National NeuroAIDS Tissue Consortium
Data Coordinating Center
INVESTIGATOR REQUEST FOR DATA

Dear Investigator:

Thank you for your inquiry about receiving clinical and/or genetic-related data (hereafter "data") from the National NeuroAIDS Tissue Consortium. In order to evaluate your request, the Consortium requires that you provide the following:

- ☐ Complete the **Investigator Request for Data form**, including an abstract that clearly describes the project for which you will use requested data.
- ☐ Provide a copy of your curriculum vitae or NIH Biosketch.
- ☐ Visit https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html#c1 to determine if your study requires a human subject research application that must be reviewed by an IRB

Read and Sign:

- ☐ ***Data Single User Agreement***. This will acknowledge your responsibility in not distributing any portion of the data disbursement to colleagues or other investigators, and that all such inquires will be directed to the NNTC Director.
- ☐ ***The NNTC Acknowledgement Agreement***. This will indicate that you have agreed to provide specific acknowledgment of the NNTC and its Federal grant number in any publications related to the use of these tissues.
- ☐ ***The NNTC Data Sharing Agreement.*** This will acknowledge your responsibility to provide the NNTC with all data within twelve (12) months of receiving materials.

All requests undergo a review process in the order received. The Data Coordinating Center (DCC) first processes this application to ensure clarity and completeness prior to broadcasting to the NNTC Allocations Committee. Please note that following this broadcast, the committee requires at least two weeks to complete their review of each data request. Upon approval, the data will be compiled by the DCC and provided to you in SAS format unless you specify otherwise. The Consortium charges no fee for providing this service.

Please feel free to contact us regarding the status of your request for data or with any other questions you may have. The Consortium is pleased to be able to provide this specialized service to help facilitate your research program.

Sincerely,

NNTC Data Coordinating Center

I. Investigator's Information

Investigator's Name:

Phone #:

Investigator's Title:

Dept.:

Project Title:

Institution's Name:

Fax #:

Investigator's Email Address:

II. Please attach a brief summary of the project for which you are using NNTC data

Include in the summary:

- Specific aims and hypotheses
- Background research
- Proposed analyses
- Rationale for the number of cases and controls requested (e.g., power analyses)

Attach additional pages as needed.

III. Specifications for Data Requested

Complete the fields below to define the sample of cases from which data is requested.

HIV status:	
Age range:	
Race/ethnicity:	
Gender:	
Inclusion[1]:	
Exclusion[2]:	

[1] **Inclusion / Exclusion**: Specify any additional inclusion and/or exclusion criteria you wish to consider for your data (examples below):

1. Substance Use History: PRISM/CIDI vs. Urine Toxicology, consistent history across all visits (use/abstinence) or defined history only at the last visit?

2. Co-morbidities: HCV, organ system disease, diabetes, risk factors, etc.

3. ARV and other concomitant medications: Currency of medications use relative to death, class of medications, etc.

4. Lab determinations: Viral load thresholds, nadir CD4, time frame of results relative to sample collection and/or death, etc.

5. Neurocognitive/Neuropsychological History: Presence/absence of impairment above or below a specified threshold.

6. Pathology: Presence/absence of certain pathologies at death. A list of brain and spinal cord pathologies is included in Tables A and B below for reference.

Lab/Clinical data required:

Indicate below the tables you would like to receive.

☐ Neuromedical Evaluation ☐ Pathology (brain/spinal cord) ☐ ARV History

☐ Neuropsychiatric PRISM/CIDI Data ☐ Study Eligibility

☐ Blood/CSF Analysis ☐ Neuropsychological Summary Score ☐ Urine Toxicology

☐ Demographics ☐ Organ Pathology ☐ Other _____

A. Brain

Diagnosis
1. Normal
2. Aseptic leptomeningitis (in absence of other local pathology)
3. HIV encephalitis
4. CMV encephalitis (includes ventriculoencephalitis, microglial nodule encephalitis with CMV inclusions, focal CMV necrosis)
5. Microglial nodule encephalitis, not otherwise specified (encephalitis without diagnostic inclusions or organisms)
6. Toxoplasmosis, active
7. Toxoplasmosis, healed
8. Cryptococcus
9. Progressive multifocal leukoencephalopathy
10. Lymphoma (primary and concurrent with systemic, meningeal and/or parenchymal)
11. Bacterial leptomeningitis
12. Bacterial parenchymal infection
13. Tuberculosis
14. Other infections
15. Anoxic-ischemic encephalopathy (focal or global)
16. Alzheimer type 2 astrocytosis
17. Focal (territorial) infarct (large or small, and due to embolism or local vascular pathology, recent or remote)
18. Hemorrhage, dura or leptomeninges (acute or organizing, due to any cause)
19. Hemorrhage, parenchymal
20. Other, non-infectious pathology
21. Minimal, non-diagnostic abnormalities

