INNOVATIVE SOLUTIONS OPENING

FOR

SYSTEMATIC TARGETING OF MICROPLASTICS

(STOMP)

HEALTH SCIENCE FUTURES

ARPA-H-SOL-26-152

April 2nd, 2026

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Innovative Solutions Opening (ISO) Overview Information

FEDERAL AGENCY: Advanced Research Projects Agency for Health (ARPA-H)

PROGRAM TITLE: Systematic Targeting of MicroPlastics (STOMP)

ANNOUNCEMENT TYPE: ISO Solicitation Number: ARPA-H-SOL-26-152

ISO CONTACT: https://solutions.arpa-h.gov/Ask-A-Question/

ANTICIPATED AWARDS AND TYPE(S): Multiple Other Transaction (OTs) Agreements

DATES: (All times listed are Eastern Time)

PROPOSERS' DAY: April 22nd, 8:30 AM – 5:00 PM

QUESTIONS & ANSWERS (Q&A) DUE DATE: May 4th, 5:00 PM

SOLUTION SUMMARIES (TA1, TA2) DUE DATE: May 6th, 5:00 PM

FULL PROPOSALS (TA1, TA2) DUE DATE: June 22nd, 5:00 PM

Where to Submit:

Solution Summaries: https://solutions.arpa-h.gov/Submit-Solution/

Proposals: https://solutions.arpa-h.gov/Submit-Proposal/

Questions : https://solutions.arpa-h.gov/Ask-A-Question/

ISO PURPOSE

ARPA-H seeks proposals from all eligible entities (see Section 3 for eligibility information) to accomplish the STOMP Program goals as described in this solicitation package. Ultimately, ARPA-H intends to negotiate OT Agreements with the team(s) whose proposal(s) are most advantageous to the Government.

ARPA-H is not currently soliciting Technical Area 3 (TA3) proposals. TA3 proposals submitted alongside TA1 and TA2 will not be reviewed. A Special Notice and amended ISO for TA3 will be released prior to completion of initial TA1 and TA2 Phase 1 studies.

ISO QUESTIONS AND ANSWERS

All questions regarding this ISO must be submitted to https://solutions.arpa-h.gov/Ask-A-Question/. ARPA-H will not respond directly to email inquiries but will post Q&As to the ARPA-H ISO Website and SAM.gov on an on-going basis. All questions must be in English and must include the name, email address, and telephone number of a point of contact, and must be submitted by the Q&A deadline posted with other dates identified in Section 1, Innovative Solutions Opening Overview Information. Proposers submitting questions to individual Government team members (e.g., PM) should not expect a response. ARPA-H will attempt to answer questions via FAQ updates in a timely manner. Questions submitted after the due date may not be answered. Further, duplicative questions may be combined and rephrased to streamline responses.

PROPOSERS' DAY

ARPA-H will host a Proposers' Day in support of the Technical Areas 1 and 2 of the STOMP Program as described in Special Notice ARPA-H-SN-26-150. The purpose is to provide potential proposers with information on the STOMP program, promote additional discussions, and encourage teaming and networking.

ARPA-H will host a Proposers' Day in support of Technical Area 3 later, and a separate Special Notice will be published announcing the TA3 Proposers' Day event.

Interested parties are not required to attend Proposers' Day in order to propose to Technical Areas 1 and 2, and materials formally presented during Proposers' Day will be posted to the ARPA-H Program Website along with a recording of the proceedings. One-on-one meetings between the program manager and prospective applicants will not occur.

ARPA-H will not reimburse potential proposers for participation at Proposers' Day (or time and effort related to submissions in response to this ISO).

1 INTRODUCTION

A growing body of evidence suggests that micro- and nano-plastics (MNPs) harm human health. The Systematic Targeting Of MicroPlastics (STOMP) program seeks to better quantify MNPs in humans; understand the mechanisms of MNP deposition; and, ultimately, improve human health by developing means to limit uptake and remove MNPs from the body.

1.1 Background

Plastics are ubiquitous in modern life, and the amount of plastic in the world increases every year[1]. With plastic comes plastic waste, and with plastic waste, microscopic plastics, or microplastics. Microplastics (also referred to in this ISO as MNPs (micro- and nano-plastics)) are fragments nanometers to microns in size, which are often degradation products of plastic materials. They can also be manufactured deliberately (e.g. microbeads in exfoliating products) or be generated inadvertently. MNPs vary in size, shape, and chemical composition. They can be fibers, spheres or fragments of various shapes; their chemical composition includes polyethylene (PE), polypropylene (PP), polystyrene (PS), polyethylene terephthalate (PET), polyvinyl chloride (PVC), polyurethane (PU), polycarbonate (PC), styrene-butadiene rubber (SBR), nylon 6 (N6), and others. They usually contain additives such as stabilizers, plasticizers, and pigments; indeed, the characteristics listed here are far from exhaustive.

MNPs are found in food and drinks, soil and air, indoors and outdoors. They enter the body mainly through ingestion and inhalation, and are deposited in most, if not all, tissues and organs. MNPs have been found in blood[2], brain[3], colon[4], liver[5] and others. Recently, the scientific community has investigated the impact of MNPs on human health, with many studies showing *correlation* between presence of MNPs and deleterious health effects. For example, 80-fold higher levels of MNPs were found in human femoral artery atherosclerotic plaques as compared with healthy, non-diseased human carotid arteries; in particular, three- and eight-fold higher PP and PU levels respectively were associated

[1] OECD (2022), Global Plastics Outlook: Economic Drivers, Environmental Impacts and Policy Options, OECD Publishing, Paris, https://doi.org/10.1787/de747aef-en.
[2] Heather A et al, Discovery and quantification of plastic particle pollution in human blood, Environment International, 163, 2022,107199, ISSN 0160-4120,https://doi.org/10.1016/j.envint.2022.107199.
[3] Nihart AJ et al, Bioaccumulation of microplastics in decedent human brains. Nat Med. 2025 Apr;31(4):1114-1119. doi: 10.1038/s41591-024-03453-1. Epub 2025 Feb 3. Erratum in: Nat Med. 2025 Apr;31(4):1367. doi: 10.1038/s41591-025-03675-x. PMID: 39901044; PMCID: PMC12003191.
[4] Ibrahim YS et al, Detection of microplastics in human colectomy specimens. JGH Open. 2020 Nov 21;5(1):116-121. doi: 10.1002/jgh3.12457. PMID: 33490620; PMCID: PMC7812470.
[5] Horvatits et al, Microplastics detected in cirrhotic liver tissue. EBioMedicine. 2022 Aug;82:104147. doi: 10.1016/j.ebiom.2022.104147. Epub 2022 Jul 11. PMID: 35835713; PMCID: PMC9386716.

with chronic limb-threatening ischemia compared to less severe disease[6]. Higher MNP levels were found in tissue obtained from cervical cancer patients compared to normal controls, and the highest accumulation was noted in patients with advanced disease[7]. MNPs were also detected in livers of liver cirrhosis patients, but not in the livers of subjects without liver disease[8]. Correlation, however, does not demonstrate causation, but causation is difficult to prove in humans. Exposure studies in animals, however, demonstrate that MNP exposure *causes* harm. Mice exposed to polystyrene nanoplastics exhibited learning and memory impairments compared to normal controls[9]; MNPs induced cardiovascular toxicity and led to atherosclerotic plaque formation in mice fed a PS-spiked diet[10]. Acute exposure to MNPs induced changes in animal behavior and inflammation[11]; ingestion of MNPs was shown to promote inflammation and tumorigenesis in the mouse colon[12]. The examples listed above represent only a small fraction of those documented in the literature.

Despite this concerning evidence, questions about MNP-related harm remain. Transit at systemic and cellular scales is not clear: how do MNPs get into organ systems? How do they get into cells? Where do they accumulate within cells? Is there an innate removal mechanism, or an equilibrium between the blood and organ levels? Toxicity mechanisms are only now beginning to be elucidated: which biochemical pathways do MNPs dysregulate, and how? How do MNPs dysregulate the microbiome? How do MNPs disrupt tissue structure and function? Furthermore, it is still not clear which MNPs are most harmful, at what dose, and why. Is it the size, shape, or chemical composition—or all the above?

There are many reasons why these questions remain unanswered. First, measuring MNPs in biological tissue is very challenging. Existing technologies require intensive sample preparation, data analysis, and/or imaging workflows that can take hours to days, with limited standardization across laboratories. No single analytical technique can determine

[6] Massie PL et al, Micro- and nanoplastics are elevated in femoral atherosclerotic plaques compared with undiseased arteries. JVS Vasc Sci. 2025 Aug 28;6:100393. doi: 10.1016/j.jvssci.2025.100393. PMID: 41069702; PMCID: PMC12506576.
[7] Xu H et al, Microplastic changes during the development of cervical cancer and its effects on the metabolomic profiles of cancer tissues. J Hazard Mater. 2025 Feb 5;483:136656. doi: 10.1016/j.jhazmat.2024.136656. Epub 2024 Nov 26. PMID: 39603134.
[8] Horvatits T et al, Microplastics detected in cirrhotic liver tissue. EBioMedicine. 2022 Aug;82:104147. doi: 10.1016/j.ebiom.2022.104147. Epub 2022 Jul 11. PMID: 35835713; PMCID: PMC9386716.
[9] Sun M et al, Polystyrene nanoplastics induced learning and memory impairments in mice by damaging the glymphatic system. Ecotoxicol Environ Saf. 2024 Oct 1;284:116874. doi: 10.1016/j.ecoenv.2024.116874. Epub 2024 Aug 16. PMID: 39153278.
[10] Wang B et al, Long-Chain Acyl Carnitines Aggravate Polystyrene Nanoplastics-Induced Atherosclerosis by Upregulating MARCO. Adv Sci (Weinh). 2023 Jul;10(19):e2205876. doi: 10.1002/advs.202205876. Epub 2023 May 5. PMID: 37144527; PMCID: PMC10323628.
[11] Gaspar L, et al, Acute Exposure to Microplastics Induced Changes in Behavior and Inflammation in Young and Old Mice. Int J Mol Sci. 2023 Aug 1;24(15):12308. doi: 10.3390/ijms241512308. PMID: 37569681; PMCID: PMC10418951.
[12] Djouina M et al. Ingestion of a human-relevant mixture of environmentally sourced microplastics promotes inflammation and tumorigenesis in the mouse colon. Environ Pollut. 2026 Feb 9;395:127794. doi: 10.1016/j.envpol.2026.127794. Epub ahead of print. PMID: 41672396.

MNP particle mass, count, size, and chemical composition simultaneously, nor is there a standard workflow for labeling and tracking MNPs *in vivo*. Furthermore, the biological matrix— the complex mixture of proteins, salts, lipids, and other materials that comprise a biological sample— interferes significantly with measurement. Notably, under pyrolysis-gas chromatography-mass spectrometry (Py-GC-MS), lipids and some types of polymers break down into similar hydrocarbons[13], complicating data analysis; and for Stimulated Raman Spectroscopy (SRS), spectra from the biological matrix require disentangling by bespoke statistical and machine learning pipelines. These are problems that need to be addressed in order to develop a gold standard quantification method. In addition, experiments are often performed with animals exposed to varying, and sometimes unreasonably high, MNP levels, which do not recapitulate human exposure. Last, but not least, there are no good MNP reference materials enabling scientists to perform experiments that can be directly compared to each other. Polystyrene spheres are used in most studies, as they are one of the few commercially available solutions, even though it is generally agreed upon that this is not a good model of human exposure. Fibers and irregular fragments may produce stronger biological effects than spheres, because they are retained longer and cause more direct membrane damage, while also potentially triggering stronger innate immune activation[14].

1.2 Program Goals and Timeline

STOMP has three technical areas (TAs) and is structured as two 30-month Phases. Note that not all program activities span the full period of performance. TA3 proposals are not being solicited in this ISO; a subsequent solicitation for TA3 proposals will be released later in Phase 1. All information pertaining to TA3 in this ISO is meant to frame and provide context for the technologies solicited for now in TA1 and TA2.

<table>
<tr><td colspan="5">Phase 1</td><td colspan="5">Phase 2</td></tr>
<tr><td>6</td><td>12</td><td>18</td><td>24</td><td>30</td><td>36</td><td>42</td><td>48</td><td>54</td><td>60</td></tr>
<tr><td colspan="10">TA1: Measurement</td></tr>
<tr><td colspan="6">TA2: Understanding</td><td colspan="4"></td></tr>
<tr><td colspan="5"></td><td>Apply to TA3</td><td colspan="4">TA3: Removal</td></tr>
</table>

Figure 1: STOMP program structure by phase and month.

