



U.S. Department of Health and Human Services
Administration for Strategic Preparedness and Response
Office of Biomedical Advanced Research and Development Authority
Division of Research, Innovation, and Ventures (DRIVE)
Washington, DC 20201

Easy Broad Agency Announcement

Title: DRIVE EZ-BAA
Announcement Number: BAA-22-100-SOL-00003

Table of Contents

- I. Introduction3**
- II. Overview Information3**
 - A. Agency and Issuing Office.....3
 - B. Objective.....3
 - C. Announcement Type and Date 4
 - D. Eligible Respondents.....4
 - E. Number of Awards.....5
 - F. Type of Award.....6
- III. EZ-BAA Process.....7**
 - A. Market Research Call.....7
 - B. Submission Preparation.....8
 - C. EZ-BAA Electronic Portal Submission Instructions..... 11
 - D. Review Process.....12
 - E. Review Timelines..... 14
 - F. Plus (+) Phase.....15
 - G. Abstract Handling and Submission Information.....15
- IV. Acquisitions Team Points of Contact.....16**
- V. Limitation on Communication after Submission 16**
- VI. Areas of Interest..... 16**
- VII. Standard Reporting Requirements..... 17**
 - A. Reports & Data Packages 17
 - B. Meetings..... 18
- VIII. Amendments to the EZ-BAA 19**
- IX. Additional Information 19**
 - A. Inspection of Facilities 19
 - B. Inspection of Records 19
 - C. Provisions and Contract Clauses..... 20

I. Introduction

The Office of Biomedical Advanced Research and Development Authority (BARDA) hereby announces to businesses, academia, and not for profit institutions the intent to solicit submissions for research efforts through this Easy Broad Agency Announcement (EZ-BAA). Authorized by 42 U.S. Code § 247d-7e, BARDA may award contracts to promote innovation in technologies that may assist research and development with respect to products that are or may become a qualified countermeasure or qualified pandemic and epidemic product and approaches for public health emergencies. In accordance with Federal Acquisition Regulation (FAR) 35.016, this broad agency announcement is used to obtain submissions for basic or applied research and development projects to advance or evaluate cutting-edge technologies and approaches, unrelated to a specific system or hardware requirement.

The following links are referenced throughout this announcement and will provide additional information regarding this EZ-BAA:

- [BARDA DRIVE website](#)
- [System for Award Management \(SAM.gov\) website](#)
- [BARDA Digital Resources \(BDR\) Portal](#)

This EZ-BAA serves as a reissuance of the previously active announcement (i.e., BAA-20-100-SOL-0002), originally issued on February 3, 2020. This announcement hereby supersedes the prior EZ-BAA for any submissions after the publishing date of this announcement.

II. Overview Information

A. Agency and Issuing Office

U.S. Department of Health and Human Services (HHS) Office of the Secretary (OS)
Administration for Strategic Preparedness and Response (ASPR)
Office of Biomedical Advanced Research and Development Authority (BARDA)
Division of Research, Innovation, and Ventures (DRIVE)
Washington, DC, 20201

B. Objective

This BARDA DRIVE EZ-BAA aims to accelerate innovation and improve the availability of transformative tools, products, and technologies to protect Americans from natural and intentional health security threats. BARDA DRIVE is seeking transformative and innovative approaches that challenge assumptions, are outside of the mainstream, address unmet needs, have the potential to radically change established practices, lead to extraordinary outcomes, and create entirely new research and development fields.

Projects awarded under this EZ-BAA may be at varying stages of technological readiness level (TRL)

and development, or at different stages along the product development path. However, each Area of Interest (AOI) may denote specific development requirements and TRL thresholds. Therefore, Respondents may propose a submission for any open AOI(s), with projects relevant to the AOI requirements, which may include but not be limited to, research in the following areas: early R&D, non-clinical development, process development, formulation, engineering, fabrication, model development, data science and development of novel algorithms, clinical studies or clinical validation, manufacturing or regulatory activities, or real-world studies.

NOTE: All prospective Respondents can learn more about the available AOIs by reading the Amendments to the EZBAA, which detail open AOI's. All Amendments are posted on the BARDA DRIVe [website](#) and on SAM.gov. Amendments are expected to be added regularly to reflect new AOI topics, modifications to existing AOI topics, changes to submission details, deadlines, etc. Therefore, Respondents are responsible for reviewing and ensuring submissions adhere to the amendment details.

C. Announcement Type and Date

Type: Broad Agency Announcement

Date: 18 October 2022

Title: BARDA DRIVe EZ-BAA

Announcement Number: BAA-22-100-SOL-00003

This overall EZ-BAA will be open until 18 October 2027, unless otherwise revised or superseded by a subsequent version of this EZ-BAA. Submission deadlines for each AOI topic may be different from the EZ-BAA close date. Deadlines are established by individual AOIs and communicated through amendments. Submissions must be submitted through our BARDA Digital Resources (BDR) Portal consistent with the applicable AOI deadline and will be reviewed as they are received when possible.

Both phases of this EZ-BAA are comprised of a two-stage process, beginning with an Abstract Submission consisting of a technical description of the project (including commercialization strategy), rough order of magnitude (ROM) of project costs, and supporting data. Abstract submissions are considered market research and used by BARDA DRIVe to collect and analyze information about capabilities within the market to satisfy agency needs. Should the Abstract Submission be reviewed favorably, then the Respondent will be invited to submit a Full Proposal, which will consist of the Abstract Submission combined with a Statement of Work, additional cost, and technical information as directed in the invitation. Further information regarding these stages of this EZ-BAA process are discussed in Section III of this announcement.

D. Eligible Respondents

This EZ-BAA is open to all responsible sources, both domestic and international. Respondents may include single entities or teams from private sector organizations, not-for-profit organizations, non-governmental organizations, and academic institutions. BARDA DRIVe strongly encourages

submissions from small businesses, historically black colleges and universities, minority institutions and minority researchers.

To be eligible for award, the Respondent must be able to demonstrate its ability to achieve the goals and objectives of the proposed project. Respondents must have the minimum financial resources and technical capabilities to comply with the proposed performance specifications, schedule, technical controls, facilities, equipment, and other organizational requirements for performance.

Duplicate submissions across more than one AOI topic or multiple submissions to the same AOI topic with little-to-no material differences are discouraged and may be rejected.

Respondents **must** be registered in the System for Award Management (SAM) with the appropriate North American Industry Classification System code prior to proposing their Abstract Submission.¹ Registration can be completed on SAM.gov. It is expected that this EZ-BAA will cover a range of NAICS codes based on the specifics of the technology proposed. The majority of those NAICS codes will be one of the following:

- 541713 Research and Development in Nanotechnology
- 541714 Research and Development in Biotechnology (except Nanobiotechnology)
- 541715 Research and Development in the Physical, Engineering, and Life Sciences (except Nanotechnology and Biotechnology)
- 541720 Research and Development in the Social Sciences and Humanities

Non-federal ASPR or BARDA personnel will be ineligible to respond to this announcement if they simultaneously provide scientific, engineering, and technical assistance (SETA) or advisory and assistance services (A&AS), or similar support, to any part of the U.S. Government. Also, former federal employees or individuals who provided SETA or A&AS services to ASPR or BARDA within the past year are ineligible to respond. Finally, any individual who contributed to the creation of this announcement is ineligible to respond.

All members of the proposed team for the project (including any subcontractors or consultants) must certify whether their organization, including its individual team members and proposed subcontractors or consultants, have provided similar support to any U.S. Government agency. If a Respondent's proposed team includes former BARDA federal employee or a member who has provided SETA or A&AS support to BARDA or another U.S. Government agency with whom BARDA engages, it is the responsibility of the Respondent to disclose this information and demonstrate that no potential conflict of interest exists.

E. Number of Awards

Multiple awards are anticipated and subject to change, dependent upon the priorities and

¹ When registering your entity at SAM.gov, please be sure to select the eligibility for "All Awards" option as opposed to "Financial Assistance Agreements Only."

relevance to current AOIs and funding availability. It is anticipated this EZ-BAA will received a large volume of submissions and it is anticipated that only a small percentage (estimated 5-10%) of those Respondents who propose an Abstract Submission will be awarded an EZ-BAA contract.

F. Type of Award

Contracts awarded under this EZ-BAA will be made in the form of any appropriate contract type under the FAR or non-FAR instruments (i.e., Other Transactional Agreement for research efforts). Grants and cooperative agreements will not be awarded from this EZ-BAA. All awards will be contingent upon the availability of funds, current program strategy, and relevance to the identified AOI.

A decision will be made as to the most appropriate award vehicle that will be used for a prospective award if and when a submissions advances to negotiations. It is anticipated that most initial awards will result in a firm fixed price (FFP) contract.

Regardless of award type, Respondents must propose a Resource Contribution as part of their project. The overall effort is defined as the combination of Resource Contributions and U.S. Government resources required for the proposed project. Resource Contributions are expected to be in the form of direct labor, equipment, consumables, travel, or other in-kind contributions expressed as U.S. dollars.² For example, an in-kind contribution for equipment or facility use should be based on fair market value with the contributions for the space or equipment limited to that necessary for the proposed effort. The target Resource Contributions proposed by a Respondent, for initial submissions and + Phase submissions should be a minimum of 30-50% of the total proposed value of the project. The amount of Resource Contributions proposed by the Respondent should depend on the extent to which the R&D effort is likely to enhance the Respondent's capabilities, expertise, or competitive position.

The expectation is that nearly all awards resulting from this EZ-BAA will include Resource Contributions by the Respondent. In the rare circumstance that a Respondent does not believe Resource Contributions are 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 the proposed project award under this EZ-BAA.³

The scope of resulting contracts from this announcement will be identified through negotiations and established in resulting contracts or agreements. The scope of work of resulting contracts or agreements may include, or be revised to include, efforts across the BARDA mission space as necessary.

