Policies & Procedures Manual

Institutional Review Board

(IRB)

Northwestern State University

University of Louisiana System

Approved 2023.08.28

Table of Contents

Policies & Procedures Manual

I. Introduction

A. NSU IRB Mission Statement

The mission of the Northwestern State University 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* (1978),[1] 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*, the National Research Act of 1974,[2] and the regulations developed by the U.S. Department of Health and Human Services (HHS) for the protection of human subjects of research—45 CFR §46, as amended.[3] These guidelines require that research with human beings must "maximize potential benefits and minimize possible harms" (*The Belmont Report*, p. 6, 1978).

B. Purpose of the Manual

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 (see I. A., above).

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.

II. Human Research Protections Program (HRPP)

A. Relationship to the IRB

The HRPP concept was instituted by the federal Office of Human Research Protections (OHRP), 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. This section of the Manual identifies those specific units, groups, and individuals at Northwestern State University of Louisiana.

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

[1] *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (1978): https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html.

[2] *The National Research Act of 1974.* U.S. House/Senate Conference Report: https://pubmed.ncbi.nlm.nih.gov/12333496/.

[3] 45 CFR §46: Complete text located at https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html

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.

B. HRPP Membership
   1. Institutional Official (NSU Dean of the Graduate School)
   2. NSU HRPP Director
   3. University Offices/Groups/Individuals
      - Academic Affairs Office
      - IRB Office
      - Administrators - Deans/Academic Unit Heads/Directors
      - University Research Coordinators
      - Researchers - including faculty sponsors and their students
      - Office of Institutional Research (OIR)
      - Sponsored Programs Office (SPO)
      - Institutional Animal Care and Use Committee (IACUC)
      - University General Counsel
      - (Other offices/groups/individuals as needed) [4]

C. IRB Membership
   1. Voting Members
   2. Chair (only votes if Voting Members tie)
   3. Ex Officio Members: Dean of the Graduate School or designee; Sponsored Programs Office Representative (non-voting)
   4. External consultants/experts, as needed (non-voting)

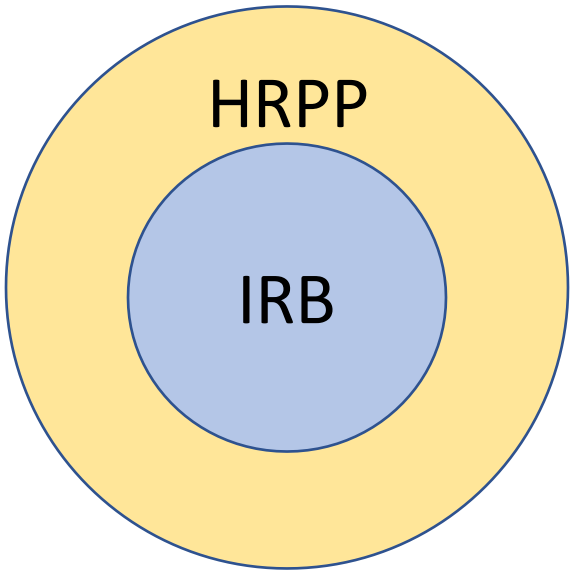


Figure 1: HRPP and IRB relationship

[4] Other NSU offices, groups, and individuals not listed can be involved in the HRPP if and when needed. For example, the University Registrar has been consulted in the past concerning the effects of data privacy procedures (proposed in particular protocols) on the university's responsibilities under the Family Educational Rights and Privacy Act (FERPA).

III. IRB Membership

A. Goals of IRB Member Selection

The IRB members must represent a variety of backgrounds, including area of expertise, experience, gender, race, and age. 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.

B. Required Member Categories

The IRB membership shall consist of, at minimum, personnel from the following university academic units/office/groups and external stakeholders—one member from each College or unit unless otherwise indicated (does not include any members designated as Alternates; see Section D., below).[5]

1. *Voting Members* [6]
    a. College of Arts and Sciences: three members (to include one member from the Louisiana Scholars' College)
    b. College of Business and Technology
    c. College of Education and Human Development: two members
    d. College of Nursing and School of Allied Health
    e. Student Affairs Representative (Dean or designee)
    f. Graduate Student Representative
    g. Community Representative (must be *unaffiliated* with NSU).[7]

2. *Non-voting Members*
    a. IRB Chair
    b. Dean of the Graduate School (or designee)
    c. Sponsored Programs Office Representative

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. [8] 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.

