

Process for Solicitation and Review of Clinical Trials for NIH StrokeNet

1. Promotion / Solicitation

Solicitation, development and submission of clinical trials will be actively pursued through various appropriate mechanisms, including some or all of the following:

- a. Communication with StrokeNet Investigators and NINDS Program Directors who can refer investigators to StrokeNet as they are approached with appropriate projects.
- b. A Funding Opportunity Announcement (FOA), Research Opportunity Announcement (ROA), or Notice in the NIH Guide.
- c. Encouraging StrokeNet investigators to engage their collaborators in academia or industry or other StrokeNet investigators to identify promising projects.
- d. Promotion of StrokeNet in appropriate journals, including *Stroke*, *Neurology* and *Annals of Neurology*, as well as at appropriate scientific meetings such as International Stroke Conference (ISC), Society for Neuroscience (SFN), American Academy of Neurology (AAN), etc.
- e. Communication with industry, biotechnology and patient group representatives about goals and availability of StrokeNet.
- f. Information about important, unanswered clinical questions and potential clinical trials on the StrokeNet website (www.NIHStrokeNet.org).

2. Concept Approval and Scientific Review

The initial determination of project suitability for StrokeNet will be made by the NINDS. Projects to be considered for funding and conduct within StrokeNet must follow the process defined below.

a. Concept approval by NINDS

- i. Once the prospective applicant (i.e., Protocol Principal Investigator or PPI) is ready to proceed with a potential grant submission of a project to be conducted within the network, he/she should contact NINDS at (StrokeNetInquiry@mail.nih.gov). The PPI will be invited to complete and submit the StrokeNet Clinical Study Concept Synopsis Form to the NINDS.
- ii. NINDS program staff will determine the completeness of the information provided and whether or not the proposed study is appropriate for the network. A telephone conference including NINDS program staff, and the PPI may be scheduled to gather missing information.
- iii. Projects referred by the NINDS to the network will be invited to present and discuss their proposed project with the appropriate StrokeNet working group to further refine concept synopsis.
- iv. Following discussions with the working group, the PPI will work with the NCC and NDMC to prepare a preliminary budget. NINDS will present the final draft of the concept synopsis and the proposed budget to the NINDS Extramural Science Committee (ESC) for evaluation of the proposal's alignment with the overall mission and priorities of the NINDS. A proposal must be approved by ESC to proceed with the development of the project and a grant application. The NINDS ESC may defer a final decision and invite the PPI to refine the concept further with additional input from the StrokeNet working group as needed.

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b. Assessment of Feasibility and Development of the Grant Application

- i. Proposed studies that are approved by the NINDS ESC for further development and grant submission are referred to the appropriate StrokeNet working group to assess feasibility and provide information relevant for determining the capacity of adding the proposed study to the StrokeNet and the number of sites needed and potentially available for the application.

Feasibility assessment will include:

- a. Confirmation of availability of patient population at StrokeNet sites.
 - b. Determination of the number of StrokeNet sites needed and whether an adequate number of sites are willing to participate in the study.
 - c. Determination of the ability of the StrokeNet sites to conduct the specific study including available technology, resources, personnel, etc.
 - d. Assessment of regulatory requirements.
 - e. Confirmation of availability of drug/placebo/devices for the proposed study, if applicable.
- ii. Proposed studies deemed to be infeasible by a working group are referred to the StrokeNet Executive Committee (EC) and NINDS for resolution.
 - iii. The PPI is responsible for writing and submitting the grant application to NIH but may work with the StrokeNet Investigators who may provide input into the proposal to ensure that is optimized to be conducted within the StrokeNet;
 - iv. The StrokeNet EC and the National StrokeNet Clinical and Data Coordinating Centers will provide any relevant information that may be needed in order to allow the PPI to comply with the NINDS regulatory submission policy (<http://grants.nih.gov/grants/guide/notice-files/NOT-NS-11-018.html>) ensuring the protocol is either under an open IND/IDE at the time of submission or has received an exemption from the FDA.
 - v. The StrokeNet NCC PI and NDMC PI will provide letters of support for the grant application and provide a letter on behalf of the network sites that could participate in the study. Individual letters from network sites are not needed for the application. If the PPI is proposing to use a non-network site, they will be encouraged to retain a separate letter of support for each added site.
 - vi. Six weeks before the grant submission due date, final budget assumptions, the near-final specific aims and the research plan sections must be sent to the NCC and NDMC MPIs, and the chair of the respective working group. Summary statements need to be included if the grant is a resubmission. This review is to allow for alignment with the NCC and the NDMC infrastructures and to provide other advice in time for the deadline.

c. Grant Submission, Scientific Review and Project Initiation

- i. Grant applications will be submitted to the NIH at the application cycle deadlines provided in the StrokeNet-specific FOA:
 - **NIH StrokeNet Clinical Trials and Biomarker Studies for Stroke Treatment, Recovery, and Prevention (UG3/UH3)** (PAR- 20-285)
- ii. Submitted applications will be reviewed by a NINDS StrokeNet Special Emphasis Panel followed by the NINDS Council review for those applications receiving meritorious scores.
- iii. Projects approved for funding by the NINDS will be prioritized for implementation in the StrokeNet as follows:

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- a. Competition with ongoing projects or other activities within the network will be assessed by the NINDS with consultation by the NCC/StrokeNet EC to determine the optimal timing when the project should begin.
- b. The project award will be made to the PPI's institution within 1 year of the Council approval in considering the projected project start within the network.
- c. Prior to the award, the PPI will begin pre-award planning and study start-up meetings to include NCC/NDMC/NINDS leadership along with all project specific personnel.