DRAFT PROGRAM SOLICITIATION
BUILDING RESILIENT ENVIRONMENTS FOR AIR AND TOTAL HEALTH (BREATHE)

RESILENT SYSTEMS OFFICE (RSO)
ADVANCED RESEARCH PROJECTS AGENCY FOR HEALTH
ARPA-H-SOL-24-107
(April 12, 2024)

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PROGRAM SOLICITATION OVERVIEW INFORMATION

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

PROGRAM SOLICITATION TITLE: Building Resilient Environments for Air and Total HEalth (BREATHE)

ANNOUNCEMENT TYPE: Draft Program Solicitation (PS), Initial Announcement

PROGRAM SOLICITATION NUMBER: ARPA-H-SOL-24-107

DATES:

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- ***Anticipated Final Program Solicitation Posting Date***: May 28st, 2024
- ***Proposers' Day:*** May 2nd, 2024
- ***Anticipated Solution Summary Due Date:*** June 7th, 2024
- ***Anticipated Proposal Due Date:*** August 12th, 2024
- ***Anticipated Period of Performance start date:*** February 2025

CONCISE DESCRIPTION OF THE FUNDING OPPORTUNITY: BUILDING RESILIENT ENVIRONMENTS FOR AIR AND TOTAL HEALTH (BREATHE) AIMS TO DEVELOP DIAGNOSTIC AND THERAPEUTIC INDOOR AIR SYSTEMS THAT AUTOMATICALLY DETECT AND REACT TO AIRBORNE PATHOGENS AND ALLERGENS.

ANTICIPATED INDIVIDUAL AWARD: Multiple awards are anticipated.

TYPES OF INSTRUMENTS THAT MAY BE AWARDED: Other Transactions awarded under the authority of 42 U.S.C. § 290c(g)(1)(D).

ANY RESOURCE SHARING REQUIREMENTS: Resource sharing may be requested in certain situations. Specifically, resourcing sharing is required for Phases II and III as described in Section 1.3.

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1.0 PROGRAM INFORMATION

1.1 BACKGROUND

A century ago, sewer and water treatment systems revolutionized public health. Scientific field trials that led to national standards for outdoor air quality redefined how the United States manages outdoor air, which ultimately prevented an estimated 230,000 early deaths in 2020 that were linked to decreases in the incidence of cardiovascular disease, lung cancer, and chronic pulmonary disease.[1] Despite these public health triumphs, indoor air today is still a major contributor to the spread and exacerbation of illness. Advances in indoor air quality technologies promise to have the same or higher impact on respiratory illness that clean water had in reducing water-borne disease and that clean outdoor air had in reducing diseases caused by exposure to air pollution.

Americans spend ~90% of their lives indoors breathing air that contains viruses, bacteria, fungi (including mold spores), pollen, and other bioaerosols. These biological components of indoor air can lead to acute and chronic respiratory illnesses (e.g., the flu, common cold, respiratory syncytial virus (RSV), COVID, pneumonia, tuberculosis, allergic rhinitis, and asthma).[2]

1.2 PROGRAM DESCRIPTION & SCOPE

The Building Resilient Environments for Air and Total HEalth (BREATHE) Program is investing in indoor air quality technologies that reduce the risk of people contracting respiratory diseases while being inside. The program will combine advances in biosensors, risk assessment, and building controls to create integrated diagnostic and therapeutic indoor air-management systems that automatically detect and react to airborne pathogens and allergens. The BREATHE Program envisions buildings embedded with sensors that autonomously and continuously monitor biological content of interior air, software that evaluates and models health risks in buildings based on sensor data and other environmental data streams, and smart automation systems that react to health risk reports by adjusting conditions inside buildings in cost-effective ways to promote well-being of occupants. These technologies will synergize to create an unprecedented ability to manage indoor air quality to the benefit of anyone who spends time indoors.

The BREATHE Program technologies will be evaluated in buildings nationwide to establish efficacy of indoor air quality monitoring and response systems. The program aims to deliver statistically meaningful results for multiple building types across broad geography and climate zones and improve health for all Americans. The statistically validated indoor air quality measures and air treatment demonstrations will lay the foundation for ubiquitous healthy indoor air that protects Americans from exposure to major causes of respiratory illnesses and airborne diseases.

[1] Industrial Economics, Incorporated, "The Benefits and Costs of U.S. Air Pollution Regulations." 2020.
[2] Manisalidis et al., "Environmental and Health Impacts of Air Pollution: A Review." 2020.

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National Health Impact

The BREATHE Program aims to develop a system that makes clean indoor air the accepted standard just as with clean outdoor air and drinking water. This program aims to deliver novel airborne pathogen and allergen diagnostic tools as well as the first comprehensive data to inform evidence-based standards for safe indoor air quality.

Poor indoor air quality is a leading cause of respiratory illness and airborne disease. The risk of viral infection transmission can be up to 18 times greater indoors relative to outdoors.[3] Pre-COVID-19, lower respiratory infections were the 8th leading cause of death in the U.S. with over 50,000 influenza and pneumonia deaths in 2019[4] and the 4th leading cause of death globally with over 2.6M influenza, pneumonia, and tuberculosis deaths in 2019.[5] COVID-19 claimed over 1M American lives and was the 3rd leading cause of death in the U.S. from 2020-2022.[6] Asthma and allergic rhinitis are associated with poor indoor air quality. While neither are a leading cause of death on a national or global scale, these conditions can significantly impact quality of life and lead to complications requiring emergency care or hospitalization. Asthma impacts 345M people globally and numbers steadily increasing in North America (9.6% from 1990-2019).[7] Over 400M people suffer from allergic rhinitis globally and in the U.S., it affects up to 30% adults and up to 40% of children making it the 5th most prevalent chronic disease.[8] Of the 85.2M U.S. physician ambulatory-care visits with respiratory disease as the primary diagnosis in 2016, allergic rhinitis accounted for 19.4% of cases.[9]

Indoor disease transmission and illness have enormous economic implications. In the U.S., total spending across all respiratory conditions exceeded $170B in 2016 with spending being highest for ambulatory care, inpatient care, and pharmaceutical care.[10] Of the total cost burden, >$45B was associated with respiratory infections, and >$35B was associated with asthma and allergic rhinitis. Meanwhile, COVID-19 alone had an economic impact of $16T in the U.S.[11] Aside from health care costs, there is a $29B loss each year in productivity (presenteeism & absenteeism) from asthma and allergic rhinitis.[12]

Indoor air pollution disproportionately affects vulnerable populations including children, the elderly, individuals with pre-existing health conditions, people of color, and low-income communities. For example, data from 2020-2022 show that in the U.S., people of color were ~1.5x at greater risk of COVID-19 infection and ~2x as likely to die from COVID-19 than their white counterparts (based on an analysis of total cumulative data for black, Hispanic, American Indian or Alaska Native (AIAN) and Native Hawaiian or Other Pacific Islander (NHOPI) people,

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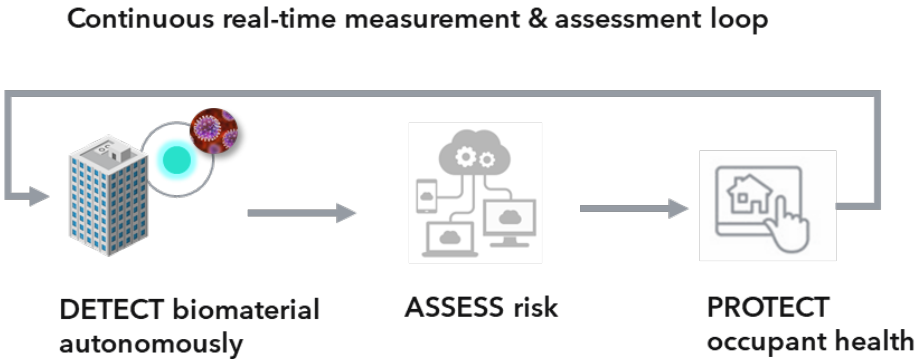
[3] Bulfone et al., "Outdoor Transmission of SARS-CoV-2 and Other Respiratory Viruses: A Systematic Review." 2021.
[4] Kochanek et al. "Mortality in the United States." 2019.
[5] World Health Organization: WHO, "The Top 10 Causes of Death." 2020.
[6] Curtin et al. "Deaths: Leading causes for 2020." 2023.
[7] Safiri et al. "Prevalence, Deaths, and Disability-Adjusted Life-Years Due to Asthma and Its Attributable Risk Factors in 204 Countries and Territories, 1990-2019." 2022.
[8] Scarupa et al. "In-Depth Review of Allergic Rhinitis | World Allergy Organization." Updated 2020.
[9] Pal, "Statistics on Respiratory Diseases in Adults." 2020.
[10] Duan et al., "Health Care Spending on Respiratory Diseases in the United States, 1996–2016." 2023.
[11] Bruns and Teran "Weighing the Cost of the Pandemic." 2022.
[12] Mudarri, "Valuing the Economic Costs of Allergic Rhinitis, Acute Bronchitis, and Asthma From Exposure to Indoor Dampness and Mold in the US." 2016.

with data adjusted to account for differences in age by race and ethnicity).[13] Additionally, it has been reported that black individuals are almost 3x more likely to die from asthma-related causes than white individuals.[14] Reasons underlying these disparities are complex and likely reflect increased exposure risk in work and home environments. Low-income individuals living in older, poorly maintained buildings are exposed to more indoor air pollutants especially after floods and extreme weather events. These disparities are amplified by climate change, which has already exacerbated dozens of airborne infectious diseases and increased levels of plant and fungal allergens.[15]

BREATHE Program Scope

As shown in Figure 1, the BREATHE Program is soliciting proposals for closed loop systems that achieve three functions: detect harmful aerosols in the air (Technical Area 1), assess the health risks associated with those bioaerosols (Technical Area 2), and automatically manage interventions to improve indoor air quality (Technical Area 3). It is envisioned that the combined system will offer a comprehensive solution to protect building occupants from respiratory illness and airborne disease in a cost effective, evidence-based, energy efficient way.