D. 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

---

[5] See the Appendices for the complete duties and responsibilities of IRB voting members

[6] 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.

[7] *Unaffiliated* here means "in any capacity": The IRB 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).

[8] For OHRP guidance concerning "scientific and "non-scientific" IRB members, see https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2011-january-24-letter-attachment-b/index.html

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 (see Part V. for details on member eligibility at meetings).

E. 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.

F. Member Training
Each member of the IRB must successfully complete the required IRB Member training certificates before beginning service and must maintain certification for the entire term of service. See Item G (below) for details.[10]

G. IRB member training requirements [11] [12]
1. *IRB Members: Stage 1 – Basic Course*.
2. *Conflicts of Interest – Basic Course*.

H. Outside Consultants
1. *By Invitation*: 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.
2. *Voting Status*: These individuals may not serve as voting IRB members.

I. HRPP Director and IRB Chair (see Appendices for complete duties and responsibilities)
1. *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 each position.
2. *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.

IV. IRB Voting Members: General Responsibilities

A. The IRB voting members shall have the following general responsibilities:
1. *Current Knowledge:* Review regularly required training courses and current NSU IRB policies and procedures.
2. *Confidentiality*: Keep confidential all content (both spoken and written) of

[9] For more information on Alternate members, see https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/irb-registration-process/index.html

[10] See the Appendices for the complete NSU IRB Training Policy (effective 6/1/2022).

[11] All NSU training certificates are awarded by CITI Program, the university training provider.

[12] NSU IRB policy states that a training certificate expires five years after the award date.

NSU IRB meetings and protocol reviews and only share such information with current members of the IRB.

3. *Protocol Reviews*: Review and have authority to approve, require modifications (to secure approval), or disapprove any university-sponsored research protocol that employs human subjects.
4. *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.
5. *Informed Consent*: Require that information given to subjects as part of *informed consent* is in accordance with 45 CFR § 46.116. The IRB may require that information, in addition to that specifically mentioned in § 46.116, be given to the subjects when, in the IRB's judgment,the information would meaningfully add to the protection of the rights and welfare of subjects.
6. *Informed Consent Documents Review*: Require review of the informed consent granted by the human participants, when appropriate, including each signed and dated consent form.
7. *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.

B. IRB Voting Member Protocol Review Categories: General Procedures[13]

1. *Non-human Subjects Research* (NHSR) 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 (see Part V. for details) apply. The reviewer completes the NHSR Review Checklist (see Appendices). 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.

2. *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 (see Part V. for details) apply; 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 (see Appendices). 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

[13] See **45 CFR §46** for the definition of each review category.

application. Records will be maintained of all activities regarding actions on the application.

3. *Limited Review* protocol: Reviewed by the IRB Chair or designated IRB voting member(s). The member eligibility rules (see Part V. for details) apply; 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 under 45 CFR §46.111(a)(7).[14] 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 Director & Chair). Records will be maintained of all activities regarding actions on the application.
4. *Expedited* protocol: Reviewed by a subcommittee of two (2) IRB voting members, determined by a pre-planned schedule of rotating reviewers. A copy of each protocol application will be delivered to the subcommittee. The member eligibility rules (see Part V. for details) apply; if one or both of the scheduled reviewers cannot serve, the IRB Chair (or designee) will select another voting member. The members of the subcommittee will complete the Protocol Review Checklist (see Appendices). Each reviewer will vote for Approval or Conditional Approval.[15] The votes will be communicated to the IRB 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 IRB meeting. Records will be maintained of all activities regarding actions on proposals.
5. *Full Board* protocol: Reviewed at a convened meeting of the full IRB voting membership (See Part V. for detailed procedures).

V. The IRB Convened Meeting: Policies and Procedures

A. Definition

An official, convened meeting of the IRB requires the following: an official agenda; minutes of the previous convened meeting; the required number and types of voting members to attend and meet the quorum requirement; copies of all documents required for formal votes (e.g., completed Protocol Review forms, Continuing

[14] **45 CFR §46.111(a)(7)** states, "When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data."

[15] Under federal law, the Expedited Review procedure cannot result in Disapproval of a research protocol; Approval or Conditional Approval are the only decisions available. If the Expedited Review of an application yields a vote for Conditional Approval requiring resubmission of a revised application, action will be deferred to a convened meeting of the IRB membership.

