OBJECTIVE

To describe policies and procedures for all types of protocol submissions that require review by the IRB after investigators receive initial approval. This includes protocol submissions to amend or modify a study, annual status updates to the IRB, and closure of a study after completion.

GENERAL DESCRIPTION

It is the responsibility of the IRB to govern approved research to ensure that research is conducted in accordance with federal, state, and institutional regulatory requirements. To carry out this mandate, the IRB Office must review investigator requests to amend or modify an approved submission, monitor the annual status of research, and ensure closure of all submissions upon completion.

Investigators may not initiate any changes in an approved research protocol submission without prior IRB review and approval, regardless of the level of initial review, except where necessary to eliminate apparent immediate hazards to the participants. OBJ

Federal regulations and NSU institutional policy require that at a minimum the IRB monitor the annual status of all human participant research occurring at NSU. All IRB protocol submissions must undergo either a status update (for Exempt studies) or continuing review (for expedited or full reviewed submissions) at least once per year. Some studies may have additional monitoring requirements as dictated by their approval. This is required for all submissions, including those where the only activity remaining is data analysis. Any lapses in approval must be documented by the IRB in the protocol submission.

After all research activities, including data analysis, have concluded, the investigator is responsible for notifying the IRB Office that the research has ended and must submit a closing report for review to officially close the study.

RESPONSIBILITY

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

PROCEDURES

A. Amendment or Modification to Approved Submissions

1. The investigator is responsible for submitting an amendment to the IRB for review prior to implementing any changes or modifications to their study for all submissions, regardless of initial review level. The investigator must complete an amendment according to the instructions provided in the appropriate form and submit it for IRB review.
2. The only exception to this requirement is where an immediate modification is necessary to eliminate apparent immediate hazards to human participants. The investigator must immediately notify the IRB Office via email for review regarding participants' continued welfare. Investigators must also submit an amendment detailing these modifications to the IRB for review.

3. IRB Office staff will review the amendment and may return it to the investigator for revisions or further information/clarification.

4. Amendments for protocol submission that were determined to be exempt from IRB review will be reviewed and approved by IRB Office Staff. The IRB Office will review and verify that the study, as amended, would continue to qualify for exemption. If the amendment alters the study, such that exemption no longer applies, then the amendment will be elevated to either expedited or full review. Investigators will be notified via email if their study remains exempt or if it has been elevated to a higher level of review.

5. Minor clerical modifications to expedited or convened review protocol submission will be reviewed and approved by IRB Office Staff. Minor clerical modifications include, but are not limited to, grammatical or typographical corrections, change in study site/address, update contact information, changes in research personnel, addition of translated versions of already approved English documents, etc.

6. Amendments to expedited or convened reviewed protocol submissions that are "no more than a minor change" to the research can be reviewed via expedited procedures. Amendments to convened reviewed protocol submissions that are more than a minor change must be reviewed by the convened IRB. Amendments to expedited submissions that are deemed more than a minor change or change the level of risk associated with the study, may also be forwarded to the convened IRB for review, at the discretion of the IRB Office in consultation with the Chair.

7. The IRB will notify the investigator regarding the approval of their amendment by emailing an approval memorandum along with stamped copies of all updated 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.

B. Annual Status Review of Exempt Submissions

1. For all submissions initially reviewed at the exempt level, investigators must submit an annual review regarding the status of their research. This annual review is to notify the IRB Office that research activities are either ongoing or have concluded.
2. Investigators must reply to the IRB Office request for an annual status update. They must respond by their institutional expiration date with sufficient time to allow for review without a lapse in institutional approval. Institutional policy does not allow for any form of grace period.
3. Research with human participants and/or their data must halt when a research status update is not submitted and approved by the IRB Office before the end of the approval period. Research with human participants may not resume until the study has their status updated and approved by the IRB Office.
4. The IRB Office will notify the investigator regarding the approval of their research status review by email. All appropriate College Representatives/Alternates, departmental personnel, faculty advisors (for student investigators), and funding agencies must be copied on this correspondence.

C. Continuing Review of Approved Expedited Reviewed Submissions

1. Investigators who require continuation of study approval must request continuation with sufficient time to allow for continuing review in order to avoid any lapse in approval. Institutional policy does not allow for any form of grace period. The IRB Office recommends that investigators submit for continuing review at least one month prior to the continuing review date to avoid a lapse in approval.
2. Continuing review for submissions initially reviewed at the expedited review level will be pre-reviewed by the IRB Office and approved by the IRB Chair or their designee.
3. The effective date of IRB approval for expedited level reviewed studies is the date on which the IRB Office has reviewed and accepted as satisfactory the continuing review submitted by

the investigator. See SOPP IRB Authorized Reviewers, Initial Levels of IRB Review, and Decisions for information regarding approval duration in procedure section C.1.

