1. General Instructions

This checklist provides a step-by-step guide to assist investigators with submitting an application to request use of NNTC specimen, data, and analysis resources. This guidance is intended to help investigators submit complete applications that include all relevant details needed for review of their request. The NNTC requires that **all applications to use NNTC resources MUST include a completed and signed copy of this checklist as part of their request application**.

1. Abbreviations

| **Abbreviation** | **Description** |
| --- | --- |
| ANI | Asymptomatic Neurocognitive Impairment |
| ARV | Antiretroviral |
| CBC | Complete Blood Count |
| CHARTER | CNS HIV Antiretroviral Therapy Effects Research Study |
| CIDI | Composite International Diagnostic Interview |
| CMV | Cytomegalovirus |
| CNS | Central Nervous System |
| covid | Coronavirus Disease |
| CSF | Cerebrospinal Fluid |
| CV | Curriculum Vitae |
| DCC | Data Coordinating Center |
| DNA | Deoxyribonucleic acid |
| dspn | Distal Sensory Polyneuropathy |
| FFPE | Formalin-fixed paraffin-embedded tissue sections |
| gi | Gastrointestinal |
| HAART | Highly Active Antiretroviral Therapy |
| HAD | HIV-Associated Dementia |
| HIV | Human Immunodeficiency Virus |
| ID | Identifier |
| INIS | Integrase Inhibitors |
| MCMD | Minor Cognitive Motor Disorder |
| mdd | Major Depressive Disorder |
| med | Medications |
| MND | Mild Neurocognitive Disorder |
| MRI | Magnetic Resonance Imaging |
| mrna | Messenger Ribonucleic Acid |
| NNTC | National NeuroHIV Tissue Consortium |
| NP | Neuropsychological |
| NPI-O | Neurocognitive Impairment Other: Probable neuropsychological impairment or dementia due to other cause |
| NRTIs | Nucleoside/nucleotide reverse transcriptase inhibitors |
| NNRTIS | Non-nucleoside/nucleotide reverse transcriptase inhibitors |
| oi | Opportunistic Infection |
| PBMC | Peripheral Blood Mononuclear Cells |
| pcp | Pneumocystis Pneumonia |
| PI | Principal Investigator |
| PIs | Protease inhibitors |
| PML | Progressive Multifocal Leukoencephalopathy |
| PRISM | Psychiatric Research Interview for Substance and Mental Disorders |
| PWH | People with HIV |
| PWoH | People without HIV |
| RNA | Ribonucleic Acid |
| ut | Urinary Tract |

1. Definitions

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| --- | --- |
| **Term** | **Description** |
| DCC | The Data Coordinating Center (DCC) is responsible for management of the review and approval process for applications. If you have any questions regarding your request, please contact [nntc@emmes.com](mailto:nntc@emmes.com). |
| Specimen | A quantity of tissue, blood, or other biologically derived material. |
| Donor | An individual person who has donated tissue to the NNTC. |

1. Request Processing Checklist

**Application Component Done?**

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| --- |
| **Start Request Tab**  The Start Request tab allows you to select the type and request complexity level (if known).  *If Request Complexity Level is not known, use the “New Level 2+” button to submit your application.* |

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| Using the buttons at the bottom of the screen, indicate whether you are updating an application, or creating a new one | * **Update Existing Request**: Option to update an existing draft application already started in the Query Tool. * **New Level 1 Request**: Option to initiate a new *LEVEL 1* request. Be advised that the Query Tool will prevent entry of non-Level 1 requests submitted via this mechanism.   + **Data Request**: Option to create a new Level 1 Data Request   + **Specimen Request**: Option to create a new Level 1 Specimen Request   **Analysis Request**: Option to create a new Level 1 Analysis Request |  |

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| --- |
| **Donor Search Tab**  The Donor Search tab allows you to define each study group in your application. Your selection of filter criteria defines the inclusion/exclusion parameters for each group. Please note that the donor list that appears in the query tool does not guarantee that those specific cases will be available.  *Multi-select: In the dropdown fields in the left-hand panel, you can select multiple options by clicking on your first choice, then clicking on any additional fields you would like to select. In addition, “Select All” and “Deselect All” toggles are available for each dropdown menu.* |
| **Demographics**  *Using the dropdown fields provided in the left-hand panel, indicate demographic criteria that should define donors for your study group. Filtering criteria are detailed below.* |

