OBJECTIVE

To describe the policies and procedures regarding the responsibilities of the Principal Investigator and other research personnel on research studies involving human participants.

GENERAL DESCRIPTION

Due to federal requirements and the desire of NSU to ensure that our research meets the highest ethical standards pertaining to the protection of human participants, investigators have certain responsibilities in regards to the IRB, conduct of research, qualifications, and training.

Definitions

Investigator (DHHS)[1]: An individual performing various tasks related to the conduct of human participants research activities, such as obtaining informed consent from participants, interacting with participants, and communicating with the IRB.

Investigator (FDA) [1]: An individual who actually conducts a clinical investigation (i.e., under whose immediate direction the drug is administered or dispensed to a participant). In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team.

Faculty Advisor/Dissertation Chair: NSU Faculty member who is responsible for monitoring their students' conduct of research involving human participants.

Co-Investigator: An individual that works in partnership with the Principal Investigator in the management, development and/or execution of a research study, but does not have overall responsibility and authority for the study. They are NOT considered a Principal Investigator.

Research Assistant: Individuals who support the Principal Investigator and Co-Investigators in the collection of data and information during the course of a research study.

Coordinator: For NSU IRB purposes, this is a specialized research professional charged with filing and maintaining clinical study records for IRB purposes ONLY and is NOT involved in the conduct of the research study.

[1] : Note, there are two (2) separate definitions for "Investigator" depending on whether DDHS or FDA regulations apply to the conduct of the research.

RESPONSIBILITY

Execution of SOPP: Principal Investigator (PI)/Research Personnel, Institutional Review Board (IRB) Office Staff, IRB Members, Faculty Advisors/Dissertation Chairs (if PI is a NSU student or CEME resident).

PROCEDURES

A. General Investigator Responsibilities

1. The Principal Investigator is responsible for ensuring that all research personnel follow all IRB policies and procedures and for the overall conduct of the study.
2. All investigators are responsible for ensuring that research is conducted according to sound research design, the terms of the grant, contract and/or signed agreement, and applicable laws and regulations for protecting the rights, safety, and welfare of human participants.
3. Investigators are responsible for ensuring that research involving human participants conforms to generally accepted scientific principles, and that it is based on a thorough knowledge of the scientific literature and other relevant sources of information. The methods to be used should be appropriate to the objectives of the research and the field of study.
4. Investigators are responsible for following all state and federal regulations along with NSU institutional policy while conducting research involving human participants.

B. Investigator Responsibilities to the IRB

1. Investigators are responsible for providing the IRB with sufficient information and materials to facilitate required determinations.
2. Before initiating research, the investigator is responsible for submitting their protocol for review by the IRB. All the required documentation such as Informed Consent Forms, recruitment materials, research instruments, etc. must be included.
3. Research may not begin until the Investigator has received an official approval memo from the IRB for their research protocol. Investigators must use the stamped documents provided by the IRB such as consent forms, participant recruitment materials (e.g., advertisements, scripts of orally presented materials), and copies of any other written information that will be provided to participants.

   a. For Exempt review research, this notification may only come from the College Representative that reviewed and approved the submission or the IRB Office.
   b. For Expedited and Full review research, this notification may only come from the IRB Office.

4. During the course of the research, investigators are responsible for maintaining IRB approval, and keeping the IRB informed about their research.

5. Investigators are required to submit submission status review or continuing review to the IRB annually, or more frequently, as the IRB requires. The NSU IRB policy document entitled "Protocol Revisions, Annual Status of Research, and Study Closure" provides additional information regarding this requirement.

6. Investigators may not make any changes in the research without prior IRB approval via an amendment, except where necessary to eliminate apparent immediate hazards to human participants. The NSU IRB policy document entitled "Protocol Revisions, Annual Status of Research, and Study Closure" provides additional information regarding this requirement.

7. Investigators are responsible for promptly reporting to the IRB any deviation from, or a change to the protocol, which was made to eliminate immediate hazards to participants without prior IRB approval to the IRB Office. The report should include a description of the deviation or change and the reasons for implementation. If appropriate, a proposed amendment to the research should be submitted to the IRB for review and approval, and to funding agencies.

8. Investigators are responsible for complying with applicable IRB policies and federal regulatory requirements related to the reporting of unanticipated problems, adverse events, and submission of IND safety reports.

9. Investigators are required to permit and facilitate post-approval monitoring by the IRB, applicable funding agencies and inspection by federal and state regulatory agencies, including inspection and observation of the informed consent process. Investigators must communicate with the IRB Office to request reasonable accommodations if necessary.

