

SOP Implementation Process

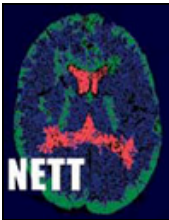
Policy Overview: This policy describes the process for requesting, creating, reviewing, revising, approving and implementing policies and procedures for the GPSNJ-NETT network.

For the policy describing the NETT process for requesting, creating, reviewing, revising, approving and implementing policies and procedures for the NETT network, go to: http://www.nett.umich.edu/nett/nett_standard_operating_procedures.

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

1. Definitions
 - a) GPSNJ-NETT entity - The Hub or any Spoke within the GPSNJ-NETT network. The GPSNJ-NETT entities comprise the GPSNJ-NETT Hub complex.
 - b) SOP - Standard operating procedure.
2. Initial process for implementation of a GPSNJ-NETT policy or procedure (hereinafter referred to as SOP)
 - a) Request for creation of a GPSNJ-NETT SOP
 - i Any member of a GPSNJ-NETT entity performing GPSNJ-NETT related activities may submit a request for development and implementation of an SOP. Requests should be submitted to the GPSNJ-NETT Project Manager 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 GPSNJ-NETT Project Manager will forward the request for creation to the GPSNJ-NETT Hub team.
 - iii The GPSNJ-NETT Hub team will authorize the Project Manager or designee to create a draft of the policy.
 - iv The Project Manager or designee will be considered the controller of the document as described in the GPSNJ-NETT version control process.
 - v An electronic copy of the document will be provided to the GPSNJ-NETT Hub team by email.
 - b) Review and revision of a GPSNJ-NETT SOP
 - i A timeline for review and revision of a GPSNJ-NETT SOP document will be provided to the Hub team.

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- ii Edits and revisions to the draft document will be made by GPSNJ-NETT Hub members using the process outlined in the version control process.
 - iii The Project Manager 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 GPSNJ-NETT Hub team during a scheduled meeting or by email.
 - ii Members present at the meeting or recipients of the email will vote on the approval of the document.
 - iv A majority vote and an assenting vote by the GPSNJ-NETT Hub PI are needed for the approval of the SOP.
 - d) Dissemination of GPSNJ-NETT SOPs
 - i Approved GPSNJ-NETT SOPs will be posted on the GPSNJ-NETT website.
 - ii An email that includes the policies and link to the website will be sent to members of the GPSNJ-NETT entities.
- 3. Revision of a GPSNJ-NETT SOP
 - a) Any member of a GPSNJ-NETT entity performing GPSNJ-NETT related activities may submit a request for revision of a GPSNJ-NETT SOP.
 - b) The GPSNJ-NETT Project Manager will forward the request for revision to the GPSNJ-NETT Hub team.
 - c) The revision process will follow the steps outlined in section 2 of this document.

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