NIH StrokeNet Network
Standard Operating Procedure

SOP Number: GCP 10
SOP NAME: Trial Recruitment
Effective Date: 19-Jul-2016 (rev 13-Feb-2023)

1. Policy

The purpose of this SOP is to describe the general process of recruiting and enrolling subjects into NIH StrokeNet research studies.

2. Definitions and Abbreviations

CIRB	Central Investigational Review Board
CPS	Clinical Performance Site
EFIC	Exception from Informed Consent
FDA	Federal Drug Administration
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
HSR	Human Subjects Research
PI	Performance Site Principal Investigator
PPI	Protocol Principal Investigator
PHI	Personal Health Information
GCP	Good Clinical Research Practice
WebDCU™	Web-based Clinical Trial Management System

3. Scope

The policies and procedures described in this SOP apply to parties involved with NIH StrokeNet research. Study personnel will use this SOP as a guide to meet study enrollment goals while fulfilling ethical responsibilities for protecting the rights and welfare of participants. Sites are expected to comply with their own institutional guidelines if procedures conflict, however, all recruitment strategies must be approved by the CIRB.

4. Procedures

A. Recruitment strategies

1. Participants can be recruited from a variety of sources including, but are not limited to, individual research teams (PI and coordinator), self-referrals via web sites and advertisements, primary caregivers, individual teams and central resources, volunteer registries, and subcontractors at outside recruiting agencies. Clinicians can be notified about research studies by letter or by word of mouth.
2. Many researchers maintain a database of patients or former research participants

from which they identify potential participants for new research. If potential participants are identified through the researcher's database, researchers must follow local requirements for contacting and recruiting subjects.

3. Researchers who get referrals from physician colleagues may not contact these referrals directly unless patients have agreed to be contacted. The physician colleagues of the researcher may also inform their patients of the research and encourage their patients to contact the researcher.
4. Researchers may identify potential participants for research from hospital medical records by getting an approved waiver of authorization from the CIRB and the Institutional Privacy Board, if locally required. Cold calling is not an approved recruitment technique. The research study should be introduced to the potential research subject by an individual who, by virtue of his/her position, would normally have access to the potential subject's confidential information.
5. Financial or other incentives provided to research staff by sponsors based on numbers of participants recruiting or enrolled are strictly prohibited.

B. Recruitment Materials
   1. Materials directed to patients or the general public with the intent of recruiting them to participate in clinical research must be submitted to the CIRB for review and approval. These may include but are not limited to announcements, advertisements, flyers, phone scripts for screening, oral scripts for consenting participants, newspaper ads, videos, radio and television announcements, bulletin board tear-offs, internet or social media postings, and posters.
   2. Information about specific HSR studies may be posted on publicly available websites.
      a. The following study-specific basic descriptive information may be posted without CIRB review.
         1. Study title
         2. Purpose of the study
         3. Protocol summary
         4. Basic eligibility criteria
         5. Study site location(s)
         6. How to contact the study site for further information
   3. Information exceeding such basic descriptive information includes, but is not limited to, descriptions of risks and potential benefits, or solicitation of identifiable information. Information that exceeds the listed basic descriptive information must be approved by the CIRB before it may be posted.
   4. Clinical trial listing services that do not need CIRB approval include, but are not limited to, the National Institutes of Health (NIH) ClinicalTrials.gov website, the NIH National Cancer Institute's cancer clinical trials listing (Physician Data Query [PDQ]), and the government-sponsored AIDS Clinical Trials Information Service (ACTIS).
   5. In sponsored research, the sponsor must also approve all recruitment materials.
   6. Advertisements may include but are not limited to:
      a. A statement that the study involves research
      b. A brief description of the disorder that the study is investigating

c. Eligibility criteria (in summary form)
d. A truthful description of potential benefits, if any, to the subject from study participation
e. The name of the institution conducting the study
f. The name and phone number of person to be contacted for further information
g. Advertisements may not include:
1. Any direct or implied claim that the purpose of the research is to treat the condition or that the study medication is safe or effective
2. Any expressed or implied claim that the research will improve the subject's medical condition
3. Expressed or implied statement that the research is FDA-approved
4. Use of the term "new" unless modified, i.e., new research medication, or new investigational medication

