

October 22, 2020

**Subject:** Consortium Policy Letter #1, Long-term Impact of Military-relevant Brain Injury Consortium – Chronic Effects of Neurotrauma Consortium (LIMBIC-CENC) External Interactions

**Background:** LIMBIC-CENC desires to collaborate with researchers, consortia, industry and other organizations that have similar goals of understanding the basic, translation, or clinical science of mild Traumatic Brain Injury (mTBI) and its chronic effects in order to improve clinical care and outcomes for persons with mTBI and/or to improve the rigor of research within the mTBI field.

**Purpose:** This consortium policy letter directs how to 1) choose and capture meaningful interactions with those entities seeking an interaction with LIMBIC-CENC personnel, 2) define the level of interactions and 3) ensure the products which those interactions create are in alignment with the LIMBIC-CENC mission (<https://www.limbic-cenc.org/index.php/about/>) and the aims of the LIMBIC-CENC Cores and its research studies.

1. LIMBIC-CENC personnel or a potential external collaborator should first define a focal purpose with which they hope to establish and guide interactions. For example, the focal purpose may be to establish a data sharing agreement or to submit a joint research proposal. Defining the focus or foci is important to ensure that each party understands the purpose and goals of the interaction(s). Appendix A contains definitions. Appendix B lists the levels of interactions. Appendix C provides possible products which may result from external interactions. Appendix D provides external-facing website instructions.
2. Once the focal purpose of the interaction is identified, an external entity may request a meeting with the LIMBIC-CENC personnel or vice-versa, by emailing the request to [cenc@vcu.edu](mailto:cenc@vcu.edu).
3. Specific requests may be delegated to LIMBIC-CENC points of contact (POC) of established policies, Core leaders or researchers with transparency of interactions being made to LIMBIC-CENC leadership through interaction summaries/reports.
4. The Consortium Operating Procedure (COP) for conducting data sharing interactions and subsequent work products (Appendix E) details data sharing efforts between LIMBIC-CENC personnel and external collaborators.
5. Interactions beyond the generally accepted brief exchange of scientific ideas will be documented as per LIMBIC-CENC policy letter governing the documentation of external and collaborative engagements (Appendix F).
6. POC for this policy letter is Sidney R. Hinds II, CO-PI and LIMBIC-CENC External Collaboration (LCEC) lead, [cenc@vcu.edu](mailto:cenc@vcu.edu).



David X. Cifu

Principal Investigator,  
Long-term Impact of Military-relevant Brain Injury Consortium-Chronic Effects of Neurotrauma Consortium (LIMBIC-CENC) <https://www.limbic-cenc.org/>

## Appendix A: Definitions

**Collaboration:** any interactions which enhance the aims, goals or inherent mission of LIMBIC-CENC, but are not stated/ aims, goals of the LIMBIC-CENC grant submission. (examples data sharing calls, brainstorming or planning for grant submissions, new analyses, novel research or clinical pathways/pipelines, translational meeting...). This may include partnerships.

**Core** (LIMBIC-CENC related); one of the 4 (Coordinating Center, Data and Biostatistics, Biomarkers or Neuroimaging) intra-consortium focus groups with a designated area of interest that enables scientific discovery, harmonization, discussion, and recommendations.

**External:** any organization, consortium, research, research entity, person, industry, academia not officially recognized as a LIMBIC-CENC participant. (examples DVBIC 15-year longitudinal study, NCAA CARE, TRACK-TBI, InTBIR, NIH, ENIGMA...)

**FITBIR:** Federal Interagency Traumatic Brain Injury Research; a NIH and DoD collaborative research effort which includes personnel who facilitate TBI data entry, TBI data policy, data access and a data repository.

**GSC:** Government Steering Committee, subject matter experts, key leaders, who comprise a contractual body which oversees the progress of LIMBIC-CENC. This body meets twice per year and receives briefings from LIMBIC-CENC leadership.

