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 www.niehs.nih.gov/sbir. Join our listserv for program announcements https://list.nih.gov/cgi-bin/wa.exe?SUBED1=sbir-niehs&A=1. The major NIEHS SBIR/STTR research topics of potential interest include:

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	

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 NON-SBIR/STTR Funding Opportunity Announcement/s where Small Businesses are eligible to apply		X	

NIEHS Non-Clinical Trials Topics:

Exposure Assessment Tools

The NIEHS Exposure Biology 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

- Technologies to assess personal exposure in population studies, including networks of fixed site and wearable monitors
- Personal, wearable, real-time devices for measurements across multiple stressors and scales (*e.g.*, time, space, route of exposures, distribution), with an emphasis on high sensitivity and specificity and low-cost devices, when feasible. High-priority analytes include ultrafine particulates, PAHs, and pesticide exposures
- 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

- Computational and statistical approaches to integrate exposure data from different sources, including publicly available databases, and monitoring approaches (*e.g.,* sensors, remote sensing, and biomonitoring), to provide quantitative exposure estimates
- Novel tools and methodologies to collect, analyze, and visualize exposure data from large population studies, especially temporally and spatially-resolved exposure data (such as crowdsourcing and exposure mapping)
- Informatics tools and platforms to organize, store and retrieve complex exposure and health data
- Improved identification and characterization methods for untargeted, high-throughput metabolomics analysis of xenobiotics
- 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/protocols#rapidd 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 Apps for collecting health and exposure survey information from study participants involved in disaster research responses.
- Mobile devices and Apps for collecting information on environmental exposures from study participants involved in disaster research responses.

Information on the NIEHS Exposure Biology 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 metal, carbonaceous engineered nanomaterials in air, water, and consumer products, and provide a contextual assessment of the toxicological potential
- Biomonitoring technologies for personal monitoring that can detect engineered nanomaterials using non- or minimally-invasive approaches

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 effects of environmental stressors on biological systems that can lead to adverse health outcomes. To increase the ability to characterize or predict the toxicity 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. Phase III of Tox21 is focused on expanding biological endpoints and relevance to humans. The following efforts support Tox21 and other NTP goals:

Improved or expanded testing methods for toxicity screening

These approaches should include the development of physiologically-relevant cell-based systems or phylogenetically lower-order animal models. *In vitro* approaches should effectively model cellular functions and responses to chemical exposure reflective of 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.,* liver, GI tract, kidney, neurological, mammary gland, lung, and cardiac). Examples include:

- Improved human organotypic models that more accurately predict *in vivo* function for characterizing toxicity and/or disease processes
- 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
- 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' compound-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 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
- Short-term tests, assays, or multiplex-systems/approaches designed specifically to help provide rapid toxicology screening level characterization of complex mixed chemical exposures in response to disasters

Computational approaches for predictive toxicology

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

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
- Devices that can continuously monitor and report exposures in real-time
- 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 reducing volatile compounds and other inhaled toxicants for use in the home, workplace, and school settings. 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 population)

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
- Documentaries, short films, or television shows on environmental health science topics with accompanying discussion guides, lessons, or activities to facilitate broader use of the programming

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 Hazardous Substance Basic Research and Training Program (SRP) supports the "Hazardous Substances Remediation and Site Characterization Small Business Innovation Research

Program" (SBIR R43, R44) to foster the commercialization of technologies, products, and devices for remediation and detection of hazardous substances in the environment. The SRP is specifically interested in proposals applying innovative engineering, bioengineering, biotechnology, computational, and materials science approaches to significantly improve the cost-effectiveness, efficiency, and speed of remediation and site characterization. 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 optimized for bioremediation
- Technologies to remediate chemical mixtures in environmental media
- Portable adsorption systems for removing chlorinated volatile organic compounds (VOCs) from indoor air to achieve risk-based indoor air standards
- Nano-enabled structures, electrochemical methods, photocatalytic processes, thermal treatments, or filtration-based methods of remediation
- New strategies for delivery of reagents for groundwater remediation: *in situ* chemical oxidation ISCO), zero valent iron (ZVI), and hydraulic fracturing (note: this excludes gas exploration)
- New strategies for delivery of reagents for recovery/extraction of contaminants in groundwater

Site Characterization

- Computational, geographical information system-based, or modeling products for predicting fate and transport of contaminants, rates of remediation, or for identifying contamination sources
- Real-time, on-site monitoring: soil, surface water, groundwater, subsurface, sediments, air (such as volatile releases from sites), etc.
- Nanotechnology-based sensors and probes, biosensors, lab-on-chip, and miniaturized analytical probes; miniaturized data analysis tools
- Products that allow for rapid sample clean-up/preparation for analysis of environmental samples
- Self-contained miniaturized toxicity-screening kits for detecting contaminant-specific hotspots
- Non-targeted or multi-analyte field sampling devices or kits, including sample collection products that can sequester a suite of analytes for later analysis
- Assays or devices to determine the extent to which a contaminant is bioavailable

Examples of remediation and site characterization needs:

- Devices to detect and measure vapor intrusion or to detect 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)
- Technologies for rapid extraction or processing of soil for incremental sampling methodologies (ISM)
- Technologies for automated elongated mineral fiber counting (e.g. for asbestos samples)
- Active or passive remediation technologies for mining influenced water
- Remediation technologies for poly- and perfluorinated alkyl substances such as perfluorooctane sulfonic acid (PFOS) and perfluorooctanoic acid (PFOA)
- Novel green or sustainable detection technologies and remediation approaches that improve energy efficiency and reduce waste generation

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 $150,000 for Phase I awards and $1,000,000 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.

Information on the NIEHS SRP can be found at
https://www.niehs.nih.gov/research/supported/centers/srp/hwaerp/index.cfm

Worker Training Program

The NIEHS Worker Training Program (WTP) is interested in the development of Advanced Technology Training (ATT) products for the health and safety training of hazardous materials (HAZMAT) workers; skilled support personnel; emergency responders in biosafety response, infectious disease training and cleanup; and 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 - contact EPA or DoD for information on SBIR funding opportunities for this topic.

NIEHS Clinical Trials Topics:

NIEHS will not accept SBIR applications that propose clinical trials and all of the topics listed must be for projects that do not propose clinical trials.

For additional information on research topics, contact:

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

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