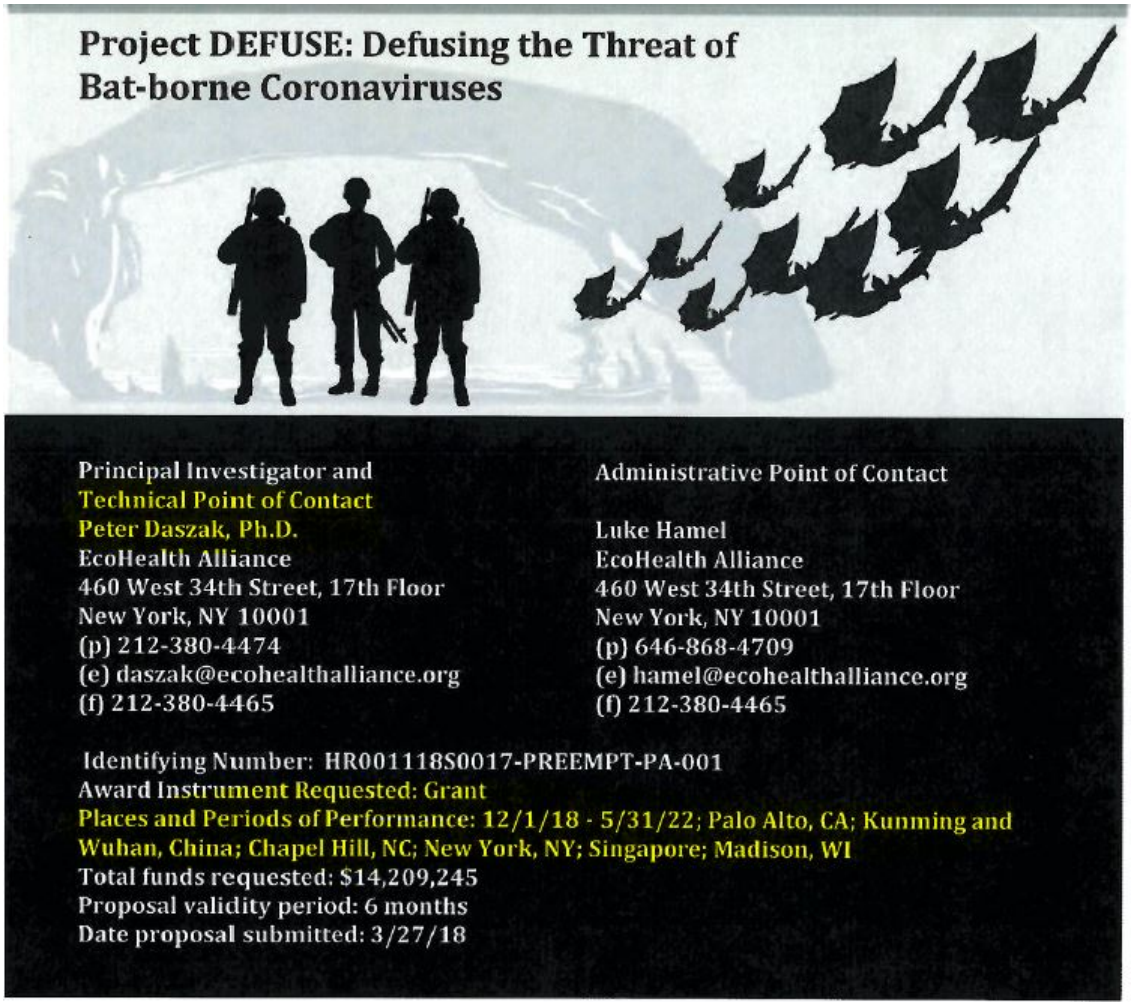
[Peter Daszak, PhD. (Posted Jan. 19, 2018). EcoHealth Alliance, DRASTIC RESEARCH, Project DEFUSE, Grant Application No. HR001118S0017 - Preventing Emerging Pathogenetic Threats. DARPA - Biological Technologies Office. Source: https://drasticresearch.files.wordpress.com/2021/09/defuse-project-drastic-analysis-1.pdf | https://drasticresearch.files.wordpress.com/2021/09/defuse-project-rejection-by-darpa.pdf]

DRASTIC RESEARCH

Project DEFUSE

DARPA - PREEMPT (HR001118S0017)



Documents made available by an anonymous source

CONTEXT & SUMMARY

These leaked documents describing bat research proposed by EcoHealth Alliance should be considered in light of the following context:

On August 27th, 2021, the US intelligence community issued a 502-word summary of the conclusions drawn up by the joint investigation ordered by President Biden in late May. Conspicuously absent from the brief statement were any indications that the evidence presented in testimony to Congress had been part of the intelligence community analysis - at least not in the unclassified version that was released.

The lifting of the gain-of-function (GOF) moratorium in late 2017, via the Potential Pandemic Pathogen Care and Oversight framework (P3CO), has allowed GOF research with SARS-like coronaviruses to resume with very few practical limits. In particular the absence of clear definitions of GoF, creative interpretations of the guidelines, and rather discretionary decisions to refer research projects or not, all contributed to reducing the effectiveness of the P3CO framework - despite the fact that other agencies of the US federal government actively maintained the GOF standards.

DRASTIC recently became aware of documents which show that EcoHealth Alliance (EHA) in concert wIth the WIV were looking towards implementing an advanced human pathogenicity BatCoV research project that clearly qualifies as GoF, in a grant proposal submitted to a funding proposal call by the Defense Advanced Research Projects Agency (DARPA) in the spring of 2018. The EHA / WIV proposal (named 'DEFUSE') was ultimately rejected for full funding (but leaving open the door for partial funding), in part because it skirted the GOF guidelines.

In other words, a branch of the federal government had already judged aspects of EHA's research, and the corresponding shared research plan with the WIV, as falling under the definition of GOF, only for HHS to approve similar work **without P3CO review** in 2018 and 2019. In particular, the P3CO framework was designed to allow greater flexibility for vaccine development, and in June of 2018 the NIH's Vaccine Research Center (VRC) expanded its existing partnership with Moderna to include full-scale research into a pan-coronavirus (CoV) vaccine platform. EcoHealth Alliance repeatedly took advantage of this flexibility to continue their work with the Wuhan Institute of Virology

DRASTIC has reviewed the contents of these documents They detail past achievements and planned experiments in collaboration with researchers from the Wuhan Institute of Virology (WIV), East China Normal University (ECNU), UNC-Chapel Hill, Duke-National University in Singapore, the USGS National Wildlife Health Center (NWHC) and Palo Alto Research Center (PARC).

The grant proposal includes some elements of research that are already public via scientific papers, as well as other elements that have never been made public; these include vaccinating wild bats using aerosolized viruses and further work on published and unpublished CoV strains that could fill the extant gaps in our understanding of the origins of SARS-CoV-2.

These grant proposal documents also show a staggeringly deep level of involvement of EHA with the WIV, on matters of national interest (such as DURC), for instance by proposing that the DARPA grant pays a good chunk of key WIV researchers salaries, or that some of these WIV researchers should be invited to DARPA headquarters in Arlington. All the while without proper risk assessment and considerations for ethical and social issues and with an incorrect evaluation of what constitutes

GoF research.

KEY DOCUMENTS

DARPA PREEMPT program (HR00111880017):

- Brief introduction': https://www.darpa.mil/program/preventing-emerging-pathogenic-threats
- Press release: https://www.darpa.mil/news-events/2018-01-04 (archived version)
- Grant Opportunity: https://www.grants.gov/web/grants/view-opportunity.html?oppId=300198
- Copies of some of the main Grant Opportunity files: https://bit.ly/39yeFNj
- Description of the Selected teams: https://www.darpa.mil/news-events/2019-02-19
  The teams are led by (1) Autonomous Therapeutics, Inc., (2) Institut Pasteur, (3) Montana State University, (4) The Pirbright Institute and (5) the University of California, Davis.
  Most of the teams are made of US, UK or Australian partners, plus one partner in Estonia (Tartu) and the Institut Pasteur network in Asia. None of the teams include Chinese partners.
- Examples of funded PREEMPT projects:
  - $9.37mln award for UCDavis team PREEMPT project
  - Montana State University team PREEMPT project.
-

EHA "DEFUSE" proposal to DARPA PREEMPT:

- **D1:** 75 page 'PROPOSAL: Volume I'
- **D2:** 8-page budget
- **D3:** Summary of Rejection Letter (DARPA): https://bit.ly/3Eyv82f
- **D4:** Executive Slides

Note: page numbers are given as the n^{th} page in the corresponding PDF document. Hence (D1, p.10) means 10^{th} PDF page of document D1.

TIMELINE

2014 May 27 — Award to EHA of NIH R01AI110964 grant ("Understanding the Risk of Bat Coronavirus Emergence") for 5 years (June 2014 - May 2019) - with subgrants to WIV, East China Normal University (Shanghai) and (starting year 3) Wuhan University.[1]

WIV:	~$695,000
East China N. Uni:	~$259,000
Wuhan University:	~$442,000

(all direct costs over 5 years, see pages 5 and 189 of grant)

Early 2017: China sets up its own version of DARPA, under the Central Military Commission.

2018 Jan 4 — Launch of DARPA Preventing Emerging Pathogenic Threats (PREEMPT) program.

2018 Jan 19 — Notice (BAA) for proposals for PREEMPT Program HR001118S0017, with a span of 3.5 years (Dec 18 - May 22).

2018 Jan 19 — Cables from U.S. Embassy health and science officials about lack of trained personnel as the WIV P4 and the potential danger of newly found BatCoVs that can directly infect humans.

2018 Mar 27 — EHA fills a proposal for DARPA PREEMPT project under HR001118S0017 by stated deadline: Project DEFUSE (Defusing the Threat of Bat-Bome Coronaviruses) for a requested amount of $14,209,245 (over 3.5 years).

2018 ?? — **Rejection** of EHA project DEFUSE due to important concerns

2018 Nov — Application for renewal of NIH R01AI110964 grant "Understanding the Risk of Bat Coronavirus Emergence' (p. 316 of grant) - with subgrants to WIV (inc. Wuhan University work), Institute of Pathogen Biology (IPB, Beijing), East China Normal University (Shanghai)

WIV:	~$353,000
IPB:	~$350,000
East China N. Uni:	~$368,000

(all direct costs over 5 years - in particular see p. 420 for East China Normal University via the consultancy of Dr Guangjian Zhu)

2019 Jul 24 — Fast renewal of NIH R01AI110964 grant grant for 5 years (June 2019 - May 2024)

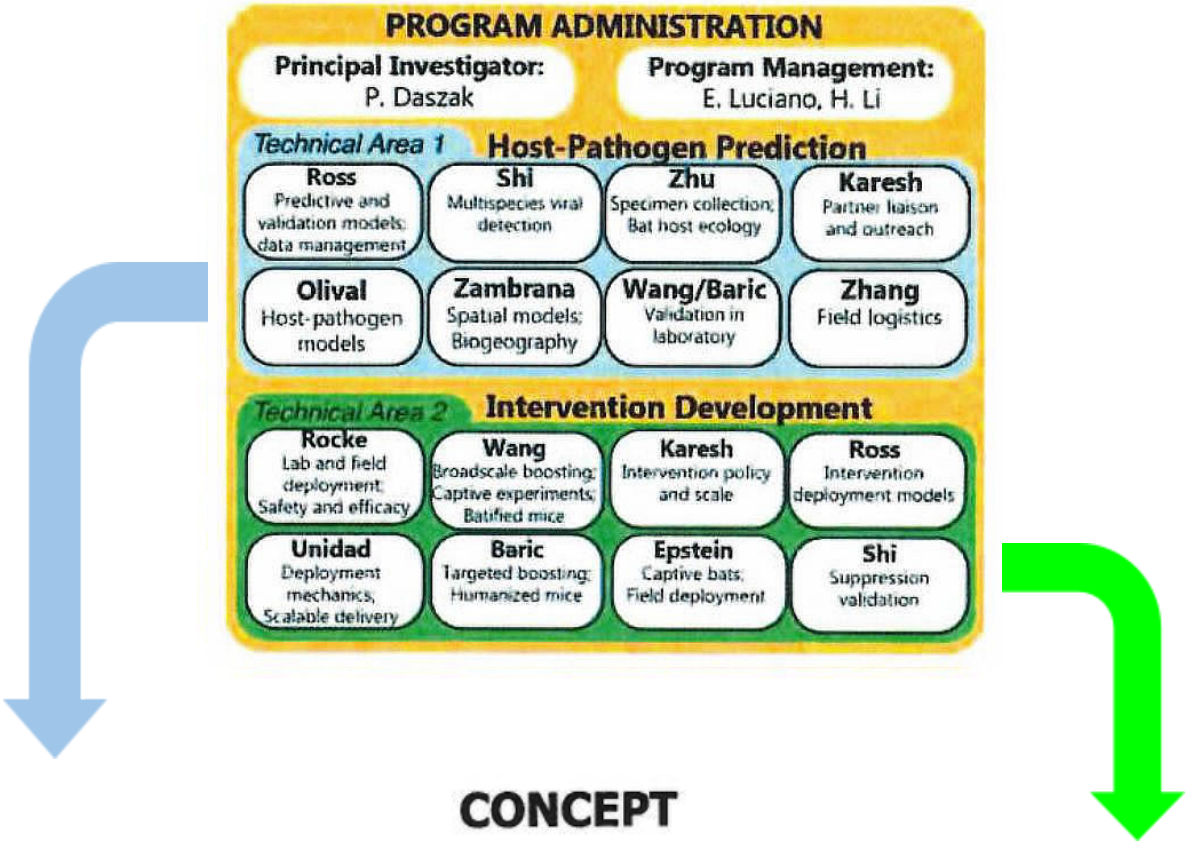
2020 Apr 24 — Suspension of NIH R01AI110964 grant

2020 Jul 8 — Reinstantiation of NIH R01AI110964 grant - but all activities are suspended until NIH conditions are satisfied (see also p 320 of grant).

