
U.S. Department of Health and Human Services
Office of the Secretary for Preparedness and Response
Office of Biomedical Advanced Research and Development Authority
Division of Research, Innovation, and Ventures

Easy Broad Agency Announcement (amended 04 June 2020)

Title: DRIVe EZ-BAA
Announcement Number: BAA-20-100-SOL-0002
200 C Street SW
Washington, DC 20201

## Table of Contents

# I. Introduction

This Easy Broad Agency Announcement (EZ-BAA) sets forth areas of interest (AOIs) for the Division of Research, Innovation, and Ventures (DRIVe) in the Office of Biomedical Advanced Research and Development Authority (BARDA), issued under paragraph 6.102(d)(2)(i) of the Federal Acquisition Regulation (FAR). Abstract submissions 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 also not be issued.

The U.S. Government reserves the right to select for award and fund all, some, or none of the abstracts in response to this announcement.

The mission of the U.S. 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 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. BARDA's support includes providing funding, technical assistance, and core services.

Today we face new health security threats that require breakthrough solutions. To address these new threats, ASPR and BARDA launched DRIVe. DRIVe's mission is to accelerate innovations, and improve availability of transformative technologies and 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 EZ-BAA aims to accelerate innovations and improve the availability of transformative products and technologies to protect Americans from natural and intentional health security

threats. DRIVe is seeking abstracts for efforts to develop revolutionary health security products, technologies, and innovations in order to increase the Government's capability and capacity to respond to national security health threats. DRIVe is seeking transformative and innovative approaches that are outside of the mainstream, challenge assumptions, require multi-disciplinary teaming, and have the potential to radically change established practices, lead to extraordinary outcomes, and create entirely new fields.

The projects awarded under this EZ-BAA may be at varying stages of technological readiness and development. DRIVe is interested in projects that span the entire product development spectrum (but may vary within each AOI). Responses should be focused on the AOIs in this EZ-BAA. Respondents may propose a variety of research and development (R&D) projects relevant to the AOIs, including early research R&D, non-clinical development, process development, formulation, engineering, fabrication, model development, data science and development of novel algorithms, descriptive clinical studies, regulatory activities, etc. The AOI sections of this announcement provide more details.

The total Government share of funding, including options, of any project awarded under this EZ-BAA shall be less than $750,000. Abstracts exceeding this amount will be considered non-responsive and will not be further reviewed. DRIVe anticipates a high-volume of abstract submissions, with only a small number of awards.

## C. Announcement Type and Date

Type: Broad Agency Announcement
Date: 03 February 2020
Title: DRIVe EZ-BAA
Announcement Number: BAA-20-100-SOL-0002

Applications may be continuously submitted electronically via www.drive.hhs.gov until 03 February 2023 at 1700 HRS ET.

Abstract submissions will not be accepted after this date, although DRIVe reserves the right to *revise* this open period, as necessary.

## D. Eligible Respondents

This EZ-BAA is open to all responsible sources. Respondents may include single entities or teams from private sector organizations, non-profit organizations, non-governmental organizations, and academic institutions.

To be eligible for award, the Respondent must be able to demonstrate its ability to achieve the stated goals and objectives in the submitted abstract, as well as the ability and capacity to perform. More specifically, the Respondent must have at a minimum the 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, Minority Institutions, 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.

Respondents must be registered in the System for Award Management (SAM) with the appropriate North American Industry Classification System code prior to proposal submission. Registration can be completed here: https://sam.gov/SAM/

Without prior approval, non-federal BARDA personnel cannot simultaneously provide scientific, engineering, technical assistance (SETA), advisory and assistance services (A&AS), or similar support, to any part of the U.S. Government and also be eligible to participate as a Respondent under this announcement. Any individual who has previously provided SETA or A&AS services to ASPR within one year is ineligible to respond. Additionally, any individual who has previously provided SETA or A&AS services to BARDA on this specific announcement is ineligible to respond. As part of the submission, all members of the proposed team (including any potential subcontractors/consultants) must certify whether or not their organization (including individual team members and proposed subcontractors/consultants) have provided similar support to any U.S. Government Agency. If a Respondent's proposed team includes a member who has provided SETA or A&AS support to BARDA or a government agency with whom BARDA engages, it is the responsibility of the Respondent to demonstrate that no conflict of interest exists or would arise.

