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:

Exposure Assessment Tools

The NIEHS Exposure Biology and Exposome Program (http://www.niehs.nih.gov/research/supported/exposure/bio/) 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 that 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 detection measurements across multiple stressors and scales (*e.g.*, time, space, route of exposures, distribution), with emphasis on high sensitivity and specificity and/or low-cost devices. High-priority analytes include ultrafine particulates and PAHs
  - Sensor technologies that can be integrated into existing smart devices for sensing personal environment

- Biomonitoring technology
  - Personal 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

- Computational and informatics-based tools and methods
  - Computational and statistical approaches to integrate exposure data from different sources to provide quantitative exposure estimates, including publicly available databases, and monitoring approaches (*e.g.,* sensors, remote sensing, and biomonitoring)
  - 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

Nano Environmental Health and Safety

http://www.niehs.nih.gov/research/supported/exposure/nanohealth/index.cfm The NIEHS Nano Environmental Health and Safety (Nano EHS) program is interested in the detection of engineered nanomaterials in the environment, in products, and in biological samples and in technologies or methods that can predict toxicity potential. 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 on the toxicological potential
- Biomonitoring technologies for personal monitoring that can detect engineered nanomaterials using non- or minimally-invasive approaches

Toxicity Screening, Testing, and Modeling

The National Toxicology Program http://ntp.niehs.nih.gov/ at NIEHS is interested in technologies to improve predictivity in toxicology testing to support the goals and initiatives of Tox21 http://ntp.niehs.nih.gov/results/tox21/index.html. Phase III of Tox21 is focused on expanding biological endpoints and human relevance with increased focus through the following efforts:

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 toxicity or disease
- Organotypic models using isolated primary cells from rat and mouse models to reduce animal use in toxicity screening, which could be developed using existing microphysiological platforms.
- Data-rich *in vitro* approaches that incorporate medium-to-high throughput 'omics and/or high-content imaging
- *In vitro* toxicology screening models to predict 'idiosyncratic' compound-induced effects in humans
- *In vitro* model systems which incorporate barrier functionality and transport functions into tissue models
- Enhanced lower organism models (*e.g.,* zebrafish or *C. elegans*) for toxicant screening
- Stem cell models and assays for 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 for genetic diversity)
- 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, or to increase the predictivity of *in vivo* animal models of acute toxicity (oral or inhalation), reproductive or developmental toxicity, carcinogenicity, or ocular toxicity
- Improved identification and characterization methods for untargeted, high-throughput metabolomics analysis of xenobiotics

Computational approaches for predictive toxicology

- New computational systems and tools for integrating toxicity data, including *in vivo* data, that 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

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) so that archival tissue blocks can be better used for molecular analysis.

Biomarkers

NIEHS supports the development and validation of biomarkers, assays, or detection systems that can distinguish reversible from irreversible changes in target organs or surrogate tissues resulting from individual responses to environmental stressors.

Biological pathways of interest include:

- Oxidative stress (*e.g.,* measurement of excess ROS in specific cell types)
- Inflammation
- DNA damage response (*e.g.,* functional assays of DNA repair phenotypes)
- Immune function
- Mitochondrial function
- Epigenetic regulation

High priority human biomarkers include, but are not limited to:

- Inflammation biomarkers
- Plasma- or serum-based markers that reflect altered RNA, miRNA, or protein expression or altered metabolite profiles in response to environmental exposures
- Markers developed in exhaled breath, buccal cells, or other easily accessible, non-invasive biological samples that characterize alterations in key pathways associated with environmental stressors
- miRNA or other exosome biomarkers for exposure to environmental toxicants
- Epigenetic markers in surrogate tissues reflecting modifications in target tissues

Education/Outreach

https://www.niehs.nih.gov/research/supported/translational/peph/index.cfm 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

Hazardous Substances Remediation and Site Characterization SBIR Program

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

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.

Worker Training Program

http://www.niehs.nih.gov/careers/hazmat/about_wetp/ The NIEHS Worker Training Program (WTP) is interested in Advanced Training Technology (ATT) products for the health and safety training of hazardous materials (HAZMAT) workers, skilled support personnel, and emergency responders in biosafety response and cleanup, community and citizen preparation and resiliency, and for ATT tools to assist in research into the acute and long-term health effects of environmental disasters. ATT as defined by WTP includes, but is not limited to, online training, virtual reality, serious gaming, and tools that 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.

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

Other Topics within the Mission of the Institute

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