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	DOCUMENT TITLE: SOP for Investigators Contributing Data	SPONSOR: National Institute of Mental Health (NIMH)	PROJECT NAME and / or PROTOCOL NUMBER: NeuroHIV Data Ecosystem	VERSION DATE: 30JUL2026
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SOP for Investigators Contributing Data

For

The National NeuroHIV Tissue Consortium

NeuroHIV Data Ecosystem

Sponsored by:

National Institute of Mental Health (NIMH)

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1. PURPOSE/SCOPE

The purpose of this SOP is to outline instructions and guidance pertinent to investigators submitting experimental result data to the repository.

2. SUBMISSION GUIDELINES

This section provides instructions on how to access the neuroHIV Data Ecosystem site and submit data.

2.1. Accessing the NeuroHIV Data Ecosystem Site to Submit Data

Creating a Profile

The profile creation process involves the following steps:

1. Go to neurohivdata.com.
2. Select the **Create account** button in the top-right corner. The **Create new account** tab appears.
3. Complete the registration form.
4. Select the **Create new account** button.

Accessing the NeuroHIV Data Ecosystem Site to Submit Research Data

To begin the process to submit research data to the NeuroHIV Data Ecosystem, users must do the following:

1. Create a user account on the NeuroHIV Data Ecosystem website
2. Sign a Data Submission Agreement (DSA)
3. Complete the Responsible Conduct of Research (RCR) Certification.

Reviewing and Acknowledging the Data Submission Agreement (DSA)

As required for access to submit data to the NeuroHIV Data Ecosystem, users must complete and submit a Data Submission Agreement before access can be granted to this area of the site. The Data Submission Agreement requires a wet signature; therefore, users must download, print, sign, scan, and upload the completed document.

To complete this process:

1. Go to neurohivdata.com and log in.
2. Select **My account** to access the user profile.
3. Select **Edit**. The **Edit** tab appears.
4. Scroll to the *User Agreements* panel.
5. Select **Data Submission Agreement**. The Data Submission Agreement appears.
6. Download, print, read, sign, scan, and upload the Data Submission Agreement.

Once submitted, the NeuroHIV Data Ecosystem administrator will review the agreement to ensure all requirements are met before granting access.

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Completing the Responsible Conduct of Research (RCR) Certification and Certification Submission

In addition to submitting the Data Submission Agreement, users must also complete and upload a Responsible Conduct of Research (RCR) certification to obtain access to the restricted tier of the NeuroHIV Data Ecosystem. This certification may be obtained from any accredited organization or institution offering RCR training; however, we recommend completing the course through the CITI Program, which requires a CITI account.

To complete the RCR certification and upload the completed certificate:

1. Go to neurohivdata.com and log in.
2. Select **My account** to access the user profile.
3. Select **Edit**. The **Edit** tab appears.
4. Scroll to the *User Agreements* panel.
5. Select **Responsible Conduct of Research (RCR) Certification**. The **Responsible Conduct of Research (RCR)** certification page on about.citiprogram.org appears.
6. On the citiprogram.org site, do the following:
 - a. Log in.
 - b. Complete the Responsible Conduct of Research certification course.
 - c. Download your certificate.
7. Return to the *User Agreements* panel on the neurohivdata.com site and upload the certificate.

Once submitted, the NeuroHIV Data Ecosystem administrator will review the certification and its corresponding effective and expiry dates before granting access.

Once these tasks are completed, a NeuroHIV Data Ecosystem administrator will do the following:

1. Review the account details, user agreement(s), and Responsible Conduct of Research (RCR) certification
2. Confirm the documentation is completed as required
3. Approve the access request
4. Create an Okta account with a link to access the NeuroHIV Data Ecosystem site and reporting module.

Following account creation, signing of the DSA, and completion of the RCR Certification, the user will receive an email from Okta (noreply@okta.com) with instructions to activate their Emmes Okta account. This email will include the activation link (which will be valid for seven days), the Okta username, and a link to the Emmes Okta sign-in page (emmes.okta.com).

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Activating an Okta account

To activate the Okta account:

1. Open the email and select **Activate Account**. A web browser opens, displaying the **Create your Emmes Account** page.
2. Complete the form.
3. After completing the initial form, another browser page will open with options to set up additional security methods.
4. Select **Continue** to finalize the setup. The **Okta Dashboard** page appears, displaying applications to which the user has access.