|  |  |  |
| --- | --- | --- |
| Cohort | Describes the study which the data was collected under.   * **CHA01 – CHARTER** (CNS HIV Antiretroviral Therapy Effects Research) Study * **NNTC01 – NNTC** (National NeuroHIV Tissue Consortium) Study |  |
| Donor ID | Numerical identifier assigned to be unique across sites in the NNTC and CHARTER studies. |  |
| HIV Status | HIV Status at the time of enrollment.   * **PWH** – Person with HIV * **PWoH** – Person without HIV * **Seroconverted** – Person who enrolled without HIV but developed a HIV viral load while enrolled and is now considered a PWH. * **Unknown** – Donors who were evaluated for a HIV diagnosis, but study staff were unable to conclusively diagnose as PWH or PWoH * **Not Available** – Data regarding HIV status was not captured |  |
| Age at Enrollment | Age in years when consent form was signed. This field allows for entry of age ranges.   * **N/A (checkbox)** –Selecting the “N/A” checkbox will allow the inclusion of any cases missing age at enrollment in your study group listing. |  |
| Sex | Indicate donor’s sex at birth.   * **Male** * **Female** |  |
| Ethnicity | Describes whether a donor identifies as Hispanic/Latino or non-Hispanic/Latino.   * **Hispanic or Latino** – Indicates donors who identify as being Hispanic or Latino. * **Non-Hispanic or Latino** – Indicates donors who do not identify as being Hispanic or Latino. |  |
| Race Derived Variable | Race is initially captured by five binary variables:   * **ASIAN** - Indicates donors who are Asian * **BLACK** – Indicates donors who are Black or African American * **NATIVEAL** – Indicates donors who are Native American, including Native Alaskan * **NATIVEHA** – Indicates donors who are Native Hawaiian or Pacific Islander * **RACEUNK** – Indicates that a donor’s race is unknown. * **WHITE** - Indicates donors who are White. * **Not Available** – Indicates donors who have no available race data. |  |
| Current Study Status | Describes NNTC donor status.   * **Abbreviated** – Indicates that a donor is an active participant in the NNTC study, but not available for all study procedures and/or visits. These donors are seen when possible and may receive abbreviated study batteries. * **Active** – Indicates that a donor is an active participant in the NNTC study. * **Administratively Censored** – Indicates that a donor is physically unable to participate in the study (e.g., incarcerated). * **Deceased with Autopsy** - Indicates a deceased donor for whom an autopsy was performed. * **Deceased without Autopsy** - Indicates a deceased donor for whom an autopsy was not performed. * **Lost to follow-up** – Indicates a donor who is no longer a part of the NNTC cohort, despite attempts to contact them. * **Not Available** – Indicates a donor whose current study status is not known or not available. * **Withdrawn** – Indicates a donor who has voluntarily concluded their participation in the NNTC. |  |
| HAART (Highly Active Antiretroviral Therapy) Exposure | Indicates individuals who had a medication regimen including 2 or more NRTIs and 1 NNRTI/PI/INI at any point during their participation.   * **Yes** – Indicates donors who have had HAART exposure. * **No** – Indicates donors who have not had HAART exposure. * **Not Available** – Indicates donors for whom HAART exposure information is not available. |  |
| Autopsy Year | Year in which autopsy was conducted. This field accommodates entry of year ranges.  NNTC autopsies formally began in 1998. From this year onward, autopsy year is presented as a categorical variable, binned every 5 years. Please note that only a limited number of autopsies were obtained prior to 1998 (from 1980-1991) have been incorporated into the NNTC.   * **N/A (checkbox)** – Selecting the “N/A” checkbox will allow the inclusion of any cases missing autopsy year, in your study group listing. |  |
| Age at Death | Age in years at death. This field accommodates entry of year ranges.   * **N/A (checkbox)** – Selecting the “N/A” checkbox will allow the inclusion of any cases missing age at death, in your study group listing. |  |

**Experimental Data Availability**

*Using the dropdown fields provided in the left-hand panel, use the filter criteria to indicate any of the categories of data available for Donors identified in your current search.*

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| --- | --- | --- |
| Specimen Availability | Indicates if donors have available specimens for request.   * **Yes** – Indicates donors who have specimens available for request. * **No** – Indicates donors who do not have specimens available for request. |  |
| Assay Data Availability | Indicates if any researcher-provided results from previously requested specimens is available for a given donor.   * **Yes** – Indicates donors who have researcher-provided results available for request. * **No** – Indicates donors who do not have researcher-provided results available for request. |  |
| Imaging Data Availability | Indicates if donors have neuroimaging data available for request.   * **N/A** – Incorporation of imaging data into the NNTC query tool is still under development. Once implemented, additional options will be made available for your selection in this field. |  |

**Diagnoses**

*Using the dropdown fields provided in the left-hand panel, use the filter criteria to indicate any diagnoses that are pertinent to your study group definitions.*

