Not currently serving on an NSU body (unit, board, committee, etc.) in a paid or unpaid role.
      iii. Immediate family members do not currently serve NSU in B.1 or B.2.
      iv. Serves for three consecutive years on the NSU IRB.
      v. Must complete the required IRB member training courses prior to service start.

II. Responsibilities
   a. Current Knowledge
      i. Review regularly required training courses and current NSU IRB policies and procedures.
   b. Confidentiality
      i. Keep confidential all NSU IRB business (both spoken and written), including NSU IRB meetings and protocol reviews, and only share such information with current members of the IRB.
   c. Attendance
      i. Attend scheduled IRB Convened Meetings and participate in member discussions of and 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 subjects, including each signed and dated consent form.
f. In-progress Observations
    i. As assigned, observe the informed consent process and any research activities—while in progress—for any approved protocol.

Appendix C

NSU IRB Training Policy

NSU IRB Training Policy[a]				
PI	Field	Training[b]		
		Required		Optional[c]
Faculty/Staff	Biomed	Biomed Foundations	COI	RCR
	Social Behavior	SBE Foundations	COI	RCR
Student	Biomed	Biomed Foundations	COI	RCR
	Social Behavior	SBE Foundations	COI	RCR
IRB Member[d]	All	IRB Member[e]	COI	RCR
IRB Administrators[f]				

Note. Biomed = Biomedical Foundations; COI = Conflicts of Interest; IRB = Institutional Review Board; NIH = National Institutes of Health; NSF = National Science Foundation; PI = Primary Investigator; RCR = Responsible Conduct of Research; SBE = Social-Behavioral-Educational; USDA = U.S. Department of Agriculture.

[a]All required IRB training is offered exclusively through CITI Program

[b]Training certificates are valid for five years after the award date for all members.

[c]RCR is no longer required but is still recommended. NIH, NSF, and USDA require RCR training for grant-funded studies.

[d]Members with voting privileges.

[e]All required IRB Member training must be completed before beginning service and must be maintained for the entire time of service.

[f]IRB administrators and Institutional Officials are required to complete separate training.

Appendix D

Public Data Sets Policy

NORTHWESTERN STATE
Institutional Review Board

Public Data Sets Policy Proposal
(Updated 2024.08.01)

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

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

If the above three criteria are met and the research will involve data collected from PDS pre-approved by the NSU IRB (see the current PDS Approved List at nsula.edu/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 IRB prior to the start of the study. Contact the NSU IRB Office for more information.
--Some data archives charge fees for the use of their data. Consult the archive policies for more information.
--The NSU IRB 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 E

Data Use Policy

NORTHWESTERN STATE
Institutional Review Board

March 1, 2024

Data Use Policy: Proposal

Data from NSU-owned databases can be approved for use in an NSU IRB-approved research study *if the following three criteria are met*:

- The data must not include NSU students or personnel under 18 years old or any student, faculty, or staff member who has requested "Confidential" status for their NSU data.
- The NSU IRB must approve the collection and use of the data for the study, in accordance with federal regulations regarding data privacy and human subject protections.
- The data categories requested must be approved by the University Registrar.

If the above criteria are met, the data will be approved for use in the study. The Registrar will then authorize the dissemination of the requested data to the principal investigator (PI).

Appendix F

External Investigator Site Approval

March 1, 2024

NSU Site Request for External Investigators: Policy Proposal

If a researcher not affiliated with NSU as a faculty, staff, or student wishes to use NSU students and/or personnel for a human subject research study, the following procedure is required to request that approval:

- The researcher must have approval for the study from another IRB prior to seeking site approval from the NSU IRB (the signed and dated approval letter must be provided to the NSU IRB upon request);
- The researcher must send a letter (or email) *from their institutional account* to irb@nsula.edu requesting the site approval;
- The message must include:

  --a description of the study purpose;

  --the location of the study (at a specific NSU campus location or online);

  --the human participants to recruit (e.g., NSU undergraduate students; Business faculty);

  --the study procedures (e.g., participants will fill out a 15-minute survey on _____).

  --the data categories to be collected, how the data will be collected (e.g., online in Survey Monkey), and whether any data is personally identifiable information (PII).