[13] Rauert, Cassandra, et al. "Extraction and Pyrolysis-GC-MS analysis of polyethylene in samples with medium to high lipid content." *Journal of Environmental Exposure Assessment* 1.2 (2022): N-A

[14] Choi D et al. In vitro toxicity from a physical perspective of polyethylene microplastics based on statistical curvature change analysis. Sci Total Environ. 2021 Jan 15;752:142242. doi: 10.1016/j.scitotenv.2020.142242. Epub 2020 Sep 7. PMID: 33207500.

TA1: Measurement

Without reliable detection, characterization, and quantification of MNPs, it is not possible to understand where MNPs are in the human body (and why/how), nor is it possible to develop and/or validate removal methods. STOMP TA1 performers will:

a. Develop a best-in-class research-grade MNP measurement technique, including sample preparation, measurement, and analysis methodology, to be used by STOMP teams to quantify data and validate results *starting before the end of the first year of the STOMP period of performance*. Because of the accelerated timeline, performers will likely develop techniques that overcome challenges with existing instrumentation, but novel approaches are welcomed with justification.
b. Develop a novel, clinically-focused measurement system capable of quantifying MNPs in human biospecimens quickly, cheaply, and at scale. This may involve the development of entirely new devices and modalities for rapid MNP detection and quantification.
c. Conduct a study in human participants, acquiring paired MNP data from biological fluids and tissue samples, to determine if tissue MNP concentration correlates with the MNP concentration in the more accessible biological fluids.

TA2: Understanding

To target the most harmful MNPs in the most effective way, it is necessary to understand which MNPs drive adverse health effects, and how. TA2 performers will:

a. Conduct acute and chronic MNP exposure studies in animal models to assess bioaccumulation and impacts to system- and organ-level harm.
b. Prioritize organ systems with the greatest MNP accumulation and indications of harm to investigate and define trafficking and accumulation mechanisms to key organ systems.
c. Determine cell types and cellular pathways impacted by MNPs, including outlining when intracellular internalization occurs and mechanisms of toxicity (oxidative stress, inflammation, protein dyshomeostasis, etc.).
d. Identify any innate mechanisms for MNP removal and degradation.

TA3: Removal

The ultimate aim of STOMP is to develop methods to remove toxic MNPs from the human body to improve health outcomes. Although TA3 solutions will not be solicited until closer to Month 24, it is anticipated that TA3 performers will develop and preclinically validate technologies that prevent further accumulation and reduce MNP burden.

2 THE PROGRAM

2.1 Technical Area 1: Measurement

For Technical Area 1 of STOMP, performers will perform three activities:

TA1.1: Develop a best-in-class, standardized, validated measurement methodology for MNP in animal and human samples, for immediate (Month 9) use during STOMP. Measurements must be provided as a service to other STOMP TA1 and TA2 performers; alternatively, assistance must be provided, so that they can replicate the optimal methodology in their own labs.

TA1.2: Develop a novel, fast, cheap, and easy-to-use system to quantify MNPs from clinical human samples at scale. While TA1.1 may extend existing technology, TA1.2 will likely involve significant technological development to reach the ambitious goal of MNP quantification for less than $50 in less than 15 minutes. The final method may lack the precision of the research-grade TA1.1 measurements but will still provide a quantitative measurement of patient MNP burden.

TA1.3: Conduct a study evaluating the correlation between MNP content in biopsy/excised tissues and bodily fluids. To determine if bodily fluid MNP levels are a valid reporter for MNPs deposition in tissues, STOMP TA1 performers will use TA1.1 measurement methods to conduct a study of clinically obtained tissue (surgical, biopsy, etc.) and bodily fluids and determine the level of correlation.

TA1 performers must address TA1.1, TA1.2, and TA1.3; teaming is likely necessary as the three goals require different approaches and expertise.

As described in Section 2.5, samples of MNPs with known composition and size distribution will be provided to TA1 performers to establish common references. Performers may develop and use their own MNP samples, but these will come in addition to the ARPA-H provided materials.

The table below illustrates the timeline for TA1 activities. Milestones are presented in more detail in the following subsections.

TA1 Activities	Year 1				Year 2				Year 3				Year 4				Year 5			
Month after award	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60

TA1.1: Best-in-class research quantification	Method dev. and validation	Sample analysis for TA2 and TA3 performers		
TA1.2: Clinical assay development	Prototype 1	Prototype 2	Preclinical device/assay	Premarket FDA submission
TA1.3: Biofluids and tissue study	IRB submission and approval	Clinical study and data analysis		

Figure 1: Notional schedule for TA1 activities. Deviation from this schedule must be described and justified in the proposals.

2.1.1 Technical Area 1.1: Best-in-class MNP Quantification Method

MNP quantification in biological samples pushes the limits of modern instrumentation and methodologies. Biological matrix hydrocarbons generate similar spectra to polymers; non-specific binding confounds attempts at fluorescent labeling; and small signal-to-noise ratios make data processing difficult. Technical Area 1 requires performers to overcome these challenges to create a best-in-class approach that will be used by the STOMP program starting in Month 9, and that will be disseminated to the broader scientific community to benefit MNP research.

Given the aggressive timeline, methodology for research-grade MNP quantification developed under TA1.1 will likely extend and enhance existing instrumentation and sample preparation methodology. It is expected that teams will already have completed significant work on this capability at time of proposal submission, but may need to improve, standardize, and document workflow. Pyrolysis gas chromatography mass spectrometry (Py-GC-MS), Stimulated Raman Spectroscopy (SRS) or flow cytometry (with correspondingly high-performance labeling strategy) may be proposed, with strategies to ameliorate current challenges. Other methods will be considered with justification[15]. Techniques must quantify, at the minimum, mass and chemical composition, or number of particles and chemical composition. Proposers must describe measures taken to avoid interference and contamination from environmental MNPs.

TA1 performers may be asked to provide measurement services to TA2 and TA3 groups, and/or assist them in deploying the best-in-class methodology with their own instruments. The exact number of samples to be processed for other performers, or extent of help to be

[15] Zhao, Jian, et al. "Detection and characterization of microplastics and nanoplastics in biological samples." *Nature Reviews Bioengineering* (2025): 1-15.

provided to other teams, along with associated costs, will be finalized in the negotiations prior to award (See General Program Requirements).

TA1.1: Best-in-Class Quantification Method	
Phase 1: Months 1-30	
Month 1	Establish preliminary methodology • Protocol to minimize MNP contamination established and validated. Controls show <10% of measured MNP signal relative to lowest experimental dose in three independent replicates
Month 3	Demonstrate initial setup: • Water-based samples • Intra-assay Coefficient of Variation (CV) <25% across ten replicates • Quantify mass or number of particles 500 nm – 1 µm • Identify chemical composition of four - six different polymer types • Characterize limit of detection/quantification
Month 9	Demonstrate best-in class method: • Sample preparation methods for blood and tissue, including quantification of purification efficiency • Intra-assay Coefficient of Variation < 10% across ten replicates • Quantify mass or number of particles 100 nm – 1 µm • Identify chemical composition of eight - ten different polymer types • Characterize limit of detection/quantification • Dissemination of full documentation to all STOMP teams
Month 12	Submit best-in-class method for publication
Month 12-30	TA1 performers will use the best-in-class method to analyze samples from TA2 performers as needed and update the methodology if further optimization becomes possible.
Phase 2: Months 30-60	
Month 30-60	TA1 performers will use the best-in-class method to analyze samples from TA3 performers as needed and update the methodology if further optimization becomes possible.

Figure 3: TA1.1 metrics

2.1.2 Technical Area 1.2: Clinical Quantification Method

Existing MNP measurement methods are currently intended for research, not for clinical use. The goal of TA1.2 is to develop a measurement system capable of rapidly and cheaply

quantifying MNPs in relevant human tissue at scale. This clinical system complements STOMP's goal of clinically removing MNPs from the human body; in the future, if patients undergo the removal treatment, their MNP levels will need to be measured before and after.

The final clinical assay must take less than 15 min/sample (not including sample prep), and cost less than $50/sample. It must measure, at minimum, total particle count *and* chemical composition, or mass *and* chemical composition of relevant 200 nm – 1 μm MNPs in biological samples. The system, including the data analysis, must be designed to be operated by technicians with minimal advanced training required.

It is anticipated that to meet STOMP requirements for the clinical system, significant instrumentation and/or methods development and innovation will be required. The development of the clinical system will constitute the majority of TA1 activity after the first year.

TA1.2: Clinical Quantification Method	
Phase 1: Months 1-30	
Month 6	Establish requirements for clinical system
Month 12	First prototype system: • Simple biological media such as saliva, or biomimetic analogue • Intra-assay coefficient of variation (CV) ≤ 30% across ten replicates • Particle count and/or mass error ± 30% • Detects particles from 500 nm – 1 μm • Identify chemical composition of at least three MNP types • 3 hr/sample
Month 24	Second prototype system: • Biological fluid, including blood or tissue sample • Intra-assay CV ≤ 25% across ten replicates • Particle count and/or mass error ± 25% • Detects particles from 200 nm – 1 μm • Identify chemical composition of at least five MNP types • 1 hr/sample
	Determine FDA regulatory pathway
Month 30	Initiate FDA pre-submission process
Phase 2: Months 30-60	

Month 48	Clinical system: • Biological fluid (including blood) or tissue sample • Intra-assay CV ≤ 10% across ten replicates • Particle count and/or mass error ± 10% • Detects particles from 200 nm – 1 µm • Characterization of particle size distribution and detection down to 50 µm is desired but not required. • Identify chemical composition of at least seven MNP types • 15 min/sample
Month 60	Validate in 100 relevant human samples
	Premarket submission to FDA

Figure 4: TA1.2 metrics; Note that not all milestones may apply to all measurement methods; depending on the method selected, adaptation of these milestones may occur in the award negotiation process.

2.1.3 Technical Area 1.3: Biofluids and Tissue Correlation Study

The main purpose of TA1.3 is to clinically validate the correlation (if any) between non-invasively collected bodily fluids and tissue MNP levels. This relationship will inform the final implementation of the clinical system developed under TA1.2. If biofluid MNP levels can be used as a proxy for tissue levels, TA1.2 devices will likely use biofluid samples. If biofluid MNP levels do not correlate well to tissue levels, TA1.2 assays will have to focus on relevant, and accessible, tissues.

Performers must enroll at least 100 subjects (or provide power analysis and justification for proposed sample size) in the study and collect two bodily fluids (urine, blood, etc.) and one type of tissue (surgical, biopsy, etc.), at the minimum. At least 3 geographically distinct clinical sites are desired, as well as a broad distribution of participant demographics, professional occupations, and other attributes, to reflect the variety in MNP exposure types and levels. Proposals may include other approaches to address heterogeneity in MNP exposure with rationale.

ARPA-H does not mandate a specific study design or tissue type; one possible choice is colon biopsies. Colonoscopies are commonly performed outpatient procedures, and the recently suggested correlation between MNP presence and the increasing rate of colon cancers[16] make colon biopsies a meaningful target. Regardless of tissue type proposed, the applicability to the clinical system should be considered and justified, addressing whether it would be practical to take a similar sample to measure MNP levels in patients.

[16] Djouina M, et al, Ingestion of a human-relevant mixture of environmentally sourced microplastics promotes inflammation and tumorigenesis in the mouse colon. Environ Pollut. 2026 Feb 9;395:127794. doi: 10.1016/j.envpol.2026.127794. Epub ahead of print. PMID: 41672396.

Including means to decrease blood MNP levels (e.g., through apheresis) in the study design may also be considered.

TA1.3: Biofluids and Tissue Correlation study	
Phase 1: Months 1-30	
3	IRB submission
9	Initiate clinical study using TA1.1 best-in-class quantification methods
24	Complete clinical study with MNP quantification from two or more bodily fluids (blood, urine, etc.) and tissue from 100 subjects
Phase 2: Months 30-60	
TA1.3 has no further activities in Phase 2.	

Figure 5: TA1.3 metrics

2.2 Technical Area 2: Understanding

Today, understanding of the mechanisms through which MNPs are taken up, and either excreted, eliminated or stored is sorely lacking. While it is currently generally understood that MNPs larger than 1 μm get excreted, smaller particles tend to accumulate in the human body, particularly in fat-rich regions including the brain, the testes, plaques, etc. An understanding of this accumulation process, its contributors, and the health impacts (TA2) will lead to better specifications and solutions for MNP removal (TA3).

TA2 will first address health effects at the whole-body level to understand systemic-level changes when animals are exposed to different MNPs, then impacts at the organ system level, and lastly effects at the level of individual cells.

Figure 6: TA2 activities should focus broadly on establishing bioaccumulation and adverse health effects across the whole organism, then assessing impacts at the organ system level, and finally determining impacts to individual cells.