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| Neurocognitive Diagnoses  (App Derived Variable) | Neurocognitive Diagnoses were concatenated from the Neuromedical battery.   * *In addition to the specific diagnoses included in the dropdown list (see* [*Appendix A*](#neurocogdx)*).* * **None** – Indicates donors who do not meet criteria for any diagnoses listed. * **Not Available** – Indicates donors who do not have any Neurocognitive Diagnoses data available. |  |
| Comorbid Diagnoses  (App Derived Variable) | Comorbidity diagnoses were concatenated for each donor if assessments determined there was sufficient evidence to make a diagnosis. Comorbidities listed reflect comorbidities diagnosed at any timepoint.   * *In addition to the specific diagnoses included in the dropdown list (*[*Appendix B*](#comorbid)*).* * **None** – Indicates donors who do not meet criteria for any diagnoses listed. * **Not Available** – Indicates donors who do not have any Comorbidity Diagnoses data available. |  |
| Psychological Domain Impairment  (App Derived Variable) | Psychological Domain Impairment is defined by a Global T Score below 40 (as determined by the Neuropsychological Variables Calculator) at any timepoint. The Neuropsychological Variables Calculator determines Global T-Score based on variables obtained via multiple assessments across the neuropsychological battery.   * **Yes** – Indicates donors who had Global T Score below 40 at any timepoint in the study. * **No** – Indicates donors who had Global T Score above 40 for all timepoints. * **Not Available** – Indicates donors who do not have Global T-Score data available. |  |
| Pathology  (App Derived Variable) | Pathology diagnoses were concatenated from binary diagnostic variables from donor autopsy, as collected by the NNTC Pathology form, Supplemental Pathology form, and/or Organ Pathology form.   * *In addition to the specific pathologies included in the dropdown list (*[*Appendix C*](#pathologies)*).* * **None** – Indicates donors who do not meet criteria for any diagnoses listed. * **Not Available** – Indicates donors who do not have any pathology data available. |  |
| Substance Abuse History  (App derived variable) | Substance abuse was calculated by looking neuropsychiatric diagnoses, legal medication use, and urine toxicology results at any timepoint.   * **Substance Abuse History Present** - Indicates that a donor has been given a substance abuse diagnosis or positive urine toxicology result without a prescription at any timepoint. * **History of Controlled Substance Use** - Indicates a participant has used controlled substances as captured in concomitant medications and positive urine toxicology results with a prescription at any timepoint. * **Substance Abuse History Absent** - Indicates a donor has not received a diagnosis of substance abuse, does not have any concomitant medications which are controlled substances, and has not had any positive urine toxicology results. * **Not Available** - Donor does not have any Concomitant Medications, Urine Toxicology, or CIDI/PRISM diagnoses data available. |  |
| Neuropsychiatric Diagnoses  (App Derived Variable) | Neuropsychiatric Diagnoses were concatenated from diagnoses given using the CIDI and PRISM assessments.   * *In addition to the specific diagnoses included in the dropdown list (see* [*Appendix D*](#neuropsychiatric)*).* * **None** – Indicates donors who do not meet criteria for any diagnoses listed. * **Not Available** – Indicates donors who do not have any Neuropsychiatric Diagnoses data available. |  |
| Viral Suppression  (App Derived Variable) | The NNTC defines two different criteria to identify virally suppressed cases:  Criterion 1. The subjects have been followed for at least 5 years before death. There must be at least 1 undetectable viral load within 1 year of death, or 2 undetectable viral loads within 2 years of death. Over the 5-year period before death, there must be at least 4 undetectable viral loads. Note that “blips” of detectable virus are allowed, however these must be <1000 copies/mL during this 5-year period.  Criterion 2. The subjects have been followed for at least 2 years before death. There must be at least 1 undetectable viral load within 6 months of death. Note that “blips” of detectable virus. are allowed, however these must be <1000 copies/mL during this 2-year period.  The dropdown options for this field are as follows:   * **Meets Criterion 1** – Indicates donors who meet viral suppression criterion 1. * **Meets Criterion 2** – Indicates donors who meet viral suppression criterion 2. * **Does Not Meet Criteria** – Indicates donors who meet neither of the viral suppression definitions. * **Not Available** – Indicates donors who do not have sufficient viral load data to determine viral suppression, by either criterion. |  |
| Save and Continue | After you have defined all desired criteria for your study group, click the Save and Continue button to proceed to the next step in building your application. |  |

**Specimen Search Tab**

The Specimen Search Tab is where you will be documenting the specimen types you are requesting as part of your NNTC application.

*Multi-select: In the dropdown fields in the left-hand panel, you can select multiple options by clicking on your first choice, then clicking on any additional fields you would like to select. In addition, there are “Select All” and “Deselect All” toggles for each dropdown menu.*

*Dynamic, Interactive Plot:*

*Please note that as you refine your specimen criteria, you will see that the plot on this tab of the query tool dynamically updates to provide real-time feedback indicating specimen availability, according to NNTC inventory data.*

*You can toggle settings in the left-hand panel under “Plot Display Options” to display either “Preparation” or “Status” along the X-axis.*

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| Specimen Category | Indicate the specimen category you are requesting. Please select all that apply to your request.   * **CNS** – Indicates that you are requesting central nervous system tissue specimens. * **Fluids** – Indicates that you are requesting fluid specimens. * **Systemic** – Indicates that you are requesting systemic tissue specimens. * **Genetic Material** – Indicates that you are requesting genetic material specimens. |  |
| Specimen Type | * For Level 1 requests, you will **not** be able to select the following specimen types.   + Nucleus accumbens   + Basal ganglia   + Hippocampus   + Striatum * Indicate the specific specimen types (e.g., Plasma, Frontal Lobe, etc.) for the specimen categories you selected above. * For a list of all available specimen types, by category, please see the appropriate Appendix:   + CNS – See [Appendix E](#cnsspecimens)   + Fluids – See [Appendix F](#fluidspecimens)   + Systemic – See [Appendix G](#systemicspecimens)   + Genetic Material – See [Appendix H](#genetictypes) * If you select any of the “Other” options from the dropdown, a free text field will appear for you to further clarify what you are requesting. This text field should not be used for options available in the dropdown menu. |  |
| Save and Continue to Dataset Search | After you have defined all desired criteria for your study group, click the Save and Continue to Dataset Search button to proceed to the Dataset Search tab. *Do not select this option if you will not be requesting data as part of your NNTC application.* |  |
| Save and Continue to Final Review | After you have defined all desired criteria for your study group, click the Save and Continue to Final Review button to proceed to the Final Review tab. *Clicking this button circumvents the Dataset Search Tab.* |  |

**Dataset Search Tab**

The Dataset Search tab is where you will define any data elements of your request. Please see [Appendix I](#datadomains) for a full list of data categories, subcategories, and variables.