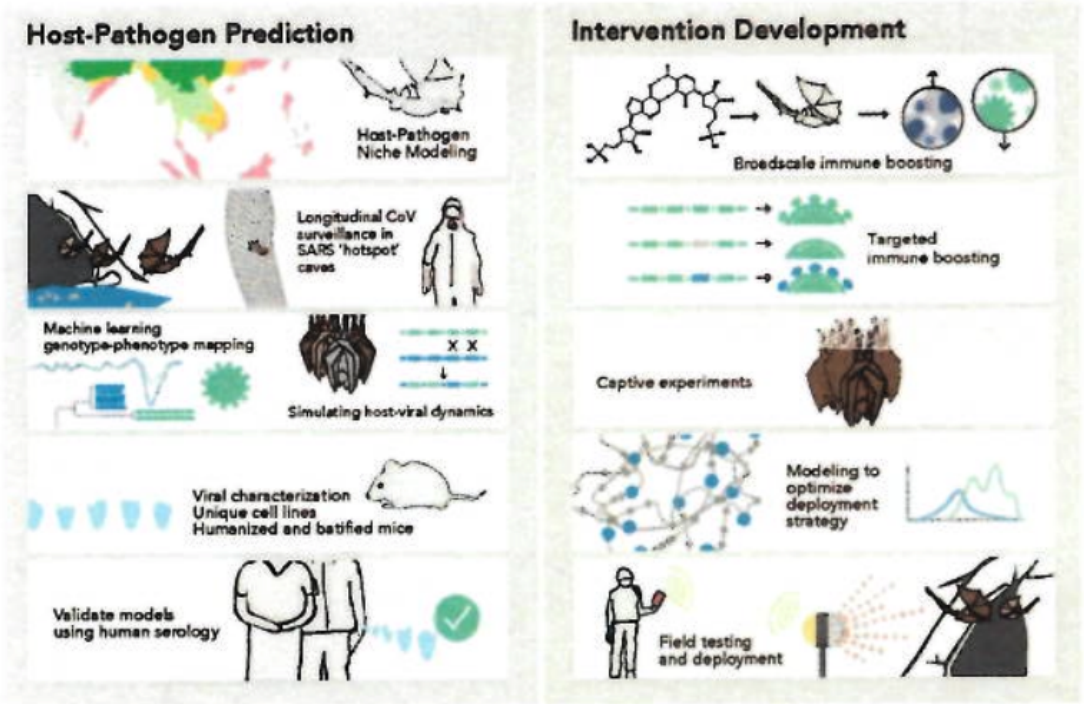
2020 Aug 20 — New 5-year grant for 'Understanding Risk of Zoonotic Virus Emergence in EID Hotspots of Southeast Asia' (excluding China

[1] As noted in the Reinstantation letter sub-wards were not (and are likely still not) correctly reported by EHA in the Federal Subaward Reporting System. The numbers above are compiled from a careful reading of the grant documents recently disclosed via an FOI request.

‘DEFUSE’ PROPOSAL OVERVIEW



CONCEPT



FINDINGS

1. ECOHEALTH ALLIANCE (EHA) TRIED TO BYPASS THE P3CO/DURC FRAMEWORKS

EHA confidently assessed in its proposal that the work to be carried was neither subject to P3CO (GoF) nor DURC (Dual Use Research of Concern) restrictions:

> *"These QSo strain viral spike glycoproteins will be synthesized, and those binding to human cell receptor ACE2 will be inserted into SARSr-CoV backbones (non-DURC, non-GoF)."* (D1, p.6)

The paragraph above actually contains the only mentions of GoF and DURC in the whole DEFUSE project proposal - and it dismisses them.

Nevertheless the DARPA review of the DEFUSE project concluded that the project potentially involved GoF. This was part of the reasons for the rejection of the project as such, and of a qualification for any partial funding:

> *"Given the team's approach does potentially involve GoF/DURC research (they aim to synthesize spike glycoproteins that may bind to human cell receptors and insert them into SARSr-CoV backbones to assess capacity to cause SARS-like disease), if selected for funding an appropriate DURC risk mitigation plan should be incorporated into contracting language that includes a responsible communications plan"*

Effectively EHA unsuccessfully proposed the use of bat-SARSr-CoV backbones and not the human evolved SARS-CoV in what looks like a deliberate attempt at circumnavigating the restrictions of the P3CO framework and related DURC restrictions.

> *"An enhanced PPP is a PPP resulting from the enhancement of a pathogen's transmissibility and/or virulence. Wild-type pathogens that are circulating in or have January 9, 2017 2 been recovered from nature are not enhanced PPPs, regardless of their pandemic potential.*
>
> Source: https://www.phe.gov/s3/dualuse/Documents/P3CO-FinalGuidanceStatement.pdf

We also know from emails FOI'd by USRTK that Jonathan Epstein asked on the 23rd March for help from Ralph Baric for some wording for a section in the proposal that would address *'communicating dual-use information'*:

To: Baric, Ralph S[rbaric@email.unc.edu]
From: Jon Epstein[epstein@ecohealthalliance.org]
Sent: Fri 3/23/2018 6:54:18 PM (UTC-04:00)
Subject: dual use safety language

Hi Ralph,
DARPA wants a written section on communicating dual-use information. Do you have some written text you could send me:

A communication plan that addresses content, timing, and the extent of distribution of potentially sensitive dual-use information. The plan must also address how input from DARPA, other government, and community stakeholders will be taken into account in decisions regarding communication and publication of potentially sensitive dual-use information.
Cheers,
Jon

That email request for help was sent 4 days before the deadline for submitting the proposals (27th Mar 2018), which suggests that little attention was being paid to this question. Not surprisingly, the review of the proposal effectively concluded than no satisfying DURC language had been included:

> ".. *if selected for funding an appropriate DURC risk mitigation plan should be incorporated into contracting language that includes a responsible communications plan"*

2. EHA WOULD HAVE USED US TAXPAYER MONEY TO PAY SHI ZHENGLI AT HALF TIME AND PENG ZHOU AND BEN HU AT QUARTER TIME

EHA DEFUSE proposed to have Shi Zheng Li work half time (8h/day, 22d/month) for the two first years on the project, with Peng Zhou and Ben Hu as 1/4th of their time, all drawing salaries through the DARPA grant (D2, p.8).

We note that, by contrast, the previous grant NIH R01AI110964 did not provide for a salary to Shi Zheng Li. See p. 71 of the previous grant): *"Dr. Shi will not take salary on this grant and is funded by discretionary sources at her Institute."*

3. EHA DEFUSE WOULD HAVE INVITED SHI ZHENG LI TO A PROJECT KICKOFF AT DARPA HEADQUARTERS

As per D2, top of page 4, the budget of EHA DEFUSE contains an entry for an invitation of Shi Zheng Li and one key WIV personnel (likely Peng Zhou or Ben Hu) to a kickoff meeting at the DARPA headquarters in Arlington, TX.

4. EHA 'HAD' 3 KEY CAVE SITES IN YUNNAN FOR SARS-R COV COLLECTION

Three caves in Yunnan Province are specified as of particular importance:

> *"Our strategy begins by a complete inventory of bats and their SARSr-CoVs at* ***our intervention test site cave complex in Yunnan****, China that harbours bats with high-risk SARSr-CoVs. We will collect data from three caves in that system (one is our intervention test site and two control sites) on: monthly bat abundance and diversity, viral prevalence and diversity, individual bat viral load and host physiological markers; and genomic characterization of low- and high-risk SARSr-CoV strains among bat species, sexes, and age classes; satellite telemetry and mark-recapture data on bat home range and inter-cave movement; and monitoring of daily, weekly and seasonal changes in bat populations."* (D1, p.5)

> *"However,* ***our test cave site in Yunnan Province****, harbours a quasispecies (QS) population assemblage that contains all the genetic components of epidemic SARS-CoV[34], We have isolated three strains there (WIV1, WIV16 and SHCO14) that unlike other SARSr-CoVs, do not contain two deletions in the receptor-binding domain (RBD) of the spike, have far higher sequence identity to SARS-CoV (****Fig. 1****), use human ACE2 receptor for cell entry, as SARS-CoV does (****Fig. 2****), and replicate efficiently in various animal and human cells."* (D1, p.7-8)

5. EHA PLANNED TO INOCULATE WILD BATS WITH AEROSOLIZED VACCINES

The proposal for **wide scale inoculation of bats in the wild** using aerosolized inoculum delivery has never been publicly released or opened to the wider scientific community for discussion as to potential risks associated with this plan.

This is a specialist area of research of Dr Rocke, Dr. Ainslie and Dr. Unidad (PARC) who have previously researched and developed the technological solutions necessary to make this possible:

Dr. Jerome Unidad is a researcher PARC, (2018a) at PARC (owned by Xerox) (PARC, 2018d), who developed the Filament Extension Atomizer (FEA) (PARC, 2019). This technology is used to spray bats with scalable high viscosity mists that stick to their skin or that are edible (PARC, 2018c).

PARC previously partnered with NHWC to develop a vaccine for White Nose Syndrome (WNS) for US bats, using FEA as the technological solution to administer vaccines via aerosol delivery (PARC, 2018b).

Dr. Tonie Rocke is a researcher at USGS National Wildlife Health Centre (NWHC in the DEFUSE proposal). She has previously worked on transdermal application of vaccines against rabies in vampire bats ``The *feasibility of controlling rabies in vampire bats through topical application of vaccines*" (USFWS, 2019), also "*Infectivity of attenuated poxvirus vaccine vectors and immunogenicity of a raccoon pox vectored rabies vaccine in the Brazilian Free-tailed bat*" (Stading *et al*., 2016). There were doubts and concerns about her work:

> "*These vaccine candidates use a viral vector (attenuated raccoon poxvirus, RCN) genetically modified to express highly-conserved fungal and specific Pd antigens. While these vaccines and other potential treatments continue to be developed, there is a need for safe and effective methods of treatment delivery*" (USFWS, 2019).

Another similar project:

> "*We recently developed a new recombinant rabies vaccine specifically for bats with available sequences from the rabies Phylogroup I glycoprotein. This sequence was cloned into raccoon pox virus (RCN) and the efficacy of this novel RCN-MoG vaccine was tested in big brown bats. Field studies are currently being conducted in Peru and Mexico to test the feasibility of oral and topical delivery of vaccine and transfer rates between vampire bats using biomarker-labelled jelly (without vaccine*)" EEFMVZ (2021).

Dr. Ainslie is a Professor at the UNC Department of Biomedical Engineering and the UNC Department of Microbiology and Immunology (Pharmacy UNC, 2021), who works on new polymers for vaccines and electrospray for fabrication of immune targeting microparticles (nanoparticles).

Her publications include "*Historical Perspective of Clinical Nano and Microparticle Formulations for Delivery of Therapeutics"* (Batty *et al*., 2021), "*Electrospray for generation of drug delivery and vaccine particles applied in vitro and in vivo***"** (Steipel et .,2019)**. "***Injectable, Ribbon-Like Microconfetti Biopolymer Platform for Vaccine APPLICATIONS"* (Moore *et al*., 2020), **"***Considerations for Size, Surface Charge, Polymer Degradation, Co-Delivery, and Manufacturability in the Development of Polymeric Particle Vaccines for Infectious Diseases*" (Genito *et al*.,2020).

One may contrast this fairly aggressive approach with the one described in a recent paper on 'Self-disseminating vaccines to suppress zoonoses'. There the recommended approach is to start with captive animals then carefully *"perform releases within carefully isolated populations in semi-natural enclosures or on small islands"*. More generally concerns have been raised about such self-disseminating vaccines.

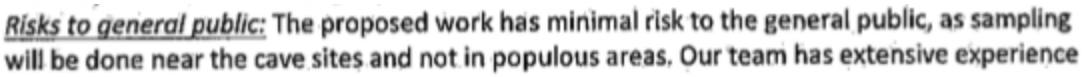
6. THE PROPOSAL DOES NOT PROPERLY DISCUSS ETHICAL, LEGAL AND SOCIAL ISSUE

The proposal has about 22 lines on Ethical, Legal and Social Issues (ELSI), most rather vague. Or even rather odd, such as when mentioning *'common practice of bat-consumption'* in Yunnan when bat-consumption is actually not common at all in Yunnan (if it ever occurs), with also a mention of 'cultural leaders', which may suggest some hasty editing based on a the text for a similar project in South-East Asia:

> *"We will conduct educational outreach to local wildlife authorities and cultural leaders so that there is a public understanding of what we are doing and why we are doing it, particularly because of the common practice of bat-consumption in the region."* (D1, p,36)

Also worth noting is the mention that *'The broader societal impact of this project could be significant, as wildlife immunization against viral zoonoses has been limited to date'* without further proper consideration (D1, p.36).

The 'PREEMPT Risk Mitigation Plan' section seems to suffer from another bad case of hasty editing with a minimalistic 2-line *'Risks to the general public section'* interrupted in mid-air:


Risks to general public: The proposed work has minimal risk to the general public, as sampling will be done near the cave sites and not in populous areas. Our team has extensive experience

Full extent of *'Risk to general public'* section (D1, p.34)

7. EHA WANTED TO OVERSEE ALL WORK IN CHINA

The PREEMPT proposal to DARPA relied on trusting EHA (a private NGO) for oversight of high risk pathogen research:

> *"The lead organisation, EcoHealth, Alliance will oversee all work."* (D1, p.3)

> *"Dr. Shi, Wuhan Institute of Virology will conduct viral testing on all collected samples, binding assays and some humanized mouse work."* (D1, p.3)

8. LIVE BATS WERE MEANT TO BE USED AT THE WIV AND VARIOUS INTERNATIONAL LABS FOR INFECTION EXPERIMENTS, OFTEN USING CAPTIVE BAT COLONIES

WIV (Shi) was to work on Rhinolophus bats:

> *"At WIV, 20 adult wild **Rhinolophus spp**. bats (10 of each sex) will be captured at our test cave site, housed within ABSL3, ACE2 receptor genes sequenced and used to pre-screen spikes as above, then bats will be tested using PCR and serology for current and prior exposure to SARSr-CoVs, and inoculated with WIV1, WIV16 or SHC014."* (D1, p.20).

> *"to Dr. Shi, Wuhan Inst. Virol., to conduct PCR testing, viral discovery and isolation from bat samples collected in China, spike protein binding.assays, humanized mouse work, and experimental trials on Rhinolophus bats."* (D1, p.25).

> *"Subtask 7.5 Test targeted immune boosting in wild-caught captive Rhinolophus spp: (WIV)."* (D1, p.30).

The WIV was not the only institution meant to work with live bats for infection experiments within its labs. As the proposal explains:

> *"Experimental work using bats and or transgenic mice will be conducted at the BSL-3 lab in WIV, Duke-NUS, UNC, or NWHC. Each partner institute will apply for and procure animal research approval from its respective IACUC. All anima! work conducted by EcoHealth Alliance in China will be overseen by both the IACUC at WIV and the IACUC at Tufts"* (D1, p.35).

Duke-NUS (Linfa Wang) has an Asian cave bat ***(Eonycteris spelaea)*** breeding colony:

> *"Our E. spelaea colony has now reached a sustainable population for infection experiments and the ABSL3 facility has been outfitted with bat-specific cages."* (D1, p.20).