Cumulatively, TA2 performers will address the "who, what, where, when, why and how" of MNP adverse health effects:

Who: Which MNP polymer types, sizes, and morphologies bioaccumulate and yield systemic negative health impacts?

What: What harm(s) do MNPs cause across scale: whole body, organ systems, and individual cells?

Where: Where do MNPs bioaccumulate in the body? What organ systems? Which cell types?

When: Are there different types or degrees of harm depending on acute or chronic exposures? On what timescale are MNPs naturally excreted and are there innate clearance pathways that could be leveraged for TA3 solutions?

Why: Why are MNPs harmful to cells and organ systems? Which cellular and organ system processes do they disrupt?

How: How do MNPs reach their organ and cellular targets? Are there specific pathways that we might reverse for MNP removal or prevention of accumulation?

TA2 has two separate components and proposers must address both:

TA2.1: Define whole body and organ system bioaccumulation and health impacts of MNPs. TA2.1 will complete both acute and chronic exposure studies in small animals to understand the health impact of MNPs, outlining at the whole body and organ level the:

Who - Which MNPs accumulate across organ systems in the body and induce disease-relevant phenotypes (polymer types, sizes and morphologies)?

What - What harms do MNPs cause at the whole organism and organ level?

Where - To which organ systems do MNPs traffic? Do levels of MNPs in the blood correspond to organ levels of MNPs?

When - Are harmful effects distinct depending on acute or chronic exposures? What is the half-life of MNPs in the body?

TA2.2: Establish the mechanistic framework for MNP trafficking and toxicity at the cellular and subcellular level. TA2.2 will complete studies at the cellular and molecular level to understand in depth how negative health affects manifest and potential cellular processes to leverage for TA3 solutions, specifically answering:

What - What toxic effects do MNPs cause at the cellular level?

Where - Which cell types are specifically affected by MNPs?

When - On what timescale are MNPs naturally degraded or cleared, and do innate clearance pathways exist that can be leveraged for TA3 solutions?

Why - Why are MNPs harmful to cells? Which pathways are disrupted when exposed to MNPs?

How - How do MNPs reach their organ and cellular targets? Are there pathways that we might reverse for TA3 solutions?

To establish a common baseline, solutions for TA2 must utilize, at the minimum, samples of MNPs with known composition and size distribution provided by ARPA-H to performers. Proposers may choose to include alternative MNP varieties beyond these common reference materials; the type and manner of generating or sourcing alternative MNPs must be described in the proposal.

<table>
<tr><th>TA2 activities</th><th colspan="4">Year 1</th><th colspan="4">Year 2</th><th colspan="4">Year 3</th><th>Years 4-5</th></tr>
<tr><td></td><td>3</td><td>6</td><td>9</td><td>12</td><td>15</td><td>18</td><td>21</td><td>24</td><td>27</td><td>30</td><td>33</td><td>36</td><td></td></tr>
<tr><td>TA2.1: Bioaccumulation and health impacts</td><td rowspan="2">Method dev. and validation</td><td colspan="4">Acute exposure studies for all MNPs</td><td colspan="4">Complete system- and organ-level measures of adverse health impacts</td><td colspan="4"></td><td rowspan="2"></td></tr>
<tr><td colspan="8">Chronic exposure studies for all MNPs</td><td colspan="4"></td></tr>
<tr><td>TA2.2: Mechanistic framework for MNP trafficking and toxicity</td><td colspan="8">Define MNP internalization and toxicity mechanism in vitro</td><td colspan="4">Validate MNP internalization and toxicity mechanism in vivo</td></tr>
</table>

Figure 7: Notional schedule for TA2 activities. Deviation from this schedule must be described and justified in the proposals. TA2 activities end after Month 36.

2.2.1 Technical Area 2.1: Bioaccumulation and health impacts

To best prioritize MNP removal—which MNPs, and from which organ systems— we need a better understanding of how MNP size, shape, chemical composition, and intake route (inhalation vs ingestion) affect their accumulation throughout the body. Unfortunately, no general approaches currently exist to provide this information. TA2.1 entails a comprehensive study, identifying sites of bioaccumulation for the most relevant plastic types, at relevant doses, with relevant geometries and a characterization of adverse health effects. The results of this study will inform TA2.2 mechanistic studies and TA3 removal strategies (See General Program Requirements on Data Sharing).

Animal models must be exposed to relevant types of MNPs (with relevant geometries) through ingestion and inhalation and evaluated for MNP biodistribution using whole body imaging approaches. Proposers may elect to use different labeling and/or imaging techniques for different MNPs. Justification for proposed labeling and imaging techniques must be provided, along with applicability to longitudinal imaging of live animals, special resolution, and the potential for multiplexing to track more than one MNP type

simultaneously. Novel methods must be supported by preliminary data justifying viability—particularly for MNPs smaller than 1μm. For positron emission tomography (PET)-based imaging, long-lived radioisotopes must be prioritized.

To address key system and organ-level questions, performers must:

1. Assess accumulation of MNPs across organ systems and across provided polymer types, sizes and morphologies at both acute and chronic exposures.
2. Assess system- and organ-level metrics of harm after MNP exposure by investigating:
    a. Systemic changes to body weight, temperature, behavior, etc.
    b. Functional, structural, and molecular damage to specific organs (i.e., histological changes, serum enzymes, inflammation, organ weights, molecular markers)
3. Assess levels of MNPs in the blood and a minimum of three impacted organ systems to determine whether blood MNP levels correspond to organ levels.
4. Define the half-life of MNPs in the body following chronic exposure

As described in Section 2.5, ARPA-H will provide reference materials for common types of MNPs. Performers will have to develop their own labeling methodology; if the method cannot be applied to existing samples, performers will have to generate common MNPs similar to those provided by ARPA-H.
Proposers shall describe and justify methods to assess and minimize MNP contamination arising from the laboratory environment (e.g. PPE, water sources, and research equipment).

TA2.1: Bioaccumulation and health impacts	
Phase 1: Months 1-30	
Month 1	Establish preliminary methodology • Protocol to minimize MNP contamination established and validated. Controls show <10% of measured MNP signal relative to lowest experimental dose in three independent replicates
Month 3	Labeling and imaging technique demonstrated and characterized for initial set of MNPs Exposure concentrations verified within 20% of target dose range Chronic and acute exposure imaging studies initiated
Month 6	Acute exposure imaging study characterizing differential effects of initial set of MNPs' tissue distribution in animal model

	Labeling and imaging technique demonstrated and characterized for second set of MNPs
Month 9	Acute exposure imaging study characterizing differential effects of second set of MNPs' tissue distribution in animal model Labeling and imaging technique demonstrated and characterized for third set of MNPs
Month 12	Acute exposure imaging study characterizing differential effects of third set of MNPs' tissue distribution in animal model
Month 24	Chronic exposure imaging studies completed for all six MNPs
Month 30	Assess system- and organ-level metrics of toxicity and harm by investigating: • Systemic changes to body weight, temperature, behavior, etc. • Functional, structural, and molecular damage to specific organs (i.e., histological changes, serum enzymes, inflammation, organ weights, molecular markers) Define the half-life of MNPs over at least five time points in blood across a >6-month time-course and at least three tissue types based on organ distribution, as well as the organ-to-blood ratio.
Phase 2: Months 30-60	
TA2.1 has no further activities in Phase 2	

Figure 8: TA2.1 metrics

2.2.2 Technical Area 2.2: Establish Mechanistic Framework for MNP Toxicity

A growing body of evidence demonstrates that MNPs accumulate in the body, interfere with bodily systems and correlate with disease states. However, we still do not have a clear understanding of when and how accumulation of MNPs becomes a toxic disease state requiring intervention. Lack of biologically relevant MNP standards, difficulties with quantitative measurements, and heterogeneity in research methods present barriers to consensus. Interdisciplinary research has also been lacking, as cell biology findings from ecology and toxicology researchers focused on marine systems have not been applied to human health.

To address the current gaps in understanding that hinder the ability to develop methods to remove or degrade MNPs from the human body, proposers must assess health impacts of acute and chronic exposure to various MNP types across biological scale – beginning with whole organism responses, zooming in on organ systems, and finally addressing cell type-specific impacts. Performers must:

1. Determine the cellular pathways impacted by prioritized MNPs identified in TA2.1 and mechanisms of toxicity (oxidative stress, inflammation, protein dyshomeostasis, etc.)
2. Determine which cell types and organelles are affected by MNPs
3. Identify innate mechanisms for MNP removal and degradation.
4. Investigate and define trafficking and accumulation mechanisms to key organ systems for prioritized MNP types identified in TA2.1 (endocytosis, M cell uptake, etc.)
5. Define the half-life of prioritized MNPs

Solutions may leverage technology developed in TA1 and advances in gold-standard absorption, distribution, metabolism, and excretion (ADME) methods, high resolution imaging and labeling of MNPs (e.g., stable and radioisotope labeling, near-IR dyes, pH-sensitive dyes, etc.), and multi-omic techniques, as well as advances in high-throughput model systems for human biology (organoids, 3D cell culture systems, etc.) and computational techniques. Proposers should validate *in vitro* results in a small animal model.

Proposals must include rationale for *in vitro* (cell lines, organoid models, etc.) and *in vivo* models used for cellular trafficking, internalization and toxicity studies.

Proposers shall define their methods for down-selecting critical organ systems for TA2.2 mechanistic studies based on TA2.1 results (See General Program Requirements on Data Sharing). Proposers may pre-define quantitative metrics for prioritization based on organ function (i.e., >10% reduction in kidney function) or methods to establish a ranking system (e.g. ranking by toxicity/accumulation, approaches that balance both systems that are highly susceptible and those highly resistant to health effects, etc.).

Proposers must apply three biologically relevant doses of the top three prioritized polymer compositions based on TA2.1 studies for *in vivo* studies. Proposers must describe and justify exposure routes (inhalation or ingestion), including verification of exposure concentration, homogeneity of exposure, and biological relevance of exposure route (presence of polymer type in airborne particles versus food and water sources). Proposers must measure both acute and long-term exposure to adequately assess toxicity as appropriate based on model system.

TA2.2: Establish mechanistic framework for MNP toxicity

Phase 1: Months 1-30

Months 3-12	Define MNP trafficking and accumulation mechanism hypothesis for prioritized MNP types identified in TA2.1 • Validated translocation assays established for models of three or more prioritized organ systems (proposer shall define metrics for prioritization or methods for establishing a ranking system based on TA2.1 results) • One or more translocation mechanism identified for three MNP types in three organ-relevant boundary models (i.e., blood-brain barrier, gut epithelium, placenta, etc.) confirmed via two independent methods (e.g. inhibition of and/or activation of pathways)
Months 6-18	Identify impacted cell types and organelles for internalized MNPs, cellular pathways implicated in MNP toxicity, and innate mechanisms for MNP removal and degradation using *in vitro* models, • One or more differentially affected cell type identified per organ system ($p<0.05$) for three polymer types using at least six doses • Three or more key mechanisms of toxicity (e.g. oxidative stress, inflammation, protein dyshomeostasis, etc.) identified for hypothesis testing based on results across organ systems (multi-omics, high resolution imaging, etc.) • Mechanisms of toxicity validated and quantified using two independent assay methods • Dose-response relationship established for three MNP types in three or more cell types • Intracellular versus extracellular MNP fraction quantified and organelle localization identified using two independent methods (e.g. high-resolution imaging, flow cytometry, etc.) in three or more cell types at a biologically relevant dose • Define the half-life of three polymer types over at least 5 time-points in three or more models for different organ systems/cellular environments • Identify one or more innate degradation mechanisms (if present) for three MNP types in three models of organ systems
Months 19-24	Validate MNP trafficking and toxicity mechanisms *in vivo* with at least one biologically relevant route of exposure (inhalation or ingestion). Further down-select polymer characteristics to prioritize for TA3 (dose, composition, morphology, size) • Validate primary translocation route for at least one polymer type. Modulation of translocation mechanism significantly reduces target organ accumulation • Validate differentially affected cell types for at least two organ systems for at least one polymer type with at least three biologically relevant doses • Validate toxicity mechanisms *in vivo* for at least one prioritized polymer type at three biologically relevant doses over three timepoints (acute, medium and long-term exposure) • Deliver initial results for TA3 proposer teams informing MNP removal strategies (24 months)

Months 19-30	• Validate innate mechanisms for prioritized polymer type removal and degradation *in vivo*
Phase 2: Months 30-60	
Months 31-36	Complete toxicity and translocation studies outlined in Phase 1 for all three prioritized polymer types. Replicate results with variation across independent experiments of <20%. Validate hypotheses and refine methods in conjunction with TA3 teams to inform therapeutic strategies and testing (See General Program Requirements on Data Sharing) • Outline standard operating procedures for core assays for TA3 performer teams
Months 36-60	No further TA2.2 activities occur from months 36-60.

