U.S. Department of Health and Human Services

Administration for Strategic Preparedness and Response

Program Office of Industrial Base Management and Supply Chain

Notice of Funding Opportunity

and Cooperative Agreement Application Instructions

Funding Opportunity Title:

ASPR Preparedness and Response Innovation (PRI) Israeli Bilateral Health Cooperative Program

Catalog of Federal Domestic Assistance (CFDA) Number:
93.360

Funding Opportunity Number: EP-IDS-22-001

Application Due Date: August 31, 2022

Contents

I. FUNDING OPPORTUNITY DESCRIPTION

1. Statutory Authority

Authorization: Section 319L of the Public Health Service Act, Sec. 319L 42 USC 247d–6a, 42 U.S.C. 247d-7e. Funding for this Cooperative Agreement was provided under the Consolidated Appropriations Act, 2021 to the Public Health Emergency and Social Services Fund, as identified in the Explanatory Statement, 166 Congressional Record H8634 (Dec. 21, 2020).

2. Executive Summary

The Administration for Strategic Preparedness and Response (ASPR), Program Office for Industrial Base Management and Supply Chain (IBMSC) (hereinafter referred to as "ASPR") is releasing this "ASPR Preparedness and Response Innovation (PRI) Israeli Bilateral Health Cooperative Program" Notice of Funding Activity (NOFO) to solicit applicants interested in working with ASPR to stimulate the public good by creating or leveraging one or more Accelerators between the United States (US) and Israel to promote national health security innovation.

ASPR will make investments through a collaborative model involving one or more cooperative agreement recipients based in the US and/or Israel, who will establish or support an existing Accelerator[1] that emphasizes revolutionary advancements in health security products, technologies, and solutions. The accelerator(s) may be attached or have established relationships to academic or clinical research centers in either or both the US and Israel. The funds awarded by ASPR will fund accelerator Research and Development (R&D) activities to address 21st century health threats facing our Nations and stimulate and advance research and development efforts in health security products, technologies, and innovations. An ASPR PRI Bilateral Health Cooperative Program Technical Accelerator (hereinafter referred to as "Accelerator") will be a non-equity accelerator[2] that provides non-dilutive funding[3] to product developers for R&D activities and enables the product developers to retain full ownership and control of their company. Accelerators will not be permitted to take an equity position in the product developers it supports through its partnership with ASPR.

The applicant(s) who enter an agreement with ASPR will become members of the Technical Accelerator Network to:

- Support ASPR and Israeli health security products and technologies as they navigate research, development, and regulatory pathways.
- Provide wrap-around services to assist the R&D efforts (such as technical and business advice, access to facilities and incubator spaces, integration services).
- Identify and foster innovations in early health security product and technology development through launch, and
- Cultivate the community of those making a difference in health security products, technologies and Innovations.

The goal of this NOFO is to fund one or more Awardees who are capable of advancing R&D activities through the creation of or leveraging of an existing Accelerator to promote and advance national health security innovation in cooperation with the US and Israel.

[1] The use of the word "Accelerator" in this NOFO implies an entity that provides unique and highly flexible combination of technical support, business development processes, infrastructure, and people designed to nurture new and small businesses grow through the difficult and vulnerable early stages of development. The term implies capabilities typical of both Accelerators and Incubators. Both types of existing organizations may have the ability to augment their existing capabilities and acquire remaining capabilities discussed in this NOFO to respond to this announcement.

[2] An accelerator [that] does not take an equity position in the companies it supports through its partnership with ASPR.

[3] **Non-dilutive funding** is financing that does not require the sale of your company's shares, and hence does not cause dilution of the existing shareholders.

3. Project Overview:

New challenges confront disaster response efforts that require novel solutions to ensure that the Department of Health and Human Services and other U.S. government agencies maintain and enlarge the capabilities and capacities to protect Americans from national security health threats. Established in FY 2021, ASPR's Preparedness and Response Innovation (PRI) program seeks to develop, prototype, and procure revolutionary health security products, technologies, and innovations that equip responders to meet unique and emerging health needs that may result from natural or manmade disasters.

This program signals the importance of ASPR's mission to develop medical countermeasures (MCMs) and adapt those technologies and practical solutions to ensure the availability of the highest standards of care, when they are most needed. The program emphasizes revolutionary advancements in health security products, technologies, and solutions, specifically to invigorate operations, response, recovery, deployment, and dispensing activities. The PRI program was additionally established to coordinate strategic innovation and industrial base expansion efforts across ASPR, federal partners, academia, and the private sector to bring novel solutions and practices for critical response and recovery operations to life.

The PRI program through ASPR will provide direct funding to one or two Accelerators (the cooperative agreement recipient(s)) that will manage a portfolio of investments of early-stage technology products and/or innovation candidates. The support needs of entities may vary widely, from entrepreneurs with successful track records to those with exciting technologies but little in the way of business acumen or experience. Navigating the regulatory environment between the US and Israel will likely additionally required guidance.

The award recipient(s) will direct project efforts; conduct meetings, workshops, and research with diverse strategic expertise; provide world-class rapid and iterative advanced development capabilities; provide foundational infrastructure to deliver project specific space for scale-up and cGMP manufacturing capability to project teams, common analytical laboratories, and office facilities; and take other actions, as appropriate, to further the mission of this cooperative program.

The agreement recipient(s) will either have existing relations or need to establish communications with US and Israeli government entities with ties to health and commerce. Prior work initiated in support of the ASPR Israeli project in October of 2021 may provide a list of applicable contacts, as well as a potential "Roadmap" for initial nascent contacts of potential innovation candidates located in the US and Israel.

SCOPE of Project:

The cooperative agreement recipient will be responsible for initiating advanced development projects for health security products, technologies, and innovations. Specifically, projects will focus on the cooperative advanced development of projects that advance the Bioeconomy for Health. The Bioeconomy for Health addresses the recent advances in technologies that catalyze global investment, spur innovation, and increase international competitiveness within health, medicine, and adjacent industries. It is critical for the US - Israeli Bilateral Health Cooperative Program to actively develop new mechanisms that leverage advantages in biotechnology for its benefit in the face of global peer competition. Through the accelerator(s) the Program will ensure that key influencers and opinion leaders can generate new technologies and work to start up new companies to advance this ecosystem.

There will be three functional areas for cooperative research and development with private and public sector partners. These areas include:

- Establish and conduct a bilateral US-Israeli program for development of health technologies.
- Work with partners identified in the bilateral program to identify start-ups and developers to create a

pipeline of data/analytics tools towards health-promoting vs. sick care applications.
- Evaluate regulatory pathways and safety/efficacy summaries to advance the BioEconomy and benefit all partners within the bilateral program.

Establish and Conduct a Bilateral Program for Development of Health Technologies:

The cooperative agreement funding will support outreach, partnering opportunities, and seedling awards by the accelerator(s) for applied clinical research and development projects in the US and Israel. The accelerator(s) will handle the logistics, execution, and facilitation of virtual and/or in-person stakeholder workshops with a variety of subject matter experts, as well as with private companies to identify needs, present novel capabilities, and identify gaps. Funding under the cooperative agreement is intended to support logistics, recruiting, planning, and execution of workshops, and the delivery of reports on outcomes. Specific activities shall include but are not limited to:

- Bring together key opinion leaders in an Advisory Panel to assess a supply chain for future health security that is inclusive of manufacturing and post- manufacturing logistics for disaster response and clinical delivery that leverages emerging hard and soft technologies and automation.
- Work with entrepreneurs and developers in medical technology and health security innovation to provide technical, strategic, operational, business, and stakeholder engagement support.
- Work with developers to develop health technologies to advance clinical delivery of treatment for current and future pandemics to the appropriate end user(s).
- Network with Research and Development (R&D) and medical technology experts to further support and advance an ecosystem for innovation.
- As an accelerator support early-stage companies throughout their journey – from identifying a need to product launch – to help them overcome their biggest business, marketing, and operational hurdles, and achieve success sooner.

Create a Pipeline of Data/Analytics Tools to Enable Transfer of Ownership of Health Records to the Patient, and Establish a New Ecosystem for Healthcare Participation and Drug Discovery:

The accelerator(s) will support the development of novel data security and analytics platforms that allow for new ways to secure patient records, enable individuals to own all of their health records in one location and participate in clinical discovery and share in the monetization of their own data as well. Such advancements would enable the analysis of data from the broadest patient population possible and potentially develop new capabilities for phenotypic and multiomic analysis. Funding from the cooperative agreement will support the accelerator(s)'s logistics, recruiting, planning, execution of these data/analytic development efforts, the funding of startup companies, and delivery of software tools and reports on outcomes. Specific activities shall include but are not limited to:

- Work with entrepreneurs and developers identified in the Bilateral Program to identify start-ups and developers to create a pipeline of data/analytics tools.
- Create new health security data architectures that can support the emerging opportunities afforded by machine learning and medical IOT (internet-of-things) devices.
- Work to develop a medical device portable power source with network connectivity to the secure source
- Conduct an infrastructure and architecture analysis to design and develop services necessary to manage and aggregate data from connected health devices, create machine learning training sets, and generate analytics and workflows to evaluate and manage health security applications.

Evaluate Regulatory Pathways and Safety and Efficacy Summaries to advance the BioEconomy and Benefit Partners within the Bilateral Program:

The accelerator(s) will conduct virtual and/or in-person stakeholder workshops with private companies to identify needs, present novel capabilities, and identify gaps. Resources will support logistics, recruiting,

planning, and execution of workshops, and delivery of reports on outcomes. Specific activities shall include but are not limited to:

- Convene key research stakeholders, regulatory experts, and representatives from patient advocacy groups to develop roadmaps. The roadmaps will establish milestones for regulatory reform for novel therapies, to inform future strategies in the implementation of the BioEconomy.
- Work in concert to facilitate communications as appropriate between the individual developers and regulatory guidance resources located in ASPR, the US Food and Drug Administration (FDA) and/or the Israeli Ministry of Health.
- Establish regulatory pathways and safety efficacy summaries for each project supported within the bilateral program.

The Technology Accelerator Concept:

The focus of the Accelerator will be the support of activities that incentivize development in the three listed functional areas for R&D, and rapidly assess whether a proof-of- concept or prototype technology will lead to a product candidate.

As depicted in Figure 1, the US - Israeli Bilateral Health Cooperative Program will work under cooperative agreements with one or more accelerators to help product developers from Israel and the US overcome the challenges and barriers to innovation, R&D, and commercialization. Accelerators will work with these developers in several ways:

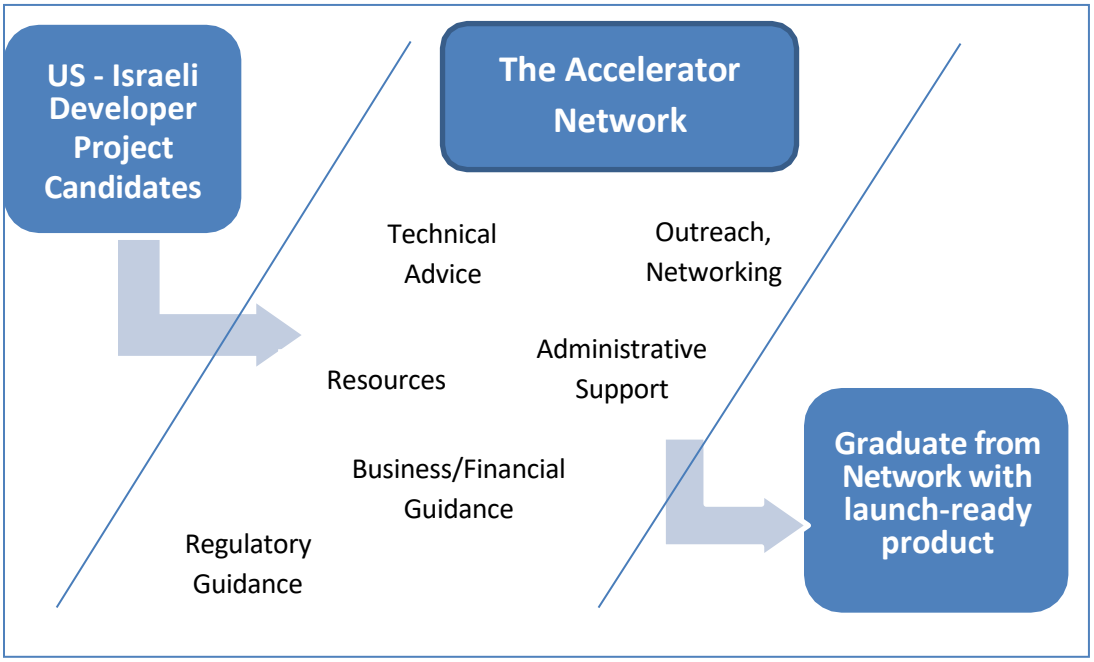

Figure 1. Technology Accelerator Concept. Early-stage products, technologies, or innovations may enter the accelerator network at various stages of maturity. The accelerator will assist/expedite the development of these products such that they are poised to graduate from the accelerator network with a launch-ready project for follow-on clinical development and commercialization