## E. Number of Awards

Multiple awards of various values are anticipated and dependent upon technical importance to agency programs priorities and funding availability, per the evaluation process described herein. However, the announcement is highly selective and it is anticipated that a small percentage (estimated 5-10%) of those Respondents who submit an abstract will result in award based on market research, programmatic needs, and available funds. The ultimate number of awards is subject to change.

## F. Type of Award

Awards under this EZ-BAA may be a FAR-based firm fixed price contract, cost-sharing contract, other transactional agreement (OTA), or other contract type as deemed appropriate based on the submission. Federal grants will NOT be awarded directly from this announcement.

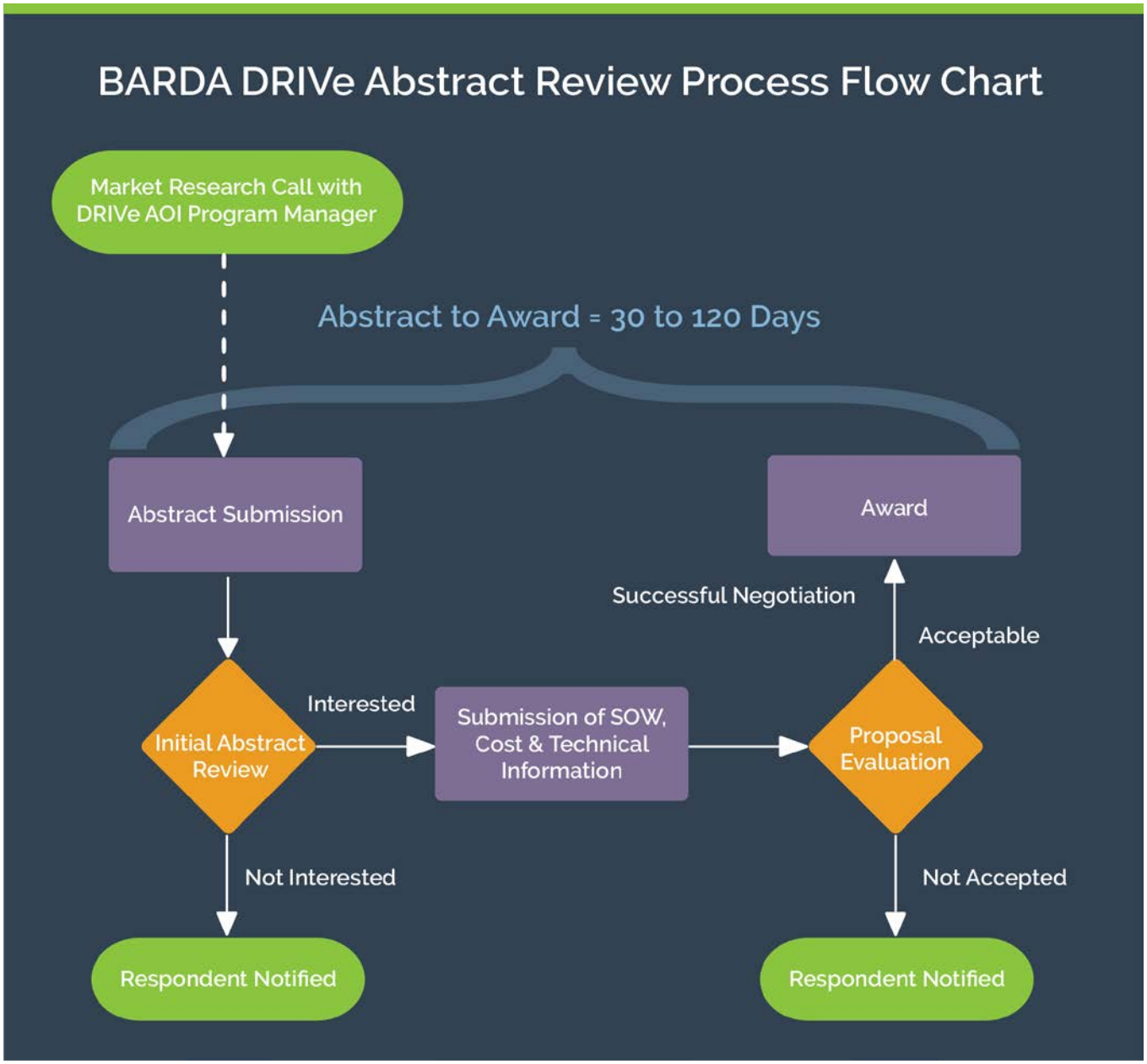
During negotiations, a decision will be made as to the most appropriate contract type that will be used for a tentative award. Based on the contract type considered, the Respondent may negotiate with either a Contracting Officer (CO), Contract Specialist (CS), or Other Transaction Agreement Officer (OTAO).

Respondents shall submit a cost-share proposal in which the Respondent clearly delineates which cost elements (or specific overall percentage) will be accounted for by the Respondent and which of those will be funded by the Government. The amount of cost-share participation should depend on the extent to which the R&D effort or results are likely to enhance the Respondent's capabilities, expertise, or competitive position. The target Respondent cost-share range is 30-50% of the total project costs (provided by your organization as a cash and/or in-kind contribution expressed in US dollars).

The general expectation is that awards resulting from this BAA will have a cost-sharing component. In the rare circumstance that a Respondent does not believe cost-sharing is appropriate, the Respondent may present a written justification demonstrating why there is no probability that the Respondent will receive any present or future benefits from an award made under this EZ-BAA pursuant to the Health and Human Services Acquisition Regulation (HHSAR) 335.070.

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

# III. EZ-BAA Process




## A. Market Engagement

DRIVe realizes that the preparation of abstracts often represents a substantial investment of time and effort by a Respondent. While not required, in an attempt to minimize this burden DRIVe encourages organizations and individuals interested in submitting abstracts to schedule a market research call with a DRIVe representative to discuss the technology and the AOI program priorities, to understand if it aligns with the scope of this announcement before expending effort in preparing a detailed abstract or submitting proprietary information.

Requests to schedule a call for the applicable AOIs may be sent to the following representatives:

AOI #1: ENACT (ENACT@hhs.gov)

AOI #2: Solving Sepsis (SolvingSepsis@hhs.gov)

AOI #3: Other Disruptive Innovations (Donna.Boston@hhs.gov)

## B. EZ-BAA DRIVe Portal Instructions

All applications in response to the DRIVe EZ-BAA must be submitted on the DRIVe Portal (https://drive.rti.org/) via the process described below and on www.drive.hhs.gov.

IMPORTANT: Respondents will be required to apply for a DRIVe Portal account. This account can be requested by visiting the DRIVe Portal site or via the process as described on www.drive.hhs.gov/partner.html and following the applicable prompts.

The account request process is simple, but may take up to one week for approval and access. Account requests will require the Respondent to enter a set of basic information about the organization, including its Data Universal Numbering System (DUNS) Number and Commercial and Government Entity (CAGE) Code. Upon receipt of a DRIVe Portal account, the Respondent will login using the prescribed two-factor authentication method. Once login is complete, the Respondent will be prompted to confirm the previously entered information about the organization and to input the abstract submission with other project-specific information.

Failure to submit the application on-time due to late registration will result in the application not being considered for award.

Respondents will be provided automated confirmation of abstract receipt upon successful submission.

The abstract must be no more than 12,500 characters (approximately 2,000 words) for the Technical Section and must also include a Rough Order of Magnitude, or ROM, for estimated costs. All abstracts must be submitted electronically via the process described on www.drive.hhs.gov. The following components must be included:

## C. Abstract Preparation

**1. Technical Section:** Met the criteria outlined in the identified DRIVe AOI Technical Approach.

**a.** Clearly describe what is being proposed and what difference it would make in the field (qualitatively and quantitatively).
**b.** Include specific tasks, milestones, deliverables, and success metrics that are expected during the course of the project (please limit project to no more than 3-4 main tasks/deliverables).

**c.** Describe how the proposed technology is a significant advancement or innovation over the current state of the art (not incremental).
**d.** Describe the preliminary data available to support the proposed technology.
**e.** Describe the ability to transition technology and expand use of application.

