NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES (NIEHS)

Mission

The mission of the National Institute of Environmental Health Sciences www.niehs.nih.gov is to discover how the environment affects people in order to promote healthier lives, with a vision of providing global leadership for innovative research that improves public health by preventing disease and disability.

NIEHS achieves its mission and vision through a multidisciplinary biomedical research program, prevention and intervention efforts, and a communication strategy that encompasses training, education, technology transfer and community outreach.

Budget Guidance

For all NIEHS research interest topic areas other than Hazardous Substances Remediation and Site Characterization SBIR Program included in this PHS 2022 Omnibus SBIR/STTR Solicitation, NIEHS will accept SBIR/STTR application total funding support (direct costs, indirect costs, fee) requests up to $275,766 for Phase I and $1,838,436 for Phase II. NIEHS will not fund applications at budget levels exceeding these hard cap budget guidelines, except through specific RFAs. For budgetary, administrative, or programmatic reasons, NIEHS may decide not to fund an application or may decrease the length of an award and/or the budget. In all cases, applicants should propose a budget that is reasonable and appropriate for completion of the research project, and the budget request must be well justified. The Hazardous Substances Remediation and Site Characterization SBIR Program has different limits on budget requests for both Phase I and Phase II; check under that topic below for details.

Specific SBIR and STTR Program Information

For additional information about NIEHS's Small Business Programs, please visit https://www.niehs.nih.gov/funding/grants/mechanisms/sbir/. NIEHS **DOES NOT** Fund technologies for the detection and remediation of pathogens in the environment.

Final Progress Reports

As detailed in NOT-OD-17-085, the NIH has implemented the Final Research Performance Progress Reports (Final RPPR) for SBIR/STTR Final Progress Reports.

The NIEHS is interested in tracking the progress of the small business concerns it funds and the products they develop. It is expected that small businesses who have received previous SBIR/STTR grants have had success in commercializing their previously supported technologies. Small businesses that are primarily interested in research and development (and not commercialization) should consider other grant mechanisms at NIH, rather than the SBIR/STTR program. Funding priority will be given to those small business concerns that demonstrate their ability to develop and commercialize products.

Specific Funding Opportunities and Programs

In addition to this omnibus program announcement, the NIEHS releases targeted SBIR/STTR Funding Opportunity Announcements (FOAs); signup for the listserv (https://list.nih.gov/cgi-bin/wa.exe?SUBED1=sbir-niehs&A=1) to be notified of FOAs.

Phase IIB Competing Renewal Awards and Commercialization Readiness Pilot (CRP)

NIEHS does not intend to support any new Phase II B grants in this funding period. NIEHS currently participates in PAR-20-128 - SBIR/STTR Commercialization Readiness Pilot (CRP) Program Technical Assistance (SB1, Clinical Trial Not Allowed).

Clinical Trials

Does NIEHS accept Clinical Trials through the Omnibus/Parent Funding Opportunity Announcement/s?	Yes	
Does NIEHS accept Clinical Trials through specific Funding Opportunity Announcement/s?	No	
Does NIEHS support Clinical Trials through NON-SBIR/STTR Funding Opportunity Announcement/s?	Yes	ES-22-002 Revolutionizing Innovative, Visionary Environmental Health Research (RIVER) (R35 Clinical Trial Optional) ES-21-007 Virtual Consortium for Translational/Transdisciplinary Environmental Research (ViCTER) (R01 Clinical Trial Optional)

Research Topics

NIEHS Non-Clinical Trials Topics:

Exposure Assessment Tools

The NIEHS Exposure Biology and the Exposome Program encompasses the totality of the exposures that a person experiences throughout the lifespan, along with the associated biological responses to those exposures. Validated tools are needed to measure, analyze, and predict a wide range of internal and external exposures and health outcomes across diverse geographic populations. These tools should be designed fit-for-purpose in collaboration with the stakeholders (*e.g.,* community outreach programs, citizen scientists, disaster response personnel, epidemiologists, or clinical researchers). Examples include:

Sensors and Other Exposure Assessment Tools

- Technologies and methodologies to assess personal exposure in population studies, including wearable monitors and sensor networks
- Devices for collecting exposure measurements across multiple stressors and scales, with an emphasis on high sensitivity and specificity and low-cost devices, when feasible. High-priority analytes include contaminants of emerging concern (*e.g.*, perfluorinated compounds, microplastics, and toxins produced in harmful algal blooms) as well as ultrafine particulates, PAHs, microplastics, and pesticide exposures
- Novel sampling technologies to enable subsequent targeted and untargeted laboratory analysis
- Sensor technologies that can be integrated into existing smart devices for sensing personal environment

- Tools and approaches for identifying and characterizing contaminants in drinking water that may pose a risk to human health, with a particular emphasis on new contaminants or compounds that are of emerging concern. Note that identification of environmental pathogens in drinking water is not within the NIEHS mission.