- Project Specific Acceleration:
  - Identify promising products and technologies of interest to address the US - Israeli Bilateral Health Cooperative Program Initiative
  - Promote Accelerator funding opportunities

  - Support product/technology developers awarded seed money through the Accelerator(s)
  - Help identify and connect product developers and technology innovators across a network of life-science and medical technology resources
  - Make connections to downstream investors, corporate and strategic partners, incubators, etc.
- Acceleration across Projects:
  - Recognize and prioritize common needs across the product development community, e.g. "understanding fundamentals of a changing regulatory and reimbursement environment," "how to develop a financing strategy," etc.
  - Develop and deliver support to the community via workshops, webinars, etc.
- Accelerating by Community (Three Functional Areas):
  - Arrange physical or virtual meet ups, providing a means to make connections with fellow practitioners
  - Facilitate introductions to potential investors, collaborators, experienced biotech executives and individuals, etc.

Metrics:

ASPR has developed Key Performance Parameters (KPP) to define the metrics for each Accelerator. Meeting all threshold objectives is required to ensure a successful program. The three over-arching KPPs summarized in Table 1 below are deemed essential for the successful implementation of the Accelerator.

Table 1: Technology Accelerator Key Performance Parameters

KPP	Top-Level Metrics	**Threshold** (Minimally Acceptable Performance)	**Objective** (Optimal or Ideal Level of Performance)
A Network of R&D capabilities and Technical Support	The ability of the Accelerator to select, foster, advance and transition product candidates requires a sufficient network of internal and external R&D capabilities	The Accelerator must maintain minimal R&D advisors or paid consultants to provide technical support to product Developers	A diversified network of R&D advisors and consultant to provide quality R&D research and development support services to product Developers
Perform the functions of an Accelerator	The Accelerator must have the experience and/ or ability to function in the role of accelerator but with specific expertise in health security products, technologies, and innovation	An established entity operating under an accelerator model with a track record of successfully transitioning R&D products from "Proof of Concept," prototype, product candidate selection and finally transitioning [graduating] the Innovator for external product development.	An accelerator with a proven track record of successfully transitioning R&D products from "Proof of Concept," prototype, product candidates, through selection and finally transitioning [graduating] the Innovator for external product development.

KPP	Top-Level Metrics	**Threshold** (Minimally Acceptable Performance)	**Objective** (Optimal or Ideal Level of Performance)
Supporting the Business Needs of Innovators	The ability of the Accelerator to provide wrap-around support capabilities and services (e.g. technical, strategic, operational, business, access to stakeholders.) to ensure innovators have access to all the necessary resources to foster success.	Provide strategic, regulatory, and operational and business development support services to innovators after selection through graduation. The Accelerator will provide introductions to follow-on support and/or R&D transition partner prior to graduation from accelerator.	Provides strategic, regulatory, and business development and support services to innovators after selection through graduation. The Innovator will secure follow-on support and/or R&D transition partner prior to graduation from accelerator.

Accelerator Portfolio Metrics:

On a quarterly basis ASPR will conduct a performance evaluation of the Accelerator. The Accelerator will be measured on several different parameters. First, the ability of the Accelerator to attract and partner with innovators will be measured. The Accelerator will also be responsible for tracking the progress and success of each project within the Accelerator. This data will be helpful in assessing how the Accelerator is progressing technically with the R&D candidate products, but also how well they are operating (i.e. within cost and schedule parameters). The effectiveness of the strategic, regulatory, and business development support services of the Accelerator will also be regularly assessed. This may include a review of external services provided through the Accelerator for the Innovators to determine if the services are helpful in maturing the business and product development strategy

4. Management of the Agreement:

This is a new public-private partnership. ASPR is providing the recipient(s) [the accelerator(s)] funding via a cooperative agreement to advance innovation in the development of health security products and technologies that advance the Bioeconomy for Health through a US - Israeli Bilateral Health Cooperative Program.

Project Meetings

- **Regular Status Update Teleconferences.** A conference call between the ASPR Program and the recipient (accelerator) shall occur at regular frequencies, for example monthly, as directed by the ASPR project officer. During this call, the accelerator will discuss the activities during the reporting period, any problems that have arisen and the activities planned for the ensuing reporting period. The accelerator POC may choose to include other key personnel on the conference call to give detailed updates on specific projects or the project officer may make this request.

- **Kick-off and Regular Project Meetings.** The Recipient and the Government shall participate in Project Meetings to coordinate the performance of the agreement. These meetings may include face-to- face or virtual teleconference meetings at the accelerator's site. Such meetings may include, but are not limited to, meetings of the accelerator to discuss technical approach, operational capability and initial portfolio that accelerator will support. Virtual or face-to-face meetings with the accelerator and HHS officials may occur as needed to discuss the technical, regulatory, and ethical aspects of the program. These meetings will also formulate and agree on activities for the subsequent three months. In order to facilitate review of agreement activities, the accelerator will provide data, reports, and presentations to groups of outside experts (subject to appropriate non-disclosure agreements) USG personnel as requested by the project officer.
- **Continuation Application Review Presentation (CARP):** At conclusion of 9 months, and *subject to the availability of additional funding*, the Government will invite the accelerator to give a presentation at a CARP meeting attended by ASPR Team, and select, invited interagency representatives (the accelerator is authorized to budget for travel to these meetings). The accelerator's key personnel will attend and present progress/tracking under the agreement over the corresponding period of time. The accelerator will discuss successes and challenges identified with the programs in their portfolio and present their action plan for an additional year of product development activity to align with the US - Israeli Bilateral Health Cooperative Program priorities. The CARP will evaluate progress against the accelerator's progress milestones as defined in their cooperative agreement and make a recommendation on the action plan and budget allocation.

Table 2: Technical and Portfolio Review Meeting Schedule

Meeting	Frequency	Method	Members	Action
Technical Meeting	Discretion of Project Officer (e.g. Monthly)	• Teleconference	• ASPR Program Staff & Technical Experts • Accelerator Staff	• Agenda and Meeting minutes
Technical Review	As needed (e.g. Quarterly)	• Face to Face or Virtual Teleconference	• ASPR Program Staff & Technical Experts • Accelerator Staff & invited product developers	• Agenda and Meeting minutes • Quarterly Technical Progress Report
CARP (*Optional*)	*Optional* 9 Month Review *Pending Availability of Funds*	• In person or Virtual Teleconference	• Senior level members from the Accelerator • Senior ASPR Program Leadership	• Agenda and Meeting minutes • Portfolio and Technical Progress Report • [Optional – Funding and Product Asset Allocation]

Reporting Table

Attachment H contains a table of reports which ASPR will include in the final agreement

Sharing of agreement reports within United States Government (USG)

In an effort to build a robust medical countermeasure pipeline through increased collaboration, ASPR may share technical reports with Government entities responsible for Medical Countermeasure Development. In accordance with agreements of confidentiality among US Government entities, ASPR may share technical reports with colleagues within the US Government. This provision applies to all reports and data developed during performance including reports and data paid for by the accelerator under the matching and cost sharing arrangements (if applicable).

Example of ASPR Substantial involvement

- Provide funding to the accelerator(s) and/or in-kind services to product developers supported by the accelerator(s).
- Share pertinent information related to the performance of the accelerator(s) between agencies on a regular basis.
- ASPR staff may participate in all technical meetings with the accelerator(s).
- Identify and release strategic priorities to the accelerator(s) on an ongoing periodic basis that identify focus areas and potential technology types to address strategic gaps
- Capture and integrate knowledge between the accelerators and ASPR to improve ASPR's "advantaged insight" to support better portfolio decisions and product acceleration.

II. AWARD INFORMATION

Total Estimated Project Cost (FY2022): Estimate $2,000,000
Total Funding Amount (FY2022): $2,000,000
Anticipated Number of Awards: 1-2
Project Period Length: 1 year
Budget Period Length: 1 year

Ceiling of Individual Award Range: $2,000,000
Anticipated Start Date: September 30, 2022
Expected Duration of Support: **1** year
Type of Application Sought: Cooperative Agreement

Funding beyond the first year is dependent on availability of appropriated funds in subsequent fiscal years, satisfactory awardee performance, endorsement at the Continuation Application Review Presentation and a decision that continued funding is in the best interest of the Federal Government.

1. Cooperative Agreement Award

The Federal Grant and Cooperative Agreement Act of 1977, 31 U.S.C. 6305, defines the cooperative agreement as similar to a grant in that a thing of value is transferred to a recipient to carry out a public purpose. However, a cooperative agreement is used whenever substantial federal involvement with the recipient during performance is anticipated. The difference between grants and cooperative agreements is the degree of

federal programmatic involvement rather than the type of administrative requirements imposed.

The administrative and funding mechanism used for this program will be the cooperative agreement for which substantial ASPR programmatic involvement with awardees is anticipated during the performance period. This award is subject to the awardee(s) and collaborative requirements and responsibilities set forth in the Cooperative Agreement outlined in the program announcement under this funding opportunity and are hereby incorporated by reference as terms and conditions of this award.

ASPR Responsibilities

ASPR will be responsible for the review and approval of program activities including, but not limited to, the proposed use of funds and activities to meet the terms and conditions of the award. ASPR will also approve timelines and review progress of the program as well as monitor reporting requirements. Progress evaluation will include the development of timelines and milestones and the oversight of proposed activities through monthly reports and virtual or on-site joint visits with Recipient staff and program managers and others in the USG as needed.

ASPR Activities:

ASPR staff collaborator(s) and/or designee(s) activities for this program are as follows:

- Participate in orientation and/or summary update meetings with the Accelerator on expectations, regulations and key management requirements, as well as reporting requirements, formats and contents.
- Participate in regular teleconferences, Virtual or Face to Face Technical Project Review meetings, as discussed in "Management of the Agreement" section of this NOFO.
- Oversee activity for the Accelerator, assisting with strategic guidance and direction to the Accelerator.
- Identify and release strategic priorities to the Accelerator as appropriate that identify focus areas and potential technology types to address strategic gaps
- Participate in the development, review and approval of the Accelerator's quarterly work plan, detailed budget, and monitoring and evaluation plan.
- Provide awardee with technical assistance and consultation in identification of appropriate resources outside of both the Accelerator and HHS to support Accelerator activities.
- Coordinate activities and synergies with the Accelerator and ASPR product developers.
- Work cooperatively with the Accelerator to assure that all necessary information and progress resulting from this agreement is provided to ASPR in a format that will allow the Department of Health and Human Services to assess the continuing benefits and communicate the successes of the agreement to Congress and the general public.

Accelerator Responsibilities

The Accelerator has the primary responsibility for defining objectives and approaches for planning, conducting, identifying and addressing risks and gaps, and fostering R&D product developers in the Bilateral Program, so that they become better positioned for success. The Bilateral Program product developers will retain custody of and primary rights to any data developed under this award, consistent with U.S. law and current Department of Health and Human Services (HHS) and Public Health Service (PHS) regulations and policies.