If the above information is provided at least 60 days before the study start date, the NSU IRB will consider the site request and provide a signed and dated letter communicating the decision.

Appendix G

Individual Investigator Agreement

Human Research Protections Program

Individual Investigator Agreement

Name of Institution with the Federalwide Assurance (FWA):
Northwestern State University of Louisiana (NSULA)

Applicable FWA #: 000031473

Individual Researcher/Analyst/Field Worker's Name:

Specify Research Covered by this Agreement:
Protocol # XX-XXX: [Study Title]

---

(1) The above-named Individual Investigator has reviewed: 1) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*; 2) the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46; 3) the FWA and applicable Terms of the FWA for the institution referenced above; 4) the relevant institutional policies and procedures for the protection of human subjects; and 5) the protocol(s) cited above.

(2) The Investigator understands and hereby accepts the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under this Agreement.

(3) The Investigator will comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this agreement.

(4) The Investigator will abide by all determinations of the NSULA Institutional Review Board (IRB) and will accept the final authority and decisions of the IRB, including but not limited to directives to terminate participation in designated research activities.

(5) The Investigator will complete any educational training required by the Institution and/or the IRB prior to initiating research covered under this Agreement.

(6) The Investigator will report promptly to the IRB any proposed changes in the research conducted under this Agreement. The investigator will not initiate changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.

(7) The Investigator will report immediately to the IRB any unanticipated problems involving risks to subjects or others in research covered under this Agreement.

Human Research Protections Program

(8) The Investigator, when responsible for enrolling subjects, will obtain, document, and maintain records of informed consent for each such subject or each subject's legally authorized representative as required under HHS regulations at 45 CFR part 46 (or any other international or national procedural standards selected on the FWA for the institution referenced above) and stipulated by the IRB.

(9) The Investigator acknowledges and agrees to cooperate in the IRB's responsibility for initial and continuing review, record keeping, reporting, and certification for the research referenced above. The Investigator will provide all information requested by the IRB in a timely fashion.

(10) The Investigator will not enroll subjects or engage in human subjects research activities under this Agreement prior to review and approval of the protocol(s) cited above by the IRB, and approval of this agreement by the FWA Institutional Official.

(11) Emergency medical care may be delivered without IRB review and approval to the extent permitted under applicable federal regulations and state law.

(12) This Agreement does not preclude the Investigator from taking part in research not covered by this Agreement.

(13) The Investigator acknowledges that he/she is primarily responsible for safeguarding the rights and welfare of each research subject, and that the subject's rights and welfare must take precedence over the goals and requirements of the research.

Signature: _____ **Date:** _____

PI Name: **Degree**(s):

Address: **Phone #:**

City, State/Province Zip/Country **Email**:

FWA Institutional Official Signature: _____ **Date**: _____

Name: Greg Handel **Institutional Title**: Vice President for Academic Affairs & Provost

Address: Northwestern State University of Louisiana
175 Sam Sibley Drive
Natchitoches, LA 71457

Phone #: 318-357-5361

Appendix H

NSU IRB Non-human Subjects Research (NHSR) Questionnaire

NSU Email:

Date:

Part I. Study Type.
Directions: Check the appropriate box for each Study Type listed below to determine if your planned protocol is "Non-human Subjects Research (NHSR)." (This is a required step in the NSU IRB review process.) NOTE: If unsure of the answer, select "No"; do not leave any question blank.
In **Part II** (next page), provide a description of the study. Submit the completed form to the NSU IRB for review.