Access to submit research data is granted only after successful account creation and authorization. Users must complete all required documentation and receive approval before data can be submitted.

Logging in to the NeuroHIV Data Ecosystem Site Through Okta

After successfully creating an account, obtaining all required approvals, and completing Okta account activation; the user should follow the steps below to login to the NeuroHIV Data Ecosystem site via Okta and gain access to the website and data submission module through single sign-on:

1. Go to neurohivdata.com.
2. Select **Log in**. The *login* page appears, displaying the *Log in* tab.
3. Select **Login to NeuroHIV Data Ecosystem using Okta**. The **Emmes.okta.com Sign In** page appears.
4. Enter the email address used to create the account and the password created during Okta account creation.
5. Select **Sign In**. The **NeuroHIV Data Ecosystem** page appears.

Submitting Data

Once the user has been granted the appropriate permissions to access the ecosystem, they are now authorized to submit their research data to the ecosystem. This section provides a step-by-step guide for preparing, pre-validating, and uploading data to ensure it meets all required standards.

To begin the data submission process:

1. Go to neurohivdata.com and log in through Okta.
2. Select **Submit Data**. The **Data Submission** page appears.
3. Complete the form. See the table below for information on some fields.
4. Upload required files.
 - a. Select **Choose File**. Your device's file explorer appears.
 - b. Navigate to and select the file you want to upload.
 - c. Select **Open**.
5. Select **Submit**.

To support consistent, high-quality data submission and integration, the NeuroHIV Data Ecosystem uses a pre-defined data submission format, required for all data submissions. Full curation will be applied to data that is submitted for integration into the ecosystem platform. Review and subsequent enhancement of metadata and

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documentation will be completed by domain experts. It is anticipated that some uncurated data may be submitted to the data ecosystem. These submissions will also undergo full curation before integration into the data ecosystem.

Once data is uploaded, the NeuroHIV Data Ecosystem team will review the data before beginning the process of integrating it into the ecosystem.

- If clarification or more information is needed, the submitter is contacted by email.
- When data is integrated, the submitter will receive a confirmation email.

Field Descriptions

The following metadata fields and associated files are required for all dataset submissions and must be provided to ensure completeness and compliance with submission standards.

Field	Description
Dataset title	Title of the dataset being submitted. This should be concise, descriptive, and reflective of the dataset's content.
Source of Funding	The organization or entity that provided financial support for the research associated with the dataset.
GrantID Number	Identifier associated with the funding grant that supported the research. This should match the official grant documentation.
Is there a supervising PI for the study data being submitted?	Indicates whether a Principal Investigator (PI) is overseeing the study and responsible for the data submission.
Supervising PI Attestation	A file containing the supervising PI's formal attestation authorizing the submission of the research data. This field is required only if the supervising PI question is answered "Yes."
Manifest File	A file that provides a detailed description of the data being submitted, including file names, formats, and relevant metadata.
Research Data	The primary file(s) containing the research data to be deposited into the repository. These should be formatted and organized according to submission guidelines.
PMCID	Publication identifier identifying the publication associated with submitted data. Note that PMCID is required to optimize access to associated manuscripts. If you are submitting unpublished data, enter "UNPUBLISHED" in this field.
Additional Supporting Documentation	This field is required only when submitting unpublished data. If submitting unpublished data, upload a detailed written methods section to enable data curation efforts.

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3. METADATA REQUIREMENTS

This section outlines clear definitions of metadata that must accompany each dataset to be submitted to the NeuroHIV Data Ecosystem.

