Q: Is the letter of intent required from renewing sites and if so how early can it be sent?
A: **No**, it is not required.

Q: Do we check Yes or No for "Are Human Subjects Involved?"
A: **YES;** The NINDS Program Official will provide NINDS GMB the cIRB approval for an NIH StrokeNet study prior to award to reduce the administrative burden for sites.

Q: Are Enrollment tables needed?
A: **NA/NO on the form**.

Q: Do we need Biosketches for PI's at ALL of our sites?
A: **No.** Biosketches are only needed for senior staff and Key Personnel.

***REMINDER*:** "Career Enhancement Program" replaces "Training Program"

***REMINDER*:** The Maximum allowable **DIRECT COST** per year for a NIH StrokeNet RCC will be 200,000. This does not include F&A costs per NIH policy.

From the PAR:

Allowable:
- Partial support for the PD/PI(s) salary but ONLY for time spent on site organizational/administrative tasks;
- Salary support for full-time research coordinator or project manager;
- Support for administrative personnel or study assistants;
- Travel to meetings directly related to study activities (e.g., research base meetings, NINDS or Network-sponsored strategy sessions/workshops, local travel);
- Special personnel resources needed to support the recruitment and retention of eligible patients on clinical trials; and
- Stroke research career enhancement (with a minimum required allocated budget of $50,000 in direct costs per year for salary support).

NOT allowable:
- Costs of clinical care provided to patients (e.g., for patient care reimbursement, transportation costs);
- Tuition;
- Clinical and Data Coordinating Center costs; and
- Physician compensation (other than specified above for PD/PIs and for their network-related administrative activities.).

Q: Please clarify what was meant by "salary support for full time research coordinator".
A: Our expectation is that at least one coordinator would be supported a minimum of **50%;** He/she will have the responsibility of managing the RCC activities.

Q: Do we need to obtain letters of support from institutions or PIs for which we already have MTA/CIRB agreements as they are already part of the network?

A: It is ok to not collect LOS's for established sites. If you choose this route you still need to include your sites & names in the body of the application and include a statement so to why you are not including the LOI's. We can instruct the reviewers that this is acceptable. However, we suggest if this is not a significant burden, include the letters. This will indicate to reviewers that your sites remain engaged. Since this is an open competition, new applying RCC's will be required to include LOS.

OTHER- from Recovery Working Group about demonstrating ability to enroll in Recovery trials.

During the Telerehabilitation trial, it has become clear that the degree of administrative organization & trial readiness for acute stroke teams is very different from stroke rehabilitation teams. An RCC may have sites that are interested in performing stroke recovery/rehab trials, but some may not be properly situated.

RCCs may want to provide support for why they are prepared to enroll into recovery/rehab trials and what features make them ready. Possible features might be prior experience successfully enrolling into multisite trials; or presence of an inpatient rehabilitation facility (IRF), which indicates a large group of patients who are accessible for several weeks while receiving rehabilitation therapy; or presence of personnel who are dedicated to recovery/rehab research; or site-specific features related to successful performance in recovery/rehab trials with respect to enrollment, biomarker testing, etc.

Added 29-Aug-2017

Q: Can we attach Appendices to the submission? The tabular data requested takes up a lot of room. Can it be provided as an appendices?

A: The tabular data **is not allowed** to be attached as appendices.

Added 5-Sep-2017

Q: Do we need the PHS Inclusion Enrollment Report?

A: Yes, you can and should include the enrollment table (permissible because this is marked as a human subjects application). In the NETT renewals which NINDS tried to model for the SN renewals, there were two different strategies used, both which worked fine. One was to have one complete table for that NETT Hub site and another was to include enrollment tables for each trial done at that Hub site. To clarify, NETT was summarizing enrollment of their consortium of sites (both hub and spokes). NINDS would recommend whichever option best represents your RCC the best.

Added 12-Sep-2017

Q: Does the resources section have page limits?
ANS: No, it doesn't but applicants are urged to present available resources in a consolidated manner/tabulated form such that it will be easy for reviewers to absorb.

Q: Can we include Recruitment tables and geographic maps of catchment area in the Human Subjects' section.
A: No, it is not advisable. I looked at your original application (on paper) from 2013. Including that much information now with electronically submitted applications
most of these sections are automatically validated. On average this section is only about a couple of pages long. Several more pages in this section runs the risk of it being flagged by DRR.
For this type of a program, since the catchment area is also a resource, you might consider including a limited no of maps (or presenting the information another way, in the resources section.

Q: Can we include minority and women recruitment data in past trials in the women and minority inclusion plans?
A: YES within limits IF you present these sections as strategies you have used in the past to increase minority/women enrollment and the actual numbers are presented as resulted those efforts netted. Again, brevity would be important given how long these sections usually are.