Study Type/Research Procedure[1]	Yes	No
Internal Data for Internal Use Only: This type is used for departmental, school, or other University administrative purposes. Examples: Course evaluations; customer service surveys.	☐	☐
Service Surveys Issued and Completed by University Personnel: The intent and purpose of the survey are to improve services and programs of the University or for developing new services or programs for students, employees, or alumni. The privacy of the subjects must be protected, the confidentiality of individual responses must be maintained, and survey participation is voluntary. Example: A survey of current university technology facilities and services.[2]	☐	☐
Information-gathering Interviews: The interview questions focus on things, products, or policies rather than people or their thoughts regarding themselves. Example: Interviews with company engineers or managers about how a product is made.	☐	☐
Course-related Activities: This type of study is designed specifically for educational or teaching purposes. The data are collected as part of a class exercise or course requirement but are not intended for use outside of the class.[3]	☐	☐
Quality Improvement (QI) Projects: The data collected from the project are used solely to improve or alter the quality of care or the efficiency of an institutional practice. Example: A new method to improve health outcomes.	☐	☐
Biography Research: A study of a living individual and the data are *not generalizable.*[4] Examples: Research in journalism, oral history/folklore, literature, and autoethnography (i.e., the researcher is the sole human subject).	☐	☐
Case History or Case Study: The study is limited to a description of the behavioral features and/or outcomes for *five or fewer* human subjects and the data are *not generalizable*[4]	☐	☐
Publicly Available Data: Examples: census data; labor statistics.[5]	Yes	No
Research with Deceased Individuals: This type includes data collected from cadavers, autopsy material, or biospecimens.[6]	☐	☐
Coded Private Information (including biological specimens). The data were not collected for the currently proposed protocol, and the investigator cannot link the coded data/specimens back to individual subjects.[7]	☐	☐

Part II. Protocol Description.
Directions: In the textbox below, provide the study details, including the title, purpose/goals, the number of human subjects involved and the age range, and the study procedures. For student investigators, provide the Research Supervisor's name and department.
Example:
Title: The Association between Athlete Emotional State and Athletic Performance
Purpose/Goals: To investigate how and when emotions contribute to and/or detract from an athlete's performance in an organized sport.
Number of Human Subjects: 25 adults (18-24 years old).
Study Procedures: Each subject will complete two self-assessments on their current emotional state, one before and one after a formal, organized athletics competition. Data on each athlete's performance will be correlated with the assessment results via statistical measurements to determine the association between the two variables.
Research Supervisor: Dr. Fred Faculty, Sports Psychology

Write the Protocol Description in the textbox below (*Note--Unlimited amount of text allowed*)

[1]Contact the NSU IRB if you are unsure whether your specific study fits any of these categories.

[2]If using previously collected and identifiable or coded service survey data for a new study intended to produce *generalizable knowledge,*[4] IRB review is required.

[3]Research for the dissertation, thesis, or "papers-in-lieu" of thesis course does not qualify as "course-related activity." IRB review is required.

[4]"Not generalizable": Data collected from individuals or groups that will not be applied to other individuals or groups outside of the study subjects. Example: Biography data collection is typically focused on the *uniqueness* of the individual or group being studied, not characteristics that the person or group shares with other people (or with people in general). Conversely, *generalizable knowledge* is applied to individuals or groups outside of the study subjects. Example: Medical research on finding a cure for childhood cancer. If the knowledge gained from the study is intended to be generalizable, IRB review is required.

[5]Contact the NSU IRB to confirm that the data to be collected are truly "publicly available."

[6]Research in this category that involves collecting information from *living* relatives of the deceased may require IRB review.

[7]If the data/specimen provider has access to the identity of the subjects (e.g., names, addresses, etc.), the investigator must enter into an agreement with the data/specimen provider that states under no circumstances will the identity of the subjects be released to the investigator. *The investigator cannot independently make this determination.* This project requires verification from the IRB Chair or designee (See http://www.hhs.gov/ohrp/policy/cdebio.pdf for more information).

Appendix I

Protocol Review Checklist

Criteria for IRB Review and Approval[2]: Please review the federal criteria for IRB approval and indicate whether the protocol meets each criterion by checking the appropriate box.

Protocol ID#	IRB Reviewer Name:	Date:

	Personnel & Study Purpose	Yes	No	N/A	Comments
1	The IRB has the expertise needed to review this protocol.	☐	☐	☐	"If "no," contact the IRB Office to consult with external experts.)
2	I, the IRB reviewer, have a conflict of interest with this protocol.	☐	☐	☐	(If "yes," contact the IRB Office to arrange re-assignment.
3	The research question/hypothesis is adequate.	☐	☐	☐	
4	Study personnel appear appropriate and qualified.	☐	☐	☐	CITI Program training required: ☐ Social Behavior ☐ Biomed Research ☐ Conflict of Interest
	Risk/Benefit Assessment[3]				
		Yes	No	N/A	Comments
5	Risks to subjects are minimized using procedures consistent with sound research design and do not unnecessarily expose subjects to risk.	☐	☐	☐	
6	Risks to subjects are minimized, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.	☐	☐	☐	
7	Risks to subjects are reasonable to both: Anticipated benefits, if any, to subjects; and The importance of the knowledge that may reasonably be expected to result	☐	☐	☐	
	Subject Selection				
		Yes	No	N/A	Comments
8	Selection of subjects is equitable to the purposes of the research and the setting in which the research will be conducted.	☐	☐	☐	
9	Selection of subjects (i.e., inclusion and exclusion criteria) is based on the protocol and the study's setting.	☐	☐	☐	
10	The recruitment process minimizes the potential for undue influence/coercion.	☐	☐	☐	
11	Compensation: Neither the amount of payment nor the proposed method and timing of disbursement is coercive or presents potential for undue influence.	☐	☐	☐	
12	Recruitment materials are appropriate.	☐	☐	☐	

Informed Consent					
		Yes	No	N/A	Comments
13	Informed consent is sought from each prospective subject or the subject's legally authorized representative and appropriately documented in accordance with and to the extent required by 45 CFR §46.116, 45 CFR §46.117, 21 CFR §50.25, and 21 CFR §50.27 as applicable.	☐	☐	☐	*(For Exempt Review protocols, informed consent is not required but is recommended by the NSU IRB, if appropriate)*
Subject Protections					
		Yes	No	N/A	Comments
14	The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. For minimal risk studies, NSU IRB requires investigators conducting clinical investigations to, at a minimum, have a DSM plan.	☐	☐	☐	
15	The research plan makes adequate provisions to protect the privacy of subjects.	☐	☐	☐	
16	The research plan makes adequate provisions to maintain the confidentiality of data.	☐	☐	☐	
17	The research **does** involve subjects likely to be vulnerable to coercion or undue influence, including: Children, prisoners, pregnant women, mentally disabled persons, economically/educationally disadvantaged persons, students, and non-native speakers of English.	☐	☐	☐	
	If YES, the research plan does include adequate safeguards to protect the subjects' rights and welfare.	☐	☐	☐	*(If "no," list additional safeguards)*
Determination					
18	If exempt, which review category[4]?	1			
	If expedited, which review category[5]?	1a			

		Approve	Approve Conditionally	Disapprove	Table
19	Final Recommendation (select one)	☐	☐	☐	☐
	Reason (s) for recommendation				

[1]Checklist adapted from the University of California – Irvine IRB
[2]Criteria for IRB approval of research in accordance with 45 CRF §46.111, 21 CFR §56.111, and NSU Policy (as of 2023.07.13).
[3]Include possible physical, psychological, economic, social, employment, educational, and legal harms.
[4]Use the Exempt Review Guidelines
[5]Use the Expedited Review Guidelines

Appendix J

Exempt Review: Research Category Guidance

Category	45 CFR §46 Citation	Exempt Category Description	Limited IRB Review	Conditions/Allowances/Limitations
1	104(d)(1)	**Research in Established or Commonly Accepted Education Settings that Involves Normal Educational Practices**	N/A	**Not Likely to Adversely Impact Students'Opportunity to Learn or Assessment of Educators Providing Instruction**
2	104(d)(2)	**Research only includes interactions involving Educational Tests, Surveys, Interviews, or Public Observation if at least ONE of the following criteria is met:**	N/A	**Data Collection Only; May include visual or auditory recording; May NOT include Intervention Only includes interactions**
		(i) Recorded information cannot readily identify the subject (directlyor indirectly/linked)	N/A	Surveys & Interviews: No Children; Educational Tests or Observation of Public Behavior: Can Only include Children When Investigators Do Not Participate in Activities being Administered/Observed
		(ii) Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation)	N/A	Surveys & Interviews: No Children; Educational Tests or Observation of Public Behavior: Can Only include Children When Investigators Do Not Participate in Activities being Administered/Observed
		(iii) Information is recorded with identifiers or code linked to identifiers & IRB conducts Limited Review	Limited Review: see 45 CFR §46.111(a)(7)	NO Children
3	104(d)(3)(i)	**Research involving Benign Behavioral Interventions (BBI) through verbal, written responses, (including data entryor audiovisual recording) from adult subject who prospectively agrees and ONE of following is met:**	N/A	**NO Children; May Not include Medical Interventions; BBI must be:** • **Brief in Duration** • **Painless/Harmless** • **Not Physically Invasive** • **Not Likely to Have a Significant AdverseLasting Impact on Subjects** • **Unlikely that Subjects Will Find Interventions Offensive or Embarrassing** **No deception unless participant is informed in the prospective agreement that he/she will be unaware of or misled regarding the true natureor purpose of the study**
		A. Recorded information cannot readily identify the subject (directly or indirectly/linked)	N/A	
		B. Any disclosure of responses outside of the protocol would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, education, reputation)	N/A	
		C. Information is recorded with identifiers & IRB conducts Limited Review	Limited Review: see 45 CFR §46.111(a)(7)	

