

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Other Than Full and Open Competition

1. **Contracting Activity:** Department of Veterans Affairs, Network Contracting Office (NCO 1 New England) on behalf of The VA National Center for Post Traumatic Stress Disorder (NCPTSD).
2. **Nature and/or Description of the Action Being Processed:**

A sole source agreement with the Lieber Institute, Baltimore, Maryland is under consideration for the US Department of Veterans Affairs to acquire donor brain organs. The proposed sole source contract is for four (4) years to acquire approximately 40 - 50 extant brain hemispheres per contract year. The total estimated cost of the contract is \$3,250,000.00 to \$4,000,000.00 for the acquisition of 40 - 50 brain hemispheres per contract year.

The US Department of Veterans Affairs and the Lieber Institute, Baltimore, Maryland shall engage in an agreement that fulfills the donative intent of the organ donor and the representatives of the organ donor. Acquisition by the Department of Veterans Affairs of donor organs is a trustee-to-trustee donative transfer and limited to reimbursable costs of the trustee custodian Lieber Institute, a non-profit incorporated under the State of Maryland.

The biological basis of PTSD is an area of intense scientific interest, as it is clear that “omics” approaches (genomics, transcriptomics, proteomics, methlyomics, etc...) offer the possibility of significantly advancing an understanding of the underlying mechanisms contributing to the systems-level abnormalities of brain circuits in this stress-related disorder. In addition, the recent development of new methods for staining, visualizing and imaging neuronal circuits on a macro-scale opens up never-before imagined opportunities for quantifying neuronal circuit morphometrics. Understanding the cellular and circuit contributions to abnormal brain activity in PTSD is critical in the search for potential biomarkers of susceptibility, illness and treatment response and for developing new treatments targeting the conditions at the cellular level. This requires both experience and knowledge in the area of PTSD as well as neuroanatomy and molecular approaches to psychiatric illnesses.

There will be three primary areas to identifying quality brains for the National Center Post Traumatic Stress Disorder Brain Bank :

1. **Administrative Infrastructure:** The NCPTSD requires a brain bank to oversee the collection, processing, postmortem clinical assessments, and distribution procedures of postmortem tissue for the scientific community. The Lieber Institute for Brain Development is located in Baltimore in the Johns Hopkins Bioscience Park where there are many opportunities for collaboration and partnerships with Johns Hopkins University (JHU) School of Medicine and Hospital. Lieber Institute scientists and staff have full access to all research and clinical facilities of the JHU Medical Campus and additional resources, including the Kennedy Krieger Institute and the National Institutes of Health. The Lieber Institute is a premier Brain Bank and the only Brain Bank that will be able to fulfill the needs of the NCPTSD and the National PTSD Brain Bank.

2. Collection: Tissue preservation procedures will follow standard protocols of preserving fresh-frozen specimens to facilitate systematic omics studies. In addition, specialized protocols (modified Golgi staining, immunohistochemistry, *in situ* hybridization) will be implemented to facilitate the examination of structural changes of these same brain regions. The Lieber Institute facilities include a large fully outfitted state-of-the-art general laboratory and specialty in-house facilities for organic chemistry, genetics, cell and tissue culture, advanced imaging and laser capture microscopy, neuropathology, and molecular biology.
3. Diagnostic Interviews: Clinical assessment of tissue donors across all collection sites will undergo a centralized clinical review process that includes interviewing donor families to determine a post-mortem psychiatric diagnosis of the donor, prior experiences that may present co-morbid effects such as Traumatic Brain Injury (TBI), determining mood state in the last week of life, assessment of childhood trauma and review of medical records, toxicology and neuropathology reports. The Lieber Institute has experience conducting diagnostic interviews and is the only brain bank that will be able to meet the NCPTSD needs by supplying the quantity of brain hemispheres supported by diagnostic and clinical assessment.

3. Description of Supplies/Services Required to Meet the Agency's Needs:

This will be a per brain hemisphere fixed price IDIQ contract for a term of four (4) years. The contractor shall provide all labor, post-mortem diagnostic interviews, clinical assessments, and tissue preparation required to deliver brain hemispheres to the NCPTSD Brain Bank. The contractor shall use standard protocols in preserving fresh-frozen specimens to facilitate systematic omics studies. The contractor shall also conduct centralized clinical review processes that include interviewing donor families to determine a post-mortem psychiatric diagnosis of the donor, prior experiences that may present co-morbid effects such as TBI, determining mood state in the last week of life, assessment of childhood trauma and review of medical records, toxicology and neuropathology reports.