Accelerators will be responsible for coordinating activities approved under the award. The Accelerator will be

responsible for developing achievable program plans. The Accelerator will also be responsible for tracking that all activities and processes follow the terms and conditions of the agreement, and satisfactorily adhere to budget and monitoring reporting plans. Accelerators will compile their results into monthly and annual reports.

The Accelerators will be responsible for planning and participating collaboratively with ASPR under this agreement. Through participation in regular teleconferences, Virtual or Face to Face Review meetings, and if applicable, annual CARP meetings as outlined in the "Management of the Agreement" section of this NOFO.

The following is a summary of the reporting requirements for Accelerators:

- Capture and summarize information on innovation opportunities *in health technologies* to deliver to ASPR on a monthly basis
- Capture and summarize information on innovation opportunities for *the development of data/analytics tools* to ASPR IBx on a monthly basis
- Summarize project progress with individual developers on a monthly basis
- Submit required overall program progress reports and financial data quarterly.
- Have in place fiscal and programmatic systems to document accountability and performance.

III. ELIGIBILITY INFORMATION

1. Eligible applicants that can apply for this funding opportunity are listed below:

- Nonprofit with 501C3 IRS status (other than institution of higher education)
- For-profit organizations (other than small business)
- Small, minority, and women-owned businesses
- Universities
- Colleges
- Research institutions
- Non-domestic (non-U.S.) entity

2. Cost Sharing or Matching:

Cost sharing or matching is not required for this award.

3. Mandatory Meetings:

If awarded, the Accelerator is required to attend all teleconferences, Face to Face Technical Quarterly Review meetings, and JOC meetings as outlined in the "Management of the Agreement" section of this NOFO.

4. Screening and Responsiveness Criteria

Application Screening Criteria

Applications that fail to meet the screening criteria described below will **not** be reviewed and will receive **no** further consideration.

1. Applications must be submitted electronically via http://www.grants.gov by **August 31, 2022, at 11:59PM EDT**

2. The Project Narrative section of the Application must be **double-spaced**, on 8 ½" x 11" plain white paper with **1" margins** on both sides, and a **font size of not less than 11**.

3. **The Project Narrative must not exceed 10 pages**. NOTE: The Project Work Plan, Letters of Commitment, budget narrative and justification forms, Vitae of Key Project Personnel and Other Relevant Annexes **are not counted** as part of the Project Narrative for purposes of the 10-page limit.

Application Responsiveness Criteria

Applications that do not meet the following responsiveness criteria will be administratively eliminated and will not be reviewed:

- Applications submitted after the due date and time will not be reviewed.
- Applications submitted by non-eligible entities will not be reviewed.
- Applications submitted by individuals will not be reviewed.
- Applications failing to include the required forms will not be reviewed.
- ASPR will not accept applications with a Project Narrative that exceeds 10 pages. NOTE: The Project Work Plan, Letters of Commitment, budget narrative and justification forms, Vitae of Key Project Personnel and Other Relevant Annexes **are not counted** as part of the Project Narrative for purposes of the 10-page limit. Show these documents as attachments to clearly note that the project narrative does not exceed 10 pages.

IV. APPLICATION AND SUBMISSION INFORMATION

1. Application Package

Application materials can be obtained from www.grants.gov. You must register with grants.gov prior to submitting an application. Applicants previously registered must assure that the registration is still valid and up-to-date. Registration and re-registration may take up to 10 working days to process. Failure to submit the application on time due to late registration will result in ASPR not accepting the application.

Applications must be submitted electronically through www.grants.gov by the application deadline of **August 31, 2022 at 11:59PM EDT**. ASPR will not accept any applications that are not submitted electronically via www.grants.gov.

Grants.gov (http://www.grants.gov) will automatically send applicants a tracking number and date of receipt verification electronically once the application has been successfully received and validated in http://www.grants.gov. After ASPR retrieves your application form from http://www.grants.gov, a return receipt will be emailed to the applicant contact. This will be in addition to the validation number provided by http://www.grants.gov.

2. Required registrations:

Central Contractor Registration and Data Universal Numbering System Requirements

Except for those entities exempt from requirements listed at 2 CFR §25.110(b) or (c) (individuals), effective October 1, 2010, HHS requires all entities that plan to apply for and ultimately receive federal cooperative agreement funds from any HHS Operating/Staff Division (OPDIV/STAFFDIV) or receive subawards directly from recipients of those cooperative agreement funds to:

- Be registered in the Central Contractor Registration (CCR) prior to submitting an application of plan;
- Maintain an active CCR registration with current information at all times during which it has an active award or an application or plan under consideration by an OPDIV/STAFFDIV; and
- Provide its Unique Entity Identifier (UEI), or the Entity ID number in each application or plan it submits to the OPDIV/STAFFDIV.

An award cannot be made until an applicant has complied with these requirements. At the time an award is ready to be made, if the intended recipient has not complied with these requirements, the OPDIV/STAFFDIV may determine that the applicant is not qualified to receive an award; and may use that determination as a basis for making an award to another applicant.

Applicants **must** provide a UEI number to apply for a grant or cooperative agreement from the federal government. ASPR applicants are required to provide their UEI numbers on the face page of the application. Obtaining a UEI number is easy and there is no charge. To obtain a UEI number, please visit www.sam.gov ,the Federal Service Desk FSD.gov, or call 1-866-606-8220. To expedite the process, let the help desk know that you are a public/private nonprofit organization getting ready to submit a federal cooperative agreement application. In addition, you **must** be registered in the System for Award Management (SAM). **Registration in the System for Award Management (SAM) is mandatory. Failure to register with SAM will lead to an application being deemed ineligible and will not proceed to peer review.** Due to the possibility of heavy traffic at the sam.gov website, applicants are strongly encouraged to register well in advance of the application due date. **SAM information must be updated at least every 12 months to remain active (for both recipients and sub-recipients). Once you update your record in SAM, it will take 48 to 72 hours to complete the validation processes. Grants.gov will reject submissions from applicants who are not registered in SAM or those with expired SAM registrations (Entity Registrations). The UEI number you use on your application must be registered and active in SAM for the anticipated start date of the award. To create a user account, Register/Update an entity and/or Search Records go to SAM, at** http://www.sam.gov or visit Customer Service at https://sam.gov/content/entity-registration .

Grants.gov registration: All entities must register and/or renew registration with grants.gov prior to submitting an application. Grantees previously registered must assure that the registration is still valid and up-to-date. Registration and re-registration take up to 10 working days to process. Failure to submit the application on time due to late registration will result in ASPR not accepting the application.

3. Content and Form of Application Submission (See section VIII. OTHER INFORMATION)

The following document and sections need to be submitted to ASPR in order to be considered for funding; forms are available on grants.gov within the application package:

- Application for Federal Assistance – Standard Form SF 424. By signing the SF 424 the applicant agrees not only to assurances and certification, as described on the form, but to all the requirements for this specific appropriation including, but not limited to, the insurance statement as seen on Attachment E.
- Budget Information – Standard Form SF 242A
- Assurances (Non-Construction Programs) - Standard Form SF 424B
- If human subjects are involved you must complete and submit Attachment F.

Project Narrative

The Project Narrative must be double-spaced, on 8 ½" x 11" paper with 1" margins on both sides, and a font size of not less than 11. You can use smaller font sizes to fill in the Standard Forms and Sample Formats. ASPR will not accept applications with a Project Narrative that exceeds 10 pages. The Monitoring and Evaluation Plan, Curriculum Vitae of Key Personnel, and other Annexes are not counted as part of the Project Narrative for purposes of the 10-page limit, but all of the other sections noted below are included in the limit.

The components of the Project Narrative counted as part of the page limit include:

Abstract
Goal(s) and Objective(s)
Proposed Approach, Work Plan, and Timeline of Proposed Activities – these plans may be in narrative or chart form (see attachments for suggested formats). Any forms submitted to meet this required section will be counted as part of the page limitation. Applicants should provide their proposed approach to the following:

1) Their approach to provide support services – e.g. technical, business, and regulatory consultation to a diverse R&D portfolio of medical product candidates to supporting health security innovation
2) Their plan for balancing and ensuring participation of both US and Israeli innovators.
3) Their approach to and/or track record of performing the functions of a product Accelerator.
4) Their approach to and/or experience of the organization in evaluating early-stage technologies from a scientific and regulatory perspective to assess risks and gaps in R&D by existing product developers.
5) Their approach to and/or track record of supporting the business and entrepreneurial needs of innovators, provide wrap-around support capabilities and services (e.g. technical, strategic, business, access to stakeholders.)
6) Their approach to and/or track record of leveraging the best practices from incubators, accelerators, technical hubs, co-working sites, etc. to promote innovation and collaboration.
7) Their approach to and/or track record of fostering a physical and virtual environment that is programed to increase collaboration and spurs product innovation
8) Their approach to and/or track record of bringing multiple parties together, forming alliances, identifying external funding opportunities which could demonstrate their ability to maximize impact of the Accelerator.

Evaluation Plan – these plans may be in narrative or chart form (see "Attachment H" for suggested formats). Any forms submitted to meet this required section will be counted as part of the 10-page limitation. Please provide definitive and measurable metrics that tie towards progress related to the 8 parameters listed above.

Any Other Relevant Annexes that do not count toward the page limit include:

- Key Personnel CV –critical personnel or technical consultants that are part of this project
- Letters of Commitment – only required between collaborating agencies or Alliance members proposing cost sharing/matching.

- Budget Narrative – see suggested format in attachment section
- Self-monitoring plan and contingency activities identified to ensure project completion and funding outlays are completed within the 12 month project period
- Other documents, as needed

The Project Narrative is the most important part of the application since it will be used as the primary basis to determine whether the project meets the minimum requirements for grants/cooperative agreements under Section 319L of the Public Health Service Act. The Project Narrative should provide a clear and concise description of the project. ASPR recommends that the project narrative include the following components.

Abstract

This section should include a brief (no more than 200 words maximum) description of the proposed project, including: goal(s), objectives, outcomes, and products to be developed. Detailed instructions for completing the abstract are included in Attachment D of this document.

Goal and Objectives

This section should consist of a description of the project's goal(s) and major objectives. Unless the project involves multiple, complex interventions, we recommend you have only one overall goal. The goal and objectives stated in Section I "Funding Opportunity Description" are suggestions and the applicant is free to modify, edit or propose other goal and objectives, but they must similarly align with the ones proposed in this Funding Opportunity Announcement.

Workplan and Timeline of Proposed Activities

Each proposed cooperative agreement should have clear timelines for execution and completion.

The Project Work Plan should reflect and be consistent with the Project Narrative and Budget and should cover all of the project period. It should include a statement of the project's overall goal, anticipated outcome(s), key objectives, and the major tasks / action steps that will be pursued to achieve the goal and outcome(s). For each major task / action step, the work plan should identify timeframes involved (including start- and end-dates), and the lead person responsible for completing the task. Please use the Sample Work Plan format included in Attachment C.

Organizational Capability

Each application should include an organizational capability statement. The organizational capability statement should describe how the applicant agency (or the particular division of a larger agency which will have responsibility for this project) is organized, the nature and scope of its work and/or the capabilities it possesses.

This description should cover capabilities of the applicant agency not included elsewhere in the narrative, such as any current or previous relevant experience and/or the record of the project team in producing cogent and useful reports, publications, or other products.

This section should also include a clear delineation of the roles and responsibilities of project staff, consultants and partner organizations, and how they will contribute to achieving the project's objectives and outcomes. It should specify who would have day-to-day responsibility for key tasks such as: leadership of the project; monitoring the project's on-going progress; preparation of reports; and communications with other partners and ASPR. Curriculum vitae for key project personnel should feature in the annexes.

Annexes

*** Personnel***

Please attach short curriculum vitae for key project staff only (no more than one page each). Neither curriculum vitae nor an organizational chart will count towards the narrative page limit. Also include information about any contractual organization(s) that will have a significant role(s) in implementing the project and achieving project goals. Please ensure to include key personnel not only for the operations of the Accelerator but also the key consultants with the technical expertise in the functional areas of device development that will be responsible for evaluating a diverse landscape of health security products, technologies and innovation candidates.

