# SOP Implementation Process

Policy Overview: This policy describes the process for requesting, creating, reviewing, revising, approving and implementing policies and procedures for the NETT network.

Participating Individuals: Study staff and investigators performing NETT related activities within a NETT network entity.

1. Definitions
   a) Affiliate Hub complex - A performance site that was not designated as a Hub complex by NINDS but will serve as a performance site for a specific trial. The affiliate Hub designation is restricted to a site at which the trial Principal Investigator is not affiliated with a Hub complex but would like to enroll subjects in his/her trial at his/her institution.
   b) Hub complex - The Hub institution and the spokes affiliated with the Hub.
   c) NETT entity - Any Hub complex, affiliate Hub, coordinating center, vendor, or subcontracted agent of the NETT network.
   d) SOP - Standard operating procedure.

2. Initial process for implementation of a NETT policy or procedure (hereinafter referred to as SOP)
   a) Request for creation of a SOP
      i   Any member of a NETT entity performing NETT related activities may submit a request for development and implementation of an SOP. Requests should be submitted to the NETT Administrative Director for consideration. The request should include the activity and reason to be considered for the creation of the policy. Inclusion of SOP outlines or draft documents with the request is encouraged.
      ii The NETT Administrative Director will forward the request for creation to the NETT Executive Committee.
      iii The NETT Executive Committee will authorize the Adminsitrative Director or designee to create a draft of the policy.
      iv The Administrative Director or designee will be considered the controller of the document as described in the NETT version control process.
      v   An electronic copy of the document and link to the document on the CTools site will be provided to the Executive Committee.
   b) Review and revision of a SOP
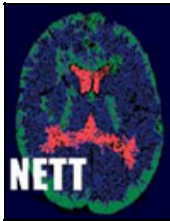
     i   A timeline for review and revision of an SOP document will be provided to the Executive Committee with the notification of the SOP's availability.

     ii Edits and revisions to the draft document will be made by Executive Committee members using the process outlined in the version control process.

     iii The Administrative Director or designee will collate the comments received in the specified timeline and provide an updated draft document.

  c) Approval of an SOP

     i   SOP will be presented to members of the Executive Committee during a scheduled meeting.

     ii Members present at the meeting will vote on the approval of the document.

     iii Members may provide comment and vote in absentia to the Administrative Director prior to the meeting.

     iv A majority vote is needed for the approval of the SOP.

  d) Dissemination of NETT SOPs

     i   NETT SOPs will be posted on the NETT website.

     ii An email that includes the policies and link to the website will be sent to members of the NETT entities.

3. Revision of a NETT SOP
   a) Any member of NETT Executive or Steering Committees performing NETT related activities may submit a request for revision of an SOP.
   b) The NETT Administrative Director will forward the request for revision to the NETT Executive Committee
   c) The revision process will follow the steps outlined in section 2 of this document.