Developing Good Clinical Practice SOPS for RCCs and Trial Performance Sites
• The StrokeNet Network NCC has identified 12 components of Good Clinical Practice (GCP).

• This framework will be used to assure compliance with established International GCP, DHHS and NIH principles, policies and procedures.

• Network-level GCP SOPs will be available on the NIH StrokeNet website.

• The cIRB will use the content from these documents as a resource for assessing local context information.
12 Components of GCP

1. Human Subjects Protection
2. Qualified Investigative Personnel/Sites
3. Informed Consent and Stroke Trials
4. Safety Reporting
5. Privacy and Confidentiality
6. Handling of Investigative Products
7. Maintaining Data Quality
8. Laboratory/Radiology Competence/Reliability
9. Site Performance Monitoring
10. Trial Recruitment
11. Per Subject Payment
12. Data Maintenance and Storage
RCC SOP documents must address:

- Specific State or Local Regulations for all of RCC’s and their performance sites
- Ancillary Reviews (radiation safety, biosafety, nursing, pharmacy, mechanical engineering etc...)
- Vulnerable Populations (minors, prisoners, pregnant women fetuses and neonates and cognitively impaired)
- Note: RCC will assess and manage compliance with local HSP SOPs for all performance sites.
RCC SOP documents must address:

- Notification of subjects’ primary physician concerning trial participation
- Training requirements for investigators and/or primary investigators
- Requirements for HSP training for all research staff
- Requirements/practices for Delegation of Authority to research staff
GCP #3  Informed Consent for Stroke Trials

RCC SOP documents must address:

- Local consent process requirements including recruitment and compensation practices - provide all institutional “verbatim” language
- Use of telemedicine in the consent process
- Emergent consent process
- Authorized signature for consent into a research trial
  - Use of Proxy consent, must indicate order of authority
- Special Populations - safeguards required for consenting adults with impaired decision-making or aphasia
- Vulnerable populations – describe local additional safeguards for non-English speaking, minors, prisoners, pregnant/fetus
RCC SOP documents must address:

- Identify institutional IRB expectations for reporting safety information for a protocol locally reviewed

- Identify institutional IRB expectations for reporting safety information for a protocol reviewed by the Network cIRB

- Identify process for how RCC will “assess and manage” compliance with cIRB Safety Reporting SOP at the satellite/CPS level
GCP #5 Maintaining Subject Privacy and Confidentiality

RCC SOP documents must address:

• Identify specific institutional practices for managing PHI collected for research

• Describe if HIPAA Authorization is typically a separate document or included in the Informed Consent Document

• Describe if there are State/local specific privacy laws regarding management of PHI collected for research
GCP #6 Handling of Investigational Products (IP)

RCC SOP documents must address:

- Identify local institutional practices and responsible individuals for the handling and management of investigational products

- Identify process for how RCC will “assess and manage” compliance with local handling Investigational Product SOP at the satellite/CPS level
RCC SOP documents must address:

- Identify local institutional practices/processes for obtaining source data from the EMR or paper worksheets for trial databases

- Identify process for how RCC will “assess and manage” compliance with local Data Quality SOP at the satellite/CPS level
GCP #8 Laboratory/Radiology Competence and Reliability

RCC SOP documents must address:

- Identify local institutional practices/processes to assure accurate laboratory and diagnostic data:
  - current laboratory certifying agencies
  - practices for quality control in POC testing
- Verify laboratory/research staff ITAT compliant standard practices for “send out” specimens
- Describe process for routine/final and Stat imaging reports and (responsible contacts) for obtaining “blinded” imaging data
- Provide institutional policy/practices for compliance with American College of Radiology Practice Guidelines (or similar standards) for using contrast and patient radiation exposure
RCC SOP documents must address:

• Provide the institutional policy/procedures for access to EMR records for research and monitoring purposes
• Provide the institutional process/policy (contact persons) for establishing:
  • site initiation and training visits
  • site source data verification monitoring visits
  • site network performance visits and audits
  • site study closeout
RCC SOP documents must:

- Describe local practice for subject screening requirements including approval of screening activities and approval of materials used for ‘advertisement’

- Identify process for how RCC will assure compliance with cIRB “approved” study materials and recruitment tools.

- Identify local participation in any registry or database tracking local stroke incidence/practices
RCC SOP documents must address:

- Describe policies for the payment of subject research related expenses

- Describe local policies and contacts for national coverage determination (by CMS standards) and other special billing requirements for patient care costs in cIRB approved research protocols

- Any agreements detailing personnel and/or patient care reimbursement agreements between the RCC and their performance sites must be included in the electronic essential document file
GCP #12  Regulatory and Clinical Data Maintenance and Data Storage

RCC SOP documents must address:

- The process for collection and maintaining trial specific regulatory documents - Trial Specific compliance checklist
- The process for internal and external review of trial specific regulatory documents
- The process for archiving trial specific original signed and electronic regulatory documents
Discussion

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If you prefer you can type your question(s) into the ‘Question and Answer’ pod