Responding to Allegations of Non-compliance with IRB Procedures

Scope

These policies and procedures apply to (1) all human research conducted by SCSU faculty, students, staff, administrators, or others who wish to conduct research under the auspices of SCSU; (2) all human research conducted on the SCSU campus or in cooperation with other research agencies and sites, regardless of whether the project is funded internally, externally or receives no funding support.

In particular, these policies and procedures will:

1. Define the scope and nature of non-compliance with federal, state, university and SCSU regulations regarding human subject research.
2. Describe the procedures for reporting, investigation, and resolving allegations of non-compliance.

These policies and procedures do not apply to incidents that are unanticipated problems or adverse events that threaten the safety of research participants and/or the integrity of the study. [1]

Definitions

Human subjects research: According to 45 CFR 46, a human subject is a living individual about whom an investigator conducting research obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or obtains uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. [2]

Non-compliance is defined as the intentional or unintentional failure of an investigator(s) to comply with 45 CFR part 46 (including any applicable subparts), SCSU policies relating to the protection of human subject research, and the requirements of the SCSU IRB-approved research study. Non-compliance can also occur when an act(s) is performed that violate(s) requirements or is a result of failing to act when required. [1][3]

SCSU IRB Purview

The IRB, through human research protocol review, assures that: (1) anticipated risks to human research participants are balanced by benefits to the individual and society; (2) selection of participants is just and equitable; (3) research designs are appropriate to protect human research participants; (4) anonymity, privacy, and confidentiality of participants are not compromised; and, (5) when applicable, research participants have given knowledgeable, voluntary and autonomous consent to take part in the research.

The IRB reviews all new research project protocols, project continuances, and revisions in approved research, and renders decisions regarding: (1) exemption from IRB review and review level; (2) the need for protocol modification; (3) protocol approval; and, (4) protocol disapproval.

Researcher Responsibilities

All research protocols involving human subjects are expected to comply with human subject protections as defined in federal, state, university and IRB regulations. All human subject research protocols must be reviewed by the IRB for compliance with these regulations before they are implemented. Investigators must implement the research protocol and consent documents as approved by the IRB, comply with additional conditions imposed by the IRB, seek IRB approval for changes to the protocol, and submit a completion report. They must report adverse events, major and minor incidents of non-compliance, breaches of scientific integrity and ethics, in accordance with IRB policies and procedures.

Noncompliance with Human Subject Protection Regulations

Examples of unintentional or intentional breach of human subject protection federal, state, university and IRB regulations and policies include: failure to obtain IRB approval prior to commencing research, falsifying research or medical records, performing tests or procedures beyond the individual's professional scope or privilege status, improper destruction or disposal of records, inadequate, absent, untimely or inadequate informed consent procedures, lapse in approval or failure to apply for renewal, failure to report serious adverse events and unanticipated problems, deviating from IRB research protocol without IRB approval, and failure to submit a completion report. [4]

Protocol Violations

Protocol violations are deviations from an IRB-approved study design and procedures that have not been pre-approved by the IRB. There are two levels of violations: major (reportable) and minor (not-reportable). [1] [3]

Minor violations: An unplanned or planned divergence from an IRB- approved protocol is considered minor when, in the judgment of the IRB, it does not have significant negative consequences on the scientific integrity or validity of the research data, or on the physical and mental well-being, safety, and the rights to privacy of research participants. [3]

Examples of these violations include completing a study visit outside of the approved time frame if there are no safety implications, use of an expired consent form if the contents are not substantially different from the current form, minimal enrollment above the approved numbers, signed copy of the consent form is not given to the participant, and document deficiencies such as a missing investigator's signature. [3]

Major violations: Major violations from an IRB-approved protocol are unapproved changes to the research protocol that in the judgment of the IRB, results or indicates a potential to substantially affect the scientific integrity or the validity of the study or increase adverse risks to the physical and mental well-being, safety and rights to privacy of research participants. [3] A major violation may be one-time or continuing noncompliance. Continuing non-compliance occurs when the disregard for regulations is repeated over time or across multiple projects. [1]

Examples of challenges to the quality of the data include: enrollment of research participants who do not meet eligibility criteria or substantially more than the number in the approved protocol, failure to apply research protocol that relates to outcomes efficacy, improper revelation of blinding assignments, lost or multiple missed tests, samples or data, inadequate record keeping, and data collection beyond the designated project duration. [4][5]

Examples of violations pertinent to the informed consent process include: breach of confidentiality and privacy by releasing identifiable study participant information to an unauthorized individual by mistake or intentionally, document deficiencies such as missing participant signature or date prior to receiving treatment, and missing informed consent checklist items as required by 45 CFR 45.116. These checklist items include nature and duration of participation, research procedures, and potential harms and benefits specific to the research participant, among others. [6]

Examples of violations that pose a significant risk of harm to research participants include administration of a prohibited medication or wrong dose, and failure to follow research procedures that were designed to ensure the safety and privacy of research participants. [4] [5]

Reporting of Noncompliance and Major Violations

Lead investigators of a study have a responsibility to report incidents of noncompliance and major violations to the IRB Chair. Upon request of the IRB Chair, these reports will be reviewed by the ORI following the procedures set-up for investigating allegations of research misconduct. These procedures are described in Policies and Procedures for Responding to Allegations of Research Misconduct, dated April 2020. The Provost will consult with the IRB Chair or the full IRB to determine corrective action(s) when non-compliance is verified. The IRB Chair will decide whether deliberations by the full IRB is needed.

Sources:

[1] Borror, K. (2014). Guidance to reporting incidents to OHRP. Office of Human Research Protections, Department of Health and Human Services. Retrieved December 7, 2020 from https://videocast.nih.gov/pdf/ohrp072414.pdf[1

[2] NIH Grants Policy Statement (December 2019). US Department of Health and Human Services, National Institutes of Health. Retrieved December 8, 2020 from https://grants.nih.gov/policy/nihgps/index.htm

[3] Sanders, P. (2019) 2019 NIH Intramural Research Program new policies: Reporting research events and non-compliance in human subjects research, Office of Human Subjects Research Protections. Retrieved December 8, 2020 from https://irbo.nih.gov/confluence/pages/viewpage.action?pageId=38961203

[4] Draft protocol deviation definitions. NIH IRB Professional Administrators Committee, Version 5.1. Regulatory Process Workgroup, 11/18/2005. Protocol deviations and violations. Retrieved December 8, 2020 from ccord.cancer.gov

[5] Bhatt A. (2012). Protocol deviation and violation. *Perspectives in clinical research*, *3*(3), 117. https://doi.org/10.4103/2229-3485.100663

[6] Informed consent checklist 1998. Office of Human Research Protections. Retrieved December 8, 2020 from https://www.hhs.gov/ohrp/regulations-and-policy/guidance/checklists/index.html