

U.S. Department of Health and Human Services

Office of the Secretary for Preparedness and Response

Office of Biomedical Advanced Research and Development Authority (BARDA)

Division of Research, Innovation, and Ventures (DRIVe)

Easy Broad Agency Announcement (EZ-BAA)

Title: DRIVe EZ-BAA

Solicitation Number: BAA-18-100-SOL-00018

200 C Street SW

Washington, DC 20201

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I. INTRODUCTION

This Easy Broad Agency Announcement (EZ-BAA), which sets forth areas of interest (AOI) for the Division of Research, Innovation and Ventures (DRIVe) in the Office of Biomedical Advanced Research and Development Authority (BARDA), is issued under paragraph 6.102(d)(2)(i) of the Federal Acquisition Regulation (FAR). Abstracts selected for award are considered to be the result of full and open competition and in full compliance with 41 U.S.C. § 3301. A formal Request for Abstract will not be issued. Paper copies of this announcement will not be issued. The U.S. Government (USG) reserves the right to select for award and fund all, some, or none of the abstracts in response to this announcement. All abstracts will be treated as sensitive competitive information and the contents only disclosed for the purposes of evaluation to authorized personnel. Other data you provide (e.g., general location, business size and type) may be displayed in aggregate reports but will not identify your organization specifically.

The mission of the US Department of Health and Human Services' (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR) is to save lives and protect Americans from 21st Century health security threats. Within ASPR, BARDA was established to aid in securing our nation from chemical, biological, radiological, and nuclear (CBRN) threats, pandemic influenza and emerging infectious diseases. BARDA supports the transition of medical countermeasures such as vaccines, drugs, diagnostics, and medical devices from research through advanced development towards consideration for approval by the Food and Drug Administration (FDA) and inclusion into the Strategic National Stockpile (SNS). BARDA's support includes providing funding, technical assistance, and core services. To date, BARDA's support has resulted (or led to) 35 FDA approvals for 31 unique products addressing CBRN, pandemic influenza, and emerging infectious disease threats.

Today we face new health security threats that require breakthrough solutions. ASPR under HHS has charged BARDA with launching DRIVe to accelerate innovations, and improve the availability of transformative countermeasures to protect Americans from natural and intentional health security threats. DRIVe's Mission is to accelerate innovations, and improve availability of transformative countermeasures to protect Americans from natural and intentional health security threats.

Additional information about DRIVe can be found at www.drive.hhs.gov.

II. OVERVIEW INFORMATION

A. Agency and Issuing Office

U.S. Department of Health and Human Services (HHS)
Office of the Secretary (OS)
Office of the Assistant Secretary for Preparedness and Response (ASPR)
Office of Biomedical Advanced Research and Development Authority (BARDA)
Division of Research, Innovation and Ventures (DRIVe)

200 C Street SW
Washington, DC, 20201

B. Objective

This DRIVe EZ-BAA specifically aims to accelerate innovations, and improve the availability of transformative products and technologies to protect Americans from natural and intentional health security threats by soliciting revolutionary technologies and innovations in health security. DRIVe is seeking abstracts for efforts to develop revolutionary health security products, technologies and innovations in order to increase USG's capability and capacity to respond to national security health threats. DRIVe seeks unconventional approaches that are outside the mainstream, challenge assumptions, require multi-disciplinary teaming, and have the potential to radically change established practice, lead to extraordinary outcomes, and create entirely new fields. Specifically excluded is research or innovations that primarily result in incremental improvements to the existing state of the art.

The projects awarded under this DRIVe EZ-BAA might be at varying stages of technological readiness and prototype development. DRIVe is interested in projects that span the entire development spectrum and are hyper-focused on the specific Areas of Interest (AOI) described in the Areas of Interest (AOI) of this EZ-BAA. Offerors may propose feasibility demonstration, non-clinical development, prototype and process development, formulation, engineering, fabrication, model development, data science and development of novel algorithms, descriptive clinical studies, regulatory activities, etc. Areas of Interest (AOI) of this announcement provides more details.

The total proposed value including fees of any effort awarded under this EZ-BAA cannot exceed $749k. Abstracts exceeding this amount will be considered non-responsive and not evaluated and notified thereof. DRIVe anticipates that there will be a high-volume of abstract submissions, with only a small number of awards.

C. Announcement Type and Date

Type: Broad Agency Announcement (BAA)
Date: June 4, 2018
Title: DRIVe EZ-BAA
Solicitation Number: BAA-18-100-SOL-00018

Applications may be continuously submitted electronically via www.drive.hhs.gov until May 31, 2019, at 11:59PM EDT

D. Eligible Offerors

This EZ-BAA is open to all responsible sources. Offerors may include single entities or teams from private sector organizations, Non-Governmental Organizations (NGOs), and academic institutions.

To be eligible for award, a prospective recipient must be able to perform and demonstrate their ability to achieve the stated goals and objectives of their submitted abstract.

To be eligible for award, a prospective recipient must be able to demonstrate their ability to achieve the stated goals and objectives of their submitted abstract. The prospective awardee must have the ability and capacity to perform. More specifically a prospective Offeror must have at minimum financial resources, ability to comply with the performance schedule, satisfactory performance, integrity, organization, experience, operational controls, technical controls, technical skills, facilities, and equipment as required for performance.

Historically Black Colleges and Universities (HBCU), Minority Institutions (MI), Small Business concerns, Small Disadvantaged Business concerns, Women-Owned Small Business concerns, Veteran-Owned Small Business concerns, Service-Disabled Veteran-Owned Small Business concerns, and HUB Zone Small Business concerns are encouraged to submit abstracts and to join other entities as team members in submitting abstracts.

In accordance with federal statutes, regulations, and HHS policies, no person on grounds of race, color, age, sex, national origin, or disability shall be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving financial assistance from the HHS.

E. Number of Awards

Multiple awards of various values are anticipated and are dependent upon technical importance to agency programs and funds availability.

F. Type of Award

Awards under this EZ-BAA may use Cost-Reimbursement, Fixed Price, Cost-Sharing (CS), Other Transactions Agreements (OTA), Grants, or Cooperative Agreements, as authorized for BARDA under the Pandemic and All Hazards Preparedness Reauthorization Act and 21st Century Cures Act.

During negotiations a decision will be made as to the most appropriate procurement instrument that will be used for a tentative award. Based on the procurement instrument selected, the Offeror may negotiate with either a Contracting Officer (CO), a Grants Officer (GO), or Other Transaction Agreement Officer (OTAO).

However, if cost sharing is proposed, the amount of cost participation should depend on the extent to which the Research and Development (R&D) effort or results are likely to enhance the Offeror's expertise, capability, or competitive position. If USG contemplates the award of a cost-reimbursement type contract, the Offeror must demonstrate prior to award that its accounting system is adequate for administering a cost-reimbursement contract. Offerors should propose the type of arrangement they believe best satisfies the requirement.

The costs of preparing responses to this EZ-BAA are not considered an allowable direct charge on any resultant award.

III. Submission Process

A. EZ-BAA DRIVe Portal Instructions

All applications in response to the DRIVe EZ-BAA must be submitted via www.drive.hhs.gov. Abstracts will not be accepted via physical mail nor email. The DRIVe portal is the only accepted means to submit an abstract in response to the EZ-BAA. The DRIVe portal is estimated to be made available starting June-July 2018, with notification of any change to this solicitation posted via www.drive.hhs.gov and FedBizOps.

IMPORTANT: Offerors will be required to apply for an application portal account. This account can be requested by via www.drive.hhs.gov, and following the applicable prompts. The account process is simple but may take up to one business week to complete. Upon receipt of an account, the Offeror logs in using the prescribed two-factor authentication method and will be prompted to enter a series of basic information about their organization, enter their abstract, and other supporting information if applicable.

Failure to submit the application on time due to late registration will result in DRIVe not accepting the application. The EZ-BAA will expire on May 31, 2019. In order for an Offeror to be considered for an on-time submission, the Offeror must

submit their abstract at least one week prior to the anticipated end date of May 31, 2019.

IMPORTANT: The EZ-BAA end date is May 31, 2019 the final submission for abstracts will be no later than May 24, 2019.

Offerors will be provided confirmation of abstract recite upon successfully submission.

