This form is used for any data and/or specimen requests made by any LIMBIC-CENC affiliated investigators, researchers and staff or their invited collaborators. This form is not used for requests from non-LIMBIC-CENC investigators and public uses. Please see the publication and data request policy for a detailed definition of entities covered

*Complete this form to describe your proposed research and requested use of existing LIMBIC-CENC data and/or biospecimen. A complete application includes:*

* *This completed form (no longer than 6 pages, excluding tables and graphs; instruction text in italics can be removed to stay within the page limit if needed).*
* *Selected variables from data dictionary*
* *For any collaborators not directly affiliated with the LIMBIC-CENC, a biosketch is required.*
* *IRB approval letter, if applicable*

*Any LIMBIC-CENC investigator may initiate a proposal by emailing a completed submission form and data dictionary with requested variables specified to* *cencdbc@vcu.edu**; indicate “Data Request” in the subject line. The Data and Biostatistics Core will first perform a screening assessment for scientific value, potential duplication or conflict with completed or pending projects, and general suitability of data and/or specimens requested, as well as confirm* *approval by relevant overall study PIs and/or core directors. The LIMBIC-CENC Data and Biostatistics Core will then vet further the details of the request if support from the LIMBIC-CENC Data and Biostatistics Core is requested. Once they confirm feasibility of project, the LIMBIC-CENC Research Committee will give final approval. During this evaluation process, the Research Committee may communicate back to the project PI to seek further details, seek clarifications, and/or recommend changes. Please note that, all data requests will be based on the number of participants “graduated to follow-up” (i.e., completed PCE mapping, portions of neuropsychological tests battery, DRRI-2) unless otherwise requested.*

*Once your request has been submitted and is final, it will take up to 10 business days (or longer if support from the LIMBIC-CENC Data and Biostatistics Core is requested) for the LIMBIC-CENC Research Committee to review and in consultation with the LIMBIC-CENC Director to vote on the proposal. The requestor will be notified shortly thereafter of the final decision.*

**1.** Project Title

**2.** Targeted final products *(if more than one manuscript or presentation is planned, provide details on how aims will be divided among manuscripts or presentations; e.g. 3 manuscripts total, 1 for each aim)*

|  |  |
| --- | --- |
| # of manuscripts planned: |  |
| # of presentations planned: |  |
| Other: |  |

 **Proposed target journal(s):** [Journal]

 **Proposed meeting presentations/abstracts**

 **Timeline**

|  |  |
| --- | --- |
| Start Date: |  |
| Completion Date: |  |
| Other key dates/deadlines:  |  |

**Status of IRB Approval** [ ] Included in LIMBIC-CENC approved protocol[ ]  Attached [ ]  Pending

**3.** Proposed Research Project Investigators (including PI (lead author) and co-investigators)

|  |  |  |
| --- | --- | --- |
| Research Project PI | Affiliation (include contact information) | Role/Specialty for Proposed Research |
|  |  |  |
| Collaborators | Affiliation | Role/Specialty for Proposed Research |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

**4.** Notification and Approval Dates [For Internal Use only]

|  |  |
| --- | --- |
| Approval Level | Relevant Dates |
| Research Committee Screening: [ ]  Approved [ ]  Denied | Denied or pushed to Data Core on: \_\_\_\_\_ |
| Final Decision on data/specimen release: [ ]  Approved [ ]  Denied | Expected transfer by: \_\_\_\_\_\_\_ |
| Decision on central biostats: [ ]  n/a [ ]  Approved [ ]  Denied | Expected availability by: \_\_\_\_\_\_\_\_\_ |

If any denials, rationale: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*For approved projects involving data from the Multicenter Observational Study (LIMBIC-CENC Prospective Longitudinal Study, i.e., CENC Study 1), all Prospective Longitudinal Study investigators must also be notified of the research proposal to allow for identification of additional potential collaborators. Notification occurs via* CENCSTUDY1INVESTIGATORS-L@LISTS.VCU.EDU *with a 10 business day response period. Interested collaborators should express what value they would add to the project and the project PI has final decision on who to include as collaborator and/or coauthor. The documentation for this should be listed below after the notification period is complete. For request of use of LIMBIC-CENC resources for new funding proposals, solicitation of potential collaborators is not required; however a justification is required in the comments field below for why collaborators were not pursued.*

|  |  |
| --- | --- |
| Notification Date: |  |
| Additional Interested Collaborators | Affiliation | Potential Role/Specialty for Proposed Research (include any comments or questions you have regarding inclusion of potential collaborators) |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

**[ ]**  No collaborators requested (only applicable for use of resources for new funding proposals and justification must be provided in comments field)

|  |
| --- |
| Comments:  |

**5.** Background/rationale: [Provide brief overview of background and rationale for current project. Key references may be attached separately.]

