



**National Institutes of Health and
National Institute of Environmental Health Sciences:
SBIR/STTR Program**

Jerry Heindel, Ph.D.

SBIR/STTR Program Administrator NIEHS

Beth Anderson

Superfund SBIR/STTR Program Coordinator NIEHS

J. (Chip) Hughes Jr.

Worker Education and Training Program SBIR/STTR Coordinator NIEHS



**Innovations that can
change the way we
work, think and live.**

• SBIR/STTR

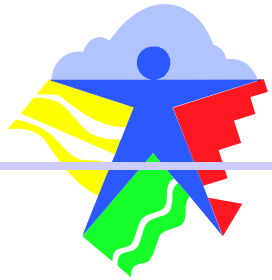


National Institutes of Health



Our Mission

Improve human health through biomedical and behavioral research, research training and communications.



THE NIH “CULTURE”

In its mission to protect and improve human health, the NIH conducts and supports basic, applied, and clinical and health services research to understand the processes underlying human health and to acquire new knowledge to help prevent, diagnose, and treat human diseases and disabilities.



SBIR/STTR PLAYS IMPORTANT ROLE IN NIH MISSION

- SBIR/STTR Programs **integrated** into overall NIH research agenda
- **Small companies** recognized as **prolific innovators**
- SBIR/STTR assists in **translating research** from the “test tube to the medicine cabinet”
- SBIR/STTR supports “**enabling technologies**” and **disruptive technologies** that have potential to make significant societal impact

National Institutes of Health

<http://www.nih.gov/icd/>



Use SBIR/STTR Help NIH

Meet Its Mission

Conduct innovative R/R&D that results in product, process, or service that will...

- Improve human health
- Speed process of discovery
- Reduce cost of medical care/
cost of research
- Improve research tools

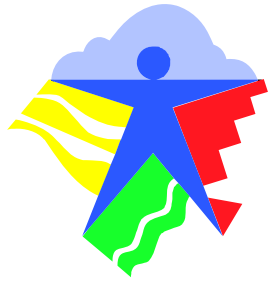




AN ADDED DIMENSION TO THE NIH “CULTURE”

*“The National Institutes of Health **needs to work much more closely with industry** to find cures for disease and improve global health and will **‘aggressively’ seek out partnerships with private companies.**”*

*-- Dr. Elias Zerhouni
NIH Director*



DOES MY TECHNOLOGY “FIT” IN NIH?

***Solution to...
Real Problem....
that affects Real People!***



NIH Institutes and Centers



National Heart, Lung
and Blood
Institute



National Institute of
General Medical
Sciences



National Institute of
Nursing Research



National Institute of
Arthritis
Musculoskeletal
and Skin Diseases



National Institute of
Allergy and
Infectious Diseases



National Institute
on Aging



National Human
Genome Research
Institute



National Institute of
Environmental
Health Sciences



National Eye Institute



National Center for
Research Resources



National Center on
Minority Health and
Health Disparities



National Cancer Institute



National Institute of
Diabetes and Digestive
and Kidney Diseases



Center for Information
Technology



National Institute of
Dental and Craniofacial
Research



National Institute on
Drug Abuse



National Institute For
Biomedical Imaging
and Bioengineering



National Institute of
Mental Health



National Institute of Child
Health and Human
Development



National Center for
Complementary and
Alternative Medicine



John E. Fogarty
International Center



Center for Scientific
Review



SBIR/STTR Omnibus Solicitation

<http://grants.nih.gov/grants/funding/sbirsttr1/index.pdf>

- Mission statement
- General areas of research
- Topics of interest
- “**Other**” Research Topics
Within the Mission of the IC

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

PHS 2002-2

OMNIBUS SOLICITATION OF THE
NATIONAL INSTITUTES OF HEALTH,
CENTERS FOR DISEASE CONTROL AND PREVENTION,
AND FOOD AND DRUG ADMINISTRATION FOR

**SMALL BUSINESS
INNOVATION RESEARCH
(SBIR)**

AND

**SMALL BUSINESS
TECHNOLOGY TRANSFER
(STTR)**

GRANT APPLICATIONS

GRANT APPLICATION RECEIPT DATES

National Institutes of Health
April 1, August 1, December 1, 2002 (SBIR and STTR)