**2. Rough Order of Magnitude (ROM) Section:** In preparing the ROM, please use the EZ-BAA ROM Template located under the Resources tab on the DRIVe website, while providing narrative descriptions of the below cost elements. Please provide the following for each main task/deliverable listed in the Technical Section.

**3. Task/Deliverable 1** (please limit project to no more than 3-4 main tasks/deliverables):

**a. Direct Labor**. Briefly describe the employee, position/labor category, level of effort, and functions being performed in the proposed project.
**b. Materials, Supplies, and Equipment.** Briefly describe proposed materials, supplies, and equipment and how it will be used in the proposed project. Provide brief justification of how vendor costs were determined to be reasonable.
**c. Travel.** Briefly describe the purpose of proposed travel, destinations, and number of travelers. Travel may be limited or not authorized based on the final negotiated award type.
**d. Subcontractors (including Consultants).** Please provide narrative description of how the proposed Subcontractors were selected and determined to be reasonable.
**e. Other Direct Costs (or, ODCs).** Include as necessary.
**f. Total Proposed Cost.** Abstracts exceeding $750,000 in proposed Government funding will be considered non-conforming and will not be reviewed.
**g. Proposed Cost-Share.** Clearly indicate and describe the proposed Respondent cost-share, which may consist of cash and/or in-kind contributions. This cost-share may be satisfied by proposing specific line item costs to be provided by the Respondent or may be represented as an overall percentage of proposed total project costs. Regardless, this proposed Respondent cost-share must be quantified. The proposed cost elements should include a breakdown for the entire project value, not just the Government's portion of the cost-share. As previously mentioned, the $750,000 limitation applies only to the proposed amount of Government funding. It is possible that the total proposed project cost (i.e. Respondent cost-share plus Government funding) exceeds $750,000, so long as the Government funding requested is less than the $750,000 threshold.

More detailed cost information may be requested by the CO, the CS, or the OTAO for those selected for further consideration.

The period of performance (POP) for awards resulting from the EZ-BAA for all AOIs will be based on the selected contract type and the specific project requirements or stage of development under the award. Establishing the POP gives consideration to the unknown or unexpected results of advanced research and development, industry practices, market conditions, and capabilities of small business concerns. We anticipate the POP for most contracts will be 12-24 months.

## D. Review Process

IMPORTANT: All Respondents will be notified regarding the status of their submission. The target date for notification, or resultant award, is 30-120 days after receipt of abstract.

### 1. Stage I: Initial Review of Abstracts

Abstracts must comply with all requirements detailed in this EZ-BAA. Abstracts that fail to do so will be deemed non-compliant and will not be reviewed. Abstracts which propose technology deemed to be outside the scope of the AOIs defined in this EZ-BAA will be considered non-compliant. Additionally, abstracts which do not propose a cost-share in the 30-50% range (or a justification as to why there is no probability that the Respondent will receive any present or future benefits from an award) may not be considered for award.

Compliant abstracts will be reviewed in whole based on the potential enhancement of the overall AOI portfolio by the proposed project. This initial review will result in the Respondent receiving a notice of "Interested" or "Not Interested" based on the potential enhancement to the overall AOI portfolio. Respondents receiving a Not Interested notification will receive a brief rationale for the decision, but formal debriefings will not be provided at this phase under FAR 15.5.

Respondents receiving an "Interested" notification will be invited to submit a Statement of Work (SOW), respond to relevant questions, and provide additional supporting cost and technical data as requested. Specific instructions will be provided to Respondents at the time of notification. That information will be evaluated in accordance with criteria outlined in Stage II: Evaluation section below.

### 2. Stage II: Evaluation

Consistent with FAR Part 35.016, submissions will not be evaluated against each other as they are not submitted in accordance with a common work statement. Each submission is evaluated only against the evaluation criteria defined herein. Submissions received at this phase will be evaluated in whole (i.e. revised initial abstract with additional information requested) and are considered the proposal.

