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	DOCUMENT TITLE: SOP for Investigators Accessing Data	SPONSOR: National Institute of Mental Health (NIMH)	PROJECT NAME and / or PROTOCOL NUMBER: NeuroHIV Data Ecosystem	VERSION DATE: 30JUL2026
				EFFECTIVE DATE: 05AUG2026



SOP for Investigators Accessing 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 provide instructions and guidance for researchers submitting requests for data from the neuroHIV repository.

2. DATA ACCESS

This section provides information and instructions for accessing data in the NeuroHIV data ecosystem.

2.1. How Data Are Made Available to the Research Community

Data in the ecosystem are available on the NeuroHIV Data Ecosystem site (neurohivdata.com).

Access to data within the ecosystem is determined by both the tier of data the user desires to view/access and the completion of the required authorization process. There are two tiers of access:

- **Public Access:** Data in this tier is openly available to the public and does not require any additional authorization or documentation.
- **Restricted Access:** Access to this tier requires submission of a Data Use Agreement (DUA) and certification of Responsible Conduct of Research (RCR) training. These documents must be reviewed and approved by the Data Coordinating Center (DCC) prior to access being granted.

Tier	Dataset	Availability	Status
Public	Contains only de-identified, aggregate data.	All users immediately with no additional authorization needed.	Active
Restricted	Contains individual-level data. All data in this tier will be stored in relational format to enable self-service access. No PHI will be present.	Authorized researchers only.	Active

Timelines for Access Request Review

When a user queries the ecosystem within the public or restricted tiers, packaged datasets (pre-packaged or custom) are made available immediately through the Query Tool module, provided the user has the appropriate authorization for the restricted tier. No additional access request is required for either of these tiers at the time of query.

Fulfillment of Access Requests

Public and restricted tier data are available immediately after submission, validation, curation, and integration, assuming proper access to restricted tier data has been obtained during account creation.

Formats for Exported Data

Data exported from the ecosystem can be downloaded via comma-separated values (CSV) file.

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2.2. Requesting Access and Accessing Data Tiers

All users are encouraged to create a user profile on the NeuroHIV Data Ecosystem site. User registration is recommended to facilitate user engagement with the NeuroHIV research community, allow them to receive updates related to the network, and to help them stay informed about changes or enhancements to the website and its resources.

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 to submit the request.

Public Tier

Requesting Access to Public Tier Data

No registration or special permissions are required to access data within the public tier of the ecosystem.

Accessing the Public Tier Query Tool

To access the Public Tier of the NeuroHIV Data Ecosystem Query Tool, users should follow these steps:

1. Go to neurohivdata.com.
2. Select **Request Data**. The **NeuroHIV Data Ecosystem Query Tool** page appears.
3. Under Public Tier Access, select **Click here**. The **Public Tier Summary Dashboard** page appears, displaying a summary of datasets, charts, and a data table.

Restricted Tier

Accessing the NeuroHIV Data Ecosystem Site to Query and Export Restricted Tier Data

To access data in the restricted tier of the NeuroHIV Data Ecosystem, users must do the following:

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

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Reviewing and Acknowledging the Data Use Agreement (DUA)

As required for access to the restricted tier of the NeuroHIV Data Ecosystem's Query Tool, users must complete and submit a Data Use Agreement before access can be granted to these areas of the site. The Data Use 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 Use Agreement**. The Data Use Agreement appears.
6. Download, print, read, sign, scan, and upload the Data Use Agreement.

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

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

In addition to submitting the Data Use 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**. The user account profile appears.
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 the certificate upon completion.
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.

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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 DUA, 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).

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 restricted tier data is granted only after successful account creation and authorization. Users must complete all required documentation and receive approval before accessing data in this tier.

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 restricted tier reporting 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.

Accessing the Restricted Tier Query Tool

1. Go to neurohivdata.com and log in through Okta.
2. Select **Request Data**. The **NeuroHIV Data Ecosystem Query Tool** page appears.
3. Under Restricted Tier Access, select **Click here**. The **NeuroHIV Data Ecosystem - Restricted Tier** page opens in

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a new tab.

3. QUERY AND EXPORT GUIDELINES

This section contains instructions on how to query datasets and export data from the neuroHIV Data Ecosystem Query Tool.

3.1. Querying Datasets

Public Tier

1. Access the public tier query tool.
2. Use filters and search to find the data needed. Summary information about datasets meeting filter criteria, visualization charts, and a data table appear.