Centers for Disease Control and Prevention
August 1, 2002 (SBIR)

Food and Drug Administration
April 1, August 1, December 1, 2002 (SBIR)



NIH SBIR/STTR Solicitation(s)

- **SBIR/STTR Omnibus Grant Solicitation
(NIH, CDC and FDA)**

<http://grants.nih.gov/grants/funding/sbirsttr1/index.pdf>

Release: January *Open for entire Calendar Year*

- **NIH SBIR Contract Solicitation**

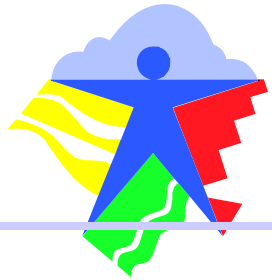
Release: August *Open for ~ 3 months*

**Open
Now**

- **NIH Guide for Grants and Contracts**

Release: Weekly *Open as noted*

<http://grants.nih.gov/grants/guide/index.html>



Beyond the Omnibus Solicitation

Institute/Center Research Interests

➤ NIH Guide for Grants and Contracts

- ❖ Program Announcements (PAs)

- ❖ Requests for Applications (RFAs)

Weekly announcements of new initiatives

<http://grants.nih.gov/grants/guide/index.html>

If you don't get it...



NIH SBIR/STTR Solicitation(s)

NIH Guide

➤ **NIH Guide for Grants and Contracts**

Weekly announcements of new initiatives

- ❖ **Program Announcements:** Open 3 years
 - ✓ Specific area of interest to one or more ICs
 - ✓ Reviewed by Center for Scientific Review (generally)
 - ✓ Receipt Dates may vary from standard

- ❖ **Requests for Applications:** Usually single receipt date
 - ✓ Targeted area of research for single IC
 - ✓ Reviewed by issuing IC
 - ✓ Set-aside (within a set-aside!) of funds



SPECIFIC AREAS OF INTEREST

- **COMPETING CONTINUATION AWARDS OF SBIR
PHASE II GRANTS FOR PHARMACOLOGIC AGENTS
AND DRUGS FOR MENTAL DISORDERS**

<http://grants2.nih.gov/grants/guide/pa-files/PA-02-173.html>

WHO: NIMH

- **INNOVATIVE TOXICOLOGY MODELS**

<http://grants2.nih.gov/grants/guide/pa-files/PA-02-075.html>

WHO: NCI, NIDCD, NIMH, NIDDK, NIDA, NIEHS

- **BIOENGINEERING NANOTECHNOLOGY INITIATIVE**

<http://grants2.nih.gov/grants/guide/pa-files/PA-02-125.html>

WHO: Trans-NIH

Plus many more..... See NIH Guide



NIH SBIR/STTR PROGRAM

Research Topics

Our ideas(examples)

- **Biodefense**
- **Biosensors**
- **Nanotechnologies**
- **Bioinformatics**
- **Proteomics/Genomics**
- **Behavioral research**
- **Computational Biology**
- **Biosilicon devices**
- **Biocompatible materials**
- **Acousto-optics /opto-electronics**
- **Imaging technologies**
- **Genetically engineered proteins**
- **Telehealth technologies**
- ...



Examples of Nanotechnologies

- **Nanoplumbing components**...valves, microfluidic channels, motors....that can be operated from a distance
- **Logic circuits**...based on quantum dots which carry out computing functions without current flow
- **Fluorescent probes**....at nanometer scale for monitoring biochemical processes on the surface and inside the cell



Examples of Nanotechnologies (cont.)