Per FAR 35.016, the primary basis for selecting submissions for acceptance shall be technical, importance to agency programs, and fund availability. Accordingly, the Stage II submission will be evaluated pursuant to all of the criteria listed below. The following evaluation factors are listed in descending order of importance. Evaluation factors i - iii, when combined, are significantly more important than evaluation factor iv.

i. Alignment with relevant AOI strategy
ii. Technical Approach
iii. Ability to transition technology and expand use of application
iv. Cost/Price (including proposed cost-share)
v. Past Performance

Cost/price reasonableness or cost/price realism will be conducted, as appropriate, based on the award vehicle. Cost-share will be evaluated pursuant to HHSAR 335.070. Past Performance evaluations will be conducted utilizing the Contract Performance Assessment Reporting System (CPARS) and other available Government resources. If no relevant past performance is available, a submission will not be negatively or positively impacted and will be rated as "Neutral" for the past performance evaluation factor.

The outcome of the Stage II evaluation will result in an overall "Acceptable" or "Not Accepted" rating, as defined in paragraph E below. Respondents who receive a "Not Accepted" rating will be notified and provided a rationale for the decision. Respondents who receive an "Acceptable" rating will be invited to enter into negotiations. Assuming all terms and conditions are mutually agreed upon, negotiations will be deemed successful and an award will be made, subject to the availability of funds.

In rare instances, Respondents may receive a rating of "Acceptable, Funding Not Yet Identified." Notification of this rating does not initiate negotiations, but it notifies the Respondent that its submission satisfies the definition of "Acceptable," but available program funding has not been identified for the award. This rating does not commit DRIVe to enter into negotiations, but reserves the right for DRIVe to invite the Respondent to enter into negotiations if/when funding is identified. The Respondent may be notified at any time after receiving the notice of this rating that DRIVe will not proceed as the availability of funding for the project becomes clear.

Government representatives will be impartial, equitable, and comprehensive when evaluating abstracts.

## E. Review Definitions

### 1. Initial Abstract Review Definitions (Stage I):

**a) Interested**: DRIVe is interested in the concept. The project aligns with the relevant AOI program strategy and would likely enhance the overall AOI portfolio by proposing an innovative and realistic technology which fits within the needs of the program. The technology would likely expand the breadth, or significantly enhance or improve, an existing technology in the current AOI portfolio.

Potential enhancement to the portfolio also includes technical risk versus reward, in the context of where the technology is in the development process. Abstracts with little or no evidence of supporting data (e.g. proof of concept phase) will receive an "Interested" notification only when the idea and/or project plan are realistic and the potential innovation to the AOI outweighs the risk inherent to technologies in the early phases of development.

**b) Not Interested:** DRIVe is not interested in the concept at this time. The project does not align with the relevant AOI program strategy. The technology would not likely enhance the overall AOI portfolio, is not innovative, or the idea or project plan are not realistic. The technology would

not expand the breadth of the current AOI portfolio or would not significantly enhance or improve an existing portfolio technology.

**2. Stage II Evaluation Definitions:**

**a) Acceptable:** The submission (1) aligns with the AOI strategy, (2) illustrates a clear and feasible technical approach, (3) is likely to result in successful progression of the technology and expanded use in the relative AOI, and (4) includes a cost proposal and past performance that is satisfactory to DRIVe. A finding of Acceptable results in the submission being considered for award, subject to successful negotiations and availability of funding.

**b) Not Accepted:** The submission (1) does not align with the AOI strategy, (2) does not illustrate a clear and feasible technical approach, (3) is unlikely to result in successful progression of the technology or expanded use in the relevant AOI, or (4) does not include a cost proposal or past performance that is satisfactory to DRIVe. A finding of Not Accepted will result in the submission not being considered for award. Respondents whose abstracts are deemed Not Accepted will be provided the weaknesses of their abstract.

**c) Acceptable, Funding Not Yet Identified:** The submission satisfies the definition of "Acceptable" as defined above, however, available program funding has not been identified for award. This rating does not commit DRIVe to enter negotiations, but reserves DRIVe's right to invite the Respondent to enter into negotiations if/when funding is identified. The Respondent may be notified at any time after receiving the notice of this rating that DRIVe will not proceed as the availability of funding for the project becomes clearer.

