

## 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 of Brain Development (LIBD) is under consideration for the US Department of Veterans Affairs to acquire donor brain organs. The proposed sole source contract is for five (5) years to acquire approximately 40 extant brain hemispheres per contract year. The total estimated cost of the contract is \$4,150,000.00 for the acquisition of 40 brain hemispheres per contract year.

There will be three primary areas to identifying quality brains for the NCPTSD:

1. **Administrative Infrastructure:** The NCPTSD requires the continued development of a brain bank to oversee the collection, processing, postmortem clinical assessments, and distribution procedures of postmortem tissue for the scientific community. The LIBD 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 five (5) 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 be 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.

**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 would meet the needs of the 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 have specifically discussed the acquisition of brain hemispheres with both the University of Pittsburgh and the University of Miami. Neither institution was capable and/or willing to contract for the quantity and quality available from the Lieber institute.

**7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:**

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.

Certified cost or pricing data for both direct and indirect costs to determine cost reimbursement reasonableness is required under FAR 15.403-3.

The Lieber Institute's agreement with DHHS for the indirect cost rate and fringe benefit rate will be used as required for all federal grants and contracts.

**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 is the only brain bank able to provide the quantity and quality of extant PTSD brain hemispheres.

See attached statement from Dr. Friedman as Senior Consultant for the National Center for PTSD.

**9. Any Other Facts Supporting the Use of Other than Full and Open Competition:**

The FY14 contract was solicited on the open market via FBO and received only one response which was 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.

**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

\_\_\_\_\_  
Date

**13. Approvals in accordance with the [VHAPM, Volume 6, Chapter VI: OFOC SOP](#).**

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

\_\_\_\_\_  
Name

\_\_\_\_\_  
Date

- b. **Director of Contracting /Designee (Required over\$150K but not exceeding \$700K)**: I certify the justification meets requirements for other than full and open competition.

\_\_\_\_\_  
Name  
NCO01 Director of Contracting or Designee

08/22/2017  
\_\_\_\_\_  
Date

- c. **VHA SAO 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 \$13.5 million) or approve (\$700K to 13.5 million) for other than full and open competition.

\_\_\_\_\_  
Name  
VHA Head of Contracting Activity (HCA)

08/23/2017  
\_\_\_\_\_  
Date



**DEPARTMENT OF VETERANS AFFAIRS**  
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June 23, 2017

In Reply Refer To: 405/00

Matthew J. Friedman, MD, PhD  
Senior Consultant (116D)  
National Center for PTSD  
WRJ VAMC & RO  
215 N. Main Street  
White River Junction, VT 05009

Dear Ms. Clements,

I am writing to address your request for additional information on our proposed contract to purchase brain hemispheres from the Lieber Institute for Brain Development (LIBD) located in Baltimore, MD. , It is important to recognize that until the National Center for PTSD established the VA's National PTSD Brain Bank (NPBB), no resource of this kind existed in the world. The LIBD has been acquiring PTSD brains (along with many other brains with psychiatric disorders) for over 4 years. It is clearly the only facility in the U.S. that has the inventory of brain tissue needed to carry out the research described in the proposed contract.

I know of only two other potential sources of PTSD brain tissue, the University of Pittsburgh (UP) and University of Miami (UM), both of which rank among the best psychiatric brains banks in the U.S. and both of which have collaborated in some way with National PTSD Brain Bank (NPBB).

I spoke with Ronald Duman PhD at the West Haven VA and Yale (6/22/2017) who directs NPBB's intramural research program. He has a long-standing research collaboration with Dr. David Lewis, Chair of Psychiatry and Director of UP's brain bank. Dr. Duman has been asking Dr. Lewis for PTSD brains for many years and has repeated such requests recently. Although Dr. Lewis has shared some specific brain sections with Dr. Duman, he continues to refuse to send NPBB either whole brain hemispheres or anywhere near the large number of brain sections needed for the proposed LIBD contract.

Dr. Deborah Mash directs the University of Miami Brain Bank and is also regarded, by NIMH as one of the top psychiatric brain banks in the US. Dr. Mash has recently joined the NPBB consortium and will provide 10 PTSD brains over the next year. She will be able to meet this relatively modest requirement for PTSD brains but has no other such tissue in her current inventory. As she told me by phone today (6/22/2017), she is unable to provide additional PTSD brains needed to carry out the research in the proposed LIBD contract or the additional brains from normal controls and from individuals who were depressed during their lives.

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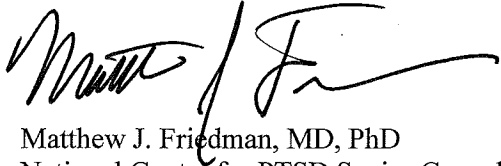
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I hope that this addresses questions that you may have and if you need to reach me you can contact me at [matthew.friedman@dartmouth.edu](mailto:matthew.friedman@dartmouth.edu) or 802-296-5132. We appreciate all of your work on this contract and I am confident that we will be able to award this contract prior to the end of the fiscal year.

Sincerely,

A handwritten signature in black ink, appearing to read "Matt J. Friedman". The signature is fluid and cursive, with a large initial "M" and "F".

Matthew J. Friedman, MD, PhD  
National Center for PTSD Senior Consultant