- “Smart” nanostructured biocompatible materials
- Nanofabricated barriers to control rejection of implantable materials
- Nanoparticles and nanospheres that enable controlled release of therapeutic agents, antibodies, genes and vaccines
- Biotemplates and sensor technologies for detection and analysis of DNA and RNA targets in body fluid samples



NIH Program Activities and Areas of Research

NHLBI-- diseases of heart, blood vessels, lungs, blood, and transfusion medicine

NIDCR-- understand, treat and prevent infectious and inherited craniofacial-oral-dental diseases and disorders

NINDS-- diagnosis, treatment, and prevention of disorders of the nervous system, neuromuscular apparatus, and special senses of touch/pain

NIDDK-- diabetes, endocrinology, and metabolic diseases; digestive diseases and nutrition; kidney, urologic and hematologic diseases

NIAID-- understand, treat and prevent infectious, immunologic, and allergic diseases

NCI-- cancer cause, prevention, detection, diagnosis, treatment and control



NIH Program Activities and Areas of Research (cont.)

NCRR-- R&D in instrumentation and specialized technologies for biomedical research; R&D in comparative medicine; discovery-oriented software for science education

NCCAM-- complementary and alternative treatment, diagnostic, and prevention modalities, disciplines and systems: education and public information; patient management; botanical products; research-related issues (e.g., models, methods)

NLM-- innovative methods, systems, and services for managing health knowledge and information

NIHGRI-- efforts toward achieving the goals of the Human Genome Project



NIH Program Activities and Areas of Research (cont.)

NIAMS-- arthritis/rheumatic diseases, connective tissue diseases, musculoskeletal and skin disorders

NIDCD-- normal mechanisms diseases, and disorders of hearing, balance, smell, taste, voice, speech and language

NIMH-- understanding, treating, preventing behavioral and mental disorders (including HIV prevention, neuro-AIDS research)

NIDA-- treatment of drug addiction; behavioral strategies for treatment medication; training in drug abuse treatment techniques; drug abuse treatment

NIAAA-- treatment and prevention of alcoholism and alcohol-related problems

NINR-- understand effects of acute and chronic illness, improving QOL, approaches to promote health and prevent disease, improving clinical environments



NIH Program Activities and Areas of Research (cont.)

NIBIB-- basic research relating to the discovery, design, development, translation and assessment of new knowledge in biomedical imaging and bioengineering.

NIGMS-- basic biomedical research not targeted to diseases or disorders; recombinant DNA technology

NICHD-- fertility, pregnancy, growth, development, and medical rehabilitation

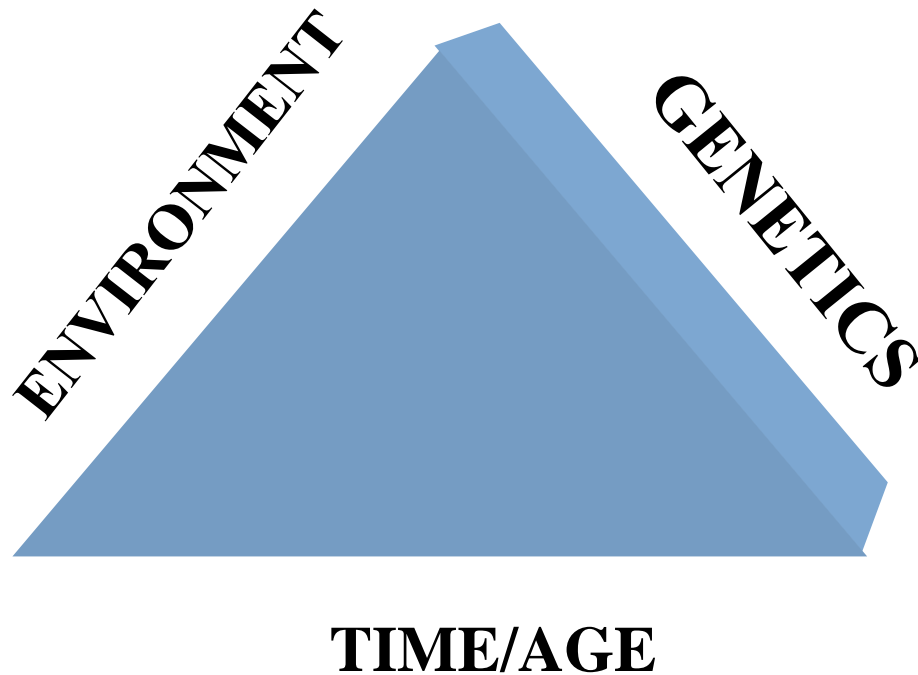
NEI-- blinding eye diseases, visual disorders, mechanisms of visual function, preservation of sight, requirements of the blind