Figure 9: TA2.2 metrics

2.3 Technical Area 3: Removal

ARPA-H is not currently accepting proposals for TA3. TA3 proposals submitted alongside TA1 and TA2 will not be reviewed. A Special Notice and amended ISO will be released upon completion of initial TA1 and TA2 Phase 1 studies.

To our knowledge, the only existing technique to remove MNPs from the human body is based on apheresis, a dialysis-like technique that separates and filters blood outside the body. This type of treatment is not FDA-approved, and insufficient evidence has been offered to support its efficacy[17]. It is unclear if these treatments reduce levels of MNP in blood —and even if they do, it is unclear if this translates to reduced levels in organs. Furthermore, these treatments are expensive, invasive and time-consuming.

The development and clinical translation of MNP removal methods have been limited by a lack of measurement methods to characterize the MNP burden and validate removal, and a lack of mechanistic understanding of how these MNPs transit, localize, and cause harm in the human body. By leveraging well-characterized, biologically relevant reference materials, TA1 detection technologies, and TA2 knowledge of MNP trafficking and bioaccumulation (See General Program Requirements on Data Sharing), TA3 performers will develop technologies to minimize accumulation, remove and/or degrade MNPs from living human patients in a clinically impactful fashion: fast, cheaply and safely.

[17] E.g., Bornstein et. al. 2025 and Scholkmann & Gatti 2022

Environmental bioremediation research and understanding of MNP degradation and clearance in other species provide possible avenues for translation to human therapeutics. Multiple bacteria and fungus species are innately capable of degrading plastics in the environment, with some species able to degrade large-scale quantities of plastics on the order of weeks to months[18]. Several researchers focused on bioremediation have demonstrated the ability to engineer microorganisms to degrade MNPs and hydrolyze polymers into neutral degradation products safe for aquatic ecosystems[19]. While such techniques have not been validated in living systems, MNP degradation and clearance occurring in other species *in vivo* suggest potential pathways that could be leveraged and translated to human biology. For example, waxworms are capable of digesting large quantities of MNPs, demonstrated to occur via initial degradation via enzymes in the saliva[20], followed by further breakdown by bacteria in the gut[21]. Mice treated with bacterial strains demonstrating a high degree of binding to polystyrene particles exhibited increased excretion of particles, demonstrating increased clearance in a vertebrate system[22].

TA3 solutions may: 1) degrade MNPs into non-toxic byproducts; 2) expel MNPs from cells and tissues for excretion by reversing internalization and trafficking pathways; or 3) prevent MNPs from invading tissues in the first place.

Solutions may include *in vivo* delivery of clearance agents to intended anatomical locations. Biomimicry could serve as the guide by adapting existing organismal capabilities to break down plastics in the human body, or it may be possible to use genetically engineered enzyme-secreting bacteria in a controlled fashion. Beyond this, novel drugs that promote the removal of MNPs (analogous to chelation) or use the body's own immune system may be viable.

TA3 metrics below are notional and will be revised when soliciting for TA3 proposals.

TA3: Removing MNPs from the Body
Phase 2: Months 30-60

[18] Gao R, et al. A marine fungus Alternaria alternata FB1 efficiently degrades polyethylene. J Hazardous Materials. 2022 June 431: 128617. doi: 10.1016/j.jhazmat.2022.128617.
[19] Tian J, et al. Discovery and remodeling of Vibrio natriegens as a microbial platform for efficient formic acid biorefinery. Nat Commun. 2023 Nov 27;14(1):7758. doi: 10.1038/s41467-023-43631-2. PMID: 38012202; PMCID: PMC10682008.
[20] Sanluis-Verdes, A., et al. Wax worm saliva and the enzymes therein are the key to polyethylene degradation by Galleria mellonella. Nat Commun. 2022; 13(1): 5568.
[21] Ali SS, et al. Biodegradability of polyethylene by efficient bacteria from the guts of plastic-eating waxworms and investigation of its degradation mechanism. J Hazard Mater. 2023 Feb 5;443(Pt B):130287. doi: 10.1016/j.jhazmat.2022.130287. Epub 2022 Oct 31. PMID: 36335905.
[22] Teng X et al. Novel probiotics adsorbing and excreting microplastics in vivo show potential gut health benefits. Front. Microbiol. 2025; 15:1522794. doi: 10.3389/fmicb.2024.1522794

Months 30-36	Demonstrate proof of concept (e.g. MNP digestion) with 50% efficacy for one polymer type *in vitro* (cell lines, organoid models, etc.)
Months 36-48	Refine MNP removal candidate and demonstrate 50% efficacy for removal, degradation or prevention of uptake to key organ systems of one polymer type *in vivo* Demonstrate 50% efficacy for two additional polymer types *in vitro* Initiate safety screening studies Determine the regulatory pathway
Months 48-60	Refine MNP removal candidate and demonstrate 80% efficacy for removal, degradation or prevention of uptake to key organ systems of one polymer type *in vivo* Demonstrate 50% efficacy for two additional polymer types *in vivo*

Figure 10: Notional TA3 metrics

2.4 Independent Verification and Validation

Qualified US Government personnel will serve as advisers to ARPA-H during Phase 1 of the STOMP program (months 1-30). They will be part of program review meetings and provide independent verification and validation of the measurement methods developed by TA1 performers.

2.5 Microplastics Samples

ARPA-H is aware that no reference standards currently exist for MNPs. ARPA-H will arrange to provide awardees with relevant MNP materials; these will have various shapes, with sizes including sub-micron.

Throughout the program, STOMP performers should expect to receive annual supplies of at least six MNP polymer types, tentatively polyethylene (PE), polyethylene terephthalate (PET), polypropylene (PP), polystyrene (PS), polyvinyl chloride (PVC), and Nylon 6 (N6). The first two MNP polymer types will be provided at program initiation, with two more MNP polymer types provided three months later and the final two MNP polymer types provided at six months. Efforts will also be made to supply STOMP performers with sub-micron fragments of polyurethane (PU), styrene butadiene rubber (SBR) and Nylon 66 (N66).

TA1 and TA2 proposers may choose to include alternative MNP polymer types beyond these common reference materials; the type and manner of generating or sourcing alternative MNPs should be described in the proposal.

2.6 Special STOMP Requirements

1. **Participation in multiple proposals** – Only a small fraction of solution summaries are expected to be encouraged for full proposal submissions. At the solution summary stage, proposing entities may submit separate solution summaries for TA1 and TA2 as the prime. However, at the full proposal stage, proposing entities may only submit **one** full proposal (either TA1 or TA2) as the prime. Proposing entities may be part of multiple full proposal submissions as subcontractors. In this context a 'proposing entity' is an academic lab, small business, or unit of a large business. Different labs with different PIs from the same academic institution are considered separate proposing entities.
2. **Data Sharing** - All participants must commit to sharing preliminary data with all the other STOMP awardees—even within the same TA—twice a year (once virtual, once in person), regardless of whether data was made public by that time or not. All participants will commit to not sharing findings outside of the confines of STOMP prior to publication.
3. **Program Meetings** - All proposals must include travel to Washington, DC for program meetings once a year, 2 nights, 2 participants per project, starting with a kickoff at the beginning of year 1.
4. **Contamination Mitigation** - All proposers shall describe and quantify methods to assess and minimize MNP contamination arising from the laboratory environment (e.g. PPE, water sources, and research equipment). Methods to mitigate MNP contamination must be validated by Month 1 for both TA1 and TA2.
5. **MNP Dosing** - The kickoff meeting will include external stakeholders and members from the scientific community, at which all teams will discuss reasonable doses for ingestion and inhalation.
6. **Study Justifications** - Proposers are expected to provide detailed information on intended experimental methods, including justification of study sizes. Proposers should clearly articulate methods and discuss strengths and mitigation plans for technical risks.
7. **TA3 Proposers' Day** - The third program meeting, at the beginning of year 3 of the period of performance, will also be the TA3 Proposers' Day. All data will be presented at that time; participants external to STOMP will sign a non-disclosure agreement certifying that they may only use the data for the sole purpose of proposing to TA3.

8. **Cross-Program Sample Analysis** - Depending on the exact composition of other teams, TA1 performers may be asked to perform sample analysis for other teams. The exact number of samples to be analyzed for other teams and associated costs will be established during award negotiations.
9. **Separate Budgets** - The budgets for the sub-Technical Areas (TA1.1: gold standard measurement, TA1.2: clinical test, and TA1.3: clinical study for TA1; and TA2.1: Imaging MNP Bioaccumulation and TA2.2: Establish mechanistic framework for MNP toxicity for TA2) must be designated separately by the teams applying to TA1 and TA2. See Appendix A for instructions for the Solution Summary and Appendix B for instructions for the Full Proposal. ARPA-H reserves the right to select only certain components of TA1 or TA2 (e.g. TA1.1 but not TA1.2 or TA1.3) submitted by the same performer team, and pair performers to complete TA1 or TA2 together. Performers must commit to working with the partners selected by ARPA-H, in the case that only certain sub-areas are selected from one team's proposal.
10. **Associate Performer Agreement** - The STOMP management team may request that performers work together to meet program goals by bringing together the highest performing teams. To accomplish this close collaboration, performers will be asked to execute an Associate Performer Agreement with other performers. Each Associate Performer Agreement will address data-sharing, technology transfer, and personnel management and communication when working collaboratively with other program performers in each phase of the program. The data sharing will be composed of and limited to the data utilized and developed in the completion of the TAs. The requirements of the Associate Performer Agreement will be a term within the award.

2.7 Commercialization Requirements

STOMP TA1 clinical assays/systems and TA3 removal methods are intended to be used by the American public. To increase the likelihood of successful transition, TA1 and TA3 proposers must address commercialization throughout the program, starting at the proposal stage.

As a reminder, **TA3 is not being solicited at this time**; a separate solicitation will be issued that reiterates TA3-relevant commercialization metrics.

Commercialization Requirements	
Commercialization Plan (1 page total)	TA1 and TA3 proposers must include a draft commercialization plan for the clinical system/assay designed in TA1 or the

	removal system designed in TA3, as applicable, as part of the full proposal. TA1: Revisions to the commercialization plan must be submitted by Month 24 with established commercial relationship (see below). TA3: Revisions to the commercialization plan must be submitted by Month 48 with established commercial relationship (see below).
Translation Advisory Board	To ensure transition of STOMP technologies and assets, performer teams must convene a Translation Advisory Board. The Board must consist of > three members and can consist of expertise from a university Office of Technology Transfer, venture capital, consultants, or industry partners. Proposals must provide intended Board member area(s) of expertise, and the Board should be finalized by Month 6. The Board must meet at least annually and should help advise the Commercial Partnership.
Commercial Partnerships	TA1 and TA3 Teams are strongly encouraged to demonstrate an active partnership with a designated commercial entity at the time of proposal. The active partnership must be supported by documentation, including but not limited to a Letter of Interest, Memorandum of Understanding, or term sheet. If a team is a consortium of all non-commercial entities, a clear commercialization plan addressing the challenges of this approach must be proposed. TA1 team progression to Phase 2 will require establishing a relationship with a commercial entity, including but not limited to a Letter of interest, Memorandum of understanding, or term sheet by Month 24.

Figure 11: Commercialization Requirements

3 ELIGIBILITY INFORMATION

3.1 Eligible Proposers

All responsible sources capable of satisfying the Government's needs may submit a proposal to this ISO. Specifically, universities, non-profit organizations, small businesses and other than small businesses are eligible and encouraged to propose to this ISO.

3.1.1 Prohibition of Performer Participation from Federally Funded Research and Development Centers (FFRDCs) and other Government Entities

ARPA-H is primarily interested in responses to this solicitation from commercial performers, academia, non-profit organizations, etc. In certain circumstances, FFRDCs and Government Entities may have unique capabilities that are not available to proposing teams through any other resource. Accordingly, the following principles will apply to this solicitation.

- FFRDCs and Government entities, including federal Government employees, are not permitted to respond to this solicitation as a prime or sub-performer on a proposed performer team.
- If an FFRDC or Government entity has a unique research idea that is within the technology scope of this solicitation that they would like considered for funding; OR, if an FFRDC or Government entity, including a federal Government employee, is interested in working directly with the Government team supporting the research described by this solicitation, contact STOMP@arpa-h.gov.
- If a potential prime performer believes an FFRDC has a unique capability without which their solution is unachievable, they may provide documentation as part of their Solution Summary submission demonstrating they have exhausted all other options. ARPA-H will consider the documentation to determine if inclusion of the FFRDC is necessary for the Solution.

3.1.2 Current Professional Support

Individuals/entities currently providing contracted support services to ARPA-H have an organizational conflict of interest (OCI) that cannot be mitigated and thus are ineligible for award.