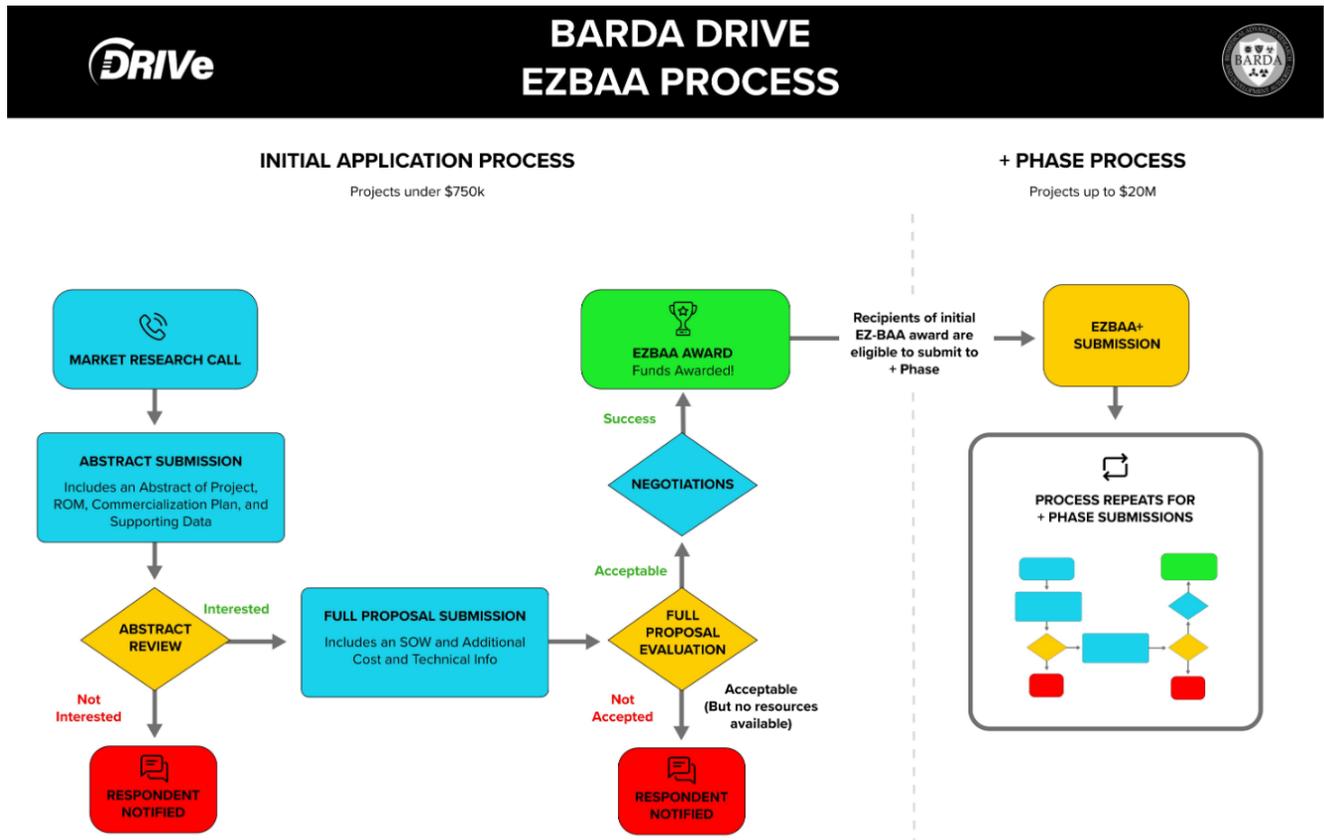
NOTE: The costs of preparing submissions to this EZ-BAA will not be considered an allowable cost

² Note that the value of other simultaneous government awards (federal, state or local) received by a Respondent (e.g., grants, contracts, etc.) are not considered to be acceptable forms of Resource Contributions.

³ Examples include increased technical know-how, training for employees, acquisition of goods or services, development of a commercially viable product that can be sold in the commercial market and use of background knowledge in future contracts. Resource Contributions are intended to serve the mutual interests of the U.S. Government and its contractors by helping to ensure efficient utilization of the resources available for the conduct of R&D projects and by promoting sound planning and prudent fiscal policies of the contractor.

on any resulting award. In accordance with IAW 31 U.S.C. 1342, the Government may not accept volunteer services, or employ personal services not authorized by law, except in cases of an emergency involving the safety of human life or the protection of property. If a Respondent's submission includes a labor mix with a level of effort dedicated to the R&D project, then all Resource Contributions and proposed costs for the project must be quantified and indicated as being incurred by either the U.S. Government or the Respondent.