Figure 1. The ideal BREATHE Program system for detecting harmful aerosols (TA1), assessing health risks associated with bioaerosols (TA2), and protecting occupants from associated health risks by removal of harmful bioaerosols (TA3).



The BREATHE Program seeks integrated solutions in air-managing systems that optimize the balance between specificity of response, health protections, and operational costs. Autonomous biosensors will act as vigilant monitors, continuously scanning the indoor air for bioaerosols. The respiratory risk assessment software will then process this data to evaluate health risks, guiding the building control systems in implementing precise and targeted interventions. This orchestrated interaction ensures interventions will be specific, effective, and will minimize unnecessary resource use while maximizing occupant health and comfort.

The BREATHE Program systems must be adaptable to different threat levels. Under steady-state conditions, systems should operate in a preventative mode that is continuously

[13] Hill and Artiga, "COVID-19 Cases and Deaths by Race/Ethnicity: Current Data and Changes Over Time." 2022.
[14] AHRQ, "National Healthcare Quality and Disparities Reports." 2022.
[15] Prillaman, "Climate Change Is Making Hundreds of Diseases Much Worse." 2022.

operating. This mode emphasizes prevention, efficiency, and minimal intervention to sustain a healthy indoor environment without disrupting daily operations or incurring unnecessary costs. Conversely, during emergency conditions such as the rapid emergence of a new pathogen, the BREATHE systems must be able to update and adapt its different functions. For example, existing sensors are recalibrated, or samples are sent to a centralized lab for genomic sequencing. Meanwhile, risk assessment models are updated to include new threat profiles, and building control systems are adjusted to implement more stringent protective measures if needed, such as continually increased ventilation rates. This dual operational mode ensures continuous protection against bioaerosols while maintaining the agility to respond to acute public health threats.

Extensive real-world testing is a critical component of ensuring the practical viability and efficacy of BREATHE technologies. By conducting trials in selected buildings across different climates and geographic areas, the BREATHE Program aims to demonstrate the robustness and reliability of its integrated approach to managing indoor air quality.

The BREATHE Program will take an interdisciplinary approach to advancing technologies across biosensing, environmental learning models, and indoor air management as part of a comprehensive strategy to create an integrated capability. As such, ARPA-H is soliciting innovative solutions that address all three Technical Areas (TAs) introduced below.

1. ***Indoor Air Biosensors (TA1):*** *Autonomously monitor the biological content of indoor air*. Emerging technologies, including aerosol capture, molecular diagnostics, and microfluidics will enable the creation of scalable, multiplexed bioaerosol-sensing devices capable of simultaneously detecting dozens of known pathogens and allergens.
2. ***Respiratory Risk Assessment Software (TA2):*** *Assess health risks of breathing a wide variety of bioaerosols*. Modeling techniques powered by a plethora of data streams including biosensor outputs, health outcome data, outdoor air quality and imagery data (e.g., satellite and street view), occupancy rates, and wastewater surveillance will lead to effective prediction of building occupants' health risks due to exposure to biological components in the indoor air.
3. ***Healthy Building Controls & System Integration (TA3):*** *Leverage protective and responsive building interventions to reduce bioaerosol exposure risk at optimal costs*. Efficient, real-time, data-driven technologies developed by the program, coupled with optimization analytics, will reduce occupant health risks, and improve indoor air quality by leveraging existing intervention approaches.

The following is considered out of scope for the BREATHE program:

- Proposals that do not address all TAs or that offer only incremental advances in the state-of-the-art for biosensors, respiratory risk modeling, or healthy building controls.
- Proposals to advance sensor technologies for monitoring non-biological air pollutants (e.g., particulate matter, ozone, CO_2, VOCs, and radon).
- Proposals that offer solutions to addressing outdoor air quality, even with the expectation of indirect improvements to indoor air quality.

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- Proposals involving brick and mortar construction of new buildings or extensive remodeling of existing buildings.
- Proposals that require research and development for novel HVAC, UVC light disinfection, or other types of environmental remediation technologies. However, innovative ways of using commercially available interventions (e.g. ventilation, filtration, and disinfection technologies) are encouraged.

Proposers are encouraged to read the detailed description of the program's requirements for each TA below before responding to this solicitation.

Program Structure

The BREATHE Program endeavors to catalyze the creation and validation of first-generation scalable healthy building systems for monitoring and managing indoor air quality. Components resulting from each TA will be integrated into an automated closed loop system to achieve the BREATHE program objective. Performers in TA1 (Indoor Air Biosensors) will seek to develop low-cost indoor air biosensors that are autonomous, highly multiplexable, and able to identify pollutants and known bioaerosols that are allergenic, pathogenic, or safe in near real-time. Performers in TA2 (Respiratory Risk Assessment Software) will seek to develop models that translate data collected from biosensors and other sources into actionable health risk thresholds. Performers in TA3 (Healthy Building Controls and System Integration) will integrate sensors and models with existing and concurrently developed mitigation technologies and protocols that respond to airborne threats quickly and efficiently. Proposers will be expected to provide proposals as a unified team, addressing all three technical areas detailed below.

TA1: INDOOR AIR BIOSENSORS

The goal of TA1 is to develop and validate cost-effective air biosensors for autonomously detecting and quantifying airborne viruses, bacteria, fungi, and allergens that are detrimental to health. By leveraging recent advances in clinical molecular diagnostics, these biosensors will achieve rapid reporting with high sensitivity and specificity; thus fundamentally transforming the approach to air quality surveillance and health risk assessment in indoor environments. Proposals should detail how the integration of air sampling tools, molecular bioassays, and user-informed design will engineer novel indoor air biosensing packages that are **autonomous, cost-effective, multiplexable, and timely from air collection to biological target detection**.

Proposals should include the following information in the TA1 section:

- *Prototype development and testing plans:*
    - A detailed design description for a biosensor capable of monitoring indoor air bioaerosols distributed across three broad categories—viruses, bacteria, and either fungi or allergens. Except in the most ideal outcome, there will be trade-offs between speed, sensitivity, and specificity so proposers are encouraged to describe how to balance these parameters in designing the biosensor development approach.

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Proposers should also explain how their designs will minimize the required user interaction for consumables replacement as well as general hardware maintenance and servicing.

- Project plans for building and testing a prototype indoor air biosensor capable of continuously quantifying a total of 25 different biological targets across the three broad categories. Methods for benchmarking biosensor capabilities should be included and justified. Proposals should communicate consideration for the prevalence of pathogens and allergens across different populations, geographies, seasons and building types. A schedule of intermediate milestones should be provided that will allow the team to assess progress to achieving ≥95% sensitivity and ≥99.5% specificity with a turnaround time of 45 minutes or less (see Section 1.4 Metrics, Table 1).
- A viable R&D path for expanding biosensor coverage to at least the 100-plex scale (i.e., to monitor for at least 100 different biological targets within indoor air in parallel). Proposers must demonstrate 100-plex capabilities in a lab setting and at least 25-plex capabilities in a real-world setting. Additionally, proposers should provide a plan to demonstrate rapid adaptation of biological targets for detection of novel pathogen variants (in less than 3-weeks following the publication of a novel variant).
- Detailed technical plans for testing and refining biosensor performance throughout the program including a plan for delivering reliable and reproducible biosensor data outputs that support exposure risk assessment analytics and effective interventions.

- *Manufacturing and installation strategy:*
  - A manufacturing plan for producing biosensor prototypes (consumables and hardware components) for use throughout the program. Note the timetables for chamber studies and field trials in Section 1.3, and identify any risks associated with manufacturing prototypes in time for these milestones. Proposals should address those manufacturing risks by describing sound mitigation strategies. This will be informed by risk modeling (TA2) needs and dependent on building characteristics such as size, population, population distribution, airflow, etc. While initial manufacturing estimates should be provided in the proposal, final target metrics (i.e. the number of required prototypes during Phase II and Phase III) will be established 6 months into the program.
  - A technical plan for assessing the installation and maintenance of sensors in buildings that will be necessary for tasks in Phase III (see Section 1.3 Phase III (months 37-60): Field Trials). This will be informed both by the risk modeling (TA2), and the building selection and implementation strategy (TA3) needs.
- *A path to commercial viability:*
  - Design strategies for biosensor hardware and consumables that demonstrate a path to commercial viability.
  - A plan for assessing commercial viability (e.g., via hardware installation and maintenance requirements, consumables usage requirements, and end-user feedback survey insights (see Section 1.4 TA1 Metrics).

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TA2: Respiratory Risk Assessment Software

The goal of TA2 is to develop quantitative models that accurately assess indoor air quality and bioaerosol exposure risk. The core deliverable of TA2 will be software and a database that generates indoor air quality indices using bioaerosol profiles and models for a specific building and its occupant population under normal operations. The ultimate goal of TA2 is to furnish stakeholders with tools for making informed decisions about indoor air quality management thereby reducing health risks associated with bioaerosol exposure. Proposals should establish the **data requirements and experimental design for exposure-response analytics**, identify instrumental methods for **risk model development and validation**, and outline a roadmap for assessing bioaerosol exposure risk **in real world settings**.