Letters of Commitment

Include confirmation of the commitments to the project (should it be funded) made by key collaborating organizations, agencies and Alliance Members in this part of the application. Any organization that is specifically named to have a significant role in carrying out the project should be considered an essential collaborator. For applications submitted electronically via http://www.grants.gov, signed letters of commitment should be scanned and included as attachments. Do not submit or obtain product developers Letters of Commitment in response to this announcement.

Budget Narrative

The Budget Narrative/Justification should be provided. The Budget Narrative is used to determine reasonableness and allowability of costs for the project. All proposed costs listed, whether supported by federal funds or non-federal match, must be reasonable, necessary to accomplish project objectives, allowable in accordance with applicable federal cost principles, auditable, and incurred during the budget period.

A sample format is included as Attachment B of this Funding Opportunity Announcement. Applicants are encouraged to pay particular attention to Attachment B, which provides an example of the level of detail sought. A combined multi-year Budget Narrative/Justification, as well as a detailed Budget Narrative/Justification for each year of potential cooperative agreement funding, is required.

A self-monitoring plan and contingency activities should be identified for each budget period to ensure project completion and funding outlays are completed within each budget period and across the 5 year project period.

Conflicts of Interest

The accelerator should propose a plan to address, identify, avoid and/or mitigate, any actual and/or perceived organizational Conflict of Interests (COI) associated with managing the ASPR accelerator. The Plan should provide the accelerator with the necessary policies and procedures to identify, avoid, and/or mitigate any actual and/or perceived organizational COI. The plan should be included as an appendix.

Of special note, the COI plan should also extend to include intellectual property. COI may arise in the Accelerator as a result of the early stage of development. The COI plan should include necessary policies and procedures to ensure product developers maintain all intellectual property associated with their products for work supported by the accelerator to ensure there are no barriers to product developers engaging the accelerator for support.

The accelerator shall propose necessary policies and procedures to ensure their role does not result in unequal access of information, impaired objectivity, or biased ground rules.

Intergovernmental Review

This funding opportunity announcement is not subject to the requirements of Executive Order 12372, "Intergovernmental Review of Federal Programs."

Funding Restrictions

The following activities are not fundable:

- Cost of money is not allowed even if it's in your negotiated rate agreement
- All salaries are capped at the rate of Executive Level II.
- Construction is not allowed.
- To carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.
- To advocate or promote gun control.
- Funds cannot be used to lobby.
- Pre-award costs are not allowed.
- Lobbying Restrictions: http://www.hhs.gov/grants/grants/grants-policies-regulations/lobbying-restrictions.html

In addition to the restrictions listed above the following funding restriction apply to all foreign entities applying under this application:

- *Continuation of existing projects without expansion or new and innovative approaches*
- *Alteration and Renovation (A&R). Major A&R or construction costs are unallowable under foreign cooperative agreements and domestic cooperative agreements with foreign components (unless specifically authorized in legislation)*
- *Customs and import duties. These costs, which include consular fees, customs surtax, value-added taxes, and other related charges, are unallowable under foreign cooperative agreements and domestic cooperative agreements with foreign components.*
- *Indirect costs. Indirect costs will not be reimbursed, with the exception of the American University of Beirut, which is not considered a foreign organization, and the World Health Organization. Research patient care costs. Research patient care costs are allowable only in exceptional circumstances as determined by the OBDIV*

V. APPLICATION REVIEW INFORMATION

1. Criteria

The application will be reviewed using the following criteria. Scores assigned will assist the reviewer in scoring the applications. The US Government may award 0-1 applications to this NOFO.

Scoring of each criterion is based on the following four categories

- **Excellent:** Submission exceeds or meets all specified requirements; technically sound submission pertinent to program goals and objectives **(5 Points)**
- **Good:** Submission meets most specified requirements; scientifically is technically acceptable **(3 Points)**

- **Fair:** Submission does not meet some specified requirements or the submission contains weaknesses that may be correctable without major revision. May be recommended for acceptance but at a lower priority **(2 points)**
- **Poor:** Submission fails to meet specified requirements or contains significant weakness; does not meet program requirements; not correctable without major revision. Submissions with a "Poor" rating are not awardable **(1 point)**

The following scoring system will be used:

1. Technical Approach – (30%)
2. Organizational Capability and Experience – (40%)
3. Key Personnel – (10%)
4. Ability to leverage incentives – (20%)

The following table describes how the scores are weighted:

Available Points per Criteria		
Criteria	**Weight**	**Points Available**
Technical Approach	3X	15
Organizational Capability and Experience	4X	20
Key Personnel	1X	5
Ability to Leverage Incentives	2X	10
Total		**50**

The following table is a "Sample Score sheet" noting the ranking, weight, scoring and cumulative scores for a hypothetical proposal:

Sample Score Sheet			
Criteria	**Score**	**Weight**	**Points**
Technical Approach	Excellent = 5	3X	15
Organizational Capability and Experience	Good = 3	4X	12
Key Personnel	Excellent = 5	1X	5
Ability to Leverage Incentives	Poor = 1	2X	2
Total			**34**

Criterion 1. Technical Approach (30%)

i. Does the applicant describe a technical approach for:
   a. Fostering and Identifying promising early stage R&D portfolio of national health security product and technology innovation
   b. Fostering a physical and virtual environment that is programed to increase collaboration and spur product innovation.
   c. Supporting the business and entrepreneurial needs of innovators, provide wrap-around support capabilities and services (e.g. technical, strategic, business, access to stakeholders.)
   d. Leveraging the best practices from incubators, accelerators, technical hubs, co-working sites, etc. to promote innovation and collaboration.

Criterion 2. Organizational Capability and Experience (40%)

i. Does the applicant's organization have the capability and prior experience of:
   a. Establishing and maintaining a network of R&D capabilities and technical support that is suitable for accelerating heath security innovation
   b. Performing the functions of a product Accelerator.
   c. Successfully identifying and transitioning R&D products from early development to the clinical and [graduating] the product developer for follow-on investment.

Criterion 3. Key Personnel (10%)

i. Does the applicant's Key Personnel have the capability and prior experience of:
   a. Evaluating early stage technologies from a scientific and regulatory perspective to facilitate R&D investment decisions.

Criterion 4. Ability to Leverage Incentives (20%)

i. Does the applicant provide written commitments and demonstrate prior experience:
   a. Bringing multiple parties together, forming Alliances, identifying external funding opportunities which could demonstrate their ability to maximize the impact of the accelerator.

Additional Items

Protections for Human Subjects

The accelerator should propose a plan for how the accelerator after award will provide protections for Human Subjects. At the time of award, ASPR does not expect the Applicant to have a sub-recipient clinical protocol identified in this proposal. Post award, ASPR will require the accelerator to address the below guidance for research that involves human subjects.

If the research involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46 , the committee evaluating the application (hereinafter referred to as "the committee") will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation. The committee will assess any Institutional Review Board (IRB) materials included in the application, including IRB assessment of standard review criteria (1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials.

If the proposed research involves the use of human data and/or biological specimens, a justification must be provided for the claim that no human subjects are involved in the Protection of Human Subjects section of the Research Plan.

Inclusion of Women, Minorities, and Children

Post award, when the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children.

Vertebrate Animals

The Accelerator should propose a plan for how the Accelerator after award will evaluate and conduct research on live vertebrate animals. At the time of award, ASPR does not expect the Applicant to have a sub- recipient non-clinical protocol identified in this proposal. Post award, ASPR will require the Accelerator to address the below guidance for research that involves live vertebrate animals.

If the proposed research involves vertebrate animals, the Accelerator will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia.

Biohazards

The Accelerator should propose a plan for how the Accelerator will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed. Post award, ASPR will require the Accelerator to complete this assessment.

Resource Sharing Plans

Accelerators receiving a cooperative agreement award should make research resources and data readily available for research purposes to qualified individuals within the scientific community after publication. Applicants responding to this funding opportunity should include a plan on sharing non-proprietary research resources and data.

Budget and Period of Support

ASPR Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research. Research partnerships or collaborations with organizations in and their specific role and contribution to the conduct of the proposed study should be reflected in the proposed budget.

VI. AWARD ADMINISTRATION INFORMATION

1. Award notice

The Notice of Award is the authorizing document from the ASPR authorizing official, the Officer of Grants Management. The Notice of Award will be sent electronically upon successful review of the application. The Notice of Award sets forth the amount of funds granted, the terms and conditions of the award, the effective date of the award, the budget period for which initial support will be given, the non- federal share to be provided (if applicable), and the total project period for which support is contemplated.

Each applicant will receive written notification of the outcome of the objective review process, including a summary of the expert committee's assessment of the application, and whether the application was selected for funding. Applicants who are selected for funding may be required to respond in a satisfactory manner to Conditions placed on their application before funding can proceed. Letters of notification do not provide authorization to begin performance.

2. Administrative and National Policy Requirements

The award is subject to HHS Administrative Requirements, which can be found in 2 CFR 200 (Subparts A through F), 45 CFR Part 75 and the Standard Terms and Conditions implemented through the HHS Grants Policy Statement located at http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf.

The signature of the authorized organizational representative on the application indicates that the organization complies, or intends to comply, with all applicable public policy requirements as listed in Attachment E of this document.

3. Reporting

Applicants funded under this announcement will be required to electronically submit a semi-annual program progress report and Federal Financial Report (FFR) SF-425 via GrantSolutions (GS). In addition, applicants must submit an end-of-year program progress report and end-of-year Federal Financial Report, both due 90 days after the budget period ends. Awardees will receive instructions for both reports with their Notice of Award. Final performance and financial reports are due 90 days after the end of the project period. For more information see DHHS/ASPR Standard Terms and Conditions.

Progress Reporting: Applicants funded under this announcement will be required to electronically submit an annual program progress report. As part of the progress report financial information will be reported both per major category of expense, and by objectives.

Subaward and Executive Compensation Reporting: Applicants must ensure that they have the necessary processes and systems in place to comply with the sub-award and executive total compensation reporting requirements established under OMB guidance at *2 CFR Part 170*, unless they qualify for an exception from the requirements, should they be selected for funding.

Quarterly Cash Transaction Reporting Recipients must report cash transaction data using the Federal Financial Report (FFR), SF-425. Recipients will utilize the SF-425 lines 10.a through 10.c to report cash transaction data to the Division of Payment Management. The FFR SF-425 (lines 10.a through 10.c) is due to the Payment Management System 30 days after the end of each calendar quarter. The FFR SF-425 electronic submission and dates for the new quarters will be announced through the Payment Management/SmartLink Payment System's bulletin board. Funds will be frozen if the report is not filed on or before the due date.

Federal Disbursement Reporting: The SF-425 will also be used for reporting of expenditure data to meet ASPR's semi-annual and annual financial reporting requirement. All other lines except 10.a through 10.c should be completed.

Tangible Property Report: Awardees will be required to submit an annual Tangible Property Report (SF 428) at the time the annual SF 425 is submitted to ASPR. Final SF 428 reports are due 90 days after the end of the project period.

Audits

If your organization receives $750,000 or greater of Federal funds, it must undergo an independent audit in accordance with 45 CFR part 75, subpart F or regulations and policy effective at the time of the award.

Reporting of Matters Relating to Recipient Integrity and Performance

If the total value of your currently active grants, cooperative agreements, and procurement contracts from all Federal awarding agencies exceeds $10,000,000 for any period of time during the period of performance of this Federal award, then you must maintain the currency of information reported to the System for Award Management (SAM) that is made available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)) about civil, criminal, or administrative proceedings described in paragraph 2 of Appendix XII to 2 CFR part 200—Award Term and Condition for Recipient Integrity and Performance Matters. This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. For more information about this reporting requirement related to recipient integrity and performance matters, see Appendix XII to 2 CFR Part 200.