4. Statutory Authority Permitting Other than Full and Open Competition:

(1) Only One Responsible Source and No Other Supplies or Services Will Satisfy

Agency Requirements per FAR 6.302-1;

(2) Unusual and Compelling Urgency per FAR 6.302-2;

(3) Industrial Mobilization, Engineering, Developmental or Research Capability

or Expert Services per FAR 6.302-3;

(4) International Agreement per FAR 6.302-4

(5) Authorized or Required by Statute FAR 6.302-5;

(6) National Security per FAR 6.302-6;

(7) Public Interest per FAR 6.302-7;

5. Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):

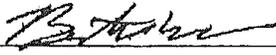
Only One Responsible Source ([FAR 6.302-1](#)):

Lieber Institute is the only brain bank in the nation that can provide this quantity of appropriately processed brains from well-diagnosed PTSD individuals.

The Lieber Institute's background working with brains will enable the NCPTSD brain bank to continue to move efficiently from the start-up phase to a fully developed national brain bank. Once established, the National PTSD Brain Bank will allow VA researchers to use postmortem brain tissue in order to conduct research on genes and microRNAs that may contribute not only to known drug-responsive pathways, but also novel pathways that have not yet been targeted for pharmacological manipulations including genes linked with Alzheimer's dementia.

- 6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** Very few brain banks are qualified to deliver quality brains and infrastructure that will allow for the continuation of the start-up of a national PTSD Brain Bank. Among those qualified brain banks that were contacted only the Lieber Institute had the capability to supply the quantity and quality of brain hemispheres. VA researchers at the NCPTSD also contacted colleagues at the National Institute of Mental Health, Yale University, Harvard University, Boston University, Dartmouth College, the DOD, US Uniformed Health Service (USUHS) and Texas A&M for recommendations of a capable brain bank for both quantity and quality. The contacts at these institutions either did not have a suggestion or suggested that the NCPTSD contact the Lieber Institute.
- 7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:**
Data other than cost and pricing data for both direct and indirect costs to determine cost reimbursement reasonableness is required under FAR 15.403-3. Cost information is required to include the appropriate data on the costs reimbursed for the same or similar item.
- 8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:**
There are very few Brain Banks that are qualified to facilitate this type of research by supplying brain hemispheres with a confirmed PTSD diagnosis. The Lieber Institute has unique qualifications necessary to work with the NCPTSD to continue to develop the National PTSD Brain Bank. The Lieber Institute is the only brain bank able to provide the quantity and quality of extant PTSD brain hemispheres.
- 9. Any Other Facts Supporting the Use of Other than Full and Open Competition:** The prior FY14 contract was solicited on the open market via FBO and received only one response from the Lieber Institute.
- 10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** None known.
- 11. A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required:**
The VA Research Team will continue to monitor the existing brain banks to determine if the availability of PTSD extant brain hemispheres should change. Any future year with a need for a significantly reduced quantity may provide an opportunity for competition. The NCPTSD shall continue to monitor and survey national organ banks. The US Department of Veterans Affairs shall publish this Justification and Approval to Federal Business Opportunities (FBO), the Government Point of Entry (GPE).

12. **Requirements Certification:** I certify that the requirement outlined in this justification is a *bona fide* need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.


Bertrand Huber M.D.
Facility Director, PTSD Brain Bank
VA Boston Healthcare

9-9-15
Date

13. **Approvals in accordance with FAR 6.304**

a. **Contracting Officer's Certification (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

MICHAEL R.
CORRIVEAULT 223457
Michael Corriveau
CONTRACTING OFFICER
Facility:

Digitally signed by MICHAEL R. CORRIVEAULT 223457
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b. **Director of Contracting / Designee (Required \$150K and above):** I certify the justification meets requirements for other than full and open competition.

Deborah F. Mattingly 180153
Deborah Mattingly
NCO 1 (New England) Director of Contracting

Date

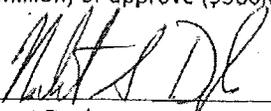
c. **SAO:** I certify the justification meets requirements for other than full and open competition.

TERRY L.
SPITZMILLER
394683
Terry Spitzmiller
Director, Service Area Office East

Digitally signed by TERRY L. SPITZMILLER 394683
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8/17/2015
Date

d. **VHA HCA Review and Approval:** I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and recommend approval (if over \$10million) or approve (\$500K to 10 million) for other than full and open competition.


Norbert Doyle
VHA Head of Contracting Activity (HCA)

9/21/15
Date