Proposals should include the following information in the TA2 section:

- *Experimental design:*
  - One or more appropriate respiratory disease to address in field demonstrations.
  - A detailed sample collection strategy outlined for demonstration buildings, including sampling density and frequency, that begins with manual collection of indoor bioaerosol data using existing biosensor technology in the first phases of the program and transitions to testing automatic 25-plex biosensors in the final phases of the program.
  - A description and justification for the number of buildings (and the estimated number of associated occupants) that will be used to assess TA1, TA2, and TA3 capabilities. Include an explanation to why these chosen numbers are adequate to ensure statistical validity. Performers are encouraged to include control buildings and matched populations whenever feasible in their studies, aligning with the experimental buildings.
- *Innovative software approach to assess the risk associated with bioaerosol exposure:*
  - A description of a software R&D and data analytics approach to determine safe thresholds of bioaerosols in the BREATHE Program's demonstration buildings. Performers are encouraged to conduct a comparative analysis of several modeling, artificial intelligence, machine learning, or data analysis approaches to determine which approach provides the most accurate empirical predictions.
  - Determination of what data sources will be used to assess dose-response to known pathogens or allergens across various environmental conditions. Include details about what types of information will be drawn from literature versus empirical data collected during the program versus data feeds from other sources.
  - An approach described for assessing bioaerosol risk to the room level or at a spatial resolution appropriate for the selected building type. Proposers should specify and justify the spatial resolution targeted.
  - A plan for ensuring software is adaptive and requires minimal manual optimization across different geographies, seasons, and built environments.
  - A development road map that includes software deliverables and details features such

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as graphical user interface (GUI), types of visualizations (e.g., a program visualizing indoor air quality score of specific rooms in a building), and time series tracking the building's indoor air quality.

- *Model evaluation and validation approach:*
  - A description of what approach will be used to ensure that risk assessment models are both accurate and validated (e.g., aligning model risk prediction to building occupant health outcome data (e.g., wearables, self-reports, human resources (HR) data, or nasal swabs)).
  - Rationale for how exposure thresholds will be determined and a plan to minimize the number of false positive and/or false negative results. Include a plan to establish these thresholds based on the proposer team selected building type, target occupants, pathogens, etc.
  - Anticipated methodologies or techniques under consideration to validate model input and output data (see Section 1.4 TA2 Metrics).
  - Detailed technical plans for testing and refining models throughout the program including a description of methods used in model assessment and expected results at each stage of the program.
- *Strategy to establish and manage shared data infrastructure:*
  - A comprehensive system architecture plan outlining the process for collecting, storing, and analyzing data feeds from all facilities used to evaluate proposers' TA1, TA2, and TA3 components to include collection of empirical data about bioaerosols incidence rates and their effects.
  - Descriptions of the expected data feeds, integration approach, validation strategy, and quality assurance methods for capturing the data necessary to assess bioaerosol exposure risk. Datasets may include, but are not limited to, biosensor multivariate target microbial concentrations, building occupant health outcomes, additional indoor air quality data, wastewater surveillance data, and outdoor air quality trend data.
  - A data acquisition and management plan that describes how and where data will be sourced and preserved while ensuring the integrity of the data collected throughout the program period of performance. This plan should delineate risks and risk mitigation plans for handling data types being considered and address any concerns regarding personally identifiable information, HIPAA-protected information, etc.
  - A coordination plan describing how performers will establish data access agreements across academic, government, non-profit, and/or private organizations to obtain data that can aid in developing risk assessment software.
  - A plan for sourcing any external data needed for the success of the performer team during the BREATHE Program.
- *Implementation resources:*
  - A plan for acquiring necessary commercial capabilities to develop the software and database (e.g., computing infrastructure requirements, cloud resources, and access to

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external application programming interfaces (APIs)).

- *User experience testing strategy:*
  - An outline detailing the approach to provide a user-friendly interface allowing for easy-to-implement updates. Plans for assessing user experience should include at minimum end-user satisfaction surveys using Likert scale format (see Section 1.4 Metrics).
  - A detailed plan for creating the database, ensuring appropriately de-identified and aggregated data outputs, and/or software prototypes publicly available, for performers opting to deliver open-source tools or data feeds (see Section 1.5 General Requirements).

TA3: Healthy Building Controls and System Integration

TA3 performers will leverage technologies developed by TA1 and TA2 to create building control systems that can rapidly respond to unhealthy indoor air by triggering interventions to mitigate air quality threats. These systems are expected to reduce facility-related indoor respiratory illness incidence by at least 25% relative to baseline health data while achieving a ≥10% return on investment from indoor air quality interventions (see Section 1.4 Program Metrics). The interventions proposed should be suitable for the buildings under study and available to their performer team. These approaches may include minor modifications to existing infrastructure, such as adding variable air exchange rates or filtration to existing HVAC systems, or commercial-off-the-shelf capabilities such as UV sanitization. Mitigations may also include changes in operations (individual testing, social distancing, work from home) or personal protective equipment (masking).

TA3 performers within the consolidated team will lead the integration and provide field testing of TA1 biosensors, TA2 risk exposure software, and TA3 building control algorithms in a nationwide efficacy trial during Phase III of the program. Indoor air quality can vary due to many factors including building type, age, geography, climate, and season. To reduce this variation, **TA3 performers will lead the selection of a single building type** to focus on throughout the entire BREATHE program. To provide diverse real-world context for research, development, and demonstration of BREATHE technologies, buildings must be located in at least three US cities. Specific locations can be rural, suburban, or urban, but the three selected cities must be distributed across three separate climate zones (as defined by USDA at https://planthardiness.ars.usda.gov/).

In sum, TA3 performers are integral to many aspects of the program including **building selection, data collection, system integration, and field testing** to demonstrate a closed loop system that enables real-time responses from **building control systems** as well as ensuring **optimization and delivery of cost-effective building interventions**.

Proposals should include the following information in the TA3 section:

- *Building operations and intervention approach:*
  - An outline and supporting documentation for the types of risk mitigation interventions that will be operationalized in the proposed buildings. Example

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interventions include, but are not limited to, dynamic control of humidity, temperature, filtration, dilution with outside air, airflow management, UV air sterilization, occupant masking, and/or reducing occupancy.

- An innovative approach to optimize the application of responsive risk mitigation measures in a manner that balances health and cost. The optimization approach should dynamically adjust the application of risk mitigation measures based on bioaerosol exposure risk while considering cost implications and human comfort.

- *Building type selection and access:*
  - An outline detailing the type, location, and number of buildings to be included in field studies. Ensure that the selected locations cover at least three different geographic areas with distinct climates. Justify the focal building type from the perspective of ensuring statistically significant outcomes throughout the BREATHE program. Proposals will focus on a building type where exposure incidence can be statistically linked with in-building exposure (e.g., non-ambulatory care sites not limited to nursing homes and facilities, assisted living, inpatient hospice, convalescent homes, and group homes with nursing care, single family homes, schools, and ambulatory care sites such as hospitals.). Proposers are encouraged to include under-represented groups in their target building occupant populations.
  - Evidence of buy-in from building owners and operators, which indicates permission to perform all tasks relevant to TA3 of the program at the specified location. Example documentation may include letters of intent (LOI), executed partnership agreements, or similar items.
  - A plan to coordinate access to operational buildings and biosensor data for the performer team to include the Government Independent Verification and Validation (IV&V) team (see Section 1.3 Program Timeline, Phases & Milestones).

- *Data collection strategy:*
  - Detailed description on how the TA3 team will coordinate with the consolidated performer team to support the continual collection of relevant health information from occupants to track and inform mitigation of multiple types of airborne illnesses as well as documentation defining the usage and protection of such data.
  - An outline of the types of data that the team intends to collect from the facilities. Example data types may include, but are not limited to, the Community Assessment for Public Health Emergency Response (CASPER), respiratory illness events, occupant absenteeism data, individual occupant health data, occupant health surveys, wearable device biodata, nasal swab testing, or similar.
  - Detailed plans to manually collect baseline indoor air quality data within facilities (bioaerosol and non-bioaerosol).
  - An explanation of what commercially available equipment must be procured and installed to supply data to the bioaerosol risk exposure software developers, which could include, but may not be limited to, temperature, humidity, chemical sensors, and/or wastewater surveillance.

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  - A strategy for the performer team to access and model building floor plans, occupant traffic, and air flows.

- *Implementation strategy and timeline:*
  - A deployment and maintenance plan for TA1 and TA2 technologies, along with TA3 risk mitigation measures, within performer-selected facilities, including collection of sensor data in buildings.
  - A strategy for the deployment of modular BREATHE systems that can be integrated into facilities at the zone, room, floor and/or entire facility level. For example, systems that can be easily moved around a facility with minimal re-calibration.
  - A comprehensive and cost-effective plan, detailing forward-looking cost profile estimates for data acquisition, annual system operation and maintenance, and the implementation and execution of chosen dynamic mitigation measures.
  - A strategy that utilizes the associated costs of false positives and false negatives to inform the setting of thresholds for test sensitivity and specificity, considering variables such as occupancy, building type, and pathogen dependent threat levels for systems response. Associated costs may consider factors such as health consequences, resource utilization, and occupant psychological impact.
  - A strategy for the implementation of building systems to validate risk warnings prior to triggering high-cost interventions (e.g. evacuation of a building), or otherwise mitigate the possibility of false positive or false negative triggering.
  - A plan for user experience testing, ensuring a scalable and generalizable solution to improving the safety and quality of indoor air.
  - A defined comparator and benefit measure for return-on-investment determination or a sufficient plan to obtain one.
  - A plan for conducting a cost-benefit analysis under the scenarios where facilities are operated per the CDC guidance on ventilation and the American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) Standard 241.