10. Investigators are responsible for notifying the IRB of any relevant communications received from any applicable regulatory agencies, including but not limited to, Sponsors, the Food and Drug Administration (FDA) and the Office for Human Research Protections (OHRP). Contact the IRB Office if you are unsure if a communication is relevant to your IRB protocol.

11. Upon completion of the research, investigators are responsible for promptly notifying the IRB by submitting a Closing Report (non-Exempt) or Exempt Status Update (Exempt) within 30 days of study completion.

C. Investigators Responsibilities while Conducting Human Participant Research

1. Investigators are responsible for conducting research in compliance with the research protocol as approved by the IRB.
2. Investigators are responsible for complying with the eligibility criteria as specified in the approved protocol.
3. Investigators are responsible for ensuring that participant selection is equitable; taking into account the purposes of the research, the setting, and be cognizant of special concerns such as vulnerable populations.
4. Investigators are responsible for ensuring that informed consent/assent/HIPAA authorization, if applicable, is obtained and, when applicable, documented, unless a waiver of the requirement has been approved by the IRB prior to a prospective participant's enrollment in a research study. The NSU IRB policy document entitled "Informed Consent" provides additional information regarding this requirement.
5. Investigators are responsible for adhering to the procedures as specified in the approved protocol, including randomization procedures, if any.
6. Investigators conducting research that involves the use of an investigational device must adhere to the plans that abide by Good Clinical Practice (GCP), FDA regulations, and other required standards for control, storage, and accountability of the device.
7. If the research is blinded, the investigators are responsible for only breaking the code in accordance with the protocol and promptly document and explain to the IRB any un-blinding due to unanticipated problems involving risks to a participant.
8. Investigators are responsible for obtaining prior IRB approval for all payments, reimbursements, and medical services to be provided to research participants.
9. Investigators are responsible for the accuracy, completeness, legibility, and timeliness of the data recorded and reported in research and in publications about the research.
10. As appropriate to the research and as specified by applicable regulations, investigators are responsible for maintaining documents, which individually and collectively permit

evaluation of the conduct of the research and the quality of the data produced. These include all protocol documents, current and signed copies of consent/assent/HIPAA forms, any written materials given to participants, correspondence from the IRB including approval memos, data collection forms, and reports of unanticipated problems/serious adverse events or IND safety reports.

11. Investigators are required to retain all research records for a minimum of three (3) years from the end-date/closing of the research study. For FDA-related research, the retention period begins on the date the study is closed by the sponsor. For some clinical research at NSU, the retention period may be longer. Investigators should discuss retention of their records with the applicable individuals in clinical operations.

D. Investigators Qualifications and Training

1. Investigators are responsible for being able to provide evidence of such qualifications through up-to-date curriculum vitae and/or other relevant documentation requested by the IRB, funding agencies, and/or regulatory agencies.

2. NSU Investigators, including Faculty Advisors/Dissertation Chairs for student researchers, are responsible for completing the required *CITI Human Subjects Protection Training* and submit proof of completion to the IRB prior to submitting a research protocol. Human subject protection training is a federal requirement that must be completed by all individuals involved with human participant research. This training will be verified for all submissions; Initial, Continuing Review, and Amendment. All research personnel being added to a submission must have current training before their addition to the study team can be approved. NSU institutional policy requires this training be completed every three years.

3. Human subjects protection training for non-NSU investigators, may do one of the following:
    a. Complete the NSU CITI training modules as designated by the academic unit of the Principal Investigator they are collaborating with and submit to the IRB Office for review.
    b. Send completion report from CITI training completed with another institution that lists all the modules they completed to the IRB Office for review.
    c. In the case of internationally based investigators, send documentation that a CITI training course equivalent has been completed while affiliated with another institution to the IRB Office for review.

4. Other training may be required by a researcher's academic unit or NSU administrative office per institutional policy, sponsor requirements, and/or other conditions.

REFERENCES

45 CFR 46.108
45 CFR 46.109
45 CFR 46.111
45 CFR 46.115
21 CFR 56.103(a) and 56.115(a)(1)
21 CFR 56.111 (a)(1 - 2, 4 - 5)
21 CFR 56.108(a)(1, 4)
21 CFR 56.108(b)(1), 56.115(a)(3 - 4)
21 CFR 56.113
21 CFR 56.115(a)(1, 3 and 4)
21 CFR 56.115(b)(1)
21 CFR 312.55