SOP Number: GCP 01
SOP NAME: Human Subject Protection
Effective Date: 4-Jan-2016 (rev 17-May-2023)

1. POLICY

The National Institutes of Health StrokeNet Network National Coordinating Center (NCC) and National Data Management Center (NDMC) will work together with each Regional Coordinating Center (RCC) and performance sites (PS) to ensure that all individuals involved in the design or conduct of NIH-funded or network affiliated human research receives training and certification in Human Subjects Protection (HSP).

2. DEFINITIONS AND ABBREVIATIONS

Abbreviations

HSP	Human Subjects Protection
NCC	National Coordinating Center at the University of Cincinnati
NDMC	National Data Management Center at the Medical University of South Carolina
NIH	National Institutes of Health
PS	Performance Site - clinical location that serves as an execution site for a clinical trial
RCC	Regional Coordinating Center
SS	Satellite Site

3. SCOPE

The NIH requires training and certification for all investigators and other key personnel involved in the design and/or conduct of NIH-funded human research. HSP training topics must include, but are not limited to, understanding risk, adequacy of protection against risks, potential benefits to subjects, including the importance of knowledge gained, data and safety monitoring, and the inclusion of women and minorities, and children with questionable capacity to consent.

4. PROCEDURES

A. The RCC is responsible for ensuring that all key personnel in an NIH StrokeNet clinical trial at the RCC, satellites sites (SS) and performance sites (PS) receive and satisfactorily complete HSP training.
   1. All StrokeNet researchers must provide certification of HSP training completion. Certification of training completion can be obtained in the following ways:
      a. Completing institutional specific programs and obtaining certification of completion (e.g., institutional access to the Collaborative Institutional Training Initiative (CITI) program's HSP course)
      b. Completing NIH Office of Extramural Research tutorial on "Protecting Human Research Participants" and obtaining certification of completion

2. Upon completion, HSP training certification must be uploaded into the Regulatory Document Module in WebDCU™.
3. If deemed a requirement for participation in a trial by the CIRB, all NIH StrokeNet researchers must provide certification of HIPAA training completion either as a part of the HSP training or separately as provided by the corresponding covered entity.

B. The NCC will monitor and approve regulatory documents for each project to ensure that all required HSP/HIPAA certifications are present and current.

5. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46 Federal Policy for the Protection of Human Subjects "Common Rule"
21 CFR Parts 50, 54, 56, 312 and 812 FDA policy and regulations as relevant to all clinical trials
ICH-E6 Good Clinical Practice: Consolidated Guidance

6. REFERENCES TO OTHER APPLICABLE SOPS

ADM 16 Network Process for Trial "Master" and "Site" Regulatory File Management
GCP 12 Regulatory and Clinical Data Maintenance and Data Storage

7. ATTACHMENTS AND REFERENCES

8. DOCUMENT HISTORY

Version	Description of Modification	Completion Date	Issue Date	Effective Date
1.0	Final	21-Dec-2015	21-Dec-2015	04-Jan-2016
2.0	Review with administrative changes	17-May-2023	31-May-2023	31-May-2023