*Multi-select: In the dropdown fields in the left-hand panel, you can select multiple options by clicking on your first choice, then clicking on any additional fields you would like to select. In addition, there are “Select All” and “Deselect All” toggles for each dropdown menu.*

|  |  |  |
| --- | --- | --- |
| Category | Select the highest-level data category(ies) appropriate for your request. Options are as follows:   * Quality of Life * Demographics * Psychiatric Profile * Laboratory Results * Medication Use * Diagnoses * Neurocognitive Profile * Pathology * Researcher-Derived Data |  |
| Subcategory | For the data category(ies) selected, indicate all subcategories appropriate for your request. Please see [Appendix I](#datadomains) for a detailed list of subcategory options. |  |
| Variables | For the data subcategory(ies) selected, indicate all variables of interest for your request. |  |
| Visits | If you are requesting data specific to any study visit(s), select all visits that apply. Visits available for selection are as follows:   * Baseline/Initial Visit (00) * 6 Months (01) * 12 Months (02) * 18 Months (03) * 24 Months (04) * 30 Months (05) * 36 Months (06) * 42 Months (07) * 48 Months (08) * 54 Months (09) * 60 Months (10) * 66 Months (11) * 72 Months (12) * 78 Months (13) * 84 Months (14) * 90 Months (15) * 96 Months (16) * 102 Months (17) * 108 Months (18) * 114 Months (19) * 120 Months (20) * 126 Months (21) * 132 Months (22) * 138 Months (23) * 144 Months (24) * 150 Months (25) * 156 Months (26) * 162 Months (27) * 168 Months (28) * 174 Months (29) * 180 Months (30) * 186 Months (31) * 192 Months (32) * 198 Months (33) * 204 Months (34) * 210 Months (35) * 216 Months (36) * 222 Months (37) * 228 Months (38) * 234 Months (39) * 240 Months (40) * 246 Months (41) * 252 Months (42) * 258 Months (43) * 264 Months (44) * 270 Months (45) * 276 Months (46) * 282 Months (47) * 288 Months (48) * 294 Months (49) * 300 Months (50) * Historical (98) * Post-mortem (99) * Last Visit – This is a calculated variable that will indicate you are requesting data for donors’ last visit, whatever that specific visit number might have been. |  |

**Final Review Tab**

The Final Review tab is where you will complete entry of required specimen details as well as other administrative fields.

|  |  |  |
| --- | --- | --- |
| Donor Search Details Table  *(Summary information)* | This is a summary table detailing all study group details for your application. Carefully review to ensure that all details are accurate. |  |
| Specimen Search Details Table  *(Summary Information)* | This is a summary table detailing the specimen category(ies), type(s), and preparation(s) for your application. Carefully review to ensure that all details are accurate. |  |

**Specimen Details Table**

Enter specimen details for each study group and unique specimen type defined in your application. Specimen details to be entered in this table defined below.

*In the table provided, you must double-click the field of interest to open it up for data entry.*

*Please note that NNTC “standard” specimen types, preparations are defined throughout this portion of the checklist. Please be reminded that selecting options beyond NNTC standards may impact your Request Complexity Level. Non-standard selections are likely to lead to longer review and fulfillment timeframes.*

|  |  |  |
| --- | --- | --- |
| Preparation | * Specify the specimen preparation you require for your specimen type. * Options for **CNS tissues** include:   + Snap frozen block -70oC (not treated with cryopreservatives) **(standard)**   + Fixed in 10% buffered formalin **(standard)**   + Formalin-fixed paraffin-embedded tissue sections (FFPE) **(standard)**   + Fresh (**not standard** for NNTC, will require special arrangement) * Options for **Systemic tissues** include:   + Snap frozen block -70oC (not treated with cryopreservatives) (**standard**)   + Fixed in 10% buffered formalin (**standard**)   + Paraffin sections (**standard**) |  |
| Non-fluid Specimen: Weight/Dimensions | * *Weight/Dimensions are to be completed only for Frozen preparations.* * Specify the weight or dimensions for any tissue blocks you are requesting. * *Standard block size is ~500mg (1 cm x 1 cm x 0.5 cm). If you are requesting a different thickness, please ensure that you include justification for non-standard thickness in your concept outline.* |  |
| Non-fluid Specimen: Sections/thickness | * *This section is N/A for Level 1 requests.* |  |
| Fluid Specimen Volume | * *Fluid Specimen Volume is to be completed only for applications that include a request for fluid specimens.* * Enter the volume per aliquot being requested. Be sure that sufficient justification is included in your Concept Outline to justify the specific volume being requested. * *The standard NNTC aliquot volume is 0.5 mL for plasma, CSF, serum, and urine and 5x106 for PBMCs (non-viable). If a non-standard aliquot volume is required, you may indicate this in the table; however, please include justification in your Concept Outline section.* * *For CHARTER, the standard aliquot volume is 0.5 mL for CSF and CSF pellets, 1 mL for plasma, 1.8 mL for PBMCs, 2.5 mL for PaxRNA, 4 mL for whole blood, 8 mL for PaxDNA, and 100 µL at 10ng/µL for DNA. For any non-standard CHARTER volumes requested, please include justification in your Concept Outline section.* |  |
| # Donors | * Enter the number of donors needed for each study group. * *As you determine the number of donors needed, please remain mindful that request complexity level is driven, in part, by the total # of specimens you are requesting.* |  |
| # Specimens per Donor | * For Level 1 requests, you will not be permitted to submit an application requesting greater than 12 total specimens. * Specify the number of sections per donor you are requesting from the NNTC. * *For applications requesting sections: Standard number of sections per case is < 6. If you are requesting a different number of sections per case, please ensure that you include justification for non-standard amounts in your concept outline.* |  |
| Specimens Critical for Protocol? | * Indicate whether these specimens are critical for the completion of your proposed research. |  |
| Dataset Search Details Table  *(Summary Information)* | This is a summary table detailing the data elements of your request. Carefully review to ensure that all details are accurate. |  |

