OBJECTIVE

To describe the policies and procedures relating to the Federal Wide Assurance for Nova Southeastern University and the Institutional Review Board's (IRB) authority to review all research involving human participants to ensure it meets all regulatory requirements.

GENERAL DESCRIPTION

The IRB Office will maintain the university's Federal Wide Assurance in good standing with the Office of Human Research Protections (OHRP) by submitting renewals and maintaining current roster information.

Federal regulations require that any institution requesting and receiving funds from a federal department or agency for research involving human participants must assure that such research is reviewed and approved by the university's IRB. In accordance with these federal regulations and institutional policies, the Nova Southeastern University (NSU) IRB has authority to review and approve all research involving human participants conducted by faculty, staff, or student investigators prior to implementation. The NSU IRB policy document entitled "Does my study need NSU IRB approval?" outlines activities that are considered human participants research or clinical investigation, requiring IRB review and approval.

Definitions

Federal Wide Assurance (FWA): This is documentation of an institution's commitment to comply with Federal regulations and maintain policies and procedures for the protection of human participants. An institution must have an FWA in order to receive Department of Health and Human Services support for research involving human participants.

Department of Health and Human Services (DHHS)/Common Rule

Clinical Trial: A research study in which one or more human participants are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Human participant (DHHS): A living individual about whom an investigator conducting research (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains or generates individually identifiable private information or identifiable biospecimens.

Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Intervention: Physical procedures by which information or biospecimens are gathered, or manipulations of the participant(s) environment are performed for research purposes.

Interaction: Communication or interpersonal contact between investigator and participant.

Individually identifiable: Information for which the identity of the participant is or may readily be ascertained by the investigator or associated with the information.

Private information: Information provided by an individual for specific purposes, and which the individual can reasonably expect will not be made public, or information about behavior that occurs in a context that the individual can reasonably expect that no observation or recording is taking place

Food and Drug Administration (FDA)

Clinical Investigation: Involves the use of a test article (i.e. drug, device, food substance, or biologic), one or more human participants, meets requirements for prior submission to the FDA (involves drugs or medical devices other than the use of FDA approved drugs or medical devices in the course of medical practice), or results are intended to be part of an application for research or a marketing permit.

If the activity involves the use of an FDA regulated test article (i.e. drug, device, food substance, or biologic under the purview of the FDA), the FDA definitions of “human participant” applies.

Human participants (FDA Drug): An individual who is or becomes a participant in research as either a recipient of a test article or as a control, or as an individual on whose specimen a device is used. A participant may be either a healthy individual or a patient [21 CFR 56.102(e)] (Drug, Food, Biologic).

Human participants (FDA Device): A human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used, or as a control. A participant may be in normal health or may have a medical condition or disease [21 CFR 812.3(p)] (Medical Devices). This definition includes the use of tissue as specimens, even if they are unidentified.

If research activity involves any of the following, FDA regulations 21 CFR 50 & 56 apply and require IRB approval prior to implementation.

- Any use of a drug in research other than the use of FDA approved drug in the course of medical practice;
- Any use of a medical device in studies where the purpose is to determine the safety or effectiveness of the device; or
- Data will be submitted to or held for inspection by FDA as part of a marketing permit.

RESPONSIBILITY

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

PROCEDURES

A. Federal Wide Assurance

1. The IRB Office will maintain the FWA by submitting requests for renewal and by submitting periodic updates of the IRB members and their alternates to OHRP.

B. IRB Authority to Review Human Participant Research

1. It is the responsibility of each investigator to seek IRB review and approval prior to initiation of any research involving human participants or before conducting any clinical investigation. Investigators must submit the protocol for review and approval by the IRB.

2. If investigator believes their research does not fall under the jurisdiction of the IRB Office, they may file for a “Not Human Subjects Research Determination”. The IRB Office will determine if the activity meets the criteria for a “Not Human Subjects Research Determination” and will notify the investigator of their determination. The document entitled “Does my study need NSU IRB approval?” is available on our website that will guide the investigator in determining whether their study requires IRB approval.

3. The IRB only reviews HIPAA Authorizations as a part of the review of a protocol submission submitted for IRB review. Investigators whose research includes Protected Health Information are advised to review the HIPAA for Research Purposes policies on the IRB website.

4. Investigators should contact their College Representative or IRB Office staff for advice on the applicability of the federal regulations and NSU policy.

5. The IRB Office communicates all decisions of the IRB or the Board to the investigator via their official email (for NSU faculty, staff, and students) or professional email (for all non-NSU investigators).

6. The IRB has final authority on its determinations, including but not limited to decisions to defer a submission for more information, approval pending required modifications, and disapproval. No university official or committee may set aside or overrule a determination by the IRB

7. Subject to generally applicable principles of academic freedom, the university may determine not to conduct research that has been approved by the IRB, including but not limited to the following reasons:
    a. A satisfactory contractual agreement could not be reached with a sponsor.
    b. The research would require resources that the university could not provide.
    c. The research would not be consistent with the university's mission or values.
    d. The research could expose the institution to unacceptable liability.

REFERENCES

21 CFR 56.102
21 CFR 56.109(a)
21 CFR 56.108(a)(1) and 56.109(f)
21 CFR 56.108(a)(1), 56.109(a), 56.112, and 56.113
21 CFR 812.3
45 CFR 46.102
45 CFR 46.103
45 CFR 46.109(a)
45 CFR 46.112