3.1. Manifest Metadata

Variable	Description	Codelist
FileName	Name of file containing data	<i>Free text</i>
DataCategory	Broad qualitative description of what kind of measurement(s) the dataset contains	Molecular, Cellular and Immunologic, Neurology, Clinical
DataSubCategory	Specific description of what kind of measurement(s) the dataset contains	Genomics Sequencing, Genomics Epigenomics, Transcriptomics Bulk, Transcriptomics Single cell, Transcriptomics Spatial, Proteomics, Metabolomics, Lipidomics, Immune Profiling, Tumor microenvironment, Functional Assays, Histopathology, Cytopathology, Viral Load Quantification, Neuropathology, Neurophysiology, Neuroimaging, Neuropsychology, Demographics and Social Determinants of Health, Medical History and Comorbidities, Medications and Treatments, Physiological Measurements, Complete Blood Count (CBC), Toxicology, Disease Characterization and Diagnosis, Pharmacokinetics and Drug Response, Quality of Life Metrics, Adverse Events, Survival and Disease-Free Data
DataModel	The organism or type of model used to obtain the data.	Human, Animal, In vitro, Ex vivo, In silico
DataModelSpecies	Species if animal model	<i>Free text</i>
ModelSource	Cell line or specimen source (i.e. NNTC or specific specimen request)	<i>Free text</i>
DataExperiment	The experiment(s) used to generate the data.	Microarray-DNA Microarray, Microarray-RNA Microarray, Microarray-Protein Microarray, Next Generation Sequencing (NGS)-WGS (whole genome sequencing), Next Generation Sequencing (NGS)-WES (whole exome sequencing), Next Generation Sequencing (NGS)-RNA-seq, Next Generation Sequencing (NGS)-scRNA-seq, Next Generation Sequencing (NGS)-miRNA-seq, Next Generation Sequencing (NGS)-ATAC-seq, Next

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Variable	Description	Codelist
		Generation Sequencing (NGS)-CHIP-seq, Next Generation Sequencing (NGS)-TCR-seq, Next Generation Sequencing (NGS)-BCR-seq, Polymerase Chain Reaction (PCR) Methods-RT-PCR, Polymerase Chain Reaction (PCR) Methods-RT-qPCR, Mass Spectrometry (MS) Methods-MS/MS (tandem mass spectrometry), Mass Spectrometry (MS) Methods-LC-MS (liquid chromatography-mass spectrometry), Mass Spectrometry (MS) Methods-LC-MS/MS (liquid chromatography with tandem mass spectrometry), Mass Spectrometry (MS) Methods-GC-MS (Gas chromatography-mass spectrometry), Flow Cytometry and Cell Sorting Methods-FACS (fluorescence-activated cell sorting), Flow Cytometry and Cell Sorting Methods-MACS (magnetic-activated cell sorting), Flow Cytometry and Cell Sorting Methods-CyTOF (cytometry by time of flight), Flow Cytometry and Cell Sorting Methods-ICS (intracellular cytokine staining), Immunoassays and Serological Assays-ELISA (Enzyme-linked immunosorbent assay), Immunoassays and Serological Assays-VNA (viral neutralizing assay), Immunoassays and Serological Assays-PRNT (plaque reduction neutralization test), Immunoassays and Serological Assays-ELISpot (Enzyme-linked immunosorbent assay), Immunoassays and Serological Assays-Western blot, Cytotoxicity Assays-Chromium release assay, Histology and Microscopy Methods-Hematoxylin and eosin (H&E) staining, Histology and Microscopy Methods-Immunohistochemistry (IHC), Histology and Microscopy Methods-Immunofluorescence (IF), Histology and Microscopy Methods-Multiplexed immunofluorescence (IMC, MIBI, CODEX), Radiological Methods-Magnetic Resonance Imaging (MRI, fMRI), Radiological Methods-Positron Emission Tomography (PET), Radiological

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Variable	Description	Codelist
		Methods-Computed Tomography (CT), Radiological Methods-Ultrasound Imaging, Physiological-Physical Exam, Physiological-Hematology Analyzer, Physiological-Electroencephalogram (EEG), Other-Electronic Health Record, Other-Self-report
DataCuration	Data curations status to NDA or CDISC standard	1-Yes, 0-No
DataStandard	Data standard that submitted data follows	1-NDA, 2-CDISC
LinkageDataset	Data Stored in another repository that can be linked	1- Yes, 0 - No
LinkageRepository	Repository where additional data is stored	<i>Free text, if applicable</i>
LinkageRepositoryID	Native ID of repository for linkage	<i>Free text, if applicable</i>
LinkageRepositoryHyperLink	Hyperlink of where linked data sit	<i>Free text, if applicable</i>
FileType	The file type the data are stored in.	<i>Free text</i>

4. DATA VALIDATION

This section outlines procedures for ensuring data quality before submission to the neuroHIV Data Ecosystem.

