

Broad Agency Announcement Epigenetic CHaracterization and Observation BIOLOGICAL TECHNOLOGIES OFFICE HR001118S0023 February 12, 2018

TABLE OF CONTENTS

PART I: (OVERVIEW INFORMATION	3		
PART II:	FULL TEXT OF ANNOUNCEMENT	4		
1. Fui	nding Opportunity Description	4		
1.1.	Program Overview			
1.2.	Technical Approach	5		
1.3.	Program Metrics and Schedule	9		
1.4.	Controlled Unclassified Information Statement	13		
2. Aw	ard Information	14		
2.1.	General Award Information	14		
2.2.	Fundamental Research			
3. Elig	gibility Information	16		
3.1.	Eligible Applicants			
3.2.	Organizational Conflicts of Interest	17		
3.3.	Cost Sharing/Matching	17		
4. Ap	plication and Submission Information	18		
4.1.	Address to Request Application Package	18		
4.2.	Content and Form of Application Submission	18		
4.3.	Funding Restrictions	30		
4.4.	Other Submission Requirements	30		
5. Ap	plication Review Information	30		
5.1.	Evaluation Criteria	30		
5.2.	Review of Proposals	32		
6. Aw	ard Administration Information	33		
6.1.	Selection Notices	33		
6.2.	Administrative and National Policy Requirements	33		
6.3.	Reporting	34		
6.4.	Electronic Systems	34		
7. Agency Contacts				
8. Other Information				
9. APPENDIX 1 – Volume II checklist				

PART I: OVERVIEW INFORMATION

- Federal Agency Name Defense Advanced Research Projects Agency (DARPA), Biological Technologies Office
- Funding Opportunity Title Epigenetic CHaracterization and Observation
- Announcement Type Initial Announcement
- Funding Opportunity Number HR001118S0023
- Catalog of Federal Domestic Assistance Numbers (CFDA) 12.910 Research and Technology Development
- Dates
 - Posting Date February 12, 2018
 - Proposal Abstract Due Date and Time March 22, 2018, 4:00 PM ET
 - Proposal Due Date and Time May 3, 2018, 4:00 PM ET
 - BAA Closing Date May 3, 2018, 4:00 PM ET
 - Proposers Day February 23rd, 2018

https://www.fbo.gov/spg/ODA/DARPA/CMO/DARPA-SN-18-23/listing.html

- Concise description of the funding opportunity: The Epigenetic CHaracterization and Observation (ECHO) program will utilize an individual's epigenome to reveal their history of exposure to weapons of mass destruction (WMD) and WMD precursors. The program will build a field-deployable platform capable of using the epigenome to diagnose biothreat exposures and infections and support military forensics operations to counter-WMD proliferation.
- Anticipated individual awards Multiple awards are anticipated.
- **Types of instruments that may be awarded** Procurement contract, cooperative agreement or other transaction.
- Agency contact

 Points of Contact The BAA Coordinator for this effort may be reached at: <u>ECHO@darpa.mil</u> DARPA/BTO ATTN: HR001118S0023 675 North Randolph Street Arlington, VA 22203-2114

PART II: FULL TEXT OF ANNOUNCEMENT

1. Funding Opportunity Description

This publication constitutes a Broad Agency Announcement (BAA) as contemplated in Federal Acquisition Regulation (FAR) 6.102(d)(2) and 35.016 and 2 CFR § 200.203. Any resultant award negotiations will follow all pertinent law and regulation, and any negotiations and/or awards for procurement contracts will use procedures under FAR 15.4, Contract Pricing, as specified in the BAA.

The Defense Advanced Research Projects Agency (DARPA) is soliciting innovative proposals to provide a field-forward system that evaluates an individual's epigenome, revealing their history of exposure to threats, including weapons of mass destruction (WMD) and their molecular precursors. Success in this program will require groundbreaking approaches to characterize epigenetic signatures from militarily relevant exposure events, and new bioinformatics tools to perform forensic analysis and disease diagnostics with high sensitivity, specificity and temporal resolution. These novel signatures and associated analytics will integrate into a single, manportable device that operates in an austere setting with an untrained user. Proposing teams should be multidisciplinary with expertise in WMD threat agents, chromatin biology, epigenetics, gene expression, bioinformatics, microfluidics, next-generation sequencing, forensics, circulating biomarker discovery, point-of-care diagnostic device development, and computational modeling. Proposals describing incremental research and device development will be excluded.

1.1. PROGRAM OVERVIEW

WMD production is dramatically proliferating among terror groups and non-state actors, severely impacting foreign policy and national security. To disrupt this growing threat, our military must identify and stop WMD development while also mitigating the increased risk of exposure to DoD personnel while deployed. Current practice uses residues associated with weapons manufacture or exposure which are often transient and in such low concentrations that samples are not available to collect. Even when remaining traces are collected, detection requires controlled laboratory environments that are not available in austere settings. Addressing the emerging WMD threat requires a capability that can move beyond the state of the art to forensically link an individual to WMD manufacture and diagnose WMD exposure, with high specificity and temporal resolution.

The Epigenetic CHaracterization and Observation (ECHO) program aims to reveal an individual's exposure history, recorded in their own epigenome after exposure events, with a focus on WMD and molecular precursors. ECHO will build a new forensic and diagnostic modality that provides an advantage over current tools, as the epigenome is persistent and detectable even when physical evidence has been erased. For this BAA, the epigenome is considered the combination of all genomic modifications that do not alter the DNA sequence but change gene activity. Exposure to environmental factors change these epigenetic features. Depending upon the exposure type, the epigenetic features can change within minutes, while also leaving a lasting 'mark' on the epigenome for decades. ECHO will build signatures that incorporate the pattern of unique epigenetic changes associated with a specific exposure to a single compound or agent (hereafter referred to as "*exposure-specific*"). The exposure-specific

signatures will contain information that denotes the specific exposure and time since exposure. The final epigenetic signature panel (ECHO Signature Panel - *ESP*) will consist of all identified exposure-specific signatures within the program, and integrate these into a point-of-need forensic and diagnostic system.

1.2. TECHNICAL APPROACH

The ECHO program will consist of two Technical Areas (TAs) with a total period of performance of 48 months. TA1 will focus on epigenetic signature identification, and TA2 will focus on the integrated device. *Proposing teams will be required to address both TAs*, and thus will need multidisciplinary backgrounds. Teams are strongly encouraged to propose with industry partners that can develop commercial applications based on work performed in the ECHO program. The breadth and depth of a proposing technical team's capabilities and related experience will be considereded as part of the evaluation of proposals. The comprehensive team must accomplish the following goals for each technical area:

TA1 will sequentially:

- 1) Generate molecular epigenetic datasets associated with relevant WMD and/or precursor exposure
- 2) Characterize and define exposure-specific epigenetic signatures
- 3) Identify unknown exposures using the ESP

TA2 will build an integrated device to achieve:

- 1) Epigenetic molecular analysis integration
- 2) Onboard computational and bio-analytical capability

Teams will be required to produce epigenetic signatures from a *minimum of 21* total exposurespecific agents or compounds. ECHO teams must develop an exposure-specific signature for each of the *4 required biological agents* listed in Table 1. These required exposure-specific signatures will be created from Government-provided, de-identified human samples comprised of blood, nasal and buccal swabs, and sputum from infectious disease surveillance sites. Teams must source human samples to develop an *additional 17* exposure-specific signatures spanning across the 10 sub-categories listed in Table 1. Proposers are strongly encouraged to address militarily-relevant compounds or agents. As ECHO aims to maximize the forensic and diagnostic capability of the ESP on the final device, proposals will be evaluated on the diversity of the additional 17 compound or agents selected. Proposals will be evaluated on applicable team experience in the proposed exposure category. Teams may also propose animal models and human organ chip approaches to supplement the human samples for better time-resolution, dosing control, and creation of exposure scenarios involving highly dangerous pathogens and compounds.

Exposure Category	Exposure Sub-category	Minimum Required List of Exposure-		
		Specific Agents/Compounds		
Biological	1. Bacterial agents*	Staphylococcus aureus (MRSA)		
		Burkholderia pseudomallei		
		(2 total)		
	2. Viral agents*:	Human immunodeficiency virus (HIV)		
		Lassa fever virus		
		(2 total)		
	3. Other emerging infectious	Proposers may select exposure-specific		
	diseases	samples from any of the additional		
Chemical	4. Chemical agent precursors [‡]	exposure categories. Teams are strongly		
	5. Conventional agents [†]	encouraged to address militarily		
	6. Toxic industrial compounds	relevant compounds, precursors, or agents from each of the 10 sub-		
Radiological	7. Medical isotopes	categories		
	8. Isotopes associated with	(17 total)		
	weapons production	, , ,		
Explosives	9. Explosives precursors			
	10. Explosives compounds [#]			

Table 1. Classification of Exposures

*https://www.selectagents.gov/selectagentsandtoxinslist.html

*Precursors in schedules 1, 2, 3 of the OPCW CWC list: <u>https://www.opcw.org/chemical-weapons-convention/annexes/annex-on-chemicals/schedule-1/</u>

[†]Agents listed in schedules 1,2,3, of the OPCW CWC list: <u>https://www.opcw.org/chemical-weapons-convention/annexes/annex-on-chemicals/schedule-1/</u>

[#]https://www.atf.gov/file/97721/download

•Precursors should be selected based on their importance and uniqueness to a specific agent production process, while also considering the likelihood of acquiring human samples for a given precursor exposure.