Category	45 CFR §46 Citation	Exempt Category Description	Limited IRB Review	Conditions/Allowances/Limitations
4	104(d)(4)	**Secondary Research for Which Consent is Not Required: Use of Identifiable Information or Identifiable Biospecimens that have been or will be collected for some other 'primary' or 'initial' activity,if ONE of following criteria is met:**		No Primary Collection from subjects for the research; allows Both Retrospective and Prospective Secondary Use.
		(i) Biospecimens or Information is Publicly Available	N/A	Must be publicly available (e.g., commercially available specimen or open access data). Mayalso qualify as not human research (NHR). However, IRB review generally required for thesis, dissertation, or academic programs.
		(ii) Information recorded so subject cannot readily be identified (directly or indirectly/linked); Investigator does not contact subjects and will not re-identify the subjects	N/A	PI does not contact; Will not re-identify.
		(iii) Collection and Analysis involving Investigators Use of Identifiable Health Information when use is regulated by HIPAA "health care operations" or "research" or "public health activities and purposes"	N/A	HIPAA regulations still apply; HIPAA protections include authorization or waiver of authorization; Does not include Biospecimens (only PHI); Only covers "investigator's use"; does not indicate that sharing is permitted under this exemption.
		(iv) Research information collected by or on behalf of federal governmentusing government generated or collected information obtained for non-research activities	N/A	If research generates identifiable private information it is subject to specified federal privacy laws (see iv for list).
5	104(d)(5)	**Research and demonstration projects supported by a Federal Agency/Dept. AND designed to study…improve…public benefit or service programs.**	N/A	Must be posted on a federal website.
6	104(d)(6)	**Taste and Food Quality**	N/A	Wholesome food without additives; ingredient level and use found to be safe.
7*	104(d)(7) NSU NOT USING	**Storage or Maintenance of Identifiable Private Information or Identifiable Biospecimens for Secondary Research for which Broad Consent Is Required.**	Limited Review: see 45 CFR §46.111(a)(7)	**(Details not included here)**
8*	104(d)(8) NSU NOT USING	**Secondary research involving use of Identifiable Private Information or Identifiable Biospecimens for which Broad Consent was Required.**	Limited Review: see 45 CFR §46.111(a)(7)	**(Details not included here)**

Appendix K

Expedited Review: Research Category Guidance

#	Part	Research Category	Conditions/Allowances/Limitations
1		Clinical studies of drugs and medical devices only when condition (a) or (b) is met.	
	a.	Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required.	Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.
	b.	Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.	
2		Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:	
	a.	from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; OR	
	b.	from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected.	For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.
3		Prospective collection of biological specimens for research purposes by noninvasive means.	Examples: [See https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html]
4		Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing.	Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications. Examples: [See https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html]
5		Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).	Some research in this category may be exempt from the HHS regulations for the protection of human subjects; see the Non-human Subjects Research (NHSR) Questionnaire. This listing refers only to research that is not exempt.
6		Collection of data from voice, video, digital, or image recordings made for research purposes.	

[1] See the OHRP guidance document for the Expedited Review categories. See 45 CFR §46.110 for the Expedited Review procedures.

7		Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.	Some research in this category may be exempt from the HHS regulations for the protection of human subjects; see the Non-human Subjects Research (NHSR) Questionnaire.. This listing refers only to research that is not exempt.
8		Continuing review of research previously approved by the convened IRB as follows:	
	a.	where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; OR	
	b.	where no subjects have been enrolled and no additional risks have been identified; OR	
	c.	where the remaining research activities are limited to data analysis.	
9		Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.	