**Final Request Info**

The remainder of fields on the Final Review tab document the remaining specifications for your application.

|  |  |  |
| --- | --- | --- |
| Contact Details | The contact details captured in this portion of your application should be *your (applicant’s)* information.   * For this you will need to provide:   + Applicant Name   + Applicant Title   + Applicant Institution   + Applicant Department   + Applicant Phone   + Applicant Phone Ext   + Applicant Fax   + Applicant Email   + Is there a supervising PI on this project? * If there is a supervising PI, provide   + Supervising PI Name   + Supervising PI Institution   + Supervising PI Email   + Supervising PI Phone   + Supervising PI Phone Extension   + In the file attachment area (*see below*), upload a copy of the supervising PI’s CV or biosketch. |  |
| Shipment Details | * Enter all shipment-related information in this portion of your application. * Is there someone other than you who should be contacted for specimen shipments?   + If there is another point of contact for shipments, you will be asked to provide the following:     - Shipment Contact Email     - Shipment Contact Phone     - Shipment Contact Phone Ext     - Shipment Contact Fax * For all requests, the following shipment details must be entered:   + Shipment Address   + Shipment City   + Shipment State   + Shipment Zip Code   + Shipment Country   + Shipment Continent   + Courier Name     - *(If Other)* Specify Other Courier   + Courier Account Number |  |

**Project Details**

Enter basic project and funding information in this portion of your application.

|  |  |  |
| --- | --- | --- |
| Project Title | * Provide the title of your proposed project.   + ***Note****: This is the project title that will be reflected on any communication from NNTC (e.g., Letter of Support). Ensure that the project title is entered exactly as you would like it to appear in any such documentation.* |  |
| Project Duration | * Enter the total number of months your project is expected to take, overall. |  |
| Funding Status | * Indicate whether funding is:   + Currently being sought,   + Pending award decision, or   + Currently available. |  |
| Letter of Support Requested | * *This is applicable* ***only*** *if you are actively seeking funding and would like to request a provisional Letter of Support from the NNTC to support the funding application.* * Indicate if a provisional letter of support is required from the NNTC.   + If you require a provisional letter of support from the NNTC, it is **imperative** for you to provide any **submission deadline** you have for your funding application. |  |
| Grant/Contract Number | * *This is applicable* ***only*** *if funding is available.* * Enter the grant/contract number associated with the funding being used to support the proposed project. |  |
| Funding Source | * *This is applicable* ***only*** *if funding is available.* * Select the funding agency/type from the options provided in the dropdown menu. |  |

**General Application Details**

|  |  |  |
| --- | --- | --- |
| Post-mortem interval (hours) | * *This is applicable* ***only*** *if you are requesting post-mortem specimens.* * Enter the maximum acceptable post-mortem interval for specimens requested in your application. |  |
| Do fluids have to come from the same donor providing tissue specimens? | * Indicate if any fluid specimens ***must*** come from the same donors providing any tissue specimens for your request. |  |
| Comments | * Use this field to document any additional information relevant to your application. This is not a required field. |  |

**File Attachments**

|  |  |  |
| --- | --- | --- |
| File upload | Using the upload field provided, upload copies of all required materials. You may download these materials from the [Training/Guidance Material](https://nntc.org/trainingguidance-material) page on the study website. These include:   * NNTC Request Processing Checklist (required) * Biosketch or CV (required) * Supervising PI's Biosketch or CV (required if supervising PI included) * Project Outline Upload (required) * Supporting Documentation (optional) * Specimen Request User Agreement Upload (required for specimen requests) * Data Request User Agreement Upload (required for data requests). * Allowed file types: **pdf docx** |  |

**All requestors must sign and date this checklist document below. The *signed version* MUST be included as part of your NNTC application:**

**Requestor Name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Requestor Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (ddMMMyyyy)