Technical Area 1 (TA1):

The aim of TA1 is to build an ESP and associated bioinformatics algorithms to identify militarily relevant exposures. The signatures and algorithms will be iteratively refined throughout TA1 and transitioned to the device developed in TA2.

1) Generate molecular epigenetic datasets associated with relevant WMD and/or precursor exposure

To characterize the specific exposure event and time since exposure, teams will construct molecular epigenetic datasets from each of the 21 exposure-specific compounds/agents outlined above.

When building these datasets, teams must consider the following factors including, but not limited to:

- Sample types such as buccal, nasal, sputum or blood
- Cell types including, but not limited to T-cells, B-cells, and keratinocytes

• The combination of molecular methods used to reveal epigenetic marks. Epigenetic marks to consider include, but are not limited to, gene expression profiles, chromatin access/state, histone modifications, regulatory marks on cellular or cell-free DNA (cfDNA), circulating non-coding RNA, and cellular or circulating mitochondrial DNA (mtDNA).

Teams will generate the molecular epigenetic datasets by achieving a balance of the factors above, with the metric of maximizing the uniqueness of the epigenetic signature associated with a specific exposure. Of the factors above, proposers should aim to identify approaches that combine the minimum set of molecular methods that fully captures epigenetic events that correlate to a given exposure. Proposals should include a specific plan to develop molecular methods to maximize the uniqueness of the exposure-specific epigenetic signature. Table 2 describes an example set of epigenetic events and molecular methods that may be employed for generating molecular epigenetic datasets.

Example Epigenetic Target	Example Epigenetic Event(s)	Example Method(s)		
mRNA	Up or down regulation	RNA-SEQ		
Chromatin State	Open, condensed	SONO-SEQ, ATAC-SEQ, DNase-SEQ, FAIRE-SEQ, MNase-SEQ		
Histone Modifications	Activating, poised for activation, or repressing: For example, H3K4me2/3, H3K27me3	ChIP-SEQ, MINT-ChIP		
Cellular or Circulating DNA (cfDNA) Modifications	Methylation, hydroxylation, or alkyklation: 5-mC, 5-hMC, 5-fC, 5-caC, and 3-mC	Meth-SEQ, WGBS, TAB- SEQ,		
Cellular or Circulating Mitochondrial DNA (mtDNA)	Methylation	Meth-SEQ		
Circulating Non-coding RNA	MicroRNA (miRNA), long non-coding RNAs (lncRNAs), and piwiRNAs (piRNA)	RNA-SEQ, ChIRP-SEQ		
Chromosomal Interactions	Interaction of Genomic Loci	Hi-C, 3C, 4C, 5C, ChIA-PET		

Table 2. Exemplar epigenetic events and molecular methods

Teams will be required to share all molecular epigenetic datasets on a DARPA-specified database. This will provide other teams the opportunity to build exposure-specific signatures from samples to which they do not have access, increase the power of the bioinformatics analysis algorithms, as well as provide a means for verification and validation.

2) Characterize and define exposure-specific epigenetic signatures

The molecular epigenetic datasets discussed above will serve as the foundation to develop exposure-specific signatures. Teams must use quantitative approaches to justify which cell type(s), epigenetic changes, or combination of changes maximize specificity and temporal resolution of exposure-specific signatures.

Teams should additionally consider variability across individuals and other factors that can adversely affect signal-to-noise ratio. Algorithms should refine signature signal to noise ratio by segregating epigenetic components that are dynamic and static. These signatures will then populate the ESP.

3) Identify unknown exposures using the ESP

The developed algorithms will need to compare an unknown exposure against the ESP to identify the specific exposure, and when the individual was exposed. Therefore, algorithm developers will leverage a wide range of analytical approaches, which may include multifactorial, topographical, principal component, and other dimensional reduction methods.

Figure 1 summarizes a potential technical approach and factors to consider when building a signature and associated algorithms to identify unknown exposures against the ESP.

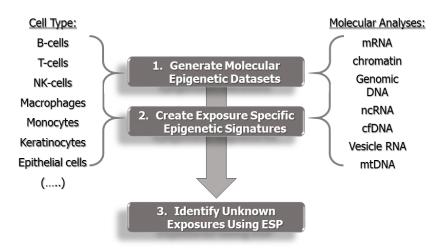


Figure 1. Possible pathway to generate signatures, include them in the ESP, and perform identification.

Technical Area 2 (TA2):

TA2 will require teams to integrate the down-selected molecular methods and bioinformatics tools necessary for exposure identification from TA1 into a single epigenetics analysis platform. The integrated platform should operate as man-portable device with a size, weight and power (SWaP) footprint equivalent to a point-of-care clinical diagnostic device, and should perform rapid analysis (< 30 minutes) in a field forward setting by minimally trained personnel.

1) Epigenetic molecular analysis integration

The TA2 system must ultimately produce an epigenetic profile from an unknown exposure for comparison to the ESP. The final epigenetic analysis system is expected to be an integrated sample-answer system capable of the following functions:

- Extract material for epigenetic analysis from blood, nasal and buccal swabs, and surface samples that may contain residual genetic material;
- Isolate nucleic acid and prepare it for epigenetic analysis; and
- Perform multiple epigenetic analyses via sequencing or other molecular analyses.

Fully automated execution of the above functions will require fluidics transfer, appropriatelytimed activation of reaction and analysis modules, and data acquisition to occur through a builtin control system. Iterative progress towards a fully automated sample-to-answer device is expected. Teams may first demonstrate independent operation of subcomponents, with manual fluids transfer, before engineering the integration of all of the device components. Ultimately, by the end of the program, the system should operate with no human intervention between the time the sample is introduced and results pertinent to exposure and timing is provided.

2) Onboard computational and bio-analytical capability

Teams will translate the bioinformatics analysis capability from TA1 into purpose-built computing hardware, firmware, and software to support operations in a field-forward setting. Signature analyses must be performed onboard, rather than via cloud computing, to enable read assembly and identification in low Quality of Service (QoS) environments. This new informatics capability should rapidly identify an exposure type and time since exposure while being used by a minimally trained operator. This computational and analytical pipeline should operate seamlessly with the molecular analysis modules, on the same device.

1.3. PROGRAM METRICS AND SCHEDULE

Proposals should include a Gantt chart of the quantitative and qualitative milestones proposed to meet ECHO program metrics, listed by phase and technical area. Figure 2 lists the minimum DARPA-desired programmatic milestones and metrics. Although the following minimum milestones and metrics are specified, the Government identifies these to bound the effort while affording the maximum flexibility, creativity, and innovation in proposing solutions to the stated problems. Proposers are encouraged to add additional milestones or metrics based on the team's specific technical approach. Proposals must address all key milestones, technical metrics, and pressure tests described in this section. Proposers must clearly and uniquely itemize tasks needed to accomplish planned milestones, metrics and deliverables.

Phase I (Base) and Phase II (Option)

DARPA anticipates that the ECHO program will provide up to four years of funding for research and development to be performed over Phase I (base) and II (option). ECHO spans a 48-month effort with a 24-month Phase I base effort and 24-month Phase II option effort. In general, Phase I should provide seven exposure-specific signatures and functional small-scale epigenetic analysis modules, and, if awarded, Phase II should provide an additional 14 exposure-specific signatures and a final integrated man-portable epigenetic analysis device.

TA1 Phase I (Base)

Under TA1, teams will be required to generate two molecular epigenetic datasets (one virus and one bacteria) within six months of contract award. The samples for these datasets will be provided by the Government to support this early milestone, as indicated above. At 12 months after contract, teams will create exposure-specific signatures from the initial two biological epigenetic datasets. Also, at 12 months after contract award, teams will create five additional, non-biological exposure-specific signatures, over a range of compounds to include chemical, radiological, and explosive materials (per Table 1). At 18 months after contract, teams will be required to distinguish bacterial from viral signatures when presented with an unknown sample. By the end of Phase I, at 24 months after contract award, teams will have a multi-target test against an unknown sample to identify the specific exposure substance, organism, or biological agent, and when in time the exposure occurred (within +/- 1 year).

Teams are required to share the molecular epigenetic datasets with Independent Verification and Validation (IV&V) partners within 30 days of completing the molecular analyses for a specific exposure. IV&V partners will measure the quality of the datasets provided by each proposer team using method-specific parameters, such as read depth, error rates, and review of molecular analysis protocols. IV&V teams will identify discrepancies, which may lead to a request for teams to re-run analyses.

TA1 Phase II (Option)

By 36 months after contract award, teams will need to deliver seven additional exposure-specific signatures, with a demonstrated positive predictive value (PPV) of 65%. At 48 months after contract, teams must complete an additional seven finalized signatures with PPV increased to 85%. At program completion, 21 total exposure-specific signatures will be identified and incorporated onto the TA2 device by each team.

Phase I (Base)	Phase II (Option)
TA1: Epigenetic Signature Identification	
6 mos. – Molecular epigenetic dataset creation from 1 virus and 1 bacterium.	36 mos. – 7 additional exposure-specific signatures per team.
12 mos. – Generation of 7 (1 virus, 1 bacterium, and 5 non-biological) exposure- specific signatures.	48 mos. – 7 additional exposure-specific signatures per team.
18 mos. – Determination of unknown sample. Distinguish between bacterial or viral.	
24 mos. – Multi-target test against an unknown sample. Identify the specific exposure	
substance, organism, or biological agent, and timing of exposure (within +/- 1 year).	