Restricted Tier

1. Access the restricted tier query tool.
2. Follow on-screen instructions on the **Start Request** page to start a new request or update an existing request.

Starting a new request

1. Follow on-screen instructions to start a new prepackaged or custom data request.

Requesting prepackaged data

1. On the **Prepackaged Data Request** page, use filters and search to find the data needed. Summary information and an inventory of datasets meeting filter criteria appear.
2. From the inventory grid, mark checkboxes for datasets to be viewed.
3. Select **Proceed to Check-out**. The **Final Review** page appears.

Requesting custom data

1. On the **Custom Data Request – Donor Selection** page, use filters and search to find the data needed. For custom data requests, an option from every drop-down filter must be selected. Variables meeting filter criteria appear in the *Data Dictionary* panel.
2. Select a variable. The selected variable appears in the *Query Builder* panel.
3. In the *Query Builder* panel, do the following:
 - a. Select options from drop-down lists.
 - b. Select **Run**. Results appear in the *Combine Query* panel.
4. In the *Combine Query* panel, do the following:
 - a. To merge datasets, mark checkboxes for the datasets and select **Merge**.
 - b. To set a dataset as the base dataset, mark the checkbox for the dataset and select **Make Base**.

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- c. When finished building and combining queries, select **Proceed With Query**. The query appears in the *Final Query* panel.
2. Select **Save and Continue to Variable Selection**. The *Custom Data Request – Variable Selection* page appears.
3. Use filters and search to find the data needed. Drop-down lists contain only valid data for donors selected on the *Custom Data Request – Donor Selection* page. For custom data requests, an option from every drop-down filter must be selected. Variables meeting filter criteria appear in the *Donor Listing* panel.
4. After selecting variables, select **Save current Variables Selected**. Results appear in the *Summary Variables Selected* panel.
5. After saving selected variables, select **Proceed to Check-out**. The *Final Review* page appears.

Updating an existing request

1. From the *Data Listing* table, select the saved data request draft to be resumed.
2. Select **Edit Search**.
3. To resume a Prepackaged Data Request, do the following:
 - a. The collections previously selected are prepopulated in the Data Inventory Table.
 - b. To browse and select other data collections, select options in the drop-down lists.
 - c. Select **Proceed to Check-out**. The *Final Review* page appears.
4. To resume a Custom Data Request - Donor Selection, do the following:
 - a. The previously selected final query for obtaining donors of interest is prepopulated in the *Combine Queries* panel and the Final Query panel.
 - b. Create and select any new query as final query.
 - c. Proceed to *Custom Variable Selection* page.
5. To resume a Custom Data Request - Variable Selection, do the following:
 - a. The previously selected data/variable selections are prepopulated in the *Summary Variables Selected* panel.
 - b. Save or delete any custom data/variable selections. The *Final Review* page appears.

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Final review and request form

The **Final Review** page shows all requested prepackaged and custom datasets and a form to submit so that the data requested can be downloaded.

1. Complete the form.
2. Select **Submit and Download**. The requested datasets download to the user's device.

3.2. Exporting Data

Public Tier

1. To download public tier data from the data table to a CSV file, select **Download CSV**.

Restricted Tier

1. To download restricted tier data from the inventory to a CSV file, select **Download Inventory Summary**.

4. USER RESPONSIBILITIES

The terms and conditions found in the **Data Use Agreement** specify the responsibilities researchers have when using data acquired via the neuroHIV Data Ecosystem, including data sharing restrictions and ethical considerations.

5. ABBREVIATIONS AND DEFINITIONS

Abbreviation	Definition
CITI	Collaborative Institutional Training Initiative
CSV	Comma-Separated Values
DCC	Data Coordinating Center
DOI	Digital Object Identifier
DUA	Data Use Agreement
FWA	Federal Wide Assurance
GUID	Global Unique Identifier
HIPAA	Health Insurance Portability and Accountability Act of 1996
HIV	Human Immunodeficiency Virus
IRB	Institutional Review Board
MRI	Magnetic Resonance Imaging
OHRP	Office for Human Research Protections
PHI	Protected Health Information
RCR	Responsible Conduct of Research
SOP	Standard Operating Procedure

6. DOCUMENT HISTORY

Version No.	Summary of Changes
1.0	Initial document