> "*We will use the unique Duke-NUS Asian cave bat (Eonycteris spelaea) breeding colony to conduct initial proof-of-concept tests, extended to small groups of wild-caught Rhinolophus sinicus bats at WIV.*" (D1, p.6-7)

> "***Subtask 7.4****.Test immune modulation in 'captive Eonycteris sp. colony, using Malaka virus and SARSr-CoV infections. (Duke-NUS)."* (D1, p.30)

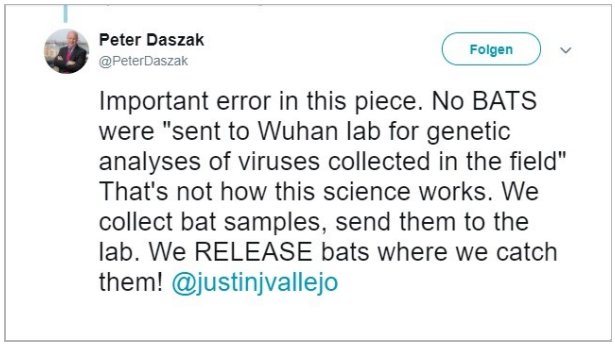
NWHC (Rocke) has a captive bat colony colony:

> *"We will use the NWHC captive bat colony and wild bats in US caves to trial delivery vehicles using the biomarker rhodamine B (which fluorescently marks hair on consumption) to assess uptake."* (D1, p.7)

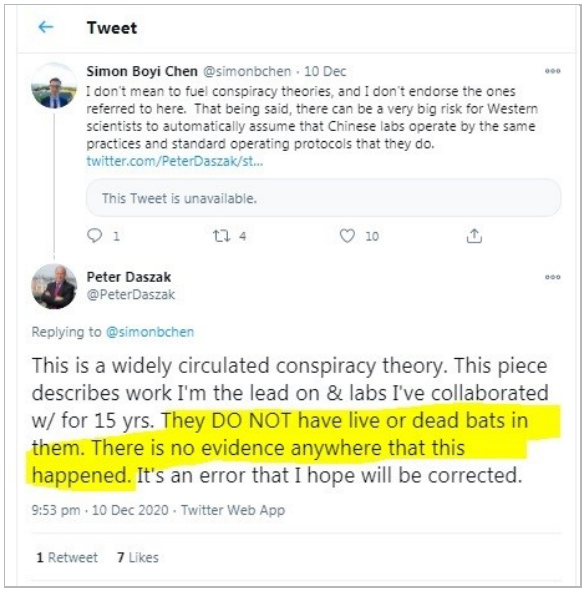
CSIRO (Australia, with Linfa Wang at the time) and **University of Queensland** were already using or are planning to be using live bats for experiments

> *"Previous infection studies were completed in **Pteropus** and **Rhinolophus** bats in Australia by L-F Wang at CSIRO, AAHL and an additional Pteropus infection trial is currently planned through the University of Queensland in Australia."* (D1, p.20)

As DRASTIC has previously discovered, the WIV was already keeping wild-caught bats more than a decade ago, and established a colony around 2017 - as has been attested by patents, official records and videos (see https://bit.ly/3pxL8IR). These revelations have been regularly characterised as 'conspiracy theories' by Peter Daszak (see examples in Bostickson & Ghannam, 2021c; Taiwan News, 2021; Sky News, 2021).



Screenshot: Peter Daszak Denies WIV keeps Live Bats. Source: Twitter via Taiwan News (2021).



Screenshot: Peter Daszak Denies WIV keeps Live Bats. Source: Twitter via Taiwan News (2021).

9. EHA PROPOSED MULTIPLE, REGULAR VISITS TO 3 YUNNAN CAVE SITES

> "*In phase I will sample 60 bats each of R. sinicus, R. ferrumequinum, and R. affinis, (180 bats per cave) every three months non-destructively for 18 months from our three cave sites.*" (D1, p.9)

> *"We will conduct pre- and post-intervention sampling (biweekly faecal pellet sampling for 4 months, and 10 male and 10 female bats per species tested every 2 weeks post-intervention for 4 months, prior to- and post-deployment) to monitor SARSr-CoV QS and bat immune status changes in test and control site bats during Phase I (TA2).*" (D1, p.9)

10. EHA PLANNED TO SEND SAMPLES TO DUKE UNIVERSITY (SINGAPORE) AND UNC CHAPEL HILL

The proposal states that:

> "*Samples will be preserved in viral transport medium, immediately frozen in liquid nitrogen dry shippers, and transported to partner laboratories with a maintained cold chain and under strict biosafety protocols.*" (D1, p.9)

This is further confirmed by items 37 and 38 on page 5 of D2 (Budget).

Incidentally we also know from the recently released documents for the NIH R01AI110964 grant ("Understanding the Risk of Bat Coronavirus Emergence") that EHA has plenty of experience shipping samples from and to China.

grant, p. 15:

> "*This gives us unique access to working on-the- ground in countries where surveillance is difficult, such as China,* ***where our group has proven capacity to export samples from.***"

p. 141:

> *"Drs Shi, Zhang, and Daszak have collaborated together since 2002 and have been involved in running joint conferences,* ***and shipping samples into and out of China.****"*

This practically means that it is likely that Duke (Singapore) and UNC Chapel Hill have undocumented samples that could help trace the origins of SARS-CoV-2.

11. THE PROPOSAL SET A CLEAR PATHWAY FOR CHIMERIC VIRUS CONSTRUCTION

The use of known backbones is specified in the proposal:

> "*Synthesis of Chimeric Novel SARSr-CoV QS: We will commercially synthesize*[2] *SARSr-CoV S glycoprotein genes, designed for insertion into SHC014 or WIV16 molecular clone backbones (88% and 97% S-protein identity to epidemic SARS-Urbani). These are BSL-3, not select agents or subject to P3CO (they use bat SARSr-CoV backbones which are exempt) and are pathogenic to hACE2 transgenic mice.*" (D1, p.9)

However we do not know what additional, unpublished SARS-r CoV and MERS-r CoV research was conducted by the WIV, Wuhan University and other Chinese institutions. Indeed, using analysis of raw metagenomic datasets, unpublished MERS-r CoV infectious clone research in Wuhan has recently been documented (Zhang *et al*. 2021).

12. EHA HAS 180 UNPUBLISHED SARSr-CoV STRAINS

> "*This will be supplemented by characterization of isolated viruses under DEFUSE (at WIV), approximately 15-20 bat SARSr-CoV spike proteins/year (at UNC, WIV), and >180 bat SARSr-CoV strains sequenced in our prior work and not yet examined for spillover potential.*" (D1, p.12)

Very little of this planned work has been published.

[2] As per budget (D2, p.5, item 13) the primer synthesis was to be done by Sangon Biological Engineering Technology & Services (Shanghai).

13. ALL CORONAVIRUSES WERE TO BE SCREENED AT THE WIV

"*We will conduct in vitro pseudovirus binding assays, using established techniques[2], and live virus binding assays (at WIV to prevent delays and unnecessary dissemination of viral cultures) for isolated strains.*" (D1, p.12)

14. THREE TO FIVE CHIMERIC CORONAVIRUSES WERE TO BE CREATED PER YEAR

"*We will validate results from chimeric viruses by re-characterizing full-length genome versions, testing whether backbone genome sequence alters full length SARSr-CoV spillover potential. QS for full-genome characterization will be selected to reflect strain differences in antigenicity, receptor usage, growth in human cells and pathogenesis."* (D1, p.13)

"We will test growth in primary HAE cultures and in vivo in hACE2 transgenic mice. We anticipate recovering ~3-5 full length genome viruses/year." (D1, p.13)

15. THE PROPOSAL PLANNED TO IDENTIFY "KEY MINOR DELETIONS" IN THE RECEPTOR BINDING DOMAIN (RBD) TO ALTER HUMAN PATHOGENICITY

"Testing Synthetic Modifications:
"We will synthesize QS with novel combinations of mutations to determine the effects of specific genetic traits and the jump potential of future and unknown recombinants.

RBD deletions:
Small deletions at specific sites in the SARSr-CoV RBD alter risk of human infection. We will analyze the functional consequences of these RBD deletions on SARSr-CoV hACE2 receptor usage, growth in HAE cultures and in vivo pathogenesis."
(D1, p.13)

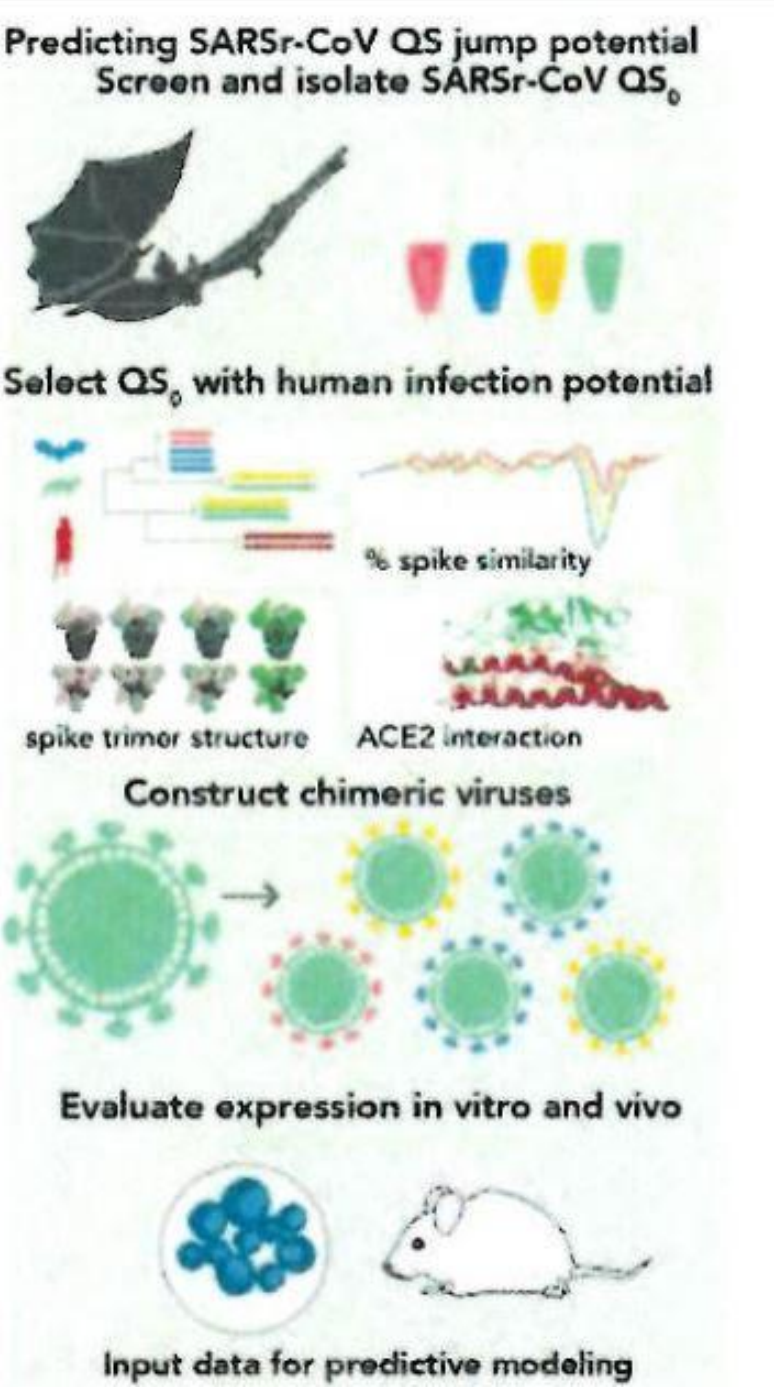
16. THE PROPOSAL INCLUDES THE INTRODUCTION OF "HUMAN-SPECIFIC CLEAVAGE SITES"

Human protease-specific site insertion was proposed. The proposal does not specify exactly which protease, but does discuss Furin in the preceding text.

"*We will analyze all SARSr-CoV S gene sequences for appropriately conserved proteolytic cleavage sites in S2 and for the presence of potential Furin cleavage sites[74,75]".*

SARSr-CoV S with mismatches in proteolytic cleavage sites can be activated by exogenous Trypsin or Cathepsin L.

Where clear mismatches occur, we will introduce appropriate human-specific cleavage sites and evaluate growth potential in Vero cells and HAE cultures."
(D1, p.13)



Furin recognition cleavage motifs are widely used in laboratory research. Furin is an endoprotease which cleaves proteins at a specific motif (RxxR|x) which for virus envelope glycoproteins, can enhance viral fusion with host cell membranes (Coutard *et al*., 2020).

For SARS-CoV-2 the Furin cleavage site (FCS) has been shown to be key for pathogenicity (Bestle *et al*. 2020; Hoffmann *et al*. 2020; Johnson *et al*., 2021).

No other sarbecovirus subgenus CoV including SARS-CoV possesses a Furin cleavage site, and as Furin cleavage sites have previously be inserted into coronaviruses in laboratories to increase

tropism and pathogenicity (Cheng et al. 2019), the origin of the FCS has been widely debated (Wade 2021). Wu and Zhao (2021) propose the FCS arose through natural insertion.

Segreto and Deigin (2020) note the "CGGCGG" coding for the two leading arginines is rare for bat origin coronaviruses and note a FauI restriction site just upstream of a leading proline and propose the fcs could have been inserted in a laboratory.

Kaina (2021) proposes that in vitro recombination in human cell culture of a SARS-CoV-2 progenitor with a virus containing the Furin cleavage site as a possible source; Segreto *et al*. (2021) propose laboratory insertion of a more potent motif and insect cell culture passage to generate the "RRAR" FCS sequence.

Given that we find in this EHA proposal, a discussion of the planned introduction of human-specific cleavage sites into novel SARS-r CoVs, a review by the wider scientific community of the plausibility of artificial insertion of an FCS into SARS-CoV-2 or a progenitor is warranted.

17. THE PROPOSAL PLANNED TO "INTRODUCE" NATURALLY OCCURRING PROTEOLYTIC CLEAVAGE SITES TO CREATE NOVEL CORONAVIRUSES

The proposal planned to introduce 'wild type' proteolytic cleavage sites from high risk strains into more abundant low risk strains, presumably to increase the pathogenicity of the low risk strains:

> "*We will also review deep sequence data for low abundant high risk SARSr-CoV that encode functional proteolytic cleavage sites, and if so, introduce these changes into the appropriate high abundant, low risk parental strain.*" (D1, p.13)

18. THE PROPOSAL PLANNED TO RESEARCH ALTERNATE RECEPTORS TO ACE2

> "*To evaluate this, we will sequentially introduce clade 2 disrupting residues of SARS-CoV and SHCO14 and evaluate virus growth in Vero cells, non-permissive cells ectopically expressing DC-SIGN, and in human monocytes and macrophages anticipating reduced virus growth efficiency.*" (D1, p.13)

We note that while SARS-CoV was documented to use DC-SIGN as an attachment receptor (Marzi *et al*. 2004), L-SIGN and DC-SIGN act as entry receptors for SARS-CoV-2 (Amraei *et al*. 2020; Thépaut *et al.* 2021).