NIA-- biomedical, social, and behavioral aspects of aging process; prevention of age-related diseases and disabilities; promotion of better QOL for older Americans

NIEHS-- identification, assessment, and mechanism of action of environmental agents that are potentially harmful to human health

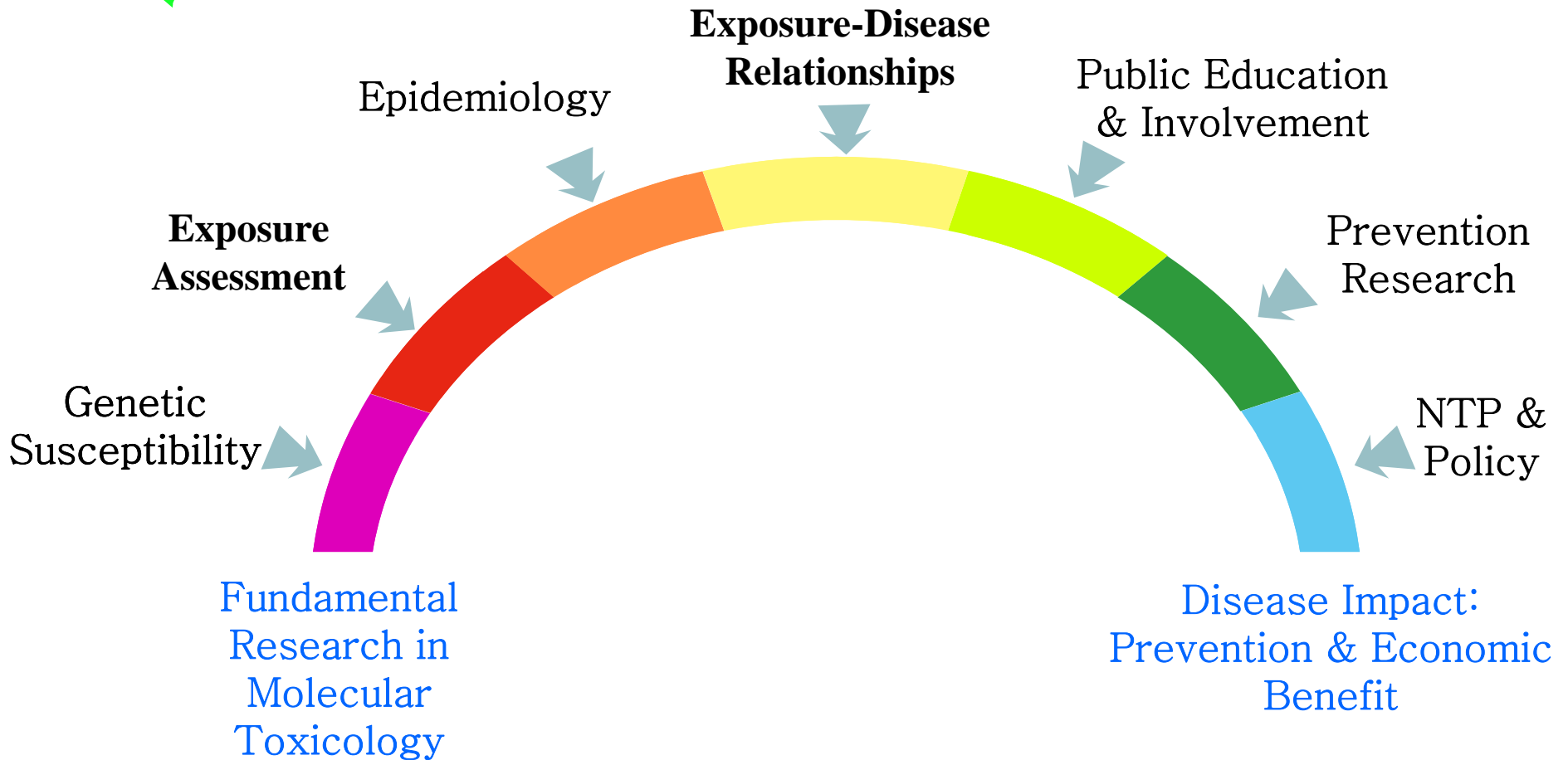


The mission of the National Institute of Environmental Health Sciences (NIEHS) is to reduce the burden of human illness and dysfunction from environmental causes by understanding each of these elements and how they interrelate.





