

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

Acquisition Plan Action ID:526-18-2-1917-0148 (\$496,291.41)- BD Influx Cell Sorter

1. **Contracting Activity:** Department of Veterans Affairs, SAO-E, R&D Contracting. End User: VA Bronx Medical Center.
2. **Nature and/or Description of the Action Being Processed:** New award- firm, fixed-price contract. The vast majority of quantitative studies of gene and protein expression and epigenetic features such as promoters and regulatory elements in the brain, whether in animal models or in postmortem human samples have been conducted in bulk tissue specimens dissected from various regions. This approach has greatly enhanced our knowledge and understanding of brain neurobiology. However, these studies, by their very nature, have had to contend with the inability to address the *in situ* neurobiology of the many specific cell types that are present in any given brain region. Okaty et. al. wrote "Complicating this enterprise [referring to whole-genome-transcriptomics and proteomics] is the fact that the brain is comprised of a famously diverse menagerie of cell types, limiting the utility of data obtained from tissue homogenates"³. Since many, if not most transcripts and proteins are expressed in most cell types, it has been difficult to determine the cells of origin contributing to changes observed in experimental models, experimental (e.g., pharmacological) manipulations or disease states. Perhaps more importantly, the amalgamation of different cell types in studied samples has had the potential of obscuring extant differences in specific cell types due to absence of changes, or changes in opposing directions, in other cell types. A ShEEP grant has provided us with the funds to purchase a BD Influx fluorescence activated cell sorting (FACS) system to enable separation of different cell types from bulk tissue. The BD Influx will enable us to study gene and protein expression in different human organ cell types individually.

FAR13.5 Simplified Procedures for Certain Commercial Items: *This procurement is for commercial items (BD Influx Cell Sorter) in accordance with FAR 13.5 Simplified Procedures for Certain Commercial Items and specifically FAR 13.501 Special Documentation Requirements, where acquisitions conducted under Simplified Acquisition Procedures are exempt from the requirements of FAR Part 6, but still require a justification using the format of FAR 6.303-2.*

Description of Supplies/Services Required to Meet the Agency's Needs: Different FACS systems are available; however, we have selected the BD Influx system because it provides the most capabilities for the varied cell types that we plan to study. Significant expertise exists at our local affiliate for the service, maintenance and use of this system; and because inquiries of different FACS cores in the New York City area have lauded the BD service of this high maintenance system to be far superior to the service provided by other manufacturers. In addition, the BD Influx system has the following features that are essential to the research projects that were originally proposed and subsequently funded by the ShEEP application:

- Smaller footprint. This feature is Key since physical space is for the instrument is limited
 - Moveable frame on wheels
 - Pair of forward scatter detectors capable of separating polarized fluorescence and scatter signals
 - Configurable, exchangeable fluorescence detectors
 - 4.5 decade, low-noise logarithmic PMT amplifiers
 - Special ADC conversion mode to determine background signal
 - Quick-exchange nozzle assembly and exchangeable fluidics to prevent contamination in PCR reactions
 - 16 analog preamplifiers and 16 logarithmic amplifiers

- 5 microsecond cycle time at 16 parameters input
- Real-time cross-talk compensation
- Spatial separation of fluorescence signals by pinholes in mirrored surface for ease of instrument alignment
- Separate laser excitation paths
- Option for fluorescence polarizer
- Sensitivity scatter: >0.2 micrometer standard (<0.2 micrometer with optional Small Particle Scatter)
- Fluorescence: better than 125 MESF FITC
- Noise level of non-integrating signal input 2 photons or less
- Goniometric nozzle positioner alignment
- Spatial filter with pinhole for each channel
- Phase check for easy and accurate sort adjustment
- Closed work space with spill area, stainless steel, cleanable
- Laser in vertical plane can be reconfigured
- Detector array coupled to microscope image guarantees resolution and background suppression close to theoretical performance limits
- Very short sample path, no dead corners, low dead volume
- UV sterilization of work space
- High-current photomultipliers for extended linearity
- Sort stream observation
- Forward scatter measured with PMT
- Center pinhole for measuring very weak signals or for special experiments
- Sort plates move out of the way and can be cleaned
- Internal RS-485 loop for steppers and other peripheral devices
- Data bus collates event information in transparent package; includes sort decision; will combine compensated and raw data
- Accepts a range of nozzle diameters: 70, 100, 140, and 200um
- Instrument available with HEPA-filtered enclosure for operator or product protection

We have performed extensive market research for different cell sorter instruments and found that BD Influx better meets our demands along with reasonable long-term cost – maintenance. The specific configurations that we have selected for the BD Influx cell sorter were designed to meet all of our major user's scientific protocols requirements. While the Beckman Coulter MoFlo Astrios EQ and BD Influx cell sorters have many features in common, the BD Influx has analog data processing necessary for precise measurements of brain-related cellular parameters outlined in major user's protocols. MoFlo Astrios EQ and BD Arias have only digital data processing.

Additionally, the sterilization by UV light of sorting chamber to provide clean environment for sorting presents in BD Influx that is very important for our major user's scientific protocols. This is a critical feature since we will be using the instrument for research with human postmortem brain tissues. This feature is absent in the Beckman Coulter MoFlo Astrios EQ.