**INTERACTIONS/ENGAGEMENTS:** telephone call, meeting (face-to-face, teleconference, conference contact, exchange of ideas or other interface which are potential, possible, probable and current which involve a LIMBIC-CENC member and another individual or organization.

**LIMBIC-CENC:** Long-term Impact of Military-relevant Brain Injury Consortium – Chronic Effects of Neurotrauma Consortium

**LIMBIC-CENC External Collaboration PI (LCEC):** General umbrella title for the POC responsible for the governance of the “Consortium Policy Letter #1, Long-term Impact of Military-relevant Brain Injury Consortium – Chronic Effects of Neurotrauma Consortium (LIMBIC-CENC) External Interactions”

## **Appendix B: Possible LIMBIC-CENC interactions/levels of interactions**

1. General information inquiries about LIMBIC-CENC or LIMBIC-CENC inquiries of external entities
2. Initial interaction with a potential collaborator
3. Data sharing agreement/Data/Specimen request (Appendix I)
4. Knowledge translation
5. Research proposal inquiries or discussions/publications requests (see Appendix J)
6. Research proposal collaboration
7. Conducting other mutually beneficial research interaction
8. Leadership discussions
9. Conference or meeting interaction
  - a. request for a speaker
  - b. request for attendance
  - c. other representation request
10. Request for membership
  - a. profession organization
  - b. medical advisory board
  - c. scientific advisory board
11. Request to be a SME on a panel discussion
12. Request to present a potentially useful knowledge product to LIMBIC-CENC personnel
13. Focused researcher, industry, consortium research information presentation

## Appendix B: Possible LIMBIC-CENC interactions/levels of interactions

Levels of Interaction		
	Interaction Type	Rationale/comment
<b>Tier 1</b>	<ul style="list-style-type: none"> <li>• Data/Specimen Sharing</li> <li>• Research proposal collaboration</li> <li>• Consensus Conference preparation and execution</li> </ul>	These efforts will consume the most time and research resources to successfully complete; High yield; may involve urgent use of resources and potentially a delay in other efforts; requires LIMBIC-CENC committee approval
<b>Tier 2</b>	<ul style="list-style-type: none"> <li>• Knowledge translation</li> <li>• Research proposal inquiries or discussions</li> <li>• Conducting other mutually beneficial research interaction</li> <li>• Leadership discussions</li> <li>• Publication Committee requests</li> </ul>	These efforts usually use less resources and are not as time sensitive as Tier 1 efforts; High research and clinical yield; Necessary interactions to move Tier 1 efforts forward; requires/may require LIMBIC-CENC committee approval
<b>Tier 3</b>	<ul style="list-style-type: none"> <li>• Request to present a potentially useful knowledge product to LIMBIC-CENC personnel</li> <li>• Focused researcher, industry, consortium research information presentation</li> </ul>	External organization that has knowledge it wants to share with LIMBIC-CENC personnel/leadership to either inform, gain more knowledge, form a collaboration or are seeking advice
<b>Tier 4</b>	<ul style="list-style-type: none"> <li>• Conference or meeting interaction               <ol style="list-style-type: none"> <li>a. request for a speaker</li> <li>b. request for attendance</li> <li>c. other representation request</li> </ol> </li> <li>• Initial interaction with a potential collaborator</li> </ul>	Essential and important interactions to share knowledge and promote LIMBIC-CENC awareness and education; interactions will feed other Tier efforts; actions may have or need LIMBIC-CENC committee approval/awareness



## Tier 5

- General information inquiries about LIMBIC-CENC or LIMBIC-CENC inquiries of external entities
- Initial interaction with a potential collaborator
- Requests for membership
  - a. profession organization
  - b. medical advisory board
  - c. scientific advisory board
- Requests to be a SME on a panel discussion

Represents many day to day operations of any LIMBIC-CENC personnel; may not seem as an formal request; efforts that in large numbers or requested within a short-frame use a moderate amount of resources; may lead to escalation in Tier after initial interaction; actions may have or need LIMBIC-CENC committee approval/awareness.