Other Required Notifications

Before you enter into a covered transaction at the primary tier, in accordance with 2 CFR § 180.335, you as the participant must notify ASPR, if you know that you or any of the principals for that covered transaction:

(a) Are presently excluded or disqualified;

(b) Have been convicted within the preceding three years of any of the offenses listed in 2 CFR § 180.800(a) or had a civil judgment rendered against you for one of those offenses within that time period;

(c) Are presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State or local) with commission of any of the offenses listed in 2 CFR § 180.800(a); or

(d) Have had one or more public transactions (Federal, State, or local) terminated within the preceding three years for cause or default.

At any time after you enter into a covered transaction, in accordance with 2 CFR § 180.350, you must give immediate written notice to HHS/ASPRASPR if you learn either that—

(a) You failed to disclose information earlier, as required by 2 CFR § 180.335; or

(b) Due to changed circumstances, you or any of the principals for the transaction now meet any of the criteria in 2 CFR § 180.335.ASPR

FFATA and FSRS Reporting

The Federal Financial Accountability and Transparency Act (FFATA) requires data entry at the FFATA Subaward Reporting System (http://www.FSRS.gov) for all sub-awards and sub-contracts issued for $25,000 or more as well as addressing executive compensation for both grantee and sub-award organizations.

VII. AGENCY CONTACTS

Grants Management Officer:

U.S. Department of Health and Human Services
Office of the Assistant Secretary for Preparedness and Response
Acquisition Management Contracts and Grants
Washington, D.C. 20201
Attn: Virginia Simmons
Telephone: (202) 260-0400
Email: asprgrants@hhs.gov

Project Officer:

U.S. Department of Health and Human Services
Office of the Assistant Secretary for Preparedness and Response
Washington, DC 20201
Attn: Rebekka Lueptow
Telephone: 202-868-9769
e-mail: rebekka.Lueptow@hhs.gov

VIII. OTHER INFORMATION

1. Review and Selection Process

Proposals will be reviewed and evaluated by a panel of subject matter experts that are either federal employees of, or consultants to ASPR. ASPR may also elect to utilize subject matter experts that are not federal employees or direct consultants to ASPR. Outside reviewers would be vetted for any potential conflicts of interest and will sign non-disclosure agreements. Proposals will be scored based on the Application Review Criteria listed in Section V. The proposals with the highest technical scores will be further evaluated based on cost. The Applicant that represents the best value to the Government will be invited into negotiations. If negotiations are successful, the Government will make an award(s) to the Applicant that represents the best value to the Government.

2. Attachments

- Attachment A: Instructions for Completing Required Forms (SF 424, Budget (SF 424A), Budget Narrative/Justification)
- Attachment B: Budget Narrative/Justification - Sample Format

- Attachment C: Project Work Plan - Sample Template
- Attachment D: Instructions for Completing the Project Abstract
- Attachment E: Potentially Applicable Public Policy Requirements
- Attachment F: Research and Related Project Information
- Attachment G: Reporting Table
- Attachment H: Sample Monitoring and Evaluation Plan at the Portfolio and the Product Level

Attachment A: Instructions for Completing Required Forms (SF 424, Budget (SF 424A), Budget Narrative/Justification)

This section provides step-by-step instructions for completing the four (4) standard federal forms required as part of your grant application, including special instructions for completing Standard Budget Forms 424 and 424A. Standard Forms 424 and 424A are used for a wide variety of federal grant programs, and federal agencies have the discretion to require some or all of the information on these forms. ASPR does not require all the information on these Standard Forms. Accordingly, please use the instructions below to complete these forms in lieu of the standard instructions attached to SF 424 and 424A.

a. Standard Form 424

1. **Type of Submission:** (Required): Select one type of submission in accordance with agency instructions.
   - Application
2. **Type of Application**: (Required) Select one type of application in accordance with agency instructions.
   - New
3. **Date Received:** Leave this field blank.
4. **Applicant Identifier**: Leave this field blank

5a **Federal Entity Identifier**: Leave this field blank

5b. **Federal Award Identifier**: For new applications leave blank.

6. **Date Received by State:** Leave this field blank.

7. **State Application Identifier:** Leave this field blank.

8. **Applicant Information**: Enter the following in accordance with agency instructions:

a. Legal Name (Required): Enter the name that the organization has registered with the Central Contractor Registry. Information on registering with CCR may be obtained by visiting the Grants.gov website (http://www.grants.gov).

b. Employer/Taxpayer Number (EIN/TIN)(Required): Enter the Employer or Taxpayer Identification Number (EIN or TIN) as assigned by the Internal Revenue Service.

c. Organizational UEI (Required): Enter the organization's UEI. Information on obtaining a UEI number may be obtained by visiting the Grants.gov website (http://www.grants.gov).

d. Address (Required): Enter the complete address including the county.

e. Organizational Unit: Enter the name of the primary organizational unit (and department or division, if applicable**)** that will undertake the project.

f. Name and contact information of person to be contacted on matters involving this application: Enter the name (first and last name required), organizational affiliation (if affiliated with an organization other than the applicant organization), telephone number (Required), fax number, and e-mail address (required) of the person to contact on matters related to this application.

9. **Type of Applicant** (Required): Select the applicant organization "type" from the drop down list.

10. **Name of Federal Agency** (Required): Enter U.S. Assistant Secretary for Preparedness and Response

11. **Catalog of Federal Domestic Assistance Number/Title:** The CFDA number can be found on page one of the NOFO

12. **Funding Opportunity Number/Title** (Required): The Funding Opportunity Number and title of the opportunity can be found on page one of the NOFO.

13. **Competition Identification Number/Title:** Leave this field blank.

14. **Areas Affected By Project:** List the largest political entity affected (cities, counties, state etc.).

15. **Descriptive Title of Applicant's Project** (Required): Enter a brief descriptive title of the project.

16. **Congressional Districts Of** (Required): **16a**. Enter the applicant's Congressional District, and **16b.** Enter all district(s) affected by the program or project. Enter in the following format: 2 characters state abbreviation – 3 characters district number, CA-005 for California 5th district. If all congressional districts in a state are affected, enter "all" for the district number, (e.g. MD-all for all congressional districts in Maryland). If nationwide enter US-all.

17. **Proposed Project Start and End Dates** (Required): Enter the proposed start date and final end date of the project. Therefore, if you are applying for a multi-year cooperative agreement, such as a 2 year cooperative agreement project, the final project end date will be 2 years after the proposed start date. The Grants Office can alter the start and end date at their discretion.

18. **Estimated Funding** (Required): Enter the amount requested or to be contributed during the first funding/budget period by each contributor. Value of in-kind contributions should be included on appropriate lines, as applicable.

19. **Is Application Subject to Review by State Under Executive Order 12372 Process?** Check appropriate box

20. **Is the Applicant Delinquent on any Federal Debt?** (Required): This question applies to the applicant organization, not the person who signs as the authorized representative. If yes, include an explanation on the continuation sheet.

21. **Authorized Representative** (Required): To be signed and dated by the authorized representative of the applicant organization. Enter the name (first and last name required) title (required), telephone number (required), fax number, and e-mail address (required) of the person authorized to sign for the applicant. A copy of the governing body's authorization for you to sign this application as the official representative must be on file in the applicant's office. (Certain federal agencies may require that this authorization be submitted as part of the application.)

b. Standard Form 424A

NOTE: Standard Form 424A is designed to accommodate applications for multiple grant/cooperative agreement programs; thus, for purposes of this ASPR program, many of the budget item columns and rows are not applicable. You should only consider and respond to the budget items for which guidance is provided below. Unless otherwise indicated, the SF 424A should reflect a one-year budget.

Section A - Budget Summary

Line 5: Leave columns (c) and (d) blank. Enter TOTAL federal costs in column (e) and total non-federal costs (including third party in-kind contributions and any program income to be used as part of the awardee match) in column (f). Enter the sum of columns (e) and (f) in column (g).

Section B - Budget Categories

Column 3: Enter the breakdown of how you plan to use the federal funds being requested by object class category (see instructions for each object class category below).

Column 4: Enter the breakdown of how you plan to use the non-federal share by object class category. [DOES NOT APPLY TO THIS NOFO.]

Column 5: Enter the total funds required for the project (sum of Columns 3 and 4) by object class category.

Separate Budget Narrative/Justification Requirement

Applicants requesting funding for multi-year grant programs are REQUIRED to provide a combined multi-year Budget Narrative/Justification, as well as a detailed Budget Narrative/Justification for each year of potential cooperative agreement funding. A separate Budget Narrative/Justification is also REQUIRED for each potential year of cooperative agreement funding requested.

For your use in developing and presenting your Budget Narrative/Justification, a sample format with examples and a blank sample template have been included in these Attachments. In your Budget Narrative/Justification, you should include a breakdown of the budgetary costs for all of the object class categories noted in Section B, across three columns: federal; non-federal cash; and non-federal in-kind. Cost breakdowns, or justifications, are required for any cost of $1,000 or for the thresholds as established in the examples. The Budget Narratives/Justifications should fully explain and justify the costs in each of the major budget items for each of the object class categories, as described below. Non-federal cash as well as, sub-contractor or sub-Awardee (third party) in-kind contributions designated as match must be clearly identified and explained in the Budget Narrative/Justification The full Budget Narrative/Justification should be included in the application immediately following the SF 424 forms.

Line 6a - **Personnel**: Enter total costs of salaries and wages of applicant/awardee staff. Do not include the costs of consultants, which should be included under 6h - Other.

In the Justification: Identify the project director, if known. Specify the key staff, their titles, and time commitments in the budget justification.

Line 6 - **Fringe Benefits**: Enter the total costs of fringe benefits unless treated as part of an approved indirect cost rate.

In the Justification: If the total fringe benefit rate exceeds 35% of personnel costs, provide a break-down of amounts and percentages that comprise fringe benefit costs, such as health insurance, FICA, retirement, etc. A percentage of 35% or less does not require a break down but you must show the percentage charged for each full/part time employee.

Line 6c - **Travel**: Enter total costs of all travel (local and non-local) for staff on the project. NEW: Local travel is considered under this cost item not under the "Other" cost category.
Local transportation (all travel which does not require per diem is considered local travel). Do not enter costs for consultant's travel - this should be included in line 6h.

In the Justification: Include the total number of trips, number of travelers, destinations, purpose (attend conference), length of stay, subsistence allowances (per diem), and transportation costs (including mileage rates).

Line 6d - **Equipment**: Enter the total costs of all equipment to be acquired by the project. For all awardees, "equipment" is non-expendable tangible personal property having a useful life of more than one year and an acquisition cost of $5,000 or more *per unit*. If the item does not meet the $5,000 threshold, include it in your budget under Supplies, line 6e.

In the Justification: Equipment to be purchased with federal funds must be justified as necessary for the conduct of the project. The equipment must be used for project-related functions. Further, the purchase of specific items of equipment should not be included in the submitted budget if those items of equipment, or a reasonable facsimile, are otherwise available to the applicant or its sub-awardees.

Line 6e: **Supplies** - Enter the total costs of all tangible expendable personal property (supplies) other than those included on line 6d.

In the Justification: For any cooperative agreement award that has supply costs in excess of 5% of total direct costs (federal or non-federal), you must provide a detailed breakdown of the supply items (6% of $100,000 = $6,000 – breakdown of supplies needed). If the 5% is applied against $1 million total direct costs (5% x $1,000,000 =
$50,000) a detailed breakdown of supplies is not needed. Please note: any supply costs of $5,000 or less regardless of total direct costs does not require a detailed budget breakdown (5% x $100,000 = $5,000 – no breakdown needed).

Line 6f - **Contractual**: Regardless of the dollar value of any contract, you must follow your established policies and procedures for procurements and meet the minimum standards established in the Code of Federal Regulations (CFR's) mentioned below. Enter the total costs of all contracts, including procurement contracts (except those which belong on other lines such as equipment, supplies, etc.). Note: The 33% provision has been removed and line item budget detail is not required as long as you meet the established procurement standards. Also include any contracts with organizations for the provision of technical assistance. Do not include payments to individuals on this line.