Review forms, policy proposals, etc.); and, the minutes of the convened meeting must be recorded during the meeting. (See Sections B. through E., below, for detailed policies and procedures for convened meetings.)

B. Member Eligibility

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

1. *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 (see Part III. above for details).

2. *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.

C. Meeting Organization

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

1. *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.

2. *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 (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.

D. Meeting Procedures

1. *Approval of Meeting Agenda:* If quorum is established, the first item of business at a convened meeting is to vote 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.

2. *Approval of Minutes*: Next, there is a vote to approve the minutes from the previous convened meeting. The IRB Chair (or designee) will call for a motion to approve the minutes. Once the motion is seconded by a voting member, a voice vote is taken and the results are recorded in the minutes, using the format shown in section 5.D.1. (above).

3. *Discussion and Voting: Protocol Applications*

   a. 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.

b. 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 the vote on the protocol.[17]

c. Formal Vote: Any voting IRB member present may make a motion to take the vote (once quorum has been established). Once the motion is seconded and approved by voice vote, the IRB Chair (or designee) will call the roll of currently present and eligible voting members (established in the quorum procedure; see F. 3., above), and each member (not including the Chair; see Item #8 below) votes for one of three options: Approve, Approve with Conditions, or Disapprove.

d. Passing Vote: To pass, any of the three options (see Item b., above) requires a simple majority vote of the established quorum.[18]

e. Vote Record: The IRB Chair (or designee) will record (tally) the votes 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 following format: Total eligible members present = 11 of 18 total voting members (50% + 2; non-scientific member present? = Yes). Vote: Approved = 9, Disapproved = 0, Approved with Conditions = 2. Motion approved.[19]

4. Vote Results Other Than Approval

a. Approved Conditionally: The conditions to receive approval must be recorded in detail in the meeting minutes. In addition, the PI must submit a revised protocol application incorporating the required changes.

i. **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.

ii. **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.

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

---

[16] IRB convened meeting regular business items (except for protocol applications; see Section D. 2.) follow the same voting procedure as the approval of the agenda and the previous meeting minutes.

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

[18] In case the voting members' vote ends in a tie, the IRB Chair may vote to break the tie.

[19] Items a.-e. (above) are followed in the order shown for each protocol application listed in the meeting agenda. (NOTE: One or more of the items may not apply to a specific application under consideration for a vote.)

5. *Other Decisions on Protocol Applications*
    a. Continuing Review Requirements:
        i. **Time Frame**: The IRB members shall determine when a continuation review will be conducted for Expedited and Full Board application reviews.
        ii. **Stipulations**: The IRB members shall determine any special requirements for the review.
        iii. **Reviewer Assignment**: The IRB members will vote to determine the IRB member(s) who will conduct the review.
    b. Waiver of/Changes to Informed Consent Requirements: The IRB 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. This also applies when approving procedures that waive the requirement for obtaining a signed consent form for research involving i. pregnant women, human fetuses, or neonates; ii. prisoners; iii. cognitively impaired persons; iv. children.[20]

E. Meeting Minutes
1. *Content*: All meetings will record the following in the official minutes:[21]
    a. date, time, and location of the meeting;
    b. the time the meeting was called to order;
    c. the name of the person recording the minutes;
    d. the attendance or absence of each IRB member;
    e. the eligibility of each attending member for quorum and voting (including recusals from protocol application deliberations and those excused while the meeting is in progress);
    f. the voice vote for the approval of the current meeting's agenda and the previous meeting's minutes;
    g. a summary of the discussion of each protocol application—in particular, issues raised by an application that caused debate among the members (called "controverted issues"). The resolution of the controverted issue must also be recorded;
    h. the establishment of quorum before a formal vote;
    i. the final tally of the formal vote for each protocol application;

[20] 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.

[21] For more information on meeting minutes administration, see the guidelines established by the Office of Human Research Protections (OHRP), U.S. Department of Health and Human Services: https://www.hhs.gov/ohrp/minutes-institutional-review-board-irb-meetings-guidance-institutions-and-irbs.html-0.

j. any other decisions or actions taken on protocol applications, such as the requirements for a continuing review, waivers/changes to informed consent, and similar items.
k. other agenda items requiring a vote, such as the approval of changes to NSU IRB policies;
l. other business not requiring a vote (i.e., "housekeeping"), such as announcements, IRB recent activity reports,[22] membership changes, upcoming meeting schedules, and similar items.
m. the time that the meeting was adjourned.
n. The signature of the Meeting Recorder and the date signed.