7. If potential participants who respond to advertisements will be queried to determine whether they meet inclusion/exclusion criteria, the telephone script used by researchers must also be reviewed and approved by the CIRB. Any questions about criteria should be referred to the Protocol Principal Investigator (PPI). All such contacts/discussions must be documented.
   a. The recruitment process conducted must not be coercive or misleading. Subjects should be provided with the opportunity to volunteer in an environment that is free of coercion, and those persons considered vulnerable should have additional protections in this process.
8. In addition to submitting recruitment materials to the CIRB, the PI must describe in the CIRB submission, the way in which the materials will be used and any other methods that will be used to recruit participants to the study.

C. Enrollment Procedures

1. The PPI or designee will ensure that all study team members are trained in the study protocol specifics, recruitment requirements, good clinical practice, and human subjects' protection.
2. Recruitment rates should be regularly evaluated during the recruitment period, with reassessment of the strategy when recruitment targets are not being met. When there is competitive enrollment, recruitment must be continually reassessed to manage screening of participants.
3. The CPS will keep records of screen failure an enrollment in WebDCU™. The CPS will enter the screening and enrollment data based on the trial specific WebDCU™ Data Collection Guidelines' instructions. The PPI, project manager and site monitors will have access to the CPS entries. The CPS will keep local paper or electronic screening log, but all screen failures must be entered into WebDCU™ within 30 days of screening.
4. Subjects screened from records or in person using a CIRB waiver of informed consent for whom PHI is collected and retained for later contact need to be documented on a local site paper screening list. All lists containing PHI must be stored in a GCP confidential manner. All PHI collected should be destroyed once it is determined the

subject no longer meets eligibility criteria.

5. At the screening visit, the potential participant must give informed consent prior to any screening procedures, unless the trial has an approved partial HIPAA waiver for screening, or the trial is determined to be except from informed consent (EFIC). Signed informed consent forms from subjects who terminated their participation in the study during the screening process should be retained. Local screening logs will clearly indicate consented but not randomized subjects. The CIRB will require documentation of those subjects at the time of the trials continuing review by the CIRB.

D. At randomization, the participant is assigned a Subject ID. This Subject ID should be entered in the local screening and enrollment log. The enrollment log can serve as the coded subject list, which must be archived at the end of the study. Early Termination due to Subject Requested Withdrawal

1. Subjects who have consented to participate in a trial but later request to withdraw consent after "treatment" has been begun can and should be encouraged to complete subject follow-up visits. If the subject refuses he will be considered lost to follow-up. All lost to follow-up subjects are reported to the CIRB at the time of continuing review.

5. Applicable Regulations and Guidelines

21 CFR 312.50	General Responsibilities of Sponsors
ICH E6	The Principles of ICH GCP

6. References to Other Applicable SOPs

University of Cincinnati Human Research Protection Program Policy (II.04) *Reviewing Recruitment Materials in Human Subjects Research.*
University of Cincinnati Human Research Protection Program Institutional Review Board Procedure Number: 106 Participant Outreach
University of Iowa IRB Expectations for a Successful Research Recruitment Portfolio, http://hso.research.uiowa.edu/iii-cold-calling
Advarra IRB Handbook v05_Sept2021

7. Attachments and References

Kost, et al. Accrual and Recruitment Practices at Clinical and Translational Science Award (CTSA) Institutions: A Call for Expectations, Expertise, and Evaluation. *Acad Med, 2014, Aug; 89(8):1180-1189.*

Screening Enrollment Log

University of Cincinnati Human Research Protection Program (HRPP) Guidance on Recruitment

8. Document History

Version	Description of Modification	Completion Date	Issue Date	Effective Date
0.1	Draft	21-Jun-2016		
0.2	Draft	29-Jun-2016		
1.0	Final	19-Jul-2016	19-Jul-2016	20-Jul-2016
2.0	General updates and review to ensure Advarra recruitment matches UC IRB	13-Feb-2023	17-Feb-2023	17-Feb-2023