



National Institute of Environmental Health Sciences  
*Your Environment. Your Health.*

**NIEHS Small Business (SBIR/STTR)  
Funding Opportunity for the  
*“Validation and Commercialization of Approaches to  
Reduce Animal Use in Toxicology Testing (U44)”***

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**[www.niehs.nih.gov/sbir](http://www.niehs.nih.gov/sbir)**

**<http://grants.nih.gov/grants/guide/rfa-files/RFA-ES-15-016.html>**

# Overview

- **SBIR/STTR Program Overview**
- **Solicitation**
  - Guiding Principles and Key Dates
  - Small Business Eligibility
  - Technology Eligibility
  - High Priority Areas
  - Additional Application Requirements
  - Cooperative Agreement Requirements
  - Application Resources



**SBIR = Small Business Innovation Research**

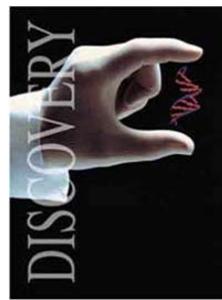
- For Profit
- <500 employees
- US owned and operated
- 11 Federal Agencies w/ extramural budgets >\$100M

FY	SBIR Required Allocations
2015	2.90%
2016	3.00%
2017	3.20%

**STTR = Small Business Technology Transfer**

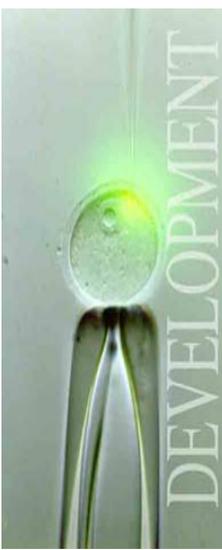
- For Profit (40%) + Nonprofit (30%)
- <500 employees at For Profit
- US owned and operated
- 5 Federal Agencies w/ extramural budgets >\$1B

FY	STTR Required Allocations
2015	0.40%
2016	0.45%
2017	0.45%



## PHASE I Feasibility Study

- Budget Guide: \$225K (SBIR); \$225K (STTR) Total Costs
- Project Period: 6 months (SBIR); 1 year (STTR)

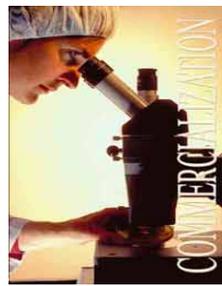


## PHASE II Full Research/R&D

- \$1.5M (STTR), \$1.5M (SBIR) over two years

## **PHASE IIB Competing Renewal/R&D**

- Clinical R&D; Complex Instrumentation/Tools to FDA
- Many, but not all, ICs participate
- Varies ~\$1M/year for 3 years



## PHASE III Commercialization Stage

- NIH, generally, not the “customer”
- Consider partnering and exit strategy early



## RFA-ES-15-016 NIEHS SBIR Phase IIB Awards for Validation and Commercialization of Approaches to Reduce Animal Use in Toxicology Testing (U44)

### *Guiding Principles*

- Supports validation efforts to accelerate the acceptance and commercialization of alternative methods/approaches that directly reduce or replace the use of animals in toxicological testing
- As a cooperative agreement, grantees will work through the Steering Committee and ICCVAM/NICEATM to address validation steps needed for acceptance by US Federal Agencies of alternative test methods

### **Key Dates for the First Cycle**

Letter of Intent:	Oct 17, 2015
Application:	Nov 17, 2015 – and 2016, 2017
Review:	Mar 2016 (Dr. Tilotta)
Awards:	Jul 2016 (2-3 per cycle)



## RFA-ES-15-016 NIEHS SBIR Phase IIB Awards for Validation and Commercialization of Approaches to Reduce Animal Use in Toxicology Testing (U44)

### *Small Business Eligibility*

- Phase II SBIR and STTR **grant** and **contract** awardees are eligible
- Phase II awardees from other NIH Institutes or other Federal Agencies are eligible
- Phase II award must have been completed in the last 24 months
- Grantees cannot receive Phase IIB funding if they have an active Ph II for the same project; funding periods cannot overlap



## RFA-ES-15-016 NIEHS SBIR Phase IIB Awards for Validation and Commercialization of Approaches to Reduce Animal Use in Toxicology Testing (U44)

### ***Technology Eligibility***

- Fully developed and ready for validation, which includes **prior testing** with relevant reference chemicals
- Must result in a **direct** reduction of animals used in non-clinical toxicology testing required by a **US Federal Agency**
- May be a **standalone** replacement or part of a **weight-of-evidence** approach
- **Highest priority** will be given to **standalone** alternative test approaches
- This funding opportunity **will not** fund additional *in vivo* studies