2. *Format*: The organization and layout of the convened meeting minutes will follow the NSU IRB Meeting Minutes Template (see Appendices).

F. Decision Letter

1. *Responsibility*: The official decision letter is written by the HRPP Director on official letterhead with a date and signature (hand-signed or digital).

2. *Content:* The content of the letter will follow the information recorded in the official minutes from the convened IRB meeting where the decision was made.

3. *Recipients:* The letter will be sent to the PI named in the IRB application. Other possible recipients include the faculty advisor, department head, Dean, and/or Institutional Official, if applicable, for communication purposes or as required by the policies in this Manual.

4. *Timeline*: The decision resulting from the vote for each protocol application will be communicated within five business days after the convened IRB meeting that made the decision concerning the protocol.

5. *Conditional approvals and disapprovals*: The conditions/reasons for the decision must be included in the letter.

VI. Post-approval Monitoring: Policies and Procedures

A. Continuing Review [23]

Review Time Frame: If the research time frame is less than one year in length (e.g., NHSR or Exempt protocols), continuing review is not required unless changes in the protocol are requested, changes occur, or adverse events occur. If the research time frame is one or more years (i.e., some Expedited and all Full Board-approved protocols), a continuing review is required within 12 months of the date that the protocol was approved by the IRB; thereafter, a continuing review will be conducted at least once every 12 months until the study is officially closed.

[22] *IRB recent activity reports* include HRPP Director, IRB Chair, or IRB member or sub-committee reviews of Exempt, Limited Review, and Expedited protocols; Adverse Events; Continuing Review results; and, changes in HRPP/IRB Office policies.

[23] Continuing Review for Pre-2018 Common Rule-Approved Protocols: 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

requirements. If the research was approved under the 2018 requirements, then it is eligible for continuing review and must follow the current NSU IRB policy.

1. *Assessment of Risk:* Any protocol that was approved by the NSU IRB and deemed more than minimal risk requires continuing review in all cases.
2. *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.
3. *Review Procedure:*
    a. Reviewer Assignment: The HRPP Director will designate a current IRB voting member to conduct the continuing review of the protocol. (The member eligibility rules apply; see Part V., Section B. If the selected reviewer is not eligible, the next voting member will be chosen).
    b. The 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 Checklist (see Appendices).
    c. Findings 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.
    d. Written Records for the Review: Prior to the convened meeting that will discuss the continuing review case, all IRB members will receive a copy of the original proposal and a summary report of the reviewer's findings. This report should include:
        i. the completed Continuing Review Checklist form;
        ii. a complete copy of the original IRB application form and all supplemental documentation;
        iii. any information related to risks currently associated with the protocol;
        iv. a summary of any relevant recent IRB documentation, such as interim findings, amendments or other modifications to the protocol, and/or adverse event reports since the last review;
        v. any relevant multicenter trial reports;
        vi. any proposed consent document(s) written after the protocol was initially approved;
        vii. any written documentation of complaints or concerns about the protocol from study participants.
    e. Membership Vote:

        Review Approved: If the Findings 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.

        i. **Further Action Required**: If the Findings 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 the suspension of the protocol, if applicable) must be recorded in the meeting minutes in detail.

f. Decision Letter: The HRPP Director (or designee) will contact the principal investigator (PI) named in the IRB application and inform them in writing of the findings, the IRB membership decision, and any required actions.
   i. **Approved**: The PI is directed to keep a copy of the approval letter in their research records for the required length of records maintenance (see Part IX., Records Maintenance Policies).
   ii. **Further Action Required**: The PI must complete and submit to the IRB either an Amendment Request form or an Adverse Events form (the IRB will determine which form is appropriate) and wait for written approval from the IRB to continue the research protocol. The form will be considered at the next convened IRB meeting, and the voting members will decide whether to continue, suspend, or terminate the research protocol at that time. If the motion is to approve the amendment request, the date of the next scheduled continuing review must be included in that motion. The result of the vote is recorded in the meeting minutes, and the HRPP Director (or designee) communicates the result to the PI, and as appropriate, to the Faculty Advisor, the department head, and the Institutional Official.