Management Plan

Proposals should include a management plan with one Principal Investigator (PI) identified as the prime for the consolidated team. Proposals should provide good faith estimates of metrics and target values that are appropriate and specific to proposed use-cases. For instance, indication in a metrics table stating "target set at 6 months" or similar language (see Section 1.4, Table 1) as well as detailed plans for meeting stated milestones on the prescribed program schedule (see Section 1.3 Program Timeline, Phases & Milestones). Technical risks along with mitigation strategies or alternative approaches should be identified where appropriate.

Internal Review Board

Proposals must include a draft Internal Review Board (IRB) protocol, or at minimum, a plan for having an IRB protocol approved by month 6 of performing in the BREATHE program for acquiring the building's baseline attributable respiratory illness of occupants and outcome data during field trials. Additionally, proposals must clearly outline which IRB will review and draft agreements involving any external organizations participating in the study, ensuring compliance with the FDA. Proposals should describe risk mitigation and compliance efforts

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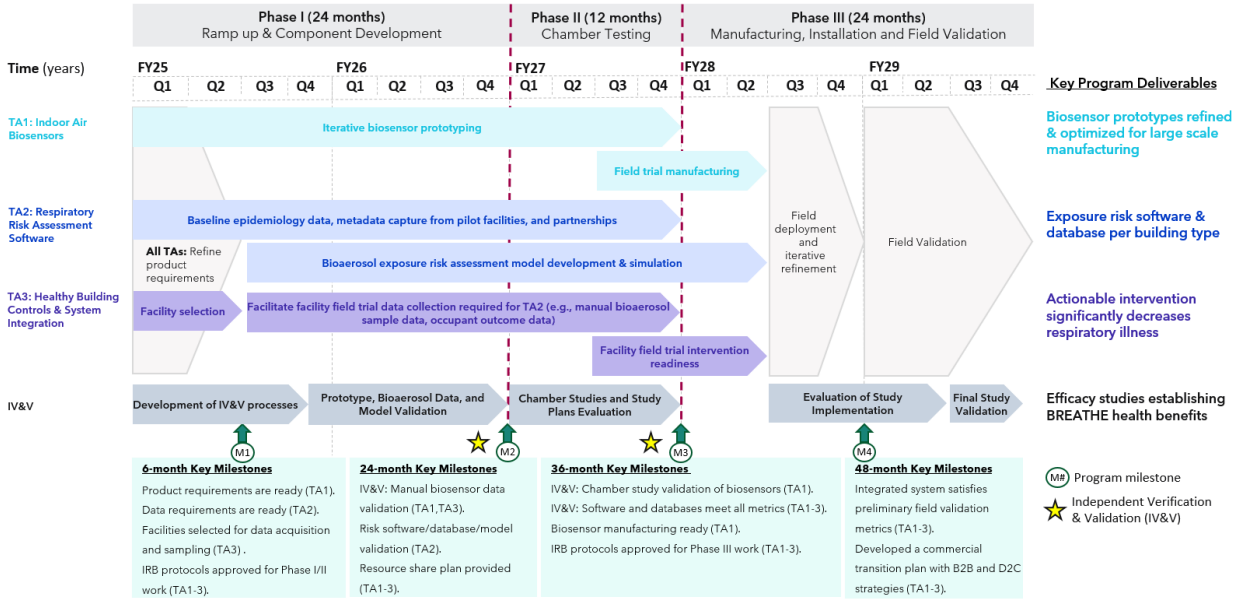
related to handling sensitive data (e.g., data on workplace personnel). The TA3 performers should conduct a thorough risk-mitigation analysis and develop comprehensive plans tailored to their specific settings. For instance, different thresholds for interventions, such as mask-wearing or demand-controlled ventilation, may be set based on the type of facility, ranging from long-term care facilities to schools. To proactively manage potential liabilities and ethical considerations arising from the implementation of these technologies, each performer group is required to formulate and present a detailed risk-mitigation plan alongside their IRB draft (see Figure 2 below).

1.3 PROGRAM TIMELINE, PHASES & MILESTONES

Figure 2. BREATHE Program Timeline, Key Milestones and Deliverables across TA1-TA3. Timeframes are relative to the start of the program. Note, dotted red lines depict program phase transitions, while gray-dotted lines depict end of fiscal-year.



BREATHE is a 60-month, three-phase program with a 24-month Phase I (Base) period, a 12-month Phase II (Option 1) period, and a 24-month Phase III (Option 2) period. Multiple awards are anticipated, and it is expected that fewer performers may be funded to participate in Phases II and III. The Phase II and III options may be exercised, at the Government's sole discretion, based on technical progress measured against the metrics (Table 1) and milestones (Figure 2) defined in the Program Solicitation, and based on funding availability. Each Phase has key technical milestone goals. A description of the Phases, which are aligned with critical program milestones are described below:

Phase I (months 0-24): Ramp Up & Component Development

Performing teams are expected to take up to six months to collaboratively refine details of their plan for developing the technologies for each TA. Performers will use the remaining 18 months of Phase I to iteratively refine and validate the performance of developed technologies and continue acquisition of necessary data. Progress reviews will be conducted at 24 months.

During the first six months of Phase I, performers will finalize product requirements for biosensor hardware and consumables (TA1), product and data requirements for bioaerosol risk database and software (TA2), finalize the selection of buildings used for baseline data acquisition and sampling, establish health outcome and return on investment (ROI) goals based on selected buildings and occupant populations (TA3), and refine intervention strategies. It is expected that all IRB protocols will be approved by the end of this 6-month period.

Phase II (months 25-36): Chamber Studies

Performers will be given 12 months to perform chamber studies in collaboration with BREATHE's IV&V team. The purpose of the chamber studies is to simulate built environments (indoor spaces) where many different types of microbes and allergens can be added at a range of concentrations. These controlled tests will be used to determine whether the biosensor technology can effectively capture and detect various biological targets as this will be required to inform occupants' health risk assessments in subsequent field trials. Additional validations will be done by the IV&V team for TA2 and TA3 performers to ensure software and automation systems are meeting the specified metrics (see Section 1.4). Teams will be assessed at 36 months. While further development of biosensors continues during Phase II, teams will be supporting IV&V by providing hardware and consumables for chamber studies. Performers will also use this time to prepare for manufacturing in support of Phase III field studies and amending IRB protocols if necessary for Phase III work.

Phase III (months 37-60): Field Trials

Performers will test their technologies in Phase III field trials. Phase III will culminate in a final demonstration of reduced risk of indoor air disease prevalence in buildings deploying the BREATHE technologies. The field trial will span multiple cities or locations accounting for rural, suburban, and urban communities as well as several building types across the portfolio (note that each performer team will select one building type). During this phase, overall programmatic success will be measured in field trials. TA1 performers will provide consumables and hardware support to installed sensors. TA2 performers will provide software support and updates to integrated risk assessment tools. TA3 performers will manage execution and outcome collection for field trials in their operational buildings.

Phase II and Phase III Resource Share

To facilitate technology transition, Phase II and III of the BREATHE program has a resource share requirement. For Phase II, resource sharing must cover 20% of the total proposed Phase II budget, and Phase III must cover 40% of the total proposal Phase III budget. Proposals must include a resource sharing strategy that outlines how the share requirement is addressed. Appropriate mechanisms may include cash, direct labor offset (e.g. to hours and or fully burdened rates), and in-kind share (e.g. equipment, materials, property). Resource sharing may be contributed by any non-federal or federal sources (e.g., BREATHE team prime or subawardees, venture or angel investors, private philanthropy, other agency funding); however, only contributions that are directly relevant to the goals and objectives of the BREATHE program will be considered in the calculation of the required resource share. It is acknowledged that proposers may have limited resources to fulfill the program's resource

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share requirements at the onset of the program. ARPA-H's Investor Catalyst Hub[16] may provide resource sharing guidance and strategies for fulfilling the Phase II and III requirement during Phase I of the program. Therefore, proposals should provide a resource sharing plan that details the team's contributions (known or projected at proposal submission) for Phases II and III. The plan should also identify if assistance is necessary to meet this program requirement by the end of Phase I; an updated resource share plan will be a Phase I deliverable as stipulated in Figure 2 above.

Independent Verification and Validation (IV&V):
IV&V will be conducted by an ARPA-H identified entity with the necessary capabilities to evaluate performance during the program. Performers are expected to work closely with the IV&V team throughout the program's duration. In particular, evaluations will take place before scheduled Phase transitions to ensure validation and real-world performance of developed technologies in Phases I - III. At the end of Phase I, performance of the initial 25-plex biosensor prototypes will be assessed by IV&V and prepared for initial production to support chamber studies (TA1) (see Section 1.4 Metrics, Table 1); initial risk assessment software and database development will be completed (TA2); and baseline data will be collected from manual biosensors (TA3). In Phase II, the IV&V team will evaluate TA1 performance in chamber studies. During Phase III, the IV&V team will assess the system's performance by monitoring performers' outputs during the Phase III trial.