III. EZ-BAA Process



A. Market Research Call

BARDA DRIVE acknowledges that the preparation of submissions often represents a substantial investment of time and effort by a Respondent. In attempt to minimize this burden, DRIVE **highly encourages** Respondents that are interested in proposing a submission to schedule a market research call with an AOI representative to discuss their general technology and alignment with programmatic priorities. This should allow a Respondent to better understand if their project aligns with the intent of the AOI before expending effort in preparing a submission or sending proprietary information.

Again, participating in a market research call before proposing a submission to the applicable AOI

is **strongly encouraged and in some cases may be required by a specific AOI.**

NOTE: The AOI points of contact are subject to change. Amendments are regularly added to include new AOI topics, modifications to existing AOI topics, and changes to submission details, deadlines, etc. Therefore, all Respondents should review the most recent Amendments to this EZ-BAA to ensure they have the most up to date AOI information posted on the BARDA DRIVE website and on SAM.gov. **Lastly, no abstracts/proposals should be sent via email at any time.** Abstracts/proposal submissions will only be reviewed after they are submitted in the BDR Portal, and in accordance with the process defined below.

B. Submission Preparation

The following components must be included in Abstract Submissions that will be processed through our electronic submission:

1. Technical Section

A) Problem statement:

- Which major health security problem are you addressing? What is the motivation for this proposed project? (1-2 sentences)

B) Solution:

- Briefly describe the proposed solution and the desired use case, if relevant. Outline the technology / tool / device / process and, if appropriate, the research & development question. (1-2 sentences)
- Explain how your solution is responsive to the goals of this program. (1 sentence)

C) Impact:

- If you are successful, what difference will it make to health security (1-2 sentences)

D) Innovation:

- What is unique and innovative about your proposed solution? Is the innovation in the technology / tool / process itself or is it in the application? How is this solution better than competing ones? (2-3 sentences)

E) Supporting data / feasibility:

- Introduce relevant preliminary data generated by the Respondent (please include the data in the text as a narrative, do not merely list references from other researchers). (1 paragraph)
- Ensure that all solicitation and special instructions requirements are addressed.
- Relevant supporting figures can be provided as part of a single attachment.

F) Technical approach:

- How does your solution (technology / tool / device / process) work? Be methodical

and specific. (1-2 paragraphs)

- How mature is the Respondent’s solution (technology / tool / device / process)? If possible, describe the Technology Readiness Levels (<https://www.medicalcountermeasures.gov/trl>) for major components of the solution in Respondent’s organization. (1 paragraph)
- Which R&D work will be conducted on each major component of the solution? Be specific and use quantitative metrics, whenever possible, and structure this section in terms of deliverables and milestones. What are the goal specifications (e.g. analytes of choice, limits of detection, relevant clinical ranges, algorithm accuracy etc.)? How will you assess the performance of your solution? (2-3 paragraphs)
- *If relevant to your project:* Provide details on pre-clinical studies (justification for model, alignment with regulatory path), clinical study or trial design (# of patients, endpoints, enrollment population, clinical partners etc.), regulatory approach, and how the proposed project aligns with these next steps. Relevant documentation can be supplied in the attachment, to include but not limited to Investigator’s Brochure, clinical protocol or synopsis, FDA feedback, subcontractor proposals / agreements / letters of commitment etc.
- *If relevant to your proposal:* Include a target product profile (TPP) for the product/platform under development (<https://www.phe.gov/about/amcg/BARDA-BAA/Documents/Target-Product-Profile.pdf>) in the attachment.
- Ensure that all requirements in the broad agency announcement, including amendments, are addressed.
- Relevant supporting figures can be provided as part of a single attachment file.

G) Regulatory approach (*if relevant to your proposal*):

- Please provide your regulatory strategy and associated clinical development approach.
- Please elaborate on any engagement with FDA that has occurred or will occur in the near future and summarize (or attach) feedback from FDA. (1 paragraph)

H) Manufacturing (*if relevant to your proposal*):

- Have commercial contract manufacturers for the product have been identified? If so, which ones? Please provide remaining activities needed for scale up, if needed, and a timeline of activities. Address whether the proposed solution is ready for technology transfer and/or further qualification/verification/validation. (2-3 sentences)

I) Intellectual Property:

- Please address the ownership and/or pending status of any patents, or related intellectual property, related to the subject technology. (1-2 sentences)⁴

⁴ If the proposed project contains the cost or payment of any royalties, please reference FAR 52.227-6, which is

J) Risks:

- What are the major internal and external risks associated with the project and what is your mitigation strategy? (1-2 sentences)

2. Project Price/Costs

- A. **Rough Order of Magnitude (ROM):** Please use the *EZ-BAA ROM Template* located on the BDR Portal when submitting your Abstract Submission, as well as providing narrative descriptions for each of the cost elements. The *EZ-BAA ROM Template* will not count against the character count while the narrative description would. The ROM will require you to value the following cost elements for each project deliverable that are described in the Technical Section. Additionally, you will need to provide a written narrative for each of the cost elements as detailed below. **NOTE:** Ideally, the project deliverables.