Table 3. ECHO Signature Development Timetable

TA2 Phase I (Base)

In Phase I of TA2, the device will have to demonstrate capacity that will include human-in-theloop fluid transfer, subsystem manual operation, and off-platform bioinformatics processing sample preparation, processing, and analysis components optimized independently. At 18 months after contract, a pressure test will evaluate the ability of the systems to operate as a complete unit for end-end epigenetic signature generation and analysis. This performance will be compared to traditional lab-based systems to ensure equivalent signature quality. QoS will initially be at 100% or the equivalent of 5 Mbps, but will be reduced to 85% by the end of Phase I to encourage a more local data analysis strategy (24 months after contract).

TA1 and TA2 Phase II (Option)

TA1 and TA2 will produce a fully integrated system with automatic fluid transfer, full subsystem automation, and onboard bioinformatics processing in Phase II. During Phase II, the QoS will continue to decrease gradually. At 30 months after contract, QoS will be 50% with intermittent coverage, and at 36 months after contract, QoS will be 25% with intermittent coverage. The final SWaP of the epigenetic deployable platform is expected to be equivalent to today's POC diagnostics systems: 1 ft³, < 10 lbs., and < 20 W. The final system will have to pass a field forward system demonstration with military staff operating it, using < $5x10^4$ cells, with sample to answer under 30 min, 85% PPV, QoS 10% with intermittent coverage with minimally trained operators.

	Phase I				Phase II			
Mo	0-6	6-12	12-18	18-24	24-30	30-36	36-42	42-48
	6 M Milestone:		•	•	30 M Milestone:7			
	virus & bacteria				additional			
	molecular				molecular			
	epigenetic data sets				epigenetic data sets			
u o	Metric: IV&V QC				Metric: IV&V QC			
ati	of 1 virus & 1				of data-sets			
fic	bacterial data sets				-			
E.	12 M Milestone Gen	erate 7 exposure-]		36 M Milestone:De	velop 7 additional		
de	specific signatures (2	biological & 5 non-			(14 total) exposure s	pecific signatures		
TA1: Epigenetic Signature Identification	biological WMD exp	osure specific						
E		Metric: 7 exposure				Metric: 7 +		
na		specific signatures,				signatures; 65%		
in the second se		(2 bio/5 non-bio)				PPV		
ie.	18 M Milestone:Der	nonstrate biological s	ignature ID against	1	42 M Milestone:7 a	dditional molecular er	nigenetic data sets	1
let	unknown exposure sa		ignature no against		42 M Minestoner, a	authonal molecular cj	ingenetic data sets	
6	annio ni enposare s		Metric: ID	4			Metric: IV&V OC	
jā.			bacteria from viral				of 7 + data sets	
			in unknown sample				of 7 Fuana seis	
N.	24 M Milestone:Der	nonstrate multiple tar		k non-biological)	48 M Milestone:De	velop 7 additional exp	osure specific signet	ures (21 total) per
T	24 M Milestone:Demonstrate multiple target (bacterial, viral, & non-biological) signature ID against unknown exposure samples			e non-otological)	team	verop / additional exp	osure specific signad	ares (21 total) per
				Metric: ID targets				Metric: 7 +
				with +/- 1 year				signatures; 85%
				temporal resolution				PPV
	18 M Milestone Mo	lecular reaction devel	opment at lab-scale		30 M Milestone			
					Man-portable scale			
_					(air-gapped)			
E			Metric:	1	Metric: Demo			
tto			Demonstrate		w/50% QoS			
2la			epigenetics		~			
[]			analysis on					42-48 M: Integrate
H B			platform; 100%					ESP in device
oy			QoS					
p f	24 M Milestone:Ass	embly and separate f	unctional testing of sr	nall-scale system	36 M Milestone:Epi	genetic test of all		
etic Deployah Development	modules				modules	0		
De leti				Metric:		Metric: <50,000		
G				Demonstrate		cells, 65% PPV;		
. <mark>9</mark> .				function; 85% QoS		QoS - 25%		
TA2: Epigenetic Deployable Platform Development				48 M Milestone: Fit	nal system demonstrat	tion with ESP		
A2:					to he hencedone. Ph	an system demonstra		Metric: <50.000
Î								cells, under 30 min,
								85% PPV, QoS -
								10%
			T '		136.42			

Figure 2. ECHO Milestones and Metrics

In addition to the pressure tests and system demonstration milestones, teams will be required to participate in program review meetings every six months. These meetings will include all ECHO team participants, allowing the researchers to present their latest results and update progress toward program goals. The meetings may include Government participation, program agents, defense laboratories, and the potential customers including IV&V partners. Government sidebars will be held to provide individual feedback to the performers and to ensure they are developing relevant technologies.

Deliverables

The following is the list of anticipated minimum deliverables for the Phase I base effort and Phase II option effort. Proposers may supplement this list with additional deliverables as appropriate.

Phase I Base:

- Monthly Technical/Financial Status Reports
- Epigenetic Datasets for seven compounds/agents (see table 1)
- Exposure-specific signatures for seven compounds/agents (see table 1)
- Demonstration (2) of signatures against unknown exposure samples at month 18 and 24
- Demonstration (2) of epigenetics analysis platform at month 18 and 24
- Final Report (if Phase II option is not awarded)

Phase II Option

- Monthly Technical/Financial Status Reports
- Epigenetic Datasets for an additional fourteen (see table 1)
- Exposure-specific signatures for additional fourteen (see table 1)
- Demonstration (3) of epigenetics analysis platform at months 30, 36, and 48
- ESP Prototype with operating instructions, collection cartridges, and software licenses (add description of all other items that may accompany delivery of the prototype)
- Final Report

Not all proposer teams selected for the Phase I base effort will be awarded the Phase II option effort. This decision will be based on funding availability and the performance against the metrics and milestones, and according to performance during the pressure tests described in this section.

1.4. CONTROLLED UNCLASSIFIED INFORMATION STATEMENT

To prevent the release of sensitive technical information, certain aspects of proposals may be considered Controlled Unclassified Information (CUI) and may require safeguarding or dissemination controls, pursuant to and consistent with applicable law, regulations, and Government-wide policies.

The following applied military technical information could be considered Controlled Technical Information (CTI) by DARPA:

- Potential procedure to evade ECHO Signature Panel identification: Any known techniques for rendering the exposure-specific signature undetectable.
- Epigenetic Signature Variances: Any known variances between populations that could lead to bias towards race, gender, geographic region, or inherited traits that cannot be controlled through careful clinical sampling design.
- DoD Collected Genetic or Epigenetic Data: Any genetic and epigenetic data collected from DoD efforts that has not been de-identified.

Proposals that produce any such information must deliver a detailed risk mitigation plan to DARPA (see 4.2.2. Proposal Format Section II: I). Proposers must partition potentially sensitive tasks from non-sensitive research efforts. All proposers (prime contractor and subcontractor) desiring public release of project information that may contain CTI, as defined above, must submit a request for public release to DARPA's Public Release Center (DARPA/PRC) in accordance with their contractual requirements.

2. Award Information

2.1. GENERAL AWARD INFORMATION

Multiple awards are possible. The amount of resources made available under this BAA will depend on the quality of the proposals received and the availability of funds.

The Government reserves the right to select for negotiation all, some, one, or none of the proposals received in response to this solicitation and to make awards without discussions with proposers. The Government also reserves the right to conduct discussions if it is later determined to be necessary. If warranted, portions of resulting awards may be segregated into pre-priced options. Additionally, DARPA reserves the right to accept proposals in their entirety or to select only portions of proposals for award. In the event that DARPA desires to award only portions of a proposal, negotiations may be opened with that proposer. The Government reserves the right to fund proposals in phases with options for continued work, as applicable. The Government reserves the right to fund a Phase II option based on funding availability, an assessment of Phase I research results, and a determination that awarding the option is in the best interest of the Government.

The Government reserves the right to request any additional, necessary documentation once it makes the award instrument determination. Such additional information may include but is not limited to Representations and Certifications (see Section VI.B.2., "Representations and Certifications"). The Government reserves the right to remove proposers from award consideration should the parties fail to reach agreement on award terms, conditions, and/or cost/price within a reasonable time, and the proposer fails to timely provide requested additional information. Proposals identified for negotiation may result in a procurement contract, grant, cooperative agreement, or other transaction, depending upon the nature of the work proposed, the

required degree of interaction between parties, whether or not the research is classified as Fundamental Research, and other factors.

Proposers looking for innovative, commercial-like contractual arrangements are encouraged to consider requesting Other Transactions. To understand the flexibility and options associated with Other Transactions, consult <u>http://www.darpa.mil/work-with-us/contract-management#OtherTransactions</u>.

In all cases, the Government contracting officer shall have sole discretion to select award instrument type, regardless of instrument type proposed, and to negotiate all instrument terms and conditions with selectees. DARPA will apply publication or other restrictions, as necessary, if it determines that the research resulting from the proposed effort will present a high likelihood of disclosing performance characteristics of military systems or manufacturing technologies that are unique and critical to defense. Any award resulting from such a determination will include a requirement for DARPA permission before publishing any information or results on the program. For more information on publication restrictions, see the section below on Fundamental Research.

2.2. FUNDAMENTAL RESEARCH

It is DoD policy that the publication of products of fundamental research will remain unrestricted to the maximum extent possible. National Security Decision Directive (NSDD) 189 defines fundamental research as follows:

'Fundamental research' means basic and applied research in science and engineering, the results of which ordinarily are published and shared broadly within the scientific community, as distinguished from proprietary research and from industrial development, design, production, and product utilization, the results of which ordinarily are restricted for proprietary or national security reasons.

