SOP Number: ADM 12
SOP NAME: Central Institutional Review Board (CIRB) Reporting
Effective Date: 3-Jun-2014

1. POLICY

The purpose of this Standard Operating Procedure (SOP) is to define the process for required reporting by sites engaged in National Institutes of Health (NIH) NIH StrokeNet (StrokeNet) affiliated research to the Central IRB (CIRB). Sponsors and sites engaged in StrokeNet research are required to report unanticipated problems (including adverse events), injuries to subjects, protocol deviations/violations, changes initiated without CIRB approval to eliminate apparent immediate hazards to subject/s, complaints, non-compliance and cessation of research activities (collectively "required reports") that are determined, discovered, or learned by them in connection with the conduct of a StrokeNet human research study. This could also include any reports external to the trial site, including, but not limited to, Data Safety Monitoring Board (DSMB) reports and MedWatch reports. This SOP provides a description of these types of required reports and defines the standards, time frames, and procedures for these reports.

2. ABBREVIATIONS AND DEFINITIONS

Abbreviations:

AE	Adverse Event
CIRB	Central Institutional Review Board
CFR	Code of Federal Regulations
CIRB	Central Institutional Review Board
CPS	Clinical Performance Site
DHHS	Department of Health and Human Services
NDMC	National Data Management Center
DSMB	Data Safety Monitoring Board
DSMP	Data Safety Monitoring Plan
FCOI	Financial Conflict of Interest
HIPAA	Health Insurance Portability and Accountability Act
IO	Institutional Official
IRB	Institutional Review Board

NCC	National Coordinating Center
NIH	National Institutes of Health
NINDS	National Institute of Neurological Disorders and Stroke
OHRP	Office for Human Research Protection
PAC	Protocol Awarded Centers Non-Network Site
PIPrincipal Investigator	
PPI	Parent Protocol Principal Investigator
RA	Reliance Agreement
RCC	Regional Coordinating Center
SOP	Standard Operating Procedure
UADE	Unanticipated Adverse Device Effect
UPIRSO	Unanticipated Problems Involving Risks to Subjects or Others

Definitions:

Central Institutional Review Board (CIRB): A single Institutional review Board (IRB) that performs the required human subjects review under the Federal Policy for the Protection of Human Subjects and other applicable regulations as deemed necessary for a multicenter trial.

Clinical Performance Sites (CPS): A site: 1) where patients are enrolled for a StrokeNet trial, and or treated as part of a StrokeNet trial and/or data is entered into the NDMC WebDCU for a StrokeNet trial; and/or 2) that can be a legally affiliated entity of a RCC or Satellite (educational institution hospital or clinic, healthcare system sites, educational institution sites under an affiliation agreement to act on their behalf for federal research funding); and/or 3) that has made a business decision to not directly accept research funding and the regulatory audit requirements that doing so entails.

Data Safety Monitoring Plan (DSMP)-A trial specific plan designed to provide sufficient oversight and monitoring to assure participant safety and validity of safety data. The monitoring plan should specify: type of monitoring of safety data, responsibility of safety staff and monitoring body, procedure for data review and reporting for adverse events, contents and format of the safety reports.

Institution: An entity engaged in StrokeNet research and that has contractually agreed to rely upon the review of the StrokeNet CIRB.

Investigator: A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

National Coordinating Center (NCC): An institution designed and directly funded by NINDS/NIH to provide leadership for the NIH StrokeNet on a national level.

National Data Management Center (NDMC): An institution designed and directly funded by NINDS/NIH to oversee all aspects of data collection and management as well as full statistical support for StrokeNet research protocols.

Parent Protocol Principal Investigator: The individual who is responsible for the development of the protocol and the coordination of the conduct of the clinical investigation at multiple sites, including required regulatory reporting to the CIRB. If this person is the IND or IDE holder, this individual is also responsible for all applicable FDA regulatory requirements, which includes all Sponsor-Investigator responsibilities.

Protocol Awarded Centers Non-Network Site: A site that is engaged in research operationally supported by StrokeNet, but that is not a StrokeNet Regional Coordinating Center, a satellite or a clinical performance site (CPS).

Regional Coordinating Center (RCC): An institution designed and directly funded by the NINDS/NIH to provide leadership for the NIH StrokeNet on a regional level.

