DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval (J&A) For Other Than Full and Open Competition (>\$150K)

Acquisition Plan Action ID: VA241-17-AP-5861

1. <u>Contracting Activity</u>: 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:

The service entails DNA and RNA extraction and data analysis from 320 Lieber Institute of Brain Development (LIBD) tissue samples. The overall goal is to identify therapeutic targets of relevance to PTSD utilizing human brain derived datasets from postmortem tissue across multiple brain regions and diagnostic groups.

A firm fixed price contract with an estimated value of \$3,695,000 is planned.

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

Laboratory services to conduct RNA-sequencing (RNAseq), whole genome bisulfite sequencing (WGBS), and genotyping across several brain regions of tissue samples from the brains of PTSD, MDD and control groups.

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

- (X) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
- 5. <u>Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires</u> the Use of the Authority Cited Above (applicability of authority):

Only One Responsible Source (FAR 6.302-1)

Revision 05 Date: 05/02/2016

Lieber Institute is the only brain bank in the nation that has the quantity and quality of appropriately processed brains from well-diagnosed PTSD individuals, psychiatric and normal controls. Lieber Institute is the only brain bank able to supply the tissue used in this contract. The brain tissue is being contributed by the Lieber Institute, at no cost to the VA, so long as we use their laboratory services. If we were to acquire the brain tissue from Lieber and then use different laboratory analysis services we would incur a substantial cost for the brain tissue. Cost of the brain tissue is estimated at \$640,000. (This is assuming that Lieber would be willing to allow us to acquire the brain tissue and take it elsewhere for analysis.)

6. <u>Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable</u>:

We could solicit the laboratory services from other sources. But doing so would require us to acquire the brain tissue from the Lieber institute at an estimated cost of \$640,000. This cost is substantially larger than any cost savings that could be achieved by using a different laboratory service. (This is assuming that Lieber would be willing to allow us to acquire the brain tissue and take it elsewhere for analysis.)

See attached statement documenting difficulty in acquiring brain tissue from other than the Lieber Institute.

7. <u>Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:</u>

Data other than cost and pricing data for both direct and indirect costs to determine cost reimbursement reasonableness will be requested.

DHHS agreement as to indirect cost rate and fringe benefit rate will be used as required for all federal grants and contracts.

Potential cost savings from using a different laboratory service will be compared to the additional cost of acquiring the brain tissue from the Lieber Institute.

8. <u>Description of the Market Research Conducted and the Results, or a Statement of the Reasons</u> <u>Market Research Was Not Conducted:</u>

The Lieber Institute is the only brain bank able to provide the quantity and quality of brain tissue for analysis. Since the Lieber Institute is making the brain tissue available at no cost we are restricted to using their laboratory services.

- **9.** Any Other Facts Supporting the Use of Other than Full and Open Competition: The national Center for PTSD has established an MOU for the sharing of research
- **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 NCPTSD shall continue to monitor and survey national organ banks to determine if there are alternate sources for the brain tissue that would allow the use of other laboratory services.

Revision 05 Date: 05/02/2016

Request for Sole Source Justification Format >\$150K

	Name Title	Date
	Facility	
App	provals in accordance with the VHAPN	Л, Volume 6, Chapter VI: OFOC SOP.
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a.		ertification (required): I certify that the foregoing e to the best of my knowledge and belief.
	Contracting Officer	Date
b.		Required over\$150K but not exceeding \$700K):
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b.	the justification meets requirements NCO 01 Director of Contracting	for other than full and open competition. 8/22/2017 Date
b.	NCO 01 Director of Contracting VHA SAO HCA Review and Approval be complete and accurate to the best	8/22/2017 Date or Designee I have reviewed the foregoing justification and t of my knowledge and belief and approve (\$700)
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Revision 05 Date: 05/02/2016



DEPARTMENT OF VETERANS AFFAIRS

Veterans Affairs Medical Center 215 North Main Street White River Junction, VT 05009 866-687-8387 (Toll Free in New England) 802-295-9363 (Commercial)

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.

Bennington CBOC 186 North Street Bennington, VT 05201 (802) 440-3300 Brattleboro CBOC 71 GSP Drive Brattleboro, VT 05301 (802) 251-2200 Burlington CBOC 128 Lakeside Avenue Burlington, VT 05401 (802) 657-7000 Littleton CBOC 264 Cottage Street Littleton, NH 03561 (603) 575-6701 Rutland CBOC 232 West St Rutland, VT 05701 (802) 772-2300 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 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,

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