Ongoing Clinical Trial Information Reporting Within the Network

Procedure Overview
This procedure describes how information related to ongoing clinical trials being performed within the NETT is shared within the Network.

Responsible Individuals and Applicability
Qualified NETT personnel including members of the NETT Steering Committee.

Scope
Information about ongoing clinical trials covered by this SOP includes, but is not necessarily limited to: study protocols, amendments to study protocol and regulatory documents, investigators' brochures, distributed reports and letters from/to oversight bodies, distributed reports and letters related to protocol unanticipated problems or adverse events, or other reportable information or occurrences involving risks to subjects or others.

Guiding Principles
The NETT Network is a cooperative operation involving the NINDS, CCC, SDMC, and Hub Complexes. Participation in clinical trials is undertaken by the group as a whole, through the NETT Steering Committee. Essential to this cooperative structure is transparency and open sharing of information among all NETT investigators related to ongoing clinical trials being conducted within the Network.

The safety of human research subjects participating in clinical trials is paramount. Access for all NETT investigators to all reportable information involving risks to subjects or others relating to trials conducted in the network supports complete, accurate reporting to the investigators' respective institutional Human Subjects Protection Programs/Institutional Review Boards, and compliance with regulatory responsibilities.

Implementation
1. Information within the scope of this SOP for ongoing clinical trials being conducted within the Network will be reported to the NETT CCC by the clinical trial's principal investigator, sponsor, or (less commonly) by an oversight body as written in the trial-specific Data Safety Monitoring Plan. If a trial-specific plan is not in place the NETT CCC timeline will be as follows:

   The following events will be reported within 7 days of becoming aware of the event:
   - Serious Adverse Events (SAE) or events involving risk to other subjects
   - The event or information in the report constitutes an 'unanticipated problem' that poses risk to current and/or future subjects
   - The report requires a change in the research protocol or procedures

- Report that is an analysis, safety, or statistical report from an oversight entity [(e.g., FDA letter, Periodic Sponsor Report of all Adverse Events (AEs), Medwatch, Data and Safety Monitoring Board Report)]

2. The NETT CCC will then distribute the information to all NETT Hub Complex investigators on the NETT Steering Committee members and designated staff consistent with the applicable reporting timelines.

3. NETT investigators are responsible for reporting information to their Institutional Human Subjects Protection Program/Institutional Review Board per the regulatory requirements and their own institutional guidelines.