3.1.3 Non-U.S. Entities

ARPA-H will prioritize awards to entities (organization and/or individuals) that will conduct funded work in the United States. Non-U.S. entities may participate to the extent that such participants comply with any necessary non-disclosure agreements, security regulations, export control laws, and other governing statutes applicable under the circumstances. In accordance with these laws and regulations, in no case will awards be made to entities organized under the laws of a covered foreign country [as defined in section 119C of the National Security Act of 1947 (50 U.S.C. Ch 44 § 3059)]; a foreign entity of concern meeting any of the criteria in section 10638(3) of the CHIPS and Science Act of 2022; an individual that is party to a malign foreign talent recruitment program, as defined in Section 10638(4) of the CHIPS and Science Act of 2022; or entities suspended or debarred from business with the Government.

3.2 System for Award Management (SAM)

All proposers must have an active registration in SAM.gov for their proposal to be found conforming. Proposers must maintain an active registration in SAM.gov with current information at all times during which a proposal is under consideration or a current award from ARPA-H is held. Information on SAM.gov registration is available at SAM.gov.

NOTE: New registrations as well as renewals may take more than 14 business days to process in SAM.gov. SAM.gov is independent of ARPA-H and thus ARPA-H representatives have no influence over processing timeframes.

Information related to updates to this ISO can be found on the SAM.gov listing along with ancillary material to support proposal submission. ARPA-H cannot provide technical support for software issues encountered while using these materials. If you believe there is an error in the content of these materials, please email STOMP@arpa-h.gov.

4 SUBMISSION PROCESS

4.1 Submission Process Overview

Submissions for STOMP are as follows:

- **Step 1:** Submit Solution Summary (Proposers are encouraged or discouraged to move to Step 2).
- **Step 2:** Submit Full Proposals (Proposers may submit full proposals, regardless of whether encouraged or discouraged in Step 1).

4.2 Solution Summary Submissions

Solution Summary submissions are **required** and are due by the date listed in the ISO Summary Information Section on page 4. Solution summaries received after this date will not be reviewed. See APPENDIX A: SOLUTION SUMMARY TEMPLATE for the required Solution Summary format. Separate submissions are required for TA1 and TA2.

4.3 Full Proposal Submissions

Full proposal submissions are due by the date listed in the ISO Summary Information Section on page 4. See APPENDIX B: FULL PROPOSAL CONTENT AND INSTRUCTIONS for the **required** Full Proposal format, which includes four (4) Volumes: Volume I, Technical and Management Proposal; Volume II, Cost Proposal; Volume III, Draft OT Response; and Volume IV, Administrative and National Policy Requirements. Separate submissions are required for TA1 and TA2.

4.4 Submission Information

Non-conforming submissions that do not follow ISO instructions may be rejected without further review at any stage of the process.

All submissions in response to this solicitation must be written in English and must be consistent with the content and formatting requirements of APPENDIX A: SOLUTION SUMMARY TEMPLATE, and APPENDIX B: FULL PROPOSAL CONTENT AND INSTRUCTIONS.

Proposers are responsible for submitting all written submissions via the ARPA-H Solution Submission Portal and ensuring receipt by the date and time specified in the ISO. No other method of submission is permitted.

Registration is required to submit via the ARPA-H Solution Submission Portal and registration may take several business days to process. Plan to register well in advance of the solution summary submission deadline as late submissions resulting from delays with registration may not be accepted or considered. Issues with account access or other account issues should be reported to STOMP@arpa-h.gov.

4.5 Proprietary Information

Proposers are responsible for identifying proprietary information in any submissions. Submissions containing proprietary information must have the cover page and each page containing such information clearly marked with a label such as “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. Neither should other government-specific

document designations be used (e.g., "Controlled Unclassified Information").

ARPA-H is responsible for handling submissions in accordance with applicable federal law, including the Freedom of Information Act (FOIA).

5 SUBMISSION REVIEW AND EVALUATION PROCESSES

5.1 Conforming Proposals

Conforming proposals contain all requirements detailed in this ISO. Full Proposals and/or Solution Summaries that fail to include required information may be deemed non-conforming and may be removed from further consideration and/or rejected without further review. A proposal may be deemed non-conforming under this ISO if it fails to meet one or more of the following solicitation requirements:

- The proposed concept is applicable to the STOMP program.
- The proposers meet the eligibility requirements.
- The submission meets the submission requirements.
- The submission meets the content and formatting requirements in the attached instructions.
- The submission is received by the designated deadline date.
- The proposer's concept has not already received funding or been selected for award negotiations for another funding opportunity (whether from ARPA-H or another Government agency).

Proposers will be notified of non-conforming determinations via email.

Please note that ARPA-H may reject as non-conforming proposals that it determines are duplicative of previously submitted solution summaries and proposals under this or other ARPA-H solicitations.

Prior to submission deadlines, errors in submitted materials may be corrected via resubmission to the Submission Portal, provided an email is sent to STOMP@arpa-h.gov documenting this action and its intent. After the submission deadline, the most recently received conforming proposal version will be reviewed.

5.2 Solution Summary Review Process

ARPA-H will review and respond to all proposers submitting solution summaries. Solution Summaries will be evaluated using the same three evaluation criteria as the full proposals (see Section 5.4 for full details). Potential proposers will be provided with feedback on whether ARPA-H is interested in the proposed solution/concept. At a minimum, the response will indicate whether a proposer is encouraged or discouraged from submitting a proposal. Although potential proposers may submit a proposal regardless of the feedback provided in response to a solution summary, prospective proposers are reminded that ARPA-H review practices result in many times more encouraged solution summaries than can ultimately be funded. ARPA-H solution summary feedback is provided to ensure that potential proposers are making an informed decision on the investment of time and resources toward a full proposal. Feedback will be provided to the administrative and technical points of contact noted on the solution summary cover page.

5.3 Proposal Review Process

ARPA-H will conduct a scientific and technical review of each conforming full proposal, evaluating proposals on how well the submission meets the criteria stated in this ISO. At a minimum, proposers will be provided with notification of the Government's decision on whether the proposal was selected for negotiation of an award. Notification of the Government's decision will be provided to the primary technical point of contact included in the solutions tool.

5.4 Evaluation Criteria for Proposals

All proposals will be evaluated using the following evaluation criteria, listed in descending order of importance.

5.4.1 Criteria 1: Overall Scientific and Technical Merit

The proposed technical approach is innovative, feasible, and complete. Task descriptions and associated technical elements provided are complete and in a logical sequence with all proposed deliverables clearly defined such that an outcome that achieves the goal can be expected as a result of the award. The proposal identifies major technical risks and planned mitigation efforts are clearly defined and feasible. In addition, the evaluation may take into consideration the extent to which the proposed intellectual property (IP) rights structure and software components will potentially impact the ability to commercialize the technology.

5.4.2 Criteria 2: Proposer's Capabilities and/or Related Experience

The proposed technical team has the expertise and experience to accomplish the proposed tasks; the proposer's prior experience in similar efforts clearly demonstrates an ability to deliver products that meet the proposed technical performance within the proposed budget and schedule; the proposed team has the expertise to manage the cost and schedule and; similar efforts completed/ongoing by the proposer in this area are fully described, including identification of other Government entities (see Section 3.1.1).

In terms of capability, the Government may assess the Volume I biosketches provided for the performer team members including the Principal Investigator, Project Manager, and any other key personnel on the project team as requested by ARPA-H.

5.4.3 Criteria 3: Assessment of Proposed Cost/Price

All proposals will be evaluated to determine the reasonableness or value of the estimated price/cost proposed to accomplish the work in the Preliminary Task Description Document (TDD). Analysis may be performed to ensure proposed costs are realistic for the proposed scientific and technical approach and capabilities/related experience, accurately reflect the technical goals and objectives of the solicitation, are consistent with the proposer's TDD, and reflect a sufficient understanding of the costs and effort needed to successfully accomplish the proposed technical approach. The costs for the prime proposer and proposed sub-awardees must be 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 including the basis for the estimates).

It is expected the effort will leverage all available relevant prior research to obtain the maximum benefit from the available funding. For efforts with a likelihood of commercial application, appropriate resource sharing may be a positive factor in the evaluation.

NOTE: Proposers are encouraged to propose the best technical solution. For example, proposers are discouraged from proposing low-risk ideas with minimum uncertainty or to staff the proposed effort with junior personnel to be more appealing from a budget perspective. ARPA-H seeks novel solutions that are reflective of the level of effort and risk proposed.

5.5 Handling Competition-Sensitive Information

It is the intent of ARPA-H to protect all proposals as competition sensitive information and to disclose their contents only for the purpose of evaluation, and only to screened personnel for authorized reasons, in accordance with applicable federal laws and regulations, including FOIA. Restrictive notices notwithstanding, submissions may be handled by ARPA-H support contractors during the evaluation process for administrative purposes and/or to assist with technical evaluation.

ARPA-H support contractors are expressly prohibited from performing ARPA-H-sponsored technical research and are bound by appropriate non-disclosure agreements. Input on technical aspects of a proposal may be solicited by ARPA-H from non-government consultants/experts who are strictly bound by appropriate non-disclosure requirements.

During the proposal and evaluation phase, proposers are expected to be detailed about their proposed approaches and technologies. Intent to protect sensitive information is not viewed as a mitigating circumstance for proposals lacking detail.

5.6 Evaluation and Award Disclaimers

The Government reserves the right to select for negotiation all, some, one, or none of the proposals received in response to this ISO. In the event the Government desires to award only portions of a proposal, negotiations will commence upon selection notification. The Government reserves the right to fund proposals with phases or options for continued work, as applicable.

The Government reserves the right to request any additional necessary documentation to support the negotiation and award process. The Government reserves the right to remove a proposal from award consideration should the parties fail to reach agreement on award terms, conditions, price, and/or if the proposer fails to provide requested additional information in a timely manner.

In all cases, the government Agreements Officer (AO) will have sole discretion to negotiate all terms and conditions with proposers. ARPA-H will apply publication or other restrictions, as necessary, if it is determined the research resulting from the proposed effort will present a high likelihood of disclosing sensitive information including Personally Identifiable Information (PII), Protected Health Information (PHI), financial records, proprietary data, any information marked Sensitive but Unclassified (SBU), etc. Any award resulting from such a determination will include a requirement for ARPA-H concurrence before publishing any information or results on the effort.

6 POLICY REQUIREMENTS AND MISCELLANEOUS OTHER INFORMATION

6.1 Controlled Unclassified Information (CUI) on Non-Federal Information Systems

Information on Controlled Unclassified Information (CUI) identification, marking, protection, and control is incorporated herein and can be found at 32 CFR § 2002.

6.2 Organizational Conflicts of Interest (OCI)

Proposers are required to identify and disclose all facts relevant to potential or actual OCIs involving the proposer's organization and any proposed team member (proposed subawardee). Although the FAR does not apply to OTs, ARPA-H requires OCIs be addressed in the same manner prescribed in FAR subpart 9.5. Regardless of whether the proposer has identified potential or actual OCIs under this section, the proposer is responsible for providing a disclosure with its proposal. If a potential or actual OCI has been identified, the disclosure must include the proposers', and as applicable, proposed team members' OCI mitigation plans. The OCI mitigation plan(s) 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 an 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. The disclosure and mitigation plan(s) do not count toward the page limit.

If the Government determines that the Proposer failed to fully disclose an OCI; or failed to provide the affirmation of ARPA-H support; 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.

6.2.1 Agency Supplemental OCI Policy

ARPA-H restricts Performers from concurrently providing professional support services, including Advisory and Assistance Services or similar contracted support services, in addition to performing as an R&D technical Performer. Therefore, the Proposer must affirm whether it or any proposed team member (proposed subawardee, etc.) is providing professional support services to any ARPA-H office(s) under: (1) a current award or subaward; or (2) a past award or subaward that ended within one calendar year prior to the proposal's submission date.

If any professional support services are or were provided to any ARPA-H office(s), the proposal must include:

- The name of the ARPA-H office receiving the support,
- The prime contract number, and
- Identification of proposed team member (including any proposed subawardee) providing the support.

6.2.2 Research Security Disclosures

Conforming full proposals selected for negotiation of a potential award will undergo a Research Security Review (RSR). Solution Summaries are not subjected to this process. The RSR involves a review of the Proposer's disclosures made as part of the Administrative & National Policy Requirements document, and a validation and comparison of those disclosures utilizing publicly available information and commercially available information tools. Section 10631 of the CHIPS and Science Act of 2022 prohibits federal research agencies, such as ARPA-H, from providing R&D awards in response to any proposal in which a covered individual is participating in a Malign Foreign Talent Recruitment Program (MFTRP). It also requires federal agencies to require recipient institutions to prohibit covered individuals participating in MFTRPs from working on projects supported by federal R&D awards.

