StrokeNet Memorandum for Local Site Context Review at Relying Institutions

The purpose of this memorandum is to provide guidance for Relying Institutions (RIs) responsible for conducting local review of National Institutes of Health (NIH) StrokeNet research. The NIH StrokeNet provides a single, or central, Institutional Review Board (CIRB) of record for all trials conducted within the network. This guidance is consistent with the NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research.[1]

Each Regional Coordinating Center, and its performance sites and satellite sites, have agreed to cede review of research as outlined in their site-specific Reliance Agreement and the NIH StrokeNet Funding Announcement-NS-23-010, and consistent with NIH,[1] Food and Drug Administration (FDA),[2] and NIH StrokeNet policies.[3]

The NIH StrokeNet CIRB responsibilities include initial protocol review, initial PI/site review, continuing review, review of all amendments, unanticipated problems, and noncompliance issues, and approval of all informed consent documents (ICDs) and processes for all multi-site protocols initiated within the network. The CIRB also can perform the determinations required by HIPAA regulations, namely waivers of authorization for use and disclosure of protected health information (PHI). However standalone HIPAA document determinations may instead fall to the RI when using the Advarra CIRB, if preferred by the RI, as standalone site-specific HIPAA documents do not require CIRB review. The RI responsibilities include review of site-specific and local context, including local laws, institutional policies, community considerations, and conflict of interest (COI) local review and management (see figure below).

Distinct Responsibilities

CIRB Requirements	Relying Institution Requirements
IRB Review Tasks • Initial protocol review • Initial PI/site review • Continuing review • Amendments, unanticipated events, noncompliance • COI study review and management • Approve informed consent documents and processes	**Site-Specific Context** • Local laws • Institutional policies • Local context • COI local review and management (prior to CIRB review for cost and time efficiency)
HIPAA Determinations of: • Authorizations for research • Requests for waivers of authorization	**Local Ancillary Review Requirements** • Nursing, Radiation, Bio Safety etc.
Local Context Review • Collect local information required for IRB review	**Other Compliance Areas** • Ongoing oversight of research conduct • COI

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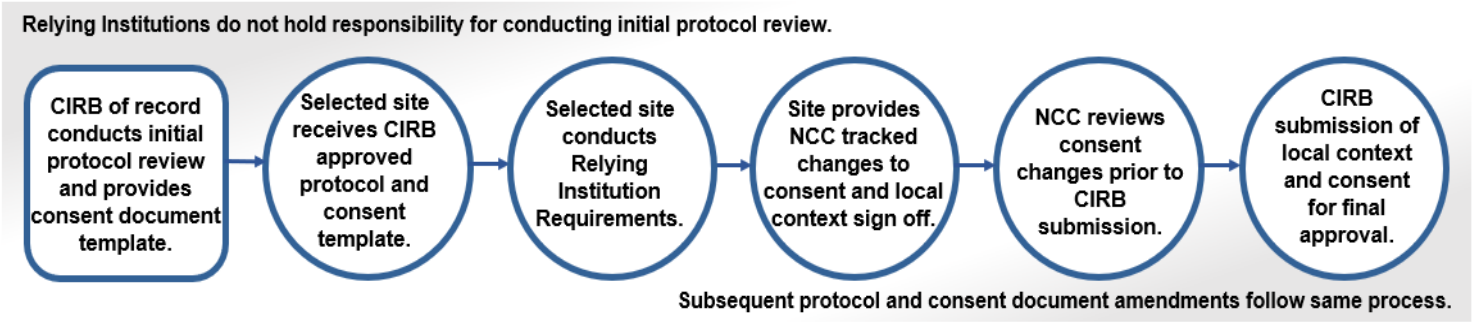
To allow the CIRB to review and approve site-specific information incorporated into study documents and verify that the RI has performed its responsibilities, **the initial Relying Institution Requirements must be performed prior to submitting to the reviewing CIRB for final approval.** RIs do not hold the responsibility for conducting initial protocol review or providing final approval for ICDs.

Also please note that the StrokeNet National Coordinating Center (NCC) ensures and verifies that the most recent site-specific CIRB-approved version of the ICD and HIPAA is available to sites and should be used immediately upon receipt. For sites utilizing the StrokeNet centrally managed electronic consent (eConsent), the ICD available on the REDCap platform is considered the most current version for local site use.[4]

StrokeNet has encountered significant delays in site approvals when local IRBs conduct a full regulatory review of studies already approved by the StrokeNet CIRB. Not only do these redundant reviews delay the start of research, but they also create confusion for local investigators and lead to more work for the CIRB to address concerns on studies that were fully vetted during the CIRB review process. The National Institute of Neurological Disorders and Stroke (NINDS) and the NCC strongly discourage local IRBs from doing a full regulatory review of studies approved by the CIRB. This duplicate review is inconsistent with the NIH and common rule requirement for single IRB review of multisite studies. The correct sequence of regulatory review events is outlined in the figure below.



For questions regarding these expectations, please reach out to the StrokeNet NCC leadership team. Failure to comply with this guidance and the applicable regulations may result in financial liability of the RI for additional unnecessary CIRB review costs, or loss of partnership with the NIH StrokeNet due to noncompliance with federal regulations.[2]

References:

1. Reminder of Guidance on Requirement for NIH Single Institutional Review Board (IRB) Plan
2. 45 Code of Federal Regulations Part 46, Food and Drug Administration (FDA) guidance
3. NIH StrokeNet SOP ADM 11
4. NIH StrokeNet SOP ADM 24

NIH StrokeNet
PREVENTION | TREATMENT | RECOVERY

Khatri, Pooja (khatrip)
Digitally signed by Khatri, Pooja (khatrip)
Date: 2023.11.29 14:19:14 -05'00'

Pooja Khatri, MD MS, NCC Contact MPI
khatrip@ucmail.uc.edu

DocuSigned by:
Joseph Broderick
902F552ED80940B...

Joseph Broderick, MD, NCC MPI
broderjp@ucmail.uc.edu

Lawrence S. Janis -S
Digitally signed by Lawrence S. Janis -S
Date: 2023.11.29 12:50:16 -05'00'

Scott Janis, PhD, NINDS Program Director

University of Cincinnati StrokeNet CIRB Representative

Lauri Carlile

Advarra CIRB Representative

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