CLINICAL RESEARCH APPLICATION Checklist

- ❑ Clinical Research Application (Below Fillable PDF)
- ❑ NIH formatted Biosketch for First investigator
- ❑ NIH formatted Biosketch for Second investigator
- ❑ NIH formatted Biosketch for Third investigator
- ❑ IRB approval status Letter (if Applicable)
- ❑ IRB approval status Informed Consent Form (if Applicable)
- ❑ Budget and budget justification
- ❑ Supplemental Materials (optional)
- ❑ Research Proposal (See Proposal Narrative)
- ❑ Data management and analysis plan including how you plan to transfer data from other sites
- ❑ Target sponsor, mechanism, and date for planned scaled-up, follow-on external funding application

Please attach and label files as listed above. Submit in one PDF to info@asnr.com.

CLINICAL RESEARCH APPLICATION

Project Title:_____

Project Narrative (Lay language, 1-3 sentences):

Abstract (300 Words):

Principal and Co-investigator(s):
Please list names and affiliation of the Principal and Co-Investigator(s) for the proposed research. Please attach a NIH formatted Biosketch for each investigator.

It is the responsibility of the Principal Investigator to ensure that all participating sites receive IRB/REB approval before engaging in any study related activities.

Name: _____
Please include a NIH formatted Biosketch for investigator in your final application packet

Title/Position: _____

Affiliation: _____

Name: _____
Please include a NIH formatted Biosketch for investigator in your final application packet

Title/Position: _____

Affiliation: _____

Name: _____

Please include a NIH formatted Biosketch for investigator in your final application packet

Title/Position: _____

Affiliation: _____

Is the Principal investigator a member of the ASNR?

- ❑ Yes
- ❑ No

The proposing Principal investigator must be a member of ASNR. If you wish to propose a study and are not a member, you can easily become a member.

Contact information for Principal Investigator

Phone Number: _____

Email: _____

IRB/REB approval status:

- ❑ Yes (attach approval letter and a copy of the Informed Consent Form.)
- ❑ Pending, when do you expect approval?

(if not yet approved, see note below pertaining to review process)_____

Study Population:

- ❑ Stroke
- ❑ TBI
- ❑ SCI
- ❑ Other: _____

Setting:

- ❑ Inpatient
- ❑ Out Patient
- ❑ Other: _____

Will you be recruiting research participants at your site?

- ❑ Yes
- ❑ No

How many sites do you anticipate involving in the study? _____

Have any sites confirmed interest as of now?

- ❑ Yes
- ❑ No

Have you previously worked with any of the sites/investigators before?

- ❑ Yes
- ❑ No

Would you be interested in contacting the ASNR membership to locate sites and collaborators?

- ❑ Yes
- ❑ No

Would you be available to present your proposal to interested ASNR members at the annual meeting to solicit interested sites for your proposal?

- ❑ Yes
- ❑ No

Anticipated study duration (Proposed research should be able to be completed in 2 years, include in your proposal how you determined study duration). Please explain how you determined the duration of the project:

Do you have data management and biostatistical support?

- ❑ Yes
- ❑ No

Briefly explain your data management and analysis plan, if applicable and include how you plan to transfer data from the recruitment sites to the administering site?

Provide a detailed budget and budget justification for how you plan to use the requested funding. Remember that these funds are to be used mainly for the costs of initiating a collaborative clinical research project.

Allowable expense categories include: travel between sites (e.g., car mileage, train); catering (excluding alcoholic beverages) for collaboration meetings; fees for specific services are acceptable, but salary costs are not, (e.g., 10 hours of work on a justifiable task is allowed); focus group meetings; Online meeting services (e.g., WebEx or Go-to-Meeting); conference call services etc.; training and start-up costs; and IRB costs for additional sites. See below for a full list of eligible expenses.

Non-allowable expense categories include: salary for PI or co-PI, salary for research assistants or students; excessive travel costs; alcoholic beverages.

Budget Justification must include a rationale for how the expense category is necessary to foster ground work and initiation of a collaboration for the proposed pilot study. Explain how the 5K funds will be used to develop your collaboration and/or research project and provide a timeline for achieving the goals of this award. A statement from the PI that she/he will review and approve all expenses according to ASNR guidelines should this seed grant be funded. (See Review Criteria F)

Note: If IRB/REB approval at the proposing site is pending, ASNR can only provide a conditional approval until this is obtained. An IRB/REB approved protocol at the proposing site is eligible for full consideration by ASNR and full funding if everything else meets criteria.

It is the responsibility of the Principal Investigator to assure that all participating sites receive IRB/REB approval before engaging in any study related activities.

If your proposal is selected for funding there will be some reporting responsibilities detailed at the time of notification. When the study is completed, a final report must be submitted within 6 months of completion.

If you have questions pertaining to appropriateness of your research, contact: Dr. Prue Plummer at prue@med.unc.edu. If you have questions pertaining to the submission process, contact ASNR staff support. In the subject line indicate: ASNR Clinical Trial Application Question

Eligible expenses with examples:

1. Travel

Economy airfare, or other ground transportation for planning meetings; for initial training of personnel at different sites

2. Planning Meeting expenses

Including catering and accommodation (no alcoholic beverages)

3. Communication between sites for planning

Teleconference charges; long distance charges

4. Biostatistical consultation

If you think you need biostatistical consultation for design, stats, power analysis etc. we encourage use of these funds for such purposes. There are too many underpowered studies that are of little value to clinical practice. Note: Costs for biostatistical support needed for project development are permissible, but investigator salary support is otherwise not an allowable cost.

5. Specific Training for standardized assessments and start-up expenses within reason and commensurate with a relatively simple protocol.

Charges for certification on assessments, (e.g., UPDRS; NIHSS)

6. Student Worker/Research Assistants

Help with specific and justifiable tasks specifically associated with start-up of collaboration (e.g., creation of standard operating procedure manuals; Case report forms for recording data; photocopying, printing); fees for services are acceptable but salary costs are not (e.g., 10 hrs of work on a specific task is allowed; 25% RA salary is not)

7. IRB/REB ethics application review fees for collaborating sites only

While the PI might have approval (and it is needed for the application), a new site might still need to obtain IRB approval.