NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES (NIEHS)

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.

For additional information about NIEHS's Small Business Programs, please visit https://www.niehs.nih.gov/funding/grants/mechanisms/sbir/ . 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.

Limited Amount of Award

For all NIEHS research interest topic areas other than Hazardous Substances Remediation and Site Characterization SBIR Program included in this PHS 2020 Omnibus SBIR/STTR Solicitation, NIEHS will accept SBIR/STTR applications up to $256,580 total costs for Phase I and $1,710,531 for Phase II. 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 the details. NIEHS will generally not fund applications at budget levels exceeding these budget guidelines. 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.

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.

Phase IIB Competing Renewal Awards

NIEHS will accept Phase IIB SBIR Competing Renewal grant applications only in response to specific RFAs focused on the validation of environmental exposure assessment sensor technologies that were previously developed with Phase II SBIR or STTR funding from NIEHS or federal agencies. The proposed work must align with the NIEHS mission.

Research Topics of Interest to NIEHS

The specific set of topics that are funded by a particular IC/Office/Agency depends on whether the IC/Office/Agency funds/supports Clinical Trials under SBIR/STTR Awards. Use the following table and explanations to determine which list of topics is applicable.

	No*	Yes**
Does IC/Office/Agency Fund/Support Clinical Trials under SBIR/STTR Awards?		X

*If No,

- This IC/Office/Agency funds only those topics listed under the Non-Clinical Trials Topics section below, **UNLESS** the IC/Office/Agency funds a Small Business Concern for clinical trials under a NON-SBIR/STTR award.

**If Yes or the IC/Office/Agency funds small businesses for clinical trials under a NON-SBIR/STTR funding opportunity,

- See the table below for which mechanisms the IC/Office/Agency will allow for clinical trials research. Also, see the Clinical Trials Topics section below for a list of funded topics. This IC/Office/Agency also funds research listed under the Non-Clinical Trials Topics section below.

Does IC/Office/Agency accept clinical trials applications under this mechanism?	**Yes**	**No**	**Other Information: If funding an SBC for clinical trials under a NON-SBIR/STTR award, please identify activity code(s) and other relevant information.**
Clinical Trials SBIR/STTR Omnibus/Parent Funding Opportunity Announcement/s	X		
Clinical Trials SBIR/STTR IC/Office/Agency - Specific Funding Opportunity Announcement/s		X	
Clinical Trials NON-SBIR/STTR Funding Opportunity Announcement/s where Small Businesses are eligible to apply	X		ES 20-003 Environmental Health Sciences Core Centers (EHSCC) (P30 Clinical Trial Optional) ES 18-007 Virtual Consortium for Translational/Transdisciplinary Environmental Research (ViCTER) (R01 Clinical Trial Optional)

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 from conception to death 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 to assess personal exposure in population studies, including networks of stationary and wearable monitors
- Devices for collecting exposure measurements across multiple stressors and scales (*i.e.,* recording time and location of exposures), with an emphasis on high sensitivity and specificity and low-cost devices, when feasible. High-priority analytes include emerging contaminants (*e.g.*, perfluorinated compounds and herbicides) as well as ultrafine particulates, PAHs, and pesticide exposures
- Technologies to collect environmental samples for subsequent targeted and untargeted laboratory analysis
- Sensor technologies that can be integrated into existing smart devices for sensing personal environment
- Personal sensors that are easily worn and durable that can be rapidly deployed after a disaster by researchers to emergency response workers and individuals in the community to help understand dermal and/or airborne exposure levels, locations, and times.

Computational and Informatics-based Tools and Methods

- 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
- Adapting or developing new methods and tools for automating literature and systematic reviews, including article selection and prioritization, data extraction, study quality evaluation, and summarization of articles. This may include new methods for scanning and compiling information from gray literature and web content for environmental health impacts
- Informatic tools that can be used by the research community 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 in the U.S. and globally.
- Informatic and 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 using mobile platforms.
- Mobile devices and Apps for collecting information on environmental exposures from study participants involved in disaster research responses.

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 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, characterization, and quantitation of various forms of nanoplastics from diverse aqueous sources and food samples

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

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.

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 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).

Examples include:

- Improved human organotypic culture models (OCM) and microphysiological systems (MPS) that more accurately predict *in vivo* function for characterizing toxicity and/or 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 isolated primary cells from rat or mouse models or other experimental animal models, which can enable 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
- Data-rich *in vitro* approaches that incorporate medium-throughput ‘omics and/or high-content imaging for toxicity screening

- *In vitro* toxicology screening models to predict 'idiosyncratic' chemical-induced effects in humans (*e.g.,* drug-induced liver injury or cytokine storm)
- *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* assays to model chronic inflammatory responses to xenobiotics
- 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

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 experimental and computational tools for *in vitro* to *in vivo* extrapolation of xenobiotic exposures across a range of assay types
- Computational tools for quantitatively modeling metabolic transformation of xenobiotics
- Computational tools or systems for rapidly assessing results of literature searches, short-term tests, assays, or other relevant testing to help provide screening level risk characterization of complex mixed chemical exposures in response to disasters

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.
- Approaches to improve efficiency of laboratory-based toxicology studies, including more rapid, cost-effective methods for RNA isolation from tissue lysate, and novel methods for removing necrotic cells in complex cell culture models
- 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 stressors that affect human health. Technologies to reduce exposure may include:

- Technologies for removing contaminants from drinking water 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 alert about relevant environmental exposures in 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, water, or consumer products. These may include
  - Apps that provide the context for the exposures such as single or multiple, interacting exposures, level of exposure, frequency and proximity to source
  - Apps that can be adapted for various age groups (*e.g.,* children or the elderly), races, ethnicities and/or languages
  - Apps that visualize exposure risks with respect to levels of exposure, sources and health risks

- 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 (*e.g.,* Photovoice projects or GIS mapping)
- Training materials for wider dissemination of risk information (*e*.g., resources for high school students to train younger students; or community leaders to build capacity of other community residents)
- Continuing medical education classes, on-line courses, or on-line tools to build the environmental health literacy of health care professionals

- Tools to disseminate current information on exposure risks or hazards. This may include signage and other materials to communicate hazards, including risks from fish consumption, marine toxins, or air quality alerts in multiple languages for affected communities

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

Hazardous Substances Remediation and Site Characterization SBIR Program

The NIEHS Superfund Research Program (SRP) "Hazardous Substances Detection and Remediation Program" supports Small Business Innovation Research Grants (SBIR R43, R44) to foster the commercialization of novel 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, and biotechnology approaches to develop sustainable strategies to characterize and remediate hazardous substances at contaminated sites.

Topics of interest include, but are not limited to:

Remediation

- Novel technologies for *in situ* remediation of contaminated sediments, soils, and groundwater
- Innovative bioremediation and phytoremediation technologies including development and culturing/propagation of plants, bacterial strains, or fungal species for implementing bioremediation
- Remediation strategies designed to emulate/enhance biological processes or functions (e.g. biomimicry) by applying novel replacement materials/technologies to source areas or downgradient plumes
- Technologies to remediate chemical mixtures 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
- Technologies and strategies to cleanup large complex sites with multiple sources

Site Characterization

- 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 analysis: soil, surface water, groundwater, subsurface, sediments, air (such as volatile releases from sites), etc.
    - monitoring and screening of contaminants
    - bioavailability (i.e. biologically-accessible portion of contamination)
    - miniaturized toxicity-screening kits
- Products that allow for rapid sample clean-up/preparation for analysis of environmental samples
- 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, and field analytical methods and real-time mapping/data visualization for development of subsurface conceptual site models

Examples of remediation and site characterization needs:

- Devices to detect and measure vapor intrusion and solutions for mitigation, including tools to determine when vapor mitigation is complete
- Devices to detect and measure non-aqueous phase liquids (NAPLs) and dense non-aqueous phase liquids (DNAPLs) in the subsurface
- Site characterization techniques and strategies for complex geology (fractured, karst and heterogeneous layered deposits) including understanding the fate of contaminants within rock matrices and properties that affect back diffusion
- Technologies for rapid extraction or processing of soil for incremental sampling methodologies (ISM)
- Technologies for rapid analysis of total and/or biologically-accessible (e.g. bioavailable/bioaccumulating) metal fractions in soils and sediments (including easy-to-use kits for soil/sediment screening)
- In-well real-time and/or continuous monitoring tools to assess the efficacy of remediation; presence/absence of key factors required for remediation (e.g. biological, geological, chemical); and/or to identify rebound events
- Technologies for automated elongated mineral fiber counting (e.g. for asbestos samples)
- Active or passive remediation technologies for mining influenced water; technologies to mitigate effects from acidic drainage; portable neutralization treatment systems; and strategies to target remediation of sources such as mining waste piles
- Soil, sediment, and groundwater remediation technologies for mixtures and degradation byproducts of poly- and perfluorinated alkyl substances (PFAS), including sustainable solutions with low energy input and/or minimal secondary waste generation
- Performance enhancements to existing remedial technologies (permeable reactive barriers, funnel and gate systems, capping to limit infiltration, etc.)
- Novel detection technologies and remediation approaches that: improve energy efficiency and reduce waste generation; and/or are capable of improving resilience such as: withstanding fire, flooding, land use changes, and other catastrophic events
- Technologies for measuring/treating environmental contamination as part of a disaster response effort

Applicants must demonstrate that the proposed technologies are relevant to Superfund. 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 $168,087 for Phase I awards and $1,120,586 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.

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 DOES NOT Fund

- Technologies for the detection and remediation of pathogens in the environment.

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

For additional information on research topics, contact:

Dr. Daniel Shaughnessy
National Institute of Environmental Health Sciences
Division of Extramural Research and Training
POB 12233 (K3-12)
Research Triangle Park, NC 27709
(984) 287-3321
Email: shaughn1@niehs.nih.gov

Dr. Lingamanaidu Ravichandran
National Institute of Environmental Health Sciences
Division of Extramural Research and Training
POB 12233 (K3-05)
Research Triangle Park, NC 27709
(984)-287-3309
Email: lingamanaidu.ravichandran@nih.gov

For information on the NIEHS Superfund Research Program - Hazardous Substances Remediation and Site Characterization SBIR Program, contact:

Dr. Heather Henry
National Institute of Environmental Health Sciences
Division of Extramural Research and Training
POB 12233 (K3-12)
Research Triangle Park, NC 27709
(984) 287-3268
Email: henryh@niehs.nih.gov

For administrative and business management questions contact:

Mr. Aaron Nicholas
National Institute of Environmental Health Sciences
Division of Extramural Research and Training
Grants Management Branch
(984) 287-3297
Email: nicholaa@nih.gov