Narrative Component of the ROM:

- Direct Labor.** Briefly describe the employees, positions/labor categories, level of effort, and functions being performed in the proposed project.
- Fringe Benefits (if applicable).**
- Overhead Expenses (if applicable).**
- 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.
- 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 contract.
- Subcontractors (including Consultants).** Please provide a description of what work will be conducted by a proposed subcontractor (or consultant) and how the subcontractor (or consultant) was selected and determined to be reasonable for the project.
- Other Direct Costs (ODCs).** Include as necessary.
- General & Administrative (G&A) Expenses (if applicable).**
- Total Proposed Project Value.** Proposals that include \$750,000 or more in U.S. Government funding toward the total proposed project value will be considered non-conforming and will not be reviewed.
- Resource Contribution.** Clearly indicate and describe the proposed Resource Contribution by the Respondent, which may consist of cash investment or in-kind contributions expressed in U.S. dollars. The Resource Contribution may be satisfied by proposing specific cost elements to be funded by the Respondent or may be represented as an overall percentage of total proposed project costs., The proposed Resource Contribution by the Respondent must be quantified and should reflect at least 30-50% of the total proposed project value.

hereby incorporated, for a list of royalty information which would be required for a subsequent Full Proposal, should a submission progress to that stage.

NOTE: All of the cost/price elements above should be reflective of the total proposed project value, rather than for the portion of U.S. Government funding. The funding limitations (e.g. <\$750,000) applies to the proposed amount of U.S. Government funding for the project. It is possible for the total proposed project value (i.e., Resources Contributions from the Respondent plus U.S. Government funding) to be valued above the funding limitation (e.g. \$750,000+), so long as the U.S. Government funding being requested is <\$750,000.

More detailed cost information may be requested by the CO, CS, or the OTA0 for those submissions selected for further consideration. Additionally, the period of performance for contracts resulting from the EZ-BAA will be based on the contract type, specific project requirements, and stage of development. Establishing the period of performance considers the unknown or unexpected results of advanced R&D, industry practices, market conditions, and capabilities of small business concerns. We anticipate the period of performance for most initial awards under this announcement to be 12-24 months in duration.

3. Project Deliverables

- A. List individual deliverables and (quantitative) metrics of success.

C. EZ-BAA Electronic Portal Submission Instructions

All submissions in response to this EZ-BAA must be made on the BDR Portal via the process described below and on our BARDA DRIVE website.

Respondents will be required to apply for a 1) SAM.gov account as well as a 2) BDR Portal account before a proposal can be submitted. The BDR portal account can be requested by visiting the BDR Portal and following the applicable prompts. The account request process is simple, straightforward, and secure. However, if you experience any issues please reach out to [BDR Admin Inbox@hhs.gov](mailto:BDR_Admin_Inbox@hhs.gov) to resolve them.

The Abstract Submission will consist of: (1) technical description of the project (which must be no more than 12,500 characters); ROM of project costs, and supporting data and other documentation. An attachment including supporting data, references, or visual representations for the proposed project. Note the abstract should stand on its own and the attachment should only supplement the submission. The attachment may or may not be reviewed by the reviewers, as necessary. Information contained in an attachment is not guaranteed to be reviewed.

All submission documents must be submitted electronically via the process described on the BDR Portal for it to be reviewed. Respondents will be emailed a confirmation receipt upon successful Abstract Submission.

D. Review Process

1. Determination of Interest in the Abstract Submission

Abstract Submissions must comply with all requirements detailed in this EZ-BAA announcement as well as the description of the relevant AOI topic which would be detailed in the Amendments. Submissions that fail to do so will be deemed non-compliant and will not be reviewed. Submissions which propose technology deemed to be outside the scope of the specific AOI will be considered non-compliant. Additionally, submissions which do not propose Resource Contributions of at least 30-50% of the total proposed project value will not be considered for award, unless a justification is included as to why there is no probability that the Respondent will receive any present or future benefits from an award.

Compliant submissions will be reviewed in whole based on the AOI requirements and on the potential enhancement to the current AOI portfolio. This review will result in the Respondent receiving a notice of “Interested” or “Not Interested” based on the following definitions:

Interested: BARDA DRIVE is interested in the concept. The project (1) aligns with the relevant AOI program strategy and fits within the current needs of the program; and (2) the project appears to be feasible based on the information and supporting data provided; and (3) the project would likely enhance the AOI portfolio with an innovative technology or meet an unmet need, thereby significantly enhancing or improving the state of the art.

Not Interested: BARDA DRIVE is not interested in the concept at this time. The proposed project (1) does not align with the relevant AOI program strategy or does not fit within the current needs / resources of the program; or (2) the project does not appear to be feasible based on the information and supporting data provided (or lack thereof); or (3) the project would not likely enhance the AOI portfolio with an innovative technology or does not meet an unmet need, thereby significantly enhancing or improving the state of the art.

The determination will not be based on the content of the submission and prior communication with BARDA that may have occurred during a market research call will not be considered. The Contracting Officer will issue the notice to the Respondent.

Respondents receiving a “Not Interested” notification following an abstract review will receive a brief rationale for the decision, but debriefings will not be offered following market research phase.

Respondents receiving an “Interested” notification will be invited to submit a Full Proposal which will consist of a Statement of Work, as well as additional cost and technical information. Specific instructions will be provided to Respondents at the time of said notification. Full Proposals will be evaluated in accordance with the evaluation criteria outlined in the section below.

2. Full Proposal Evaluation

Consistent with FAR Part 35.016, Full Proposals will not be evaluated against each other as they are not submitted in accordance with a common work statement. Instead, each proposal is evaluated only against the defined evaluation criteria. Full Proposals will be evaluated in whole (i.e. Abstract Submission combined with a Statement of Work, as well as additional cost and technical information), and the evaluation will not be based on any prior communication with BARDA that may have occurred during a market research call.

The evaluation criteria for Full Proposals is as follows:

- I. Alignment with current AOI requirements, program strategy, and resources
- II. Technical Approach
- III. Ability to transition technology and expand use of its application
- IV. Cost/Price Reasonableness (including proposed Resource Contributions by the Respondent)
- V. Past Performance

Technical evaluation factors I - III, when combined, are significantly more important than evaluation factor IV, Cost/Price Reasonableness, which is more important than evaluation factor V, Past Performance. Note, a Respondent may receive a negative overall evaluation if just one of the evaluation factors is rated unfavorably.

Cost/price reasonableness and realism evaluations will be conducted, as appropriate, based on the contract type. Resource Contributions proposed by the Respondent will be evaluated pursuant to HHSAR 335.070, while Past Performance evaluations will be conducted utilizing the Contract Performance Assessment Reporting System (CPARS) and other available Government resources. In the event the government receives adverse past performance information during the course of the evaluation that would result in a negative past performance evaluation, the Respondent will be given an opportunity to respond to such information prior to an award decision. 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 full proposal evaluations will result in one of the following ratings defined under Section E below: (1) "Acceptable"; (2) "Not Accepted"; or (3) "Acceptable but No Resources Available". Respondents who receive a rating of "Not Accepted" will be notified and provided a rationale for the decision. Respondents who receive a rating of "Acceptable" will be invited to enter negotiations with the possibility of award. Assuming all terms and conditions, as well as scope of work, project deliverables, and budget are mutually agreed upon during negotiations, an award will be made subject to the availability of funds.

In rare instances, Respondents may receive a rating of "Acceptable but No Resources Available". Notification of this rating does not initiate negotiations, but instead informs the Respondent that its proposal satisfies the definition of "Acceptable", however our program team has determined that there is insufficient funding or strategic resources. This rating reserves the right for BARDA DRIVE to enter negotiations with the Respondent at a future date but no more than 6 months after

the Respondent receives this rating notification. The Respondent may also be contacted at any time after receiving notice of this rating that BARDA DRIVE will not advance its proposal in this EZ-BAA process.

NOTE: An individual AOI may establish slightly review processes based on the specifics of the technical research area. Please refer to the corresponding EZ-BAA Amendment for any variations.

Full Proposal Review Definitions:

Acceptable: The proposal (1) aligns with the relevant AOI program strategy and resources; and (2) describes a feasible approach to successfully accomplishing the project deliverables; and (3) may likely result in successful progression of the technology and expanded use of its technology in the relative AOI; and (4) the cost/price is deemed reasonable (including proposed Resource Contributions). A finding of Acceptable results in the proposal being considered for negotiations, and if successful terms and conditions are agreed upon a subsequent award will be made subject to availability of funding.

Not Accepted: The proposal does not (1) align with the relevant AOI program strategy and resources; or (2) describe a feasible approach to successfully accomplishing the project deliverables; or (3) may not likely result in successful progression of the technology and expanded use of its technology in the relative AOI; or (4) the cost/price is not deemed reasonable (including proposed Resource Contributions). A finding of Not Accepted will result in the proposal not being considered for negotiations or subsequent award. Respondents whose proposals are deemed Not Accepted will be provided the identified weaknesses of the proposal to support the determination.

Acceptable but No Resources Available: The proposal satisfies the definition of “Acceptable”, however the program has determined that there may be insufficient funding or strategic resources. This rating reserves the right for BARDA DRIVE to enter negotiations with the Respondent at a future date but no more than 90 days after the Respondent receives this rating notification. The Respondent may also be contacted at any time after receiving notice of this rating that BARDA DRIVE will not advance its proposal in the EZ-BAA process.

E. Review Timelines

Abstracts property received will be reviewed as they are received. The target date for notification of Respondents of disposition is 30-90 days following receipt of abstract, although Respondents will be notified as soon as possible to the maximum extent practicable. All Respondents will be notified regarding the final disposition of their submission.

NOTE: An individual AOI may establish different review schedules or timelines. Please refer to the corresponding EZ-BAA Amendment for any variation.

F. Plus (+) Phase

Respondents who received an award under the EZ-BAA also have an opportunity to apply to the Plus (+) Phase. Open only to Respondents who received an initial award under the EZ-BAA, the Plus Phase is an opportunity for organizations to submit an abstract for the development of their technology beyond that which has been supported by an EZ-BAA award. Submissions must be for the development of the same technology supported by the EZ-BAA award and must be received by BARDA DRIVe before two years after the completion date of the initial EZ-BAA award. All other submissions will be deemed ineligible for consideration under the EZ-BAA+ Phase and those entities will be directed to submit an Abstract Submission for consideration of an initial award under this EZ-BAA. Unless this announcement is modified otherwise, awards resulting from the EZ-BAA+ Phase may not exceed \$20 million in U.S. Government funding, inclusive of any proposed optional periods of performance. While \$20 million is the maximum amount, it is anticipated that most EZ-BAA+ awards will result in projects between \$2 - \$10 million of U.S. Government funding.

The + Phase of the EZ-BAA will use the same scientific review procedures as those described in this EZ-BAA announcement for an award. The only key differences with the EZ-BAA+ Phase may be with respect to any resulting awards' contract type, anticipated contract duration, funding threshold, and cost accounting standards as required by 41 U.S. Code § 1502.

G. Abstract Handling and Submission Information

1. Safeguarding of Information

BARDA DRIVe takes the protection of Respondent information very seriously to ensure that such information is safeguarded in full compliance with all applicable regulations and laws. All information proposed in either phase of this EZ-BAA process, except where clearly marked in the submission as non-proprietary, will be treated as the Respondent's proprietary information.

By engaging in a market research call, proposing information related to this EZ-BAA announcement, or accepting a contract resulting from this EZ-BAA announcement, Respondents acknowledge that non-federal personnel may participate in the process and provide input throughout the evaluation or contract administration process compliant with FAR 37.203(d) and serves as the agreement for purposes of FAR 9.505-4. Non-federal personnel may also handle submissions for administrative purposes and for analysis of non-proprietary information as denoted on the submission form. All non-governmental personnel who support BARDA DRIVe are strictly bound by appropriate non-disclosure and conflict of interest requirements. Respondents should not engage in any portion of this EZ-BAA process if they do not consent to the participation of non-federal consultants and partners described in this subparagraph.

BARDA DRIVe takes all prudent measures to avoid "technical transfusion" (i.e., sharing one Respondent's proprietary information or data with another Respondent). Any discourse with a Respondent will not reveal this information to any other Respondent or prospective Respondent.

2. Classified Information

Classified submissions, 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 should this situation arise.

4. Unsuccessful Abstract Disposition

The electronic filing of each submission will be retained by BARDA DRIVE pursuant to FAR 4.805.

IV. Acquisitions Team Points of Contact

The points of contact information is posted on sam.gov. Please check sam.gov for the appropriate points of contact.

All inquires to include contact made with a CO regarding this EZ-BAA must be submitted to DRIVEAcquisitions@hhs.gov.

V. Limitation on Communication after Submission

After receipt of a submission under this EZ-BAA, all interactions with Respondents must be made through the Contracting Officer / Contract Specialist regardless of its communication method (i.e., email, telephone, or in-person). It is important to note that the Contracting Officer, Contract Specialist, or Program Manager cannot advise or direct a Respondent on how to prepare or revise a submission.

NOTE: You may not present through the BARDA TechWatch program if it is related to the same proposed work of a pending submission review under this announcement. If you have questions about timing of these complementary activities (BARDA TechWatch and EZ-BAA reviews) then please email the contracting points of contact listed above.

VI. Areas of Interest

This EZ-BAA is seeking submissions for basic and applied research and development to advance cutting edge technologies or products relevant to health security. DRIVE wants to emphasize revolutionary and technically sound approaches that are responsive to the AOIs described in detail

via the Amendments posted on our [BARDA DRIVE website](#) and the EZ-BAA announcement on SAM.gov. For additional information please also 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.”
- BDR Portal

NOTE: The AOI points of contact may change over time, and Amendments are regularly added regularly to reflect new AOI topics, modifications to existing AOI topics, changes to submission details, deadlines, etc. Therefore, all Respondents should ensure they are reviewing the most recent Amendments that are relevant to the AOI topic which are posted on our BARDA DRIVE website and this EZ-BAA announcement on SAM.gov.

VII. Standard Reporting Requirements

Some reporting requirements relevant to specific activities performed during the period of performance under an awarded contract or other transaction agreement (OTA) will be required to be delivered to BARDA DRIVE’s program team. The Respondent and BARDA DRIVE will agree during negotiations which standard reporting requirements and other deliverables are necessary as determined by the final, mutually agreed-upon Statement of Work, project deliverables, and other relevant reporting sections in the contract or OTA. Any required reports should be submitted electronically in Microsoft Word, Microsoft Excel, Microsoft Project, Adobe Acrobat PDF, or data-fields applicable to a U.S. Government-identified system. Additionally, all contracts awarded under the EZ-BAA that involve the delivery of audiovisual materials or publications will be subject to 508 compliance. The following are representative of the standard reporting requirements for an EZ-BAA contract and provided here for purposes of preparing your submission:

A. Reports & Data Packages

The due dates for each item will be specific and quantifiable in each resulting contract. They will be based on the specific needs of each project and subject to agreement.

