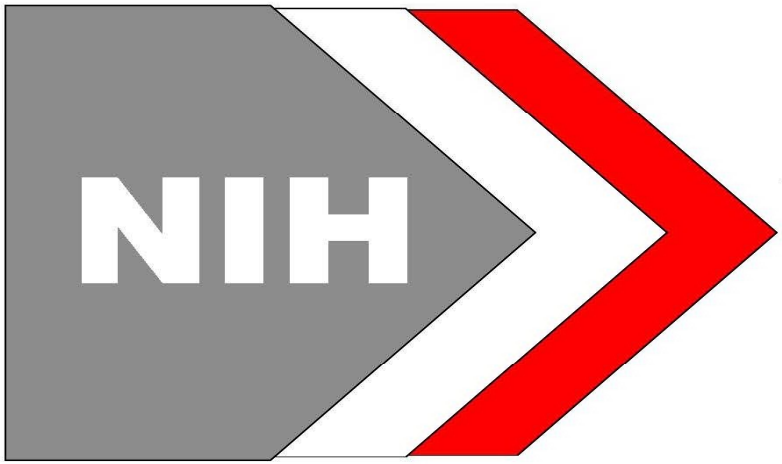
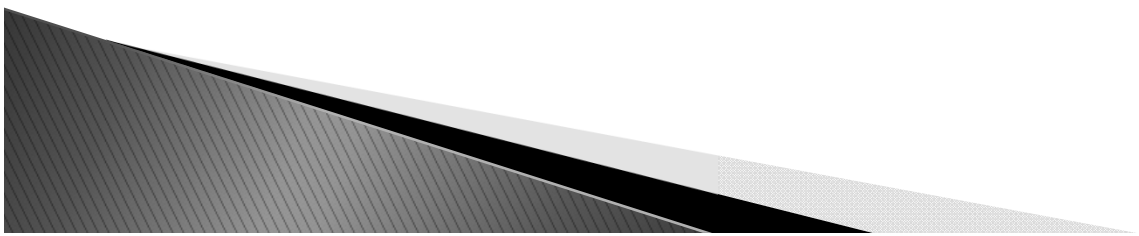


StrokeNet

Prevention Treatment Recovery

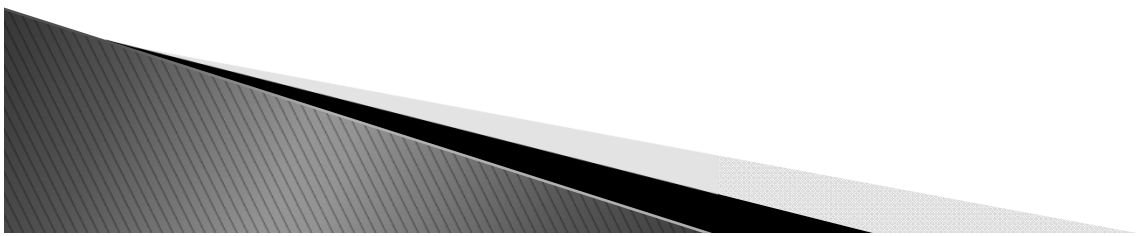
Developing Good Clinical Practice SOPS for RCCs and Trial Performance Sites

- 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



GCP #1 Human Subjects Protection

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.

GCP #2 Qualified Investigative Personnel and 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

GCP #4 Safety Reporting

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

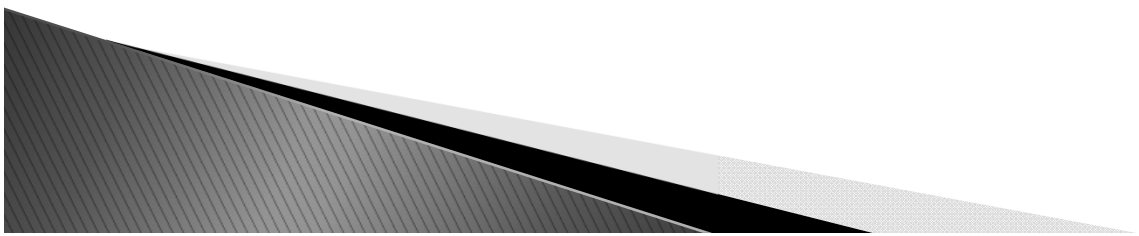
- Identify process for how RCC will “assess and manage” compliance with local handling Investigational Product SOP at the satellite/CPS level

GCP #7 Maintain Data Quality

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

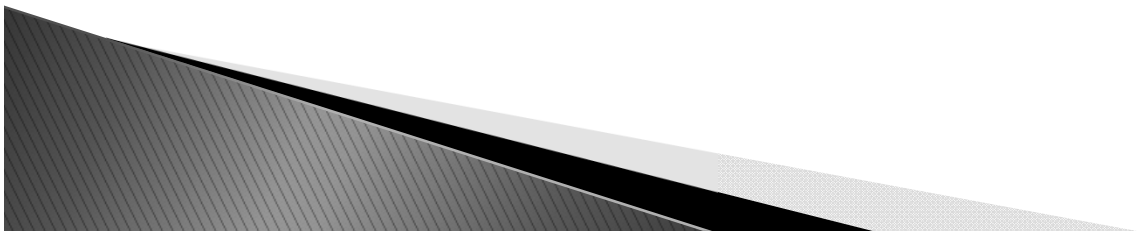
RCC SOP documents must address:

- 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

GCP #9 Site Performance Monitoring, Audits/Inspections

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



GCP #10 Trial Recruitment

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

GCP #11 Management of Per Subject Payments

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

Press *6 to mute or “un-mute” your phone

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