Key Points of New Safety Information SOPs

Per federal regulations, institutions engaged in human subjects research are required to have written procedures in place for ensuring prompt reporting of (i) Unanticipated Problems Involving Risk to Subjects or Others, (ii) Serious or Continuing Non-compliance, and (iii) suspension or a termination of IRB approval to the IRB, appropriate institutional officials, and applicable federal agencies. SOP 1401, 1402, and 1403 serve to fulfill the requirements of these regulations and to protect the rights, safety, and welfare of research participants. These new SOPs replace SOP 19.0, 22.0, 23.0, 36.0., and 37.2.

SOP 1401 provides investigators with the type of information that is promptly reportable to the IRB as well as considerations for determining if new information represents increased risk to the participant or others. SOP 1402 provides a detailed description of how the IRB reviews and processes new safety information, including the pre-review process by the Safety and Welfare Analysis Group (SWAG) and review by the convened IRB (Safety Committee). SOP 1403 describes how complaints from participants and third parties are managed by the investigator and the IRB. Please see below for the key points of each SOP.

SOP 1401: Reporting New Safety Information

1. What type of information is promptly reportable to the IRB: TABLE 1, New Safety Information
2. Promptly reportable = 7 calendar days
3. Assessment of Risk
4. Root Cause Analysis
5. Corrective and Preventative Action (CAPA) Plans
6. Detailed examples of New Safety Information: SUPPLEMENT 1.

SOP 1402: IRB Management of New Safety Information:

1. Pre-review by the Safety and Welfare Analysis Group (SWAG)
2. Safety Committee Review
3. Types of Determinations
7. Review of Corrective and Preventative Action (CAPA) Plans
4. Reporting to federal agencies

SOP 1403: Questions, Concerns, or Complaints from Research Participants or Third Parties

1. Requirement to include the contact information of the investigator (or designee) and the IRB in the UNC consent document.
2. Procedures for managing complaints from participants or third parties.
3. Procedures for IRB review and resolution of complaints from participants or third parties.