In accordance with National Security Policy Memorandum 33, to receive federal funding, research organizations should identify and mitigate conflicts of commitment (COCs) and conflicts of interest (COIs). COCs and COIs involving foreign countries of concern (FCOCs), including the People's Republic of China, the Russian Federation, the Islamic Republic of Iran, and the Democratic People's Republic of Korea (also known as North Korea), will require risk mitigation plans. A research organization proposing in response to this ISO must provide research security disclosures as described in the Administrative & National Policy Requirements document and the Office of Science and Technology Policy-identified Common Forms. The Common Forms are required for all senior or key personnel.

After a proposal is selected for negotiations of a potential award, ARPA-H will conduct an RSR of each Proposer and its senior or key personnel. The RSR is not part of the ARPA-H scientific merit review process. The RSR reviews include assessments of potential risks associated with covered individuals' disclosed or undisclosed participation in MFTRPs, funding received from FCOCs, collaboration with FCOC entities (including researchers and research institutions that have been identified on various entity lists), foreign ownership control or influence with regard to FCOCs identified in proposals, and the pursuit of foreign patents stemming from U.S. government funded research prior to obtaining U.S. patent protections.

If ARPA-H determines the Proposer failed to provide all requisite research security disclosures or failed to reasonably provide information requested by ARPA-H to assist in evaluating the Proposer's disclosures and/or research security mitigations, ARPA-H may eliminate the proposal from award consideration. ARPA-H may also eliminate the proposal from award consideration if ARPA-H determines the Proposer did not or cannot properly mitigate research security-related risks.

The format for this submission can be found in VOLUME IV: ADMINISTRATIVE AND NATIONAL POLICY REQUIREMENTS.

6.3 Intellectual Property

Proposers must provide a good faith representation that the proposer either owns, possesses, or will come to own or possess the appropriate licensing rights to all IP that will be utilized for the proposed effort. ARPA-H strongly encourages IP rights to be aligned with open-source regimes. IP delivered to the Government should align with project or Program goals and be consistent with the level of government funding provided. Proposers should clearly and explicitly designate what proposer-team-owned IP will be leveraged in the solution. Plans for the use of this IP after the period of ARPA-H performance should be specified as well. Separately, the fate of IP developed during the ARPA-H period of performance should be clearly designated as well (e.g., open-source release, commercialization).

6.4 Data Sharing

Performers are expected to openly publish scientific discoveries made during the period of performance. Exceptions to this obligation may be made in accordance with circumstances noted in the August 25, 2022 OSTP Memo. Additionally, scientific data collected during the period of performance is to be made publicly available as well, barring the aforementioned exceptions.

For the STOMP program specifically, there is an expectation that substantial data sharing will occur, both across the various teams performing specific TAs (e.g., TA 1 teams) and across teams working on different TAs (See General Program Requirements).

6.5 Human Subjects Research

A proposal for funding that will involve engagement in human subjects research (HSR) (as defined in 45 CFR § 46) must provide documentation of one or more current *Assurance(s) of Compliance* with federal regulations for human subjects' protection, including at least a Department of Health and Human Services (HHS), Office of Human Research Protection Federal Wide Assurance. All HSR must be reviewed and approved by an Institutional Review Board (IRB), as applicable under 45 CFR § 46 and/or 21 CFR § 56. The entity's HSR protocol must include a detailed description of the research plan, study population, risks and benefits of study participation, recruitment and consent process, data collection, and data analysis. Recipients of ARPA-H funding must comply with all applicable laws, regulations, and policies for ARPA-H funded work. This includes, but is not limited to, laws, regulations, and policies regarding the conduct of HSR, such as the U.S. federal regulations protecting human subjects in research (e.g., 45 CFR § 46, 21 CFR § 50, § 56, § 312, § 812) and any other equivalent requirements of the applicable jurisdiction.

The informed consent document utilized in HSR funded by ARPA-H must comply with all applicable laws, regulations, and policies, including but not limited to U.S. federal regulations protecting human subjects in research (45 CFR § 46, and, as applicable, 21 CFR § 50). The protocol package submitted to the IRB must demonstrate completion of HSR training by all investigators and key personnel who will be involved in the design or conduct of the ARPA-H funded HSR. Funding cannot be used toward HSR until ALL approvals are granted.

6.6 Animal Subjects Research

All entities submitting a proposal for funding that will involve engagement in animal subjects research (award recipients performing research, experimentation, or testing involving the use of animals) shall comply with the laws, regulations, and policies on animal acquisition, transport, care, handling, and use as outlined in:

- 9 CFR parts 1–4, U.S. Department of Agriculture rules that implement the Animal Welfare Act of 1966, as amended, (7 U.S.C. § 2131-2159); and,
- Public Health Service Policy on Humane Care and Use of Laboratory Animals, which incorporates the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training," and "Guide for the Care and Use of Laboratory Animals" (8th Edition)."

Proposers must provide documentation of a current Animal Welfare Assurance (AWA) on file with the Office of Laboratory Animal Welfare (OLAW).

The Proposer must complete and submit the Vertebrate Animal Section OLAW Worksheet for all proposed research anticipating Animal Subject Research (ASR).

All Animal Use Research must undergo review and approval by the local Institutional Animal Care Use Committee (IACUC) prior to incurring any costs related to the animal use research. For all proposed research anticipating animal use, proposals should briefly describe plans for IACUC review and approval.

6.7 Electronic Invoicing and Payments

Performers will be required to register in, and submit invoices for payment through, the Payment Management Services (PMS) https://pms.psc.gov/.

6.8 Procurement of Synthetic Nucleic Acids or Benchtop Synthesizers

Beginning April 26, 2025, HHS funds may only be used to procure synthetic nucleic acids or benchtop nucleic acid synthesis equipment from sources adhering to the Office of Science and Technology Policy Framework for Nucleic Acid Synthesis Screening. HHS awardees are expected to adhere to the Office of Science and Technology Policy Framework for Nucleic Acid Synthesis Screening for HHS projects.

7 APPENDIX A: SOLUTION SUMMARY TEMPLATE

Solution Summary COVER LETTER
<TEAM LEAD ORGANIZATION LOGO (OPTIONAL)>

Innovative Solutions Opening	ARPA-H-SOL-26-152
Solution Summary Title	
Technical Area	
Team Lead Organization	
UEI (Unique Entity Identifier)	
Type of Organization	**Choose all that apply:** Large Business, Small Disadvantaged Business, Other Small Business, HBCU, MSI, Other Educational, or Other Nonprofit
Technical Point of Contact (POC)	Name: Mailing Address: Telephone: Email:
Administrative POC	Name: Mailing Address: Telephone: Email:
Total Basis of Estimate	Total: $
Place(s) of Performance	
Other Team Members (please indicate if they are team members or subawards/consultants)	Technical POC Name: Organization: Organization Type:

NOTE: All submissions must be written in English with font type NOT smaller than 12-point font (Arial or non-serif font). Smaller font may be used for figures, tables, and charts. All pages shall be formatted for printing on 8-1/2 by 11- inch paper. Margins must be 1-inch on all sides and page numbers should be included at the bottom of each page. Delete all formatting and content instructions prior to submission. Please do not generate solution summary text using generative AI. Solution summaries have a limit of four (4) pages. The cover page, key personnel table, BOE, and citations do not count towards the four (4)-page limit. If applying to both TA1 and TA2, separate submissions are required for TA1 and TA2.

CONCEPT SUMMARY

Clearly identify the applicable technical area for the proposed program project. Describe the solution concept with minimal jargon and explain how it addresses the applicable technical area.

INNOVATION AND IMPACT

Clearly identify the outcome(s) sought and/or the problem(s) to be solved with the proposed technology concept. Describe how the proposed effort represents an innovative and potentially revolutionary solution to the applicable program technical area. Explain how the proposed approach will go far beyond current existing capabilities. To the extent possible, provide quantitative metrics in a table that compares the proposed technology concept to current and emerging technologies which may include:

- A progression of increasingly complex technical challenges.
- State of the art / emerging technology "baseline".
- Aggressive metrics in for each year of the proposed project.
- Summary of specific outcomes from the proposed research.

PROPOSED WORK

Describe the final deliverable(s) for the project, key interim milestones, and the overall technical approach used to achieve project objectives. Discuss alternative approaches considered, if any, and why the proposed approach is most appropriate for the project objectives. Describe the background, theory, simulation, modeling, experimental data, or other sound engineering and scientific practices or principles that support the proposed approach. Provide specific examples of supporting data and/or appropriate citations to the scientific and technical literature. If relevant, identify adoption challenges to be overcome for the proposed technology to be successful. Describe why the proposed effort is a significant technical challenge and the key technical risks. At a minimum, the solution summary should address:

- Does the approach require one or more entirely new technical developments to succeed?
- How will technical risk be mitigated?
- What use cases, capabilities, or demonstrations will be featured?

TEAM ORGANIZATION AND CAPABILITIES

Indicate the roles and responsibilities of the organizations and key personnel that comprise the project team. Provide the name, position, and institution of each key team member and describe in 1-2 sentences the skills and experience they bring to the team.

Separately, please complete the below table for key personnel on a separate page of the solution summary. The table does not count towards the page limit but must not exceed one page.

Institution	Last Name	First Name	City	State	Country

BASIS OF ESTIMATE (BOE)

Please include a BOE of timeline and federal funds requested, as well as the total project cost including cost sharing, if applicable. The BOE should also include a breakdown of the work by direct labor (fully-burdened), labor hours, subcontracts, materials, equipment, other direct costs (e.g., travel), profit, cost sharing, and any other relevant costs. The below table may be used for this breakdown:

Categories	Amount
Direct Labor (fully burdened)	
Labor hours	
Subcontracts/Consultants	
Materials	
Equipment	
Travel	
Other Direct Costs	
Indirect Costs	
Total	
Cost Sharing (if applicable/appropriate)	

Additionally, please include a BOE by applicable sub-Technical Area:

Technical Area 1 Breakdown	Amount
TA1.1	
TA1.2	
TA1.3	
TA1 Total	

Technical Area 2 Breakdown	Amount
TA2.1	
TA2.2	
TA2 Total	

8 APPENDIX B: FULL PROPOSAL CONTENT AND INSTRUCTIONS

Proposers must have submitted a Solution Summary to be eligible to submit a full proposal.

A proposal will represent a consolidated effort in support of one technical area. Proposals shall consist of four (4) volumes:

1) Volume I, Technical and Management Proposal
2) Volume II, Cost Proposal
3) Volume III, Draft OT Response
4) Volume IV, Administrative and National Policy Requirements

The cost proposal will be provided both in PDF format (Cost Proposal Document) and Excel spreadsheet (Cost Proposal Excel sheet (i.e., line-item budget)). All PDFs must have searchable text (i.e., via CTRL-F). ARPA-H reserves the right to not evaluate a given proposal if the submitted package includes more or less than the four required volumes and the Excel cost spreadsheet(s), or if the text is not searchable.

The page limitation includes all figures, tables, and charts. All pages shall be formatted for printing on 8-1/2 by 11-inch paper. Margins must be 1 inch on all sides, sans serif font size should be no less than 11 pt (e.g., Arial, Calibri, Avenir Next LT Pro), and page numbers must be included at the bottom of each page. 10-point sans serif font may be used for figures, tables, and charts.

Documents must be clearly labeled with the ISO number, proposer organization, and proposal title/proposal short title (in the header of each page). Use the following Title Format: “Volume I_XYZ Institution”, “Volume II_XYZ Institution”, etc.

8.1 VOLUME I: TECHNICAL AND MANAGEMENT PROPOSAL

Volume I must be in .pdf format and must not exceed twenty-five (25) pages.

The page limit applies to sections A–G described below (Executive Summary (A), Background and Impact (B), Technical Plan (C), Risk Mitigation (D), Timeline (E), Commercialization (TA1 and TA3 only) (F), Capabilities/Management Plan (G)). The cover page and sections H–K below are not included in the page limit (Preliminary Task Description Document (TDD) (H), Bibliography (I), Biosketches (J), Letters of Support (K)). ARPA-H encourages conciseness to the maximum extent practicable for all sections. Please do not rehash the ISO material without providing explicit solutions for the challenges presented. Please do not generate proposal text using generative AI. Proposers are encouraged to submit proposals shorter than the page limit. No other supporting materials may be submitted for review.

A detailed description of the components that need to be included in Volume I is provided below:

Cover Page. The template for the cover page needs to be followed by all submitting teams.