National Institute of Environmental Health Sciences





NIEHS: Major Scientific Programs

- National Center for Toxicogenomics
 - Toxicogenomics Research Consortium
- Environmental Genome Project
- Comparative Mouse Genomics Centers
- NIEHS Core Centers Program
- Children's Environmental Health Research Centers
- Translational Research (Health Disparities, Environmental Justice)
- Superfund Basic Research Program
- Parkinson's Disease Environmental Health Centers
- Breast Cancer and the Environment Centers



National Institute of Environmental Health Sciences

The effect of environmental factors on....

- NIEHS funds research to understand how environmental factors or gene-environment interactions perturb a process/disease.
- Our ultimate goal is intervention/prevention .

.



Priority Environmental Agents (chemical, physical, biological and social and psychosocial)

- **Metals**

- lead, cadmium, mercury, arsenic

- **Hormonally Active Agents (receptor-mediated toxicity)**

- environmental estrogens, antiestrogens, antiandrogens
 - TCDD, PCBs, pesticides

- **Agricultural Chemicals**

- pesticides, herbicides

- **Industrial Chemicals**

- solvents, intermediates, alkylating agents, plasticizers

- **Botanicals/Nutrition**

- **Air Particulates**

- **Drugs/Lifestyle**

- **Social and psychosocial environmental factors**

- Socioeconomic status
 - Education
 - Cultural variables
 - Built environment



NIEHS SBIR/STTR Program

- Grants
 - NIH Omnibus Solicitation
 - Requests for Applications (RFA)
 - Program Announcements
- Contracts
 - NIH Omnibus Solicitation
- Worker Education and Training Program--RFA only



NIEHS SBIR/STTR Program

- Emphasis is on the development of new and novel approaches using state-of-the-art technologies
 - genomics
 - proteomics
 - bioinformatics
 - biotechnology and nanotechnology
- We are looking for interdisciplinary approaches--- biology, toxicology and “technology”.



NIEHS SBIR/STTR Grant Program: Areas of Emphasis

- **Predictive Test Systems for Safety Evaluation Program**
 - animal stem cell models
 - differentiated human cell lines
 - biokinetic models of toxicity
 - non mammalian or invertebrate models using endpoints that are conserved across species
 - battery of receptor binding or activity assays
 - assays to assess ability of chemicals to pass barriers (blood, brain, kidney, lung, gastrointestinal)



NIEHS SBIR/STTR Grant Program:

Predictive Models-Examples of Funded Projects

- **Endocrine disruptors**
 - Multiplexed receptor device to detect hormone disruptors
 - Biosensor for screening specific interactions with AhReceptor
 - A novel assay for measurement of PCB arochlors
 - An in vitro robotic assay for estrogenic activity
- **General**
 - Development of a biochip device for in vitro toxicology
 - Whole animal microplate assay for toxicity screening
 - Comprehensive gene expression profiling for toxicology
 - High throughput screening of therapeutics
- **Organ Toxicity**
 - Cultured corneal epithelium: Draize test replacement
 - Reporter gene expression assays for skin irritation



NIEHS SBIR/STTR Grant Program: Areas of Emphasis

● **Exposure Assessment Program**

- Biomarkers of tissue specific damage measurable in saliva, urine, or serum
- Personal multiplexed monitors to measure current or cumulative exposures to environmental agents
- Miniaturized sampling instruments for use with children
- Nanotechniques to detect and assay environmental agents and their metabolites that could be used for screening populations
- High throughput fingerprinting of genetic polymorphisms
- Use of genomics, proteomics and metabolomics to provide molecular fingerprints of exposure to environmental agents.