Computational and Informatics-based Tools and Methods for Exposure Assessment

- Informatics tools and platforms to organize, store, retrieve, extract, and integrate information on exposures and health effects data

- Application of machine learning methods and natural language processing for extracting and integrating diverse data types and for generating causal networks from experimental data and public knowledgebases

- Computational and statistical approaches to integrate exposure data from different sources, including publicly available databases and information from monitoring approaches (*e.g.*, sensors, remote sensing, and biomonitoring), to provide quantitative exposure estimates, identification and characterization of adverse effects on human health.

- Adapting or developing new methods and tools for automating environmental health-related literature and systematic reviews, including article selection and prioritization, data extraction, study quality evaluation, and summarization of for environmental health impacts

Information on the NIEHS Exposure Biology and the Exposome Program can be found at http://www.niehs.nih.gov/research/supported/exposure/bio/

Nano Environmental Health and Safety

The NIEHS Nano Environmental Health and Safety (Nano EHS) program is interested in the detection of engineered nanomaterials (ENMs) in the environment, in consumer products, and in biological samples, and is interested in technologies or methods that can predict toxicity potential of ENMs.

High priority engineered nanomaterials of interest are those with a potential for human exposure.

Examples include:

- Sensors that can detect engineered nanomaterials or micro/nanoplastics in air, water, and consumer products, and provide a contextual assessment of the toxicological potential

- Mid- to high-throughput and high-content assays using *in vitro* or tissue chip technologies to screen and rank toxicity of emerging engineered nanomaterials for cytotoxicity, genotoxicity, and metabolic toxicity.

- Methods and tools to assess leaching of engineered nanomaterials from nanotechnology-based water filtration systems

- Technologies to assess the life cycle of nanomaterials from nano-enabled products in the market

- Development of tools and technology platforms for the isolation, quantification, physical and chemical characterization of various forms of nanoplastics from diverse media including aqueous sources, air and food samples and assessment of their toxicity potential and human health effects

Information on the Nano EHS program can be found at http://www.niehs.nih.gov/research/supported/exposure/nanohealth/index.cfm

Toxicity Screening, Testing, and Modeling

NIEHS supports research to identify the hazards, as well as the mechanistic understanding, of the effects of environmental stressors on biological systems that can lead to adverse human health outcomes. To increase the ability to characterize or predict the toxicity and hazard of environmental stressors, the National Toxicology Program (NTP) http://ntp.niehs.nih.gov/ at NIEHS is interested in technologies to support the goals and initiatives of the Tox21 Program http://ntp.niehs.nih.gov/results/tox21/index.html.

Technologies that support Tox21 and other NTP goals may include the development and/or application of *in vitro* physiologically relevant cell-based systems that effectively model responses in humans or animals and may be used to reduce or replace *in vivo* animal use. High priority areas are the development of metabolically competent *in vitro* screening models and assay systems for various tissue types *(e.g.,* cardiac, neurological, liver, GI tract, kidney, mammary gland, lung, and immune function) for assessing the effects of the environmental stressors .

Toxicity Screening Approaches

- Improved human organotypic culture models (OCM) and microphysiological systems (MPS) that more accurately predict *in vivo* function for characterizing toxicity and/or related disease processes. Priority areas are improved capability for generating more mature cells from embryonic stem (ES) or induced pluripotent (iPS) cells for organotypic models and the ability to conduct *in vitro* pathology studies using OCM, MPS or 3D culture models.

- Organotypic models using cells from rat or mouse models or other experimental animal models, with a focus on comparisons between *in vivo* and *in vitro* toxicity endpoints

- Approaches to characterize and integrate key molecular and cellular changes related to effects of toxicant exposures in carcinogenicity, developmental neurotoxicity, or cardiotoxicity

- *In vitro* model systems that incorporate barrier functionality and transport functions into tissue models (*e.g.,* kidney, placenta, or blood-brain barrier)

- Enhanced lower organism models (*e.g.,* zebrafish or *C. elegans*) for toxicity screening

- Stem cell models and assays for evaluating the effects of toxicants on cell differentiation with multiple functional endpoints

- Screening systems that incorporate genetic diversity into toxicology testing (*e.g.,* panels of human iPS cells or rodent stem cells)

- *In vitro* systems that enable and focus on responses to xenobiotics, chronic exposure studies, intestinal absorption of mixtures or provide insights into the molecular characteristics of chemical-biological interactions and toxicodynamics.

- Short-term tests, assays, or systems designed specifically to reduce or replace existing regulatory animal studies for acute toxicity (oral or inhalation), reproductive or developmental toxicity, carcinogenicity, or ocular toxicity

- Cage- based technologies to monitor physiological and behavioral changes in experimental animals in chemical toxicology studies

Computational Approaches for Predictive Toxicology

- New computational systems and tools for integrating toxicity data, including *in vivo* and *in vitro* data, to analyze and visualize data across different screening systems

- Computational tools to integrate and visualize transcriptomic and metabolomic data into affected signaling and biochemical pathways
- Improved computational tools for *in vitro* to *in vivo* extrapolation of xenobiotic exposures and modeling metabolic transformation of xenobiotics

Other Technologies for Enhanced Toxicology Testing

- Alternative or improved methods for fixing and preserving tissues that maintain cellular structure for histopathology while minimizing degradation of nucleic acids (RNA, miRNA, DNA, methylated DNA), proteins or metabolites, so that archival tissue blocks can be better used for molecular analysis
- Liquid biopsy methods for isolation and novel assays of circulating nucleic acids that reflect environmental chemical exposures or toxicity. These could include exosome-packaged or cell-free nucleic acids
- Alternative or improved methods for extracting high quality RNA, miRNA, DNA, methylated DNA, proteins, or metabolites from existing archived tissues

Biomarkers of Exposure and Response

To better understand the risks to human health from environmental agents, NIEHS supports the development and validation of biomarkers of exposure, including improved measures of internal dose, DNA adduct identification, and untargeted analysis for metabolite identification, and biomarkers of response, including assays that can distinguish reversible from irreversible changes in target organs or surrogate tissues. Examples include:

Biomonitoring Technology

- Personal or point-of-care monitoring technologies for rapid detection of multiple exposures in biospecimens using non- or minimally invasive approaches
- Improved methods to detect DNA or protein adducts resulting from exogenous exposures

Biological Response Markers

- Markers of oxidative stress, inflammation, DNA damage response, immune function, mitochondrial dysfunction, or altered epigenetic regulation

  High priority human biomarkers include, but are not limited to inflammation biomarkers, plasma- or serum-based markers that reflect altered RNA, protein expression, or metabolite profiles, markers developed in exhaled breath, buccal cells, or other easily accessible, non-invasive biological samples, miRNA or other exosome biomarkers, and epigenetic markers in surrogate tissue reflecting modifications in target tissues

Intervention Technologies

NIEHS supports efforts to prevent or reduce exposures to environmental chemical stressors that affect human health. Technologies to reduce exposure may include:

- Technologies for detecting and/or removing contaminants from drinking water, primarily for home use

- Approaches for use in the home, workplace, and school settings for reducing volatile compounds and other inhaled toxicants. Examples may include improved air filtration systems as well as technologies to monitor the efficacy of filtration systems

- Technologies and applications that can provide real-time alerts about relevant environmental exposure levels for sensitive populations (such as asthmatic populations)

Education/Outreach

As part of its Partnerships for Environmental Public Health (PEPH) Program, NIEHS is interested in developing tools that build capacity, improve environmental health literacy, and support citizen science endeavors. These approaches or resources should be fit for purpose to meet the needs of the following audiences: community members, health care and public health professionals, educators, and students of all ages. Approaches may include:

- Mobile applications that provide environmental health information about exposures of concern in food, air, drinking water, or consumer products. These may include

    - Interactive apps that provide the context and risks of exposures such as single or multiple, interacting exposures, level of exposure, frequency and proximity to source and health risks

    - Apps that can be adapted for various age groups, races, ethnicities and/or languages

- Devices for collecting and reporting information on exposures in environmental samples for educational purposes in schools or communities

- Systems that can utilize public and voluntary population data from sensors, activity trackers, GIS enabled devices, social communications, and surveillance cameras; for example, to assist disaster response and communication

- Educational resources related to environmental health in school settings or community education programs

- Training materials for wider dissemination of risk information (*e.*g., resources for high school students or community leaders to build capacity of other community residents)

Information on the PEPH program can be found at
https://www.niehs.nih.gov/research/supported/translational/peph/index.cfm

Other Areas of Interest

Vaping and Electronic Nicotine Delivery Systems (ENDS)

NIEHS is interested in technologies to assess exposure to aerosols from e-cigarettes and other vaping devices, including analyses of the chemical constituents in these aerosols. In addition, approaches to test the toxicity and biological responses to ENDS aerosol constituents are of interest.

Disaster Response

NIEHS is interested in sensors and informatics tools that can be rapidly deployed after disasters, including extreme weather events or climate change-related events. These tools can be used by researchers to follow emergency response workers and individuals in the community to help understand dermal, water and/or airborne exposure levels, locations, and times.

- Environmental sensors that can be rapidly deployed during or after a disaster to track exposures.
- Informatic tools to rapidly build environmental health disaster research protocols similar to the NIEHS RAPIDD Protocol https://dr2.nlm.nih.gov/ from existing information, tools, and platforms (e.g., PhenX, PROMIS, and Disaster Research Response DR2 Repository) to support rapid research response efforts
- Data management tools for disaster response that enable rapid collation and integration of data from stationary sources and personal exposure monitors and survey information collected from individuals
- Mobile devices and applications for collecting information on environmental exposures from study participants involved in disaster research responses

Hazardous Substances Remediation and Site Characterization SBIR Program

The NIEHS Superfund Research Program (SRP) "Hazardous Substances Remediation and Detection Program" supports Small Business Innovation Research Grants (SBIR R43, R44) to foster the commercialization of novel, cost-competitive technologies, products, and devices for remediation and detection of hazardous substances in the environment. The SRP is specifically interested in proposals applying new engineering, materials science, remote technologies, and biotechnology approaches. In addition, applicants are encouraged to develop sustainable strategies such as offering low carbon footprint, reduced energy consumption, utilization of renewable energy sources, resilient to weather extremes, and with reuse / regeneration capabilities.

Topics of interest include, but are not limited to:

Remediation

- Novel technologies or approaches for in situ remediation of contaminated sediments, soils, and groundwater
- Innovative bioremediation technologies and applications, including development and culturing/propagation of plants, bacterial strains, or fungal species
- Nanomaterials and newly developed compounds and processes to capture contaminants
- Technologies to remediate chemical mixtures and radiological contaminants in environmental media
- New strategies for delivery of reagents/amendments for groundwater remediation and/or recovery/extraction of contaminants in groundwater
- New amendments to stabilize contaminants and/or to stabilize caps for soil and sediment remediation
- New technologies and strategies to clean up large complex sites with multiple sources
- Resilient novel remediation approaches capable of withstanding climate change-related impacts such as: fire, flooding, land use changes, and other catastrophic events
- Sustainable, energy efficient approaches with a net lifecycle benefit such as net zero emission technologies; technologies that reduce waste generation; processes that recycle/reuse/regenerate active components; long-term remediation approaches equipped with solar or wind energy

- New strategies that actively monitor progress of the remediation and actively adjust according to the changing conditions to maintain and or boost the efficiency of the approach

- New artificial intelligence (AI) and machine learning products to analyze large data sets, guiding development or selection of remediation technologies and/or analyze data across multiple sites

Detection Technologies

- Machine learning, artificial intelligence, computational, geographical information system-based, or modeling products for predicting fate and transport of contaminants, rates of remediation, bioavailability, or for identifying contamination sources

- Real-time, field deployable, on-site characterization and analysis of soil, surface water, groundwater, subsurface, sediments, air (such as volatile releases from sites), including: rapid, portable monitoring and screening of contaminants, and multi-analyte (contaminant mixture) sensors

- Remote monitoring/data capture/data processing capabilities such as time-integrated and/or repeated measures

- Quantitative, accurate and reliable new passive sampler devices

- Products that improve sample preparation, extraction or processing of soil for incremental sampling methodologies (ISM)

- Non-targeted or multi-analyte field sampling devices or kits, including sample collection products that can sequester a suite of analytes for later analysis

- Novel techniques, sensors, field analytical methods and/or real-time mapping/data visualization for development of subsurface conceptual site models

- Innovative tracer technologies for tracking contaminant transport

Specific topics of interest include but are not limited to the following:

- Poly- and perfluorinated alkyl substances (PFAS): Soil, sediment, and groundwater remediation technologies for mixtures and degradation byproducts of PFAS; including technologies for complete PFAS destruction; sustainable solutions with low energy input or minimal secondary waste generation; or PFAS removal technologies for heterogenous water chemistries; remediation, modeling platforms, or detection technologies for vapor-phase PFAS, PFAS vapor intrusion

- Vapor Intrusion: Devices to detect and measure vapor intrusion and solutions for mitigation, including tools to determine when vapor mitigation is complete

- Mining: Active or passive remediation technologies for mining influenced water; technologies to mitigate effects from acidic drainage; portable neutralization treatment systems; strategies to target remediation of sources such as mining waste piles; and separation technologies that remove elements or compounds of concern from water and/or reclaim potentially valuable critical elements dissolved in contaminated fluids

- Complex Site/Geology (fractured rock, karst, or heterogeneous sedimentary deposits):

- Site characterization strategies that address fate of contaminants within rock matrices and properties that affect back diffusion
- Improved technologies for treating low permeability and heterogeneous lithology, including amendment delivery methods
- Devices to detect and measure non-aqueous phase liquids (NAPLs) in the subsurface
- In-well real-time or continuous monitoring tools to assess remedy performance; presence/absence of key factors required for remediation (e.g., biological, geological, chemical); and/or to identify rebound events presence/absence of key factors required for remediation (e.g. biological, geological, chemical); and/or to identify rebound events

- Disaster Response: Technologies for measuring/treating environmental contamination as part of a disaster response effort

Applicants must demonstrate that the proposed technologies are relevant to Superfund and/or other sites impacted by hazardous substances. Per program mandates described in the Superfund Amendment Reauthorization Act (SARA), SRP does not accept applications targeting oil or gas site characterization/remediation. Applicants are strongly encouraged to stay within the statutory budget guidelines whereby total funding support (direct costs, indirect costs, fees) does not exceed $173,075 for Phase I awards and $1,153,834 for Phase II awards. Applicants are encouraged to contact NIH program officials prior to submitting any award budget for the "Hazardous Substances Remediation and Site Characterization Small Business Innovation Research Program" in excess of these amounts. Please note: the NIEHS Superfund Research Program (SRP) "Hazardous Substances Remediation and Site Characterization Small Business Innovation Research Program" no longer accepts Small Business Technology Transfer Grant (STTR: R41, R42) applications. Funding decisions will be made based on programmatic need with an emphasis on novel technologies distinct from current or recently-funded SBIR grants that are applicable to Superfund and/or other sites impacted by hazardous substances.

https://www.niehs.nih.gov/research/supported/centers/srp/funding/hwaerp/index.cfm.

Worker Training Program

The NIEHS Worker Training Program (WTP) is interested in the development of e-Learning health and safety Advanced Technology Training (ATT) products from a variety of delivery methods to assist both students and instructors in the training and education process. These ATT products are for the health and safety training of hazardous materials (HAZMAT) workers; waste treatment personnel; skilled support personnel associated with an emergency/disaster; emergency responders in biosafety response, infectious disease training and cleanup; emergency responders in disasters; and resiliency training. ATT as defined by the Worker Training Program (WTP) includes, but is not limited to, online training, virtual reality, and serious gaming, which complement all aspects of training from development to evaluation including advance technologies that enhance, supplement, improve, and provide health and safety training for hazardous materials workers. **WTP accepts solicitations via requests for applications (RFA).** Please contact Kathy Ahlmark (ahlmark@niehs.nih.gov) for information on the next solicitation date, which differs from the standard receipt dates of this NIH omnibus.

Information on the WTP program can be found at https://www.niehs.nih.gov/careers/hazmat/about_wetp/.

NIEHS Clinical Trials Topics:

NIEHS will accept SBIR/STTR applications that propose clinical trials related to:

- Development and testing of sensor technology, biomarkers, or biomonitoring technologies, including field testing of new technologies for exposure assessment and biological responses to environmental exposures

- Evaluation of tools or approaches for education and dissemination of information on environmental hazards, including evaluation of changes in behavior

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