Program Deliverables:
The BREATHE program anticipates three key deliverables, one aligned with each TA (see Figure 2 above). The first deliverable from TA1 will be refined and scalable biosensing hardware optimized for large scale manufacturing and deployment. The second deliverable from TA2 will be a risk assessment software and exposure database per building type that can be used by companies, researchers, and policymakers to obtain deeper insights into indoor air quality standards. The third deliverable will be an integrated system that has successfully demonstrated a significant reduction in the incidence of respiratory disease through the BREATHE Programs actionable interventions from TA3.

An overarching program objective is technology transition and ultimately commercialization. All performer teams will be expected to develop a commercial transition plan that explicitly includes 'Business-to-business' (B2B) or a 'Direct-to-consumer' (D2C) commercialization plans. These plans should account for technical feasibility and the logistics of integration into commercial settings (e.g., elderly care facilities, hospitals, etc.) and residential settings (e.g. compatibility with prevalent residential HVAC systems). Commercialization plans should explore pathways that make the technology equitably accessible to end consumers. For example, BREATHE systems that can be easily adapted into different building and/or facility types through modular and/or mobile capabilities, providing healthy indoor air at the zone, room or floor level, are strongly encouraged to enable broad user-accessibility.

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[16] The Investor Catalyst Hub is part of the ARPANET-H Health Innovation Network (https://investorcatalysthub.org).

1.4 PROGRAM METRICS

Table 1 BREATHE Program Metrics across TA1-TA3. Timeframes are relative to the start of the program.

		Phase I (0-24 mo) Ramp up & Component Development		Phase II (25-36 mo) Chamber Testing	Phase III (37-60 mo) Manufacturing and Field Testing	
Technical Area	**Metric**	**End of 6 months**	**End of year 2**	**End of year 3**	**End of year 4**	**End of year 5**
TA1: Indoor Air Biosensor	**Limit of Detection** (lowest detectable number of targets per sample)	Target set at 6 months	≥10% target	≥50% target	>95% target	100% target
	Sensitivity (true positives/(true positives + false negatives) at ≥95%)	n/a	≥75% target	≥90% target	>95% target	100% target
	Target specificity (how accurately assays can identify targets at ≥99.5%)	n/a	≥25% target	≥50% target	≥75% target	100% target
	Multiplexing Capability (100-plex detection to include 50% viral variants, 25% bacteria, & 25% mold and/or allergens)	n/a	≥10% target	≥25% target	≥50% target	≥100% target
	Turnaround Time (biosensor results (sample to answer) ≤45 min)	n/a	≥50% target	≥75% target	≥90% target	≥100% target
	Useability (Likert-scale assessment by user)	Target set at 6 months	≥25% target	≥50% target	≥75% target	≥100% target
	Production and Deployment (# prototypes)	Target set at 6 months	≥3	≥25% target (by end of year 3.5)	≥100% target	≥100% target
	Cost (sensor installation, maintenance, and annual service fees meet TA3 ROI requirements)	Target set at 6 months	≥10% target	≥50% target	≥95% target	≥100% target
TA2: Respiratory Risk Assessment Software	**Indoor Air Exposure Risk Model Performance** (model health risk assessment scores are consistent with validation sources (e.g manual bioaerosol data))	Target set at 6 months	≥50% target	≥75% target	≥90% target	≥100% target
	Model Adapability (models generalize across facilities, geographies and seasons)	n/a	≥50% facilities	≥75% facilities	≥90% facilities	≥95% facilities, 3 seasons
	Usability (ease navigating software and understanding outputs; Likert-scale assessment by user)	Target set at 6 months	≥50% target	≥75% target	≥90% target	≥95% target
TA3: Healthy Building Controls and System Integration	**Intervention Efficacy** (25% decrease in facility-related incidence for each targeted respiratory illness: incidence is relative to baseline)	Health threat and outcome data collected for baseline		Target set at end of year 3 relative to baseline	≥75% target based on modeling	≥100% target based on observed data
	Real-time Automated Response (platforms will have ≤5 minute delay from alert to effective intervention)	n/a	≥20% target	≥50% target	≥75% target	≥100% target
	Return on Investment (>10%)	Target set at 6 months	n/a	n/a	≥50% target	≥100% target
	Usability (ease navigating software and understanding outputs; Likert-scale assessment by user)	Target set at 6 months	≥50% target	≥75% target	≥90% target	≥95% target

The metrics illustrated in Table 1 will be used to track progress as performers progress through the TA and Phase. Performers will be required to report progress against these metrics as needed to the Program Manager, and to the designated IV&V team(s). Technical progress towards the program metrics is a significant deciding factor for continuation into subsequent Phases. Table 1 defines the metrics and specific goals for the 6-month checkpoint as well as the 2-, 3-, 4-, and 5-year checkpoints. For metrics that are expressed in terms of targets, these are either explicitly quoted in the metric description or are indicated as being set at a particular time after the beginning of the program. These targets are expected to vary between individual BREATHE performer groups depending on the use-case, building type, focal respiratory disease states, and monitored pathogens and allergens. The final definition of these targets will be subject to Program Manager's approval at the indicated program checkpoints. However, proposers are encouraged to state the expected range of achievable values for metrics labeled as "Target/Standards set at 6 months" to illustrate the expected performance

capabilities of the proposed technologies (see Section 1.2). Proposers are also encouraged to include in the proposal any additional quantitative metrics and milestones not part of Table 1 that they plan to use for tracking progress toward the final deliverables of each TA. Clarifying details on specific metrics are provided below in the program metrics table. Select metrics are detailed below.

TA1 Indoor Air Biosensors:

Metric: Limit of Detection
The required limits of detection performance metrics for each of the bioaerosol components will be determined during the first six months of the program by the performing team. Implicit in this metric is the requirement that each BREATHE team identify the specific bioaerosol components related to the respiratory diseases of interest in each of their demonstration cities by the 6-month milestone. Limits of detection should be established for bioaerosols known to cause illness such that when the sensors are deployed, meaningful health risks can be identified based on biosensor data. TA1 and TA2 performers of each team will need to collaborate to determine the limits of detection that will enable eventual success in field trials.

Metric: Multiplexing Capability
Performers will be expected to demonstrate the ability to detect 100 distinct biological targets including 50% viral variants, 25% bacteria, and 25% mold and/or allergens by the end of the program. By the end of Phase II, biosensor prototype devices will be capable of detecting 25 unique targets prior to deployment in field trials and validated through IV&V. The IV&V team will determine whether the prototype biosensor meets the program's performance standards for each class of bioaerosol. During the Phase III field trials, performers will be expected to deploy prototype biosensors that will be multiplexed for 25 unique biological targets including those known to contribute to the respiratory diseases of interest.

Metric: Production and Deployment
Performers will be expected to demonstrate the capability to manufacture biosensor devices at scale as set by the performer in the first six months of the program. The frequency, number, and placement of the biosensor prototypes will be informed by collaborative efforts between the TA1, TA2 and TA3 performers. By month 24/Phase I, at least three prototypes must be manufactured, whereby at least one biosensor will be used for initial IV&V assessment for validation of progress toward TA1 metrics. At the beginning of Phase II, at least three manufactured prototypes will be tested by the IV&V team in chamber studies for simulating biosensor performance reproducibility. By the end of month 42/Phase III, sufficient sensors must be manufactured such that field deployment and testing can commence thus allowing sufficient time for refinements prior to full deployment for the Phase III field validation studies.

Metric: Cost
Within the initial six months, performers are tasked with developing a detailed cost analysis related to the deployment of biosensor technologies, ensuring alignment with TA3's Return on Investment (ROI) metric. This analysis will comprehensively outline the direct costs associated with sensor installation, ongoing maintenance, and annual service fees. To ascertain the financial viability and alignment with TA3's ROI, performers must compare these costs outlined in TA3 Metric 3. By the conclusion of year 4/Phase III, performers are expected to have refined

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this cost analysis based on initial deployment feedback, recalibrating estimates as needed to ensure that the costs of sensor deployment do not exceed the projected health-related savings.

TA2 Respiratory Risk Assessment Software:

Metric: Indoor Air Risk Model Performance
During the first six months of performance, the performers will choose data and analysis methods to incorporate into the risk model and identify techniques to be used to validate model performance. These methods must allow the biosensor data to be used for measuring clinically meaningful doses of bioaerosols and translated into the exposure risk that building occupants have received. Possible methodologies for evaluating and validating models may include air flow models, manual bioaerosol testing, mock sample releases, and additional data alignments. Importantly, the validation framework will also address the model's ability to discern between actual and non-actual exposure events, effectively minimizing false positives (erroneous risk identification) and false negatives (missed risk identification) and weighting them appropriately as mentioned in Section 1.2 of TA2.

Metric: Model Adaptability
Risk models are expected to be generalizable across different buildings of the same type independent of the buildings' location and environment without needing to be individually trained or extensively calibrated.

TA3 Healthy Building Controls and System Integration:

Metric: Intervention Efficacy
During Phase I and II, performers will establish the baseline incidence of their target respiratory illnesses for human occupants in test buildings and calculate the likely proportion of incidents attributable to time spent in the test buildings. The 25% reduction targets will be relative to this baseline calculation.