4. The IRB will notify the investigator regarding the approval of their continuing review 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, departments, faculty advisors/dissertation chairs (for student investigators), and funding agencies must be copied on this correspondence.

5. The IRB maintains all records of continuing review in the IRBManager electronic submission system. All expedited continuing review approvals will be documented in the meeting minutes.

D. Continuing Review of Approved Convened Review Submissions

1. Investigators who require continuation of study approval must request continuation with sufficient time to allow for continuing review without a lapse in approval. Institutional policy does not allow for any form of grace period. The IRB Office recommends that investigators submit for continuing review with sufficient time for the IRB Office to review and possibly request revisions prior to their continuing review date. This is to ensure that the submission is ready to be reviewed at the next convened IRB meeting.

2. Continuing review of submissions initially reviewed at the convened review level will be reviewed by the convened IRB, unless otherwise eligible for expedited review. This will be determined by the convened IRB in keeping with the expedited categories enumerated by the Office for Human Research Protections (OHRP) and Food and Drug Administration (FDA).

3. The effective date of IRB approval for convened level reviewed studies is the date on which the convened IRB or Chair, in the case of approval with modification, has reviewed and accepted as satisfactory, the continuing review submitted by the investigator. The date of the convened IRB when the continuing review was conducted and approved (with or without modification) determines the latest permissible date of the next continuing review. See SOPP "IRB Authorized Reviewers, Initial Levels of IRB Review, and Decisions" for information regarding approval duration in procedure section C.1.

4. The IRB will notify the investigator regarding the approval of their continuing review 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.

5. The IRB maintains all records of continuing review in the IRBManager electronic submission system. For continuing review conducted by the convened IRB, the meeting minutes will reflect any discussions related to the continuing review process and list the items submitted for review by investigators.

E. Lapse in Continuing Review for Approved Expedited or Full Reviewed Submissions

1. If an investigator fails to submit and receive approval for continuing review or close their submission by their approval date, the submission will be administratively closed. The IRB Office will notify the investigator that the study has been administratively closed due to a lapse in approval. All research with human participants and/or their data must halt, unless it is determined to be in the best interests of already enrolled subjects to continue participating in the research as outlined in Section E.2. of this SOPP. Research with human participants may not resume until the study has been approved for another continuing review period by the IRB Office.

2. The investigator should determine whether it is in the best interests of participants already enrolled to continue to participate in the research after IRB approval has expired. If applicable to ensure participant safety, the investigator should consult with their treating physician (if the researcher is not the participants' treating physician).
    a. This determination may be made for all enrolled participants as a group or for each individual participant.
    b. The investigator must submit a request for confirmation that the IRB agrees with this determination within one business day of receipt of the protocol closure notification which are sent out automatically by the IRBManager submission system.
    c. The determination may be made by the IRB Office in consultation with the IRB Chair and Vice Chairs.
    d. If the investigators and/or the IRB determines that it is not in the best interests of already enrolled participants to continue to participate, all research activities involving human participants, including intervening/interacting with participants and obtaining or analyzing data, must halt.

3. After submission has been administratively closed due to a lapse in continuing review, if an investigator wishes to continue their research, continuing review must be submitted to the IRB Office for review at the appropriate level, via the procedures described in this SOPP. The investigator must document why the lapse in approval occurred.

4. The investigator may not resume the human participant research activity until a continuing review has been approved via procedures described in this policy. The IRB Office will document any corrective actions that the investigator, institution, or IRB Office must take to prevent any future lapse of approval, if appropriate.

F. Closure of Approved Expedited or Full Reviewed Submissions

1. After all research activities, including data analysis, have concluded, the investigator will submit the closing report to the IRB Office for review.
2. Regardless of initial review type, the IRB Office will review closing reports for all protocol submissions.
3. The IRB Office may request the investigator to revise the closing report form and re-submit for review.
4. Once the IRB Office approves the closure of a protocol submission, the investigator will receive email notification that their protocol submission has been officially closed and the submission will no longer be active in IRBManager.

REFERENCES

21 CFR 312
21 CFR 56.108(a)(1)&(2)
21 CFR 56.109(f)
21 CFR 56.110
21 CFR 56.111
21 CFR 56.115(a)(3)&(7)
21 CFR 812
38 CFR 16.110(b)(2)
38 CFR 16.111
45 CFR 160
45 CFR 164
45 CFR 46.103(b)(4)
45 CFR 46.108
45 CFR 46.109
45 CFR 46.110
45 CFR 46.111
45 CFR 46.115(a)