As of the date of publication of this BAA, the Government expects that program goals as described herein may be met by proposers intending to perform fundamental research and proposers not intending to perform fundamental research or the proposed research may present a high likelihood of disclosing performance characteristics of military systems or manufacturing technologies that are unique and critical to defense. Based on the nature of the performer and the nature of the work, the Government anticipates that some awards will include restrictions on the resultant research that will require the awardee to seek DARPA permission before publishing any information or results relative to the program.

Proposers should indicate in their proposal whether they believe the scope of the research included in their proposal is fundamental or not. While proposers should clearly explain the intended results of their research, the Government shall have sole discretion to select award instrument type and to negotiate all instrument terms and conditions with selectees. Appropriate clauses will be included in resultant awards for non-fundamental research to prescribe publication requirements and other restrictions, as appropriate. This clause can be found at http://www.darpa.mil/work-with-us/additional-baa.

For certain research projects, it may be possible that although the research being performed by the awardee is restricted research, a subawardee may be conducting fundamental research. In those cases, it is the awardee's responsibility to explain in their proposal why its subawardee's effort is fundamental research

3. Eligibility Information

3.1. ELIGIBLE APPLICANTS

All responsible sources capable of satisfying the Government's needs may submit a proposal that shall be considered by DARPA.

3.1.1. Federally Funded Research and Development Centers (FFRDCs) and Government Entities

FFRDCs

FFRDCs are subject to applicable direct competition limitations and cannot propose to this BAA in any capacity unless they meet the following conditions: (1) FFRDCs must clearly demonstrate that the proposed work is not otherwise available from the private sector. (2) FFRDCs must provide a letter on official letterhead from their sponsoring organization citing the specific authority establishing their eligibility to propose to Government solicitations and compete with industry, and their compliance with the associated FFRDC sponsor agreement's terms and conditions. This information is required for FFRDCs proposing to be awardees or subawardees.

Government Entities

Government Entities (e.g., Government/National laboratories, military educational institutions, etc.) are subject to applicable direct competition limitations. Government entities must clearly demonstrate that the work is not otherwise available from the private sector and provide written documentation citing the specific statutory authority and contractual authority, if relevant, establishing their ability to propose to Government solicitations.

Authority and Eligibility

At the present time, DARPA does not consider 15 U.S.C. § 3710a to be sufficient legal authority to show eligibility. While 10 U.S.C.§ 2539b may be the appropriate statutory starting point for some entities, specific supporting regulatory guidance, together with evidence of agency approval, will still be required to fully establish eligibility. DARPA will consider FFRDC and Government entity eligibility submissions on a case-by-case basis; however, the burden to prove eligibility for all team members rests solely with the proposer.

3.1.2. Non-U.S. Organizations

Non-U.S. organizations and/or individuals may participate to the extent that such participants comply with any necessary nondisclosure agreements, security regulations, export control laws, and other governing statutes applicable under the circumstances.

3.2. ORGANIZATIONAL CONFLICTS OF INTEREST

FAR 9.5 Requirements

In accordance with FAR 9.5, proposers are required to identify and disclose all facts relevant to potential OCIs involving the proposer's organization and *any* proposed team member (subawardee, consultant). Under this Section, the proposer is responsible for providing this disclosure with each proposal submitted to the BAA. The disclosure must include the proposer's, and as applicable, proposed team member's OCI mitigation plan. The OCI mitigation plan must include a description of the actions the proposer has taken, or intends to take, to prevent the existence of conflicting roles that might bias the proposer's judgment and to prevent the proposer from having unfair competitive advantage. The OCI mitigation plan will specifically discuss the disclosed OCI in the context of each of the OCI limitations outlined in FAR 9.505-1 through FAR 9.505-4.

Agency Supplemental OCI Policy

In addition, DARPA has a supplemental OCI policy that prohibits contractors/performers from concurrently providing Scientific Engineering Technical Assistance (SETA), Advisory and Assistance Services (A&AS) or similar support services and being a technical performer. Therefore, as part of the FAR 9.5 disclosure requirement above, a proposer must affirm whether the proposer or *any* proposed team member (subawardee, consultant) is providing SETA, A&AS, or similar support to any DARPA office(s) under: (a) a current award or subaward; or (b) a past award or subaward that ended within one calendar year prior to the proposal's submission date.

If SETA, A&AS, or similar support is being or was provided to any DARPA office(s), the proposal must include:

- The name of the DARPA office receiving the support;
- The prime contract number;
- Identification of proposed team member (subawardee, consultant) providing the support; and
- An OCI mitigation plan in accordance with FAR 9.5.

Government Procedures

In accordance with FAR 9.503, 9.504 and 9.506, the Government will evaluate OCI mitigation plans to avoid, neutralize or mitigate potential OCI issues before award and to determine whether it is in the Government's interest to grant a waiver. The Government will only evaluate OCI mitigation plans for proposals that are determined selectable under the BAA evaluation criteria and funding availability.

The Government may require proposers to provide additional information to assist the Government in evaluating the proposer's OCI mitigation plan.

If the Government determines that a proposer failed to fully disclose an OCI; or failed to provide the affirmation of DARPA support as described above; or failed to reasonably provide additional information requested by the Government to assist in evaluating the proposer's OCI mitigation plan, the Government may reject the proposal and withdraw it from consideration for award.

3.3. COST SHARING/MATCHING

Cost sharing is not required; however, it will be carefully considered where there is an applicable statutory condition relating to the selected funding instrument. Cost sharing is encouraged where there is a reasonable probability of a potential commercial application related to the proposed research and development effort.

For more information on potential cost sharing requirements for Other Transactions for Prototype, see <u>http://www.darpa.mil/work-with-us/contract-management#OtherTransactions</u>

4. Application and Submission Information

4.1. ADDRESS TO REQUEST APPLICATION PACKAGE

This announcement, any attachments, and any references to external websites herein constitute the total solicitation. If proposers cannot access the referenced material posted in the announcement found at <u>http://www.darpa.mil</u>, contact the administrative contact listed herein.

4.2. CONTENT AND FORM OF APPLICATION SUBMISSION

All submissions, including abstracts and proposals must be written in English with type not smaller than 12 point font. Smaller font may be used for figures, tables, and charts. Copies of all documents submitted must be clearly labeled with the DARPA BAA number, proposer organization, and proposal title/proposal short title.

4.2.1. Proposal Abstract Format

Proposers are strongly encouraged to submit an abstract in advance of a proposal to minimize effort and reduce the potential expense of preparing an out of scope proposal. The abstract is a concise version of the proposal comprising a maximum of **6** pages including all figures, tables, and charts. The (optional) submission letter is not included in the page count. All pages shall be formatted for printing on 8-1/2 by 11 inch paper with font size not smaller than 12 point. Smaller font sizes (not smaller than 9 point) may be used for figures, tables, and charts.

Submissions must be written in English.

Abstracts must include the following components:

A. Cover Sheet (does not count towards page limit): Include the administrative and technical points of contact (name, address, phone, fax, email, lead organization). Also include the BAA number, title of the proposed project, primary subcontractors, estimated cost, duration of the project, and the label "ABSTRACT."

B. Goals and Impact (1 page): Clearly describe what is being proposed and what difference it will make (qualitatively and quantitatively), including brief answers to the following questions:

- 1. What is the proposed work attempting to accomplish or do?
- 2. How is it done today? And what are the limitations?
- 3. What is innovative in your approach and how does it compare to SOA?

- 4. What are the key technical challenges in your approach and how do you plan to overcome these?
- 5. Who will care and what will the impact be if you are successful?
- 6. How much will it cost and how long will it take?

C. Technical Plan (3-4 pages): Outline and address all technical challenges inherent in the approach and possible solutions for overcoming potential problems. The technical plan should address both TA1 and TA2. For TA1, the abstract should include a description of the epigenetic analysis methods used to generate ESP, the proposed exposure targets (i.e. chemical agents, biological agents, radiological, nuclear, and explosives); the proposed human sample type (buccal, nasal, or blood); and the proposed cell types (e.g., T-cells, B-cells, keratinocytes, etc.) your team plans to use. Any novel techniques or approaches that are unique to your organization should be highlighted. For TA2, the abstract should include your level of access and plan for incorporating the molecular and epigenetic analysis technologies in Phase I and a brief description of the components your final system will house. Where possible, please provide data and examples to support your plan. This section should provide appropriate specific milestones (quantitative, if possible) at intermediate stages of the project to demonstrate progress, and a brief plan for accomplishment of the milestones.

D. Capabilities (.5-1 page): Provide a brief summary of expertise of the team, including subcontractors and key personnel. A principal investigator for the project must be identified, and a description of the team's organization. Include a description of the team's organization including roles and responsibilities. Describe the organizational experience in this area, existing intellectual property required to complete the project, any specialized facilities, and access to epigenetics and molecular analysis technologies to be used as part of the project. List Government-furnished materials or data assumed to be available. If desired, include a brief bibliography with links to relevant papers, reports, or resumes of key performers. Do not include more than two resumes as part of the abstract. Resumes count against the abstract page limit.

E. Budget (.5 page): Please provide a rough order of magnitude of the costs of accomplishing the goals of the ECHO program. Costs should be broken out by technical area and phase. Any anticipated Government furnished equipment should be identified.