In the Justification: Provide the following three items – 1) a list of contractors indicating the name of the organization; 2) the purpose of the contract; and 3) the estimated dollar amount. If the name of the contractor and estimated costs are not available or have not been negotiated, indicate when this information will be

available. The federal government reserves the right to request the final executed contracts at any time. If an individual contractual item is over the small purchase threshold, currently set at $100K in the CFR, you must certify that your procurement standards are in accordance with the policies and procedures as stated in 45 CFR 74.44 for non-profits and 45 CFR 92.36 for states, in lieu of providing separate detailed budgets. This certification should be referenced in the justification and attached to the budget narrative.

Line 6g - **Construction**: While construction is not an allowable cost for this program, minor A&R is permitted.

Line 6h - **Other**: Enter the total of all other costs. Such costs, where applicable, may include, but are not limited to: insurance, medical and dental costs (e.g. for project volunteers this is different from personnel fringe benefits), non-contractual fees and travel paid directly to *individual* consultants, postage, space and equipment rentals/lease, printing and publication, computer use, training and staff development costs (e.g. registration fees). If a cost does not clearly fit under another category, and it qualifies as an allowable cost, then it belongs in this section.

In the Justification: Provide a reasonable explanation for items in this category. For example, individual consultants explain the nature of services provided and the relation to activities in the Work Plan or indicate where it is described in the Work Plan. Describe the types of activities for staff development costs.

Line 6i - **Total Direct Charges**: Show the totals of Lines 6a through 6h.

Line 6j - **Indirect Charges**: Enter the total amount of indirect charges (costs), if any. If no indirect costs are requested, enter "none." Indirect charges may be requested if: (1) the applicant has a current indirect cost rate agreement approved by the HHS or another federal agency; or (2) the applicant is a state or local government agency. **State governments should enter the amount of indirect costs determined in accordance with HHS requirements.** An applicant that will charge indirect costs to the cooperative agreement must enclose a copy of the current rate agreement. Indirect Costs can only be claimed on Federal funds, more specifically, they are to only be claimed on the federal share of your direct costs. Any unused portion of the awardee's eligible Indirect Cost amount that are not claimed on the federal share of direct charges can be claimed as un-reimbursed indirect charges, and that portion can be used towards meeting the recipient match.

NOTE: **If indirect costs are to be included in the application, a copy of the approved indirect cost agreement must be included with the application. Further, if any sub-contractors or sub-awardees are requesting indirect costs, copies of their indirect cost agreements must also be included with the application.**

Line 6k - **Total**: Enter the total amounts of Lines 6i and 6j.

Line 7- **Program Income**: As appropriate, include the estimated amount of income, if any, you expect to be generated from this project that you wish to designate as match (equal to the amount shown for Item 15(f) on Form 424). **Note:** Any program income indicated at the bottom of Section B and for item 15(f) on the face sheet of Form 424 will be included as part of non-federal match and will be subject to the rules for documenting completion of this pledge. If program income is expected, but is not needed to achieve matching funds, **do not** include that portion here or on Item 15(f) of the Form 424 face sheet. Any anticipated program income that will not be applied as Awardee match should be described in the Level of Effort section of the Program Narrative.

Section C - Non-Federal Resources

Line 12: Enter the amounts of non-federal resources that will be used in carrying out the proposed project, by source (applicant; state; other) and enter the total amount in Column (e). Federal match is not required for this NOFO.

Section D - Forecasted Cash Needs - Not applicable.

Section E - Budget Estimate of Federal Funds Needed for Balance of the Project

Line 20: Section E is relevant for multi-year cooperative agreement applications, where the project period is 24 months or longer. This section does not apply to cooperative agreement awards where the project period is less than 17 months.

Section F - Other Budget Information

Line 22 - Indirect Charges: Enter the type of indirect rate (provisional, predetermined, final or fixed) to be in effect during the funding period, the base to which the rate is applied, and the total indirect costs. Include a copy of your current Indirect Cost Rate Agreement.

Line 23 - Remarks: Provide any other comments deemed necessary.

c. Standard Form 424B - Assurances

This form contains assurances required of applicants under the discretionary funds programs administered by the Assistant Secretary for Preparedness and Response. Please note that a duly authorized representative of the applicant organization must certify that the organization is in compliance with these assurances.

d. Certification Regarding Lobbying

This form contains certifications that are required of the applicant organization regarding lobbying. Please note that a duly authorized representative of the applicant organization must attest to the applicant's compliance with these certifications.

Proof of Non-Profit Status

Non-profit applicants must submit proof of non-profit status. Any of the following constitutes acceptable proof of such status:

- A copy of a currently valid IRS tax exemption certificate.
- A statement from a state taxing body, State Attorney General, or other appropriate State official certifying that the applicant organization has a non-profit status and that none of the net earnings accrue to any private shareholders or individuals.
- A certified copy of the organization's certificate of incorporation or similar document that clearly establishes non-profit status.

Indirect Cost Agreement

Applicants that have included indirect costs in their budgets must include a copy of the current indirect cost rate agreement approved by the HHS or another Federal agency. This is optional for applicants that have not included indirect costs in their budge

Attachment B: Budget Narrative/Justification Sample Format

The Budget Summary is used to determine reasonableness and allowability of costs for the project. All of the proposed costs listed, supported by Federal funds, must be reasonable, necessary to accomplish project objectives, allowable in accordance with applicable Federal cost principles, auditable, and incurred during the budget period.

Non-Federal Match: (*Not Applicable to this Cooperative Agreement*)

Matching funds provide support for the purpose and goals of this proposal and enhance the Federal budget request. Applicant is required to provide a detailed listing of all matches. In the narrative justification sections describe how the funds support the project and enhance the Federal budget.

All funding used for match must be documented in the same manner as Federal funds. All match funds must follow the same cost principles and regulations that are used for Federal funds – to count as match you must be able to use Federal funds to purchase the item.

An allowable project cost is a cost that is:

- Necessary for the performance of the award.
- Allocable to the project.
- In conformance with any limitations or exclusions set forth in the Federal cost principles applicable to the organization incurring the cost.
- Consistent with the recipient's regulations, policies, and procedures which are applied uniformly to both Federally-supported and other activities of the organization.
- Accorded consistent treatment as a direct or indirect cost.
- Determined in accordance with generally accepted accounting principles.
- Not included as a cost in any other Federally-supported award.

The following four tests are used in determining the allowability of costs:

- **Reasonableness (including necessity)**. A cost is reasonable if it does not exceed that which would be incurred by a prudent person under the circumstances prevailing at the time the decision was made to incur the cost. The cost principles elaborate on this concept and address considerations such as whether the cost is of a type generally necessary for the organization's operations or the cooperative agreement's performance, whether the recipient complied with its established organizational policies in incurring the cost or charge, and whether the individuals responsible for the expenditure acted with due prudence in carrying out their responsibilities to the Federal government and the public at large, as well as to their organization.

- **Allocability.** A cost is allocable to a specific cooperative agreement, function, department, or other component, known as a cost objective, if the goods or services involved are chargeable or assignable to that cost objective in accordance with the relative benefits received or other equitable relationship. A cost is allocable if it is incurred solely to advance work under the cooperative agreement; it benefits both the cooperative agreement and other work of the organization, including other cooperative agreement-supported projects or programs; or it is necessary to the overall operation of the organization and is deemed to be assignable, at least in part, to the cooperative agreement.

- **Consistency.** Accelerator must be consistent in assigning costs to cost objectives. Regulations regarding cost assignment must be consistent for all work of the organization under similar circumstances, regardless of the source of funding, to avoid duplicate charges.

- **Conformance.** Conformance with limitations and exclusions contained in the Terms and Conditions of award, including those in the cost principles, may vary by the type of activity, the type of recipient, and other characteristics of individual awards.

Budget Summary

(only include section for Non-Federal Match if required by the application)

Section A: Personnel - An employee of the applying agency whose work is tied to the application. Proposed salaries must be reasonable. Compensation paid for employees must be reasonable and consistent with that paid for similar work within the applicant's organization and similar positions in the industry. No overtime (premium) compensation is authorized under this agreement

Non-Federal Match: Separately list all personnel that will be working on the project and whose time and effort will be used to meet the non-Federal Match requirement. Personnel used as match must be documented through signed time cards and payroll documents. List the source of the match – i.e. State funds.

Table 1: Personnel

Position	Name	Annual Salary/Rate	Level of Effort	Federal Cost	Match
Project Director	Susan Jones	$45,000/year	100%	$45,000	N/A
Project Coordinator	Brad Smith	$42,000/year	50%	$21,000	N/A
			TOTAL	$66,000	N/A

NARRATIVE JUSTIFICAITON: Enter a description of the personnel funds requested and how their use will support the purpose and goals of this proposal. Describe the role, responsibilities, and unique qualifications of each position.

B. Fringe Benefits: Fringe benefits may include contributions for items such as social security, employee insurance, and pension plans. Only those benefits not included in an organization's indirect cost pool may be shown as direct costs. If fringe benefits are not computed as a percentage of salary (i.e. 25%), list all components of the fringe benefits rate, for example:

Non-Federal Match: List for all personnel shown in table 1 under the match section. Match documentation includes payroll records and pay slips. List the source of the match – i.e. State funds.

Table 2: Fringe Benefits

Component	Rate	Wage	Federal Cost	Match

Component	Rate	Wage	Federal Cost	Match
FICA	7.65%	66,000	$5,049	N/A
Insurance	5%	66,000	$3,300	N/A
		TOTAL	$8,349	N/A

NARRATIVE JUSTIFICATION: Enter a description of the fringe funds requested and how the rate was determined.

C. Travel: Federal funds requested for travel are for staff travel only (travel for consultants is listed in consultant category). Travel for other participants, committee members, etc. should be listed under the cost category "other". Applicants are to use the lowest available commercial fares for coach or equivalent accommodations. Note that Applicants will be expected to follow Federal travel policies found at http://www.gsa.gov.
Non-Federal Match: The travel costs must be documented through travel authorizations and paid vouchers. Local travel should be documented by miles traveled. List the source of the match – i.e. State funds.

Table 3: Travel

Purpose of Travel	Location	Item	Rate	Federal Cost	Match
Attend awardee meeting	Washington, DC	Air Fare Per Diem Airport Parking Airport Shuttle Hotel	$350 X 4 people $71/day X 4 days X 4 people $10/day X 4 days $28/RT X 4 people $211/night X 3 nights X 4 people **Subtotal**	$1,400 $1,136 $40 $112 $2532 **$4,120**	N/A
Local travel	Various	POV	.44/mile X 2,000 miles/year	$880	N/A
			TOTAL	$5,000	N/A

NARRATIVE JUSTIFICATION: Explain the purpose for all travel and how costs were determined. List any required travel, funds for local travel that are needed to attend local meetings, project activities, and training events. Local travel rate should be based on agency's personally owned vehicle (POV) reimbursement rate, which should correspond with the GSA rate found at http://www.gsa.gov.

D. Equipment: Permanent equipment is defined as tangible nonexpendable personal property having a useful life of more than one year and an acquisition cost of $5,000 or more. If the applying agency defines "equipment" at a different rate, then follow the applying agency's policy. In the case of vehicles, etc. applicant should justify purchase rather than rental. If equipment is used by several different projects, you may only charge a percentage of the costs for the purchase based on the amount of time, etc. that the equipment will be used for this cooperative agreement program. Any purchased equipment must be inventoried according to the guidelines in the HHS Grants Policy Statement.
Non-Federal Match: Enter a description of the equipment match provided and how its use will support the purpose and goals of this proposal. Documentation of match should be in inventory and use records. List the source of the match – i.e. State funds.

Table 4: Equipment

Item(s)	Rate	Federal Cost	Match
Computer Work Station	$5,500 X 2	$11,000	N/A
Computer	$6,000 X .5FTE	$3,000	N/A
	TOTAL	$ 14,000	N/A

NARRATIVE JUSTIFICATION: Enter a description of the equipment and how its purchase will support the purpose and goals of this proposal.

E. Supplies: Materials costing less than $5,000 per unit and often having one-time use, for example – general office supplies, postage, printers, etc.

Non-Federal Match: Please note that items such as computers, desks, and projection equipment may be counted as match only once throughout the life of the project. Documentation includes invoices and donation records. List the source of the match – i.e. State funds.