<PRIME ORGANIZATION LOGO (OPTIONAL)>

ARPA-H ISO FOR SYSTEMATIC TARGETING OF MICROPLASTICS (STOMP)

VOLUME I: TECHNICAL AND MANAGEMENT

ISO#	ARPA-H-SOL-26-152
Proposal Title	
Technical Area	
Prime Proposer/Entity submitting proposal	
Unique Entity Identifier of prime proposer (UEI)	
Type of Organization	**Choose all that apply:** Large Business, Small Disadvantaged Business, Other Small Business, HBCU, MSI, Other Educational, or Other Nonprofit
Other Team Members (subawards and consultants), if any	Technical POC Name: Organization: Organization Type:
Technical Point of Contact (POC)	Name: Mailing Address: Telephone: Email:
Administrative POC	Name: Mailing Address: Telephone: Email:
Award Instrument Requested	Other Transaction Agreement
Total funds requested from ARPA-H	Total: $
Total cost share, if applicable	Cost share: $
Place(s) of Performance	
Proposal Submission Date	
Proposal Validity Period (minimum 180 days)	
Human Subjects Research (Yes/No)	
Animal Subjects Research (Yes/No)	

A. Executive Summary (do not exceed one page)

[Summarize the technical approach. Provide a description of the key technical challenges, a concise review of the technologies proposed to overcome these challenges and achieve the project's goal, and a clear statement of the novelty and uniqueness of the proposed work. The executive summary should capture 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?*
- *How will you do it? What is innovative in your approach?*
- *What are the key technical challenges in your approach, and how do you plan to overcome these?]*

B. Background and Impact (do not exceed one page)

[Detail the existing technical solutions, why they are not adequate, and how the proposed approach will overcome existing challenges. State who or what will be affected and what will be the impact if the work is successful. Use quantitative terms, detailing number of patients affected, cost savings, etc.]

C. Technical Plan

[This section is the centerpiece of the proposal and should succinctly summarize the innovative claims for the proposed research and clearly describe the proposed approach without using jargon]

(a) *Present a credible plan to achieve the project's goal. High-risk, high-reward projects are welcomed.*

(b) *Describe how the solution will achieve the Program-level and TA-specific requirements listed in the STOMP ISO.*

(c) *Outline and address technical challenges inherent in the approach and possible solutions for overcoming potential problems.*

(d) *Provide appropriate measurable milestones (quantitative where possible) at intermediate stages of the project to demonstrate progress; milestones should be clearly articulated and defined in time relative to the start of the project.*

(e) *Provide a description/narrative of the milestones, tasks, and the interrelationships among tasks. The task structure must be consistent with that in the Preliminary Task Description Document (TDD).]*

D. Risk Mitigation/Contingency Plans and Alternative Approaches

[Identify potential areas of risk (e.g., technical, managerial) and propose solutions that maximize the scientific and health impact, budget considerations, and timeliness of deliverables.]

E. Gantt Chart Timeline (do not exceed one page)

[Provide a detailed timeline in Gantt chart format]

F. Commercialization Plan (do not exceed one page; TA1 and TA3 only)

[Include names of prospective transition partners, identify potential bottlenecks and hurdles to commercialization, and describe solutions for market access, sustainability, and scaling.]

G. Capabilities/Management Plan

[Provide a summary of expertise of the proposed team, including any sub-awardees/consultants and key personnel who will be executing the work. Identify a technical lead for the project and provide a clear description of the team's organization including roles and responsibilities. Graphical representations are appreciated.]

H. Preliminary Task Description Document (TDD) – Not included in the page limit

[Provide a detailed task breakdown, citing specific tasks and their connection to the metrics, as applicable. Do not include proprietary information. See the Preliminary Task Description Document (TDD) Template provided on SAM.gov for content requirements and instructions.

I. Bibliography – Not included in the page limit

[Provide a brief bibliography with links to relevant papers, references, reports, etc.]

J. Biosketches – Not included in the page limit

[Provide key personnel biosketches using NSF Biographical Sketch Common Form format: https://www.nsf.gov/policies/nspm-33/common-form-biosketch. Only one document per key person should be provided, including the technical lead of the overall effort.]

K. Letters of Support – Not included in the page limit

[Provide letters of support from relevant parties, if desired.]

8.2 VOLUME II: COST PROPOSAL

There is no maximum page count for Volume II. The Cost Proposal shall be comprised of the editable Excel Cost Proposal spreadsheet, cost narrative (for both prime and subs) and associated supporting materials, which will be provided in a single PDF attachment led by a cover page as follows.

<PRIME ORGANIZATION LOGO (OPTIONAL)>

ARPA-H ISO FOR SYSTEMATIC TARGETING OF MICROPLASTICS (STOMP)

VOLUME II: COST PROPOSAL SUPPORTING MATERIALS

THE FOLLOWING MUST BE USED BY THE PRIME ORGANIZATION AND ALL SUBAWARDEES AT ANY TIER.

ISO#	ARPA-H-SOL-26-152
Proposal Title	
Technical Area	
Prime Proposer/Entity submitting proposal	
Unique Entity Identifier of prime proposer (UEI)	
Type of Organization	**Choose all that apply:** Large Business, Small Disadvantaged Business, Other Small Business, HBCU, MSI, Other Educational, or Other Nonprofit
Other Team Members (subawardees and consultants), if any	Technical POC Name: Organization: Organization Type:
Technical Point of Contact (POC)	Name: Mailing Address: Telephone: Email:
Administrative POC	Name: Mailing Address: Telephone: Email:
Award Instrument Requested	Other Transaction Agreement
Total funds requested from ARPA-H	$ Total: $ Phase 1: $ Phase 2
Total cost share, if applicable	Cost share: $
Total project cost	Total: $ Phase 1 + $ Phase 2 + $ Cost Share
Place(s) of Performance	
Proposal Submission Date	
Proposal Validity Period (minimum 180 days)	
Commercial and Government Entity (CAGE) Code	

A. Cost Proposal Spreadsheet: ARPA-H Standard Excel Cost Proposal Spreadsheet shall be provided with all full proposals. At the time of full proposal submission, an abbreviated materials-supplies cost proposal is acceptable, with estimates provided for broader categories of materials rather than individual line items (e.g. general lab supplies, antibodies, etc.). Selected proposals will be required to submit fully itemized materials-supplies with estimates at a later date. All tabs and tables in the cost proposal spreadsheet must be developed in an editable format with calculation formulas intact to allow traceability of the cost proposal. The cost proposal spreadsheet must be used by the prime organization and all subawardees at any tier. Subaward cost proposal spreadsheets may be submitted directly to the Government by the proposed subawardee via email to STOMP@arpa-h.gov. The excel workbook should contain cost broken down by Task and shall clearly identify which staff will be contributing to specific tasks. No staff salaries are permitted to exceed the NIH salary cap of $228,000. Concise descriptions shall be offered for all personnel.

Naming convention: Volume II_XYZ Institution

B. Cost and Pricing Data Support: In addition to using the cost proposal spreadsheet, the cost proposal must include a cost narrative and documentation to support the proposed price/budget. Supporting documentation must be in sufficient detail to substantiate the summary cost estimates and must include a description of the method used to estimate costs. For other direct costs (ODCs) (e.g., equipment, IT) with unit costs greater than $10,000, proposers must provide screenshots/quotes or other independent substantiation. For indirect costs, provide the most current indirect cost agreement (e.g., Colleges and Universities Rate Agreement, Forward Pricing Agreement, Provisional Billing Rates, etc.). Supporting materials shall be arranged by Institution and clearly marked to align with the cost proposal workbook (i.e. MAT001, EQU001, SUP001, etc.).

C. Subaward Proposals: The lead proposer is responsible for compiling and providing all subaward proposals with its proposal (or by ensuring direct submission to the Government from co-investigators as noted above). Subaward proposals must include Interdivisional Work Transfer Agreements or similar arrangements between the proposer and divisions within the same organization as the proposer. All proprietary subaward proposal documentation, prepared at the same level of detail as that required of the proposer's proposal and which cannot be uploaded with the proposer's full proposal, shall be provided to the Government either by the proposer or by the co-investigator when the proposal is submitted. Subaward proprietary proposals may be submitted directly to ARPA-H at STOMP@arpa-h.gov. Concise description shall be offered for all personnel.

Naming convention: Volume II_subrecipient_XYZ Institution

NOTE: vendor procurement need not be documented as though it were a subaward.

D. Value Analysis Supporting Information: Respondents to the ISO should include any additional information regarding value-added resources or conditions that are not immediately obvious in the Cost Proposal Spreadsheet or the Supporting Cost and Pricing Data section (e.g., intended intellectual property terms and conditions with perceived future value).

8.3 VOLUME III: DRAFT OT RESPONSE

An initial draft of the ARPA-H agreement for this effort has been made available on SAM.gov. The proposer must include a copy of the draft agreement with any redlines, comments, and/or proposed edits to ARPA-H as a part of the proposal package. If no redline, comments, and/or edits are proposed, the proposer must provide a written statement that there are no proposed changes. There is no page limit for this document.

The document must be in .pdf, .odx, .doc, or .docx format. Please use the following cover page for Volume III.

<PRIME ORGANIZATION LOGO (OPTIONAL)>

ARPA-H ISO FOR SYSTEMATIC TARGETING OF MICROPLASTICS (STOMP)

VOLUME III: DRAFT OT RESPONSE

ISO#	ARPA-H-SOL-26-152
Proposal Title	
Proposer Organization	
Technical Point of Contact (POC)	Name: Address: Telephone: Email:
Administrative POC	Name: Address: Telephone: Email:
Date of Proposal Submission	
Proposal Validity Period (minimum 180 days)	

8.4 VOLUME IV: ADMINISTRATIVE AND NATIONAL POLICY REQUIREMENTS

This Administrative & National Policy Requirements Document must be completed in full and included as part of the proposal submission. Other than the instructions in blue font, do not delete any portion of this document.

All pages must be formatted for printing on 8-1/2 by 11-inch paper with 1-inch margins and sans-serif font size not smaller than 11 points. Sans-serif font sizes of 8 or 10 point may be used for figures, tables, and charts. There is no page limit for this document.

The Administrative & National Policy Requirements Document must be in .pdf, .doc, or .docx formats. Submissions must be in English.

CONTENTS

<PRIME ORGANIZATION LOGO (OPTIONAL)>

COVER PAGE

Proposal Title	
Proposer Organization	
Technical Point of Contact (TPOC)	Name: Address: Telephone: Email:
Administrative POC (APOC)	Name: Address: Telephone: Email:
Date of Proposal Submission	(MM/DD/YYYY)
Proposal Validity Period (minimum 120 days)	_____ Days

- TEAM MEMBER IDENTIFICATION

  List the organizations/institutions that comprise your team. Organization/Institution roles include prime awardees, sub-awardees, team members, contractors, and vendors that will be supplying components, information, data, or material that is critical to your proposal. Add rows as needed.

Organization /Institution Name	Status	Organization/Institution Role
	☐ U.S. ☐ non-U.S.	
	☐ U.S. ☐ non-U.S.	
	☐ U.S. ☐ non-U.S.	
	☐ U.S. ☐ non-U.S.	
	☐ U.S. ☐ non-U.S.	
	☐ U.S. ☐ non-U.S.	
	☐ U.S. ☐ non-U.S.	
	☐ U.S. ☐ non-U.S.	

SENIOR/KEY PERSONNEL (I.E., COVERED PERSONNEL)

Complete the following table for each Senior/Key Person[23]. Add rows, as needed.

Senior/Key Personnel Names	Organization/Institution	Confirmation Common Forms Are Attached
		Biographical Sketch Attached: ☐ Yes ☐ No Current & Pending Support Attached: ☐ Yes ☐ No
		Biographical Sketch Attached: ☐ Yes ☐ No Current & Pending Support Attached: ☐ Yes ☐ No
		Biographical Sketch Attached: ☐ Yes ☐ No Current & Pending Support Attached: ☐ Yes ☐ No

[23] In addition to the Principal Investigator or Program/Project Director, Senior/Key Personnel includes individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, regardless of whether they receive salaries or compensation under the award. These include individuals whose absence from the project would significantly impact the approved scope of the project; in other words, were the individual to leave the program, the change would be so substantial that ARPA-H would need to be notified. It is typical that each awardee has at least one Principal Investigator or Program/Project Director, including one from each sub-awardee or teaming partner that is expected to perform critical work for the proposed effort.

- FEDERALLY FUNDED RESEARCH AND DEVELOPMENT CENTER (FFRDC) PARTICIPATION

  Is any member of your proposed team an FFRDC?

  ☐ No ☐ Yes

  If yes, provide justification for inclusion of the FFRDC and separate documentation that indicates that no other source will meet the needs that the FFRDC will meet.