B. DRIVe EZ-BAA Pre-proposal Teleconference

A Pre-proposal teleconference will be held on June 22, 2018, at 2:00PM EDT. This meeting is designed to address any questions associated with the application process. Applicants can visit www.drive.hhs.gov to obtain information on the Pre-proposal teleconference.

C. Abstract Instructions

The open period for receipt of abstracts for all areas of interest under the EZ-BAA is from **June 4, 2018** to **May 31, 2019**. Offerors must submit their Abstracts per the instructions provided below in accordance with Part VI of this solicitation.

Abstract Submission Process	Deadline for Submission	USG Response
Abstract Instructions	Anytime	Receipt confirmation within 1 week. Decision within 30 to 120 days (pending availability of funds)

Section 1 – Preparation and Abstract

The abstract must be no more than 2000 words and submitted electronically via www.drive.hhs.gov.

Abstracts submitted through www.drive.hhs.gov will be text-based submissions only. No other documents, files, templates, or other items will be authorized for upload or submission as part of abstract. Instructions on this will be included as part of abstract submission within the DRIVe portal.

Section 2 – Abstracts must include the following components:

Technical

- Relevance to DRIVe Areas of Interest (AOI)
- Technical Approach
  - Clearly describe what is being proposed and what difference it will make (qualitatively and quantitatively).
- Ability to transition technology and expand use of application

Cost

In preparing the cost estimate, provide a breakdown of the cost categories, using the following listed below as guidance:

a. Direct Labor
   - Name, position/labor category, annual rate, level of effort

b. Materials, Supplies, and Equipment
   - Include breakdown when total amount is over $3,500

c. Travel
   - Identify travelers, number of trips, destination (e.g., city and state), purpose of trip, and total amount. List separately, domestic travel, general scientific meeting travel, and foreign travel.
     - o Travel may be limited or not authorized based on the final negotiated award type

d. Other Direct Costs (ODCs)
   - Consultants, subcontractors, etc.

e. Total Proposed Cost
   - Abstracts exceeding $749K in proposed costs will be considered non-conforming and will not be reviewed

Detailed cost proposals may be requested by the CO, GO, or OTAO for those selected for negotiations.

Period of performance (POP) for awards resulting from the EZ-BAA for all areas of interest (see Areas of Interest (AOI) will be based on the procurement instrument selected and the specific project requirements (stage of development) under the award. Establishing the POP gives consideration to the unknown or unexpected results of advance research and development; industry practices; market conditions; and capabilities of small business concerns.

Section 3 – Abstract Handling and Submission Information

Treatment of Submission Documents: All abstracts are treated as the Offeror's proprietary information prior to award and the contents are disclosed only for the purpose of evaluation. Other data you provide (e.g. general location, business size and type) may be displayed in aggregate reports but will not identify your organization specifically.

IMPORTANT: Classified abstracts, in part or in whole, will not be accepted. All submissions must be Unclassified.

Post-Employment Conflict of Interest: There are certain post-employment restrictions on former federal officers and employees, including special USG employees (Section 207 of Title 18, U.S.C.). If a prospective Offeror believes a conflict of interest may exist, the situation should be addressed with the Contracting Office through DRIVeContracting@hhs.gov prior to abstract

submission. The appropriate USG personnel will discuss any conflict of interest with the prospective Offeror.

Unsuccessful Abstract Disposition: The original copy of each abstract received will be retained by ASPR pursuant to FAR 4.805 and all other non-required copies destroyed.

Section 4 – Review of Abstracts

The primary basis for reviewing abstracts is to ensure they adhere to the EZ-BAA requirements identified herein. The review is based on technical, relevance to AOIs, satisfactory performance, cost realism, and subject to the availability of funds. All things being considered as part of abstract review technical, relevance to AOIs, satisfactory performance, and cost are listed in descending order of importance pursuant to FAR Part 35.

It is the responsibility of the CO, GO, OTAO, COR, OTTR, or other USG technical representative to be impartial, equitable, and comprehensive when reviewing abstracts. Abstract reviews will result in a finding of either Acceptable or Unacceptable, with definitions listed in this section.