4.1. Validation During Data Submission

To contribute data, investigators must first populate and submit a manifest file and submission form with required fields (refer to section 3.1 for a detailed description of each of the required fields).

- The submitter downloads, completes, and uploads a manifest file and maps datasets to the pre-specified ecosystem data standards.
- The submitter completes a submission form with some required fields.
- Uploaded files are restricted by file size and extension.

4.2. Data Flow for Investigators Contributing Data

1. Submitter downloads the manifest file, populates for their dataset and maps datasets to the pre-specified ecosystem data standards.
2. Submitter completes the submission form and uploads the completed manifest file, their research data, and the Supervising PI Attestation (if applicable).
3. Uploaded files are sent to Drupal's S3 bucket on AWS via custom scripting.
4. Metadata properties from the submission form and user profile are written to uploaded files via custom scripting.
5. Files are copied to Data Ingestion S3 bucket via custom scripting.

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5. ABBREVIATIONS AND DEFINITIONS

Abbreviation	Definition
ATAC	Assay for Transposase-Accessible Chromatin
AWS	Amazon Web Services
BCR	B-cell receptor sequencing
CBC	Complete Blood Count
CDISC	Clinical Data Interchange Standards Consortium
CHIP	Chromatin Immunoprecipitation
CITI	Collaborative Institutional Training Initiative
CT	Computed Tomography
CytoF	Cytometry by Time of Flight
DM	Demographics
DNA	Deoxyribonucleic Acid
DSA	Data Submission Agreement
DOI	Digital Object Identifier
EEG	Electroencephalogram
ELISA	Enzyme-linked immunosorbent assay
ELISpot	Enzyme-linked immunospot assay
FACS	Fluorescence-Activated Cell Sorting
fMRI	Functional Magnetic Resonance Imaging
GC	Gas chromatography
H&E	Hematoxylin and Eosin
HIV	Human Immunodeficiency Virus
ICS	intracellular cytokine staining
ID	Identifier
IF	Immunofluorescence
IHC	Immunohistochemistry
IMC	Imaging Mass Cytometry
LC-MS	Liquid Chromatography-Mass Spectrometry
MACS	Magnetic-Activated Cell Sorting
MB	Microbiology
MIBI	Multiplexed Ion-Beam Imaging
MRI	Magnetic Resonance Imaging
MS	Mass Spectrometry
MS/MS	Tandem Mass Spectrometry
NCI	National Cancer Institute
NDA	NIMH Data Archive
NEI	National Eye Institute
NGS	Next Generation Sequencing
NHGRI	National Human Genome Research Institute
NHLBI	National Heart, Lung, and Blood Institute
NIA	National Institute on Aging
NIAAA	National Institute on Alcohol Abuse and Alcoholism
NIAID	National Institute of Allergy and Infectious Diseases
NIAMS	National Institute of Arthritis and Musculoskeletal and Skin Diseases

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Abbreviation	Definition
NIBIB	National Institute of Biomedical Imaging and Bioengineering
NIDA	National Institute on Drug Abuse
NIDCD	National Institute on Deafness and Other Communication Disorders
NIDCR	National Institute of Dental and Craniofacial Research
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NIEHS	National Institute of Environmental Health Sciences
NIGMS	National Institute of General Medical Sciences
NIMH	National Institute of Mental Health
NIMHD	National Institute on Minority Health and Health Disparities
NINDS	National Institute of Neurological Disorders and Stroke
NINR	National Institute of Nursing Research
NLM	National Library of Medicine
NNTC	National NeuroHIV Tissue Consortium
PCR	Polymerase Chain Reaction
PET	Positron Emission Tomography
PI	Principal Investigator
PRNT	Plaque Reduction Neutralization Test
RCR	Responsible Conduct of Research
RNA	Ribonucleic Acid
RT	Reverse transcription
SOP	Standard Operating Procedure
TCR	T-cell receptor
URL	Uniform Resource Locator
VNA	Viral Neutralizing Assay
WES	Whole Exome Sequencing
WGS	Whole Genome Sequencing

6. DOCUMENT HISTORY

Version No.	Summary of Changes
1.0	Initial document

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