Metric: Return on Investment
In order to establish the target at six months, performers will calculate the expected monetary benefits resulting from improvements in the building occupants' health due to deployment of BREATHE systems, which will vary based on performer use-cases. For instance, performers may model decreases in employee absenteeism, improvements in productivity, reductions in health care costs, quality-adjusted life years (QALYs) gained, etc. Performers must also calculate costs associated with false positive and false negatives, including the decrease in value of the system incurred by either. Similarly, performers will calculate all costs associated with deployment and use of these systems including sensor installation, maintenance, consumables, and increased (or decreased) costs incurred by building interventions relative to normal building operations without the BREATHE system enabled. Baseline estimates and calculations will be subject to review by ARPA-H and IV&V.

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1.5 GENERAL REQUIREMENTS

Proposers must submit a single, integrated proposal led by a Principal Investigator (PI), under a single prime contractor that addresses all program Phases, TAs and metrics, as applicable. Proposals that do not address all TAs, Phases, and metrics will be deemed non-conforming and will not be reviewed. It is expected that proposals will involve teams with the range of expertise needed to achieve the goals of all three TAs collectively. Specific content, communications, networking, and team formation are the sole responsibility of the proposer.

To facilitate teaming, ARPA-H will hold a hybrid Proposers' Day (see Section 8) and will host a teaming page on the BREATHE Program webpage.

Handling of Competition-Sensitive Information
It is the policy 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, to the extent permitted under applicable laws. Restrictive notices notwithstanding, during the evaluation process, submissions may be handled by ARPA-H support contractors for administrative purposes and/or to assist with technical evaluation.

All ARPA-H support contractors are expressly prohibited from performing ARPA-H sponsored technical research and are bound by appropriate nondisclosure agreements. Input on technical aspects of the proposals may be solicited by ARPA-H from non-Government consultants/experts who are strictly bound by appropriate non-disclosure requirements. No submissions will be returned.

Software Component Standards
The health and healthcare data eco-system is complex and multi-dimensional with a variety of standards for data models, data transmission protocols, data routing methods etc. that are similar to and extend the International Standards Organization (ISO) Open Systems Interconnection Model (OSI).[17] ARPA-H programs are likely to involve research that touches on multiple layers of the OSI model from low level radio frequency (RF) based protocols for transmission of data from implantable devices (potentially OSI layers 1-5), to secure and fault tolerant networking protocols for medical devices (potentially OSI layers 3-6) to the exchange of health information including Electronic Health Records, lab results and medical images related to a patient between healthcare facilities and health data brokers including but not limited to Health Information Exchanges (HIE) and Trusted Exchange Framework and Common Agreement (TEFCA) Qualified Health Information Networks using protocols such as HL7 FHIR (OSI Layer 7). This diversity requires careful consideration of the most appropriate standards to be used for the specific technologies in development and the layer at which they operate.

ARPA-H is committed to advancing interoperability in today's health ecosystem through the adoption of open, consensus driven standards and laying the foundation for emerging technologies to interoperate in the health ecosystem of the future through the evolution of these standards across all layers of the health data IT eco-system. With that in mind, we anticipate that potential performers will develop software and data communication

[17] https://www.iso.org/ics/35.100/x/

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components that fall into three categories: (1) components that can leverage today's existing standards without impeding the R&D, (2) components where extensions to existing standards will be necessary to unlock new capabilities in an interoperable way, and (3) components in areas where consensus-based standards do not yet exist or where use of standards would seriously limit the ability to efficiently conduct R&D.

Whenever such an existing standard is available that meets the scientific, technical, and research needs of the proposed effort, proposers must use the existing standard instead of creating their own. In cases where an existing standard provides only partial functionality, proposers should expand upon the existing standard, ideally in a way that does not prohibit or interfere with backward compatibility, and create sufficient documentation for Office of the National Coordinator for Health Information Technology (ONC), the U.S. Department of Health and Human Services (HHS) agencies or standards organizations, to evaluate extensions for potential inclusion in the standard (including open APIs and open data formats).

In the case of information relating health and healthcare data at higher layers of the OSI model, all health information technology (IT) components should adhere to or (as needed) expand upon applicable national standards adopted by HHS, including the ONC (e.g., Fast Healthcare Interoperability Resources (FHIR) and United States Core Data for Interoperability (USCDI)).[18]

Technical solutions that contain software elements, commercial-friendly open-source licenses (e.g., MIT, BSD, or Apache 2.0) are preferred. If an open, consensus-based standard does not yet exist, proposers should identify the aspects that lack an open standard, describe a plan to develop a general-purpose open data model and to prototype new open APIs. Proposals should explain how the performer will enhance data interoperability (including semantic interoperability) and expand the availability of open, consensus-based standards and data models.

Proposals must include a technical plan to align with applicable standards based on the OSI layer at which they are operating including but not limited to HHS-adopted health IT standards (45 CFR Part 170 Subpart B). For the full description of standards adopted in CFR Part 170, Subpart B, please review the complete text of the regulations when applicable, technical solutions should also outline integration with the Trusted Exchange Framework and Common Agreement (TEFCA). Adhering to international standard ISO/IEEE 11073 will enable broad support for current and future devices, especially those developed internationally. At other layers of the OSI model, and for software components operating outside the network stack e.g. health databases, Picture Archiving and Communication Systems (PACS) etc. other standards will be relevant and strong technical solutions should seek to utilize or expand upon appropriate open, consensus-based standards.[19]

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[18] https://www.healthit.gov/sites/default/files/page/2022-07/Standards_And_Implementation_Specifications_Adopted_Under_Section_3004.pdf

[19] https://www.iso.org/standard/77338.html

2.0 PS AWARD INFORMATION

This PS may result in multiple awards of Other Transaction (OT) agreements. However, the number of awards selected will depend on the quality of the proposals received and the availability of funds. If warranted, portions of resulting awards may be segregated into pre-priced options. In the event that the Government desires to award only portions of a proposal, negotiations will commence upon selection notification. The Government reserves the right to fund proposals in Phases with 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, cost, and/or the proposer fails to provide requested additional information in a timely manner.

The Government reserves the right to award an OT or make no award at all. It is anticipated that a model Agreement with basic terms and conditions will be posted with the Final PS (see additional details in Section 4.5.2).

ARPA-H will apply pre-publication reviews, as necessary, if it is determined that 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) or Controlled Unclassified Information (CUI), etc. Any award resulting from such a determination will include a requirement for ARPA-H permission before publishing any information or results on the effort.

2.1 Acquisition Strategy

(a) ARPA-H aims to lower the administrative burden typically associated with working with the federal government, reduce program risk, foster competition, and have performers begin work faster. To facilitate this objective ARPA-H will use the following acquisition process for BREATHE:

1. **Draft Solicitation**: ARPA-H will utilize the comment period associated with the BREATHE draft solicitation, in conjunction with Proposers' Day to gauge interest in the program and to help facilitate teaming (see Section 8.0) given the need to address all TAs and phases within a proposal submission. The draft Solicitation, Question and Answers (Q&A) process (see Section 7.0), and final BREATH PS will be solicited through both the BREATHE team webpage (https://arpa-h.gov/research-and-funding/programs/breathe) and SAM.gov (https://sam.gov/content/home).
2. **Solution Summaries**: Solution summaries are strongly encouraged in advance of a full proposal submission. The ARPA-H team will review all Solution Summaries for compliance; only conforming Solution Summaries will receive feedback. ARPA-H will provide feedback to encourage or discourage submission of a full proposal; however, proposals can be submitted regardless of the feedback received. See Section 4.3, Proposal Instructions, for further details.

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(b) ARPA-H will not pay the costs associated with the preparation or submission of a Solution Summary and/or Proposal.
(c) ARPA-H will review and evaluate proposals based on the evaluation criteria described in Section 5.0, Evaluation of Proposals.

2.2 Other Transaction (OT) Awards

Any resulting award under the BREATHE program will be an OT Agreement. Use of an OT will also allow for streamlined practices to be employed, such as milestone-driven performance, intended to reduce time and effort on award administration tasks and permit Performers to focus on the research effort. Payable milestones allow for payment under the OT Agreement when there is successful completion of the milestone accomplishments agreed to in the Milestone Plan.

Accordingly, proposers must include a detailed list of payment milestones (Milestone Plan) in the proposal submission. Each Milestone must include the following:

- Milestone description
- Completion/Exit criteria (to include identifying all associated data deliverables excluding those specifically providing project status)
- Due Date
- Payment/funding schedule (to include, if resource share is proposed, awardee and Government share amounts)
- For each data deliverable, identify the proposed Government data rights (keeping in mind how each data deliverable will need to be used by the Government given the goals and objectives of the proposed project).

It is noted that, at a minimum, milestones should relate directly to the accomplishment of program technical metrics as defined in the PS and/or the proposer's proposal. Agreement type, expenditure or fixed-price based, will be subject to negotiation by the Agreements Officer. Do not include proprietary data.

3.0 ELIGIBILITY INFORMATION

3.1 ELIGIBLE APPLICANTS

All responsible sources capable of satisfying the Government's needs may submit a solution summary and/or proposal to the PS. Specifically, universities, non-profit organizations, small businesses and other than small businesses, hospitals, community health centers and non-Federal research centers are eligible and encouraged to propose to this PS.

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

(a) FFRDCs are subject to applicable direct competition limitations and cannot propose to this PS in any capacity, including as sub awardees. The prime

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proposer may reference potential collaboration with FFRDCs but may not commit those resources within their proposal.

(b) The prime performer can propose Government Entities as a sub performer only if they provide a statement from the Government Entity's direct supervisor or agency ethics attorney, stating the individual(s) have no ethical challenges receiving compensation for their services as a Federal employee and have no Conflicts of Interest to support the prime performer.

