

Full Proposal for LIMBIC-CENC Data and Specimen Use

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):

Proposed meeting presentations/abstracts

Timeline

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

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

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

Proposal for LIMBIC-CENC Data and Specimen Use

4. Background/rationale: [If unchanged, copy and paste from the preliminary form. Otherwise, provide brief overview of background/rationale for current project. Key references may be attached separately.]

5. Research objectives and hypotheses: [If unchanged, copy and paste from the preliminary form. Otherwise, provide numbered list of research objectives and related hypotheses:]

6. Population definition: [Which records should be used in the analysis? If unchanged, copy and paste from the preliminary form. Otherwise, detail any specific inclusion and exclusion criteria (beyond general study entry criteria) here.]

Description of subset of study subjects as well as visit records (*e.g. inclusion/exclusion criteria such as only males, only individuals from sites x, y and z, or only those consenting for biospecimen collection.*)

6a. Data time-point:

Proposal for LIMBIC-CENC Data and Specimen Use

VARIABLES AND DEFINITIONS

7. Outcome: *Use LIMBIC-CENC Data Dictionary to select all variables requested.**

If variables of interest are not listed in the Data Dictionary, please list them here.

DATA SUMMARY AND ANALYSIS PLAN

Sample size/power justification:

8. Analysis plan

*****All indicated variables selected from Data Dictionary must be clearly justified in your 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.]

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

10. Who will conduct the analyses (Select all that apply)

Applicant

LIMBIC-CENC Data and Biostatistics Core

LIMBIC-CENC Neuroimaging Core

Data Recipient	POC Name:	
	Phone:	
	Email:	
Secure File Transfer Capability	Yes	No

11. Status of IRB Approval:

Proposal for LIMBIC-CENC Data and Specimen Use

OTHER SPECIMENS or COMPLEX DATA FILES

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

No complex data files requested

13. Describe LIMBIC-CENC biologic specimens requested

No biologic specimens requested

13.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	

<input type="checkbox"/> RNA PaxGene Tube (whole blood)	
<input type="checkbox"/> Saliva	
<input type="checkbox"/> Other: <i>specify</i>	
Total Requested Volume	

13b. Delivery Information

Ship To Address:	POC Name:		
	Address:		
	Phone:		
	Email:		
Is a Material Transfer Agreement (MTA) Required? (<i>An MTA is required for specimens from the LIMBIC-CENC Biomarkers Core</i>)	Yes	No	
Please list all institutions participating in the MTA			
MTA Status	<input type="checkbox"/> Under Review	<input type="checkbox"/> Executed	<input type="checkbox"/> Pending <input type="checkbox"/> 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.