Related: Associated or having a timely relationship with the study agent or procedures; a reasonable possibility exists that an outcome may have been caused or influenced by the study in question, although an alternative cause/influence may also be present. *Reasonable possibility* means there is a >50% likelihood that the event is related to the research procedures. For reporting purposes, the term *probable relationship* is synonymous with *reasonable possibility*. See Attachment B.

Required Report(s): A report that must be submitted to the CIRB during the course of a trial. These reports include: unanticipated problems (including adverse events), injuries to subjects, protocol deviations/violations, changes initiated without CIRB approval to eliminate apparent immediate hazards to subject/s, complaints, non-compliance and cessation of research activities. Required reports also can include reports generated by an entity other than a trial site, such as, safety monitoring reports from a Sponsor or NDMC or a Data Safety Monitoring Board (DSMB) report.

Unexpected: An incident, experience, or outcome is considered unexpected when the nature, severity or frequency of the incident, experience or outcome is not described in the protocol-related documents, such as the CIRB-approved research protocol and informed consent document or the characteristics of the study population being studied.

Unrelated: Unassociated or without a timely relationship to the study agent or procedures; evidence exists that an outcome is definitely related to a cause other than the event in question

Satellite Site (SS): An institution named by an RCC as a branch of its regional network that is not legally affiliated with the RCC.

Site: An institution engaged in StrokeNet research. This could be a site at an RCC, a SS, a CPS, or a PAC.

Sponsor: An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical trial.

Working Days: Synonymous with business days; unit used in determining the maximum number of days to report an event.

3. SCOPE

The policies and procedures in this SOP apply to parties involved with StrokeNet research, including the National Coordinating Center (NCC), the CIRB, the National Data Management Center (NDMC) and all StrokeNet Regional Coordinating Centers (RCC), Satellite Sites (SS) and Clinical Performance Sites (CPS) engaged in StrokeNet research. For purposes of this SOP, a site is any institution that is engaged in research, that is, either a site at a RCC, an SS, a CPS or a PAC. If a PAC is involved in a study, the Sponsor of the study must work with the NDMC and the CIRB to establish procedures for meeting these reporting requirements. If a trial does not use the NDMC, but uses the StrokeNet CIRB, the Sponsor of the study must work with the CIRB to establish procedures for meeting these reporting requirements.

4. PROCEDURES

A. Reportable Event Overview

<u>Unanticipated Problems Involving Risks to Subjects or Others (UPIRSO)</u>

According to the Federal Policy for the Protection of Human Subjects ("The Common Rule"), an institution engaged in human subjects research conducted or supported by the Department of Health and Human Services (DHHS), must have policies for reporting unanticipated problems to an Institutional Review Board (IRB) and the DHHS, Office for Human Research Protection (OHRP). The term unanticipated problems involving risks to subjects or others (UPIRSO) is found (but not defined) in the HHS regulations at 45 CFR 46.103(b)(5), and is found in the Food and Drug Administration regulations at 21 CFR 56.108(b)(1). OHRP guidance defines a UPIRSO

as "any incident, experience, or outcome that [is] … unexpected … related or possibly related … and that suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized."

Adverse Events

A small subset of adverse events are UPIRSO. The FDA defines adverse event as "any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related". OHRP defines adverse events as "any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research."

Adverse events that are identified as serious, unexpected, and related or possibly related to participation in research will meet the criteria for an UPIRSO. Other adverse events that are unexpected and related or possibly related to participation in the research, but *not* serious, could also be unanticipated problems if they suggest that the research places subjects or others at a greater risk of physical or psychological harm than was previously known or recognized.

If an investigator or sponsor decides an incident, experience, or outcome meets the criteria for a UPIRSO, an IRB must confirm this classification and determine whether it is significant enough to warrant consideration of changes in the: research protocol, informed consent process, informed consent documentation, and/or corrective actions to protect the safety, welfare, or rights of subjects or others. As OHRP grants IRBs the authority to suspend or terminate approval of research that, among other things, has been associated with unexpected serious harm to subjects, it is critical that the CIRB be promptly informed of UPIRSO, so it may act accordingly.