## **Appendix C: Desired products and outcomes of interactions, collaborations, and partnerships**

1. Knowledge translation product
  - a. Clinical recommendation (creation of or input to)
  - b. Input into a clinical practice guideline
  - c. scientific-based recommendation of a research or clinical technological solution
2. Leadership agreement
3. Investigator initiated research proposal creation/submission
4. Joint request for information/request for proposal submissions
5. Panel discussions, invitations to present consortium scientific/clinical findings
6. Letters or memorandums of agreement or cooperation
7. Planning and executing formal meetings
8. Data sharing agreements
9. Publications (articles, abstracts, presentations)
10. Requests to serve on scientific and medical advisory boards
11. Request to join larger consortia
12. Forming intellectual and goal driven organizations comprise of consortia and researchers.

## **Appendix D: Website instructions for beginning a dialogue with LIMBIC-CENC to begin an interaction**

### **Interacting with LIMBIC-CENC**

CENC had an unwritten goal and operating practice of encouraging and participating in scientific discovery interactions and collaborations. LIMBIC-CENC continues this practice in a more formal process. We maintain our commitment to share ideas but would like to have our interactions to be mutually beneficial and productive.

Consortia, researchers, industry and other external entities should first define a focus with which they hope to guide interactions. For example, the focus may be to establish a data sharing agreement or to work together to submit a research proposal. Regardless, the focus or foci are important to ensure that each party understands the purpose and goals of the interaction(s). Please refer to the example of both levels with which you may want to engage LIMBIC-CENC personnel and possible products from these interactions: Appendix B (Possible LIMBIC-CENC interactions/levels of interactions) and Appendix C (Desired products and outcomes of interactions, collaborations, and partnerships).

To request a meeting with the LIMBIC-CENC personnel, please email [cenc@vcu.edu](mailto:cenc@vcu.edu).

Thank you for your interest and we look forward to communicating with you.



**Long-Term Impact of Military-Relevant Brain Injury Consortium**  
**Chronic Effects of Neurotrauma Consortium**

1223 E Marshall Street  
Box number 980677  
Richmond, Virginia 23298  
[cencdbc@vcu.edu](mailto:cencdbc@vcu.edu)



## **Appendix E: Consortium Operation Procedure (COP) for conducting data sharing interactions and subsequent work products**

Purpose: This COP is designed to ensure LIMBIC-CENC personnel have awareness of external interaction efforts, avoid duplication of effort, and to ensure that LIMBIC-CENC senior leadership has approved or is aware of external interactions.

1. The LIMBIC-CENC External Collaboration Lead (LCEC) will meet with the LIMBIC-CENC PI before each LIMBIC-CENC Leadership meeting to report on recent interactions.
2. The LCEC will be responsible for leading, monitoring and ensuring the interactions and corresponding policies adherence.
3. The LCEC will coordinate with the corresponding leadership of the Consortia to discuss interest and goals, are in keeping the LIMBIC-CENC mission, goals and aims. If these are concordant, then the LCEC will facilitate moving forward, elevate the degree of collaboration or continuing a current collaboration.
4. Regarding data usage and sharing with external collaborators: The LCEC will facilitate telephonic or video calls among requestor, data leaders and/or study PIs. The discussion may include and are not limited to agreement upon how data is to be collected, what elements should be included, what inclusion/exclusion criteria are, to share data sets. Written agreement signed by involved parties will constitute the clearance for moving forward.
5. All agreements will be approved by the established LIMBIC-CENC governance. The LCEC will facilitate the signing of data sharing agreements and practices, sharing datasets and data dictionaries.
6. A publication agreement may be part of or in addition to the data sharing agreement. The LCEC will ensure that the collaboration participants have a written publication agreement on record with the LIMBIC -CENC Publication Committee.
7. The LCEC will ensure that the database leads and PI's agree to publish at least one article describing the two or more data sets side-by-side, with emphasis on overlapping participants and elements and highlighting potential research analyses and modifications to ongoing data collection to enhance collaboration.
8. The publication agreement will identify the writing team, agree on authorship, identify target publications and scientific conferences, generate the article(s) and proceed to next item database analysis article(s). The publication agreement should cover all potential articles that may arise from the collaboration.
  - a. The LCEC will ensure that the collaborators of each interaction gather the appropriate level of LIMBIC-CENC expertise, subject matter participation and