NIEHS SBIR/STTR Grant Program:

Exposure Assessment-Examples of Funded Projects

- **Exposure Detection/Monitors**

- Development of hand held trace metal analyzer
- Chemically amplified detection of organic vapors
- Reagentless biochip for inorganic and organic contaminants
- Direct reading personal monitor for vinyl chloride
- Myo-chem monitor for organophosphates
- Personal dosimeter for organophosphates using nano-structure surface
- Pneumatic focusing gas chromatography for breath assessment
- Nanostructured sensor array for air quality monitoring

- **General**

- Stroodle: a GIS foundation class library
- Miniature sensor platform for detecting toxic gases
- Exposure assessment using hyperspatial imagery



NIEHS SBIR/STTR Grant Program:

Areas of Emphasis

- **Hazardous Waste Assessment, Evaluation and Remediation Program**
 - Field ready instruments to measure chemical contaminants
 - Methods/instruments to detect and measure non or dense aqueous phase liquids in the subsurface
 - Monitors for bioavailability of toxic waste and the change after remediation
 - Phytoremediation using genetically engineered plants
 - Remediation methods specific to metals and metal-organic mixtures
 - Bioremediation using genetically engineered microbes and or bioreactors
 - Nano structures, electrochemical methods, photocatalytic processes, thermal treatments or filtration-based methods of remediation



NIEHS SBIR/STTR Grant Program:

General-Examples of Funded Projects

- Oligonucleotide ligands for pesticide detection in food
- Miniature system for removal of disinfection byproducts
- CBW protective clothing of civilian protection
- High throughput colormetric genotyping
- Automatic systems for aneuploidy detection in sperm
- Phytofiltration of arsenic-contaminated drinking water
- Future Conditional: A PBS documentary
- Rapid field test for Iodine in urine and salt
- A prototype neurological database



NIEHS SBIR/STTR Contract Program: Topics 2004

- Development and validation of high throughput in vitro estrogen receptor and androgen receptor binding assays based on the use of recombinant receptors
- Development and validation of metabolically competent in vitro toxicity test systems
- Development of an indoor allergen assay for asthma studies
- Development of a comprehensive system to control indoor humidity and reduced indoor allergen levels in residential buildings
- Development of mouse tissue informatics software
- Development of assays for the analysis and quantitation of eicosinoid and regulatory pathways
- Development of metabonomic profiles of liver diseases



Worker Education and Training SBIR Program

- **Purpose:** To develop innovative E-learning products for worker safety and health training in hazardous waste and chemical emergency response.
- **Areas of emphasis**
 - Computerized database of case studies in hazardous materials response for use in courses.
 - Applications for electronic distribution of self study and classroom based curricula.
 - Online resources to improve instructor competence.
 - Web-based support for online discussions.
 - An electronic performance support system as a post training resource.

This is not an ongoing solicitation but announced via RFAs on a periodic basis.



How can I as a University faculty member take advantage of the SBIR/STTR program?

- Own a small business (assign another PI)
- Senior personnel on SBIR/STTR
- Consultant on SBIR/STTR
- PI on STTR (with University Permission)
- Subcontract on SBIR/STTR
- Provide analytical or other service support



NIEHS SBIR/STTR PROGRAM: SUMMARY

- Mission is to prevent disease and dysfunction by understanding the interaction of environment, genetics and age.
- SBIR program focuses on new technology, high throughput and multi/interdisciplinary approaches.
- Areas of interest
 - Predictive models (new toxicity tests)
 - Exposure assessment/biomarkers of toxicity and disease
 - Remediation
 - Intervention/prevention



SBIR Program Contacts

- **Jerry Heindel** (General coordinator NIEHS)
 - (919 541-0781
 - heindelj@niehs.nih.gov
- **Beth Anderson** (Hazardous waste program)
 - 919 541-4481
 - tainer@niehs.nih.gov
 - <http://benson.niehs.nih.gov/sbrp>
- **Jo Anne Goodnight.** (NIH General Coordinator)
 - 301 435-2688
 - Jg128w@nih.gov