- ORGANIZATIONAL CONFLICT OF INTEREST (OCI) AFFIRMATIONS AND DISCLOSURE

  In accordance with the National Security Presidential Memorandum (NSPM)-33 and the associated White House Office of Science and Technology Policy Implementation Guidance, senior/key personnel are required to disclose potential conflicts of interest (COIs) and conflicts of commitment (COCs). Those disclosures are captured by senior/key personnel completing the Biographical Common Form, the Current and Pending (other) Support Common Form, and the Collaborators and Other Affiliations document as attachments to this template. These forms can be found at: https://www.nsf.gov/bfa/dias/policy/nstc_disclosure.jsp.

  Additional information about potential collaborations can be found at: https://www.nsf.gov/funding/senior-personnel-documents#collaborators-and-other-affiliations-2b3.

  a. Are any of the proposed team members or organizations (whether prime, sub-awardee, or consultant) providing support in the form of an Internal Support Contractor (ISC)/Systems Engineering Technical Assistance (SETA) Agreement, Partnership Intermediary Agreement (PIA), or similar support to ARPA-H?

     ☐ No ☐ Yes

  b. Has any proposed team member or organization (whether prime or sub-awardee or consultant) provided ISC/SETA support or similar support to ARPA-H within one calendar year of this proposal submission?

     ☐ No ☐ Yes

     If the answer to 3.a. or 3.b. is yes, provide a separate document with the following information for each such team member:

     - The name of the ARPA-H office receiving the support
     - The prime contract number
     - Name and type of support (e.g., prime, sub-awardee, consultant)
     - An OCI mitigation plan

  c. Are there other potential Organizational Conflicts of Interest involving a proposed team member *or* organization (whether prime, sub-awardee, or consultant)?

     ☐ No ☐ Yes

If yes, for each team member for which an OCI or a potential OCI exists, provide a separate document with the following information:

- Identification (name), and
- An OCI mitigation plan

- RESEARCH SECURITY DISCLOSURE

ARPA-H's research security program (RSP) involves research security reviews (RSRs) to determine whether Proposers are covered individuals or have behaviors that: (a) may be contrary to federal policy; (b) undermine the integrity of ARPA-H-funded research; or (c) bring risk to the agency's research programs. The RSP aims to mitigate the risk of unwanted knowledge and technology transfers to foreign countries of concern (FCOCs)[24]

In addition to the senior/key personnel disclosures, answer the following:

a. Has every PI and senior/key person certified (in writing or by digital signature) that they are (or are not) party to a malign foreign talent recruitment program (FTRP)? In accordance with 42 USC §19232, individuals are prohibited from being a party in a malign FTRP (as defined in 42 USC §19232).

☐ No ☐ Yes

b. Are any members of the proposal team participating in, or previously participated in, any FTRPs?

☐ No ☐ Yes

If yes, please list the name(s) of the team member(s), the year(s) of their participation, the FCOC(s) in which the program(s) is/are based, and the terms of the FTRP.

c. Are any of the proposed team organizations/entities or partners (e.g., the prime proposer, sub-awardees) owned wholly or in part by foreign individuals, entities, or governments?

☐ No ☐ Yes

If yes, provide the name(s) of the foreign-owned entities, and the name(s) of the owner(s) (e.g., individual(s), partner(s), or government(s), etc.) and identify the percentage(s) owned.

d. Is any of the proposed research projected to be executed within an FCOC?

☐ No ☐ Yes

If yes, please identify each FCOC, each entity executing research in an FCOC,

[24] Public Law 117-167, The CHIPS and Science Act, Section 10612, Aug 9. 2022; the People's Republic of China, the Russian Federation, the Islamic Republic of Iran, the Democratic People's Republic of North Korea, and any other country so designated by the Department of State.

and a narrative discussing the criticality of executing research to your proposal.

e. Do any of the proposing entities (e.g., prime, sub-awardee, or consultant) intend to rely on technology, information, data sets, or equipment (including known supply chain) that will be provided by or transmit data to or through an FCOC?

☐ No ☐ Yes

If yes, identify each entity that intends to do so, and provide a narrative discussing the criticality to your proposal.

By submitting this document to ARPA-H, you are certifying that the information provided in this section is current, accurate, and complete. This includes (but is not limited to) information related to current-, pending-, and other support (both foreign and domestic) as defined in 42 U.S.C. § 6605.

By submitting this document to ARPA-H, you are also certifying that at the time of submission, no member of the proposed team is a party in a malign foreign talent recruitment program.

By submitting this document to ARPA-H, you acknowledge that misrepresentations and/or omissions may be subject to prosecution and liability pursuant to, but not limited to, 18 U.S.C. §§ 287, 1001, 1031 and 31 U.S.C. §§ 3729-3733, and 3802.

- NOVELTY OF PROPOSED WORK

  Has the proposed work been submitted to any other government solicitation?

  ☐ No ☐ Yes

  If yes, provide the following information (and change the font color to black):

  1. Solicitation number _____
  2. Agency/Office _____
  3. Has the proposed work already received funding or a positive funding decision?

     ☐ No ☐ Yes ☐ Decision pending

- INTELLECTUAL PROPERTY (IP)

  6.1 Proposer information regarding IP and data restrictions promotes transparency, impacts ARPA-H's proposal evaluation efforts, and allows ARPA-H to evaluate how this information will affect the project/program and the government's rights in deliverables. Complete and accurate information also reduces the chances of delays and conflicts affecting negotiations and eventual project performance.

  6.2 For the primary proposer or any teaming partner or sub-awardee, identify background IP or otherwise restricted data (e.g., data subject to confidentiality agreement) that would be relevant to/incorporated into the proposed work and any deliverables in the table below. Furthermore, identify what rights the government can expect to have in that data or IP.

  - Background IP consists of trade secrets, patents, data, or non-provisional patent applications owned or controlled by the proposer team that exist prior to the date of any future agreement with ARPA-H or are conceived and otherwise created outside the scope of any future agreement with ARPA-H.

  6.3 Use the following rights categories in completing the "Associated Rights" column of the table.

  - *Unlimited Rights*: The government's right to use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, in any manner and for any purpose, and to have or permit others to do so.

  - *Government Purpose Rights*: The government's right to use, modify, reproduce, perform, display, release, or disclose, in whole or in part and in any manner, for government purposes only, and to have or permit others to do so for government purposes only. Government purposes are activities in which the U.S. government is a party, including cooperative agreements with international or multi-national organizations, or sales or

transfers by the U.S. government to foreign governments or international organizations. Government purposes include competitive procurement, but do not include the rights to use, modify, reproduce, release, perform, display, or disclose for commercial purposes or authorize others to do so.

- *Limited Rights*: The government's right to use, modify, reproduce, release, perform, display, or disclose, in whole or in part, within the government. The government may not, without the written permission of the Performer, release or disclose outside the government, use for manufacture, or authorize use by another party. The government may release or disclose to a covered government support contractor in performance of a covered government support contract.

- *Specially Negotiated/Other Rights*: Rights proposed by the Performer that differ from the standard categories described above. Open Source/End User License Agreements/Data Use Agreements might fall under this category. Include a description of the license proposed.

6.4 The table below includes an example to assist Proposers complete it. Add rows to the table if needed. In general, Proposers can assume the following in completing this table.

a. ARPA-H does not, unless specified in the solicitation, intend to own IP. Rather, ARPA-H's expectation is that it will receive licenses to IP sufficient to meet the needs of the project or program.

b. ARPA-H generally expects to receive license rights commensurate with its contribution to the IP's/data's development. Where ARPA-H has funded some or all of the IP/data, the agency would typically expect at least Government Purpose Rights. This may vary based on the needs of the program or in recognition of a proposer's heavy prior/internal investment. Where IP/data has been created entirely at private expense, Limited Rights or Specially Negotiated/Other Rights would be appropriate, though Government Purpose Rights are also common. Proposed resource share may be a factor in the rights proposed. The "Basis for Assertion" would typically have to do with the source of the IP, how it was funded, and when the IP/data was created.

Background IP and Data Assertions

General description of background IP or restricted data (e.g., inventions, proprietary information or data subject to confidentiality agreements, computer software, etc.). For inventions, please provide the application/patent number if available.	Expected role of this IP or data in performance of the work	Basis for Assertion	Associated Rights (see rights categories above)	Name of person/entity asserting the restriction and their role in the requirement (i.e., primary proposer, teaming partner, or sub-awardee)
ARPA-H Example Background IP ("Image-recognition software" or "wireless biosensor technology")	*ARPA-H Example Used as a core software module in the prototype system or Embedded into the device as the primary sensing component*	*ARPA-H Example Developed exclusively at private expense or developed under agreement number ABC.*	*ARPA-H Example Limited or Government Purpose Rights*	*ARPA-H Example ("Company Name (Prime)" or "Company Name (Sub-Awardee)")*

- PATENTS

7.1 For patents identified above, provide documentation demonstrating ownership or possession of appropriate licensing rights for the proposed work. If a patent application has been filed for an invention, but it includes proprietary information and is not publicly available, provide the following information:

- The patent number
- The inventor name(s)
- The assignee names (if any)
- The filing date
- The filing date of any related provisional application and
- A summary of the patent title, with either:
  (1) a representation of invention ownership; or
  (2) proof of possession of appropriate licensing rights in the invention (i.e., an agreement from the owner of the patent-granting license to the proposer).

7.2 If any IP listed was developed in whole or in part with government funding from any Agency, specify under what agreements that IP was developed.

7.3 Background IP of teaming partners and sub-awardees should be included if restrictions on that IP have implications for the success of the award or the rights the Government can expect to receive.

- HUMAN SUBJECTS RESEARCH (HSR)

Does the proposed work involve Human Subjects Research?

☐ No ☐ Yes

If yes, provide separate documentation showing evidence of, or a plan for, review by an Institutional Review Board (IRB) and include evidence of a Federal-wide Assurance for the Protection of Human Subjects. Complete the following table to identify each organization, team member, and sub-awardee performing HSR. Add rows as needed.

Organization Performing HSR	Institution Site	Federal-Wide Assurance Number	Approved IRB Protocol (Y/N)

- ANIMAL SUBJECTS RESEARCH (ASR)

  Does the proposed work involve Animal Subjects Research?

  ☐ No ☐ Yes

  If yes, provide:

  - separate documentation that gives a brief description of the plan for Institutional Animal Care and Use Committee (IACUC) review and approval
  - the Vertebrate Animal Section (VAS) worksheet, found at:

  https://olaw.nih.gov/sites/default/files/VAChecklist.pdf

  - evidence of each applicable organization's Animal Welfare Assurance

  Complete the following table to identify each organization, team member, and sub-awardee performing ASR. Add rows as needed.

Organization Performing ASR	Institution Site	Approved IACUC Protocol (Y/N)	Completed VAS (Y/N)	Animal Welfare Assurance Number

- REPRESENTATIONS REGARDING UNPAID DELINQUENT TAX LIABILITY OR A FELONY CONVICTION UNDER ANY FEDERAL LAW

  The Proposer represents that it –

  a. Is ☐ Is not ☐
  a corporation that has any unpaid federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability.

  b. Is ☐ Is not ☐
  a corporation that was convicted of a felony criminal violation under a federal law within the preceding 24 months.

- CYBERSECURITY

  a. Does your organization implement a cybersecurity program leveraging industry and/or government standards to secure and defend your systems, networks, and/or data?

  ☐ No ☐ Yes

  If yes, provide a brief description of the program, including the specific standard(s) that guide the program, the abilities of the organization to respond

to a cybersecurity incident, and how the organization assesses the security posture of its systems and/or networks.

b. Does your organization have experience with managing and securing Controlled Unclassified Information (CUI)?

☐ No ☐ Yes

Describe how the proposing institution and sub-awardee/subcontractor organizations manage CUI, including details of access control for research designated as CUI, information systems security protocols, storage, communicating unclassified fundamental research with foreign nationals, and risk mitigation strategies for unclassified research that may ultimately become CUI as the research proceeds.

- BIOSECURITY

a. Dangerous Gain-of-Function Research: Does the proposal involve dangerous gain-of-function research, per the definition in Section 8 of Executive Order (E.O.) 14292 on *Improving the Safety and Security of Biological Research*[25]?

☐ No ☐ Yes

b. Synthetic Nucleic Acids or Benchtop Nucleic Acid Synthesis Equipment: Does the proposed work include the potential to procure synthetic nucleic acids or benchtop nucleic acid synthesis equipment?

- This includes, but is not limited to, procuring synthetic DNA and RNA, as well as whole organism genomes (e.g., viruses, bacteria) containing any synthetic nucleic acid 200 nucleotides or greater, and benchtop equipment capable of synthesizing nucleic acids.

☐ No ☐ Yes

If yes, refer to the OSTP Framework for Nucleic Acid Synthesis Screening for guidance, attestation requirements, and definitions of terms. The requirement to use the framework applies to all work performed under the award.

[25] https://www.whitehouse.gov/presidential-actions/2025/05/improving-the-safety-and-security-of-biological-research/