## F. Abstract Handling and Submission Information

**1. DRIVe Safeguarding of Information:** DRIVe takes the protection of Respondent information very seriously to ensure that such information is safeguarded in full compliance with all applicable regulation and law. All information on abstracts, except where clearly marked in the application as non-proprietary, will be treated as the Respondent's proprietary information.

By engaging in a market research call, submitting information related to this announcement, or entering into a contract resulting from this announcement, Respondents acknowledge that non-federal BARDA personnel may participate in the process and provide input compliant with FAR 37.203(d). Non-federal BARDA personnel may also handle submissions for administrative purposes and for collection/analysis of non-proprietary submission information (e.g. business size) as denoted on the submission form. All non-federal BARDA personnel who support DRIVe are strictly bound by the appropriate non-disclosure requirements. Respondents should not engage in any part of the announcement process if they do not consent to the participation of non-federal consultants as described in this subparagraph.

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

**3. Post-Employment Conflict of Interest:** There are certain post-employment restrictions on former federal officers and employees, including special Government employees (Section 207 of Title 18, U.S.C.). The appropriate Government personnel will discuss any conflict of interest with the Respondent.

**4. Unsuccessful Abstract Disposition:** The e-filling copy of each abstract received will be retained by DRIVe pursuant to FAR 4.805.

# IV. Contact Information

**Primary Contracting Officer:**
Troy Francis
Contracting Officer (Team Lead), DRIVe
Email – Troy.Francis@hhs.gov

**Secondary Point of Contact:**
Matthew McCord
Chief of Partnering, DRIVe
Email – Matthew.McCord@hhs.gov

If you have specific questions, you may contact a CO above. 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 a review and response to all inquiries submitted in regard to this EZ-BAA.

# V. Limitation on Communication after Submission

Be advised that while you are encouraged to contact DRIVe program representatives before submitting an abstract, the opposite is true after an EZ-BAA abstract has been submitted. At that point, all communication related to that submission must be through DRIVeContracting@hhs.gov, which is closely tracked and monitored. All communications in response to a submission will be from the CO, CS, or OTAO as required.

# VI. Areas of Interest (AOI)

DRIVe is seeking abstracts for technologies and innovations to increase our capability and capacity to respond to national security health threats, with an emphasis on the AOIs described herein. 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, forecasting, and visual analytics.

DRIVe wants to emphasize revolutionary approaches that are hyper-focused on the AOIs 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:

- The DRIVe website: www.DRIVe.hhs.gov
- 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."

DRIVe reserves the right to add, remove, or refine any AOI description in this announcement that falls within BARDA's mission space, as deemed appropriate.

## Descriptions of Areas of Interest

## A. AOI #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 signal health security threat infections or exposures prior to symptoms. ENACT areas of interest include discovery and validation of biomarkers and other health signatures, diagnostics suitable for use in the home or on the body, novel sensing and other wearable technologies coupled with cloud-based reporting and data analytics, and disease prognostication to empower individuals with early notification to act, control, and treat illnesses.

In the event of a public health emergency, the ability to detect, triage, and prognosticate outcomes is critical to saving lives and providing help to those in need.

Current focus areas include:

- Host-based quantitative diagnostics, sensors, and/or technologies that can be deployed and used by a lay person in the home to monitor and measure innate and adaptive immunity that can predict illness at minimum 12 hours prior to symptoms. Wearable technologies that can be continuous or as near to continuous as possible that are non-invasive or minimally invasive (finger prick). Special weighting will be placed on technologies that sample in novel ways (saliva, interstitial, sweat, etc.).
- The ENACT team has available retrospective and prospective wearable data including heart rate, heart rate variability, accelerometer, electrocardiogram, and other health signature data sets that can be made available for data analytics, algorithm development, and data mining. The program will support any development and validation of models from prospective partners and can make data available including de-identified clinical data sets including polymerase chain reaction positive data for model development.

The following areas that are considered out of scope at this time:

- Pathogen based detection or technologies – any technologies that are based on the identification of pathogens will not be considered responsive at this time.
- Any technology that is not minimally invasive – any technology that requires sample preparation and cannot be used by a lay person, as considered by the FDA, will not be considered responsive at this time.

NOTE: All awarded ENACT partners will be required to share de-identified data in effort to advance the field and knowledge. Interested partners are encouraged to commercialize their technology and algorithms but data collected through the use of Government funding will be made available through full Government purpose rights.