Table 5: Supplies

Item(s)	Rate	Federal Cost	Match
General Office Supplies	$50/month X 4 FTE	$200	N/A
	TOTAL	$200	N/A

NARRATIVE JUSTIFICATION: Enter a description of the supplies requested and how their purchase will support the purpose and goals of this proposal. Rates for office supplies, etc. may be based on average monthly costs, FTE, etc.

F. Contracts and Consultants: An arrangement to carry out a portion of the programmatic effort by a third-party or for the acquisition of goods or services is allowed under the cooperative agreement. Such arrangements may be in the form of sub awards (grants) or contracts. A consultant is a non-employee retained to provide advice and expertise in a specific program area for a fee. List each contract, consultant or sub award separately and provide an itemization of the costs. If a contractor is to be determined, provide a best estimate as to costs for the goods or services to be purchased.

The awardee must establish written procurement policies and procedures that are consistently applied. All procurement transactions are required to be conducted in a manner to provide to the maximum extent practical, open and free competition. The awardee should be alert to organizational conflicts of interest as well as to noncompetitive practices among contractors that may restrict or eliminate competition or otherwise restrain trade.

Method of Selection: This will be sole source, competition, or cooperative agreement.

Scope of Work: Provide a breakout of the goods and/or services being provided by the contractor. If personnel are being charged then should list name, position, hours and rate/hour. Goods will be listed at number of units and cost/unit. List method to be used for sub-recipient monitoring – site visit, semi-annual reports, etc. Documentation of monitoring should be kept with the contract/award file.

Non-Federal Match: Enter any contracts, etc. that are being used to meet this requirement. When making a contract, a portion may be "donated" to this project by the contracted organizations and should be so noted in the contractual agreement (i.e.: Media outlets may give one free ad for each purchased). If this arrangement has been reached, it should be noted in the justification section. Documentation includes copies of contractual agreements, payment and donation records.

Table 6: Contract/Sub award

Activity	Name	Method of Selection	Scope of Work	Federal Cost	Match
Public Information	WMTV	Sole source	Paid Ads 12/month X $250/ad X 6 mo. Paid Ads 12/month X $250/ad X 6 mo **Monitoring:** semi-annual report	$18,000	N/A
Mobil Medical Assets	To Be Determined	Competition	Medical supply inventory ($1,600) Wheelchair bus conversions (6 X $37,000) **Monitoring:** semi-annual report	$223,600	N/A
			TOTAL	$ 241,600	$18,000

NARRATIVE JUSTIFICATION: Provide information as to how the contracted services or goods will enhance the project goals and objectives. Provide sole source justification.

Table 7: Consultant

Organization	Name	Number of Days	Rates	Federal Cost	Match
Trepid	Jon Smith	20	$150/day Travel 4 trips X 1,204 (travel @ $475; lodging @ $175/night X 3; Per Diem @ $51 x4) = $4,816	$ 7,816	N/A
			TOTAL	$ 7,816	N/A

NARRATIVE JUSTIFICATION: Provide information as to how the consultant services or goods will enhance the project goals and objectives.

G. Other:

Expenses not covered in any of the previous budget categories. If rent is requested (direct or indirect), provide the name of the owner(s) of the space/facility. If anyone related to the project owns the building which is less than an arm's length arrangement, provide cost of ownership/use allowance calculations.

Non-Federal Match: Break down costs into cost/unit (e.g., cost/square foot) and explain the use of each item requested. Documentation includes donation, usage, transaction and/or payment records. List the source of match funds – i.e. State funds.

Table 8: Other

Item	Rate	Federal Cost	Match
Postage	$65/mo. X 4 FTE	$3,120	N/A
	TOTAL	$3,120	N/A

NARRATIVE JUSTIFICATION: Explain the need for each item and how it will support the purpose and goals of this proposal. Break down costs into cost/unit (e.g., cost/square foot or cost/month or cost/FTE).

H. Indirect Costs:

Also known as "facilities and administrative costs", indirect costs are costs that cannot be specifically identified with a particular project, program, or activity, but are necessary to the operation of the organization (i.e., overhead). Facilities operation and maintenance costs, depreciation, and administrative expenses are examples of costs that are usually treated as indirect costs. The organization must not include costs associated with its indirect rate as direct costs. If indirect costs are claimed, applicant is to submit a copy of a current negotiated indirect cost rate agreement. Indirect costs are only charged on the items cited in the indirect cost rate agreement (i.e. – personnel and fringe, subawards over $25,000).

Non-Federal Match: Unclaimed indirect costs for costs incurred by using the Federal funds may be used to meet the match requirement. Indirect costs may be charged on the appropriate costs listed in the match categories that are provided by the applicant agency. Documentation should be included in the accounting records of the applicant agency.

Table 9: Indirect costs

Total Direct Cost applied to Indirect Cost	Indirect Cost Rate	Federal Cost	Match
$450,000	22%	$99,000	N/A
	TOTAL	$99,000	N/A

I. FUNDING REQUESTED FOR THE TOTAL PROJECT PERIOD

Table 10: FUNDING REQUESTED FOR THE TOTAL PROJECT PERIOD

Provide a summary of the one year proposed costs (both direct and indirect). Provide the best estimate of the funding that will be needed to complete the total project period.

REQUESTED FUTURE YEARS

Please provide the projected funding for any future years (if applicable).

1. **Please justify and explain any changes to the budget that differs from the reflected amounts reported in the 01 Year Budget Summary.**

2. **If a cost of living adjustment (COLA) is included in future years, provide your organization's personnel policies and procedures that state all employees within the organization will receive a COLA.**

Attachment C: Project Work Plan Sample Template

Year #1: Accelerators Work Plan to identify, foster and accelerate Health Security Innovation

Goal:

Measurable Outcome(s):

* **Time Frame** (Start/End Dates by Month in Project Cycle)

#	Major Objectives	Key Tasks to identify and support promising innovation	Lead Person/ Organization	1*	2*	3*	4*	5*	6*	7*	8*	9*	10*	11*	12*	Budget[5] ASPR/ Match
1																
2																
3																
4																
5																
….																

Add as many pages as needed

[5] When all product lines on this tabled are summed it should equal the **"Total Federal Costs for Year #1**

Attachment D: Instructions for Completing the Project Summary/Abstract

- All applications for cooperative agreement funding must include a Summary/Abstract that concisely describes the proposed project. It should be written for the general public.
- To ensure uniformity, please limit the length to no more than 200 words on a single page with a font size of not less than 11, doubled-spaced.
- The abstract must include the project's goal(s), objectives, overall approach (including target population and significant partnerships), anticipated outcomes, products, and duration. The following are very simple descriptions of these terms, and a sample Compendium abstract.

  Goal(s) – broad, overall purpose, usually in a mission statement, i.e. what you want to do, where you want to be

  Objective(s) – narrow, more specific, identifiable or measurable steps toward a goal. Part of the planning process or sequence (the "how"). Specific performances which will result in the attainment of a goal.

  Outcomes - measurable results of a project. Positive benefits or negative changes, or measurable characteristics that occur as a result of an organization's or program's activities. (outcomes are the end-point)

  Products – materials, reports.

- A model abstract/summary is provided below:

The Awardee, Okoboji University, supports this three year Dementia Disease demonstration (DD) project in collaboration with the local Alzheimer's Association and related Dementias groups. The **goal** of the project is to provide comprehensive, coordinated care to individuals with memory concerns and to their caregivers. The approach is to expand the services and to integrate the bio-psycho-social aspects of care. The **objectives** are: 1) to provide dementia specific care, i.e., care management fully integrated into the services provided; 2) to train staff, students and volunteers; 3) to establish a system infrastructure to support services to individuals with early stage dementia and to their caregivers; 4) to develop linkages with community agencies; 5) to expand the assessment and intervention services; 6) to evaluate the impact of the added services; 7) to disseminate project information. The expected **outcomes** of this DD project are: patients will maintain as high a level of mental function and physical functions (thru Yoga) as possible; caregivers will increase ability to cope with changes; and pre and post – project patient evaluation will reflect positive results from expanded and integrated services. The **products** from this project are: a final report, including evaluation results; a website; articles for publication; data on driver assessment and in-home cognitive retraining; abstracts for national conferences.

Attachment E: Potentially Applicable Public Policy Requirements

The following table specifies those public policy requirements that may apply to all or a subset of HHS cooperative agreement programs and awards. The following key applies to use of this table. The "Types of Applicants/Accelerator" column indicates applicability by type of entity, the "Types of Sub-recipients" and "Contractors under cooperative agreement" columns indicate whether the requirement flows down, as well as applicability by organizational type. An "NA" means it does not flow-down.

Public Policy Mandates or Encouragements				
Requirement	**Applicability**	**Types of Applicants/ Accelerator**	**Subawards**	**Contracts for routine goods/services**
Age Discrimination Act of 1975	All applications from and awards to domestic entities	NA to foreign and international organizations	NA to foreign and international organizations	NA to foreign and international organizations
Animal Welfare	Applications and awards for activities involving warm-blooded animals	All	All	All
Ban on Cloning of Human Beings (Presidential memorandum of March 4, 1997)	All awards	All	All	All
Certificates of Confidentiality	Research awards (includes research training in each case specified as "research")	All	All	All
Civil Rights Act of 1964 (Title VI)	All applications from and awards to domestic entities	NA to foreign and international organizations	NA to foreign and international organizations	NA to foreign and international organizations
Confidentiality of Patient/Client Records	All research awards and awards to substance abuse programs	All	All	All
Drug-Free Workplace	All covered applications and awards	All	NA	NA
Education Amendments of 1972 (Title IX)	All applications from and awards to domestic entities	Does not apply to foreign and international organizations	Does not apply to foreign and international organizations	Does not apply to foreign and international organizations

Public Policy Mandates or Encouragements				
Requirement	**Applicability**	**Types of Applicants/ Accelerator**	**Subawards**	**Contracts for routine goods/services**
Financial Conflict of Interest	All applications and awards for research	Does not apply to Phase I of the SBIR/STTR programs and to Federal institutions	All except Federal institutions	NA
Fly America Act/ U.S. Flag Air Carriers	All types of awards	All	All	All
Hatch Act	Awards to State or local governments	All	All	NA
Health Insurance Portability and Accountability Act (HIPAA)	All awards to covered entities	All covered entities	All covered entities	All covered entities
Historic Preservation/ Archaeological Sites	All awards that include major or minor A&R, construction, or any work that will result in physical changes to real property	All	All (Note: applicability to subrecipients is being considered based on recent litigation)	All
Human Subjects Protections	Research applications and awards	All	All	All
Investigational New Drug Applications/ Investigational Device Exceptions	Research awards	All	All	All
Limited English Proficiency	All types of awards	All	All	NA
Lobbying	Varies depending on source of requirement Byrd Anti-Lobbying Amendment applies to all awards expected to exceed $100,000 (except that Indian tribes, tribal organizations, and any	All consistent with "Applicability"	All consistent with "Applicability"	All consistent with "Applicability"

Public Policy Mandates or Encouragements				
Requirement	**Applicability**	**Types of Applicants/ Accelerator**	**Subawards**	**Contracts for routine goods/services**
	other Indian organizations may be exempted from the Byrd Anti-Lobbying Amendment with respect to expenditures specifically permitted by other federal law) Cost principles apply as indicated therein Limitations in 18 U.S.C. 1913 apply to all awards			
Military Recruiting and Reserve Officer Training Corps Access	All types of applications and awards	Institutions of higher education	Institutions of higher education	NA
Pro-Children Act	All awards performed in facilities where children are served	All	All	All
Protection of Research Subjects' Identity	All research awards	All	All	All
Public Health Security and Bioterrorism Preparedness and Response Act	All types of awards	All	All	All
Recombinant DNA Molecules and Human Gene Transfer Research	Applications and awards for research	All	All	All
Research Misconduct	Applications and awards for research and research training	All	NA	NA
Research on Transplantation of Human Fetal Tissue	Research awards	All	All	All

Public Policy Mandates or Encouragements				
Requirement	**Applicability**	**Types of Applicants/ Accelerator**	**Subawards**	**Contracts for routine goods/services**
Resource Conservation and Recovery Act	All awards to States or agency of a political subdivision of a State (which for this purpose includes State and local institutions of higher education or hospitals)	All	All	All
Seat Belt Use (EO 13043)	All types of awards	All	NA	NA
Smoke-Free Workplace	All awards	All	NA	NA
Standards of Conduct	All types of awards	All	NA	NA
Text Messaging While Driving (EO 13513)	All			
Trafficking in Persons (Trafficking Victims Protection Act, as amended; 2 CFR part 175	All types of awards	Private entities	Private entities	NA
Uniform Relocation Assistance and Real Property Acquisition Policies Act	All awards, but, in particular, those involving acquisition of real property	All	All	NA
USA PATRIOT Act	All types of awards	All	All	All

Attachment F: Research and Related Project Information

(IF APPLICABLE)

Provide the following information to the related questions. This form will be required after award of the agreement only if the Accelerator proposes a study with human subjects. If specific studies are not identified at this time, please note and sign below.

