SOP Number: GCP 08
SOP NAME: Laboratory/Radiology Competency and Reliability
Effective Date: 1-Aug-2016 (rev 29-Jun-2023)

1. POLICY

The purpose of this Standard Operating Procedure (SOP) is to provide guidelines for accurate laboratory and diagnostic imaging data acquisition and process and for the safe shipment of biological specimens during conduct of NIH StrokeNet clinical trials.

2. DEFINITIONS AND ABBREVIATIONS

CAP	College of American Pathologist
CIRB	Central Institutional Review Board
CLIA	Clinical Laboratory Improvement Amendments
CT	Computed Tomography
IATA	International Air Transport Association
MOP	Manual of Procedures
MRI	Magnetic Resonance Imaging
NINDS	National Institute of Neurological Disorders and Stroke
PHI	Protected Health Information
PS	Performance Sites
RCC	Regional Coordinating Centers
SS	Satellite Sites

3. SCOPE

This SOP has been developed to ensure compliance with federal regulations and Good Clinical Practice, as set forth in the ICH E6 Consolidated Guidance Manual (1996). The policies and procedures described in this SOP apply to the NIH StrokeNet Performance Sites (PS), the National Coordinating Center (NCC) and the National Data Management Center (NDMC) within the context of their oversight and advisory roles for the NIH StrokeNet Network, and to all investigators, staff, subcontractors, and other entities associated with the NIH StrokeNet who manage, oversee, and conduct research regulated by the FDA and/or applicable review committees.

4. PROCEDURES

NIH StrokeNet Regional Coordinating Centers (RCCs), Satellites (SS), and Performance Sites (PS) must ensure that accurate and reliable laboratory and imaging test information is obtained, collected and provided to the NDMC during the conduct of NIH StrokeNet clinical trials, if requested.

A. Clinical Laboratory – All clinical trial PSs are responsible for:
    1. Identifying clinical laboratory departments or personnel that will perform the study-

specific tests and the clinical tests required by each research study protocol.

2. Identifying personnel who will assure the correct protocol/Manual of Procedures (MOP) required sample processing, labeling and storage prior to shipping central laboratory samples or specimens.
    a. Lab personnel are required to monitor refrigerators or freezers and maintain adequate temperature logs for proper study specimen storage.
3. Ensuring their institution's clinical laboratories maintain current certification by the required agencies (Clinical Laboratory Improvement Amendments (CLIA), College of American Pathologist (CAP)).
4. Ensuring research personnel and/or laboratory staff involved in shipping specimens or biological samples are properly trained and certified in packing, labeling and shipping of dangerous good as required by International Air Transport Association (IATA) prior to shipping biological samples or specimens to a central laboratory.
5. Following the basic steps for shipping biological samples or specimens:
    a. Determining if the shipment is classified as an Infectious Substance or Dangerous Good.
    b. Determining proper packaging and labeling based on the above classification and specified study instructions.
    c. Completing all necessary documentation required for sample or specimen identification and confirmation of shipment.
    d. Assuring that all laboratory samples or test results are stripped of personal identifiers before submitting the information for central processing or review. PSs are also responsible for complying with the institutional regulations regarding confidentiality of the study laboratory test results.

B. Protocol Designated Central Laboratories – Any research samples processed in a "central" research laboratory will follow good clinical laboratory practices, institutional, state, and federal regulations. Any research laboratory being inspected that is found inadequate will be reported as required by the local requirements.

C. Radiology – All PSs are responsible for:
    1. Identifying all clinical or radiology departments that will perform protocol specific and other clinical imaging tests required by the trial.
    2. Communicating with radiology personnel to ensure that the identified radiology departments maintain current required certifications.
    3. Retaining copies of appropriate radiology certifications (including but not limited to College of Radiology Practice Guidelines) for imaging data used in a research trial (both local and outside the institution) and make them available to monitoring or auditing agencies upon request.
    4. Assuring all imaging data submitted for analysis is appropriately and completely stripped of protected health information (PHI) before it leaves the treatment facility for central analysis. Each PS must also comply with their institutional regulations regarding confidentiality and protection of PHI when acquiring imaging study data or imaging test

results.

5. Assuring proper management and performance of contrast-enhanced imaging tests when required by the study protocol. This includes compliance with institutional policies for appropriate and adequate history for each study participant, screening and preparing the participant appropriately for the examination, having equipment available to treat reactions, and ensuring that expertise sufficient to treat even the most severe reactions is readily available.
6. Identifying appropriate radiology staff to facilitate the acquisition of complete and correct study imaging data (as defined by the trial protocol/ MOP) from radiology servers or other resources.
7. Identifying the institutional or trial personnel who will upload (or ship) the collected trial images for central review to the trial identified imaging repository.
8. Ensuring participating facilities have and adhere to policies and procedures to optimize the relationship between minimal radiation dose and adequate image quality as outlined in the ACR-ASNR Practice Guideline for the Performance of Computed Tomography (CT) of the Brain.
   http://www.acr.org/~/media/ACR/Documents/PGTS/guidelines/CT_Brain.pdf

   http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/ucm115329.htm
9. Confirming participating facilities have specific policies and procedures related to Magnetic Resonance Imaging (MRI) safety in place. Guidelines should be available that deal with potential hazards associated with the MRI examination of the patient. Screening forms must also be provided to detect those patients who may be at risk for adverse events associated with the MRI examination. Equipment monitoring should be performed in accordance with the ACR Technical Standard for Diagnostic Medical Physics Performance Monitoring of MRI Equipment.
   http://www.acr.org/~/media/6D14C0958CD143DA9C3BFD8E545F06E6.pdf

5. APPLICABLE REGULATIONS AND GUIDELINES

IATA Dangerous Goods Regulations (DGR) 49 CFR §171-180

http://www.gpo.gov/fdsys/pkg/CFR-2012-title49-vol2/xml/CFR-2012-title49-vol2- subtitleB-chapI-subchapC.xml

21 CFR 361.1; RADIOACTIVE DRUGS FOR CERTAIN RESEARCH USES

ACR Manual on Contrast Media. Version 10.1, 2015. ACR Committee on Drugs and Contrast Media

http://www.acr.org/~/media/ACR/Documents/PDF/QualitySafety/Resources/Contrast%

20Manual/2 015_Contrast_Media.pdf

AAHRPP Element I.7

6. REFERENCES TO OTHER APPLICABLE SOPs

7. ATTACHMENTS AND REFERENCES

Expert Panel on MR Safety:, Kanal, E., Barkovich, A. J., Bell, C., Borgstede, J. P., Bradley, W. G., Froelich, J. W., Gimbel, J. R., Gosbee, J. W., Kuhni-Kaminski, E., Larson, P. A., Lester, J. W., Nyenhuis, J., Schaefer, D. J., Sebek, E. A., Weinreb, J., Wilkoff, B. L., Woods, T. O., Lucey, L. and Hernandez, D. (2013), ACR guidance document on MR safe practices: 2013. J. Magn. Reson. Imaging, 37: 501–530. doi: 10.1002/jmri.24011

8. DOCUMENT HISTORY

Version	Description of Modification	Completion Date	Issue Date	Effective Date
0.1	Draft 2	14-Jul-2016		
1.0	Final	29-Jul-2016	1-Aug-2016	1-Aug-2016
2.0	Administrative review	30-Jun-2023	5-Jul-23	5-Jul-23