4. *External Consultants*: If the IRB reviewer who conducts the continuing review determines the need for verification from sources other than the investigator 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.

5. *High-risk Protocols*: The IRB may set a shorter continuing review period for high-risk research protocols. The IRB reserves the right to select such projects for regular continuing review (e.g., every quarter, every month, etc.). The IRB also reserves the right to conduct continuing reviews at any time in the following cases:
   a. Complex Projects: These involve unusual levels or types of risk to subjects.
   b. 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.
   c. Previous Non-compliance: PIs or Co-PIs who previously were found to have failed to comply with federal regulations and/or with the requirements or determinations of the IRB.

B. Amendments to Protocols

1. *Definition*: An amendment is a change to any part of an IRB-approved protocol.

2. *Examples:*
   a. Time Frame Changes: Convert the protocol from a short-term project (less than one year) into a longitudinal (multiyear) study.
   b. Procedure Changes: These may include the subject population, study methodology, administration procedures, data privacy/security procedures,

and/or any other part of the initially approved protocol.

3. Request Procedure:
   a. Required Form: The PI completes and submits the Amendment Request Form (see Appendices or the NSU IRB website).
   b. Protocol Suspension: The PI discontinues the protocol activities while the Amendment Request is in process.

4. Approval Procedure:
   a. Review: The request is reviewed at the next convened IRB meeting.
   b. Notification: The HRPP Director (or designee) will inform the PI of the decision in writing.
   c. Recommencement: If approved, the research may be recommenced with the revised protocol once the letter is received. The PI must keep the letter with the research records for the length of the records maintenance policy requirements.

C. Adverse Events

1. *Definition*: 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 PIs/Co-PIs, project staff members, students, IRB members or other observers, etc.).

2. *Procedure:* 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 do the following:
   a. Suspend Protocol: Stop all research activities;
   b. Report to the IRB: Contact the IRB Office immediately and report the event;
   c. Submit Report: Complete and submit the Adverse Effects Report (see the IRB website for a copy) explaining the issue to the IRB.

3. IRB Decision:
   a. Consideration: The Adverse Events Report is discussed at the next convened IRB meeting.
   b. Further Actions: The IRB will communicate to the PI alternatives and/or other actions to assist in dealing with the adverse events/effects.
   c. Submit Required Changes: The PI completes the Continuation/Change in Protocol Application and sends it to the IRB Office.
   d. IRB Approval: If the changes are approved, a continuation letter is issued by the HRPP Director (or designee).
   e. Recommencement: Once the approved continuation letter is received, the PI may recommend the protocol with the revised procedures.

VII. Reporting of IRB Findings and Actions

A. Formal Votes

All findings and actions determined by vote at a convened meeting will be documented in the meeting minutes. Those actions/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.

B. 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.

VIII. HRPP/IRB Office Staff Responsibilities

A. Protocol Number Assignment:
The 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 the Protocol Number 22-001.

B. Records Updating
The 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.

C. Records Management
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 [see Part IX, below, for details).

D. Correspondence with Applicants
The Office staff will send correspondence in a timely manner to the applicant(s) concerning the status of the application for the following purposes:

1. *Acknowledgement*: The application has been received by the IRB Office.
2. *Intake Review Results:* The office staff determines whether the protocol application is/is not complete; includes/does not include all required documentation; and, all required training has been/has not been completed. That is, identify any missing or incomplete information in the application materials prior to the (formal) initial review of a new protocol or another review of an approved protocol.
3. *Official Decision Letter*: Approval or disapproval of any IRB formal decision (e.g., for the initial protocol application, Continuing Review, Protocol Amendments, Adverse Events Report, etc.), including all necessary details and reasoning concerning the decision.
4. *Other Information*: Any other information deemed necessary to provide to the applicant(s) a full accounting during and after the review process as well as the results of that process.

IX. IRB Records Maintenance Policies

A. 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 close and accessible only to the PI (or faculty advisor, if applicable).

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 Office personnel.

