Clinical Monitoring- Records of Project Monitor Visits to Investigative Sites

Procedure Overview
To define record-keeping requirements for Project Monitor reports documenting visits to NETT Hub Complex investigative sites.

Responsible Individuals
Qualified NETT and Hub Complex personnel (including, but not limited to, Site Manager and Project Monitor); Contracted Clinical Research Associates; NETT Director of Site Operations and/or designee.

Procedure
Records of all visits to investigative sites by the Project Monitor will be entered into NETT WebDCU™. The NETT SOPs for reporting monitoring activities are followed. NETT standard visit reports include, but are not limited to, the following:

- Protocol Name and Number
- Date(s) of the visit
- Name of the Project Monitor
- Name of Investigator or other individuals present at the time of the visit
- Summary of the findings which describe the investigator's ability to fulfill or actual fulfillment of their obligations
- Summary of the findings sufficient to describe the acceptability of the investigative site facilities
- Description of current patient status
- Identification of the subjects verified
- Identification of any deficiencies noted during the visit and description of any actions taken by the Project Monitor and/or investigator to remedy such deficiencies
- Actions items those were not resolved at the time of the visit.
- Timeframe for resolution of action items
- Any additional comments regarding the investigative site, staff, supplies, enrollment, or study conduct that the Project Monitor deems important.
- Identification of protocol violations and steps taken to prevent future violations.

Documentation
The Project Monitor submits a report via WebDCU™ after each site visit or study-related communication. This report will be viewable by NETT CCC personnel, the site study staff, and the protocol-specific PI. Visits include, but are not limited to, the following:

- Site Initiation Visits
- Monitoring site visits
- Study close-out visits

The standard report templates for these monitoring visits may be found as appendices to the corresponding SOPs that cover these visits.

In addition to the afore noted documents, the Project Monitor signs the Monitor Visit Log located in the investigator's study file binder. This document is not maintained in WebDCU™.

Deviation Approval
NETT Director of Site Operations and/or designee must approve deviation from this procedure. The Director, NETT or designee must store documentation of the deviation approval.

Relevant Definitions
CCC – Clinical Coordinating Center
PI – Principal Investigator

Procedure Author
NETT Network Operations Committee, NETT CCC