Unanticipated adverse device effect (UADE)

The investigational device exemption (IDE) regulations define an UADE as "any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects" (21 CFR 812.3(s)).

Consistent with FDA requirements, investigators for StrokeNet device studies must submit a report of a UADE to the Sponsor, NDMC and the reviewing IRB as soon as possible, but in no event later than 10 working days after the investigator first learns of the event. The Sponsor, or Sponsor's designee, must immediately conduct an evaluation of a UADE and must report the results of the evaluation to FDA, the CIRB, and participating investigators within 10 working days after the sponsor first

receives notice of the effect (§§ 812.46(b), 812.150(b)(1)). The CIRB then will review the UPIRSO as summarized below per University of Cincinnati IRB Procedure # 320: http://researchcompliance.uc.edu/HSR/IRB/Policies_and_Procedures.aspx The processing of UADEs is efficiently managed by and through the NDMC both for investigator reporting to the Sponsor and CIRB and from the Sponsor to the CIRB.

B. Division of Responsibilities

StrokeNet CIRB and the Parent Protocol Principal Investigator (PPI)

The PPI retains responsibility for reporting to the CIRB; however, the NDMC and the DSMB support this reporting requirement to the CIRB, as noted below. The PPI also remains responsible for all investigator duties stipulated under the *NINDS Guidelines for Data and Safety Monitoring in Clinical Trials*, last updated August 8, 2013.

StrokeNet CIRB and the Child Study Site Principal Investigator (CSS PI)

The Child Study Site Principal Investigator is responsible for reporting to the CIRB as detailed in this SOP, including Attachment A.

StrokeNet CIRB and the NDMC

The NDMC is responsible for collecting trial data, including reports of adverse events for StrokeNet sponsored research. As such, the NDMC is able to identify those adverse events that meet the criteria for a UPIRSO, either through the adverse event collection or unanticipated problem form. The NDMC should report those incidents, experiences or outcomes to the reporting investigator and the CIRB after the Sponsor, or Sponsor designee, has appropriately reviewed the event and made a determination that the events meet the criteria for an UPIRSO. The NDMC should report UPIRSOs to the CIRB as soon as possible, but in no event later than 10 working days after the investigator became aware of the event. Upon submission, the CIRB will review the UPIRSO as summarized below per University of Cincinnati IRB Procedure # 320: *Review of Reportable Events.*

StrokeNet CIRB and DSMB

The DSMB shall meet as stipulated in the trial specific DSMP. After each meeting of the StrokeNet DSMB, the DSMB must draft a brief summary report or letter to be made available to the CIRB and each investigator as described in the DSMP. The CIRB must also have an opportunity to review the DSMB procedures. The DSMB procedures should be consistent with the DSMP for any given trial.

The DSMB should use the report:

- to document that a review of data and outcomes across all centers took place on a given date;
- to summarize the DSMB members' review of the adverse events reported from all participating (such a summary could be a brief statement that there have been no unanticipated problems (i.e., adverse events have occurred at the expected

frequency and level of severity as documented in the research protocol, the informed consent document, and Investigator's Brochure (if applicable)); and

- to inform study investigators of the DSMB members' conclusions with respect to progress or need for modification of the protocol.

C. Required Reporting

Using the NDMC Form

Required reporting may be submitted through the NDMC as indicated on the CIRB Reporting Table (Attachment A). The site Principal Investigator, or designee, will submit the form to the NDMC by completing the form online in the NDMC's WebDCU™ website.

The original report to the NDMC must be completed within the timeframe specified in Attachment A. The AE or Other form is then reviewed and submitted to the CIRB by the CIRB Liaison within the timeframe specified in Attachment A.

Not Using NDMC Form

For required reporting for which there is no NDMC form, the responsible party, as designated in Attachment A, must submit to the CIRB Liaison within the time period specified in Attachment A. Such reporting may include safety monitoring reports from a Sponsor or a DSMB report. In turn, the CIRB Liaison is responsible for submitting these reports to the CIRB.

D. Submission of Other Events not Indicated as Required Reporting

The CIRB liaison will accept other reports when the investigator is unsure whether the event should be reported. The CIRB will review such reports to determine whether the event meets the threshold UPIRSO or falls under any other required reporting category.