(c) If an FFRDC or Government entity is interested in working directly with the Government team supporting this program, please contact the BREATHE PM at BREATHE@arpa-h.gov.

3.1.2 Non-U.S. Organizations

ARPA-H will prioritize awards to entities (organization and/or individuals) that will conduct funded work in the United States. However, non-U.S. entities may participate to the extent that such participants comply with any necessary nondisclosure agreements, security regulations, export control laws, and other governing statutes applicable under the circumstances. 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 ORGANIZATIONAL CONFLICTS OF INTEREST (OCI)

Proposers, through submission of a proposal, are required to identify and disclose all facts relevant to a potential OCI involving the proposer, the proposer's organization and/or any proposed team member (proposed sub awardee). Along with the disclosure, the proposer shall submit a mitigation plan, which is a description of the action the performer has taken to avoid, neutralize or mitigate the stated OCI. The Government may require proposers to provide additional information to assist the Government in evaluating the OCI mitigation plan.

If the Government determines a 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.

AGENCY SUPPLEMENTAL OCI POLICY

In addition, ARPA-H restricts performers from concurrently providing professional support services, including Advisory and Assistance Services or similar support contractor services in addition to performing as an R&D technical performer. Therefore, a proposer must affirm whether the proposer or any proposed team member (proposed sub awardee, etc.) is

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providing professional support services to any ARPA-H office(s) under: (a) a current award or subaward; or (b) a past award or subaward that ended within one calendar year prior to the proposal's submission date.

If any professional support services are being 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 (proposed subawardee) providing the support.

RESEARCH SECURITY DISCLOSURE

In accordance with National Security Presidential Memorandum (NSPM)-33, Presidential Memorandum on United States Government-Supported Research and Development National Security Policy, research organizations should identify and mitigate conflicts of commitment and conflicts of interest (CoC/CoI) to receive federal funding. Research organizations submitting a proposal in response to this PS must provide additional documentation for Senior/Key Personnel when requested for ARPA-H to determine whether there is any CoC/CoI risk. The format for this submission can be found in Attachment 1, OT Bundle, Attachment Volume 3, Admin & National Policy Requirements (to be provided with the final PS).

4.0 SOLUTION SUMMARY AND PROPOSAL INFORMATION AND SUBMISSION INSTRUCTIONS

4.1 GENERAL GUIDELINES

- Do not include elaborate brochures or marketing materials; only include information relevant to the submission requirements or evaluation criteria.
- Use of a diagram(s) or figure(s) to depict the essence of the proposed solution is permitted.
- All Solution Summaries and Proposals shall be unclassified. Files containing proprietary information must have the cover page and each page containing such information clearly marked with a label such as "Proprietary" or "Company Proprietary." NOTE: "Confidential" is a classification marking used to control the dissemination of U.S. Government National Security Information as dictated in Executive Order 13526 and should not be used to identify proprietary business information.
- Proposers are responsible for clearly identifying proprietary information.
- Submissions containing proprietary information must have the cover page and each page containing such information clearly marked with a label such as "Proprietary" or "Company Proprietary."

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- Files containing Controlled Unclassified Information (CUI) must be encrypted when sending over the Internet.
- ARPA-H will post a consolidated Questions & Answers document on a regular basis. See Section 7.0, Communications.
- Submissions sent through other mediums, channels other than what is prescribed herein, or after the prescribed PS deadline will not be considered, reviewed, nor evaluated.

4.2 SOLUTION SUMMARY INSTRUCTIONS

Proposers are strongly encouraged to submit a Solution Summary to this PS. A Solution Summary submitted in response to the BREATHE PS **must address all TAs and Phases**. The Government is anticipating releasing a Special Notice (SN) to solicit Solution Summaries by April 27, 2024. The SN will be issued on SAM.gov. The anticipated due date for Solution Summaries is 5:00 pm on June 7, 2024. Proposers are required to follow the content and submission instructions in the SN when submitting solution summary responses.

4.3 PROPOSAL INSTRUCTIONS

4.3.1 Proposal Volume Templates

Proposers must provide the following information when submitting a proposal. Templates and instructions for Volume 1, 2, and 3 will be attachments to the final PS (Attachment 1, OT Bundle). Failure to utilize the templates and/or provide the information requested may result in a proposal being deemed non-conforming and/or delay the evaluation process discussed in Section 5.2, Review and Selection Process.

Volume 1 must consist of the following documents *(page count stipulated within Volume 1)***:**
TECHNICAL & MANAGEMENT
TASK DESCRIPTION DOCUMENT (TDD)

Volume 2 must consist of the following documents (*no page count*):
PRICE/COST PROPOSAL
MODEL AGREEMENT

Volume 3 must consist of the following documents (*no page count*)**:**
ADMINISTRATIVE & NATIONAL POLICY REQUIREMENTS

4.3.2 Model Other Transaction Agreement

Prior to submitting a proposal, proposers must review the model OT that will be provided as an attachment to the final PS (included within Attachment 1, OT Bundle). ARPA-H will provide the model OT to expedite the negotiation and award process. The model OT is representative of the basic terms and conditions. Proposers should

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suggest edits to the model OT for consideration by ARPA-H and provide a copy of it with changes identified (with revision markings) as part of the proposal package in order to expedite subsequent negotiations if selected. It is required that Proposers include comments providing rationale for any suggested edits of a non-administrative nature. The government Agreement Officer (AO) shall have sole discretion to negotiate the Agreement terms and conditions with selected Proposers.

4.4 PROPOSAL DUE DATE AND TIME

Proposals should be submitted to https://solitions.arpa-h.gov/Submit-Proposal/, and the anticipated due date is no later than 5:00 PM ET on August, 12th, 2024. Full proposal packages must be submitted per the instructions outlined in the BREATHE PS and in accordance with Attachment 1, OT Bundle and received by ARPA-H no later than the above time and date. Proposals received after this time and date will not be reviewed.

Proposers are warned that the proposal deadline outlined herein is in Eastern Time (ET) and will be strictly enforced. When planning a response to this notice, proposers should consider that some parts of the submission process may take from one business day to one month to complete.

5.0 EVALUATION OF PROPOSALS

5.1 EVALUATION CRITERIA FOR AWARD

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

1. **OVERALL SCIENTIFIC AND TECHNICAL MERIT**
   The proposed technical approach is innovative, feasible, achievable, and complete. Task descriptions and associated technical elements provided are complete and in a logical sequence with all proposed deliverables clearly defined such that a final outcome that achieves the goal can be expected as a result of award. The proposal identifies major technical risks and planned mitigation efforts are clearly defined and feasible.

2. **POTENTIAL CONTRIBUTION TO RELEVANCE TO THE ARPA-H MISSION**
   The proposed technical approach is diverse and targets high risk populations. The proposed technical approach has potential future R&D, commercial, and/or government applications, including the potential to improve public health and wellbeing outcomes. The evaluation will take into consideration the degree to which the proposed project has the potential to transform public health. The evaluation will also consider the potential for the project to take an interdisciplinary approach. In addition, the evaluation will 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.

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3. **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. Similar efforts completed/ongoing by the proposer in this area are fully described, including identification of other Government entities.

4. **COST REALISM**
   The proposed costs are realistic for the technical and management approach, accurately reflect the technical goals and objectives of the solicitation, the proposed costs are consistent with the proposer's technical approach (as detailed in the Task Description Document (TDD)) and reflect a sufficient understanding of the costs and level of effort needed to successfully accomplish the proposed technical approach.

   The costs (inclusive of TA1, TA2, and TA3) are substantiated by the details provided in the proposal (e.g., the type and number of labor hours proposed per task, the types and quantities of materials, equipment, software and fabrication costs, travel and any other applicable costs and the basis for the estimates).

   It is expected that the effort will leverage all available relevant prior research in order to obtain the maximum benefit from the available funding. The evaluation will also take into consideration the resource sharing strategy to include the type of resource share proposed (e.g. cash, direct labor, equipment, etc.) and the appropriateness of the cost share arrangement relative to the objectives of the proposed solution.

   NOTE: Proposers are encouraged to propose the best technical solution. Proposers are discouraged from proposing low-risk ideas with minimum uncertainty and staff the proposed effort with junior personnel to be more appealing from a dollar threshold. ARPA-H seeks novel solutions that are accompanied by a cost proposal that is reflective of the level of effort and risk proposed.

5.2 REVIEW AND SELECTION PROCESS

It is the policy of ARPA-H to ensure impartial, equitable, comprehensive proposal evaluations based on the evaluation criteria listed above and to select the source (or sources) whose offer meets ARPA-H's mission objectives and programmatic goals.

ARPA-H will conduct a scientific and technical review of each conforming proposal. All proposal evaluations will be based solely on the evaluation criteria in Section 5.1, Evaluation Criteria for Award, regardless of the response to the organization's Solution Summary.

Relative to the evaluation criteria, the Government will evaluate each conforming proposal in its entirety, documenting the strengths and weaknesses. Based on the identified strengths and weaknesses, ARPA-H will determine whether a proposal will be selected for negotiation and/or award. Proposals will not be evaluated against each other during the scientific review process,

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but rather evaluated on their own individual merit to determine how well the proposal meets the criteria stated in BREATHE PS.

An award will be made to the Proposer(s) whose proposal is determined to be the most advantageous to the Government, consistent with instructions and evaluation criteria specified herein and based on availability of funding.

For the purposes of this proposal evaluation process, a selectable proposal is defined as follows:

SELECTABLE: A selectable proposal is a proposal that has been evaluated by the Government against the evaluation criteria listed in the PS, and the positive aspects of the overall proposal outweigh its negative aspects. Additionally, there are no accumulated weaknesses that would require extensive negotiations.

For the purposes of this proposal evaluation process, a non-selectable proposal is defined as follows:

NON-SELECTABLE: A proposal is considered non-selectable when the proposal has been evaluated by the Government against the evaluation criteria listed in the PS, and the positive aspects of the overall proposal do not outweigh its negative aspects. Additionally, there are accumulated weaknesses that would require extensive negotiations and/or a resubmitted proposal.

CONFORMING PROPOSALS: Conforming proposals contain all requirements detailed in BREATHE PS to which the proposal is submitted. Proposals that fail to include required information may be deemed non-conforming and may be removed from consideration. Non-conforming submissions may be rejected without further review. A proposal will be deemed non-conforming if the proposal fails to meet one or more of the following requirements:

1. The proposed concept is applicable to the technical area(s) described in the BREATHE PS.
2. The proposers meet the eligibility requirements of the BREATHE PS.
3. The proposal met the submission requirements of the BREATHE PS.
4. The proposal met the content and formatting requirements in the attached templates to this BREATHE PS.
5. The proposal provided sufficient information to assess the validity/feasibility of its claims.
6. The proposer has not already received funding or a positive funding decision for the proposed concept (whether from ARPA-H or another Government agency).

Non-conforming proposals may be removed from consideration. Proposers will be notified of non-conforming determinations via email correspondence.

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5.3 HANDLING OF COMPETITIVE SENSITIVE INFORMATION

It is the policy of ARPA-H to protect all proposals as competitive sensitive information and to disclose their contents only for the purpose of evaluation and only to screened personnel for authorized reasons, to the extent permitted under applicable laws. Restrictive notices notwithstanding, during the evaluation process, submissions may be handled by ARPA-H support contractors for administrative purposes and/or to assist with technical evaluation.

All ARPA-H support contractors are expressly prohibited from performing ARPA-H sponsored technical research and are bound by appropriate nondisclosure agreements. Input on technical aspects of the proposals may be solicited by ARPA-H from non-Government consultants/experts who are strictly bound by appropriate non-disclosure requirements. No submissions will be returned.

6.0 AWARDS

6.1 GENERAL GUIDELINES

The Agreement Officer reserves the right to negotiate directly with the proposer on the terms and conditions prior to award of the resulting OT agreement, including payment terms, and will execute the agreement on behalf of the Government. Proposers are advised that only a Government Agreements Officer has the authority to enter into, or modify, a binding agreement on behalf of the United States Government.

To receive an award:

- Proposers must register in the System for Award Management (SAM). See Section 6.3.1, System for Award Management Registration and Unique Entity Identifier Requirements.
- Proposers must be determined to be responsible by the Agreements Officer and must not be suspended or debarred from award by the Federal Government nor be prohibited by Presidential Executive Order and/or law from receiving an award.

6.2 NOTICES

The following notices will be provided as applicable:

- Request for clarifying details (if applicable) *May occur at any time during the evaluation process after proposal submission. Will not include requests for proposal changes and changes will not be permitted;*
- Notice of non-selection; or
- Notice of selection

As soon as the evaluation of proposals is complete, the proposers will be notified that (1) the proposal has been selected for funding, subject to OT Agreement negotiations. This notification may indicate that only a part of the effort has been selected for negotiation and may request a revised proposal for only those selected

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portions, if not apparent through the delineation of proposed tasks; or (2) the proposal has not been selected for funding.

The above-listed notifications will be sent via electronic mail to the Technical and Administrative points of contact identified on the proposal coversheet.

6.3 ADMINISTRATIVE AND NATIONAL POLICY REQUIREMENTS

6.3.1 System for Award Management (SAM) Registration and Unique Entity Identifier (UEI) Requirements

All proposers must be registered in SAM and have a valid Unique Entity ID (UEI) number at time of proposal submission. You must maintain an active registration in SAM.gov with current information at all times during which you have an active Federal award or idea under consideration by ARPA-H. Information on SAM.gov registration is available at https://sam.gov/content/home.

NOTE: New registrations can take an average of 7-10 business days to process in SAM.gov. Registration requires the following information:

- TIN (Taxpayer Identification Number)
- Commercial and Government Entity Code (CAGE) Code. If a proposer does not already have a CAGE code, one will be assigned during SAM registration.
- Electronic Funds Transfer (EFT) information (e.g., proposer's bank account number, routing number, and bank phone or telefacsimile (fax) number).

6.3.2 Controlled Unclassified Information (CUI) or Controlled Technical Information (CTI) on Non-DoD Information Systems

Information on Controlled Unclassified Information identification, marking, protecting, and control is incorporated herein and can be found at 32 CFR § 2002 (https://www.ecfr.gov/current/title-32/subtitle-B/chapter-XX/part-2002).

6.3.3 Intellectual Property

Proposers must provide a good faith representation that the proposer either owns or possesses the appropriate licensing rights to all intellectual property that will be utilized for the proposed effort. Proposers should appropriately identify any desired restrictions on the Government's use of any Intellectual Property contemplated under the award instrument in question. This includes both noncommercial items and commercial items. Respondents should utilize the prescribed format within the Administrative & National Policy Requirements Document Template (Volume 3 of Attachment 1, OT Bundle) when asserting restrictions. If no restrictions are intended, then the proposal should state "NONE."

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6.3.4 Human Subjects Research

(a) All entities submitting a proposal for funding that will involve engagement in Human Subjects Research (as defined in 45 CFR § 46)(https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46) must provide documentation of one or more current Assurance of Compliance with federal regulations for human subject protection, including at least a Department of Health and Human Services (HHS), Office of Human Research Protection (OHRP), Federal Wide Assurance (https://www.hhs.gov/ohrp/index.html). All research involving Human Subjects must be reviewed and approved by an Institutional Review Board (IRB), as applicable under 45 CFR § 46 (https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46) and/or 21 CFR § 56 (https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-56). The entity's Human Subjects Research 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 the ARPA-H funded work. This includes, but is not limited to, laws, regulations, and policies regarding the conduct of Human Subjects research, 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.

(b) The informed consent document utilized in human subject research 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 (https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46) and, as applicable, 21 CFR § 50 (https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-50). The protocol package submitted to the IRB must contain evidence of completion of appropriate Human Subject Research training by all investigators and key personnel who will be involved in the design or conduct of the ARPA-H funded human subject research. Funding cannot be used toward human subject research until ALL approvals are granted.

6.3.5 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: (i) 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); (ii) the 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 complete and submit the Vertebrate Animal Section (see https://olaw.nih.gov/sites/default/files/VAChecklist.pdf) for all proposed research anticipating Animal Subject Research. All Animal Use Research must undergo review

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and approval by the local Institutional Animal Care Use Committee (IACUC) prior to incurring any costs related to the animal use research.

6.4 ELECTRONIC INVOICING AND PAYMENTS

Performers will be required register in and to submit invoices for payment for invoicing in the Payment Management Services (PMS) system. PMS is a centralized payment and cash management system. ARPA-H other transaction are made by PMS, operated by PSC, in accordance with Department of the Treasury and OMB requirements. PMS guidance can be found here: https://pms.psc.gov/training/grant-recipient-training.html.

6.5 GOVERNMENT-FURNISHED INFORMATION/PROPERTY/EQUIPMENT/FACILITIES

Proposers should document any Government furnished information, equipment and/or facility assumptions within proposal submissions that would be helpful during the BREATHE period of performance.

7.0 COMMUNICATIONS

(a) All questions regarding this notice must be submitted to the following:
BREATHE Program Solicitation (PS)
ARPA-H Solutions
https://solutions.arpa-h.gov/Ask-A-Question/
ATTN: ARPA-H-SOL-24-107

E-mails sent directly to the Program Manager, or any other address will be discarded.

(b) ARPA-H will post a Q&A document to SAM.gov (https://sam.gov) and the BREATHE Team webpage (https://arpa-h.gov/research-and-funding/programs/breathe) regarding all administrative questions submitted to this PS on an as needed basis. All questions must be in English. ARPA-H encourages all Proposers to review the Q&As provided before submitting additional questions to the link noted above. The Government may not answer repetitive questions already answered in the posted Q&As.

(c) ARPA-H will attempt to answer questions in a timely manner. In order to receive a response sufficiently in advance of the proposal due date, send your question/s on or before the Q&A deadline of April 18, 2024.

8.0 PROPOSERS' DAY

The BREATHE Program hybrid Proposers' Day will be held May 2nd, 2024 in Oakland, CA. This will be a one-day event. Advance registration is required for the physical meeting and the webcast. Details regarding the BREATHE Proposers' Day can be found in ARPA-H-SN-24-107, posted at https://sam.gov and the BREATHE team webpage (https://arpa-h.gov/research-and-funding/programs/breath). Attendance at the BREATHE Proposers' Day is NOT required to propose to this PS.

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ATTACHMENT 1: OT BUNDLE TEMPLATES (TO BE PROVIDED WITH THE FINAL SOLICITATION)

1. Attachment 1, Volume 1 – Task Description Document (TDD)
2. Attachment 1, Volume 1 – Technical and Management
3. Attachment 1, Volume 2 – Price (inclusive of spreadsheet template)
4. Attachment 1, Volume 2 – Model OT
5. Attachment 1, Volume 3 – Admin & National Policy Requirements

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