1. Neurocognitive Diagnoses

| **Neurocognitive Diagnoses** | |
| --- | --- |
| **Diagnosis** | **Description** |
| Neurocognitively Normal | Participant had no significant cognitive complaints, no evidence of impairment on neuropsychological testing, and/or no loss of functional capacity. |
| Asymptomatic Neurocognitive Impairment (ANI) | Participant had no significant cognitive complaints, but neuropsychological testing revealed evidence of mild NP abnormalities that do not impair activities associated with daily living or manifest themselves with clinical symptoms. |
| Mild Neurocognitive Disorder (MND) | Participant or others report symptoms of cognitive decline; evidence of mild NP impairment; decline in functional capacity that does not reach severity required to diagnose dementia.  Subject may or may not have had a diagnostic evaluation to rule out other causes of cognitive impairment. |
| HIV-Associated Dementia (HAD) | Participant or others report symptoms of cognitive decline; evidence of moderate or severe NP impairment on neuropsychological testing; decline in functional capacity that reaches the level of a dementia; subject may or may not have had a diagnostic evaluation to rule out other causes of neuropsychological impairment. |
| Neurocognitive Impairment Other: Probable neuropsychological impairment or dementia due to other cause (NPI-O) | Participant has impairment of some degree but there is history, physical finding, or laboratory evidence of one or more opportunistic infections (such as Toxoplasmosis encephalitis, Cryptococcal meningitis, etc.), tumors (such as Primary CNS Lymphoma), other acquired neurological diseases (such as stroke), metabolic disease (such as hepatic encephalopathy) or any other condition that would cause the impairment.  A specific diagnosis is given for common HIV-related CNS diseases. |

