Clinical Monitoring-Site Initiation Visit

Procedure Overview
This procedure describes the process of preparing for and conducting the site initiation visit.

Responsible Individuals
Qualified NETT CCC and Hub Complex designee (including, but not limited to, Site Manager and Project Monitor)

1. Definitions
   a) Institutional Review Board (IRB) – The board within an institution providing oversight of research as described in 45 CFR Part 46.
   b) CCC – Clinical Coordinating Center
   c) FWA- Federal Wide Assurance
   d) GCP - Good Clinical Practice
   e) IND- Investigational New Drug
   f) SDMC – Statistical and Data Management Center

Procedure
1. Prior to conducting the site initiation visit, the Project Monitor and Hub Complex designee will:
   a) Correspond with the Hub and/or Spoke PI, or designee to schedule the site visit at a mutually agreed upon time.
   b) Provide an agenda of activities, including a list of site personnel required for each, in the form of a Pre-Visit Site letter.

2. The following procedures are performed during site initiation visits by NETT CCC personnel at the Hub, and by Hub Complex designee at the Spokes:
   a) Ensure that all required regulatory documents have been uploaded to the NETT WebDCU™ as required, and/or a copy has been filed in the Investigator's Regulatory File as required, including:
      i. Signed Statement of Investigator (FDA Form 1572 for drugs) for any NETT active or pending Investigational New Drug Study.
      ii. Current and signed curricula vitae for staff listed with the IRB as investigators. CVs should reflect current addresses, institutional and/or clinical affiliations and must be no more than two years old.
      iii. IRB submission and/or approval documentation for any NETT approved protocol, amendments/addenda, informed consent form, and study related materials such as advertisements and study brochures.

iv. Investigators brochure and/or package insert.
v. Laboratory certification.
vi. IRB membership list or FWA number.

b) Ensure that the investigator and staff are fully aware of their obligations and responsibilities (refer to NETT SOP "Role of the Investigator") with regard to the conduct of the trial including compliance with the study protocol and specified procedures, timelines, number of subjects required, GCP guidelines, applicable governing agency regulations, informed consent requirements, and adverse event reporting requirements.
c) Ensure that the investigator and staff have received instruction and training on electronic data entry.
d) Review the case report forms and the case report completion requirements.
e) Check the security and proper storage of subject specific documents and the test article, and review dispensing and accounting procedures and records
f) Review source document requirements

3. Following the site initiation visit, the Project Monitor and/or Hub Complex designee will enter a Site Initiation Visit Report in the NETT WebDCU™.

4. Approval for Process Exemption
   a. The Director of Site Operations or designee must approve exemption from the processes outlined in sections two and three of this policy. The Director of Site Operations or designee must maintain documentation of the exemption approval.