



National Institute of
Neurological Disorders
and Stroke

NINDS IS A COMPONENT OF THE NATIONAL INSTITUTES OF HEALTH

ARCHIVING MATERIALS FORM AND CHECKLIST

Please record below what data and related information are available and will be sent to the National Institute of Neurological Disorders and Stroke (NINDS), part of the National Institutes of Health (NIH).

1. IF THE DATA AND RELATED INFORMATION WERE DEVELOPED WITH NIH FUNDING, PLEASE INDICATE THE FOLLOWING:

Grant Title:

Study Acronym/ Short Name:

Grant Number:

Principal Investigator (PI):

Institution:

Clinicaltrials.gov NCT (if not applicable, write "N/A"): NCT

If this study was conducted as part of a network, please indicate what network:

- | | |
|-------------|-------------|
| ▪ NETT | ▪ SIREN |
| ▪ NeuroNEXT | ▪ EPPIC-Net |
| ▪ StrokeNet | ▪ Other: |

Disease area:

- | | |
|---------------------------------|----------------------------|
| ▪ Amyotrophic Lateral Sclerosis | ▪ Parkinson's Disease |
| ▪ Epilepsy | ▪ Spinal Cord Injury |
| ▪ Migraine | ▪ Stroke |
| ▪ Multiple Sclerosis | ▪ Traumatic Brain injury |
| ▪ Myasthenia Gravis | ▪ Other (please indicate): |

Research type (please select the most appropriate):

- | | |
|-----------------|-----------------|
| ▪ Phase I | ▪ Phase III |
| ▪ Phase II | ▪ Phase IV |
| ▪ Phase II/ III | ▪ Epidemiologic |

Population:

- Adult
- Pediatric
- Adult and Pediatric

Research location(s):

- Single center
- Multicenter
- International (please indicate the country/countries):

2. IT IS ASSUMED THAT DATA AND RELATED INFORMATION WILL BE SHARED BY NINDS WITH OTHER RESEARCHERS. IF THE INFORMED CONSENT FORM INCLUDES ANY RESTRICTIONS ON FUTURE USE OF THE DATA AND RELATED INFORMATION, PLEASE PROVIDE THE LANGUAGE. IF ADDITIONAL PAGES ARE NEEDED, PLEASE ATTACH THEM TO THIS FORM.

3. IN THE FUTURE, NINDS MAY HAVE QUESTIONS OR WANT TO DISCUSS A REQUEST RELATED TO THE ITEMS LISTED BELOW. PLEASE INDICATE TWO (2) POTENTIAL CONTACTS FOR FOLLOW UP BY NINDS, INCLUDING NAME, PHONE NUMBER, EMAIL, AND AFFILIATION:

CONTACT 1

NAME:

ROLE IN THE STUDY (E.G. PI, BIOSTATISTICIAN, ETC.):

INSTITUTION:

E-MAIL:

PHONE NUMBER:

CONTACT 2

NAME:

ROLE IN THE STUDY (E.G. PI, BIOSTATISTICIAN, ETC.):

INSTITUTION:

E-MAIL:

PHONE NUMBER:

For more information on the current NINDS Archived Clinical Research Datasets, go to:

<https://www.ninds.nih.gov/Current-Research/Research-Funded-NINDS/Clinical-Research/Archived-Clinical-Research-Datasets>

4. WERE NINDS COMMON DATA ELEMENTS (CDEs) USED IN THIS STUDY?

Yes

No

5. DOCUMENTS REQUIRED WITH YOUR SUBMISSION:

File	Attached	Name of the File/ Comments*
Study Dataset		
Data Dictionary		
Most current IRB- approved Informed Consent form (boilerplate)		
Annotated CRFs		
Other Datasets (e.g. Ancillary Studies)**		
Manual of Operations and Procedures (MOP)		
Most current Study Protocol and summary of changes from version#1 to the most current		
Title and citation to the study's primary outcome publication and PMID***		
Statistical Analysis Plan (SAP) and summary of changes from version#1 to the most current		
Other (please indicate in the comments)		

* Please paste the name of the file you are submitting. If a file is not included, please explain the reason and an estimate of when it can be expected, if applicable.

** Please complete a separate form for Ancillary Studies

*** Please provide the citation. If additional pages are needed, please attach them to this form.

6. DATA TRANSFER FORMAT

- SAS
- CSV
- Excel
- Other (please indicate):

7. OTHER DATA COLLECTED

If the study collected imaging and biosamples funded by NIH, please indicate below their location.

Imaging data:

- Yes
- No

If Yes, please indicate:

Name of Repository:

Location (physical address or hyperlink):

Point of contact (name):

Point of Contact e-mail:

Biosamples:

- Yes
- No

If Yes, please indicate:

Name of Repository:

Location (physical address or hyperlink):

Point of contact (name):

Point of Contact e-mail:

8. SIGNATURES

The signatures below indicate agreement that the datasets and related information may be placed within NINDS's archived clinical research datasets for distribution to requesting researchers after approval by NINDS. Archiving data and information with NINDS for future distribution does not negate any ownership rights of the generating institution.

Printed name of authorized signatory

Date

Signature of authorized signatory

Printed name of Depositing Scientist

Date

Signature of Depositing Scientist

COMPLETED FORM SHOULD BE SENT TO:

Carolina Mendoza Puccini, MD

Carolina.mendoza-Puccini@nih.gov

And

CRLiaison@ninds.nih.gov

Note: Please label this electronic document with the short name of the study, Grant Number, PI Last name and date submitted. e.g.: HEAL_Smith_U01NS055999_07-02-2019