1. Comorbid Diagnoses
   * Cardiac Disease
   * Cerebrovascular Disease
   * Chr Obstructive Pulmon Dis
   * Chronic Renal Disease
   * Diabetes
   * End Stage Liver Disease
   * Hyperlipidemia
   * Hypertension
   * Lipodystrophy
   * Non AIDS Defining Cancer
   * None
   * Not Available
   * Tobacco Smoking
   * Viral Hepatitis
2. Pathologies
   * Alzheimer type 2 gliosis
   * Anoxic-ischemic damage
   * Arteriolonephrosclerosis
   * Aseptic Leptomeningitis
   * Aseptic leptomeningitis
   * Atheroscler, coronary art
   * Atherosclerosis of brain
   * Bacterial leptomeningitis
   * Bacterial parenchymal infection
   * Blood Vessels-Aspergillus
   * Blood Vessels-Bacterial infection
   * Blood Vessels-Candida
   * Blood Vessels-Lymphoma
   * Blood Vessels-M. avium intercellulare
   * Blood Vessels-Other
   * Bone or Bone Marrow-Bacterial infection
   * Bone or Bone Marrow-Cryptococcus
   * Bone or Bone Marrow-Lymphoma
   * Bone or Bone Marrow-M. avium intercellulare
   * Bone or Bone Marrow-M. tuberculosis
   * Bone or Bone Marrow-Other
   * Bone or Bone Marrow-Other (unlisted) fungus
   * Bone or Bone Marrow-Other (unlisted) virus
   * Chronic hypertension
   * Chronic Pulmonary Disease
   * CMV Encephalitis
   * CMV Myelitis
   * CNS Neoplasm other than lymphoreticular
   * Contusion
   * Cryptococcus
   * Descending fiber tract degeneration
   * Diffuse Alverolar Damage
   * Endocrine-Aspergillus
   * Endocrine-Bacterial infection
   * Endocrine-CMV infection
   * Endocrine-Cryptococcus
   * Endocrine-Kaposi sarcoma
   * Endocrine-Lymphoma
   * Endocrine-M. avium intercellulare
   * Endocrine-Other
   * Endocrine-Other (unlisted) fungus
   * Focal (territorial) infarct
   * Gastrointestinal-Aspergillus
   * Gastrointestinal-Bacterial infection
   * Gastrointestinal-Candida
   * Gastrointestinal-CMV infection
   * Gastrointestinal-Cryptococcus
   * Gastrointestinal-Herpes virus infection
   * Gastrointestinal-Kaposi sarcoma
   * Gastrointestinal-Lymphoma
   * Gastrointestinal-M. avium intercellulare
   * Gastrointestinal-Other
   * Gastrointestinal-Other (unlisted) fungus
   * Genitourinary-Bacterial infection
   * Genitourinary-CMV infection
   * Genitourinary-Cryptococcus
   * Genitourinary-Herpes virus infection
   * Genitourinary-Lymphoma
   * Genitourinary-Other
   * Genitourinary-Other (unlisted) fungus
   * Genitourinary-Other (unlisted) virus
   * GI Cancer
   * GI Ischemic Necrosis
   * Gracile tract atrophy (ascending tract degeneration)
   * Heart-Aspergillus
   * Heart-Bacterial infection
   * Heart-Candida
   * Heart-CMV infection
   * Heart-Cryptococcus
   * Heart-Kaposi sarcoma
   * Heart-Lymphoma
   * Heart-M. tuberculosis
   * Heart-Other
   * Heart-Other (unlisted) fungus
   * Hemorrhage-dura or leptomeninges
   * Hemorrhage-parenchymal
   * Hepatitis
   * HIV Encephalitis
   * HIV Myelitis
   * HIV-assoc Nephropathy
   * Hypoxic/ischemic damage
   * Kidney End Stage Degen
   * Kidney Glomerulopathy
   * Kidney or UT Infection
   * Kidney Other Pathology
   * Kidneys-Aspergillus
   * Kidneys-Bacterial infection
   * Kidneys-Candida
   * Kidneys-CMV infection
   * Kidneys-Cryptococcus
   * Kidneys-Kaposi sarcoma
   * Kidneys-Lymphoma
   * Kidneys-M. avium intercellulare
   * Kidneys-M. tuberculosis
   * Kidneys-Other
   * Kidneys-Other (unlisted) fungus
   * Kidneys-Other (unlisted) virus
   * Kidneys-Toxoplasmosis
   * Left Ventricle Hypertroph
   * Leukoencephalopathy
   * Liver Cirrhosis
   * Liver Other Pathology
   * Liver-Aspergillus
   * Liver-Bacterial infection
   * Liver-Candida
   * Liver-CMV infection
   * Liver-Cryptococcus
   * Liver-Kaposi sarcoma
   * Liver-Lymphoma
   * Liver-M. avium intercellulare
   * Liver-M. tuberculosis
   * Liver-Other
   * Liver-Other (unlisted) fungus
   * Liver-Other (unlisted) virus
   * Liver-Toxoplasmosis
   * Lung Cancer
   * Lung-Aspergillus
   * Lung-Bacterial infection
   * Lung-Candida
   * Lung-CMV infection
   * Lung-Cryptococcus
   * Lung-Herpes virus infection
   * Lung-Kaposi sarcoma
   * Lung-Lymphoma
   * Lung-M. avium intercellulare
   * Lung-M. tuberculosis
   * Lung-Other
   * Lung-Other (unlisted) fungus
   * Lung-Other (unlisted) virus
   * Lung-Pneumocystis
   * Lung-Toxoplasmosis
   * Lymph Node-Aspergillus
   * Lymph Node-Bacterial infection
   * Lymph Node-Candida
   * Lymph Node-CMV infection
   * Lymph Node-Cryptococcus
   * Lymph Node-Kaposi sarcoma
   * Lymph Node-Lymphoma
   * Lymph Node-M. avium intercellulare
   * Lymph Node-M. tuberculosis
   * Lymph Node-Other
   * Lymph Node-Other (unlisted) fungus
   * Lymph Node-Other (unlisted) mycobacteria
   * Lymph Node-Other (unlisted) virus
   * Lymphoma
   * Microglial nodule encephalitis
   * Microglial nodule myelitis NOS
   * Minimal non-diagnostic abnormalities
   * Motor neuron disease
   * Myelitis
   * Myocardial Infarct
   * Nerve Fiber Degeneration
   * Neurofibrillary pathology (H & E or follow up stain)
   * Neuropathy
   * None
   * Not Available
   * Optic nerve atrophy/degeneration
   * Other Cardiovascular Path
   * Other GI Pathology
   * Other infections
   * Other non-infectious pathology
   * Other Periph Nerve Path
   * Other Pulmonary Path
   * Progressive multifocal leukoencephalopathy
   * Pulmonary Thromboembolus
   * Senile plaque
   * Severe Atherosclerosis
   * Severe coronary arteries
   * Soft Tissue or Cutaneous-Aspergillus
   * Soft Tissue or Cutaneous-Bacterial infection
   * Soft Tissue or Cutaneous-CMV infection
   * Soft Tissue or Cutaneous-Cryptococcus
   * Soft Tissue or Cutaneous-Herpes virus infection
   * Soft Tissue or Cutaneous-Kaposi sarcoma
   * Soft Tissue or Cutaneous-Lymphoma
   * Soft Tissue or Cutaneous-M. avium intercellulare
   * Soft Tissue or Cutaneous-M. tuberculosis
   * Soft Tissue or Cutaneous-Other
   * Soft Tissue or Cutaneous-Other (unlisted) mycobacteria
   * Soft Tissue or Cutaneous-Other (unlisted) virus
   * Soft Tissue or Cutaneous-Toxoplasmosis
   * Spleen-Aspergillus
   * Spleen-Bacterial infection
   * Spleen-Candida
   * Spleen-CMV infection
   * Spleen-Cryptococcus
   * Spleen-Kaposi sarcoma
   * Spleen-Lymphoma
   * Spleen-M. avium intercellulare
   * Spleen-M. tuberculosis
   * Spleen-Other
   * Spleen-Other (unlisted) fungus
   * Spleen-Other (unlisted) mycobacteria
   * Spleen-Other (unlisted) virus
   * Steatosis or Steatohepat
   * Sural Nerve Inflammation
   * Synucleinopathy/Lewy body
   * Systemic Atherosclerosis
   * Thrombus/Thromboembolus
   * Toxoplasmosis-active
   * Toxoplasmosis-healed
   * Tuberculosis
   * Vacuolar myelopathy
   * Vascular siderocalcinosis
3. Neuropsychiatric Diagnoses
   * Alcohol Abuse
   * Alcohol Dependence
   * Amphetamine Abuse
   * Amphetamine Dependence
   * Bipolar I Disorder, Manic, Mild
   * Bipolar I Disorder, Moderate
   * Bipolar I Disorder, Single Manic Episode, Mild
   * Cannabis Abuse
   * Cannabis Dependence
   * Cocaine Abuse
   * Cocaine Dependence
   * Dysthymic Disorder
   * Generalized Anxiety Disorder
   * Hallucinogen Abuse
   * Hallucinogen Dependence
   * Inhalant Abuse
   * Inhalant Dependence
   * Major Depressive Disorder, Recurrent, Mild
   * Major Depressive Disorder, Recurrent, Moderate
   * Major Depressive Disorder, Recurrent, Severe Without Psychotic Features
   * Major Depressive Disorder, Single Episode, Mild
   * Major Depressive Disorder, Single Episode, Moderate
   * Major Depressive Disorder, Single Episode, Severe Without Psychotic Features
   * Nicotine Dependence
   * Nicotine Withdrawal
   * None
   * Not Available
   * Opioid Abuse
   * Opioid Dependence
   * Other Substance Abuse
   * Other Substance Dependence
   * Panic Disorder Without Agoraphobia
   * Phencyclidine Abuse
   * Phencyclidine Dependence
   * Sedative Abuse
   * Sedative Dependence
4. CNS Specimen Types
   * Amygdala
   * Basal Ganglia
   * Brain
   * Brainstem
   * Caudate
   * Cerebellum
   * Cingulum
   * Circle Of Willis
   * CNS Ventricle
   * Corpus Callosum
   * Cortex
   * Cortical Grey Matter
   * Cortical White Matter
   * Dorsal Root Ganglion
   * Dorsolateral Prefrontal Cortex
   * Frontal Cortex
   * Frontal Lobe
   * Frontal Neocortex
   * Ganglion
   * Globus Pallidus
   * Hippocampus
   * Hypothalamus
   * Inferior Olive
   * Insular Cortex
   * Leptomeninges
   * Medulla
   * Meninges
   * Midbrain
   * Motor Cortex
   * Myelin Sheath
   * Nucleus Accumbens
   * Occipital Lobe
   * Occipital Pole
   * Olfactory Bulb
   * Other CNS
   * Parietal Lobe
   * Pituitary Gland
   * Pons
   * Prefrontal Cortex
   * Putamen
   * Spinal Cord
   * Striatum
   * Substantia Nigra
   * Superior Temporal Gyrus
   * Sural Nerves
   * Temporal Gyrus
   * Temporal Lobe
   * Thalamus
   * Trigeminal Ganglia
   * Visual Cortex
5. Fluid Specimen Types
   * Any Blood **(not standard)**
   * Other Fluids **(not standard)**
   * Post-Mortem Ascites **(not standard)**
   * Post-Mortem Cardiac Aspirate **(not standard)**
   * Post-Mortem CSF **(standard)**
   * Post-Mortem Plasma **(standard)**
   * Post-Mortem Serum **(standard)**
   * Post-Mortem Urine **(not standard)**
   * Pre-Mortem Cardiac Aspirate **(not standard)**
   * Pre-Mortem CSF **(standard)**
   * Pre-Mortem PBMC **(standard)**
   * Pre-Mortem Plasma **(standard)**
   * Pre-Mortem Serum **(standard)**
   * Pre-Mortem Urine **(standard)**
6. Systemic Specimen Types
   * Adipose
   * Adrenal Gland
   * Aorta
   * Bone Marrow
   * Bowel
   * Colon
   * Coronary Artery
   * Esophagus
   * Eye
   * Gut
   * Hair
   * Heart
   * Heart Artery
   * Heart Ventricle
   * Kidney
   * Liver
   * Lung
   * Lymph Node
   * Muscle
   * Other Systemic
   * Ovaries
   * Pancreas
   * Peripheral Nerve
   * Skin
   * Spleen
   * Testes
   * Thymus
   * Thyroid Gland
   * Trachea
   * Uterus
7. Genetic Material Specimen Types
   * DNA
   * mRNA
   * Other Genetic Material
   * RNA
8. Data Categories, Subcategories