C. 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.

X. Appendices

A. IRB Policies/Procedures

NSU IRB Training Policy

Previous Policy (1/01/2019-5/31/2022)				*Revised Policy* (As of 6/01/2022)*	
PI Type	Field	1st Certificate	2nd	1st	2nd
Faculty/Staff	Biomed.	Biomed.	RCR**	Biomed.	COI^
"	Social-Behav.	SBR	RCR**	SBR	COI^
Student	Biomed.	Biomed.	None	Biomed.	COI^
"	Social-Behav.	SBR	None	SBR	COI^
IRB member	Any	IRB Member#	None	IRB Member#	COI^

Notes

* A current NSU PI will follow the Previous Policy until a certificate's expiration; a new PI (as of 6/01/2022) will follow the Revised Policy.

** Under the Revised Policy, RCR is no longer required but is still recommended. NOTE: NIH, NSF, and USDA require RCR training for grant-funded studies.

^ "Conflicts of Commitment and Conscience" certificate is recommended for any NSU PI and all IRB members; "Financial COI" certificate required when a PI and/or the institution has a **financial interest** in the protocol (e.g., grant funding; intellectual property).[24]

\# "IRB Member" certificate is for those w/ NSU IRB voting privileges; HRPP Director/Chair and Institutional Official (IO) roles require separate certificates at CITIprogram.org.

CITIprogram.org Certificates[25]

Biomed. = Biomedical Research
COI = Conflicts of Interest
RCR = Responsible Conduct of Research
SBR = Social & Behavioral Research

Other Abbreviations

PI = Principal Investigator
NIH = National Institutes of Health
NSF = National Science Foundation
USDA = U.S. Dept. of Agriculture

Rev. 2023.07.13

[24] The IRB reserves the right to require additional training for a specified protocol.

[25] Recertification policy: The NSU IRB requires recertification within five years after the certificate award date. However, the NSU College of Nursing and School of Allied Health requires recertification within three years after the award date.

NSU IRB Convened
Part A: Minutes General Business

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
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			

Minutes of Convened IRB Meetings
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"):			

Meeting Adjournment	
NOTE: Voice Vote Only	
Motion to adjourn: (Voting Member Name):	Seconded? (Voting Member Name):
Adjournment Time:	Adjournment Date:
Minutes Recorder Signature:	

HRPP Director & IRB Chair
Qualifications and Responsibilities

Rev. 2023.07.13

I. Qualifications (for both positions)

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.

B. 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.

IRB Voting Members
Qualifications and Responsibilities
Rev. 2023.07.13

I. Required Qualifications

A. NSU Faculty/Staff/Student Members

1. Full-time university employee or student in good standing.
2. Assigned to an NSU academic or administrative unit.
3. Does not currently serve as a full-time NSU administrator (except Student Affairs Rep.).
4. Serves for three consecutive academic years on the NSU IRB (except student members).
5. Must complete the required IRB member training courses prior to service start.