1. Project Plan

Soon after an award, the Respondent shall submit a project plan prior to initiation of any activities related to their project implementation outlining the goals, deliverables, strategies, and intended pathway for the project. The detailed project plan should also include a Gantt chart and risk mitigation plan.

2. Monthly Reports (Technical Progress Reports)

Typically, each month, the Respondent shall submit a technical progress report describing activities performed during the previous calendar month. The appropriate formats for the technical progress reports may be provided by the BARDA DRIVE program team. The technical progress reports may include project timelines and summaries of product manufacturing, testing,

and clinical evaluation activities, as applicable.

3. Transition Plan

Prior to the contract end date, the Respondent shall submit a summary document containing a transition strategy that includes a strategic business and technical plan for further development and transitioning the product or technology.

4. Final Report

Prior to the contract end date, the Respondent shall submit a final report that details, documents, and summarizes the results of all work performed under the contract. The appropriate formats for the final report may be provided by the BARDA DRIVE program team.

5. Final Data Package

Prior to the contract end date, the Respondent shall submit a final data package consisting of all raw data, technical documents, or data analysis produced under the contract. Data may be used by BARDA DRIVE for analysis, evaluation, shared with other agencies, or shared outside of the U.S. Government consistent with FAR 52.227-14 Rights in Data – General (May 2014). This submission package must be delivered in a non-proprietary format. If clinical trial data is included, that data must be provided consistent with applicable privacy laws to protect personal identifiable information.

B. Meetings

1. Kickoff Meeting

Soon after an award, the Respondent shall hold an initial meeting (expected to be virtual) with BARDA's project coordination team who will be overseeing the contract to outline activities for at least the first 90 days.

2. Recurring Teleconferences

The Respondent shall participate in recurring teleconferences to coordinate and manage the project updates as directed by BARDA's project coordination team. Such meetings may include, but are not limited to, the Respondent and its subcontractors to discuss technical progress, transition activities, schedule, cost, regulatory issues and updates, or other relevant activities.

3. Annual Meeting

BARDA DRIVE's program team reserves the right to convene annual, in-person meetings with key staff from the awarded contracts as needed.

VIII. Amendments to the EZ-BAA

Amendments will be advertised on our BARDA DRIVE website and SAM.gov. The Amendments will provide details regarding the AOIs and may also address any topic related to the BARDA DRIVE mission space. Amendments may include unique instructions tailored to the needs of BARDA DRIVE, but no resulting award shall exceed the size and scope of awards defined above, unless otherwise modified.

Availability of AOIs under this EZ-BAA may be postponed due to a lack of available funding. Notices of these postponements will be communicated via Amendments posted on our BARDA DRIVE website as well as this EZ-BAA announcement on SAM.gov.

Note: The AOI points of contact may change over time, and Amendments are regularly added regularly to reflect new AOI topics, modifications to existing AOI topics, changes to submission details, deadlines, etc. Therefore, all Respondents should ensure they are reviewing the most recent Amendments that are relevant to the AOI topic which are posted on our BARDA DRIVE website as well as this EZ-BAA announcement on SAM.gov.

IX. Additional Information

A. Inspection of Facilities

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

The decision to inspect facilities will be made by the CO (or OTAO) in coordination with the COR (or OTATR), or other Government representative. If inspections are performed during negotiations, the results of the inspection will be considered in the final selection for award of a contract or OTA, or the payment of project deliverables.

B. Inspection of Records

Respondents, as well as its subcontractors, will be requested to make necessary records, including previous regulatory inspection records and staff available in response to a pre-award site visit or audit by a BARDA DRIVE representative. Pre-award site visits may be made with short notice. Respondents are expected to guarantee the availability of key personnel or other staff members as determined by BARDA DRIVE's program team to be essential for the site visit.

C. Provisions and Contract Clauses

Contracts from this announcement are awarded under the authority using scientific review through the procedures described in FAR Part 35 and are not controlled by general procedures of FAR Part 15, except if noted by regulation. Given the inherent nature of a broad agency announcement, the specific terms, conditions, and contract clauses will largely be determined by the specific nature of the proposed project, as well as the appropriate contract and entity type. Accordingly, contract clauses will be identified and defined during negotiations prior to an award.

Respondents are advised to review the provisions and clauses which would be relevant to the project being considered for proposal to ensure compliance with all terms and conditions. Unless otherwise authorized, the FAR as well as the HHS Acquisition Regulations (HHSAR) will be applicable to any FAR-based contract made under this announcement. Authorities under 42 U.S. Code § 247d–7e would be applicable to any made under this announcement as applicable.