If no clinical study is being proposed at this time but a clinical study may be proposed post award**, circle** the below box and do not complete the rest of this form at this time.

We have not identified any specific Human Subjects studies at this time: Yes or No

We have not identified any specific live vertebrate animals at this time: Yes or No

<u>If you said yes to both of these questions stop here as the remaining form will be completed post award</u>

If activities involving human subjects are planned at any time during the proposed project at any performance site, check yes. Check yes even if the proposed project is exempt from Regulations for the Protection of Human Subjects. If activities involving human subjects are not planned at any time during the proposed project at any performance site, select no.

Applications proposing human subjects research may be required to submit additional information, forms, or attachments with the application, in accordance with policies covering human subjects research.

1. Are Human Subjects Involved? YES NO

1a. If YES to Human Subjects

Is the Project Exempt from Federal Regulations? **YES NO**

Yes: If the project is exempt from Federal regulations, check Yes.

No: If the project is not exempt from Federal regulations, check No.

If yes, **Select the appropriate exemption number from 1, 2, 3, 4, 5, 6**.

If human subject activities are exempt from Federal regulations, provide the exemption numbers corresponding to one or more of the exemption categories. The six categories of research that qualify for exemption from coverage by the regulations are defined in the Common Rule for the Protection of Human Subjects. These regulations can be found at http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html.

OHPR guidance states that appropriate use of Exemptions described in 45 CFR 46 should be determined by an authority independent from the investigators (http://answers.hhs.gov/ohrp/categories/1564). Institutions often designate their IRB to make this determination. Since IRB approval is not required at the time of application, the exemptions designated often represent the opinion of the PD/PI, and the justification provided for the exemption by the PD/PI is evaluated during peer review. Human subjects research should be designated as exempt if the proposed research meets the criteria for one or more of the six

exemptions.

If no, is the IRB review Pending? YES NO

Enter the latest Institutional Review Board (IRB) approval date. Leave blank if Pending.

Applicants should check "Yes" to the question "Is the IRB review Pending?" even if the IRB review/approval process has not yet begun at the time of submission. Also note that an IRB Approval Date is not required at the time of submission. This may be requested later in the pre-award cycle. If IRB is still pending at time of award then affected components of the award will be restricted. Failure to obtain IRB approval within the agreed upon time frame may result in the termination of an award.

Human Subject Assurance Number

Enter the approved Federal Wide Assurance (FWA) that the applicant has on file with the Office for Human Research Protections, if available. If the applicant has a FWA number, enter the 8-digit number.

Insert "None" if the applicant organization does not have an approved assurance on file with OHRP. In this case, the applicant organization, by the signature in item 21 on the SF424 declaring that it will comply with 45 CFR part 46 and proceed to obtain a human subjects assurances (see http://www.hhs.gov/ohrp). **Do not insert the human subjects assurance number of any collaborating institution in the space provided.**

2. Are Vertebrate Animals Used? YES NO

If activities involving vertebrate animals are planned at any time during the proposed project at any performance site, check yes. If no, skip the rest of block 2.

Note that the generation of custom antibodies constitutes an activity involving vertebrate animals.

2a. If YES to Vertebrate Animals

Is the Institutional Animal Care and Use Committee (IACUC) review Pending?

YES NO

IACUC Approval Date:

Enter the latest IACUC approval date (if available). Leave blank if Pending.

Animal Welfare Assurance Number:

Enter the Federally approved assurance number, if available.

To determine if your organization holds an Animal Welfare Assurance, see http://grants.nih.gov/grants/olaw/olaw.htm#assur. Applicants should check "Yes" to the question "Is the IACUC review Pending?" even if the IACUC review/approval process has not yet begun at the time of submission. Also note that an IACUC Approval Date is not required at the time of submission. However, the approval date and other data may be requested later in the pre-award cycle. If the applicant organization does not have an approved Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare (OLAW), NIH, enter "None" in the Animal Welfare Assurance Number field. **Do not enter the Animal Welfare Assurance number of any collaborating institution.** By inserting "None" at the time of submission, the applicant organization is essentially declaring that it will comply with the PHS Policy on Humane Care and Use of Laboratory Animals by submitting an Animal Welfare Assurance and verification

of IACUC approval when requested to do so by OLAW. If IACC approval is still pending at time of award then affected components of the award will be restricted. Failure to obtain IACC approval within the agreed upon time frame may result in the termination of an award.

3. Is proprietary/privileged information included in the application? YES NO

Patentable ideas, trade secrets, privileged or confidential commercial or financial information, disclosure of which may harm the applicant, should be included in applications only when such information is necessary to convey an understanding of the proposed project. If the application includes such information, check yes and clearly mark each line or paragraph on the pages containing the proprietary/privileged information with a legend similar to: "The following contains proprietary/privileged information that (name of applicant) requests not be released to persons outside the Government, except for purposes of review and evaluation. "

4. Environmental Questions

Most research cooperative agreements are not expected to individually or cumulatively have a significant effect on the environment, and there are several categorical exclusions allowing most applicants to answer 'No' to this question unless a specific NOFO indicates that the National Environmental Policy Act
(NEPA) applies. However, if an applicant expects that the proposed project will have an actual or potential impact on the environment, or if any part of the proposed research and/or project includes one or more of the following categorical exclusions listed below, the line marked "Yes" should be checked and an explanation provided in field 4.b.

1. The potential environmental impacts of the proposed research may be of greater scope or size than other actions included within a category.
2. The proposed research threatens to violate a Federal, State, or local law established for the protection of the environment or for public health and safety.
3. Potential effects of the proposed research are unique or highly uncertain.
4. Use of especially hazardous substances or processes is proposed for which adequate and accepted controls and safeguards are unknown or not available.
5. The proposed research may overload existing waste treatment plants due to new loads (volume, chemicals, toxicity, additional hazardous wasted, etc.)
6. The proposed research may have a possible impact on endangered or threatened species.
7. The proposed research may introduce new sources of hazardous/toxic wastes or require storage of wastes pending new technology for safe disposal.
8. The proposed research may introduce new sources of radiation or radioactive materials.
9. Substantial and reasonable controversy exists about the environmental effects of the proposed research.

4.a. Does this project have an actual or potential impact on the environment?

YES NO

4.b. If yes, please explain

Explanation of the actual or potential impact on the environment.

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an Environmental Assessment (EA) or an Environmental Impact Statement (EIS) been performed? YES NO

4.d. If yes, please explain

Enter additional details about the EA or EIS. If desired, you can provide the information in a separate file, and attach by clicking **Add Attachments** located to the right of Step 11 - Other Attachments.

5. Is the research performance site designated, or eligible to be designated, as a historic place?

YES **NO**

If any research performance site is designated, or eligible to be designated, as a historic place, if Yes, check the Yes and then provide an explanation. Otherwise, check the No.

5.a. If yes, please explain:

If you checked the Yes box indicating any performance site is designated, or eligible to be designated, as a historic place, provide the explanation here.

6. Does this project involve activities outside of the United States or partnerships with International Collaborators?

YES **NO**

Indicate whether this project involves activities outside of the United States or partnerships with international collaborators. Check yes or no.

Applicants to PHS agencies must check “Yes” if the applicant organization is a foreign institution or if the project includes a foreign component.

6.a. If yes, identify countries

Enter the countries with which international cooperative activities are involved.

Attachment G: Reporting Table

#	Reports	Report Description	Reporting Procedures and Due Dates
I.	Conflict of Interest (COI) Report and Plan	The Accelerator will provide a COI plan within 30 days of award and provide annual report on their compliance with the plan.	• The Accelerator will submit their COI plan by e-mail or other electronic format to be provided by ASPR coinciding with their first monthly report • The Accelerator will submit their COI Annual Report by e-mail or other electronic format to be provided by ASPR with their annual progress report, 20th day of the month after the end of the first year
II.	Monthly Activity Report and Information Capture on Innovation Opportunities and Portfolio Progress	On a monthly basis, the Accelerators will: 1. Report activity/progress toward milestones 2. Report key Accelerator Network Metrics 3. Describe next three months plan 4. Capture innovation opportunities and product developer portfolio progress on accelerator's objectives on a regular basis, but not less than monthly.	• The Accelerator will submit to ASPR capture information on a regular basis, in the form of a monthly report
III.	Product Transition Strategy	The Accelerator shall provide a 1-2 page summary document containing a Product Transition Strategy for each product developer they are overseeing on annual basis, if applicable. The Product Transition Strategy should provide a strategic plan for further development and transitioning the product for future commercialization.	• The Accelerator shall provide the Product Transition Strategies 30 days prior to the end of each year of the agreement.
The below section includes the Accelerator's non-routine [Ad hoc] reporting requirements These reports are event driven			
IV.	Incident Report	The Accelerator shall communicate and document all critical portfolio concerns, risks, or potential risks with ASPR.	• Due within 48 hours of activity or incident or within 24 hours for a security activity or incident. • Email or telephone with written follow-up. • Additional updates within 48 hours of additional developments. • The Accelerator shall submit within 5 business days a Corrective Action Plan (if deemed necessary by either party) to address any potential issues. • If corrective action is deemed necessary, the Accelerator must address in writing, its consideration of concerns raised by ASPR within 5 business days of receiving such concerns in writing.
V.	Publications	Any Accelerator developed manuscript or scientific meeting abstract containing data generated under this agreement must be submitted to ASPR for review prior to submission.	• The Accelerator must submit all Accelerator developed manuscript or scientific meeting abstracts to ASPR within 30 business days for manuscripts and 15 business days for abstracts. • The Accelerator must address in writing all concerns raised by ASPR in writing. • The Final submissions shall be submitted to ASPR concurrently or no later than one (1) calendar day of its submission.

#	Reports	Report Description	Reporting Procedures and Due Dates
VI.	Press Releases	The Accelerator agrees to accurately and factually represent the work conducted under this agreement in all press releases.	• The Accelerator shall ensure that ASPR has received and approved an advanced copy of any press release for this agreement not less than 5 business days prior to the issuance of the press release. • If corrective action is required, the Accelerator agrees to accurately and factually represent the work conducted under this agreement in all press releases. • Any final press releases shall be submitted to ASPR no later than 1 (one) calendar day prior to its release.

Attachment H: Sample Monitoring and Evaluation Plan

Accelerator's Objectives toward KPPs
Notes: Please provide examples on how you will measure progress towards completing Key Performance Parameters (KPPs) (Table 2, page 9). Use the table below as a template.

Top-Level KPP Metrics	Indicators			Sources of Data and Collection Methods	Frequency of Data Collection	Respons-ible Person(s) & Team
	Key Outputs	Key Outcomes	Definition of Key Outcome Indicators			
The ability of the Accelerator to select, foster, advance and transition product candidates requires sufficient network of internal and external R&D capabilities						
The Accelerator must have the structure, policies and experience to function in the role of a traditional accelerator but with specific expertise in health security innovation						
The ability of the Accelerator to provide wrap-around support capabilities and services (e.g., technical, strategic, operational, business, access to stakeholders.) to ensure innovators have access to the necessary resources to foster success.						