##

## 6. Research objectives and hypotheses:

[Provide numbered list of research objectives and related hypotheses: e.g.,
 Objective 1:
 Objective 2:
 …]

7. **Population definition:** [Which records should be used in the analysis? Detail any specific inclusion and exclusion criteria (beyond general study entry criteria) here.]

|  |
| --- |
| Description of subset of study subjects as well as visit records and their time-points to be included. (*e.g. inclusion/exclusion criteria such as only males, only individuals from sites x, y and z, or only those consenting for biospecimen collection; study 1 baseline data for all baseline graduate subjects; study 1 baseline data plus in-person follow-up visit data for all baseline graduate subjects)*  |
|  |

**VARIABLES AND DEFINITIONS**

**8. Outcomes:**

**Primary outcome(s):** [Primary outcome(s)]

**Secondary outcome(s):** [Secondary outcome(s)]

**Descriptive outcome(s):** [Additional outcomes to include for descriptive purposes]

**9. Other Variables:**

[List all other variables of interest for analyses, including any to be examined in relationship to the primary or secondary outcomes and/or that relate to the study objectives/hypotheses. Specify categories to be used for any variables that will be defined differently than in existing data (e.g., continuous age categorized into age groups). You may find it useful to group variables according to certain labels such as demographics, baseline characteristics, etc.]

**10**. Use LIMBIC-CENC Data Dictionary to select all variables requested

**DATA SUMMARY AND ANALYSIS PLAN**

**Sample size/power justification:**

**Analysis plan**

[Describe tables and figures to include in the manuscript (may be helpful to attach examples or mock up table layout). Outline planned analyses for each objective/hypothesis and any general thoughts related to analysis.]

**11.** Describe how LIMBIC-CENC resources will be combined and used with existing data or samples (or enter N/A):

**12.**  Who will conduct the analyses *(Select all that apply. Please contact the Data and Biostatistics Core and/or Neuroimaging Cores to discuss their involvement in research proposal prior to submission)*?

**[ ]**  Applicant **[ ]**  LIMBIC-CENC Data and Biostatistics Core **[ ]** LIMBIC**-**CENC Neuroimaging Core

**13. Delivery Information**

|  |  |
| --- | --- |
| Data Recipient | POC Name: |
| Address: |
|  |
| Phone: |
| Email: |
| Secure File Transfer Capability |  **[ ] Yes**  |  **[ ]  No** |

**OTHER SPECIMENS or COMPLEX DATA FILES**

**14.** Describe details of any data files requested not in CRFs or data dictionary (e.g. raw EEG or MRI)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [ ]  No complex data files requested

**15.** Describe LIMBIC-CENC biologic specimens requested

[ ]  No biologic specimens requested

15.a. Sample Descriptions: *Select all that apply and provide any additional details required to identify exact samples of interest . If help is required in identifying specific specimens of interest, please contact the Biomarkers Core.*

|  |  |
| --- | --- |
| **Specimen type** | **Details *(e.g. number of subjects, number of samples, amount per subject)*** |
| [ ]  Serum |  |
| [ ]  Plasma |  |
| [ ]  DNA |  |
| [ ]  Packed cells |  |
| [ ]  RNA PaxGene Tube (whole blood) |  |
| [ ]  Saliva |  |
| [ ]  Other: *specify* |  |
| Total Requested Volume |  |

15b. Delivery Information

|  |  |
| --- | --- |
| **Ship To Address:** | POC Name: |
| Address: |
|  |
| Phone: |
| Email: |
| Is a Material Transfer Agreement (MTA) Required? *(An MTA is required for specimens from the LIMBIC-CENC Biomarkers Core)* | [ ]  **Yes** | [ ]  **No** |
| Please list all institutions participating in the MTA  |  |
| MTA Status | [ ]  **Under Review** | [ ]  **Executed** | [ ]  **Pending** | [ ]  **N/A**  |

***NOTE:*** *Publications and/or presentations of research that use LIMBIC-CENC data or biologic specimens must be submitted to the LIMBIC-CENC Publications Committee at cenc@vcu.edu.*