The reviews will be conducted by a peer or a scientific review process for each conforming abstract. Conforming abstracts are abstracts that comply with all requirements detailed in this EZ-BAA. Abstracts that fail to do so will be deemed non-conforming and will not be considered. Abstracts will not be reviewed against each other since they are not submitted in accordance with a common work statement.

Section 5 – Review Definitions

Acceptable and Unacceptable are defined as follows:

Acceptable: The submitted abstract maps to the AOI identified in the EZ-BAA solicitation and could result in disruptive innovation, is cost realistic, and is likely to result in achievable advancements in the AOI to DRIVe. A finding of Acceptable results in the submitted abstract being considered for award and funding based on the appropriate procurement instrument to be determined by the CO, GO, OTAO and subject to the availability of funding.

Unacceptable: The submitted abstract does not map to the AOI identified in the EZ-BAA solicitation and could not reasonably result in disruptive innovation, is not cost realistic, and could not reasonably result in achievable advancements in the AOI to DRIVe. A finding of Unacceptable will result in the abstract not being considered for award or funding.

IMPORTANT: Offerors will be notified regarding the status of abstracts submitted.

IV. Contact Information

Francine L. Hemphill, D.B.A.
Contracting Officer
Office: (202) 205-9271
Email: Francine.Hemphill@hhs.gov

If you have specific questions you may contact the above CO. However, you must submit all inquiries to include contact made with the CO regarding this EZ-BAA to DRIVeContracting@HHS.gov. This is to ensure review and response to all inquiries submitted regarding this EZ-BAA.

V. Limitation on Communication after Submission

Be advised that while you can contact DRIVe before submitting an abstract, the opposite is true after an EZ-BAA abstract has been submitted. After that point, all communications related to that submission must be through the Contracting Office and only submitted through DRIVeContracting@HHS.GOV. All communications in response to a submission will be from the CO, GO, or OTAO as required.

VI. Special Instructions

Special instructions may be required and will be advertised via the EZ-BAA solicitation. These additional instructions would be tailored to specific AOI and may have unique submission and performance requirements.

VII. Areas of Interest (AOI)

DRIVe is soliciting abstracts for technologies and innovations to increase our capability and capacity to respond to national security health threats, with an emphasis on the areas of interest described herein. BARDA DRIVe anticipates that awards made as a result of this EZ-BAA may occur at any stage of development. This EZ-BAA will also serve to advance the knowledge and scientific understanding of platform technologies, inventions, modeling and forecasting, and visual analytics.

DRIVe wants to emphasize revolutionary approaches that are hyper-focused on the areas of interest described herein. DRIVe seeks novel approaches that may not have been applied to the field previously, which could include approaches that are outside the mainstream, and could help populate the health security innovations development pipeline.

For additional information, please visit:

- Section 301 of the Public Health Service (PHS) Act (42 U.S.C. 241), “Research and Investigations.”

- Section 319L of the PHS Act (42 U.S.C. 247d-7e), “Biomedical Advanced Research and Development Authority.”
- The DRIVe website: www.drive.hhs.gov

Descriptions of Areas of Interest

1. **Early Notification to Act, Control and Treat (ENACT):** Through ENACT, DRIVe is seeking technologies and methods to identify, characterize, and broadly adapt biological, biometric, behavioral and physiological signatures that can determine health status among pre-exposed pre-symptomatic and exposed pre-symptomatic disease stages, and predict health outcomes from recovery to homeostasis or progression to severe illness and death. DRIVe is seeking to achieve this through the identification, integration and application of these health signatures, development of multimodal, point-of-use diagnostics, and the advancement of biological and physiological sensing technologies. DRIVe also seeks to develop vast health information repositories to facilitate predictive disease indicators and exposure-related patterns in disparate populations. DRIVe is interested in a suite of approaches that empowers the patient with early notification of exposure that enables providers to act, control and treat the illness.

2. **Save lives by Solving Sepsis**: DRIVe is seeking technologies and methods to eliminate the effects of sepsis through the development of clinical management strategies, multimodal detection technologies and diagnostic platforms, as well as integrating health analytic technologies, novel biomarkers and predictive platforms. Performers are expected to propose efforts that will achieve a new paradigm for the clinical management of sepsis, identification and application of biological indicators (chemical, physical, molecular, immunological, serological), and diagnostics. Additionally, DRIVe seeks to develop machine and deep learning methods for early identification and intervention in both patient and pre-symptomatic populations. DRIVe is interested in a suite of approaches as an initial investment towards "solving sepsis".

