Concept Clearance

Branch: Exposure, Response, and Technology Branch

Council Period: 201610

**Concept Title:** SBIR Technologies for Environmental Health Research

Introduction

As with most federal agencies with an R&D budget over $100M, the NIEHS is required to allocate a portion of its extramural R&D budget to support small businesses through the SBIR program. With the reauthorization of the SBIR/STTR programs by Congress in December 2011, a number of key provisions were implemented, including an increase in the set-aside requirements for federal agencies for both SBIR and STTR programs. For SBIR grants, the set-aside will increase from 3.0% in FY16 to 3.2% in FY17 and will remain at that level thereafter. For STTR grants, the set-aside is currently 0.45% (increased from 0.40% in FY15) and will remain at that level. In order to focus on development and commercialization of technologies that support the NIEHS mission of reducing the exposure to environmental stressors to promote healthier lives, several SBIR RFAs are proposed here, including:

- Enhancing technologies for measuring exposures to engineered nanomaterials,
- Developing organotypic rodent and other animal models for toxicology testing to reduce the need for *in vivo* animal testing,
- Developing diversity panels of animal and human cells to incorporate genetic diversity testing in toxicity testing, and
- Supporting the development and application of educational tools and approaches to improve awareness and knowledge of environmental health science topics.

Given the increased funds set aside for SBIR projects, soliciting applications through selected RFAs will help to focus research and development of technologies and tools that have high priority for the NIEHS mission.

The NIEHS has two current RFAs for SBIR applications. RFA-ES-16-012, Novel Methods for Obtaining Molecular Information from Archived Tissue Samples (R43/R44) was re-released in August, 2016 to allow Phase II applications from the previous RFA (RFA-ES-13-009) as well as new Phase I and Fast-track applications. A total of 5 Phase I grants were funded through the previous RFA to develop methods to obtain genomics, epigenomics, and proteomics information from formalin-fixed, paraffin-embedded tissues. RFA-ES-16-012 also supports the development of methods to preserve blood and other biological samples prior to freezing, and development of testing methods to assess the quality of nucleic acid and proteins in stored samples prior to in-depth analysis. A second RFA (ES-15-016), NIEHS SBIR Phase IIB Awards for Validation and Commercialization of Approaches to Reduce Animal Use in Toxicology Testing (U44) released in July, 2015 for three years, provides support for the formal validation of *in vitro* approaches and other test methods to reduce or replace animals use in toxicology testing. Formal validation of these approaches (either through single laboratory or multi-laboratory validation efforts) is needed to increase acceptance of alternative methods by US federal agencies and to accelerate the commercialization of these methods.

