OBJECTIVE

To describe policies and procedures regarding who is authorized to review IRB protocol submissions, the various levels of IRB review, and to delineate the different decisions that can be made by the IRB.

GENERAL DESCRIPTION

All protocol submissions are reviewed by the authorized IRB reviewers and a determination is made regarding the initial level of review that is required. There are four levels of IRB review:

Research Outside the Purview of the IRB

a. This level of review is reserved for projects that do not meet the regulatory definitions for requiring IRB review.

Exempt Review

a. This level of review is reserved for research that meets the categories set forth by the federal regulations [45 CFR 46.104(d)(1)-(6); 21 CFR 56.104(d);] may qualify for exemption. Research activities are only exempt when the only involvement of human participants fall within one or more exemption categories as defined by these regulations.

Expedited Review

a. This level of review is reserved for studies that meet the categories adopted by the Department of Health and Human Services (DHHS) [45 CFR 46.110] or the Food and Drug Administration (FDA) [21 CFR 56.110] that involve no greater than "minimal risk".
b. Expedited review procedures allow the IRB to review and approve studies that meet criteria specified in federal regulations [45 CFR 46.111; 21 CFR 56.111] without a meeting of the convened IRB. Expedited reviewers also ensure that the study's informed consent process and documentation meets the requirements as specified in 45 CFR 46.116 and 21 CFR 50.25, unless the IRB waives the requirements in accord with federal regulations. (See Informed Consent SOPP.)

Convened Review

a. This level of review is reserved for studies that do not meet the federally mandated criteria for exempt or expedited review. This includes studies that present more than minimal potential risk to participants, and/or involve certain vulnerable populations including, but not limited to, prisoners. An IRB member or Chair can also recommend a study for review by the convened IRB based on study design or participant population involved.

b. Convened review ensures that the study's informed consent process and documentation meets the requirements as specified in 45 CFR 46.116 and 21 CFR 50.25, unless the convened IRB waives the requirements in accord with federal regulations. (See Informed Consent SOPP.
c. The IRB decides whether to approve, approve with modification, defer, or disapprove, based on applicable regulations and research ethics. The IRB determines the duration of approval based on risk and other factors associated with the study.

Definitions

Minimal risk: A risk determination that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

IRB approval: The determination by the IRB that the research has been reviewed and may be conducted within the constraints set forth by the IRB and by other institutional, federal, state, and local requirements.

RESPONSIBILITY

Execution of SOPP: Principal Investigator (PI)/Research Personnel, Institutional Review Board (IRB) Office Staff, IRB Members, IRB Chairs

PROCEDURES

A. Authorized Reviewers

1. Appointed and trained College Representatives and their Alternates may review IRB protocol submissions via the procedures outlined in the NSU IRB SOPP entitled "IRB Membership, Roles, and Responsibilities". Their appointment as an IRB reviewer is at the discretion of the Institutional Official. They must complete all IRB training requirements prior to beginning their duties as a reviewer.

2. IRB Office Personnel hired and appointed to the IRB Office by the Institutional Official based on their qualifications may review IRB protocol submissions. Their appointment as an IRB reviewer is at the discretion of the Institutional Official.

3. Other Reviewers, such as student research assistants, may not review IRB protocol submissions on behalf of a College Representative/Alternate or IRB Office Personnel. This may be waived with approval from the Institutional Official, granted at their discretion.

4. All IRB submissions and correspondence is confidential and authorized IRB reviewers only may view the material.

B. Levels of Initial IRB Review

1. Research Outside the Purview of the IRB
    a. This review is only conducted by the IRB Office. The College Representatives may request that the IRB Office review the protocol submission for this category. The IRB Office may also suggest that a protocol submission may qualify for this category but will not undertake a review unless the College Representative requests it.
    b. Investigators who do not feel their study meets the regulatory definitions for human participant research that requires IRB review may complete the *Human Subjects Research Determination xForm* to obtain formal documentation that their research is outside the purview of the IRB.