consensus that there is sufficient and suitable data element overlap to progress with scientific analyses.

b. If sufficient data element overlap exists, the LCEC will facilitate the interactions among the experts from each group (imaging, biomarker, PI, database, etc.) to identify and form relevant shared data set for analyses and begin analyses/manuscript formation

1.) this may be an iterative process, as there may be more than one scientific analysis and manuscript to develop

2.) regardless of the number of agreed upon analyses an a priori writing team (s), target publication(s), scientific conferences, generate article and proceed to next item (while still writing/submitting)

9. Upon completion of the agreed components of collaboration. The LCEC, in conjunction with the interaction collaborators will formulate an official long-term collaborative relationship for action and dissemination and recommend this to the LIMBIC-CENC PI for approval. Possible recommendations include but are not limited to:

- a. no further interaction is warranted
- b. develop combined data collection approach
- c. publish shared data results periodically
- d. seek joint funding to extend data collection or analyses
- e. set subsequent reassessment time points
- f. make a formal clinical or research statement

10. POC for this COP is Sidney R. Hinds II, CO-PI and LIMBIC-CENC External Collaboration (LCEC) lead, ([cenc@vcu.edu](mailto:cenc@vcu.edu)).



David X. Cifu

Principal Investigator

Long-term Impact of Military-relevant Brain Injury Consortium-Chronic Effects of Neurotrauma Consortium (LIMBIC-CENC) <https://www.limbic-cenc.org/>

## Appendix F: LIMBIC-CENC policy letter governing the documentation of external and collaborative engagements

June 8, 2020

**Subject: LIMBIC-CENC policy letter governing the documentation of external and collaborative engagements**

**Background:** LIMBIC-CENC and CENC have had since their inceptions the unwritten goal to share information/ideas with fellow researchers and research consortia which has been encouraged and promoted by the LIMBIC-CENC Government Steering Committee (GSC). LIMBIC-CENC research represents a significant and ground-breaking effort to understand the chronic effects of mild traumatic brain injury in the military and veteran populations. These efforts within the consortium are advancing the science of neurotrauma but are also poised to propel clinical care to more efficient and evidence-based practices. Collaboration and transparency are key elements of LIMBIC-CENC operations and success. Tracking the interactions of which LIMBIC-CENC researchers ensures that our researchers are focusing on the spirit of collaboration, using the aims of the consortium as a guide for interactions and setting the appropriate goals of each interaction.

### Definitions:

1. **external:** any organization, consortium, research, research entity, person, industry, academia not officially recognized as a LIMBIC-CENC participant. (examples DVBIC 15-year longitudinal study, NCAA CARE, TRACK-TBI, InTBIR, NIH, ENIGMA...)
2. **collaboration/collaborative interaction:** any interactions which enhance the aims, goals or inherent mission of LIMBIC-CENC, but are not stated/ aims, goals of the LIMBIC-CENC grant submission. (examples data sharing calls, brain storming or planning for grant submissions, new analyses, novel research or clinical pathways/pipelines, translational meeting...)
3. **interaction:** telephone call, meeting (face to face, teleconference, conference contact, exchange of ideas

### Summary:

1. Documentation of external collaborations will be tracked as a metric of LIMBIC-CENC's purposeful endeavors to promote the best science and advance clinical care in the field of chronic effects of neurotrauma.
2. **Meeting Summary Form 1.1 dtd June 8, 2020** or the most up to date form should be used to help plan interactions and document the interactions.
3. The forms may be completed electronically or may be hand-written (scanned and sent electronically to [cenc@vcu.edu](mailto:cenc@vcu.edu))
4. VCU/LIMBIC-CENC Central office will keep the summary forms and update the collaboration tracker spreadsheet.