19. THE PROPOSAL PLANNED TO INTRODUCE "KEY RBD RESIDUES" INTO LOW RISK STRAINS TO TEST PATHOGENICITY IN HUMAN AIRWAY-CELLS AND IN hACE2 MICE

> "*<u>Low abundance micro-variations:</u>*
> *We will structurally model and identify highly variable residue changes in the SARSr-CoV S RBD, use commercial gene blocks to introduce these changes singly and in combination into the S glycoprotein gene of the low risk, parental strain and test ACE2 receptor usage, growth in HAE and in-vivo pathogenesis*".
> (D1, p.13)

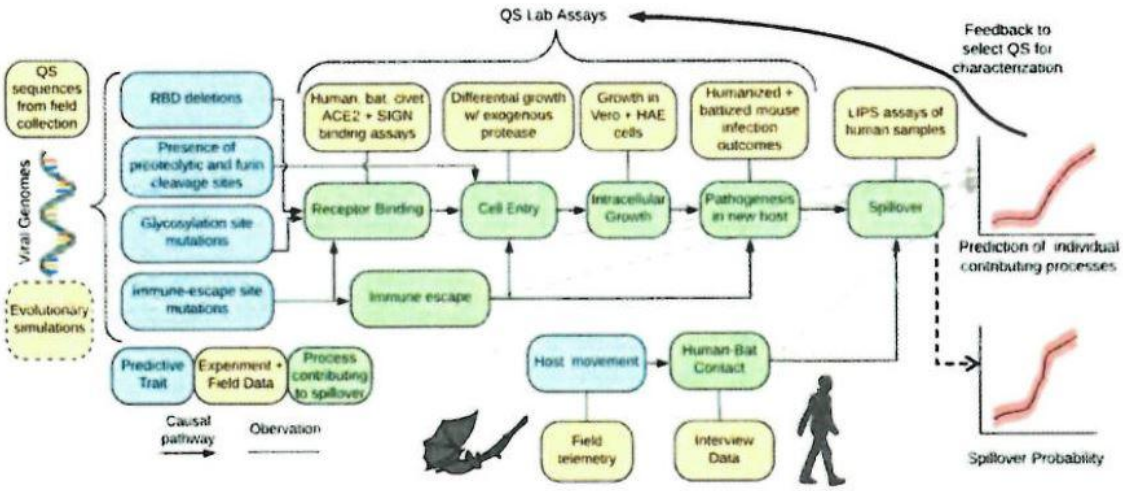


***Fig. 7**: A simplified directed graph of a Bayesian network model representing the causal relationships between input data, modeled processes, and outputs.*

20. THE PROPOSAL "SPILLOVER PROBABILITY" ASSESSMENT DOES NOT INCLUDE LAB-RESEARCH RELATED RISKS

Figure. 7 below (D1, p.14) documents an extensive sampling, and lab experimentation plan. It is quite astounding that the spillover probability calculation incorporates multiple 'processes contributing to spillover', all of which require extraction of viruses from bats and experimentation in laboratories, yet does not incorporate a risk factor for field sampling and laboratory experimentation to deliberately increase the pathogenicity of SARS-r CoVs.

21. A POTENTIALLY HIGHLY IMPORTANT "SPIKE PROTEIN DATASET" WAS NOT PUBLIC

It is not clear what that 'dataset of S protein sequences from prior work' refers to and whether EHA has ever made it public (as is generally required under its grant conditions).

> "*We will use a large dataset of S protein sequences and full-length genomes generated from prior work and DEFUSE fieldwork to estimate SARSr-CoV substitution rate and its genome-wide variation.*" (D1, p.15)

22. EHA PROPOSED MERS-CORONAVIRUS EXPERIMENTS AND HAD ALREADY INTRODUCED SARS AND MERS INTO BAT CELL LINES

> "*First, we will take wing punch biopsies from 3 individuals to sequence their ACE2 receptor gene. This will be inserted into human cell lines to pre-screen viral strains for binding. Those that bind will be used for in vivo experiments. We will use two coronaviruses (SARSr-CoV WIV1 and MERS-CoV) in ABSL3. SARS and MERS infection studies are already underway in Eonycteris and Pteropus cell lines and primary immune cells* ." (D1, p.20)

Primary cells can also harbour latent viruses that can become reactivated during in vitro cultivation when the cells are outside the host and isolated from other components of the immune system that would otherwise control virus replication" Banerjee *et al*. (2018).

In fact, experiments using non-immune bat cell lines were hallmarked by "subversion of the bat immune system" which contrasts with the effective clearance of bat viruses shown by in vivo captive bat studies into Marburg and Ebola Viruses carried out at Atlanta CDC BSL4, for example (Jones *et al*., 2015; Schuh *et al*., 2017a & 2017b).

Research into bat immune systems using bat cell lines at WIV however did not mirror results from in vivo studies, and it was precisely this feature of non-immune bat cell lines that led researchers to create the first bat bone marrow-derived dendritic immune cells (Zhou *et al*., 2016), bat-mouse bone marrow chimera (Yong *et al*., 2018) and IFNAR2 knockout bat cell lines using CRISPR/Cas9 technology (Zhang *et al*., 2017).

These novel cell lines and bat immune system mice were proposed to ensure that in vivo bat cell line and in vivo mouse experiments effectively mirrored in vivo bat immune system response to clearing of viruses (Zhou *et al.*, 2016; Yong *et al*., 2018).

However, this also suggests that unknown or undetected highly pathogenic bat viruses would have been able to replicate clandestinely in WIV bat cell lines as they would not have been constrained by a bat immune system, and in turn, this may have led to contamination of operators and equipment at the WIV BSL2 Laboratories (Bostickson & Ghannam, 2021c).

23. EHA PROPOSED A DATABASE OF ALL FIELD, LAB AND MODELLING WORK

> "Data Management and Sharing:
> *EcoHealth Alliance will maintain a central database of data collected and generated via all project field, laboratory, and modelling work.*" (D1, p.25)

This would indicate that EHA has similar databases relating to earlier projects - data that it would have not shared publicly.

24. ECOHEALTH ALLIANCE PROPOSED INDUSTRIAL SCALE BAT SAMPLING

> ***"Sub-Task 1.2***
> *Collect monthly specimens from bats at cave sites in Yunnan, China for SARSr-CoV screening and sequencing. Oral, fecal, and blood sample collected from 360 Rhinolophus spp. bats per month using live- capture and non-invasive sampling. Specimens shipped to laboratory for analysis. Associated morphological, demographic, and physiological data for individual bats collected (EHA, consultant Zhu)."* (D1, p.25)
>
> **"*Deliverables*:**
> *Specimens from 3,240 bats and fecal pellets collected from high-risk reservoir*
>
> *populations which have been obtained with all proper permits and permissions and shipped to WIV for analysis; real-time telemetry and mark-recapture data uploaded and made available to DARPA collaborators; completed database maintained.*" (D1, p.25)

25. ECOHEALTH ALLIANCE MISLED DARPA ABOUT RISKS TO GENERAL PUBLIC

EHA writes about 'Risks to general public' section:

> *"Risks to general public:*
> *The proposed work has minimal risk to the general public, as sampling will be done near the cave sites and not in populous areas. Our team has extensive experience. "*
> (D1, p.35)

That EHA could propose the identification and selection of highest risk SARS-r CoV's, chimeric CoV construction, serial passage using transgenic hACE2 mice and insertion of human adapted cleavage sites (presumably furin cleavage sites), yet totally ignore the risks of laboratory escape is inconceivable and shows a total lack of understanding of the risks of SARS-r CoV (and MERS-r CoV) laboratory research (Demaneuf 2020).

26. EHA PROPOSED TO GENERATE "BATIFIED MOUSE MODELS"

> "*We have shown efficient reconstitution of **irradiated mice using bat bone marrow from multiple species, including E. spelaea** (Fig. 10), including reconstitution of bat PBMC's in the mouse, presence of circulating bat cells and generation of bat-specific antibodies in mice incapable of producing an antibody response.*
>
> ***This 'batified' mouse model** can be utilized for both circulating infection of SARS-CoV (in the immune compartment only) and as a model for generating bat-specific antibodies against CoV proteins.*"
> (D1, p.18)
>
> "*PI-TA-02 Task 7: Experimental testing. of 'Broadscale Immune Boosting' using-**batified mice and captive bat colonies** (Duke-NUS)."*
> (D1, p.30)

QUESTIONS TO ECOHEALTH ALLIANCE

Here are some questions that journalists may like to ask EcoHealth Alliance and Peter Daszak. These questions could also be asked under a subpoena process instigated by Congress.

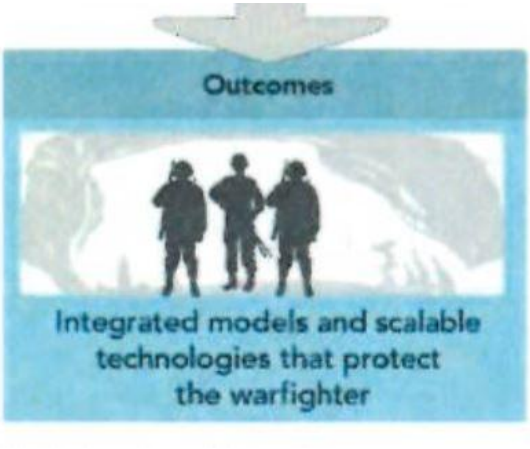
1. Why does EHA refer to one test-site cave and two control caves as “our cave test sites” (D1, p.3 & 5), “*our cave complex*” (D1, p.32; D2, p.3), as *“our three test cave sites”* (D4, slide 2) in Yunnan?

2. Does EHAand the WIV actually own the cave or control access to it?

3. Is EHA trying to suggest that DARPA has to fund EHA if they want to do research that includes these promising sites?

4. Does EHA have an actual evaluation of the *‘clear and present danger to US defense forces defenses in the region’* represented by these Yunnan viruses it is focussing on in the proposal (D4, slide 3)*?*

5. *In particular, can EHA explain under which scenarios this may affect “US warfighters”, given that “Security concerns across Asia make the region a potential deployment site for US warfighters.”? (D4, slide 3).*



6. Was this valuable aspect of the work clearly understood by the Chinese parties to the DEFUSE project?

7. Why did Peter Daszak firmly deny WIV kept live bats when the DEFUSE proposal requires the WIV to do so, and to have the necessary experience to do so - in full agreement with the ample evidence provided independently by DRASTIC?

8. Why did Peter Daszak deny that keeping live bats was common practice in laboratories, when the DEFUSE proposal shows that many of your partner labs keep bat colonies or wild-caught bats?

9. EHA referred toEco Health Alliance (EHA) databases in the Proposal with obligation of submission by their Chinese partners. Can EHA share those databases publicly?

10. What does the proposal contain no risk mitigation program at all for DURC (Dual Use Research of Concern) despite aiming to address ‘clear and present dangers’ to the US ‘war-fighters’ deployed in Asia, while proposing to hire and pay Shi Zheng Li half-time for two years, a well as Ben Hu and Peng Zhou and other WIV laboratory technicians and employees?

11. Did Scientists at WIV have or see a copy of this DEFUSE proposal and if so, what was the extent of the contribution of the WIV in drafting this proposal?

12. Did Peter Daszak discuss the Proposal with Scientists at WIV, when, who, how, where?

13. Please summarise any discussions with WIV Scientists, ZLS, PZ, BH, regarding proposed experiments and bat sampling.

14. Did you discuss the question of sending live Rhinolophus bats to WIV with Dr. Zhengli Shi or any other WIV Scientists?

15. Page 38 of the DEFUSE Proposal (D1) refers to the introduction of "*appropriate human specific cleavage sites*". Can you explain that in more detail?

16. Can you confirm whether or not any Chinese Scientists have done the sampling / protein S / recombination and animal testing work mentioned in the DEFUSE Project proposal?

17. What are the 180 Coronavirus sequences that resulted from the mentioned prior work by EcoHealth Alliance?

    “180 bat SARSr-CoV strains sequenced in our prior work and not yet examined for spillover potential”
    (D1, p.7)

18. Why were laboratory accident risk (in a foreign country where EHA could only have limited oversight at best) totally ignored in the proposal?

19. What previous experiments did EHA or its collaborators carry out on irradiated “batified mice models” (D1, p.18)? When, where and for what purpose?

20. The proposal reviewer wrote that “*there are several components of great interest in this proposed effort that are potentially fundable should additional funding become available*”.

    Did additional funding become available?

21. Can Dr. Rocke, Dr. Unidad and Dr. Ainslie confirm that they were aware of the DEFUSE project proposal and did they help draft the proposal?

22. Can Dr. Rocke, Dr. Unidad and Dr. Ainslie guarantee that no partial funding was made available after rejection of the DEFUSE proposal, and none of their technology was subsequently used by EHA or WIV or other collaborators in this proposal?

23. Outside of NIH/NIAID the WIV with CAS funding conducted a 2018.01-2021.12 project studying the evolutionary mechanisms for SARSr-CoV host receptor adaptations and cross-species infection risk (another link here and here). Does EHA have any further information as to what work was conducted and any results that could help shed light on the origin of SARS-CoV-2?.

24. Why was discussion of Yunnan miners whose illness was consistent with infection with a SARS-like illness (Rahalkar and Bahulikar, 2020) not discussed in this proposal, especially given the mention of *'Test previously-collected human sera from Yunnan Province to assess SARSr-CoV QS spillover'* (D2, p.3)?

25. Was the Mojiang mine part of 'your' Yunnan cave complex that DEFUSE proposed to use for experiments?

26. Did EHA know of the theses by Xu and Huang (see Rahalkar and Bahulikar, 2020) and the conclusions therein that the miners likely were infected with a SARS-r CoV?

27. If so, did EHA deliberately withhold this information so that the SARS-r CoV's in the Mojiang mine would not be subject to P3CO restrictions?

28. Why does the proposal fail to contain any reference to Regulatory and ELSI (Ethical, Legal, Social) issues, especially given its real-life deployment on Yunnan bat colonies?

29. Would EHA have also ignored Regulatory and ELSI issues if they had planned to deploy immune boosting solutions on bat colonies in Texas?

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REJECTION OF DEFUSE PROJECT PROPOSAL

Proposal Title:	DEFUSE - Defusing the Threat of Bat-borne Coronaviruses (2018)
Proposal Identifier:	HR001118S0017-PREEMPT-FP-019

Amounts Requested by EcoHealth Alliance:

Phase I	$8,411,546
Phase II	$5,797,699
Total:	**$14,209,245**

RESULT

The DEFUSE proposed project by EHA was **rejected by DARPA**, although *"if funding became available"*, certain components of particular interest could have gone ahead, subject to a clear contractual Dual Use Research of Concern (DURC) risk mitigation plan that *'includes a responsible communications plan'*.

