

Grant Proposal Guidance for Investigators

The steps listed below are in chronological order, broken down according to pre-Extramural Scientific Committee (ESC) and post-ESC approval stages. Contact information for key personnel from NINDS, NCC, and NDMC are listed in the right most column. There are ample resources available to PIs who wish to develop a grant for submission through the StrokeNet infrastructure. **The submitting PI is ultimately responsible for driving the process forward.**

NCC = National Coordinating Center (University of Cincinnati) **NDMC** = National Data Management Center (Medical University of South Carolina)

Pre-ESC Activities	Key Personnel
1. PI may choose to have an informal initial discussion with NCC PIs and/or Working Group Chairs and will be encouraged to discuss their concept with NINDS directly.	NINDS Program Scientist: - Scott Janis, PhD janiss@ninds.nih.gov
2. PI submits proposed StrokeNet Concept Synopsis to StrokeNetInquiry@mail.nih.gov .	NCC PIs:
3. NINDS Program Scientist sends synopsis to relevant Working Group Chairs and NCC Administrator if deemed appropriate for StrokeNet.	- Pooja Khatri, MD khatrip@ucmail.uc.edu - Joseph Broderick, MD broderjp@ucmail.uc.edu
4. Working Group Chairs will reach out to PI to schedule a call to discuss the synopsis, and when ready, a date to present the synopsis to the relevant Working Group.	NDMC PIs: - Jordan Elm, PhD elmj@musc.edu - Catherine Dillon, MS rileycp@musc.edu
5. PI presents synopsis to relevant Working Group. <ul style="list-style-type: none"> Five to ten-minute slide presentation followed by open and closed discussions, is the suggested format. Please limit to five slides. Include the estimated number of trial sites needed for enrollment and consider ending with a list of questions for the group. Working Group Chairs will provide a written summary of feedback to PI within 5 working days. After revision you may consult again with the Working Group (optional) or confer with NINDS Program Scientist regarding readiness to move forward. 	Acute Stroke Working Group Chair and Co-Chair: - Karen Johnston, MD KJ4V@virginia.edu - Jeff Saver, MD JSaver@mednet.ucla.edu Prevention Working Group Chair and Co-Chair: - Hooman Kamel, MD hok9010@med.cornell.edu - Scott Kasner, MD Scott.Kasner@penntmedicine.upenn.edu Rehabilitation and Recovery Working Group Chair and Co-Chair:
6. PI develops preliminary budget once synopsis is finalized. <ul style="list-style-type: none"> PI contacts NCC Directors and NDMC PIs for budget assumption templates and budget guidance documents. For trials involving study drug, PI reaches out to the NCC Central Pharmacist. It can take up to two months to obtain drug quotes from pharmaceutical companies. Once PI finalizes NCC and NDMC-specific budget assumptions (e.g., per patient budget, number of sites, etc.), please allow 10 business days for budget generation. PI is responsible for generating <u>the final</u>, prime budget with guidance from the NCC Trial Operations and Budget Liaison. 	- Steve Cramer, MD sccramer@mednet.ucla.edu - Steve Wolf, PhD swolf@emory.edu NCC Administrator: - Rose Beckmann beckmare@ucmail.uc.edu NCC Directors: - Iris Davis, MS deedsss@ucmail.uc.edu - Laura Benken, MBA osinsklr@ucmail.uc.edu NCC Trial Operations and Budget Liaison:
7. PI submits concept synopsis, main cost drivers document and preliminary budget to NINDS Program Scientist for NINDS Extramural Science Committee (ESC) review. <ul style="list-style-type: none"> StrokeNet concepts are discussed with ESC at one of three planned meetings during the year. The PI should discuss timing of the ESC discussion with the NINDS Program Scientist when they are ready to submit. 	- Eva Mistry, MBBS mistryea@ucmail.uc.edu NCC Central Pharmacist - Noor Sabagha, R.Ph Noor.Sabagha@UCHealth.com

ESC Approved?