**Point of contact for this policy letter** is Sidney R. Hinds II, CO-PI and LIMBIC-CENC External Collaboration (LCEC) lead, ([cenc@vcu.edu](mailto:cenc@vcu.edu)).



David X. Cifu  
Principal Investigator

Long-term Impact of Military-relevant Brain Injury Consortium-Chronic Effects of Neurotrauma Consortium (LIMBIC-CENC) <https://www.limbic-cenc.org/>



# VCU

## Appendix G: LIMBIC – CENC Iteration Summary Form



# VCU

Date: Month Day, Year

Internal, external collaborations interaction report

### LIMBIC-CENC Interaction Summary

**Purpose of the meeting or conference call:**

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**Who (include emails and phones):**

LIMBIC-CENC lead(s): \_\_\_\_\_

Other Organization: \_\_\_\_\_

Email(s) and telephone number(s) of the point(s) of contact for the main representatives of each organization:

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# VCU

## Appendix G: LIMBIC – CENC Interaction Summary Form



**Where:** \_\_\_\_\_

\_\_\_\_\_

**When:** Date: \_\_\_\_ Time: \_\_\_\_\_

**Summary of the meeting or discussion?**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**What are the next steps, actions, and due outs? When is the next planned or scheduled meeting?**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_



# VCU

## Appendix G: LIMBIC – CENC Interaction Summary Form



# VCU

Additional notes (i.e. list of participants, actions for each participant, actions which LIMBIC-CENC senior leadership need to address, concerns, challenges, successes...etc.)

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# VCU

## Appendix H: Sample letter to report an existing or to request an external collaboration



# VCU

Date: July 28, 2020

Subject: Letter to report an existing or to request an external collaboration

Dear Dr. Cifu,

The purpose of this letter is to request formal approval from you, the Principal Investigator, LIMBIC-CENC to proceed with an interaction with an external organization. This request is particularly important because the proposed interaction with *<external entity or organization name>* benefits the LIMBIC-CENC goals and aims *<specify which aims or goals specifically>* but may not be funded at the current time by the LIMBIC-CENC research award. Additionally, resources required to pursue this interaction may *<minimally/profoundly/other>* affect agreed-upon efforts and deliverables. This includes time and personnel resources to establish collaborative agreements, data sharing agreements or write a research funding proposal. The interaction which approval is sought clearly falls under the goal or aim of the *<Coordinating Center, Biomarker Core, Data and Biostatistics Core, Neuroimaging Core, research study or other>* but is not currently funded or the interaction will greatly improve LIMBIC-CENC aims and goals and the purpose of the interaction will gain additional funding support to augment these consortium goals and aims and not detract from its committed resources. This letter verifies that *<Coordinating Center, Biomarker Core, Data and Biostatistics Core, Neuroimaging Core, research study or other>* initiating this request has thoroughly coordinated with other LIMBIC-CENC cores, research studies and the Coordinating Center and has their support and approval for this external organization interaction which may impact their function or resourcing.

I, the undersigned will be taking the lead on the interaction with this entity and will keep LIMBIC-CENC External Collaboration (LCEC) lead, ([cenc@vcu.edu](mailto:cenc@vcu.edu)) as per the Long-term Impact of Military Relevant Brain Injury Consortium – Chronic Effects of Neurotrauma Consortium (LIMBIC-CENC) External Interactions policies.