2. Exempt Review
    a. The College Representative or their Alternate reviews a protocol submission and may determine that the submission qualifies for exemption. College Representatives are encouraged to consult the Office of Human Research Protections (ORHP) Decisions Charts to help make these determinations or to contact the IRB Office for further guidance.
    b. The College Representative may request revisions from the investigator completing their review.
    c. College Representatives may not conduct a review of studies in which they have a conflict of interest; a designated Alternate Representative or the IRB Office must review these protocols .
    d. The College Representative will notify the investigator of the exemption of their protocol submission by emailing an approval memorandum. All appropriate departmental personnel, faculty advisors/dissertation chairs (for student investigators), and funding agencies must be copied on this correspondence.
    e. The IRB Office may review the determinations of the College Representative and determine that a higher level of review is required. If the level of review is revised, the IRB Office will notify the investigator and the College Representative via email.

3. Expedited Review
    a. The College Representative or their Alternate reviews a protocol submission and may recommend it for expedited review to be conducted by the IRB. The College Representative should ensure that all appropriate documentation is attached to the submission, and it meets the academic and discipline standards of their unit.
    b. The IRB Office will review the recommendations of the College Representative and may determine that a higher level of review is required. If the level of review is revised, the IRB Office will notify the investigator via email.
    c. Pre-review will be conducted by IRB Office staff and revisions may be requested by the investigator prior further review.
    d. Expedited review will be conducted by the IRB Chair, Vice Chair, or their designee. The Chair, Vice Chair, or their designee may approve the study, request more information or revisions, or send the protocol to the convened IRB for a higher level of review. The IRB Chair, Vice Chair, or their designee cannot disapprove a study. If the Chair, Vice Chair, or their designee believes that the study is not approvable, the protocol submission must be reviewed by the convened IRB. The Chair, Vice Chair, or their designee will determine the appropriate length of the approval period.
    e. An amendment which includes only minor revisions to a protocol submission initially reviewed at the convened review level may be reviewed via expedited procedures. Minor changes involve changes that are no more than minimal risk and that do not significantly alter the study design or increase the potential risk to participants.
    f. The IRB Office will notify the investigator of the IRB approval of their protocol submission by emailing an approval memorandum. All appropriate College Representatives/Alternates, departmental personnel, faculty advisors/dissertation chairs (for student investigators), and funding agencies must be copied on this correspondence.
    g. IRB members are informed of expedited decisions via the IRB meeting minutes.

4. Convened Review
    a. A College Representative may always recommend, at their discretion, to be reviewed via convened review procedures even though it may qualify for expedited review.
    b. The IRB Office will review the recommendation of the College Representative and may determine that a lower level of review is applicable .
    c. An investigator may request a convened review of their protocol submission if they do not agree with requested revisions from the IRB Expedited reviewer.
    d. Convened review must follow the requirements set forth in the Conduct of IRB Meetings SOPP.

e. The convened IRB will vote to approve, approve with revisions required by the IRB, defer for re-review by the convened IRB, or disapprove the study. If a study is approved, the convened IRB will determine the appropriate length of approval.

C. Types of IRB Decisions

1. Approve
    a. The protocol is approved as submitted, in keeping with OHRP and FDA criteria for IRB approval. Approval is reserved for studies reviewed at the expedited or convened review level.
    b. Approval is valid for the time-period specified in the correspondence to the primary investigator.
        i. Expedited review submissions will be required to submit for continuing review annually until completion and closure of the study.
        ii. For convened review submission, the date of continuing review (expiration of approval) is determined by the convened IRB and may not exceed one year from the convened meeting date of the IRB where the protocol was approved. The convened IRB may also determine that there are risks of sufficient magnitude that a convened review submission requires a more than annual continuing review.
    c. The IRB will notify the investigator regarding the approval of their protocol submission by emailing an approval memorandum along with stamped copies of all consent forms, recruitment materials, etc. that must be used while conducting their study. All appropriate College Representatives/Alternates, departmental personnel, faculty advisors/dissertation chairs (for student investigators), and funding agencies must be copied on this correspondence.