4.2.2. Proposal Format

All full proposals must be in the format given below. Proposals shall consist of two volumes: 1) **Volume I, Technical and Management Proposal**, and 2) **Volume II, Cost Proposal.** All pages shall be printed on 8-1/2 by 11 inch paper with type not smaller than 12 point. Smaller font (not smaller than 9 point) may be used for figures, tables and charts. The page limitation for full proposals includes all figures, tables, and charts. Volume I, Technical and Management Proposal, may include an attached bibliography of relevant technical papers or research notes (published and unpublished), which document the technical ideas and approach upon which the proposal is based. Copies of not more than three (3) relevant papers may be included with the

submission. The bibliography and attached papers are not included in the page counts given below. The submission of other supporting materials along with the proposals is strongly discouraged and will not be considered for review. The maximum page count for Volume 1 is 25 pages. A submission letter is optional and is not included in the page count. Volume I should include the following components:

NOTE: Non-conforming submissions that do not follow the instructions herein may be rejected without further review.

a. Volume I, Technical and Management Proposal

Section I. Administrative

- A. Cover Sheet (LABELED "PROPOSAL: VOLUME I"):
- 1. BAA number (HR001118S0023);
- 2. Technical area;
- 3. Lead organization submitting proposal (prime contractor);
- 4. Type of organization, selected from among the following categories: "LARGE BUSINESS," "SMALL DISADVANTAGED BUSINESS," "OTHER SMALL BUSINESS," "HBCU," "MI," "OTHER EDUCATIONAL," OR "OTHER NONPROFIT";
- 5. Proposer's reference number (if any);
- 6. Other team members (if applicable) and type of business for each;
- 7. Proposal title;
- 8. Technical point of contact (Program Manager or Principle Investigator) to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax, e-mail;
- 9. Administrative point of contact (Contracting Officer or Grant Officer) to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax, e-mail;
- 10. Award instrument requested: cost-plus-fixed-free (CPFF), cost-contract—no fee, firm-fixed-price, grant, cooperative agreement, other transaction, or other type (specify);
- 11. Place(s) and period(s) of performance ;
- 12. Proposal validity period;
- 13. Total funds requested from DARPA, and the amount of cost share (if any); AND
- 14. Date proposal was submitted.

Information on award instruments is available at <u>http://www.darpa.mil/work-with-us/contract-management</u>.

B. Official Transmittal Letter.

Section II. Detailed Proposal Information

- **A.** Executive Summary (1-2 pages): Provide a synopsis of the proposed project, including answers to the following questions:
 - What is the proposed work attempting to accomplish or do?
 - How is it done today, and what are the limitations?
 - What is innovative in your approach?
 - What are the key technical challenges in your approach and how do you plan to overcome these?
 - Who or what will be affected and what will be the impact if the work is successful?
 - How much will it cost, and how long will it take?
- **B.** Goals and Impact (1-2 pages): Clearly describe what the team is trying to achieve and the difference it will make (qualitatively and quantitatively) if successful. Describe the innovative aspects of the project in the context of existing capabilities and approaches, clearly delineating the uniqueness and benefits of this project in the context of the state of the art, alternative approaches, and other projects from the past and present. Describe how the proposed project is revolutionary and how it significantly rises above the current state of the art. Describe the deliverables associated with the proposed project and any plans to commercialize the technology, transition it to a customer, or further the work.
- **C.** Technical Plan (7-10 pages): Outline and address technical challenges inherent in the approach and possible solutions for overcoming potential problems. This section should provide appropriate measurable milestones (qualitative and quantitative) and program metrics (see Section 1.3) at intermediate stages of the program to demonstrate progress, and a plan for achieving the milestones. The technical plan should demonstrate a deep understanding of the technical challenges and present a credible (even if risky) plan to achieve the program goal. Discuss mitigation of technical risk. The technical plan should address the TA1 and TA2 proposal content requirements detailed in Sections 1.2 and 1.3.

A complete technical plan must address the following:

• Proposed (7) candidate signatures for Phase I and (14) candidate signatures for Phase II.

- Proposed human sample types (buccal, nasal, or blood); and the proposed cell types (e.g., T-cells, B-cells, keratinocytes, etc.) your team plans to use. Any animal models and tissue chip technologies that are to be supplemented should be identified as well as the cohort or vender providing the samples.
- All molecular epigenetic analysis methods to be utilized in both TA1 and TA2 must be identified.
- Anticipated components or modules in the platform system and any anticipated off-the-shelf technologies
- Any data from other funded or internal efforts that support your approach.
- Any examples of past experience demonstrating capability of developing platform technologies
- D. Management Plan (1-2 pages): Provide a summary of expertise of the team, including any subcontractors, and key personnel who will be doing the work. Resumes count against the proposal page count. Identify a principal investigator for the project. Provide a clear description of the team's organization including an organization chart that includes, as applicable: the programmatic relationship of team members; the unique capabilities of team members; the task responsibilities of team members, the teaming strategy among the team members; and key personnel with the amount of effort to be expended by each person during each year. Provide a detailed plan for coordination including explicit guidelines for interaction among collaborators/subcontractors of the proposed effort. Include risk management approaches. Describe any formal teaming agreements that are required to execute this program.
- **E.** Capabilities (2-3 pages): Describe organizational experience in relevant subject area(s), existing intellectual property, specialized facilities, and any Government-furnished materials or information. Discuss any work in closely related research areas and previous accomplishments. Describe experience with the proposed exposure-specific agents or compounds.
- F. Statement of Work (SOW) (2-3 pages): The SOW should provide a detailed task breakdown, citing specific tasks and their connection to the interim milestones and program metrics. Each phase of the program (Phase I base and Phase II option) should be separately defined in the SOW and each task should be identified by TA (1 or 2). The SOW must not include proprietary information.

For each task/subtask, provide:

• A detailed description of the approach to be taken to accomplish each defined task/subtask.

- Identification of the primary organization responsible for task execution (prime contractor, subcontractor(s), consultant(s), by name).
- A measurable milestone, i.e., a deliverable, demonstration, or other event/activity that marks task completion. Include quantitative metrics.
- A definition of all deliverables (e.g., data, reports, software) to be provided to the Government in support of the proposed tasks/subtasks.
- **G.** Schedule and Milestones (1-2 pages): Provide a detailed schedule showing tasks (task name, duration, work breakdown structure element as applicable, performing organization), milestones, and the interrelationships among tasks. The task structure must be consistent with that in the SOW. Measurable milestones should be clearly articulated and defined in time relative to the start of the project.
- **H.** Transition Plan (.5-1- page): As this program is expecting a prototype system at the end of 48 months; proposals must address plan to complete, beta-test, and market the deployable platform to the military and commercial partners. Proposals should include a rough order of magnitude of the prototype system and disposables cost. If off-the-shelf technologies were proposed, proposals should address IP licensing and associated risks.
- I. CUI Risk Mitigation Plan (.5 page) (Required for proposers who anticipate generating work that may be considered CUI in accordance with Section 1.4 "Controlled Unclassified Information"): Provide a detailed plan for how the organization and its subcontractors will meet CUI safeguarding requirements. The plan should provide a detailed strategy to protect CUI without unnecessarily compartmentalizing information flow within or among performer teams. This plan must describe safeguard procedures for generating any sensitive program deliverables.

Section III. Additional Information (Note: Does not count towards page limit)

A brief bibliography of relevant technical papers and research notes (published and unpublished) which document the technical ideas upon which the proposal is based. Copies of not more than three (3) relevant papers can be included in the submission.

a. Volume II, Cost Management Proposal

Cover Sheet (LABELED "PROPOSAL: VOLUME II"):

- 1. BAA number;
- 2. Technical area;
- 3. Lead Organization Submitting proposal;

- 4. Type of organization, selected among the following categories: "LARGE BUSINESS", "SMALL DISADVANTAGED BUSINESS", "OTHER SMALL BUSINESS", "HBCU", "MI", "OTHER EDUCATIONAL", OR "OTHER NONPROFIT";
- 5. Proposer's reference number (if any);
- 6. Other team members (if applicable), CAGE Code(s), and type of business for each;
- 7. Proposal title;
- 8. Technical point of contact (Program Manager or Principal Investigator) to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax (if available), electronic mail (if available);
- 9. Administrative point of contact (Contracting Officer or Grant Officer) to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax (if available), and electronic mail (if available);
- 10. Award instrument requested: cost-plus-fixed-free (CPFF), cost-contract—no fee, cost sharing contract no fee, or other type of procurement contract (*specify*), cooperative agreement, or other transaction;
- 11. Place(s) and period(s) of performance;
- 12. Total proposed cost separated by basic award and option(s) (if any);
- 13. Name, address, and telephone number of the proposer's cognizant Defense Contract Management Agency (DCMA) administration office (*if known*);
- 14. Name, address, and telephone number of the proposer's cognizant Defense Contract Audit Agency (DCAA) audit office (*if known*);
- 15. Date proposal was prepared;
- 16. DUNS number (<u>http://www.dnb.com/get-a-duns-number.html</u>);
- 17. Taxpayer ID number (<u>https://www.irs.gov/Individuals/International-</u> Taxpayers/Taxpayer-Identification-Numbers-TIN);
- 18. CAGE code (<u>https://cage.dla.mil/Home/UsageAgree</u>);
- 19. Proposal validity period

Note that nonconforming proposals may be rejected without review.