REASONS FOR REJECTION

The Biological Technologies Office of DARPA reviewed the EcoHealth Alliance DEFUSE proposal and the Evaluation Reports and decided it was "**selectable**". In doing so, two out of three reviewers considered the aim of preempting "zoonotic spillover through reduction of viral shedding in the bat caves" as of interest to DARPA. These reviewers assessed the EHA and Collaborators team and concluded that:

- They have plenty of prior experience.
- They have access to Yunnan caves where bats are infected with SARSr viruses.
- They have carried out past surveillance work
- They have developed geo-based risk maps of zoonotic hotspots
- Their proposed experimental work is logical and can validate molecular and evolutionary models.
- Their proposed preemption approaches can rapidly be validated using bat and "batenized" mouse models.

However, the Biological Technologies Office did not recommend it be funded **at that time** because significant weaknesses were identified:

1. The proposal is considered to potentially involve GoF/DURC research because they propose to synthesize spike glycoproteins which bind to human cell receptors and insert them into SARSr-CoV backbones to assess whether they can cause SARS-like disease.

2. However the proposal does not mention or assess potential risks of Gain of Function (GoF) research.

3. Nor does the proposal mention or assess Dual Use Research of Concern (DURC) issues, and thus fails to present a DURC risk mitigation plan.

4. The proposal hardly addresses or discusses ethical, legal, and social issues (ELSI).

5. The proposal fails to discuss problems with the proposed vaccine delivery systems caused by the known issues of variability in vaccine dosage.

6. The proposal did not provide sufficient information about how EHA would use any data obtained and how they would model development or perform any necessary statistical analysis.

7. The proposal did not explain clearly how EHA will take advantage of their previous work, nor how that previous work could be extended.

8. The proposal failed to clearly assess how it would deploy and validate the “TA2 preemption methods” in the wild. This refers to carrying out experiments with effective immune boosting molecules and delivery techniques via FEA aerosolization mechanism at one test and. two control bat cave sites in Yunnan, China (PARC, EHA, WIV).

9. The proposal does not address concerns about these vaccines not being able to protect against the wide variety of coronaviruses in bat caves which are constantly evolving, due to insufficient epitope coverage.

DRASTIC independently assesses that the tone of the proposal (see for instance the ‘<u>our</u> cave complex’) and the deep suggested involvement of some of the WIV parties (Shi Zheng Li employed half-time for 3 years - paid via the grant - and invited to DARPA headquarters at Arlington), may not have helped either - especially in the absence of any DURC risk mitigation program.

It is clear that the proposed DEFUSE project led by Peter Daszak could have put local communities at risk by failing to consider the following issues:

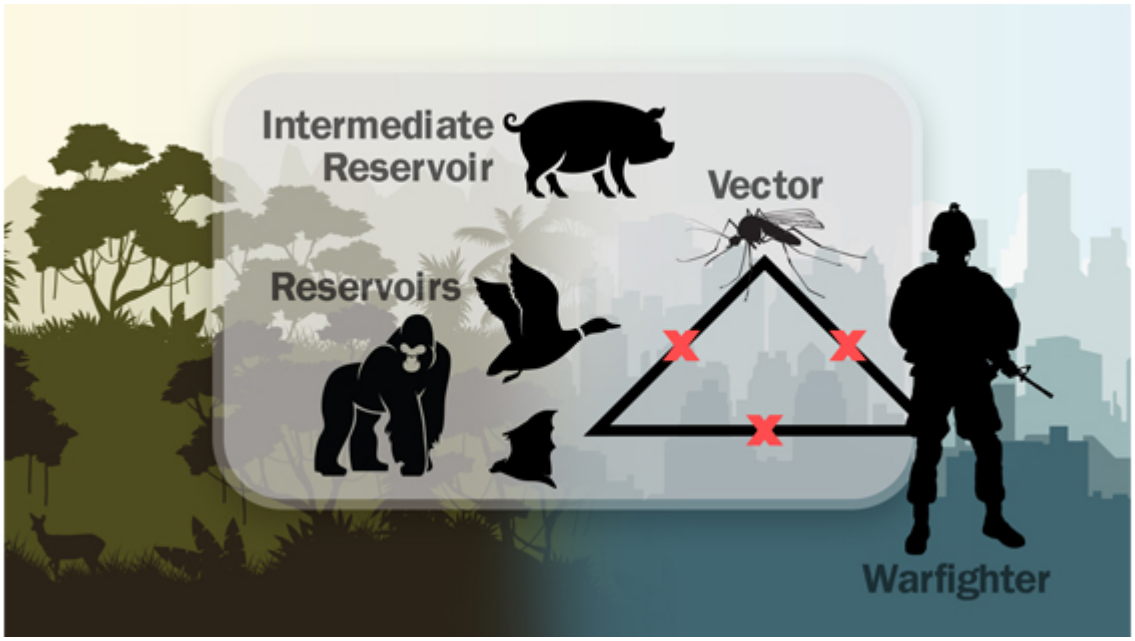
- Gain of Function
- Dual Use Research of Concern
- Vaccine epitope coverage
- Regulatory requirements
- ELSI (ethical, legal, and social issues)
- Data Usage

END

Going to the Source to Prevent Viral Disease Outbreaks

PREEMPT aims to predict and contain viral mutations to prevent cross-species transmission of disease from animals and insects to humans

OUTREACH@DARPA.MIL
1/4/2018



Avian influenza (H7N9). MERS coronavirus. Ebola. Hepatitis E. Yellow Fever. Lassa. Zika. When you consider the viral infectious diseases that emerged and reemerged around the world in 2017 alone, what many of them have in common is that they originated in animals and spilled over into humans after a series of mutations that enable the pathogens to jump species.

The U.S. Department of Defense has a vested interest in outmaneuvering infectious disease. Military service members are called upon to operate virtually anywhere in the world, often on short notice, and the locations to which they deploy frequently lack the robust public health infrastructure to identify and contain the spread of new viral infectious diseases. At the same time, numerous trends including increased interactions between human, animal, and insect populations due to globalization, densification of livestock production, and rising human encroachment into animal habitats have increased the threat of novel pathogens in regions where troops, humanitarian workers, and peacekeepers tend to deploy.

A new DARPA program called Preventing Emerging Pathogenic Threats, or PREEMPT, seeks to support military readiness by going after new viral infectious diseases at the source, animal reservoirs—the species in which a

pathogen lives, multiplies, and potentially evolves into a strain that can threaten humans. PREEMPT aims to advance understanding of viruses and their interaction with animals, insects, and humans, and deliver new, proactive interventions to reduce the risk from emerging and reemerging pathogens.

“Despite global biosurveillance efforts, viral outbreaks continue to outpace medical preparedness. That means that in volunteering to be the first ones into harm’s way, our Service members can quite literally be among the first people exposed to emerging infectious diseases,” said Jim Gimlett, the PREEMPT program manager. “DARPA wants to reorient preparedness efforts to make them more proactive, so that instead of only modeling the trajectory of an epidemic as it spreads from human to human, we contain and suppress diseases in the animal species in which they originate before they can make a jump into people.”

PREEMPT will have two technical thrusts: development of multiscale models and test beds to quantify the imminent emergence and reemergence of human pathogens; and development of new, scalable approaches to preventing pathogen spillover and transmission from animals and vectors into humans.

Understanding how viruses evolve within a species will be a core area of research. That evolutionary process contains natural bottlenecks that could be exploited to impede dangerous mutations. PREEMPT will seek to identify these opportunities for intervention by modeling the factors that enable species jump. Researchers on the program will be required to conduct field surveillance of animal and insect species in high-risk areas around the world; generate data in lab testing and sequence viruses as they evolve; analyze the jump risk by weighing factors such as past known jump events, ecology, seasonal variants, and geospatial data; and, finally, validate models using simulated natural environments.

New proactive interventions will center on methods for disarming a virus before it can make a jump across species. PREEMPT aims to prevent transmission of virus from a reservoir species direct to humans, from a reservoir species to traditional vectors, such as mosquitos, that spread disease, and from a reservoir species to a species intermediate to humans—for example, from bats to pigs.

Successful interventions will be tailored to anticipated threats. For instance, if a single mutation is identified by models as high risk, an intervention might seek to prevent its entry into a new species by removing that specific mutation from the reservoir. Alternatively, if multiple potential threats are identified, an intervention could involve treating the entire animal reservoir to reduce viral load using tools such as anti-virals, vaccines, and interfering particles. Other forms of intervention might involve new approaches to suppressing the transmission of specific viruses by insect vectors. In all cases, researchers will need to develop scalable methods that can be readily deployed even in remote locations.

During the planned 3.5-year PREEMPT program, DARPA aims to identify signatures of viral fitness and the potential for spillover from one species to another; develop risk classifiers and predict pathways of viral adaptation; and test initial intervention approaches. By the end of the program, DARPA seeks to demonstrate in controlled laboratory conditions the suppression of viral jump to a new species.

“If we are able to predict how viruses might mutate and spread, and take steps to prevent those mutations from impacting humans, then we’ll vastly diminish the possibility of future viral pandemics,” said Gimlett.

Although PREEMPT is a fundamental research program, DARPA is aware of biosafety and biosecurity sensitivities that could arise. The agency will work with external bioethics advisors to ensure efforts funded by the program adhere to regulations and ethical best practices. Proposers will also be required to address potential ethical, legal, and societal implications of the research.

DARPA will hold a Proposers Day on January 30, 2018, in Arlington, Virginia, to provide more information about PREEMPT and to answer questions from potential proposers. For details of the event, including registration requirements, visit: https://go.usa.gov/xnyzB. A full program description will be made available in a forthcoming Broad Agency Announcement.

Image caption: *Viral infectious diseases often arise in animals. Over time, as the virus multiplies and mutates, variants can gain the ability to jump between species. Transmission can be direct from animal to human, from animal to "bridge" animal to human, or animal to vector to human. DARPA's Preventing Emerging Pathogenic Threats program seeks to prevent these cross-species jumps by predicting viral evolution and transmission pathways and proactively intervening to prevent the jump to humans.*

# # #

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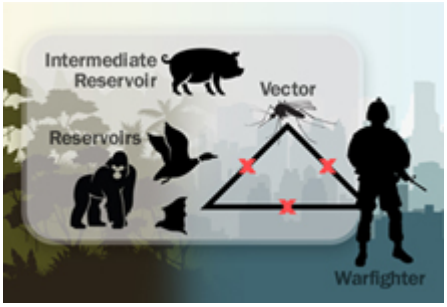

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HR001118S0017
PREventing EMerging Pathogenic Threats
Department of Defense
DARPA - Biological Technologies Office

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SYNOPSIS | VERSION HISTORY | RELATED DOCUMENTS | PACKAGE

Print Synopsis Details

General Information

Document Type:	Grants Notice
Funding Opportunity Number:	HR001118S0017
Funding Opportunity Title:	PREventing EMerging Pathogenic Threats
Opportunity Category:	Discretionary
Opportunity Category Explanation:	
Funding Instrument Type:	Cooperative Agreement Other Procurement Contract
Category of Funding Activity:	Science and Technology and other Research and Development
Category Explanation:	
Expected Number of Awards:	
CFDA Number(s):	12.910 -- Research and Technology Development
Cost Sharing or Matching Requirement:	No
Version:	Synopsis 3
Posted Date:	Jan 19, 2018
Last Updated Date:	Mar 14, 2018
Original Closing Date for Applications:	Mar 27, 2018 4:00 ET
Current Closing Date for Applications:	Mar 27, 2018 4:00 ET
Archive Date:	Apr 26, 2018
Estimated Total Program Funding:	
Award Ceiling:	
Award Floor:	

Eligibility

Eligible Applicants: Unrestricted (i.e., open to any type of entity above), subject to any clarification in text field entitled "Additional Information on Eligibility"

Additional Information on Eligibility:

Additional Information

Agency Name: DARPA - Biological Technologies Office

Description: DARPA is soliciting innovative proposals for research to develop new tools and models to quantify the likelihood of a virus to jump from an animal host into humans, and to develop and validate new scalable technologies to target potential human-capable viral pathogens in wild reservoirs and/or mosquito vectors to prevent transmission to humans.

Link to Additional Information: FedBizOpps URL for DARPA PREEMPT BAA

Grantor Contact Information: If you have difficulty accessing the full announcement electronically, please contact:

BAA Coordinator

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Synopsis History:

Version	Modification Description	Updated Date
Synopsis 3	The purpose of Amendment 1 to HR001118S0017, the PREventing EMerging Pathogenic Threats (PREEMPT) Broad Agency Announcement, is to revise Section 4.2.4 as described in the Amendment Attachment identifying additional mandatory files to be submitted with the proposal.	Mar 14, 2018
Synopsis 2	Corrected FedBizOpps link	Jan 19, 2018
Synopsis 1		Jan 19, 2018

DISPLAYING: Synopsis 3

General Information

Document Type: Grants Notice
Funding Opportunity Number: HR001118S0017
Funding Opportunity Title: PREventing EMerging Pathogenic Threats
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Category of Funding Activity: Science and Technology and other Research and Development
Category Explanation:
Expected Number of Awards:
CFDA Number(s): 12.910 -- Research and Technology Development
Cost Sharing or Matching Requirement: No

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DARPA HR001118S0017 PREEMPT BAA	HR001118S0017.pdf	Jan 19, 2018 04:06:3
HR001118S0017 Amendment 1	HR001118S0017 Amendment 1.pdf	Mar 14, 2018 02:28:2
HR001118S0017_Attachment_1_Executive_Summary_slide_template	HR001118S0017_Attachment_1_Executive_Summary_slide_template.pptx	Jan 19, 2018 04:08:1
HR001118S0017_Attachment_2_Proposal_Schedule_slide_template	HR001118S0017_Attachment_2_Proposal_Schedule_slide_template.pptx	Jan 19, 2018 04:08:4
RR_KeyPersonExpanded_2_0-V2.0 Form	RR_KeyPersonExpanded_2_0-V2.0.pdf	Mar 14, 2018 02:29:0
RR_PersonalData_1_2-V1.2 Form	RR_PersonalData_1_2-V1.2.pdf	Mar 14, 2018 02:28:4

Eligible Applicants: Unrestricted (i.e., open to any type of entity above), subject to any clarification in text field entitled "Additional Information on Eligibility"

Additional Information on Eligibility:

Additional Information

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Link to Additional Information: FedBizOpps URL for DARPA PREEMPT BAA

Grantor Contact Information: If you have difficulty accessing the full announcement electronically, please contact:

BAA Coordinator
PREEMPT@darpa.mil

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BAA Coordinator

Broad Agency Announcement

PREventing EMerging Pathogenic Threats (PREEMPT)

BIOLOGICAL TECHNOLOGIES OFFICE

HR001118S0017

January 19, 2018

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- **Funding Opportunity Title –** PREventing EMerging Pathogenic Threats
- **Announcement Type –** Initial
- **Funding Opportunity Number –** HR001118S0017
- **Catalog of Federal Domestic Assistance Numbers (CFDA) – 12.910 Research and Technology Development**
- **Dates**
  - Posting Date – January 19, 2018
  - Proposal Abstract Due Date and Time – February 13, 2018 4:00 ET
  - Proposal Due Date and Time – March 27, 2018 4:00 ET
  - BAA Closing Date – March 27, 2018
  - Proposers' Day – January 30, 2018

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

- **Concise description of the funding opportunity – DARPA is soliciting innovative proposals to develop novel and scalable approaches to preempt viral spillover and transmission from animals or vectors into humans.**

- **Anticipated individual awards - Multiple awards are anticipated.**
- **Types of instruments that may be awarded - Procurement contract, cooperative agreement or other transaction.**
- **Any cost sharing requirements -** Cost sharing may be required under applicable statutory regulations for other transactions for prototype projects awarded under the authority of 10 U.S.C. § 2371b.
- **Agency contact**
  - Points of Contact
    James Gimlett, Ph.D. Program Manager
    Biological Technologies Office

    The BAA Coordinator for this effort may be reached at:
    PREEMPT@darpa.mil
    DARPA/BTO
    ATTN: HR001118S0017
    675 North Randolph Street

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.

DARPA is soliciting innovative proposals for research to develop new tools and models to quantify the likelihood of a virus to jump from an animal host into humans, and to develop and validate new scalable technologies to target potential human-capable viral pathogens in wild reservoirs and/or mosquito vectors to prevent transmission to humans.

1.1. PROGRAM OVERVIEW

Introduction

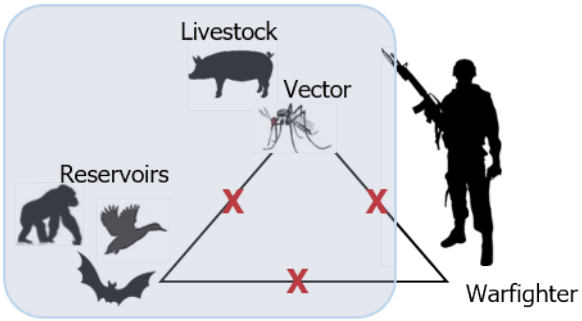
During U.S. international operations, military forces are deployed to remote locations around the globe, often in areas where endemic and emerging diseases are prevalent[1]. Most of these emerging and re-emerging diseases originate in animal reservoirs and then jump into humans. Numerous trends, including the increased interactions between human, animal and insect populations due to increased population densities, globalization, densification of livestock production, and rising human encroachment into animal habitats, have increased the risks of new viral outbreaks in those regions where Department of Defense (DoD) personnel are typically deployed. Often, DoD personnel are among the first responders in outbreak situations. Emerging infectious diseases, for which few medical countermeasures are available, represent a major threat to the warfighter and national security and could have devastating impacts on U.S. public health.

Despite biosurveillance efforts around the globe, new viral outbreaks continue to outpace preparedness efforts and show no signs of abating. During the first three quarters of 2017 outbreaks of avian influenza A (H7N9), Chikungunya, MERS coronavirus, Ebola, Seoul virus, Hepatitis E, Hepatitis A, Yellow Fever, Lassa, and Zika viruses were recorded[2]. While current biosurveillance strategies focus on detection of known pathogens within the human population following an infectious outbreak event, there is a dearth of research and surveillance on sentinel or reservoir animals[3]. Animal-specific viruses that have the potential to infect humans (*namely "*human-capable" pathogens), but have not yet spilled over into human populations, are rarely considered. As a result, infectious agents are detected only *after* an outbreak—that is, after an animal pathogen has adapted to become capable of infecting humans. Consequently, the outbreak response is largely reactive and not initiated until after an epidemic has already begun. The PREEMPT program represents a radical departure from current practice, aiming to target viral

[1] Halliday Jo E.B. et al. (2017). Driving improvements in emerging disease surveillance through locally relevant capacity strengthening. Science.
[2] World Health Organization (2017). http://www.who.int/csr/don/archive/year/2017/en/.
[3] Metcalf, J.E. and Lessler, J. (2017). Opportunities and challenges in modeling emerging infectious diseases. Science.

biothreats within the animal reservoirs where they originate and preempt their entry into human populations *before* an outbreak occurs.

Recently, the scientific community has advanced its understanding of host-pathogen genetics and mechanisms of adaptation across hosts[4,5], developed analytic tools to predict animal hosts of new and potential human-transmissible viruses, and learned how to identify "hot spot" geographic regions where an animal-to-human virus jump is imminent[6,7]. This understanding is empowered by new high-throughput data generation capabilities and sophisticated analytic and computational tools. Together, this new understanding and capability hold great promise for the development of advanced integrated models that can assess and likely provide guidance for action that prevents human virus emergence before the virus gains entry to the human population. The PREEMPT program aims to develop new tools and models to quantify the likelihood of a virus quasispecies (QS) to jump from an animal host into humans. In parallel, PREEMPT seeks to develop and validate new scalable technologies that prevent transmission of viral pathogens in wild reservoirs and/or mosquito vectors to humans or to bridge animals that serve as intermediary hosts prior to virus jump into humans.



Research Objectives

PREEMPT research objectives are structured along two Technical Areas (TAs). Both Technical Areas must be performed in parallel by vertically integrated, interdisciplinary teams. Proposers must present a plan to address both Technical Areas and meet key milestone decision points that occur at the end of year 2.

1) TA1: Develop and validate integrated, multiscale models that quantify the likelihood a human-capable virus will emerge from an animal reservoir residing in a "hot spot" geographic region.

2) TA2: Develop scalable approaches that target and suppress the animal virus in its reservoir(s) and/or vector(s), to reduce the likelihood of virus transmission into humans.

Technical Area 1 (TA1)

[4] Lloyd-Smith, J.O. (2010). Identifying genetic markers of adaptation for surveillance of viral host jumps. Nature Reviews Microbiology.
[5] Plowright, R.K. et al. (2017). Pathways to zoonotic spillover. Nature Reviews Microbiology.
[6] Olival, K.J. et al. (2017). Host and viral traits predict zoonotic spillover from mammals. Nature.
[7] Han, B.A. et al. (2016). Undiscovered Bat Hosts of Filoviruses. PLoS Negl Trop Dis.

Studies within TA1 must produce and validate models that: (a) quantify the likelihood of a virus to jump into a new animal species and/or humans, (b) identify opportunities for proactive intervention, and (c) determine likely efficacy, scalability, and sustainability of prevention strategies.

Proposers are expected to leverage high-throughput virus screening methods, metagenomics, ecological surveillance, and advanced modeling tools to generate risk models for species jump that will enable near real-time data analysis and identification of potential risks and risk factors. This far-forward biosurveillance system should also identify opportunities for preemptive intervention, assessing likely efficacy, scalability, safety, and sustainability of preemptive strategies to target viral threats in animal reservoirs and/or vectors before they enter the human population.

TA1 Components
Proposers should address, at minimum, the following aspects:

1) Selection of zoonotic or vector-borne viral pathogen(s) (multiple viruses within the same family may be addressed if they share a common animal reservoir and/or vector)
2) Field data collection
3) Multi-species field samples studied in a controlled laboratory setting
4) Data analysis, integration, and model development
5) Real-time data sharing and analysis
6) Model outputs
7) Experimental validation of model predictions in a controlled, environment-simulated laboratory setting

1. Selection of zoonotic or vector-borne viral pathogen

This BAA only will consider proposals focused on zoonotic and/or vector-borne viruses. Microorganisms other than viruses are not responsive to this announcement. A rationale for the viruses selected is required. Virus selection may be based on, but is not limited to, the following factors: high frequency of re-emergence (*e.g.* avian influenza virus), patterns of virus host range or host breadth (predicted zoonotic potential), potential for rapid spread due to vector-mediated transmissibility, severity of disease pathology, and likelihood of pandemic threat.

2. Field data collection

Proposers must identify and justify suitable geographic "hotspots" within which they will collect field data. Proposers must consider <u>all</u> of the following criteria when selecting geographic hot spots for field data collection:

1) Previous evidence of geographic distribution of zoonotic reservoirs and/or vectors for known or unknown human viruses; these maps may be based on epidemiological, phylogenetic, ecological, biogeographic, socio-economic data, or other;
2) Evidence of past species jump events in or near the selected geographic location;

3) Demonstrated capabilities and infrastructure to perform research in the selected geographic region and/or collaboration with an established DoD or Department of Health and Human Services (DHHS) partner (*e.g.*, a Naval Medical Research Unit site, Armed Forces Research Institute of Medical Sciences, or Centers for Disease Control), such that the performer can coordinate far-forward surveillance activities and access local lab and analytics capabilities;
4) Appropriate levels of in-country government approval, cooperation, infrastructure and logistical support where samples will be collected and analyzed; and
5) Rationale for reservoirs/species to be sampled.

Where applicable, proposers must consider seasonal distribution (*e.g.,* wet-dry seasons for mosquito), temporal ecological factors (*e.g.,* time of fruiting for fruit bats), and temporal behavioral traits (*e.g.,* sexual maturation) of zoonotic species for field sampling. Potential geographic areas may include, but are not limited to, endemic regions; those undergoing ecological shifts (thus increasing risk for spillover due to changes in animal-human interactions); those harboring host species with high zoonotic potential that are in proximity to human populations and "bridge" animal hosts (*e.g.,* human-bat-swine ecosystems); and prior sites of spillover events or outbreaks. The selection of geographic areas of common military deployment that also meet the above criteria is strongly encouraged. Proposers should describe feasible approaches to increase the probability of detecting viruses within animal reservoirs and/or vectors—residing in selected geographic areas—that have the potential to become human-capable. Proposers should describe sample collection methods in detail, being sure to include longitudinal sampling frequency. Development of novel and rapid sampling approaches for the real-time continuous screening of emerging or re-emerging pathogens at the human-animal interface is encouraged. Proposers are encouraged to identify field samples that were collected during past outbreak events, or field data already generated, that could be accessed for retrospective analyses. In such cases, proposers should describe how and where the data were collected, and establish quality control methods for data evaluation and use. Although human use research will not be funded by PREEMPT, the use of human samples or data from prior outbreaks obtained through other programs may be included in the research plan as long as samples are appropriately de-identified (see, for example, https://humansubjects.nih.gov/human-specimens-cell-lines-data).

3. Multi-species laboratory testing of field samples

Proposers should discuss protocols to determine and quantify the virus population QS diversity from the vector or reservoir at the time of sample collection (t=0) in a manner that minimizes QS alterations, which commonly result from cell line passaging. Proposers should assess the need for longitudinal collection of samples to understand viral QS temporal dynamics (temporal changes in sequence and fitness landscapes) in field virus populations. The initial viral QS isolated from a field sample (t=0) will be hereon annotated as "QS_0". Proposers must describe *in vitro* and/or *in vivo* experiments to assess jump potential of the QS_0 population to a relevant new host. Experimental approaches to monitor viral species jump may include, but are not limited to: changes in viral population QS during cell line passaging between relevant species; infection of appropriate animal models; infection of natural animal hosts; and controlled, multi-species laboratory ecosystems.

Lab testing should determine the key parameters influencing the probability of a viral QS_0 to jump and adapt to a new host species. Potential parameters across different host animals or vectors may include, but are not limited to:

1) QS diversity profiles
2) Rates of virus infection and amplification
3) Virus incubation period
4) Viremia and viral shedding
5) Transmission bottlenecks
6) Animal host evolutionary and immune pressures

The data generated should enable the development of genotype-to-phenotype maps and the determination of mutation(s) associated with virus jump to a new host.

4. Data analysis, integration, and model development

Proposers should identify the relevant data needed for developing integrated models of risk assessment. Proposers should discuss the development of probabilistic models of virus jump using advanced computational methods and tools, including both model-driven and data-driven approaches. Models should integrate multi-scale and cross-host species data, including but not limited to, field and experimental data (*e.g.,* QS dynamics), ecological data (*e.g.,* demographic, socio-economic, epidemiological, biogeographical, and other metadata), and other relevant data available, especially that generated from past spillover events. Models should consider all factors associated with pathogen emergence and transmission, particularly multi-host immunological landscapes. Models should also capture viral evolutionary trajectories, fitness landscapes in zoonotic and/or vector species, and quantify the transmission dynamics underlying species jump.

5. Real-time data sharing and analysis

The PREEMPT program is expected to generate significant amounts of data, primarily from next generation sequencing (NGS) of viral populations and analysis of host molecular signatures. Proposers should identify methods for near-real-time data sharing and analysis.

6. Model outputs

Proposers should explain how they will develop probabilistic models and machine learning techniques that integrate multi-scale and cross-species data (*e.g.,* molecular signatures, demographic, ecological, socio-economic, epidemiological, weather, climate, and other metadata) to quantify a pathogen's likelihood to cross species barriers and infect humans. Models should capture viral evolutionary trajectories and mutations that govern species jump. Models should quantify transmission dynamics, accounting for the diversity of viral QS. Models should identify key parameters of the pathogen, host species, vector dynamics, and ecological interactions contributing to species jump, and should inform a preemption strategy by identifying optimal pressure points (*e.g.,* jump-enabling mutations, stochastic transmission bottlenecks, and viral amplification requirements) that can be targeted to reduce the likelihood of species jump. For proposals addressing vector-borne viruses, proposers should describe methods to quantify

the likelihood of virus adaptation to a new vector and propose experimental methods to validate these predictions. Proposers should discuss metrics for grading model accuracy, sensitivity, and specificity. Models should be able to receive dynamic biosurveillance inputs and accommodate virus QS changes.

7. Experimental validation of model predictions

Proposers must describe in detail a plan to establish relevant *in vivo*, multi-species experimental approaches to validate model outputs. Experimental testing may closely resemble or recapitulate real-life settings (*e.g.,* climate, phylogenetically adjacent host species, and vector "biting" patterns) to enable the quantification of the probability of spillover and/or transmission events in a controlled manner. Approaches that closely recapitulate real-life ecosystems and natural hosts are strongly encouraged. To improve model accuracy, sensitivity, and specificity, performers must iterate both theoretical and empirical experiments.

TA1 Key Outputs
The key outputs for TA1 must include the following:

1) Integrated models that quantify likelihood of virus jump and can be easily adapted to receive dynamic surveillance and virus data input.
2) Stochastic models quantifying bottlenecks (e.g., transmission, cell entry, and infection rates) and mutational fitness maps (e.g., enabler mutations and their frequency).
3) Identification and assessment of potential preemptive intervention targets to preempt virus jump from the reservoir and/or vector.

Technical Area 2 (TA2)
Studies within this technical area aim to develop deployable and scalable methods to preempt viral jump across species.

TA2 Components
Technical Area 2 aims to develop deployable and scalable methods to preempt viral jump to other species. Proposers must address, at minimum, all of the following aspects:

1) Proof-of-concept preemption approaches;
2) Scalable delivery methods;
3) Analysis of long-term sustainability; and
4) Experimental validation.

1. Proof-of-concept preemption approaches

Proposers should describe how the output of TA1 *in silico* models will guide preventive method design, and how quantitative information of virus-host species barriers and transmission bottlenecks will be used to develop strategies to preempt emergence of human-capable viruses. Models should guide the selection of: host species to be treated (*e.g.*, wild animals, "bridge"

animals, vectors, and livestock); potential molecular targets (*e.g.,* key mutation(s) enabling receptor binding in a new host); targets associated with transmission cycle dynamics (*e.g.,* reduction of viral load within the reservoir and/or vector that would preclude transmission); and other relevant factors identified by the models. Proposers should describe the preemptive methods that address different model outputs. Examples of preemptive approaches include but are not limited to:

1) Specific disruption of jump-capable genes from virus QS in reservoirs and/or vectors using small interfering RNAs or CRISPR/Cas-based targeted deletions.
2) Suppression of virus jump to a new host through antibody-mediated virus neutralization.
3) Suppressed reservoir and/or vector viremia using virus defective interfering particles (DIPs) to outcompete virus replication.
4) Suppressed transmission among animal reservoirs through induced immunity (*e.g.,* vaccinate the animal).
5) Alternative methods informed by experimental and theoretical models. The development of novel preemptive approaches are strongly encouraged.

2. Scalable delivery methods

Proposers must describe scalable approaches to deliver the preemptive therapeutic to achieve animal and/or vector population-level control of the targeted virus, including strategies for reaching less accessible animal reservoirs (*e.g.,* rodents or non-human primates). Approaches that enable host-to-host therapeutic distribution (*i.e.,* do not require individual treatment) that are self-limiting, only activate when the viral pathogen target is present, and/or have a controllable "on/off-switch" are encouraged. Potential scalable methods of inoculation may include, but are not limited to:

1) Self-disseminating treatments or preventives (*e.g.,* transmissible recombinant vaccines, therapeutic interfering particles, or self-spreading antiviral therapies).
2) Bait vaccination or treatment of wild or domestic animals.
3) Spray-based methods.

Approaches that utilize genetic modifications of vectors (*e.g.,* engineered mitochondrial DNA) are acceptable. The proposed method of inoculation must be justified. The proposer must describe strategies for closely controlling preemptive delivery and spread.

3. Analysis of long-term safety and efficacy

Proposers must establish initial methods to assess the long-term safety and efficacy of preemptive approaches (*e.g*., determine the mechanism by which species specificity of a vaccine is maintained, and assess evolutionary stability and ecological safety).

4. Experimental validation

Proposers must describe approaches to validate preemptive methods of choice in controlled experimental models. Multi-species experimental platforms that closely recapitulate real-life ecosystems and use natural hosts are strongly encouraged.

TA2 Key Outputs
The key outputs of TA2 must include the validation of new "block-before-jump" preemption technologies for one of the following:

1) Validate suppression of virus jump from wild animal reservoir to humans and/or an intermediate animal carrier (*e.g.,* domestic livestock).
2) Validate suppression of virus jump or transmission from wild reservoir to vector, vector to a different vector species, and/or from vector to human.

Period of Performance
DARPA anticipates that the PREEMPT program will provide up to three and a half years of funding for research and development to be performed over Phase I (base) and II (option) periods of 24 and 18 months, respectively.

Timeline
PREEMPT spans a 42-month effort with a 24-month Phase I (base) and an 18-month Phase II (option). In general, Phase I should provide early validation of zoonosis risk models, and Phase II should establish efficacy and scalability of zoonosis prevention approaches.

Phase I (Base period)
Phase I efforts aim to develop experimental and mathematical models to quantify the likelihood a virus will jump from one host species to another, identify potential targets for spillover preemption, and develop scalable methods of preemption. During Phase I, performer teams will:

1) Identify the genetic adaptations that enable species jump.
2) Develop mathematical models to quantify the likelihood of species jump based on:
    a. Molecular data (*e.g.,* viral QS data from deep sequencing*)* and
    b. Ecological data *(e.g.,* immune state of the host population before pathogen emergence, species relatedness, etc.).
3) Identify bottlenecks for intervention (*e.g.. transmission, cell entry, viral amplification, infection rate, and other mechanisms associated with viral cross-species compatibility)*.
4) Develop initial scalable platforms that target viruses in reservoirs and/or vectors to prevent viral jump into other animals or humans.

By the end of year 1 (Phase I) performers will be expected to have:
1) Identified signatures of fitness and spillover potential of a pathogen between two species.
2) Quantified the genetic and transmission factors requirements of viral QS to jump to a new host (*e.g.,* develop genotype-to-phenotype maps, identify specific mutations, etc.) using far-forward biosurveillance data from selected high-risk regions.

By the end of year 2 (Phase I) performers will be expected to have:

1) Initially demonstrated that models can quantify the probability of human-capable virus pathogens to jump from one species to another species.
2) Demonstrated proof of concept methods for targeting human-capable virus pathogens in the reservoirs and/or vectors to reduce the probability of virus jump.
3) Provided initial strategies to scale up preemption methods.

Phase II (Option period)
Phase II efforts aim to develop probabilistic models for intra- and inter-species viral amplification and transmission dynamics, integrated models for risk assessment, and experimental validation of new approaches to preempt species jump. During Phase II, performer teams will extend Phase I modeling efforts to:

1) Quantify intra- and inter-species viral amplification dynamics and transmission.
2) Develop integrated models that quantify the probability of a virus QS to jump to bridge animal species or to humans.
3) Experimentally validate scalable methods for their ability to preempt zoonotic spillover.

By the end of year 3.5 (Phase II) performers will be expected to:

1) Demonstrate accuracy of risk assessment and preemption models in a relevant multi-species experimental setting.
2) Demonstrate the ability to suppress viral jump to a new species in controlled experimental settings.

It is recognized that appropriate milestones and metrics may depend upon the type of virus, the reservoir, the mechanisms of species jump, and the proposed preemption methods. Proposers must offer quantitative milestones and metrics (see Tables 1 and 2 below for notional metrics) for their proposed proof-of-principle use case. Proposers must demonstrate relevant research experience in the required technical areas. Proposals involving multiple teams and/or experimental approaches should be structured as unified efforts that address the program Technical Areas in parallel, in an integrated manner.

1.2. PROGRAM METRICS

In order for the Government to evaluate the effectiveness of a proposed solution in achieving the stated program objectives, proposers should note that the Government hereby promulgates the following program metrics that may serve as a guideline for assessing program progress, risk and impact. Although the following program metrics are provided, proposers should note that the Government has identified these goals with the intention of bounding the scope of effort while affording the maximum flexibility, creativity, and innovation in proposing solutions to the stated problem. Proposers should offer more appropriate and specific metrics for their particular use case and technical approach, including intermediate metrics (i.e. every 6 months, or sooner) to help further evaluate progress. Final metrics are to be negotiated at the time of contracting.

Table 1: Notional Milestones, Deliverables, and Program Metrics for TA1

Phase	Milestones and Deliverables	Program Metric
I	Collected field surveillance data: • Virus QS molecular data (*e.g.* from deep sequencing) and metadata from longitudinal samples (*e.g.* obtained from selected high-risk areas (*e.g.* bat cave) and/or from prior outbreak event • Host species immune molecular data	Quantitative measures of: • Longitudinal viral population QS ($QS_{t=0}$, $QS_{t=6\ months}$, $QS_{t=12\ months}$,..) diversity in selected high-risk areas (*e.g.* frequency of mutations, evolutionary trajectories) (**6 months**) • Viral QS diversity in samples obtained from animal, vector, and/or human from prior outbreak event (*e.g.* frequency of species-specific mutations) (**9 months**) • Immune molecular signatures from host reservoir or intermediate reservoir species (**12 months**)
	Multi-species lab test data: • Virus QS genotype-phenotype maps for at least 2 relevant host species	Quantitative measures of: • Cell entry and adaptation across species *in vitro* and/or *in vivo* (*e.g.* QS diversity during passage across species) (**18 months**)
	Initial mathematical models that assess risk of virus jump	Model capability to describe/predict: • Virus QS evolutionary trajectories between 2 relevant species (**9 months**) • Key molecular factors that could be targeted to prevent virus jump *in vitro* and/or *in vivo* (*e.g.* signatures of fitness of a pathogen between two relevant host species) (**18 months**) • Molecular targets for preemption (**24 months**)
	Established testbeds for validation of model predictions	Testbeds mimic natural environment as quantified by performer-defined parameters (**24 months**)
II	Multi-species lab test data • Quantify virus QS transmission factors between two species *in vivo*	Quantitative measures of: • Virus amplification and transmission dynamics (*e.g.* rate of infection vs. viremia, amplification rates, and incubation time) (**30 months**)
	Advanced mathematical models that assess risk of virus jump • Integration of molecular data and virus amplification/transmission dynamics • Integration of host immune evolutionary pressures and virus QS dynamics	Models predict: • Intra- and inter-species transmission dynamics (**36 months**) • Probability of spillover (risk assessment) (**42 months**) • Top 2 targets to reduce probability of transmission between two species to

Phase	Milestones and Deliverables	Program Metric
		inform TA2 (**42 months**)
	Further validation of model prediction in established testbeds	Validated model prediction accuracy in multispecies environment (**42 months**)

Table 2: Notional Milestones, Deliverables, and Program Metrics for TA2

Phase	Milestones and Deliverables	Program Metric
I	Proof-of-concept demonstration of preemptive approach that reduces either the probability of virus jump or the frequency of virus QS variants at high risk for species jump	Quantitative validation of preemptive approach as established by performer (**24 months**) Examples: • Frequency of high-risk mutation within virus QS in reservoir reduced >3X • Virus incubation period in vector extended >3X • Virus amplification rate in reservoir or vector reduced >3X • Viremia in host or vector reduced >5X
II	Demonstrated efficacy of preemption method	Reduced probability of transmission between two species by >5X *in vivo* for top 2 targets (**36 months**)
	Demonstrated scalability of preemption method	Quantitative scalability as established by performer (**42 months**)

Data Sharing

Proposers must ensure all technical data items (including experimental findings, processed data, methods of processing, research reports, and publications) and software (source code and executables) generated from PREEMPT program funding are made available to DARPA. Regularly submitted reports (*e.g.*, monthly or quarterly) should contain all relevant project data, including (but not limited to) raw and analyzed data and any necessary annotations and interpretation. Data and/or samples collected from de-identified human volunteers/patients from previous outbreak events must include associated anonymized metadata (*e.g.,* signs/symptoms, diagnostic test results, interventions, clinical observations, and outcomes). All raw data and metadata should be recorded according to approved experimental standards.

To gain enhanced scientific value from open collaboration in fundamental research, DARPA may seek permission to share some or all program-generated data with the broader research community as open data (including the possibility of accessing, reusing, and redistributing under appropriate licensing terms) to the extent permitted by applicable laws and regulations (*e.g.*, privacy, security, and export control).

DARPA anticipates that a large amount of data will be generated under this program by each performer and that the analyses and validation will be strengthened by compiling and integrating

information across all performers. Performers are strongly encouraged to establish the appropriate agreements to enable collaboration and data sharing. DARPA encourages sharing of pre-existing data, including those generated through funding by other sources, although this is not a requirement of the program.

As feasible, DARPA intends to share data within the PREEMPT performer community to promote program goals. To facilitate sharing and exchange of data items, performers will be required to enter an Associate Contractor Agreement (ACA); an ACA clause will be included in the contract or agreement awarded.

PREEMPT Transition Plan
Proposers must include a PREEMPT Technology Transition Plan. Proposers must indicate the types of partners (*e.g.*, government, private industry, non-profit) they plan to pursue and submit a timeline with incremental milestones toward successful engagement. Proposers should begin transition activities during the early stages of the program (Phase I). Awardees must include DARPA in the development of transition relationships. If the transition plan includes a start-up company, a business development strategy must be included as well. The extent by which the proposed intellectual property (IP) rights will impede the Government's ability to transition the technology will be considered in the proposal evaluation.

1.3. ETHICAL, LEGAL, AND SOCIETAL IMPLICATIONS (ELSI)

DARPA is committed to ensuring that efforts funded under this BAA adhere to ethical and legal regulations currently in place for federally and DoD-funded research. Program developments will be discussed with a panel of expert external advisors with expertise in bioethical and biosafety issues that may emerge as a consequence of advances in biomedical science and technology. Proposers to this BAA should address potential ethical, legal, and societal implications of the proposed technology.

1.4. PROTECTION OF SENSITIVE INFORMATION

PREEMPT is a 6.1 fundamental research program aimed at enhanced biosurveillance and novel approaches to preempt viral pathogens in animal reservoirs from jumping into human populations. DARPA follows current DoD policy for contracted fundamental research. DARPA recognizes, however, that PREEMPT program components aimed at understanding and quantifying mechanisms for viral zoonotic spillover could potentially generate sensitive information that could be misused. Since this is a fundamental research program, the risk of misuse currently cannot be reasonably evaluated. However, proposers are notified that during proposal evaluation and/or program performance, when such a risk reasonably can be evaluated, DARPA may determine that risk of misuse creates exceptional circumstances, compelling reasons, and/or national security reasons under current DoD policy for contracted fundamental research. DARPA therefore expects that proposers to this program understand and will comply with various government guidance regarding potential gain-of-function research of concern (GOFROC)[8] and dual use research of concern (DURC)[9,10,11,12,13]. See https://www.phe.gov/s3/dualuse/Pages/default.aspx for further information.

[8] Gain-of-Function Research (GOFROC) refers to studies with the potential to generate pathogens with pandemic potential exhibiting high transmissibility and high virulence.

DARPA requires that proposals include a Risk Mitigation Plan that will be incorporated into any resulting agreements or contracts and includes the following information:

1) An assessment of potential risks to public health, agriculture, plants, animals, the environment, and national security.
2) Proposed guidelines that the proposer will follow to ensure maximal biosafety and biosecurity during the course of the research.
3) A communication plan that addresses content, timing, and the extent of distribution of potentially sensitive dual-use information. The plan must also address how input from DARPA, other government, and community stakeholders will be taken into account in decisions regarding communication and publication of potentially sensitive dual-use information.

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

[9] Dual Use Research of Concern (DURC) refers to life sciences research that can be reasonably anticipated to provide knowledge, information, products or technology that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.
[10] Proposed framework for the oversight of dual use life sciences research: strategies for minimizing the potential misuse of research information, National Science Advisory Board for Biosecurity (NSABB). June 2007.
[11] Recommendations for the evaluation and oversight of proposed gain-of-function research by the National Science Advisory Board for Biosecurity (NSABB). May 2016.
[12] Tools for the Identification, Assessment, Management, and Responsible Communication of Dual Use Research of Concern: A Companion Guide to the United States Government Polices for Oversight of Life Sciences Dual Use Research of Concern. NIH. September 2014.
[13] United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern. DURC Policy. March 2012.

assessment of Phase I research results, and a determination that awarding the option is in the best interests 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 http://www.darpa.mil/work-with-us/contract-management#OtherTransactions.

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 http://www.darpa.mil/work-with-us/contract-management#OtherTransactions

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 http://www.darpa.mil, 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 8 pages** including all figures, tables, charts, and the Executive Summary slide. 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 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. Executive Summary Slide: Provide a one slide summary in PowerPoint that effectively and succinctly conveys the main objective, key innovations, expected impact, and other unique aspects of the proposed project. Proposers should use the slide template provided as Attachment 1 to the BAA posted at http://www.fbo.gov.

C. Goals and Impact: 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 current practice and state-of-the-art (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?

D. Technical Plan: Outline and address all technical challenges inherent in the approach and possible solutions for overcoming potential problems. 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.

E. Capabilities: 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, and any specialized facilities 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.

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 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 36 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 (HR001118S0017);
2. Lead organization submitting proposal (prime contractor);
3. Type of organization, selected from among the following categories: "LARGE BUSINESS," "SMALL DISADVANTAGED BUSINESS," "OTHER SMALL BUSINESS," "HBCU," "MI," "OTHER EDUCATIONAL," OR "OTHER NONPROFIT";
4. Proposer's reference number (if any);
5. Other team members (if applicable) and type of business for each;
6. Proposal title;
7. 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;
8. 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;
9. Award instrument requested: cost-plus-fixed-free (CPFF), cost-contract—no fee, firm-fixed-price, grant, cooperative agreement, other transaction, or other type (specify);
10. Place(s) and period(s) of performance ;
11. Proposal validity period;
12. Total funds requested from DARPA, and the amount of cost share (if any); AND
13. Date proposal was submitted.

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

B. Official Transmittal Letter.

Section II. Detailed Proposal Information

A. Executive Summary: 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. Executive Summary Slide: Provide a one slide summary in PowerPoint that effectively and succinctly conveys the main objective, key innovations, expected impact, and other unique aspects of the proposed project. Proposers should use the slide template provided as **Attachment 1** to the BAA posted at https://www.fbo.gov.

C. Goals and Impact: 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.

D. Technical Plan: Outline and address technical challenges inherent in the approach and possible solutions for overcoming potential problems. This section should provide appropriate measurable milestones (quantitative if possible) and program metrics (see Section 1.2) 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 Section 1.1.

E. Management Plan: 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.

F. Capabilities: 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.

G. Statement of Work (SOW): 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.

H. Schedule and Milestones: 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.

I. PREEMPT Transition Plan (see Section 1.2): Proposers must indicate the types of partners (e.g., government, private industry, non-profit) they plan to pursue and submit a timeline with incremental milestones toward successful engagement. Proposers should begin transition activities during the early stages of the program (Phase I). The plan should describe any potential DARPA roles. If the plan includes a start-up company, a business development strategy must be included as well.

J. PREEMPT Risk Mitigation Plan (see Section 1.4): Proposers must provide a risk mitigation plan that addresses the following:

- An assessment of potential risks to public health, agriculture, plants, animals, the environment, and national security.
- Proposed guidelines that the proposer will follow to ensure maximal biosafety and biosecurity during the course of the research.
- A communication plan that addresses content, timing, and the extent of distribution of potentially sensitive dual-use information. The plan must also address how input from DARPA, other government, and community stakeholders will be taken into account in decisions regarding communication and publication of potentially sensitive dual-use information.

K. Ethical, Legal, and Societal Implications (ELSI) (see Section 1.3): Proposers should address potential ethical, legal, and societal implications of the proposed technology.

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. Lead Organization Submitting proposal;
3. Type of organization, selected among the following categories: "LARGE BUSINESS", "SMALL DISADVANTAGED BUSINESS", "OTHER SMALL BUSINESS", "HBCU", "MI", "OTHER EDUCATIONAL", OR "OTHER NONPROFIT";
4. Proposer's reference number (if any);
5. Other team members (if applicable), CAGE Code(s), and type of business for each;
6. Proposal title;
7. 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);
8. 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);

9. Award instrument requested: cost-plus-fixed-free (CPFF), cost-contract—no fee, cost sharing contract – no fee, or other type of procurement contract (*specify*), grant, cooperative agreement, or other transaction;
10. Place(s) and period(s) of performance;
11. Total proposed cost separated by basic award and option(s) (if any);
12. Name, address, and telephone number of the proposer's cognizant Defense Contract Management Agency (DCMA) administration office (*if known)*;
13. Name, address, and telephone number of the proposer's cognizant Defense Contract Audit Agency (DCAA) audit office (*if known*);
14. Date proposal was prepared;
15. DUNS number (http://www.dnb.com/get-a-duns-number.html);
16. Taxpayer ID number (https://www.irs.gov/Individuals/International-Taxpayers/Taxpayer-Identification-Numbers-TIN);
17. CAGE code (https://www.dlis.dla.mil/bincs/FAQ.aspx);
18. 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.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/preaward_accounting_system_adequacy_checklist.html).

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 requires that the proposer provide a detailed cost breakdown to include:

(1) Total program cost 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 task;

(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 http://www.darpa.mil/work-with-us/additional-baa.

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 http://www.darpa.mil/work-with-us/additional-baa for further information. If no restrictions are intended, the proposer should state "NONE."

The table below captures the requested information:

Technical Data	Summary of	Basis for	Asserted Rights	Name of Person

Computer Software To be Furnished With Restrictions	Intended Use in the Conduct of the Research	Assertion	Category	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 http://www.darpa.mil/work-with-us/additional-baa 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 HR001118S0017. Submissions may not be 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 HR001118S0017, 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 https://baa.darpa.mil 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 HR001118S0017 may be submitted via DARPA's BAA Website (https://baa.darpa.mil). 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 (https://baa.darpa.mil), though proposers will likely still need to visit https://baa.darpa.mil 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 BAAT_Support@darpa.mil, 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 http://www.grants.gov/applicants/apply-for-grants.html. 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.

Grants.gov Submissions: 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 http://www.darpa.mil/work-with-us/additional-baa.

Hard-copy Submissions: 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://aaply07.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.800-171r1) 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

Not Applicable.

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; and 5.1.3 Cost Realism.

5.1.1. Overall Scientific and Technical Merit

The proposed technical approach is innovative, feasible, achievable, and complete.

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 proposed PREEMPT Risk Mitigation Plan effectively provides the following: an assessment of potential risks; proposed guidelines to ensure maximal biosafety and biosecurity; a risk management plan for responsible communications; and a plan to address how input from the Government and community stakeholders will be considered regarding communication and publication of potentially sensitive dual-use information.

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.

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.

5.1.3. 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.

5.2. 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 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 regular program-wide PI meetings and periodic site visits at the Program Manager's discretion to the Arlington, VA vicinity. 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

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 http://www.darpa.mil/work-with-us/additional-baa.

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 http://www.darpa.mil/work-with-us/additional-baa.

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 http://www.darpa.mil/work-with-us/additional-baa.

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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 https://wawf.eb.mil, 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

Communication via e-mail is preferred.

Points of Contact
The BAA Coordinator for this effort may be reached at:
PREEMPT@darpa.mil
DARPA/BTO
ATTN: HR001118S0017
675 North Randolph Street
Arlington, VA 22203-2114

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

8. Other Information

DARPA will host a Proposers Day in support of the PREEMPT program on **January 30, 2018**, at the Executive Conference Center in Arlington, VA. The purpose is to provide potential

proposers with information on the PREEMPT 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 PREEMPT 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. The event will be webcast for those who would like to participate remotely.

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, https://events.sa-meetings.com/PREEMPTProposersDay.

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, relevant publications, and a slide or poster to summarize the proposer's interests.

Participants are required to register no later than **January 23, 2018**, for physical attendance, and **January 26, 2018**, for the webcast. 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: DARPA-SN-18-18@darpa.mil.

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 25 of HR001118S0017. 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 **HR001118S0017** 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:

3. 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, 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/Consultants
   ○ **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]

   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 all 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 all 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:

11. Does your cost proposal include copies of consultant agreements, if available?
    ○ **YES** ○ **NO** **Appears on Page(s)** [Type text]

    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:

14. Does your proposal include a response regarding Organizational Conflicts of Interest?

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

If reply is "No", please explain:

15. Does your proposal include a completed Data Rights Assertions table/certification?

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

If reply is "No", please explain:

The purpose of Amendment 1 to HR001118S0017, the PREventing EMerging Pathogenic Threats (PREEMPT) Broad Agency Announcement, is to revise Section 4.2.4 as described below:

4.2.4 Submission Information

For Full Proposals Requesting Cooperative Agreements:

Proposers requesting cooperative agreements must submit proposals through one of the following methods: (1) electronic upload per the instructions at https://www.grants.gov/applicants/apply-for-grants.html; or (2) hard-copy mailed directly to DARPA. 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 Grants.gov do not submit hard-copy proposals in addition to the Grants.gov electronic submission.

Submissions: Proposers must submit the three forms listed below.

> SF 424 Research and Related (R&R) Application for Federal Assistance, available on the Grants.gov website at https://apply07.grants.gov/apply/forms/sample/RR_SF424_2_0-V2.0.pdf. *This form must be completed and submitted.*
>
> To evaluate compliance with Title IX of the Education Amendments of 1972 (20 U.S.C. A§ 1681 Et. Seq.), the Department of Defense is using the two forms below to collect certain demographic and career information to be able to assess the success rates of women who are proposed for key roles in applications in science, technology, engineering, or mathematics disciplines. Detailed instructions for each form are available on Grants.gov.
>
> Research and Related Senior/Key Person Profile (Expanded), available on the Grants.gov website at https://apply07.grants.gov/apply/forms/sample/RR_KeyPersonExpanded_2_0-V2.0.pdf. *This form must be completed and submitted.*
>
> Research and Related Personal Data, available on the Grants.gov website at https://apply07.grants.gov/apply/forms/sample/RR_PersonalData_1_2-V1.2.pdf. *Each applicant must complete the name field of this form, however, provision of the demographic information is voluntary. Regardless of whether the demographic fields are completed or not, this form must be submitted with at least the applicant's name completed.*

Grants.gov Submissions: 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 http://www.darpa.mil/work-with-us/additional-baa.

Hard-copy Submissions: Proposers electing to submit 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.

Executive Summary: Proposal Title

Organization; PI Name

CONCEPT

Provide graphic.

APPROACH

Describe new ideas.

IMPACT

Describe need and problem being addressed.

Describe goal.

	Phase I	Phase II	Total
Proposed	$-	$-	$-

☐ Human Use/☐ Animal Use

CONTEXT

Describe existing approaches; compare to state of the art.

Schedule: Proposal Title

Organization Name; PI Name

Tasks/Deliverables/Milestones/Timetable (e.g., Gantt Chart)

View Burden Statement

OMB Number: 4040-0001
Expiration Date: 12/31/2022

APPLICATION FOR FEDERAL ASSISTANCE

SF 424 (R&R)

3. DATE RECEIVED BY STATE	State Application Identifier

1. TYPE OF SUBMISSION

☐ Pre-application ☐ Application ☐ Changed/Corrected Application

2. DATE SUBMITTED

Applicant Identifier

4. a. Federal Identifier

b. Agency Routing Identifier

c. Previous Grants.gov Tracking ID

5. APPLICANT INFORMATION

Organizational DUNS:

Legal Name:

Department: Division:

Street1:

Street2:

City: County / Parish:

State: Province:

Country: USA: UNITED STATES ZIP / Postal Code:

Person to be contacted on matters involving this application

Prefix: First Name: Middle Name:

Last Name: Suffix:

Position/Title:

Street1:

Street2:

City: County / Parish:

State: Province:

Country: USA: UNITED STATES ZIP / Postal Code:

Phone Number: Fax Number:

Email:

6. EMPLOYER IDENTIFICATION *(EIN) or (TIN):*

7. TYPE OF APPLICANT: Please select one of the following

Other (Specify):

Small Business Organization Type ☐ Women Owned ☐ Socially and Economically Disadvantaged

8. TYPE OF APPLICATION:

☐ New ☐ Resubmission

☐ Renewal ☐ Continuation ☐ Revision

If Revision, mark appropriate box(es).

☐ A. Increase Award ☐ B. Decrease Award ☐ C. Increase Duration ☐ D. Decrease Duration

☐ E. Other (specify):

Is this application being submitted to other agencies? Yes No What other Agencies?

9. NAME OF FEDERAL AGENCY:

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:

TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:

12. PROPOSED PROJECT:

Start Date Ending Date

13. CONGRESSIONAL DISTRICT OF APPLICANT

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix: First Name: Middle Name:
Last Name: Suffix:
Position/Title:
Organization Name:
Department: Division:
Street1:
Street2:
City: County / Parish:
State: Province:
Country: USA: UNITED STATES ZIP / Postal Code:
Phone Number: Fax Number:
Email:

15. ESTIMATED PROJECT FUNDING

a. Total Federal Funds Requested
b. Total Non-Federal Funds
c. Total Federal & Non-Federal Funds
d. Estimated Program Income

16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?

a. YES ☐ THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:
DATE:

b. NO ☐ PROGRAM IS NOT COVERED BY E.O. 12372; OR
☐ PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

17. By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances * and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious. or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001)

☐ I agree

**The list of certifications and assurances, or an Internet site where you may obtain this list, is contained in the announcement or agency specific instructions.*

18. SFLLL (Disclosure of Lobbying Activities) or other Explanatory Documentation

Add Attachment | Delete Attachment | View Attachment

19. Authorized Representative

Prefix: First Name: Middle Name:
Last Name: Suffix:
Position/Title:
Organization:
Department: Division:
Street1:
Street2:
City: County / Parish:
State: Province:
Country: USA: UNITED STATES ZIP / Postal Code:
Phone Number: Fax Number:
Email:

Signature of Authorized Representative **Date Signed**

20. Pre-application Add Attachment | Delete Attachment | View Attachment

21. Cover Letter Attachment Add Attachment | Delete Attachment | View Attachment

VIEW GRANT OPPORTUNITY

HR001118S0017
PREventing EMerging Pathogenic Threats
Department of Defense
DARPA - Biological Technologies Office

« Back | Link

Apply Subscribe

SYNOPSIS | VERSION HISTORY | RELATED DOCUMENTS | **PACKAGE**

Print Package List

There are currently no Opportunity Packages available for submission through Grants.gov. Refer to Synopsis tab and Related Documents tab for additional information about this Opportunity.

Below are **CLOSED** Opportunity Package(s) no longer available for this Funding Opportunity:

Closed Opportunity Package(s) for this Funding Opportunity:

CFDA	Competition ID	Competition Title	Opportunity Package ID	Opening Date	Closing Date	Actions
12.910			PKG00237724	01/19/2018	03/27/2018	View