



Trial Data and Related Materials Archival Checklist

Submit a completed form to archive trial data in the NINDS Clinical Trial Repository

The repository is for Neurological Disorders and Stroke (NINDS) funded data, images, samples (and ancillary repository location information).

Submit the completed form to: Carolina.mendoza-Puccini@nih.gov AND CRLiaison@ninds.nih.gov AND the Program Officer assigned to your grant.

DO NOT SUBMIT DATA/METADATA until you are indicated to do so. Upload instructions will be provided once this form is reviewed by NINDS.

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

1. NIH-NINDS FUNDED TRIAL DATA INFORMATION:

Principal Investigator(s) (PI) Name (contact PI):

If a Data Coordinating Center is submitting the data, indicate the DCC PI's Name:

DCC Grant Number:

Trial Name:

Trial Acronym/ Short Name:

Grant Number:

Grant Title:

Institution:

Clinicaltrials.gov registration number: NCT

(CHECK ALL THAT APPLY)

Network affiliation (if applicable):

- | | |
|------------------------------------|------------------------------------|
| <input type="checkbox"/> NETT | <input type="checkbox"/> SIREN |
| <input type="checkbox"/> NeuroNEXT | <input type="checkbox"/> EPPIC NET |
| <input type="checkbox"/> StrokeNet | <input type="checkbox"/> OTHER: |

Primary Disease Focus:

- | | |
|--------------------------------------------------------|-------------------------------------------------|
| <input type="checkbox"/> Amyotrophic Lateral Sclerosis | <input type="checkbox"/> Myasthenia Gravis |
| <input type="checkbox"/> Epilepsy | <input type="checkbox"/> Parkinson's Disease |
| <input type="checkbox"/> Epidemiologic | <input type="checkbox"/> Spinal Cord Injury |
| <input type="checkbox"/> Genetic | <input type="checkbox"/> Stroke |
| <input type="checkbox"/> Migraine | <input type="checkbox"/> Traumatic Brain injury |
| <input type="checkbox"/> Multiple Sclerosis | <input type="checkbox"/> Other not listed: |

Research Type Listed on The Grant:

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

Population:

- Adult
- Pediatric
- Adult and Pediatric
- High Risk / At Risk / Protected population
- Rare or Orphan disease

Research Location(s):

- Multicenter
- International (Provide the country name(s):
- Single Center

2. REQUIRED DOCUMENTS

Required Files for submission to the repository	Check box of submitting materials	Comments Rationale for not submitting file. If submitting late, provide estimated submission date.	Name of the File Include file name, Short Study Name, Grant #, study short name date (e.g. CRFs_Annotated_NS12345_GROW_08222023)
Case Report Forms (Please indicate if Annotated or Non-Annotated)	<input type="checkbox"/> <input type="checkbox"/>		
Consent Form (Last IRB approved version) Adult Pediatric Other (Identify)	<input type="checkbox"/> - <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		
Data Dictionary	<input type="checkbox"/>		
Dataset(s)	<input type="checkbox"/>	Number of datasets:	
Data Handling Guidelines	<input type="checkbox"/>		
Limited Access Dataset*	<input type="checkbox"/>	Number of datasets: Description of Limitations	
Manual of Operations/ Procedures (MOO/MOP)	<input type="checkbox"/>		
Primary Outcome Publication (Title and Citation Link) and PMID**	<input type="checkbox"/>		
Protocol- INCLUDE a Summary of Change document listing all the changes to the original IRB approved document	<input type="checkbox"/>		
Statistical Analysis Plan (SAP)- INCLUDE	<input type="checkbox"/>		

a summary of change list listing the changes from version 1.0.			
Final Efficacy and Safety Report(s)	<input type="checkbox"/>		
Other Materials (List the Document Titles)	<input type="checkbox"/>		
<i>If NIH funded the collection samples provide the requested details below.</i>			
Biorepository or Ancillary File location-	<input type="checkbox"/>	Specify: Repository Physical Location/Address Contact Name Contact Email	
Other data collected and stored, but not listed above-	<input type="checkbox"/>	Specify: Repository Physical Location/Address Contact Name Contact Email	

* Per the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) Privacy Rule; a Limited Access Dataset can be used for research purposes, public health, or health care operations [for further information, please refer to 45 C.F.R. § 164.514 (e)]. Direct participant personal identifiers (e.g., name, addresses, social security number, place of birth, city of birth, contact data) should not be included. Verbatim responses stored as text data (e.g., specified in "Other" category) should be deleted or edited such that no identifiers are included.

** Attach additional pages if there is more than one citation.

3. DATA TRANSFER FORMAT (CHECK ALL THAT APPLY)

- SAS
- Excel
- CSV
- PDF
- Identify Other:

4. IT IS ASSUMED DEPOSITED DATA AND RELATED INFORMATION ARE ARCHIVED INDEFINITELY WITH NINDS.

IF THE PROTOCOL/CONSENT FORM OR NOTICE OF AWARD SPECIFY AN ARCHIVAL DURATION OTHER THAN INDEFINITELY, PROVIDE THE LANGUAGE BELOW.

5. NINDS STAFF OR THE DATA REQUESTING PERSONS MAY HAVE QUESTIONS ABOUT OR WANT TO DISCUSS THE ARCHIVED TRIAL DATA. FOR THIS REASON, SUPPLY TWO (2) CONTACTS. COMPLETE THE INFORMATION BELOW.

CONTACT 1

NAME:

(BIostatistician, Coordinator, Data Manager, Etc.):

E-MAIL:

TELEPHONE NUMBER:

CONTACT 2

NAME:

TITLE/ROLE (BIostatistician, Coordinator, Manager, Etc.):

E-MAIL:

TELEPHONE NUMBER:

6. 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.

X _____
Authorized Signatory Name

Date

X _____
PI/Depositing Researcher

Date

For Internal Use:

Date Archival Checklist was received:

Name of NINDS Staff receiving the Checklist:

Date the Checklist is forwarded to the contractor:

Date Contractor receives complete submission:

Date data/metadata are available: