To: Michael Linke, PhD

From: <Prime PIs>

Date: <Date>

RE: Request to Re-open <Trial Name> Enrollment Activities

Dear Dr. Linke,

The <Trial Name> trial suspended enrollment activities nationally on <date of closure> due to the COVID-19 pandemic and in accordance with the StrokeNet National Coordinating Center guidance. At this time, the <Trial Name> leadership team requests approval for re-opening enrollment for the trial. The purpose of this letter is to describe the plan for reactivating participating <Trial Name> sites considering the potential risk and benefit of the trial, minimization of exposure to COVID-19, resource utilization, and local conditions.

<Summarize trial specific procedures (either existing or newly amended) that help minimize participant and study staff COVID-19 exposure, transmission, and infection. Examples include but are not limited to: remote consent, remote study visits, in-person consent by study staff on service, study procedures required for enrollment performed as of standard of care.>

In preparation to restart enrollment activities in the setting of COVID-19, all StrokeNet Trials are adding a Case Report Form (CRF) that will be completed for all subjects to document COVID-19 testing status, and if clinically diagnosed, the severity of the outcome.

We have been monitoring the impact that COVID-19 has had on the status of research operations at each of our participating sites. Careful consideration will be given to re-activating sites that are able to demonstrate risk minimization and resource utilization according to their local governing bodies.

To summarize, the study-wide plan to reactivate enrollment is as follows.

- We will minimize participant and study staff COVID-19 exposure, transmission, and infection as detailed above in trial procedures. These procedures address:
    - Screening individuals for COVID-19 symptoms and exposure prior to study visits.
    - Potential transmission by asymptomatic infected individuals.
    - Any other study-specific precautions for research visits.
    - Remote study visit feasibility
- Site PIs will verify that study visits or procedures will not contribute to shortage of resources, such as essential clinical staff and Personal Protective Equipment (PPE) that are needed to take care of COVID-19 infected patients.
- Site PIs will verify that study procedures would not interfere with clinical procedures put in place to treat COVID-19 patients.

Once the Site PI indicates within WebDCU that there are no local restrictions, or the specific local conditions, to screening, enrollment, and randomization for <Trial Name>, the trial PI(s), working with the NCC and NDMC, will reactivate the site.

Thank you,

<Prime PI Signature>