No (communicate with NINDS)

Yes

Post-ESC Activities	Key personnel
<p>8. PI develops study feasibility survey and sends to Working Group Chairs for approval by email or Working Group discussion.</p> <ul style="list-style-type: none"> • NCC Directors will provide example feasibility surveys. • NCC Administrator will provide an email titled “Post-ESC Timeline in StrokeNet” detailing the dates for required Steering Committee, Working Group and Executive Committee meetings, described in steps 9, 12 and 13 below. 	<p>StrokeNet Epidemiology Core:</p> <ul style="list-style-type: none"> - Dawn Kleindorfer, MD dkleindo@med.umich.edu - Rob Stanton, MD stantorj@ucmail.uc.edu <p>NDMC Directors:</p> <ul style="list-style-type: none"> - Jocelyn Craven, MPH anderjoc@musc.edu - Jama Olsen, MPA olsen@musc.edu
<p>9. PI presents proposal to the StrokeNet Steering Committee to provide context to network site investigators and coordinators for the forthcoming feasibility survey. No more than fifteen-minute slide presentation is the suggested format.</p>	
<p>10. NDMC Directors send out finalized study feasibility survey to network sites right before or right after Steering Committee meeting. Sites are given approximately 3-4 weeks to respond.</p> <ul style="list-style-type: none"> • NDMC Directors collate study feasibility survey results and provides data to the PI and the StrokeNet Epidemiology Core within approximately 5 working days after survey closure. 	
<p>11. StrokeNet Epidemiology Core develops epidemiology assessment based on trial eligibility criteria and results of the study feasibility survey to inform the total number of trial sites needed.</p> <ul style="list-style-type: none"> • StrokeNet Epidemiology Core provides epidemiology assessment results to the PI and Working Group Chairs at least 5-7 business days prior to Working Group discussion (outlined in step 12). • StrokeNet Epidemiology Core will briefly present these results at subsequent Working Group and Executive Committee meetings (outlined in steps 12 and 13). 	
<p>12. PI meets with Working Group to discuss study feasibility survey, epidemiology assessment results and the range of suggested sites based on initial assumptions to determine the number of trial sites needed.</p> <ul style="list-style-type: none"> • Working Group Chairs will provide meeting summary and recommendations to PI within 5 working days. 	
<p>13. PI presents proposal to the StrokeNet Executive Committee to confirm the number of trial sites needed.</p> <ul style="list-style-type: none"> • NCC Administrator provides meeting minutes to PI within 7 working days. 	
<p>14. PI develops final budget with NCC Directors and NDMC PIs incorporating any changes suggested by Working Group or Executive Committee. If budget amount exceeds 10% of ESC approved amount, reapproval by ESC is required.</p>	
<p>15. PI sends near final specific aims and research plan to Working Group Chairs, NCC PIs and NDMC PIs. In addition, the PI sends the NCC and NDMC the near final budget. Suggested 6 weeks but no later than 4 weeks ahead of submission deadline. Failure to meet this deadline may result in the grant submission being moved to the next cycle. The NCC Administrator will send an email titled “NIH StrokeNet Deadlines” detailing this guidance.</p> <ul style="list-style-type: none"> • NCC and NDMC PIs will provide their biosketches, Letter of Support, Facilities and Resources, Statement of Work, Statement of Intent and Budget Justification documents. 	
<p>16. PI is responsible for providing the final budget numbers to the NINDS Program Scientist when ready to submit. NINDS must approve the submission and requires confirmation of the approved ESC budget to do so. Failure to notify NINDS may result in a grant being returned by CSR.</p>	
GRANT SUBMISSION	

Post Grant Submission:

- Submitted applications will be reviewed by NIH review Panel approximately six months after submission (actual date to be determined by NINDS). Grants receiving a highly meritorious score may be considered by Council for a funding decision within the Council cycle they were submitted. Approval of funding is determined by NINDS priority and availability of funds. Council makes a funding recommendation which then will be decided by the NINDS Director. Grants that are approved by NINDS for funding will be awarded no later than 3 council rounds from the council approval (i.e., about a year) but more typically within 3-4 months of the NINDS decision to fund. Note, a final decision is not official until the Notice of Award is issued by NINDS.
- If a grant is not approved for funding, the PI will receive a summary of the review addressing areas of concerns that reduced its priority to fund. Once the PI receives the summary statement, they are encouraged to discuss the review with the NINDS Program Scientist to consider resubmitting the application or next steps. The PI may, and is encouraged, to discuss the revised approach with the Working Group who can serve as a valuable resource to revise the proposal for resubmission.