Appendix L

IRB Meeting Minutes Form

Meeting Information and Call to Order					
Meeting Date:		Location (Building/Room):			
Agenda Date:	Begin Time:	Minutes Recorder (Print Full Name):			
Attendance (IRB 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					
IRB Chair					

IRB 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):			
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 IRB Chair or designee votes)			
Motion Passes?	No Yes		
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 IRB 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 IRB 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:		
	If "Yes," number 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 IRB 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			
Meeting Adjournment			
NOTE: Voice Vote Only			
Motion to adjourn (Voting Member Name):	Seconded? (Voting Member Name):		
Adjournment Time:	Adjournment Date:		
Minutes Recorder Signature:			

Appendix M

IRB 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"):			

Appendix N

Continuing Review Form

Directions: The purpose of the continuing review form is to review the approved protocol, after each 12-month period that the protocol is active ("active" means human subjects are still being recruited and data is still being collected from the subjects).
Each section of the form below contains information on the Continuing Review Request. Please read and complete each section carefully; a form missing information (or otherwise incomplete) will be returned for revision.
If you wish to report an adverse event, fill out the Adverse Events Report form.

Research		
Title of Project:		
Protocol # ID:		
Original Approval Date:		
Current Completion Date:		
Personal Information		
Principal Investigator (PI)	First Name:	Last Name:
PI NSU Email:		
PI Phone Number:		
Faculty Advisor (if applicable)	First Name:	Last Name:
Faculty Advisor NSU Email:		
Faculty Advisor Phone Number:		
Continuing Review of Approved Protocol		
For this approved protocol, do you wish to extend the current completion date for another 12 months?	◯ No	◯ Yes
Are you making any changes to the protocol as approved?	◯ No	◯ Yes
Please explain any changes and/or the reason/s for extension:		
NOTE: If you wish to make changes to the protocol as approved, you must also fill out and submit the Amendment Request Form.		

Assessment of the Approved Protocol				
Risks to subjects are minimized by using procedures which are consistent with sound research design, and which do not unnecessarily expose subjects to risk.	◯ YES	◯ NO	◯ N/A	
Risks to subjects are minimized, whenever appropriate, byusing procedures already being performed on the subjects for diagnostic or treatment purposes.	◯ YES	◯ NO	◯ N/A	
Risks to subjects are reasonable to both: • anticipated benefits, if any, to subjects; and • the importance of the knowledge that mayreasonably be expected to result.	◯ YES	◯ NO	◯ N/A	
Subject Selection				
Selection of subjects is equitable to the purposes of the research and the setting in which the research will be conducted.	◯ YES	◯ NO	◯ N/A	
Selection of subjects (i.e., inclusion and exclusion criteria) based on the protocol and the setting in which it will be conducted.	◯ YES	◯ NO	◯ N/A	
The recruitment process minimizes the potential for undue influence/coercion.	◯ YES	◯ NO	◯ N/A	
Compensation – neither the amount of payment nor the proposed method and timing of disbursement is coercive or presents potential for undue influence.	◯ YES	◯ NO	◯ N/A	
Recruitment materials are appropriate.	◯ YES	◯ NO	◯ N/A	
Informed Consent				
Informed consent is sought from each prospective subject or the subject's legally authorized representative and appropriately documented in accordance with, and to the extent required by 45 CFR §46.116, 45 CFR §46.117, 21 CFR §50.25, and 21 CFR §50.27 as applicable.	◯ YES	◯ NO	◯ N/A	*(For Exempt Review studies, informed consent is not required but is recommended by the NSU IRB for all protocols, if appropriate)*
Subject Protections				
The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. *For minimal risk studies, NSU IRB requires investigators conducting clinical investigations to, at a minimum, have a DSM plan.*	◯ YES	◯ NO	◯ N/A	