<First name Y. Last Name>

<LIMBIC-CENC Title>

Long-term Impact of Military-relevant Brain Injury Consortium-Chronic Effects of Neurotrauma Consortium (LIMBIC-CENC) <https://www.limbic-cenc.org/>

Sample letter to commence/report an existing collaboration dtd July 28, 2020



# VCU

## Appendix H: Sample letter to request termination or change in status of an external collaboration



Date: July 28, 2020

Subject: Letter to request <termination of an/reducing commitment with> external collaborator

Dear Dr. Cifu,

The purpose of this letter is to request formal approval from you, the Principal Investigator, LIMBIC-CENC to <terminate/reduce> the level of collaboration with <external entity or organization name>. After careful consideration of the reason for establishing the external collaboration, risks and benefits and need for mitigation to sustain unneeded function(s) or service(s), the <Coordinating Center, Biomarker Core, Data and Biostatistics Core, Neuroimaging Core, research study or other> recommends the following actions: <free text>. This letter verifies that <Coordinating Center, Biomarker Core, Data and Biostatistics Core, Neuroimaging Core, research study or other> making this request has thoroughly coordinated with other LIMBIC-CENC cores, research studies, Coordinating Center and has their support and approval to <terminate, reduce the commitment> with this external organization interaction because this change in collaboration status may impact their function or resourcing.

<State the main reasons for termination or reducing commitment>

I, the undersigned will ensure the LIMBIC-CENC External Collaboration (LCEC) lead, ([cenc@vcu.edu](mailto:cenc@vcu.edu)) is aware of this change in collaboration status, as per the Long-term Impact of Military Relevant Brain Injury Consortium – Chronic Effects of Neurotrauma Consortium (LIMBIC-CENC) External Interactions policies.

<First Name Y. Last Name>

<LIMBIC-CENC Title>

Long-term Impact of Military-relevant Brain Injury Consortium-Chronic Effects of Neurotrauma Consortium (LIMBIC-CENC) <https://www.limbic-cenc.org/>

Sample letter to terminate or reduce the commitment of an existing collaboration dtd July 28, 2020



## Appendix I: LONG-TERM IMPACT OF MILITARY-RELEVANT BRAIN INJURY CONSORTIUM-CHRONIC EFFECTS OF NEUROTRAUMA CONSORTIUM (LIMBIC-CENC) Proposal for LIMBIC-CENC Data and Specimen Use

### LONG-TERM IMPACT OF MILITARY RELEVANT BRAIN INJURY CONSORTIUM-CHRONIC EFFECTS OF NEUROTRAUMA CONSORTIUM (LIMBIC-CENC) Proposal for LIMBIC-CENC Data and Specimen Use

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](mailto: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:	



## Appendix I: LONG-TERM IMPACT OF MILITARY-RELEVANT BRAIN INJURY CONSORTIUM-CHRONIC EFFECTS OF NEUROTRAUMA CONSORTIUM (LIMBIC-CENC) Proposal for LIMBIC-CENC Data and Specimen Use

### LONG-TERM IMPACT OF MILITARY RELEVANT BRAIN INJURY CONSORTIUM-CHRONIC EFFECTS OF NEUROTRAUMA CONSORTIUM (LIMBIC-CENC) Proposal for LIMBIC-CENC Data and Specimen Use

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: <input type="checkbox"/> Approved <input type="checkbox"/> Denied	Denied or pushed to Data Core on: _____
Final Decision on data/specimen release: <input type="checkbox"/> Approved <input type="checkbox"/> Denied	Expected transfer by: _____
Decision on central biostats: <input type="checkbox"/> n/a <input type="checkbox"/> Approved <input type="checkbox"/> 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](mailto: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)



## Appendix I: LONG-TERM IMPACT OF MILITARY-RELEVANT BRAIN INJURY CONSORTIUM-CHRONIC EFFECTS OF NEUROTRAUMA CONSORTIUM (LIMBIC-CENC) Proposal for LIMBIC-CENC Data and Specimen Use

### LONG-TERM IMPACT OF MILITARY RELEVANT BRAIN INJURY CONSORTIUM-CHRONIC EFFECTS OF NEUROTRAUMA CONSORTIUM (LIMBIC-CENC) Proposal for LIMBIC-CENC Data and Specimen Use

☐ 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

\*\*\*All indicated variables selected must be clearly justified in your analysis plan.\*\*\*

#### 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. All variable selections must be justified in your data request.]