Lastly, in our research and coordination with other major laboratories in the New York City area (e.g., Columbia University) we find that those using the Beckman Coulter product have experienced significant delays in obtaining required services on the system, while service on BD Influx has been in days or hours vice weeks or months. Such delays have serious impact on the performance of our scientific tasks and warrant significant consideration in the purchase of a cell sorter system.

3. 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; (6.302-1(a)(1)&(2); 6.302-1(b)(1)(i)
- () (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;

a. **Only One Responsible Source (FAR 6.302-1)** –(6.302-1(a)(1)&(2); 6.302-1(b)(1)(i)

FAR13.5 Simplified Procedures for Certain Commercial Items: *The authority for applying the Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. 1901 and is implemented by for restricting competition on this procurement via FAR 13.106-1(b)(2).*

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

The end user's market research and sole-source justification are well supportive of a sole-source procurement to Becton Dickinson (BD). In particular, the end users provide in their documentation the relative capabilities between the preferred system (BD Influx) and the (including Becton Coulter (BC) MoFlo Astrore EQ clearly indicating that the BC machine did not meet their requirements in all respects- notably:

- The BD Influx provides more capabilities for the varied cell types to be studied;
- The specific configurations of the BD Influx as selected by the end users were designed to meet specific scientific protocols;
- The BD Influx as analog data processing necessary for precise measurement of brain-related cellular parameters outlined in major user's protocols. MoFlo Astrios EQ and BD Arias have only digital data processing. Curiously, analog produces better images needed in this clinical context. This is a critical feature since the end user will be using the instrument for research with human postmortem brain tissues. This feature is absent in the BC MoFloAstrios EQ;
- Professional outreach and coordination with other major laboratories in the New York City area (i.e., Columbia University) found that those using the BC product have experienced significant delays in obtaining required services on the system, while those using the BD Influx report obtaining required services in days or hours vice weeks or months. This is no small consideration and the latter delays, if experienced by the end user, would seriously impact upon the performance of their scientific tasks.
- Market research also made direct comparisons between the BD Influx system and the BC MoFlo Astrore EQ system and determined that the lasers and filters provided by the BD system were more suitable to the research they intend to implement;
- The sterilization by UV light of sorting chamber to provide clean environment for sorting presents in BD Influx that is very important for the major user's scientific protocol.

5. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:

Sources Sought Synopsis: A sources-sought synopsis was issued on 3/13/18, RFQ 36C24E18Q0073, stating the intent to sole source and listing the salient characteristics. A single response was received from Beckman Coulter (BC), an LB competitor: That response was reviewed by the CO and more importantly, by the end users including the Research Director Dr. Haroutunian. On 3/19/18, CO was notified by an email from Miriam Burgos, of Dr. Haroutunian's rejection of the claim of equal capability by BC. CO is in agreement that the BC unit does not fully meet the requirements needed. Specific objections noted by the end users are in #4 above.

"Only one (or a limited number of) responsible source(s)", since it is this survey of the market place that confirms our assumptions regarding the capability of industry to meet our needs."

Other Actions: N/A.

- 6. Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:** The anticipated cost to the Gov't of \$496,291.41 is deemed fair and reasonable and the market research conducted supports this (see Market Research Report). FPDS was most helpful in comparing award prices for similar items using search terms including 'cell sorter', 'BD', 'flow cytometer', etc. Hundreds of awards to BD were found under 'cell sorters'. 5 of those, including some awarded to the VA, were in a competitive price range of \$494K to \$590K. Award dates ranged from 2011 to the present. CO's determination is that the anticipated costs of this procurement are fair and reasonable.
- 7. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Market research was conducted by the CO utilizing Google, FPDS, SAM, VIP, BD and BC websites, Google, GSA, FBO, and Intent to Sole Source published on FBO. 1 response was received from BC and was evaluated by both the CO and the end users, including Dr. Haroutunian. More importantly, the PI/end users performed their own market research via a technical analysis of competitive alternatives- mostly focused on the Becton Dickinson (BD) Influx vs. the Beckman Coulter (BC) comparative model(s). While similar, only the BD Influx offers analog imaging. The BC model only offers digital imaging- which is not the preferred method in the research setting in which the cell sorter will be operated. CO and end user market research are both supportive of this sole-source procurement to BD.
- 8. Any Other Facts Supporting the Use of Other than Full and Open Competition:** None.
- 9. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** Beckman Coulter via 3/15/18 email (see eCMS Briefcase P02_Beckman Coulter Response to ISS) and Dr. Haroutunian's response by email on 3/19/18 (P02_Email response to BC ISS response). This response included, separately, a revised SSJ that noted additional technical comparisons between the BD and BC models- including the analog vs. digital imaging- one of the very most important requirements.
- 10. 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:** There are no actions that may be taken at this point to remove or overcome any barriers to competition for future similar acquisitions. This is a unique, but typical, R&D procurement, where 'similar' is often not enough and exact technical/operating requirements must be met to best suit the intended research purpose.

11. **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.



Name Vahram Haroutunian, Ph.D.
Title Associate Director, MIRECC
Facility James J Peters VAMC

4/5/2018
Date

12. **Approvals in accordance with the [VHAPM Part 806.3 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.

Jeff Greis
Contracting Officer
SAO-East R&D Team

Date

- b. **One Level Above the Contracting Officer (Required over \$150K but not exceeding \$700K):** I certify the justification meets requirements for other than full and open competition.

Keith Costantino
Branch Chief, R&D Team
SAO East

Date