The research plan makes adequate provisions to protect the privacy of subjects.	◯YES	◯NO		
The research plan makes adequate provisions to maintain the confidentiality of data.	◯YES	◯ NO		
The research **does** involve subjects likely to be vulnerable to coercion or undue influence, including: children, prisoners, pregnant women, mentally disabled persons, economically / educationally disadvantaged persons, students, and non-native speakers of English.	◯YES	◯NO		
If YES, the research plan **does** include <u>adequate</u> safeguards to protect their rights and welfare.	◯YES	◯NO		*If "No," additional safeguards:*
<u>Final Recommendation</u> (select ONE): ◯Approve ◯Approved Conditionally ◯Disapprove ◯Table <u>Reason(s) for recommendation</u>:				

Certification

I certify that the information provided on this form is complete and accurate. I agree to accept responsibility for the ethical conduct of this study. I also agree to notify the NSU IRB, within 10 business days after the end of all human subject recruitment and data collection activities, that the study has closed. In addition, I agree that all data collected from the human subjects will be stored securely and maintained for a minimum of 3 years from the date of the study close. Finally, I certify that I do not have any conflict of interest with this study.

Signatures (NOTE: PI and Faculty Sponsor--Type full name and date)

Principal Investigator: Date:

Faculty Sponsor (if applicable): Date:

Appendix O

Amendment Request Form

Directions: Each section of the form below contains information on the Amendment Request if applicable, that occurred in the study since the last protocol review. Please read and complete each section carefully; a form missing information (or otherwise incomplete) will be returned for revision.

Research		
Title of Project:		
Protocol Number:		
Original Approval Date:		
Personal Information		
Principal Investigator (PI)	Last Name:	First Name:
PI NSU Email:		
PI Phone Number:		
Faculty Advisor (if applicable)	Last Name:	First Name:
Faculty Advisor NSU Email:		
Faculty Advisor Phone Number:		
Amendment Request		
Have there been any changes in the study subjects?	○ No ○ Yes	
If yes, check ALL that apply:	☐ Numbers	
	☐ Age range	
	☐ Gender	
	☐ Ethnic identity	
	☐ Other (specify):	
Were there any changes to the method of recruitment of subjects since the last IRB approval?	○ No ○ Yes	
If yes, provide details:		

Have the procedures or protocols changed in any manner since the last IRB approval?	○ No	○ Yes
If yes, provide details:		
Have there any complications involved in the study since the last IRB approval?	○ No	○ Yes
If yes, provide details:		

Certification

I certify that the information provided on this form is complete and accurate. I agree to accept responsibility for the ethical conduct of this study. I also agree to notify the NSU IRB, within 10 business days after the end of all human subject recruitment and data collection activities, that the study has closed. In addition, I agree that all data collected from the human subjects will be stored securely and maintained for a minimum of 3 years from the date of the study close. Finally, I certify that I do not have any conflict of interest with this study.

Signatures (NOTE: PI and Faculty Sponsor--Type full name and date)

Principal Investigator: Date:

Faculty Sponsor (if applicable): Date:

Appendix P

Adverse Events Form

Directions: Each section of the form below requires information on the adverse event(s) that occurred in the study since the last review of the approved protocol. Please read and complete each section carefully. Additional documents/information may be attached as separate files.

Research			
Project Title:			
Protocol ID #:			
Initial Review Category:	○ Exempt	○ Expedited	◉ Full Board
Initial Approval Date:			
Principal Investigator (PI)	◉ Student	○ Faculty	○ Staff
Personal Information			
PI Name:	Last:	First:	
PI Student ID #:			
PI Address:			
PI NSU Email:	Phone:		
(Complete the section below if the PI is a student.)			
Advisor Name:	Last:	First:	
Advisor NSU Email:		Phone:	
Adverse Events			
Provide details about any adverse events that occurred since the last protocol review			

Provide recommendations to resolve the adverse events	

Certification

I certify that the information provided on this form is complete and accurate. I agree to accept responsibility for the ethical conduct of this study. I also agree to adhere to any conditions that the NSU IRB requires to resolve the adverse event(s) and recommence the study. Finally, I will report to the NSU IRB any additional adverse event(s) immediately.

Signatures (NOTE: PI and Faculty Sponsor--Type full name and date)

Principal Investigator: Date:

Faculty Sponsor (if applicable): Date:

For Office Use Only		
Date of Submission:		
Recommendations Approved	○ No	◉ Yes
If "No," state reason(s):		
Date of Decision:		