## B. AOI #2: Solving Sepsis

At least 1.7 million Americans develop sepsis each year and nearly 270,000 Americans die[1] annually as a result. Sepsis occurs when an infection leads to a dysregulated host response and organ dysfunction. In addition to the toll on health, sepsis incurs a large economic burden and sepsis survivors also sustain additional chronic illnesses and associated care expenses.

A complication of any health security threat is sepsis, which has a very high potential to arise consequent to any of these threats. In order to fully protect Americans and save lives, the DRIVe Solving Sepsis program aims to reduce the incidence, morbidity, mortality, and economic burden of sepsis by investing in key strategic areas. The program is catalyzing technological approaches along the sepsis patient continuum to empower both the patient and the healthcare provider with a focus on innovative technologies that specifically address sepsis.

Current focus areas are limited to:

- Diagnostics that predict, identify or prognosticate outcomes of sepsis in pre-hospital settings. It is important that these diagnostics are able to distinguish sepsis from infection alone or Systemic Inflammatory Response Syndrome alone.
- Technologies that improve early detection, diagnosis and/or clinical management of neonatal and/or pediatric sepsis patients.
- Post-sepsis monitoring technologies (after hospital discharge) to detect health deterioration and to inform on clinical care. These technologies should be appropriate for community settings (e.g. nursing homes, home, etc.).
- Innovative host sepsis therapies including patient stratification (e.g. endotyping) approaches to better inform on clinical management strategies to improve patient outcomes.

Submissions should be responsive to the following:

- Medical countermeasures that address sepsis of any etiology (i.e. bacterial, viral, other) versus approaches that are limited to sepsis induced by a subset of pathogens.
- Clinical or patient adoption strategies in relevant settings for use and implementation of the

[1] https://www.cdc.gov/sepsis/index.html

proposed technology.

- Prior demonstration and preliminary data to support use in sepsis relevant models (e.g. sepsis patient samples, sepsis patient clinical data).
- Technologies should focus on host-based approaches. BARDA has existing programs for pathogen-targeted approaches outside of the Solving Sepsis program.
- Research should be considered translational science. There is no interest in fundamental research projects at this time.
- A clear FDA regulatory path for approval/clearance (if appropriate) and if available, evidence of engagement with regulatory authorities.
- Consideration of commercialization strategy outside the work proposed to this announcement. This may include other ongoing relevant research, establishment of partnerships with appropriate device fabricators/manufacturers, addressing the ability to scale and intellectual property. In addition, the cost/unit, reimbursement strategy, etc. should be addressed.

The following are considered out of scope at this time:

- Pathogen-based approaches.
- Device or technologies that address prevention or detection of infection only.
- Supportive care technologies that don't specifically improve clinical outcomes for sepsis patients.
- Sepsis diagnostics that are limited to the intensive care unit hospital setting only.
- Exploratory research with no near term translational application.

## C. AOI #3: Other Disruptive Innovations (ODI)

The ODI program seeks products and solutions that will radically transform health security. DRIVe is looking for extremely bold and disruptive innovative solutions in line with its mission to produce easy-to-use, safe and effective medical countermeasures (MCMs) and devices. These ideas could not only lead to revolutionary products and technologies in health security-related patient care but also lend themselves to more novel approaches to develop, procure and deploy/distribute MCMs in a public health emergency. DRIVe has identified the following areas in which performers could propose their disruptive and innovative solutions:

- **Vaccine and Drug Administration:** Increase compliance and improve outcomes. Examples might include technologies that lead to alternative routes of administration; needle-less, micro-needle and other types of drug delivery platforms. The goal is to improve efficacy and reduce the logistical burden of ancillary equipment, adjuvants and multiple-dose regimens that is associated with the current mode of vaccine and drug administration.
- **Clinical Diagnostics:** Empower individuals and clinicians with early, actionable information. Examples include the application of technologies such as next generation diagnostics to revolutionize laboratory or near-patient testing to provide faster results for capturing and predicting health events so that timely responses and medical interventions can be deployed.
- **Development and Manufacturing:** Enable rapid drug development, and distributed or decentralized manufacturing. For example, vaccines and/or medical countermeasures that can be

produced and delivered on-demand in a distributed fashion by technologies such as 3-D printing and other advances that adopt modular approaches to vaccine production.

