**StrokeNet COVID-19 Guidance:**

The primary concern for StrokeNet is the safety of our patients or potential patients for our ongoing trials. The second concern is the safety of our own investigators and study team members. Finally, we also want to maintain, as much as possible, the integrity of the trials to potentially benefit patients and so that the data can be used to answer the questions that the trials intended. This latter point is critical for subjects in the trial and those with the specific problem in the future.

However, immediate safety issues take priority over any formal processes in ongoing trials. For example, while a current protocol may specify that a study visit needs to be in person, the FDA has guidance about the primary safety of study subjects:

From Mike Linke head of UC CIRB:

While the regulations require IRB approval before implementing any modifications to previously approved clinical research, they also state "...except those necessary to eliminate apparent immediate hazards to the clinical research volunteers”. This is consistent with Food and Drug Administration (FDA) regulations (21 CFR 56.104, 21 CFR 312.30(b), and 812.35(a)(2))". In our opinion, COVID 19 falls within this category. Thus, we would recommend the following:

1. Monitor and follow all CDC and local recommendations regarding good hygiene, avoidance of major gatherings (social distancing), travel, etc.
2. Adhere to your local institution recommendations regarding research in the COVID-19 environment including screening or enrollment into research trials (some institutions have suspended screening and enrollment temporarily, others have not). Again, potential risk to potential subjects and investigators, as well as potential benefit of the trial for the study patient, should be considered. If your institution has suspended screening and enrollment into research trials, please communicate this situation to the PIs and project managers of a given trial.
3. Maintain patient follow-up for those subjects already enrolled in trials but use telemedicine and telephone interactions whenever possible to obtain study data. This can happen now, even if the protocol has not been amended.
4. If not currently specified in the study protocol, all protocols should be amended to allow for remote patient visits for outcomes, study medications, etc. for situations like COVID-19. If protocol is amended, this will need to be communicated to CIRB.
5. For those studies that require “blinded outcome assessors”, an unblinded assessor could be used if a “blinded assessor” is not available. Similarly, outcome assessments done outside of the prescribed windows (because of illness) should still be completed. Further guidance from the CIRB about how these should be reported and the timing of reporting is forthcoming shortly.
6. For studies that require study medication, mailing of study medication is allowed (examples: Arcadia and ASPIRE). Patients who cannot receive mailed medications should be discussed with trial leadership for potential solutions including home or clinic visits.
7. Therapy trials are particularly challenging since in-clinic visits are required (TRANSPORT-2) or the therapy is provided in a home setting (I-ACQUIRE). In the case of infection of a patient, this may require suspension of therapy and restarting therapy only when the subject is no longer contagious. If a therapist becomes affected, the study may need to be halted until the therapist is no longer contagious. Each therapy trial should consider the various permutations and provide a plan for these situations.
8. The leadership from each ongoing trial should craft trial plans and specific questions and answers to COVID-19 issues unique to their trial (example – the management of equipment in SleepSmart (email already sent out to investigators), therapy issues as per #6 (see attached letter from I-ACQUIRE PIs to investigators), follow-up visits for all trials (example letter from Arcadia PIs), etc. The Arcadia letter includes great information regarding COVID-19 precautions for patients that should be distributed by the PIs of all trials to our trial subjects. These trial plans should also be placed on the StrokeNet Study webpage for reference.
9. We will not be having any in-person StrokeNet meetings until the situation has changed to minimal risk. This includes trial investigator meetings, larger StrokeNet meeting, etc.
10. Finally, any COVID-19 infections in a study patient or study investigator should be communicated to the trial PIs and also to the NCC and NDMC PIs and NINDS. We need to be monitoring, learning, and problem solving as this pandemic evolves. We do need to maintain HIPPA requirements in terms of sharing patient data outside of a trial personnel and leadership.

Joanna Vivalda has provided some links regarding the impact of COVID-19 for NIH applicants and recipients. These are relevant regarding ongoing trials but also trial applications.

[Coronavirus Disease 2019 (COVID-19): Information for NIH Applicants and Recipients](https://grants.nih.gov/grants/natural_disasters/corona-virus.htm)

Guide Notices:

[NOT-OD-20-082: NIH LATE APPLICATION POLICY Due to Public Health Emergency for United States for 2019 Novel Coronavirus (COVID-19)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-082.html)

[NOT-OD-20-083: General Frequently Asked Questions (FAQs) - Proposal Submission and Award Management Related to COVID-19](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-083.html)

[COVID-19 Flexibilities for Applicants and Recipients: FAQs](https://grants.nih.gov/faqs#/covid-19.htm)

[NOT-OD-20-086: Flexibilities Available to Applicants and Recipients of Federal Financial Assistance Affected by COVID-19](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-086.html)

[NIH Extramural Response to Natural Disasters and Other Emergencies](https://grants.nih.gov/grants/natural_disasters.htm)

In summary, our goal is to keep our patients and teams safe while completing these important trials. COVID-19 will not only affect us now but will change the way we do clinical research in the future. We will continue to communicate updates as the pandemic evolves. These will be posted on the StrokeNet website. Any ideas or creative solutions from our larger StrokeNet community are very welcome. And keep as safe and health as possible.

Yours truly,

The NCC, NDMC, and NINDS Leadership team