I. Human Tissue Handling Risks and Safety Precautions Statement

Working with human tissue carries the potential risk of exposure to infectious diseases that may be communicable to other humans. All human brain tissue should be treated as a potential contamination risk for certain diseases and should be handled with extreme care. Infectious agents that have been identified as possible risks include, but may not be limited to, Human Immunodeficiency Virus (HIV-1, HIV-2), Hepatitis-B and Creutzfeldt-Jakob disease. Although a relatively rare disease entity, Creutzfeldt-Jakob disease has been reported to be able to remain infectious for long periods of time in fixed tissue and it may withstand standard autoclave sterilization procedures.

It is recommended that universal precautions be followed when working with human tissues irrespective of the method of tissue preparation. Investigators are encouraged to incorporate double gloving, appropriate protective garments, and face or eye protection when working with tissue. Disposable instruments and/or an effective regimen of appropriate decontamination should be used routinely. All waste material should be considered as a biohazard. Waste should be disposed of according to your institution's policy for handling such material, which may include incineration, autoclaving and burial, or other approved methods. All laboratory staff that will be working with human tissues should be trained in the proper and approved methods of handling of such specimens.

The NNTC collects HIV negative and HIV positive tissue specimens representative of a wide variety of additional diagnoses from across the United States. The NNTC does not guarantee that any of the donors of specimens were not exposed to or infected by potentially transmissible infectious agents. Ultimately, it is the responsibility of the recipient investigator to ensure that proper, safe handling techniques are employed by all laboratory staff in handling human tissue.

PLEASE READ AND SIGN THE FOLLOWING STATEMENT:

I have read the Human Tissue Handling Risks & Safety Precautions Statement, and I understand the potential safety risk in handling human tissue and acknowledge these safety precautions and recommendations as essential to my safe handling of specimens.

As the Investigator of Record, I accept full responsibility to ensure that proper, safe handling techniques are employed in my laboratory when working with human tissue, and further accept responsibility to train staff in approved and customary safe handling techniques before they work with these tissues.

I understand that NNTC distributes specimens known to have been exposed to or infected with agents such as, but not limited to, HIV (HIV-1, HIV-2), Hepatitis-B or Creutzfeldt-Jakob disease, and I understand that the NNTC is unable to guarantee that any of its tissue donors were not exposed or infected with such agents.

As the Investigator of Record, I accept full responsibility to ensure that **all necessary institutional approvals are in place prior to receipt of any NNTC specimens**.

Investigator of Record

Print Name:

Investigator of Record

Sign Name: _____ **Date:**

II. Human Specimen and Data Single User Agreement

PLEASE READ AND SIGN THE FOLLOWING STATEMENT:

As the Investigator of Record, I understand that the NNTC has disbursed human tissue, fluids, and/or data to me for research purposes only. I acknowledge that these samples and/or data have been disbursed for my express use only, that I will exercise a good faith effort to keep control over such samples/data, and that I will not distribute any samples/data or fractions of samples/data to other investigators without the express permission of the NNTC. I acknowledge that providing any amount of sample and/or 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 tissue and/or data to the NNTC central office. I also acknowledge that under no circumstances will the NNTC release the key that links coded private information or specimens to a specific individual. I further agree that I will not attempt to identify any participant, directly or indirectly, based on any data or analysis results derived from the NNTC samples and/or data provided to me.

Investigator of Record

Print Name: _____

Investigator of Record

Sign Name: _____ **Date:** _____

III. NNTC Acknowledgment Agreement

PLEASE READ AND SIGN THE FOLLOWING STATEMENT:

As the Investigator of Record, I agree to provide specific acknowledgment of the National NeuroHIV Tissue Consortium and its Federal contract number(s) in any publication, presentation, abstract, preprint, or other dissemination product related to the use of NNTC specimens and/or 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 tissue and related data, and MHBB and CNTN provide tissue, 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 by funding from the National Institutes of Health (NIH) [insert author's funding source information], along with shared resources from NIH funding through the National Institute of Mental Health (NIMH), National Institute on Aging (NIA), National Institute on Drug Abuse (NIDA), and National Institute of Neurological Disorders and Stroke (NINDS) by the following contract numbers:
>
> Texas NeuroHIV Research Center (TNRC): 75N95023C00016
> California NeuroHIV Tissue Network (CNTN): 75N95023C00014
> National Neurological AIDS Bank (NNAB): 75N95023C00017
> Manhattan HIV Brain Bank (MHBB): 75N95023C00015
> Washington University in St. Louis School of Medicine (WUSM): 75N95024C00027
> Data Coordinating Center (DCC): 75N95023C00013
>
> Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the National NeuroHIV Tissue Consortium or the National Institutes of Health."

I understand that NNTC investigators and staff may be co-authors only if their contributions go beyond providing tissue specimens and/or data and meet International Committee of Medical Journal Editors (ICMJE) authorship criteria. I will disclose anticipated NNTC co-authorship as early as possible, preferably in my resource request. Substantive NNTC contributions that do not merit authorship will be described in the acknowledgments.

I agree to notify the NNTC DCC of any publication, presentation, abstract, or preprint using NNTC specimens and/or data and, upon acceptance, to provide the citation (with DOI and PubMed ID, when available) and, where permitted, the final PDF. NNTC approval before submission is not required.

Failure to meet these acknowledgments and reporting obligations may result in suspension or denial of access to NNTC resources.

Investigator of Record

Print Name:

Investigator of Record

Sign Name: _____ **Date:**

IV. NNTC Commercial Use Policy and Disclosure

Recognizing that the individual repositories constituting the NNTC must be observant of their local institutional and state regulations, the Consortium can only issue broad guidelines for commercial utilization of its specimens. The individual institutions in which the repositories reside are charged with regulatory oversight of the tissue banking operations. Individual tissue banks within the Consortium may elect to fulfill or opt out of requests entailing commercial utilization. The NNTC will neither encourage nor restrict commercial access to its specimens.

If an investigator conducting research with NNTC specimens previously distributed under a not-for-profit application, wishes to switch their utilization to commercial use, he or she must re-submit an application to the NNTC requesting permission for this switch. At that time, participating repositories will be given the option of either granting or denying permission for such utilization.

Please answer the following question:

Will the specimens you receive from the NNTC be used for any commercial purposes? Yes ☐ No ☐

Comment: _____

PLEASE READ AND SIGN THE FOLLOWING STATEMENT:

As the Investigator of Record, I understand and agree to the terms specified in the NNTC Commercial Use Policy. I also agree that my disclosure of commercial interests has been accurately reported on this application. If at some point, however, your commercial use status changes, I will promptly inform the members of the NNTC.

Investigator of Record

Print Name: _____

Investigator of Record

Sign Name: _____ **Date:** _____

V. NNTC Data Sharing Policy

PLEASE READ AND SIGN THE FOLLOWING STATEMENT:

The NIH, through the National Institute of Mental Health (NIMH), National Insitute on Aging (NIA), National Insitute on Drug Abuse (NIDA), and National Institute of Neurological Disorders and Stroke (NINDS), sponsors the NNTC through contracts with the five NNTC sites and the NNTC Data Coordinating Center (DCC). The DCC coordinates, stores, and provides access to de-identified data obtained from the NNTC participants and the specimens derived from them. As a recipient of NNTC data, 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 or within a month of publication of data using samples from NNTC, following an update at 12 months.
- 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.
- Data will be provided to the NNTC DCC in a format to be determined in conjunction with the DCC depending on the type of data. The DCC will provide templates and examples to the requestor upon approval of the request, followed by annual reminders.
- High-throughput data (genomic, gene expression, protein and metabolomics data) should be submitted to the appropriate NCBI repository (dbGap { https://www.ncbi.nlm.nih.gov/gap/} for genomic, GEO {https://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.

Important: Following receipt of NNTC specimens for any given request, all requestors *must* submit an annual progress report(s) to the DCC from prior requests (including a description of data obtained and a timeline for completion of the project), and experimental data from any completed projects, *before* any additional applications to the NNTC will be processed.

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:** _____