

National Institutes of Health
NINDS Standard Operating Procedure
Title: Research Team Clinical Care Meetings

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1.0 PURPOSE

The purpose of this SOP is to outline the procedures within the NINDS CNP to ensure the timely recognition of reportable events (AEs, UPs, and PDs) by conducting regular clinical care meetings at the level of the research team.

2.0 POLICY

Per NIH and FDA regulations, the Principal Investigator (PI) and/or Study Sponsor (if applicable) is responsible for identifying reportable events and submitting timely reports. To ensure prompt recognition, review, and discussion of study events, the Deputy Director for Intramural Research and the Deputy Director for Intramural Clinical Research instructed Principal Investigators to implement a plan to conduct routine research team rounds to fulfill this goal. This SOP aims to assist Principal Investigators to implement either new or update existing procedures for regular research team clinical care meetings.

3.0 PROCEDURE

3.1 Scope of research team clinical care meetings

Research teams meet on a regular basis to discuss patient cases and study processes, as well as to review patient care and protocol related events. While it is beyond the scope of this SOP to define how research groups should fulfill their internal research and clinical care responsibilities, regulations and policies governing the detection and communication of study events that require reporting outside of the research group need to be followed. Systems such as regular research team clinical care meetings should be in place that allow the identification and timely recognition of these reportable events.

A review of activities involving research subjects in the days immediately following the subject visit, which may include a review of clinical data, consent documents, and subject-specific protocol milestones, should ensure that any previously undetected events such as adverse events or protocol deviations will be detected.

3.2 Frequency

The meeting frequency will depend on the clinical and research activities of individual research groups. Research team clinical care meetings are to be held on a regular basis when subject visits are either actively conducted or subjects remain on the protocol in an active status. As serious study events such as serious unanticipated

problems and protocol deviations require reporting that should be done immediately but no later than 7 days after the PI learns about the event, the frequency of meetings should be on an **at least weekly** basis.

3.3 Meeting structure

Core members of regular team meetings are the **PI, key investigator(s), nurse practitioner(s)**, and the **research nurse(s)**. Additional members may include research team members responsible for **study coordination, protocol navigation, and patient care coordination**.

Regular meetings should include the following topics:

- Each subject seen in interval since last meeting under any protocol of the respective research team, including outpatient and inpatient encounters
- Other interactions with study subjects (e.g., via phone, electronically, etc.), whether planned or unplanned
- Protocol consent documents
- Adverse events, if any
- Protocol deviations, if any
- Upcoming events (e.g., future planned subjects, planned study procedures, monitoring visits / audits)

Reportable events may be identified through presentation by a study investigator or research nurse, and/or review of clinical and research records (e.g., CRIS documentation, (electronic) Case Report Forms). The PI, with the study team, is then responsible for making a determination (AE/UP/PD) of the event and reporting to all applicable entities (IRB, CD, Sponsor, FDA).