| **Category** | **Subcategory** |
| --- | --- |
| **Quality of Life** | Activities of Daily Living |
| COVID-19 Questionnaire |
| HIV Motor Scale |
| Fried Frailty Index |
| Medication Management Task |
| Patient's Assessment of Own Functioning |
| Pittsburgh Sleep Quality Index |
| **Demographics** | Anthropometric Data |
| Donor Demographics |
| NNTC Donor Eligibility |
| Visit Documentation |
| **Diagnoses** | Comorbidities |
| **Laboratory Results** | Blood CBC Results |
| Blood Chemistry Results |
| Blood T-Cell Results |
| Blood Viral Load Results |
| Cerebrospinal Fluid Results |
| Laboratory Results |
| Nadir CD4 |
| Urine Toxicology |
| **Medication Use** | Concomitant Medications |
| MED/ARV Analysis Table |
| Medication Adherence |
| **Neurocognitive Profile** | Diagnostic Worksheet 1: HIV-Associated Neurocognitive Disorders |
| Diagnostic Worksheet 3: CNS OIs |
| Diagnostic Worksheet 6: HIV-Associated DSPN |
| Diagnostic Worksheet 8: Cerebrovascular Disease |
| Neurological Diagnoses |
| **Pathology** | General Pathology |
| Organ Pathology |
| Supplemental Pathology |
| **Psychiatric Profile** | Beck Depression Inventory |
| Neuropsychiatric CIDI Data |
| Neuropsychological Assessments |
| Neuropsychiatric Prism/CIDI Data |
| **Researcher-Derived Data** | Experimental Results Data |
| Experimental Results Metadata |