B. Spinal cord/nerve

22. Normal
23. HIV myelitis
24. CMV myelitis (includes myeloradiculopathy)
25. Vacuolar myelopathy
26. Microglial nodule myelitis, not otherwise specified
27. Toxoplasmosis
28. Cryptococcus
29. Aseptic leptomeningitis
30. Lymphoma
31. Bacterial leptomeningitis
32. Bacterial parenchymal infection
33. Tuberculosis
34. Other infections
35. Anoxic-ischemic damage
36. Hemorrhage, dura or leptomeninges
37. Hemorrhage, parenchymal

38. Peripheral neuropathy
39. Other, non-infectious pathology
40. Minimal, non-diagnostic abnormalities

IV. Data Single User Agreement

INVESTIGATOR, PLEASE READ AND SIGN THE FOLLOWING STATEMENT:

As the Investigator of Record, I understand that the NNTC has provided data to me for research purposes only. I acknowledge that these data have been disbursed for my express use only, that I will exercise a good faith effort to keep control over such data, and that I will not distribute any data or fractions of data to other investigators without the express permission of the NNTC. I acknowledge that providing any amount of data to colleagues, other investigators, or other laboratory facilities is specifically prohibited without written permission from the NNTC. I will direct all such requests for data to the NNTC central office. I also acknowledge that under no circumstances will the NNTC release the key that links coded private information to a specific individual.

Investigator of Record

Print Name:

Investigator of Record

Sign Name: **Date:**

V. NNTC Acknowledgment Agreement

PLEASE READ AND SIGN THE FOLLOWING STATEMENT:

As the Investigator of Record, I agree to provide specific acknowledgment of the National NeuroAIDS Tissue Consortium and its Federal grant number(s) in any publication related to the use of these data. Individual sites and the Data Coordinating Center (DCC) should be acknowledged if their resources were used in any stage of the project. If, for example, a request is submitted through the DCC for data, and MHBB and CNTN provide data, the DCC and the two sites must be acknowledged. If two NNTC sites collaborate on a project and do not use the DCC resource, the two sites should be acknowledged.

> "This publication was made possible from NIH funding [insert author's funding source information]; along with shared resources from NIH funding through the NIMH and NINDS by the following grants:
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> Manhattan HIV Brain Bank (MHBB): U24MH100931
> Texas NeuroAIDS Research Center (TNRC): U24MH100930
> National Neurological AIDS Bank (NNAB): U24MH100929
> California NeuroAIDS Tissue Network (CNTN): U24MH100928
> Data Coordinating Center (DCC): U24MH100925
>
> Its contents are solely the responsibility of the authors and do not necessarily represent the official view of the NNTC or NIH."

I understand that no member of the NNTC staff may be listed as a co-author on any publication unless there is a substantive scientific contribution above and beyond the provision of data. To include a NNTC staff member as a co-author, contact the DCC to obtain formal permission of the NNTC Director.

Investigator of Record

Print Name:

Investigator of Record

Sign Name: **Date:**

VI. NNTC Data Sharing Agreement

PLEASE READ AND SIGN THE FOLLOWING STATEMENT:

The NIH [National Institute of Mental Health (NIMH) and The National Institute of Neurological Disorders and Stroke (NINDS)] sponsors this enterprise through cooperative agreements with the brain banking units. The NNTC Data Coordinating Center (DCC) coordinates, stores, and makes accessible all de-identified data obtained from the NNTC subjects and specimens derived from the subjects. As a recipient of data from the NNTC you agree to the following statements:

- The NIH expects NNTC recipients to provide the DCC with electronic copies of all data within twelve (12) months of receiving the materials. If this is not possible the DCC will work with the investigator to decide on an appropriate time-frame.
- Continued reporting to the DCC should occur at least annually as the analysis progresses until the analysis is completed.
- Data can be embargoed to prevent its release until publication. All data will be referenced to the investigator and publication when relevant.
- For indexing purposes the NNTC expects recipients to submit data in a specific format with an NNTC subject ID number; forms for this submission will be provided upon approval of the resource request.
- High-throughput data (genomic, gene expression, protein, and metabolomics data) should be submitted to the appropriate NCBI repository (dbGap {http://www.ncbi.nlm.nih.gov/gap} for genomic, GEO {http://www.ncbi.nlm.nih.gov/geo} for gene expression, other data types if/as they become available), using their respective formats, and the appropriate links provided to the DCC. Other high-throughput as well as medium- and low-throughput datasets and associated metadata are to be submitted to the DCC; working with the DCC to determine the best format to transfer data.
- Some data may be missing from the NNTC central database. The NNTC will attempt to provide investigators with the most up-to-date data tables. On a periodic basis, the DCC will freeze the database to create files for public distribution. The tables are subject to revision through a process of quality assurance monitoring, both centrally and locally at each site.
- Data returned to the NNTC may be shared with qualified requestors. Requestors will be notified if another investigator has received access to their submitted data.

I understand that the NNTC intends to make these data available for qualified scientific investigators.

Investigator of Record:

Print Name:

Investigator of Record:

Sign Name: **Date:**

PLEASE MAIL OR FAX COMPLETED FORMS TO:

National NeuroAIDS Tissue Consortium
Data Coordinating Center
Request Manager
401 N. Washington Street
Suite 700
Rockville, MD 20850
Tel: 1-866-NNTC-BRAIN
Fax: 301-576-4597
Email: nntc@emmes.com