B. Community Members

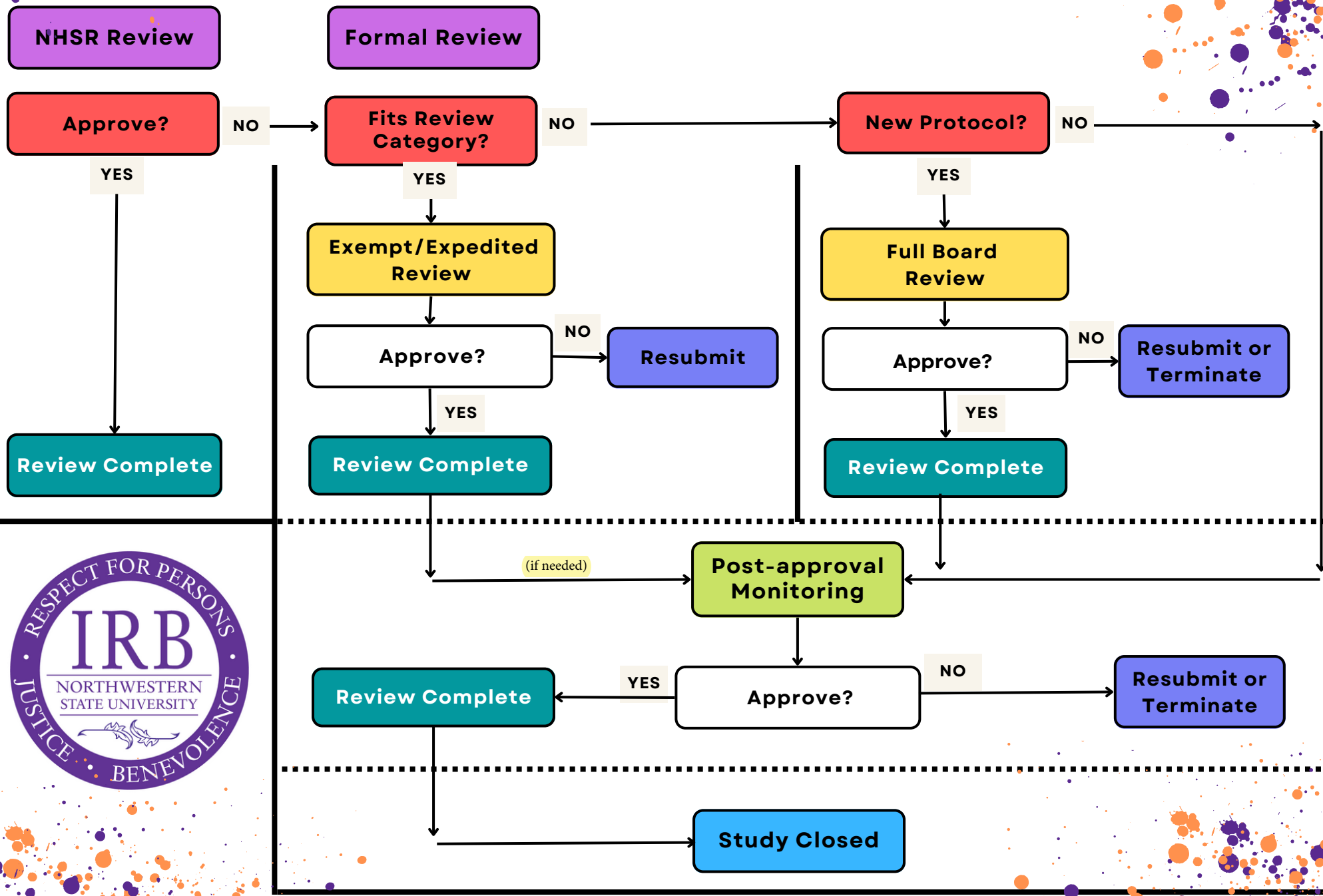
1. Not employed in any capacity by NSU.
2. Not currently serving on an NSU body (unit, board, committee, etc.) in a paid or unpaid role.
3. Immediate family members do not currently serve NSU in B.1 or B.2.
4. Serves for three consecutive years on the NSU IRB.
5. Must complete the required IRB member training courses prior to service start.

II. Responsibilities

1. *Current Knowledge:* Review regularly required training courses and current NSU IRB policies and procedures.
2. *Confidentiality*: 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.
3. *Attendance*: Attend scheduled IRB Convened Meetings and participate in member discussions of and official votes on policy questions and Full Board protocol reviews.
4. *Exempt and Expedited Reviews*: As assigned, complete in a timely manner reviews of Exempt and Expedited research protocols.
5. *Informed Consent Documents Reviews*: As assigned, review the informed consent granted by the human subjects, including each signed and dated consent form.
6. *In-progress Observations*: As assigned, observe the informed consent process and any research activities—while in progress—for any approved protocol.

.

NSU IRB Review Process



RESPECT FOR PERSONS · IRB · NORTHWESTERN STATE UNIVERSITY · JUSTICE · BENEVOLENCE

XI. Appendices
B. IRB Application & Review Process

Investigator: NSU Institutional Review Board Date:
Non-human Subjects Research (NHSR) Questionnaire
(Rev. 2023.03.10)

NSU Email:

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).	○	◉

[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* (see Footnote 4 for more information), IRB review is required.

[3] Research for the dissertation, thesis, or "papers-in-lieu" of thesis course does not qualify as "course-related activity." In that case, 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.

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* (see Footnote 4 for more information).	○	◉
Publicly Available Data: Examples: census data; labor statistics. [5]	○	◉
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. 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*):

[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).