If it is determined that an event falls under an existing category, the CIRB Liaison will inform the reporting party of such requirement within five (5) days, and the event will be handled accordingly. In the event that the CIRB Liaison can forward the received information as is to the CIRB, this will be done within five (5) days of the receipt of the information from the reporting party.

E. CIRB Review Overview

Under StrokeNet, the CIRB is responsible for reviewing required reports that they receive from the StrokeNet CIRB Liaison, which can include UPIRSO, protocol noncompliance issues, subject injuries, subject complaints, as well as protocol violations and deviations. The full list of reports can be found in Attachment A to this SOP. When reviewing any of the required reports, the CIRB is responsible for making the determination as to whether the report 1) constitutes UPIRSO or 2) rises to the level of serious or continuing noncompliance with applicable laws and regulations or the requirements and/or determinations of the CIRB.

Based on its review, the CIRB must take appropriate responsive action, which may include submitting a report to regulatory agencies and/or suspension or termination of CIRB approval of the research. Any required reporting to regulatory agencies or oversight authorities, including OHRP, will be coordinated based on a process of discussion and consensus with the reporting site and its institutional officials. These discussions will include working together to determine the responsible party for reporting, including reporting any UPIRSO to OHRP. Per OHRP guidance, any required reporting to regulatory agencies or oversight authorities must take place within one (1) month from receipt of the UPIRSO report. In the case of suspension or termination of CIRB approval, the CIRB will notify NCC leadership, NINDS staff and site officials, including the PI, and appropriate Institutional Officials, within one (1) business day.

After determining the course of action, the CIRB must then inform the appropriate site(s) of the findings, determinations, actions taken, and any modifications or remedial action required by the CIRB in response to such report(s). In certain cases, such as when an adverse event is determined to be a UPIRSO, the CIRB may determine that information contained in a report could impact either subject safety or the conduct of the trial at all sites. In this instance, the CIRB will inform all site PIs engaged in the trial.

5. APPLICABLE REGULATIONS

45 CFR 46
21 CFR 50
21 CFR 56
ICH E6

6. REFERENCES TO OTHER APPLICABLE SOPs and Guidance Documents

Guidance for Clinical Investigators, Sponsors and IRBs Adverse Event Reporting to IRBs Improving Human Subject Protection, DHHS, FDA, January 2009

Guidance on Unanticipated Problems and Adverse Events, DHHS, OHRP, January 2007
University of Cincinnati Institutional Policy II.02: *Reporting to the IRB: Unanticipated Problems Involving Risk to Participants or Others, Adverse Events, and Other Problems*

University of Cincinnati Institutional Policy VII.02: *Reporting of Unanticipated Problems, Non-Compliance, Suspensions and Termination to the Appropriate Institutional Officials, Departments and Agencies*

University of Cincinnati IRB Procedure # 320: *Review of Reportable Events*

NINDS Guidelines for Data and Safety Monitoring in Clinical Trials, last updated August 8, 2013.

7. ATTACHMENTS AND REFERENCES

Attachment A: CIRB Reporting Table
Attachment B: Relationship Definitions
Attachment C. Recommended DSMB Report Format Template

8. LINKS:

http://researchcompliance.uc.edu/HSR/IRB/Policies_and_Procedures.aspx
http://www.ninds.nih.gov/research/clinical_research/policies/data_safety_monitoring.htm

9. DOCUMENT HISTORY

Document History

Version	Description of Modifications	Completion Date	Issue Date	Effective Date
1.0	Final	3-Jun-2014	3-Jun-2014	3-Jun-2014

TABLE A – CIRB Reporting Table

24-HOUR TABLE --- Site Responsibilities To Report Through WebDCU Within 24 HOURS (CIRB Liaison must report to CIRB within 9 DAYS)	
Unless otherwise noted, responsible parties from the clinical trial sites should use the general procedure outlined above when submitting the below report types. ± Unless otherwise noted, reporting timelines are stated in terms of working days. Unless otherwise noted, times are calculated from the time the trial site PI becomes aware of the event or problem.	
Report Type	**Adverse Event (AE)**
Description	AEs that meet the definition of a UPIRSO, as described above.
Reporting Method	WebDCU™ AE Form
Report Type	**Unanticipated Adverse Device Effect (UADE)**
Description	UADE that m meet the definition of a UPIRSO, as described above.
Reporting Method	WebDCU™ AE Form
Report Type	**Significant Protocol Deviation**
Description	Any deviation from the CIRB-approved research that has the potential to negatively impact: 1) subject safety, 2) affects subject's willingness to participate in the study, or 3) alters the integrity of study data or related analyses.
Reporting Method	WebDCU™ Unanticipated Problem Form