2. Approved with Revisions Requested by Convened IRB
    a. The protocol is approved by the convened IRB with specific and minor revisions to the protocol, the informed consent, or other documents. These revisions are to be reviewed by the IRB Chair, Vice Chair, or their designee.
    b. Approval is valid for the time-period specified in the correspondence to the investigator. The date of continuing review (expiration of approval) for convened reviewed studies is determined by the convened IRB, even if the approval is contingent upon revisions or corrections and may not exceed one year from the convened meeting date of the IRB where the protocol was approved.
    c. The IRB will notify the investigator regarding the requested modifications to their protocol submission by emailing a Convened IRB Determination memorandum. All

appropriate College Representatives/Alternates, departmental personnel, faculty advisors (for student investigators), and funding agencies must be copied on this correspondence.

d. If the investigator disagrees with the revisions requested by the IRB, they may withdraw the study, revise the study for review by the convened IRB, or appeal to the IRB (see the Appeal of IRB Actions/Determinations SOPP). The study may not be started until the protocol submission has been reviewed at a meeting of the convened IRB and approved.
e. Once the investigator has submitted the requested revisions to the IRB, the revised submission will be reviewed and approved by the Chair, Vice Chair, or designee as identified at the IRB meeting.
f. Approval is valid for the time-period specified in the correspondence to the primary investigator. The date of continuing review (expiration of approval) is determined by the convened IRB and may not exceed one year from the convened meeting date of the IRB where the protocol was approved. The convened IRB may also determine that a submission requires a more than annual continuing review. The IRB will document the reasons for the determination in the meeting minutes.
g. The IRB will notify the investigator regarding the approval of their protocol submission by emailing an approval memorandum along with stamped copies of all consent forms, recruitment materials, etc. that must be used while conducting their study. All appropriate College Representatives/Alternates, departmental personnel, faculty advisors (for student investigators), and funding agencies must be copied on this correspondence.

3. Deferred for Re-Review by the Convened IRB
    a. The protocol was not approved and requires subsequent review by the convened IRB.
    b. This motion applies to circumstances where the convened IRB decides that the required revisions are substantive, the protocol lacks sufficient information relevant to the required IRB determinations required under 45 CFR 46.111/21 CFR 56.111, and/or the Board is unable to review or vote on the protocol due to quorum or expertise restrictions.
    c. The IRB will notify the investigator regarding the deferral and request for revisions to their protocol submission by emailing a Convened IRB Determination memorandum. All appropriate College Representatives/Alternates, departmental personnel, faculty advisors (for student investigators), and funding agencies must be copied on this correspondence.

4. Disapproved
    a. The IRB may disapprove the proposed protocol if the protocol:
        i. does not have a reasonable relationship between risks and anticipated benefits,
        ii. has inequitable participant selection,
        iii. does not appropriately provide for informed consent/assent,
        iv. does not safeguard data and have adequate provisions to protect patient confidentiality,
        v. raises such ethical questions as to be unacceptable, or
        vi. is otherwise not approvable under the relevant regulations and,
        vii. The IRB determines that revisions by the investigator cannot correct the deficiencies in i-vi.
    b. The IRB will notify the investigator regarding the disapproval of their protocol submission by emailing a Convened IRB Determination memorandum. All appropriate College Representatives/Alternates, departmental personnel, faculty advisors (for student investigators), and funding agencies must be copied on this correspondence.
    c. If the investigator does not concur with the decision made by the IRB, they may appeal the convened IRB's decision (see the Appeal of IRB Actions/Determinations SOPP).

REFERENCES

45 CFR 46.102
45 CFR 46.104
45 CFR 46.107(d)
45 CFR 46.109
45 CFR 46.110
45 CFR 46.111
45 CFR 46.116
45 CFR 46.117
21 CFR 56.108(a)(1) and 56.110(a - c)
21 CFR 56.111