NSU Institutional Review Board
Non-human Subjects Research (NHSR) Questionnaire
Reviewer Checklist

(Rev. 2023.02.07)

Investigator: Reviewer: Date:

Part I. Reviewer Checklist.
*Directions: Review the NHSR Questionnaire completed by the Principal Investigator (PI) and check the appropriate box for each criterion listed below. NOTE: If unsure of the answer, select "Yes"; do not leave any question blank. In **Part II**, explain the reasons for your answers.*

Review Criteria [1]	Yes	No
1. Is the study considered "research"? Under the federal regulations, **research** is defined as "a *systematic investigation*...designed to develop or contribute to *generalizable knowledge*" (i.e., applicable beyond the sample population under study).	○	◉
2. Will the study collect data from human subjects? The federal regulations define **human subject** as "a living individual about whom an investigator (whether professional or student) conducting research obtains information or biospecimens...and uses, studies, or analyzes the information or biospecimens." Additional considerations:	○	◉
a. Does the PI intervene or interact with human subjects? **Intervention** "includes both physical procedures...and manipulations of the subject or the subjects' environment." **Interaction** "includes communication or interpersonal contact between the investigator and the subject."	○	◉
b. Will the collected data include "personally identifiable information" (PII)? **PII** is any data that can be used to distinguish or trace a human subject's identity. Examples include name, social security number, date of birth, contact information, biometric records, or employment and education records.	○	◉
Reviewer Recommendation: Based on your answers to the above criteria, does the study meet the requirements for NHSR approval? (see NOTE below).	○	◉
NOTE: If #1 is "No" and "#2" is "Yes," the study qualifies for NHSR approval. If #1 and #2 are both "Yes," the study must undergo additional IRB review.		

[1] from 45 CFR 46.102

Part II. Reasons for Recommendation.
Below, provide reasons for the answers given above, especially for criteria that were difficult to determine (i.e., "Yes" given to indicate "Unsure").

Protocol Review Checklist:

Exempt, Expedited, & Full Board

Criteria for IRB Review and Approval: Please review the federal criteria for IRB approval and indicate whether the protocol meets each criterion by checking the appropriate box. *NOTE: Use the Exempt Categories Guidance and the Expedited Categories Guidance (attached) to assist in the analysis, especially #18 and #19*.

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). [NOTE: Checklist adapted from the University of California – Irvine IRB.]

Protocol ID #: ***IRB Reviewer Name:*** ***Date:***

	Personnel & Study Purpose				**COMMENTS**
1	The IRB has the expertise needed to review this protocol.	○ YES	○ NO		*(If "No," contact the IRB Office to consult with outside experts.)*
2	I, the IRB reviewer, have a conflict of interest with this protocol.	○ YES	○NO		*(If "Yes," contact the IRB Office to arrange for re-assignment.)*
3	The research question/hypothesis is adequate.	○YES	○NO		
4	Study personnel appear appropriate and qualified.	○YES	○NO		*CITI Program training required:* *1. Social-Behav. or Biomed. Research* *2. Conflicts of Interest*
	Risk/Benefit Assessment [1]				
5	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	
6	Risks to subjects are minimized, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.	○YES	○ NO	○ N/A	
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.	○YES	○ NO	○N/A	
	Subject Selection				
8	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	
9	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	

[1] Include possible physical, psychological, economic, social, employment, educational, and legal harms.

10	The recruitment process minimizes the potential for undue influence/coercion.	○ YES	○ NO	○ N/A	
11	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	
12	Recruitment materials are appropriate.	○ YES	◉ NO	○ N/A	
	Informed Consent				
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.	○ 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				
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.*	○ YES	◉ NO	○ N/A	
15	The research plan makes adequate provisions to protect the privacy of subjects.	○ YES	◉ NO	[redacted]	
16	The research plan makes adequate provisions to maintain the confidentiality of data.	○ YES	◉ NO		
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.	○ YES	◉ NO	○ N/A	
	If YES, the research plan **does** include adequate safeguards to protect their rights and welfare.	○ YES	◉ NO	○ N/A	*If "No," additional safeguards:*
18	If *Exempt*—Review Category? (see attached Exempt Review Guidance): If *Expedited*—Review Category? (see attached Expedited Review Guidance):				
19	Final Recommendation (select ONE) ○ Approve ○ Approve Conditionally ○ Disapprove ◉ Table Reason(s) for recommendation:				

Exempt Review: Research Category Guidance

[NOTE: Adapted from the University of Kentucky IRB]

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)**

Expedited Review: [2]
Research Categories 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.	

[2] 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.	