## Appendix I: LONG-TERM IMPACT OF MILITARY-RELEVANT BRAIN INJURY CONSORTIUM-CHRONIC EFFECTS OF NEUROTRAUMA CONSORTIUM (LIMBIC-CENC) Proposal for LIMBIC-CENC Data and Specimen Use

### LONG-TERM IMPACT OF MILITARY RELEVANT BRAIN INJURY CONSORTIUM-CHRONIC EFFECTS OF NEUROTRAUMA CONSORTIUM (LIMBIC-CENC) Proposal for LIMBIC-CENC Data and Specimen Use

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  
Core

☐ LIMBIC-CENC Data and Biostatistics Core

☐ LIMBIC-CENC Neuroimaging

#### 13. Delivery Information

Data Recipient	POC Name:	
	Address:	
	Phone:	
	Email:	
Secure File Transfer Capability	<input type="checkbox"/> Yes	<input type="checkbox"/> 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)
<input type="checkbox"/> Serum	
<input type="checkbox"/> Plasma	
<input type="checkbox"/> DNA	
<input type="checkbox"/> Packed cells	



## Appendix I: LONG-TERM IMPACT OF MILITARY-RELEVANT BRAIN INJURY CONSORTIUM-CHRONIC EFFECTS OF NEUROTRAUMA CONSORTIUM (LIMBIC-CENC) Proposal for LIMBIC-CENC Data and Specimen Use

### LONG-TERM IMPACT OF MILITARY RELEVANT BRAIN INJURY CONSORTIUM-CHRONIC EFFECTS OF NEUROTRAUMA CONSORTIUM (LIMBIC-CENC) Proposal for LIMBIC-CENC Data and Specimen Use

<input type="checkbox"/> RNA PaxGene Tube (whole blood)	
<input type="checkbox"/> Saliva	
<input type="checkbox"/> Other: <i>specify</i>	
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)	<input type="checkbox"/> Yes	<input type="checkbox"/> 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](mailto:cenc@vcu.edu).





# VCU

## Appendix J: PUBLICATION COMMITTEE REQUEST FORM



### Publication Committee Request Form

When submitting a publication request, please include the following **with** your submission: **1)** Publication Request Form **2)** plain language summary of the publication for posting on the CENC website and for possible distribution to DoD/VA representatives. In order to ensure accurate reporting, please fill out the entire form. All initial and subsequent submission/publication correspondence must be sent to [cenc@vcu.edu](mailto:cenc@vcu.edu).

#### Requestor Information

Name: \_\_\_\_\_

Email: \_\_\_\_\_

LIMBIC-CENC

affiliation: \_\_\_\_\_

#### Publication Details

Title : \_\_\_\_\_

Author(s): \_\_\_\_\_

Study \_\_\_\_\_

affiliation: \_\_\_\_\_

Publication  
type:

☐ Abstract/ poster

Event: Click or tap here to enter text.

Location/Date: Click or tap here to enter text.

☐ Lecture or oral presentation

Event: Click or tap here to enter text.

Location/Date: Click or tap here to enter text.

☐ Journal article

Journal name: Click or tap here to enter text.

☐ Media release

Media title: Click or tap here to enter text.

**Please ensure that the following language is included in your publication that uses LIMBIC-CENC data.**

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**Note: A different acknowledgment is used for CENC "snapshot" data. Contact [cenc@vcu.edu](mailto:cenc@vcu.edu) to obtain the CENC acknowledgment or if you have any questions.**