5 DAY TABLE --- Site Responsibilities To Report Through WebDCU Within 5 DAYS (CIRB Liaison must report to CIRB within 5 DAYS)	
Unless otherwise noted, responsible parties from the clinical trial sites should use the general procedure outlined above when submitting the below report types. [±] Unless otherwise noted, reporting timelines are stated in terms of working days. Unless otherwise noted, times are calculated from the time the trial site PI becomes aware of the event or problem.	
Report Type	**Serious Noncompliance**
Description	1) any failure to comply with: a) any applicable laws or regulations **or** b) the requirements or determinations of the CIRB **that** 2) Negatively impacts the rights and welfare of subjects or compromises the integrity of the study data.
Reporting Method	WebDCU™ Unanticipated Problem Form
Report Type	**Continuing Noncompliance**
Description	Continuing noncompliance means any noncompliance that occurs repeatedly after appropriate remedial education or corrective action has been instituted.
Reporting Method	WebDCU™ Unanticipated Problem Form
Report Type	**Major Complaint**
Description	A complaint that alleges that human participants are being put at increased risk compared with risk in consent form.
Reporting Method	WebDCU™ Unanticipated Problem Form
Report Type	**Major Subject Noncompliance**
Description	Any subject non-compliance from the CIRB-approved research that has the potential to negatively impact subject safety, affects subject's willingness to participate in the study, or alters the integrity of study data or related analyses.
Reporting Method	WebDCU™ Unanticipated Problem Form
Report Type	**Minor Unapproved Protocol Deviation**
Description	Any deviation from the CIRB-approved research that is not a significant protocol deviation (as defined above).
Reporting Method	Periodic report from WebDCU™

5 DAY TABLE (continued) -- Site Responsibilities To Report Through WebDCU™ Within 5 DAYS (CIRB Liaison must report to CIRB within 5 DAYS)	
Unless otherwise noted, responsible parties from the clinical trial sites should use the general procedure outlined above when submitting the below report types. [±] Unless otherwise noted, reporting timelines are stated in terms of working days. Unless otherwise noted, times are calculated from the time the trial site PI becomes aware of the event or problem.	
Report Type	**Unanticipated Event or Problem**
Description	Unanticipated problem involving risks to subjects or others means any incident, experience, information, outcome, or other problem that is unexpected given the research procedures and that indicates that the research places subjects at a greater risk of physical, psychological, economic, legal, or social harm than was previously known or recognized. Unanticipated problems include, but are not limited to: ▪ An event that may require a change to the protocol and/or informed consent ▪ Breach of confidentiality, e.g. loss of study data or compromised computer system ▪ Incarceration of a participant in a protocol not approved to enroll prisoners ▪ Unapproved change to protocol made to eliminate an apparent immediate hazard to a research participant
Reporting Method	WebDCU™ Unanticipated Problem Form

Site Responsibilities Outside of Reporting Through WebDCU	
Unless otherwise noted, responsible parties from the clinical trial sites should use the general procedure outlined above when submitting the below report types. [±] Unless otherwise noted, reporting timelines are stated in terms of working days. Unless otherwise noted, times are calculated from the time the trial site PI becomes aware of the event or problem.	
Report Type	**Cessation of Research**
Description	See Unanticipated Problems if cessation is for safety problems. If this is not for a safety problem, cessation of research may be submitted as an administrative amendment. See below for Site Administrative Changes.
Reporting Method	WebDCU™ Unanticipated Problem Form **or** Administrative Amendment
Report Type	**Site Administrative Changes**
Description	This includes changes in PI, staff, address of the research site, change in contact information for the research site.
Reporting Method	Within 20 days of change or cessation, site should submit Administrative Amendment.
Report Type	**Monitoring/ Audit Findings/ Enforcement Action**
Description	Any adverse findings issued to, or enforcement action taken against, the PI, e.g., FDA Form 483 or Warning Letter, change in licensure or credentialing, OHRP determination letters, other administrative actions.
Reporting Method	Within 5 days, site should submit audit report or enforcement action to CIRB Liaison.
Report Type	**Any other problem that affects risk to subject or others**
Description	The PI may report any other problem that affects the risk to subject or others, including those that might impact the Investigator Brochure, informed consent or protocol, and the IRB will address the report accordingly.
Reporting Method	Within 5 days, the site should contact CIRB Liaison for further instruction on best way to submit.

