

## NETT Hub Management of Spokes

### Procedure Overview

To define the guidelines for the addition and management of Spokes within a Hub/Spoke Complex.

### Definitions

Hub - an institution designated as a Hub via infrastructure funding from NINDS

Affiliate Hub - a performance site that was not designated as a Hub Complex by NINDS but will serve as a performance Hub for a specific trial

Spoke - an affiliated hospital enrolling patients in a clinical trial as part of a specific Hub Complex (Spokes may enroll in only one clinical trial or in multiple trials.)

Hub/Spoke Complex - the Hub institution and the Spokes affiliated with that Hub.

### Responsible Individuals

Collaborating Hub/Spoke Complex Investigators, trial-specific study team members, and NETT Clinical Coordinating Center (CCC) and Statistical Data Management Center (SDMC) investigators and staff

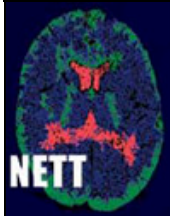
### Principles

NETT Hubs are ultimately responsible for Spoke activity and performance.

### Procedure

1. The Hub/Spoke Complex Principal Investigator (PI) or Hub/Spoke Complex Project Manager will notify the NETT CCC of the intent to add a new Spoke in anticipation of including a spoke as either a new site in an existing study or a site in a new NETT trial.
2. The Hub/Spoke Complex PI or Hub/Spoke Complex Project Manager will inform the NETT CCC of the location of the new Spoke and the distance from the primary Hub/Spoke Complex institution. The NETT CCC will approve addition of new spokes to a Hub/Spoke Complex as part of a specific trial.
3. At a minimum for each study the Hub/Spoke Complex should have a face-to-face start-up meeting with the Spoke PI, Spoke Study Coordinator and Pharmacist. This meeting should include an introduction to the NETT structure, the NETT website and lists of key contact personnel at the Hubs, CCC and SDMC.

Version Number: FINAL 1	Release Date: June 6, 2012
Original Approval Date: May 25, 2012	Revision Date: NA
Policy Number: TBD	Page 1 of 2



4. The NETT CCC will develop a Spoke start-up checklist to assist the Hub/Spoke Complex with Spoke initiation. The Hub/Spoke Complex staff will complete the checklist for each new Spoke prior to activating the new Spoke. Verification of completion of the checklist will be uploaded into WebDCU for NETT CCC review. A NETT CCC Site Manager will be responsible for requesting updates from the Hub/Spoke Complex regarding Spoke initiation for the CCC.
5. The NETT CCC and SDMC will assist the Hub/Spoke Complex staff with the training of Spoke staff and maintaining training materials. This includes protocol and WebDCU training, and presentation materials on the NETT.
6. The Hub/Spoke Complex staff will ensure that regulatory documents are properly uploaded into WebDCU.
7. The Hub/Spoke Complex PI and Hub/Spoke Complex Project Manager will contact the Spoke within two business days of the first enrollment in any new trial for that spoke to verify informed consent was properly obtained, adherence to the clinical protocol, accurate and timely data collection, and CRF completion. This evaluation is best done in person. If the spoke is remote and an on-site visit is not feasible, the Hub/Spoke Complex PI and Hub/Spoke Complex Project Manager will have to specify how this information will be verified. A mock review template will be provided to the Hub/Spoke Complex and should be reviewed with Spoke personnel prior to the first visit by a NETT monitor.
8. The Hub/Spoke Complex PI and Hub/Spoke Complex Project Manager will conduct at minimum two teleconference calls per year with Spoke institutions and one in-person visit per year. Hub/Spoke Complex PIs and Hub/Spoke Complex Project Managers will be notified when one of their spokes enters a subject in a NETT trial.
9. The Hub/Spoke Complex PI and Hub/Spoke Complex Project Manager should be copied on all communications that occur between their Spoke trial-specific investigators, Study Coordinators and NETT or trial-specific team members that refer to critical protocol deviations/violations that may require IRB involvement or corrective action plans, human subject protections, and enrollment or follow-up issues. Transparency and open communication must be maintained within the Hub/Spoke Complex to ensure that the Hub/Spoke Complex can address any Spoke issues in a timely manner. When time or logistics preclude immediate inclusion of the Hub/Spoke Complex PI in communications regarding critical protocol deviations such as these, such communications should be forwarded as soon as practicable.
10. The Hub/Spoke Complex is responsible for assuring that Spokes read and comply with NETT SOPs in the conduct of NETT trials. Corrective action plans will be developed in collaboration with the Hub/Spoke Complex. The Hub/Spoke Complex will be responsible for Spokes that do not comply with the corrective action plan and will work with the CCC to resolve outstanding issues. Failure to resolve and implement corrective action plans will result in the Hub/Spoke Complex and CCC jointly deactivating Spokes for specific NETT trials and may prevent future involvement in other NETT trials.

Version Number: FINAL 1	Release Date: June 6, 2012
Original Approval Date: May 25, 2012	Revision Date: NA
Policy Number: TBD	Page 2 of 2