Proposers that do not have a Cost Accounting Standards (CAS) complaint accounting system considered adequate for determining accurate costs that are negotiating a cost- type procurement contract must complete an SF 1408. For more information on CAS compliance, see http://www.dcaa.mil/cas.html. To facilitate this process, proposers should complete the SF 1408 found at http://www.dcaa.mil/cas.html. To facilitate this process, proposers should complete the SF 1408 found at http://www.gsa.gov/portal/forms/download/115778 and submit the completed form with the proposal. To complete the form, check the boxes on the second page, then provide a narrative explanation of your accounting system to supplement the checklist on page one. For more information, see http://www.dcaa.mil/Home/Preaward).

The Government strongly encourages that tables included in the cost proposal also be provided in an editable (e.g., MS Excel) format with calculation formulas intact to allow traceability of the cost proposal numbers across the prime and subcontractors. The Government strongly encourages that the proposer provide a detailed cost breakdown to include:

- (1) Total program costs broken down by Phase I (Base) and Phase II (Option) in Contractor Fiscal Year to include:
 - i. Direct Labor Including individual labor categories with associated labor hours and direct labor rates. If selected for award, be prepared to submit supporting documentation to justify labor rates. (i.e., screenshots of HR databases, comparison to NIH or other web-based salary database);
 - ii. Consultants If consultants are to be used, proposer must provide a copy of the consultant's proposed SOW as well as a signed consultant agreement or other document which verifies the proposed loaded daily / hourly rate, hours and any other proposed consultant costs (e.g., travel);
 - iii. Indirect Costs Including Fringe Benefits, Overhead, General and Administrative Expense, Cost of Money, Fee, etc. (must show base amount and rate), if available, provide current Forward Pricing Rate Agreement or Forward Pricing Rate Proposal. If not available, provide 2 years historical data to include pool and expense costs used to generate the rates. For academia, provide DHHS or ONR negotiated rate package or, if calculated by other than a rate, provide University documentation identifying G&A and fringe costs by position;
 - iv. Travel Provide the purpose of the trip, number of trips, number of days per trip, departure and arrival destinations, number of people, estimated rental car and airfare costs, and prevailing per diem rates as determined by gsa.gov, etc.; Quotes must be supported by screenshots from travel websites;
 - v. Other Direct Costs Itemized with costs including tuition remission, animal per diem rates, health insurance/fee; back-up documentation is to be submitted to support proposed costs;
 - vi. Equipment Purchases Itemization with individual and total costs, including quantities, unit prices, proposed vendors (if known), and the basis of estimate (e.g., quotes, prior purchases, catalog price lists, etc.); any item that exceeds \$5,000 must be supported with back-up documentation such as a copy of catalog price lists or quotes prior to purchase (NOTE: For equipment purchases, include a letter stating why the proposer cannot provide the requested resources from its own funding), and;
 - vii. Materials Itemization with costs, including quantities, unit prices, proposed vendors (if known), and the basis of estimate (e.g., quotes, prior purchases, catalog price lists, etc.); any item that exceeds \$5,000 must be supported with back-up documentation such as a copy of catalog price lists or quotes prior to purchase.
- (2) A summary of total program costs by major TA1 and TA2 tasks;
- (3) A summary of projected funding requirements by month;
- (4) An itemization of any information technology (IT) purchase (including a letter stating why the proposer cannot provide the requested resources from its own funding), as defined in FAR Part 2.101;
- (5) An itemization of Subcontracts. All subcontractor cost proposal documentation must be prepared at the same level of detail as that required of the prime. Subcontractor proposals should include Interdivisional Work Transfer Agreements (IWTA) or evidence

of similar arrangements (an IWTA is an agreement between multiple divisions of the same organization);

- (6) The source, nature, and amount of any industry cost-sharing. Where the effort consists of multiple portions which could reasonably be partitioned for purposes of funding, these should be identified as options with separate cost estimates for each;
- (7) Identification of pricing assumptions of which may require incorporation into the resulting award instrument (e.g., use of Government Furnished Property/Facilities/Information, access to Government Subject Matter Expert/s, etc.);
- (8) Any Forward Pricing Rate Agreement, DHHS rate agreement, other such approved rate information, or such documentation that may assist in expediting negotiations (if available); and
- (9) Proposers with a Government acceptable accounting system who are proposing a cost-type contract, must submit the DCAA document approving the cost accounting system.

4.2.3. Additional Proposal Information

Proprietary Markings

Proposers are responsible for clearly identifying proprietary information. Submissions containing proprietary information must have the cover page and each page containing such information clearly marked with a label such as "Proprietary" or "Company Proprietary." NOTE: "Confidential" is a classification marking used to control the dissemination of U.S. Government National Security Information as dictated in Executive Order 13526 and should not be used to identify proprietary business information.

Unclassified Submissions

DARPA anticipates that submissions received under this BAA will be unclassified. However, should a proposer wish to submit classified information, an *unclassified* email must be sent to the BAA mailbox requesting submission instructions from the Technical Office PSO. If a determination is made that the award instrument may result in access to classified information, a SCG and/or DD Form 254 will be issued by DARPA and attached as part of the award.

Human Research Subjects/Animal Use

Proposers that anticipate involving Human Research Subjects or Animal Use must comply with the approval procedures detailed at <u>http://www.darpa.mil/work-with-us/additional-baa</u>.

Approved Cost Accounting System Documentation

Proposers that do not have a Cost Accounting Standards (CAS) complaint accounting system considered adequate for determining accurate costs that are negotiating a cost- type procurement contract must complete an SF 1408. For more information on CAS compliance, see http://www.dcaa.mil/cas.html. To facilitate this process, proposers should complete the SF 1408 found at http://www.gsa.gov/portal/forms/download/115778 and submit the complete form with the proposal. To complete the form, check the boxes on the second page, then provide a narrative explanation of your accounting system to supplement the checklist on page one. For more information, see

(http://www.dcaa.mil/preaward_accounting_system_adequacy_checklist.html).

Small Business Subcontracting Plan

Pursuant to Section 8(d) of the Small Business Act (15 U.S.C. § 637(d)) and FAR 19.702(a)(1), each proposer who submits a contract proposal and includes subcontractors might be required to submit a subcontracting plan with their proposal. The plan format is outlined in FAR 19.704.

Section 508 of the Rehabilitation Act (29 U.S.C. § 749d)/FAR 39.2

All electronic and information technology acquired or created through this BAA must satisfy the accessibility requirements of Section 508 of the Rehabilitation Act (29 U.S.C. § 749d)/FAR 39.2.

Intellectual Property

All proposers must provide a good faith representation that the proposer either owns or possesses the appropriate licensing rights to all intellectual property that will be utilized under the proposed effort.

For Procurement Contracts

Proposers responding to this BAA requesting procurement contracts will need to complete the certifications at DFARS 252.227-7017. See <u>http://www.darpa.mil/work-with-us/additional-baa</u> for further information. If no restrictions are intended, the proposer should state "none." The table below captures the requested information:

Technical Data Computer Software To be Furnished With Restrictions	Summary of Intended Use in the Conduct of the Research	Basis for Assertion	Asserted Rights Category	Name of Person Asserting Restrictions
(LIST)	(NARRATIVE)	(LIST)	(LIST)	(LIST)

For All Non-Procurement Contracts

Proposers responding to this BAA requesting a Grant, Cooperative Agreement, Technology Investment Agreement, or Other Transaction for Prototypes shall follow the applicable rules and regulations governing these various award instruments, but, in all cases, should appropriately identify any potential restrictions on the Government's use of any Intellectual Property contemplated under the award instrument in question. This includes both Noncommercial Items and Commercial Items. Proposers are encouraged to use a format similar to that described in the section above. If no restrictions are intended, then the proposer should state "NONE."

System for Award Management (SAM) and Universal Identifier Requirements

All proposers must be registered in SAM unless exempt per FAR 4.1102. FAR 52.204-7, "System for Award Management" and FAR 52.204-13, "System for Award Management Maintenance" are incorporated into this BAA. See <u>http://www.darpa.mil/work-with-us/additional-baa</u> for further information.

4.2.4. Submission Information

DARPA will acknowledge receipt of all submissions and assign an identifying control number that should be used in all further correspondence regarding the submission. DARPA intends to use electronic mail correspondence regarding HR001118S0023. <u>Submissions may not be</u> submitted by fax or e-mail; any so sent will be disregarded.

Submissions will not be returned. An electronic copy of each submission received will be retained at DARPA and all other non-required copies destroyed. A certification of destruction may be requested, provided the formal request is received by DARPA within 5 days after notification that a proposal was not selected.

For abstract and proposal submission dates, see Part I., Overview Information. Submissions received after these dates and times may not be reviewed.

For Proposers Submitting Proposal Abstracts or Full Proposals as Hard Copies/On CD-ROM:

Proposers must submit an original hardcopy and one (1) electronic copy of the abstract or proposal in PDF (preferred) on a CD-ROM to the mailing address listed in Part I. Each copy must be clearly labeled with HR001118S0023, proposer organization, technical point of contact, and proposal title (short title recommended).

Please note that submitters via hardcopy/CD-ROM will still need to visit <u>https://baa.darpa.mil</u> to register their organization concurrently to ensure the BAA office can verify and finalize their submission.