PPI Responsibilities Outside of Reporting Through WebDCU	
Unless otherwise noted, responsible parties from the clinical trial sites should use the general procedure outlined above when submitting the below report types. [±] Unless otherwise noted, reporting timelines are stated in terms of working days. Unless otherwise noted, times are calculated from the time the Sponsor becomes aware of the event or problem.	
Report Type	**Change in FDA labeling or marketing approval based on safety concerns**
Description	Changes or enforcement action from the FDA
Reporting Method	Within 5 days, PPI should submit label or information indicating recall or withdrawal to CIRB Liaison.
Report Type	**News information indicating an unexpected change in risks or potential benefits (e.g., literature/scientific reports)**
Description	Based on a PPI's obligation to stay current on safety information affecting article under study, information falling into this category must be reported as noted.
Reporting Method	Within 5 days, Sponsor should submit the report or article, including source, to CIRB Liaison.
Report Type	**Safety Monitoring Report**
Description	Any NDMC or PPI analysis that describes a safety problem
Reporting Method	Within 5 days, PPI should submit the report, including source, to CIRB Liaison.

Attachment B: Adverse Event Relationship Definitions

Probably (must have 3)

- Has a reasonable temporal relationship to intervention
- Could not readily have been produced by the subject's clinical state or have been due to environmental or other interventions
- Follows a known pattern of response to intervention
- Disappears or decreases with cessation of intervention

Definitely (must have all 4)

- Has a reasonable temporal relationship to intervention
- Could not readily have been produced by the subject's clinical state or have been due to environmental or other interventions
- Follows a known pattern of response to intervention
- Disappears or decreases with cessation of intervention and recurs with re-exposure

Attachment C

RECOMMENDATION FORMAT

MEMORANDUM

Date: XXXXXX

From: NINDS DSMB Liaison

To: NAME, Principal Investigator

Re: DSMB Review of (NAME OF TRIAL)

The DSMB is an independent monitoring committee that has been appointed by the National Institute of Neurological Disorders and Stroke (NINDS) to oversee the conduct of the (NAME OF TRIAL). Meetings are held approximately twice a year to review the performance, safety and efficacy of the trial. All of the members of the DSMB are experts in one or more aspects of the subject matter of this trial.

On DATE there was a meeting held (LOCATION or by teleconference). Those attending:

DSMB Members:
NAME, (DSMB chair)
Name
Name

Investigators:
Name *(PI)*
Name
Name

NINDS staff:
Name (role)
Name (role)

The following items were discussed: (indicate protocol version number if modifications discussed, include date through date to clarify what data were reviewed)

- List general topics

The DSMB found, with NINDS concurrence, that the study was safe and ethical to continue.... (if not, continue with explanation)

It is our intention that this memo will assure the investigators and the study patients that this trial is being closely monitored for both safety and efficacy. Please note, that as PI you are responsible for all local IRB reporting. If you have any questions or comments about the NINDS DSMB, please contact me.

cc: NINDS OCR Director
NINDS Scientific PD
NINDS Admin PD

NIH StrokeNet
PREVENTION | TREATMENT | RECOVERY

NIH StrokeNet Network

Standard Operating Procedure (SOP)

Central Institutional Review Board (CIRB) Reporting

Version 1

ADM #12

Originators: NIH StrokeNet NCC Personnel

Date Reviewed and Approved by:

MD
Joseph P. Broderick, MD (StrokeNet NCC Principal Investigator)

6/3/14
Yuko Palesch PhD (StrokeNet NDMC Principle Investigator)

3 Jun 2014
NINDS/NIH Program Representative

Michael Linke, Ph.D., C.I.P. StrokeNet cIRB Chairman

23-May-2014
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