- **Therapeutics:** Develop universal therapeutics with broad-spectrum efficacy. For example new host-based drug targets, immunomodulators and microbiome-based therapeutics that can lead to new treatment opportunities for infectious diseases that threaten our national health security.

The examples provided above are pointers to some novel ideas and are by no means exhaustive. Performers are encouraged to submit innovative technologies which may not fit into the above categories but have the ability to impact health security in threat areas that are highly relevant to BARDA, namely chemical, biological, radiological and nuclear as well as in the areas of pandemic and emerging infectious disease threats.

# VII. Reporting Requirements and Deliverables

Some reports and other deliverables are relevant to specific activities performed during the period of performance under the contract, grant, or agreement. The Respondent and the Government will agree during final negotiations which reports and other deliverables are relevant and will be required as deliverables as determined in the negotiated final SOW. 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 Government identified system.

## A. Reports

**1. Technical Progress Reports:** The frequency of Technical Progress Reporting will be determined by the Government during negotiations. Typically, on the 20th day of each month, the Respondent 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 Government. 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.

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

## B. Meetings

The Respondent will participate in regular meetings to coordinate and oversee the contract effort as directed by the CO, CS, OTAO, and Contracting Officer Representative (COR), Other Transaction Agreement Technical Representative and other Government technical representatives as required. Such meetings may include, but are not limited to, all Respondent and subcontractors to discuss technical progress, transition activities, schedule, cost, regulatory issues, or other relevant activities.

Recurring teleconferences between the Respondent and subcontractors and the Government may be held to review technical progress. The Government 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 Respondent will receive feedback from the Government during the teleconference regarding contract performance. The Respondent will have an opportunity to respond and recommend corrective actions. The only contractual relationship will be between the Government and the prime Respondent.

### C. Program Management Plans and Documentation

**1. Product Development Plan (PDP):** Within one month of the effective date of an award, the successful Respondent may be required to submit a PDP, which will be approved by the CO, or OTAO prior to initiation of any activities related to their implementation. Part of the Project plan should include a Gantt chart and an identified risks and mitigation table.

**2. Commercialization Plan:** As requested.

## VIII. Intermittent Pausing of New Abstract Submissions

Acceptance of abstracts submitted under this EZ-BAA may temporarily be placed on hold as a result of a lack of available of funding. Notices of these intermissions, if necessary, will be communicated via modification to the EZ-BAA posted on www.beta.sam.gov.

## IX. Special Instructions to the EZ-BAA

Special instructions may be required and will be advertised via the EZ-BAA announcement on www.beta.sam.gov. Any Special Instructions announcement issued would describe a specific research interest and could address any topic within the BARDA mission space. Special Instructions announcements may require instructions tailored to the specific needs of Government requirements, but no resulting award shall exceed the size and scope of awards defined above.

## X. Additional Information

### A. Inspection of Facilities

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

The decision to inspect specific facilities will be made by the CO or OTAO in coordination with the COR, OTR, or other Government 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.

## B. Inspection of Records

Respondents, 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 Government representative. Pre-award site visits may be made with short notice. Respondents are expected to guarantee the availability of key staff or other staff determined by the Government as essential for purposes of this site visit.

## C. Provisions and Contract Clauses

Awards received through this announcement are not controlled by general procedures of FAR Part 15 “Contracting by Negotiation,” rather they are awarded under the authority and procedures described in FAR Part 35 “Research and Development Contracting.” Accordingly, given the inherent nature of a broad agency announcement, specific terms, conditions, and contract clauses can only be determined by specifics of a proposed project and will be determined based on the appropriate contract and entity type. Accordingly, contract clauses will be identified and defined during negotiations prior to award.

Respondents are advised to review, in advance, those provisions and clauses which would be relevant to the work contemplated by the Respondent to ensure compliance with all terms and conditions will be satisfied. Unless otherwise authorized, the FAR as well as the HHS Acquisition Regulations (HHSAR) will be applicable to any award executed under this announcement.