NOTE\*\*\* **3 receipt dates for this opportunity** (Nov 2015, 2016, 2017)  
If a technology is not eligible now, this funding opportunity provides guidelines to eligibility for future receipt dates

# RFA-ES-15-016 NIEHS SBIR Phase IIB Awards for Validation and Commercialization of Approaches to Reduce Animal Use in Toxicology Testing (U44)

## *High Priority Areas*

- **Ocular Toxicity Testing**
  - Should differentiate among EPA's 4 eye irritation hazard categories
  - Focus is on approaches that are predictive of a range of chemistries
- **Reproductive and Developmental Toxicity Testing**
  - New *in vitro* assays, combinations of assays, computational methods
  - Use of phylogenetically lower organisms may also be appropriate
  - Focus is on approaches to identify endocrine disruptors
- **Carcinogenicity Testing**
  - Integration of new *in vitro* assays and computational methods combined with QSAR, mutagenicity, and genotoxicity assays
  - Focus is on approaches to identify non-genotoxic carcinogens
- **Acute Toxicity Testing**
  - Alternative acute toxicity testing approaches have been developed and adopted by OECD, but additional validated methods are needed
  - Focus is on approaches for oral and acute inhalation toxicity



## RFA-ES-15-016 NIEHS SBIR Phase IIB Awards for Validation and Commercialization of Approaches to Reduce Animal Use in Toxicology Testing (U44)

### Additional Application Requirements

- **Commercialization Readiness and Competitive Advantage**
  - Testing of SOP method with appropriate reference compounds supported through comparison with historical *in vivo* data
  - Demonstration of approach with a clear advantage over existing approaches
- **Milestones**
  - Milestones and timelines for entire project period
  - Milestones should be specific and quantitative
- **Validation Plan**
  - Targeted US Federal Agency and current agency testing approach
  - Strategy for US Federal Agency to assess accuracy, reliability, and relevance
- **Commercialization Plan**
  - Competitive landscape and strategy to address potential roadblocks
  - Intellectual property
  - Strategy and funding sources beyond Ph IIB to reach commercialization



## **RFA-ES-15-016 NIEHS SBIR Phase IIB Awards for Validation and Commercialization of Approaches to Reduce Animal Use in Toxicology Testing (U44)**

### ***Cooperative Agreement Requirements***

- **Dominant role and prime responsibility reside with PI(s)**
- **Substantial NIH programmatic involvement**
  - NIEHS Program Official
  - NIEHS Scientific Officer
- **Steering Committee**
  - Governing board to oversee the project
  - Will meet at least once per month via teleconference
  - Voting Members: Steering Committee Chair, Small Business PIs, NIEHS Program Official or Scientific Officer
  - ICCVAM/NICEATM
  - NIEHS Program Staff

# Application Resources

## NIEHS TOP 7 Recommendations

1. **Contact the Program Official before applying – Daniel Shaughnessy [shaughn1@niehs.nih.gov](mailto:shaughn1@niehs.nih.gov)**
2. **Visit [www.niehs.nih.gov/sbir](http://www.niehs.nih.gov/sbir)**
3. Funding Announcement – read it at least 3-5 times
4. Begin the 5 required registrations 6-8 weeks in advance
5. Apply 3-5 days before the due date
6. Join the SBIR-NIEHS Listserv
7. Follow us on Twitter @NIEHS and #SBIR\_NIEHS

## NIEHS TOP 6 Resources for SBIR applicants

1. NIH FAQs [www.sbir.nih.gov/faqs](http://www.sbir.nih.gov/faqs)
2. SBA SBIR website [www.sbir.gov/faqs](http://www.sbir.gov/faqs)
3. Sample funded applications from NIAID <http://www.niaid.nih.gov/researchfunding/sb/apply/Pages/samples.aspx>
4. Annotated SBIR/STTR SF424 application forms [http://grants.nih.gov/grants/ElectronicReceipt/files/Annotated\\_Forms\\_FORMS-C\\_SmallBus-1.pdf](http://grants.nih.gov/grants/ElectronicReceipt/files/Annotated_Forms_FORMS-C_SmallBus-1.pdf)
5. Sample funded applications from NIAID <http://www.niaid.nih.gov/researchfunding/sb/apply/Pages/samples.aspx>
6. NIH rules for applying/accepting a grant <http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf>



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# Questions/Comments?