For Proposers Submitting Proposal Abstracts or Full Proposals Requesting Procurement Contracts or OTs through DARPA's BAA Submission Portal:

Abstracts and Full Proposals sent in response to HR001118S0023 may be submitted via DARPA's BAA Website (<u>https://baa.darpa.mil</u>). Visit the website to complete the two-step

registration process. Submitters will need to register for an Extranet account (via the form at the URL listed above) and wait for two separate e-mails containing a username and temporary password. After accessing the Extranet, submitters may then create an account for the DARPA BAA website (via the "Register your Organization" link along the left side of the homepage), view submission instructions, and upload/finalize the abstract. Proposers using the DARPA BAA Website may encounter heavy traffic on the submission deadline date; it is highly advised that submission process be started as early as possible.

All unclassified concepts submitted electronically through DARPA's BAA Website must be uploaded as zip files (.zip or .zipx extension). The final zip file should be no greater than 50 MB in size. Only one zip file will be accepted per submission. Classified submissions and proposals requesting assistance instruments (grants or cooperative agreements) should NOT be submitted through DARPA's BAA Website (<u>https://baa.darpa.mil</u>), though proposers will likely still need to visit <u>https://baa.darpa.mil</u> to register their organization (or verify an existing registration) to ensure the BAA office can verify and finalize their submission.

Technical support for BAA Website may be reached at <u>BAAT_Support@darpa.mil</u>, and is typically available during regular business hours, (9:00 AM- 5:00 PM EST Monday – Friday).

Proposers using the DARPA BAA Website may encounter heavy traffic on the submission deadline date; it is highly advised that submission process be started as early as possible.

For Full Proposals Requesting Cooperative Agreements:

Proposers requesting cooperative agreements may submit proposals through one of the following methods: (1) hard copy mailed directly to DARPA; or (2) electronic upload per the instructions at <u>http://www.grants.gov/applicants/apply-for-grants.html</u>. Cooperative agreement proposals may not be submitted through any other means. If proposers intend to use Grants.gov as their means of submission, then they must submit their entire proposal through Grants.gov; applications cannot be submitted in part to Grants.gov and in part as a hard-copy. Proposers using the Grants.gov do not submit paper proposals in addition to the Grants.gov electronic submission.

<u>Grants.gov Submissions:</u> Grants.gov requires proposers to complete a one-time registration process before a proposal can be electronically submitted. First time registration can take between three business days and four weeks. For more information about registering for Grants.gov, see <u>http://www.darpa.mil/work-with-us/additional-baa</u>.

<u>Hard-copy Submissions</u>: Proposers electing to submit grant or cooperative agreement proposals as hard copies must complete the SF 424 R&R form (Application for Federal Assistance,) available on the Grants.gov website http://apply07.grants.gov/apply/forms/sample/RR_SF424_2_0-V2.0.pdf

Failure to comply with the submission procedures may result in the submission not being evaluated. DARPA will acknowledge receipt of complete submissions via email and assign control numbers that should be used in all further correspondence regarding proposals.

4.2.5. Disclosure of Information and Compliance with Safeguarding Covered Defense Information Controls

The following provisions and clause apply to all solicitations and contracts; however, the definition of "controlled technical information" clearly exempts work considered fundamental research and therefore, even though included in the contract, will not apply if the work is fundamental research.

DFARS 252.204-7000, "Disclosure of Information"

DFARS 252.204-7008, "Compliance with Safeguarding Covered Defense Information Controls" DFARS 252.204-7012, "Safeguarding Covered Defense Information and Cyber Incident Reporting"

The full text of the above solicitation provision and contract clauses can be found at http://www.darpa.mil/work-with-us/additional-baa#NPRPAC.

Compliance with the above requirements includes the mandate for proposers to implement the security requirements specified by National Institute of Standards and Technology (NIST) Special Publication (SP) 800-171, "Protecting Controlled Unclassified Information in Nonfederal Information Systems and Organizations" (see https://doi.org/10.6028/NIST.SP.800-171rl) that are in effect at the time the BAA is issued, or as authorized by the Contracting Officer, not later than December 31, 2017.

For awards where the work is considered fundamental research, the contractor will not have to implement the aforementioned requirements and safeguards; however, should the nature of the work change during performance of the award, work not considered fundamental research will be subject to these requirements.

4.3. FUNDING RESTRICTIONS

There will be limitations on direct costs of equipment purchases. These limitations include any individual piece of equipment greater than \$100,000.00. DARPA is selecting performers who have a proven track record with technologies specific to this solicitation. If equipment is limited due to high internal demand, leasing and external vendors are optional solutions.

4.4. OTHER SUBMISSION REQUIREMENTS

Not applicable.

5. Application Review Information

5.1. EVALUATION CRITERIA

Proposals will be evaluated using the following criteria, listed in descending order of importance:

5.1.1 Overall Scientific and Technical Merit; 5.1.2 Potential Contribution and Relevance to the DARPA Mission; 5.1.3 Cost Realism; 5.1.4 Realism of Proposed Schedule; 5.1.5 Proposer's Capabilities and/or Related Experience; and 5.1.6 Plans and Capabilities to Accomplish Technology Transition.

5.1.1. Overall Scientific and Technical Merit

The proposed technical approach is innovative, feasible, achievable, and complete. The proposed technical team has the expertise and experience to accomplish the proposed tasks. Task descriptions and associated technical elements provided are complete and in a logical sequence with all proposed deliverables clearly defined such that a final outcome that achieves the goal can be expected as a result of award. The proposal identifies major technical risks and planned mitigation efforts are clearly defined and feasible. The diversity of the proposed additional 17 exposure compounds and agents supports the program's goal to maximize the forensic and diagnostic capability of the ESP on the final device.

5.1.2. Potential Contribution and Relevance to the DARPA Mission

The potential contributions of the proposed effort are relevant to the national technology base. Specifically, DARPA's mission is to make pivotal early technology investments that create or prevent strategic surprise for U.S. National Security.

5.1.3. Cost Realism

The proposed costs are realistic for the technical and management approach and accurately reflect the technical goals and objectives of the solicitation. The proposed costs are consistent with the proposer's Statement of Work and reflect a sufficient understanding of the costs and level of effort needed to successfully accomplish the proposed technical approach. The costs for the prime proposer and proposed subawardees are substantiated by the details provided in the proposal (e.g., the type and number of labor hours proposed per task, the types and quantities of materials, equipment and fabrication costs, travel and any other applicable costs and the basis for the estimates).

It is expected that the effort will leverage all available relevant prior research in order to obtain the maximum benefit from the available funding. For efforts with a likelihood of commercial application, appropriate direct cost sharing may be a positive factor in the evaluation. DARPA recognizes that undue emphasis on cost may motivate proposers to offer low-risk ideas with minimum uncertainty and to staff the effort with junior personnel in order to be in a more competitive posture. DARPA discourages such cost strategies.

5.1.4. Realism of Proposed Schedule

The proposed schedule aggressively pursues performance metrics in the shortest timeframe and accurately accounts for that timeframe. The proposed schedule identifies and mitigates any potential schedule risk.

5.1.5. Proposer's Capabilities and/or Related Experience

The proposer's prior experience in similar efforts must clearly demonstrate an ability to deliver products that meet the proposed technical performance within the proposed budget and schedule. The proposed team has the expertise to manage the cost and schedule. Similar efforts

completed/ongoing by the proposer in this area are fully described including identification of other Government sponsors. The proposed team has experience with the proposed exposure categories.

5.1.6. Plans and Capability to Accomplish Technology Transition

The proposer clearly demonstrates its capability to transition the technology to the research, industrial, and/or operational military communities in such a way as to enhance U.S. defense. In addition, the evaluation will take into consideration the extent to which the proposed intellectual property (IP) rights will potentially impact the Government's ability to transition the technology.

5.2. REVIEW OF PROPOSALS

Review Process

It is the policy of DARPA to ensure impartial, equitable, comprehensive proposal evaluations based on the evaluation criteria listed in Section V.A. and to select the source (or sources) whose offer meets the Government's technical, policy, and programmatic goals.

DARPA will conduct a scientific/technical review of each conforming proposal. Conforming proposals comply with all requirements detailed in this BAA; proposals that fail to do so may be deemed non-conforming and may be removed from consideration. Proposals will not be evaluated against each other since they are not submitted in accordance with a common work statement. DARPA's intent is to review proposals as soon as possible after they arrive; however, proposals may be reviewed periodically for administrative reasons

Award(s) will be made to proposers whose proposals are determined to be the most advantageous to the Government, consistent with instructions and evaluation criteria specified in the BAA herein, and availability of funding.

Handling of Source Selection Information

DARPA policy is to treat all submissions as source selection information (see FAR 2.101 and 3.104), and to disclose their contents only for the purpose of evaluation. Restrictive notices notwithstanding, during the evaluation process, submissions may be handled by support contractors for administrative purposes and/or to assist with technical evaluation. All DARPA support contractors performing this role are expressly prohibited from performing DARPA-sponsored technical research and are bound by appropriate nondisclosure agreements. Subject to the restrictions set forth in FAR 37.203(d), input on technical aspects of the proposals may be solicited by DARPA from non-Government consultants/experts who are strictly bound by the appropriate non-disclosure requirements.

Federal Awardee Performance and Integrity Information (FAPIIS)

Per 41 U.S.C. 2313, as implemented by FAR 9.103 and 2 CFR § 200.205, prior to making an award above the simplified acquisition threshold, DARPA is required to review and consider any information available through the designated integrity and performance system (currently FAPIIS). Awardees have the opportunity to comment on any information about themselves

entered in the database, and DARPA will consider any comments, along with other information in FAPIIS or other systems prior to making an award.

6. Award Administration Information

6.1. SELECTION NOTICES

As soon as the evaluation of a proposal is complete, the proposers will be notified that 1) the proposal has been selected for funding pending contract negotiations, or 2) the proposal has not been selected. These official notifications will be sent via email to the Technical POC identified on the proposal coversheet.

6.1.1. Proposal Abstracts

DARPA will respond to abstracts with a statement as to whether DARPA is interested in the idea. If DARPA does not recommend the proposer submit a full proposal, DARPA will provide feedback to the proposer regarding the rationale for this decision. Regardless of DARPA's response to an abstract, proposers may submit a full proposal. DARPA will review all full proposals submitted using the published evaluation criteria and without regard to any comments resulting from the review of an abstract.

6.1.2. Full Proposals

As soon as the evaluation of a proposal is complete, the proposer will be notified that (1) the proposal has been selected for funding pending award negotiations, in whole or in part, or (2) the proposal has not been selected. These official notifications will be sent via e-mail to the Technical POC and/or Administrative POC identified on the proposal coversheet.

6.2. ADMINISTRATIVE AND NATIONAL POLICY REQUIREMENTS

6.2.1. Meeting and Travel Requirements

There will be a program kickoff meeting in the Arlington, VA vicinity and all key participants are required to attend. Performers should also anticipate 6 month program-wide PI meetings alternating between the East and West Coast, as well as periodic site visits at the Program Manager's discretion.

Proposers shall include within the content of their proposal details and costs of any travel or meetings they deem to be necessary throughout the course of the effort, to include periodic status reviews by the Government.

6.2.1. FAR and DFARS Clauses

(Full text or text selections from website may be used in addition to or in lieu of text below.) Solicitation clauses in the FAR and DFARS relevant to procurement contracts and FAR and DFARS clauses that may be included in any resultant procurement contracts are incorporated herein and can be found at <u>http://www.darpa.mil/work-with-us/additional-baa</u>.

6.2.2. Controlled Unclassified Information (CUI) on Non-DoD Information Systems

Further information on Controlled Unclassified Information on Non-DoD Information Systems is incorporated herein can be found at <u>http://www.darpa.mil/work-with-us/additional-baa</u>.

6.2.3. Representations and Certifications

If a procurement contract is contemplated, prospective awardees will need to be registered in the SAM database prior to award and complete electronic annual representations and certifications consistent with FAR guidance at 4.1102 and 4.1201; the representations and certifications can be found at www.sam.gov. Supplementary representations and certifications can be found at <u>http://www.darpa.mil/work-with-us/additional-baa</u>.

6.2.4. Terms and Conditions

A link to the DoD General Research Terms and Conditions for Grants and Cooperative Agreements and supplemental agency terms and conditions can be found at http://www.darpa.mil/work-with-us/contract-management#GrantsCooperativeAgreements.

6.3. **REPORTING**

The number and types of reports will be specified in the award document, but will include as a minimum monthly financial status reports and quarterly technical status reports. The reports shall be prepared and submitted in accordance with the procedures contained in the award document and mutually agreed on before award. Reports and briefing material will also be required as appropriate to document progress in accomplishing program metrics. A Final Report that summarizes the project and tasks will be required at the conclusion of the performance period for the award, notwithstanding the fact that the research may be continued under a follow-on vehicle.

6.4. ELECTRONIC SYSTEMS

6.4.1. Wide Area Work Flow (WAWF)

Performers will be required to submit invoices for payment directly to <u>https://wawf.eb.mil</u>, unless an exception applies. Performers must register in WAWF prior to any award under this BAA.

6.4.2. **i-EDISON**

The award document for each proposal selected for funding will contain a mandatory requirement for patent reports and notifications to be submitted electronically through i-Edison (http://public.era.nih.gov/iedison).

7. Agency Contacts

Administrative, technical or contractual questions should be sent via e-mail (preferred) to <u>ECHO@darpa.mil</u>.

Points of Contact The BAA Coordinator for this effort may be reached at: <u>ECHO@darpa.mil</u> DARPA/BTO ATTN: HR001118S0023 675 North Randolph Street Arlington, VA 22203-2114

For information concerning agency level protests see <u>http://www.darpa.mil/work-with-us/additional-baa#NPRPAC</u>.

8. Other Information

DARPA will host a Proposers Day in support of the ECHO program on **February 23, 2018**, at the Executive Conference Center in Arlington, VA. The purpose is to provide potential proposers with information on the ECHO program, promote additional discussion on this topic, address questions, provide a forum to present their capabilities, and to encourage team formation.

Interested proposers are not required to attend to respond to the ECHO BAA, and relevant information and materials discussed at Proposers Day will be made available to all potential proposers in the form of a FAQ posted on the DARPA Opportunities Page.

DARPA will not provide cost reimbursement for interested proposers in attendance.

An online registration form and various other meeting details can be found at the registration website, <u>https://events.sa-meetings.com/ECHOProposersDay</u>.

To encourage team formation, interested proposers are encouraged to submit information to be shared with all potential proposers through the Proposers Day website and the DARPA Opportunities Page. This information may include contact information, a brief description of their technical capabilities, and the desired expertise from other teams, as applicable.

Participants are required to register no later than **February 16, 2018**, for the event. This event is not open to the Press. The Proposers Day will be open to members of the public who have registered in advance for the event; **there will be no onsite registration**.

All foreign nationals, including permanent residents, must complete and submit a DARPA Form 60 "Foreign National Visit Request," which will be provided in the registration confirmation email.

Proposers Day Point of Contact: <u>DARPA-SN-18-23@darpa.mil</u>.

9. APPENDIX 1 – Volume II checklist

Volume II, Cost Proposal Checklist and Sample Templates

The following checklist and sample templates are provided to assist the proposer in developing a complete and responsive cost volume. Full instructions appear in Section 4.2.2 beginning on Page 23 of HR001118S0023. This worksheet must be included with the coversheet of the Cost Proposal.

1. Are all items from Section 4.2.2 (Volume II, Cost Proposal) of **HR001118S0023** included on your Cost Proposal cover sheet?

• YES • NO Appears on Page(s) [Type text] If reply is "No", please explain:

2. Does your Cost Proposal include (1) a summary cost buildup by Phase, (2) a summary cost buildup by Year, and (3) a detailed cost buildup of for each Phase that breaks out each task and shows the cost per month?

• YES • NO Appears on Page(s) [Type text]

If reply is "No", please explain:

Does your cost proposal (detailed cost buildup #3 above in item 2) show a breakdown of the major cost items listed below:
 Direct Labor (Labor Categories, Hours, Pates)

Direct Labor (Labor Categories, Hours, Rates)					
○ YES	• NO	Appears on Page(s) [Type text]			
Indirect Costs/Rates (i.e., overhead charges, fringe benefits, G&A)					
∘ YES	• NO	Appears on Page(s) [Type text]			
Materials and/or	Equipment				
• YES	• NO	Appears on Page(s) [Type text]			
Subcontracts/Co	nsultants				
○ YES	• NO	Appears on Page(s) [Type text]			
Other Direct Costs					
∘ YES	• NO	Appears on Page(s) [Type text]			
Travel					
• YES	• NO	Appears on Page(s) [Type text]			
		Appears on rage(s) [1 ype text]			

If reply is "No", please explain:

4. Have you provided documentation for proposed costs related to travel, to include purpose of trips, departure and arrival destinations and sample airfare?

• YES • NO Appears on Page(s) [Type text]

If reply is "No", please explain:

5. Does your cost proposal include a complete itemized list of <u>all</u> material and equipment items to be purchased (a priced bill-of-materials (BOM))?

• YES • NO Appears on Page(s) [Type text]

If reply is "No", please explain:

6. Does your cost proposal include vendor quotes or written engineering estimates (basis of estimate) for <u>all</u> material and equipment with a unit price exceeding \$5000?

• YES • NO Appears on Page(s) [Type text]

If reply is "No", please explain:

7. Does your cost proposal include a clear justification for the cost of labor (written labor basis-of-estimate (BOE)) providing rationale for the labor categories and hours proposed for each task?
 • YES • NO Appears on Page(s) [Type text]

If reply is "No", please explain:

- 8. Do you have subcontractors/consultants? If YES, continue to question 9. If NO, skip to question 13. • YES • NO Appears on Page(s) [Type text]
- 9. Does your cost proposal include copies of all subcontractor/consultant technical (to include Statement of Work) and cost proposals?

• YES • NO Appears on Page(s) [Type text]

If reply is "No", please explain:

10. Do all subcontract proposals include the required summary buildup, detailed cost buildup, and supporting documentation (SOW, Bill-of-Materials, Basis-of-Estimate, Vendor Quotes, etc.)?
 • YES • NO Appears on Page(s) [Type text]

If reply is "No", please explain:

If reply is "No", please explain:

12. If requesting a FAR-based contract, does your cost proposal include a tech/cost analysis for all proposed subcontractors?

• YES • NO Appears on Page(s) [Type text]

If reply is "No", please explain:

13. Have all team members (prime and subcontractors) who are considered a Federally Funded Research & Development Center (FFRDC), included documentation that clearly demonstrates work is not otherwise available from the private sector AND provided a letter on letterhead from the sponsoring organization citing the specific authority establishing their eligibility to propose to government solicitations and compete with industry, and compliance with the associated FFRDC sponsor agreement and terms and conditions.

• YES • NO Appears on Page(s) [Type text]

If reply is "No", please explain:

If reply is "No", please explain:

If reply is "No", please explain: