

# Environmental Health Science and SBIR/STTR Small Business Grants

D. Shaughnessy, H. Henry, K. Ahlmark, K. Mease, D. Balshaw

National Institute of Environmental Health Sciences  
Division of Extramural Research and Training  
Research Triangle Park, NC USA 27709, [www.niehs.nih.gov/sbir](http://www.niehs.nih.gov/sbir)

## ABSTRACT

The NIEHS sets aside a percentage of extramural funds to support technology development for environmental health research through Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) grants. SBIR/STTR technologies supported by NIEHS reflect the Institute's broad mission, ranging from assays to detect DNA damage and mutations to high-throughput assays for large-scale toxicant screening to improved methods for assessing both external exposures and internal dose of chemicals. Small businesses are also developing innovative technologies, products, and devices that can be used at Superfund or other contaminated sites for the detection and remediation of hazardous substances. The NIEHS Worker Training Program (WTP) program focuses on the development of Advanced Training Technology (ATT) products for the health and safety training of hazardous materials (HAZMAT) workers, emergency responders, and skilled support personnel. The NIEHS supports the development of tools and materials to educate and train individuals and groups on environmental health topics. Technologies developed by NIEHS-supported small businesses are used in laboratory research, high-throughput screening efforts including ToxCast and Tox21, environmental epidemiology studies and community-based research to improve public health.

**Keywords:** NIEHS, small business, SBIR, environmental technologies, funding

## 1 NIEHS SBIR/STTR AREAS OF INNOVATION AND RESEARCH

NIEHS small business grant programs, SBIR and STTR, use a combination of research, technology transfer, and communication strategies to aid the mission of NIEHS. NIEHS SBIR/STTR aims to fund products that improve human health in the areas of:

- **Exposure Assessment** – technologies include wearable sensors, remote sensing, bio-monitoring, exposure biology, and Exposome research tools
- **Exposure-Disease Relationship** - toxicity screening tools such as high-content imaging, medium-high throughout *in vitro* assays, organotypic and computational models

- **Susceptibility** – tools which aide in the understanding of gene-exposure relationships, combined exposures, comorbidity, and life stage windows of susceptibility
- **Prevention and Intervention** – Technologies which detect, reduce, or eliminate exposures to environmental toxicants
- **Education/Training** - Tools which can assist HAZMAT, emergency responders, and skilled support personnel
- **Outreach** – educational tools for health literacy, community based participatory research, and citizen science

## 2 WHO WE HAVE FUNDED

Aligned with the previously mentioned areas of innovation and research at NIEHS, the following are examples of small businesses and their technologies that NIEHS has funded. These examples are only a small sampling of the technologies that NIEHS funds. Each technology described is a solution to a problem that has a sizable market and thus has significant commercial potential.

### 2.1 Exposure Assessment

R44ES021678  
TF Health, Co  
Tempe, AZ  
Program Directors: Erica Forzani,  
Francis Tsow (VP of R&D)  
[erica.forzani@breezing.co](mailto:erica.forzani@breezing.co)

**PROBLEM** it is challenging and expensive to measure environmental toxicants to study relationships between chemical exposures and diseases for more effective disease prevention

**SOLUTION** low cost, easy to use, pocket-sized, UL certified device, with high temporal and high spatial resolutions, and wireless communication for personal exposure monitoring

**MARKET** petrochemical industry, epidemiologists and exposure science professional, fire departments

## 2.2 Exposure Assessment

R44ES021678  
TF Health, Co  
Tempe, AZ  
Program Directors: Erica Forzani,  
Francis Tsow (VP of R&D)  
[erica.forzani@breezing.co](mailto:erica.forzani@breezing.co)

**PROBLEM** it is challenging and expensive to measure environmental toxicants to study relationships between chemical exposures and diseases for more effective disease prevention

**SOLUTION** low cost, easy to use, pocket-sized, UL certified device, with high temporal and high spatial resolutions, and wireless communication for personal exposure monitoring

**MARKET** petrochemical industry, epidemiologists and exposure science professional, fire departments

## 2.3 Exposure-Disease Relationship

R44ES018017  
Litron Laboratories, LTD  
Rochester, NY  
Program Director: Stephen D Dertinger  
[sdertinger@litronlabs.com](mailto:sdertinger@litronlabs.com)

**PROBLEM** current in vivo gene mutation assays require standalone toxicology studies that use expensive transgenic animals and large blood volumes

**SOLUTION** In Vivo MutaFlow® kit is a flow cytometry Pig-a gene mutation assay kit; based on low blood volume samples and an endogenous gene reporter, it readily integrates into existing in vivo toxicology studies that use standard rodent models

**MARKET** commercially available kits and fee-for-service blood analysis services support pharmaceutical and chemical companies, also CROs and government laboratories

## 2.4 Susceptibility

R44ES020074  
MatTek Corporation  
Ashland, MA  
Program Director: Yulia Kaluzhny  
[ykaluzhny@mattek.com](mailto:ykaluzhny@mattek.com)

**PROBLEM** current animal-based test methods (Draize rabbit eye test) have animal welfare concerns and in

vitro alternatives lack the ability to completely model in vivo responses

**SOLUTION** EpiOcular™ human-derived epidermal keratinocytes cultured to form a stratified squamous epithelium similar to that found in the cornea. EpiOcular™ Eye Irritation Test (EIT) will be approved as a “validated Draize replacement” in EU in 2014. OECD draft test guideline has been submitted for review.

**MARKET** direct sales of kits, training services, and POC studies to cosmetic, personal care, and ophthalmologic companies.

## 2.5 Prevention and Intervention

R43ES020634  
Seacoast Science, Inc  
Carlsbad, CA  
Program Director: Sanjay V Patel  
[sanjay@seacoastscience.com](mailto:sanjay@seacoastscience.com)

**PROBLEM** conventional remediation detection methods are expensive, require repeated user intervention, and need frequent replacing

**SOLUTION** low-cost, sensitive, unattended remote vapor intrusion monitoring using a sorbent preconcentrator to collect air samples, a gas chromatograph to separate chemical species, and a MEMS microsensor for detection of trichloroethylene, perchloroethylene, and benzene

**MARKET** remediation specialists and government agencies for remote tracking

## 2.6 Education/Training

R44ES020135  
Nicolalde R&D LLC  
West Lebanon, NH  
Program Director: Roberto Javier Nicolalde  
[roberto.nicolalde@gmail.com](mailto:roberto.nicolalde@gmail.com)

**PROBLEM** process of translating existing reference materials into mobile-friendly formats is manual and labor intensive

**SOLUTION** mRendering™ mobile method delivers just-in-time, short, incident specific safety training, and reference materials using a back-end document processing engine that automatically parses, analyzes, mark-ups, and organizes documents

MARKET mRendering™ will be a product and service to training organizations that support first responders, skilled support personnel, and volunteer emergency personnel

## 2.7 Outreach

R41ES023706  
Science Take-Out, LLC  
Pittsford, NY  
Program Director: Dina Grossman Markowitz  
contact@sciencetakeout.com

**PROBLEM** nearly 25% of death and disease is linked to environmental factors (WHO, 2006). The general public needs a basic understanding, but this can be difficult to incorporate into curriculums

**SOLUTION** six fully assembled Science Take-Out® kits, which include activities, materials, and clear/concise teacher guides on environmental health science topics

**MARKET** existing Science Take-Out® kits sell > 17,000 units annually, ranging from \$8 - \$18/kit, to middle and high schools nationally and globally

## 3 HOW TO APPLY

For detailed application, instructions please visit [www.sbir.nih.gov](http://www.sbir.nih.gov). Below is a brief overview of the application process.

Confirm your small business meets the eligibility requirements and contact an NIH Program Officer to ensure your technology is aligned with the mission of the institute.

- Complete the five required registrations (6-8 weeks to complete)
  - DUNS
  - SAM.gov
  - Grants.gov
  - eRA Commons
  - SBA Registry
- Choose the funding opportunity announcement for your application
  - SBIR Omnibus (small business)
  - STTR omnibus (small business + non-profit research institute)
  - Targeted SBIR/STTR Requests for Application (RFA)
- Submit your SBIR/STTR grant application to the NIH electronically
- NIH Center for Scientific Review evaluates your grant on scientific merit and commercialization potential

- Funding decisions and awards are made (Application to Award is ~ 6 months)

## 4 FUNDING PHASES

For detailed information about the funding phases, please visit [www.sbir.nih.gov](http://www.sbir.nih.gov). Below is a brief overview of the funding phases.

Phase I – feasibility study for 6 months - up to \$150K direct costs

- Niche assessment program – provides active Phase I awardees with market research, consumer, and competition analysis

Phase II – Full R&D for 2 years – up to \$1M in direct costs

- Commercialization Assistance Program (CAP) – Trains Phase II awardees on developing tailored market entry strategies, building strategic alliances and partnerships, and developing FDA regulatory and reimbursement paths, as well as financing strategies and expertise on intellectual property matters

Fast Track – One application for Phase I and Phase II that is submitted and reviewed together

Phase IIB – Additional funding for awards or projects that require extraordinary time and effort in the R&D phase. Must have initial Phase II award to apply. Up to \$1M total costs per year for up to 3 years.

Phase III – Commercialization - not funded by SBIR/STTR funds