3. **Other Innovative Products with potential to radically transform Health Security:** DRIVe will seek a limited number of additional extremely bold, radical and disruptive innovative solutions that will have the ability to transform Health Security.

VIII. Reporting Requirements and Deliverables

Some reports and other deliverables are relevant to specific activities performed during the contract, grant, or agreement period of performance. The Offeror and USG will agree during final negotiations on which reports and other deliverables are relevant and will be required as deliverables as determined in the negotiated final work statement (SOW, SOO, PWS, etc.). Reports required will be prepared and delivered throughout performance, and should be submitted electronically in Microsoft Word, Microsoft Excel, Microsoft Project, Adobe Acrobat PDF, and/or data-fields to a USG identified system.

A. Reports

Technical Progress Reports: The frequency of Technical Progress Reporting will be determined by the USG during negotiations. Typically, on the 20th day of each month, the Offeror must submit a Technical Progress Report describing activities performed during the previous calendar month. The appropriate formats for the Technical Progress Report will be provided by the USG. The Technical Progress Reports may include project timelines and summaries of product manufacturing, testing, and clinical evaluation activities as applicable. A Technical Progress Report will not be required for the month in which the Final Report is due.

Final Report: By the expiration date of selected procurement instrument, the Offeror will submit a Final Report that details, documents, and summarizes the results of all work performed under the contract.

B. Meetings

The Offeror will participate in regular meetings to coordinate and oversee the contract effort as directed by the CO, GO, OTAO, and Contracting Officer Representative (COR), Other Transaction Agreement Technical Representative (OTTR) and other USG technical as required. Such meetings may include, but are not limited to, all Offeror and subcontractors to discuss biomarker discovery, platform development, clinical manufacturing progress, product development, product assay development, scale-up manufacturing development, clinical sample assay development, preclinical/clinical study designs and regulatory issues, or other relevant activities; meetings with individual Offerors and other USG officials to discuss the technical, regulatory, and ethical aspects of the program; and meeting with USG technical consultants to discuss technical data provided by the Offeror.

Reoccurring teleconferences between the Offeror and subcontractors and USG may be held to review technical progress. USG reserves the right to request more frequent teleconferences and face-to-face meetings depending on the nature and importance of the work being performed. The Offeror will receive feedback from USG during the teleconference regarding contract

performance. The Offeror will have an opportunity to respond and recommend corrective actions. The only contractual relationship will be between USG and the prime Offeror.

C. Program Management Plans and Documentation

Integrated Master Schedule (IMS): Also known by its graphical representation as a Gantt chart, may be required and submitted following award. The IMS shall include the key milestones and Go/No-Go decision criteria per the final negotiated award or agreement.

Product Development Plan (PDP): Within 14 calendar days of the effective date of an award, the successful Offeror may be required to submit a PDP, which will be approved by the CO, GO, or OTAO prior to initiation of any activities related to their implementation.

Deviation Report: During the course of performance, in response to a need to change the PDP, the successful Offeror may be required to submit a Deviation Report. All changes identified in the Deviation Report will be reviewed and agreed-upon by the CO, GO, or OTAO prior to updating the PDP.

IX. Additional Information

Inspection of Facilities

Offerors selected for negotiations may be subject to inspections of their facilities and Quality Assurance/Quality Control (QA/QC) capabilities; Regulatory and Quality Management: FDA submissions and meetings; Audits/Site Visits, as applicable will be discussed during negotiations.

The decision to inspect specific facilities will be made by the CO, GO, OTAO in coordination with the COR, OTR, or other USG technical representative as required. If inspections are performed during the negotiations, the results of the inspection will be considered in final selection for award of a contract, grant or agreement.

Inspection of Records

Offerors, including proposed subcontractors, will be requested to make all non-proprietary records, including previous regulatory inspection records, and staff available in response to a pre-award site visit or audit by a BARDA representative. Pre-award site visits may be made with short notice. Offerors are expected to guarantee the availability of key staff or other staff determined by USG as essential for purposes of this site visit.