In addition to proposals submitted to NIEHS through the general Omnibus Solicitation of the NIH, CDC, FDA and ACF for Small Business Innovation Research Grant Applications (Parent SBIR [R43/R44]), soliciting SBIR applications through selected RFAs over the next 4-5 years will help to enhance the development of technologies and approaches by small businesses that support many aspects of the
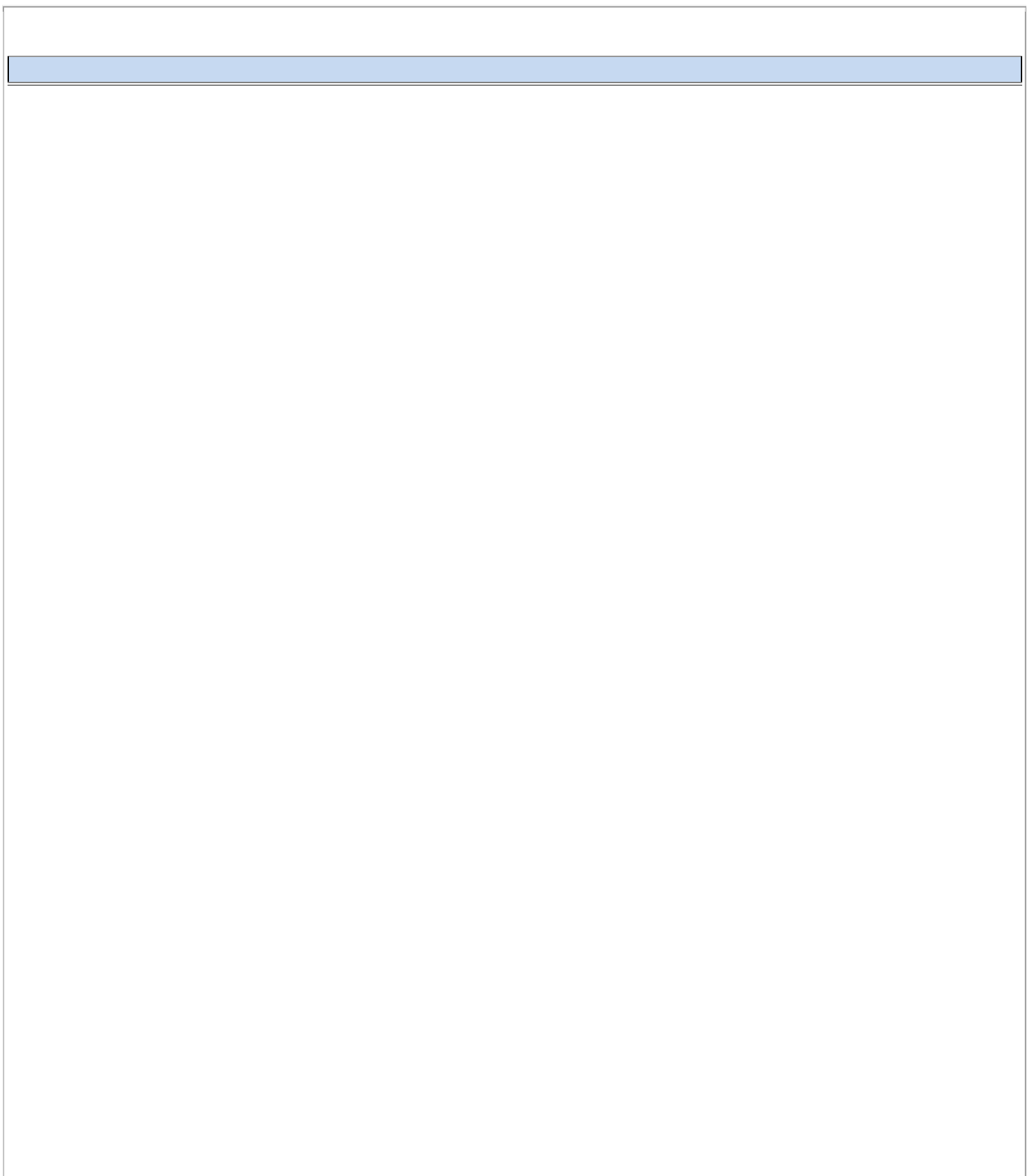
3. **Animal and Human Cells Panels to Incorporate Genetic Diversity in Toxicity Testing**

    Traditional toxicology testing in a single or limited number of laboratory rat or mouse strains may provide an inaccurate estimate of hazard by failing to capture the potentially wide variation in sensitivity to chemical exposures due to genetic diversity. In order to better simulate the genetic diversity in human populations, a number of resources have been developed, including the Collaborative Cross (CC) and Diversity Outbred (DO) mouse strains, and the HXB/BXH recombinant inbred (RI) rat strains and the Hybrid Rat Diversity Panel, to study the genetics of complex traits, including variation in response to toxicants. In order to meet the goals set out in the NAS report on "Toxicity Testing in the 21st Century" and the related initiatives, Tox21, ToxCast, and REACH, new high-throughput approaches are needed that reflect the genetic diversity in response to exposure in human populations. This may include development of panels of cells from mouse or rat resources for mid- to high-throughput biomarker, reporter or imaging assays. Also needed are genetically diverse panels of human cell lines, *e.g.*, induced pluripotent cells or progenitor cells that can be used for both toxicity screening and for identifying candidate genes that contribute to the variation in toxicant sensitivity.

4. **Educational Tools for Environmental Health Science**

    As part of its Partnerships for Environmental Public Health (PEPH) Program, NIEHS is interested in developing tools that improve environmental health literacy and awareness of environmental health research. 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 development of mobile applications that communicate health risks of exposures to environmental stressors, devices and systems for collecting and reporting information on environmental exposures for educational purposes in schools or communities, STEM education resources related to environmental health, and systems that can utilize public and voluntary population data from sensors, activity trackers, GIS enabled devices, social communications, and surveillance cameras to inform communities about environmental health concerns.

Mechanism and Justification

Phase I (1R43) and Fast Track (1R44) applications will be solicited for initial development of technologies for each of these four topic areas. Subsequent RFAs will solicit Phase II (2R44) applications from Phase I grantees supported through these four RFAs.

Soliciting applications from small businesses through selected RFAs in these scientific areas will help to focus technology development in areas that support many aspects of the NIEHS mission.