2019 SBIR/STTR Funding & Commercialization-Arizona Regional Summit:

Takin' Care of Business

UA Tech Park - Event Center

Tuesday, March 26, 2019

Robert Vinson

NIH SBIR/STTR Program Office,
Office of Extramural Research

SBIR/STTR Website

https://sbir.nih.gov

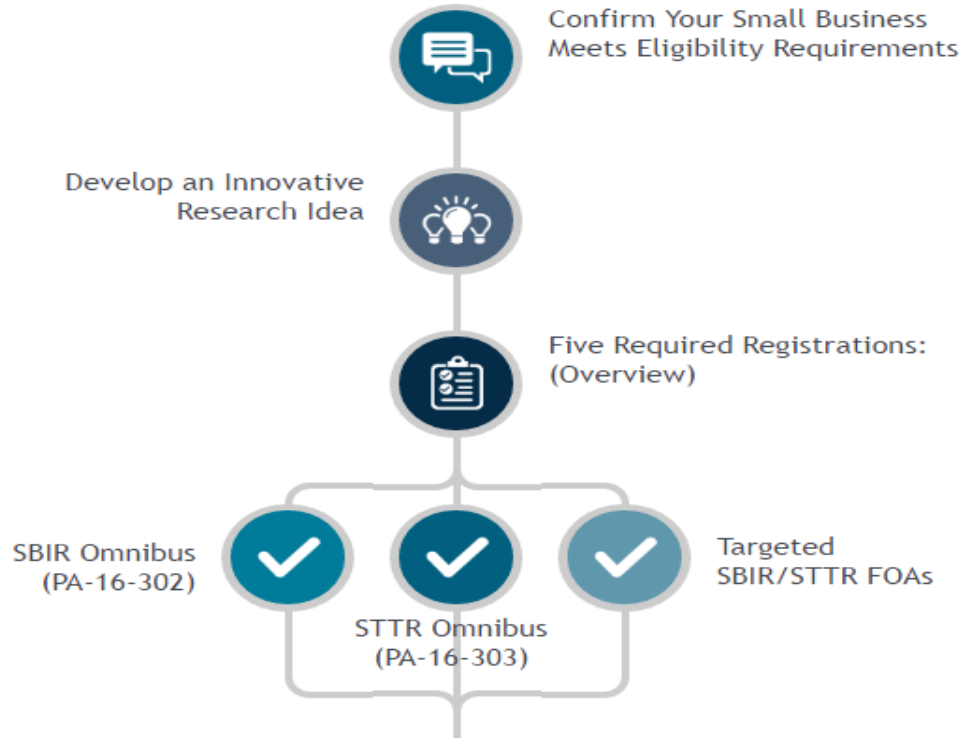
Small Business Innovation Research (SBIR)
Small Business Technology Transfer (STTR)

New to SBIR/STTR?

SBIR/STTR Application Process Infographic

Use this interactive chart that contains helpful information to guide you through the NIH SBIR/STTR application process. Click though the chart for answers to your related questions.

START THE SBIR/STTR APPLICATION PROCESS INFOGRAPHIC



http://sbir.nih.gov/infographic

Congressionally Mandated Programs

SET ASIDE

3.2%

(FY18)

SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM

Set-aside program for small business concerns to engage in federal R&D -- with potential for commercialization

.45%

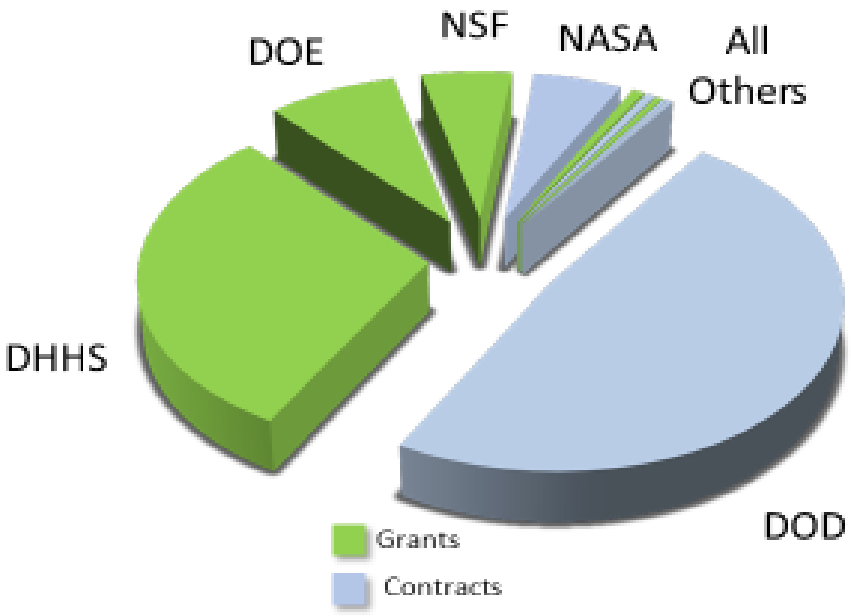
(FY18)

SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAM

Set-aside program to facilitate cooperative R&D between small business concerns and US research institutions -- with potential for commercialization

Budgets by Agency 2018

Approximate SBIR/STTR Budgets by Agency, FY2018



~ $3.6B in FY2018 across all agencies

Agencies with SBIR & STTR Programs	Approx. Budget
Department of Defense (DOD)	$1.750B
Department of Health & Human Services (DHHS), including the National Institutes of Health (NIH)* **DHHS also issues contracts*	**$1.088B**
Department of Energy (DOE), including Advanced Research Projects Agency –Energy (ARPA-E)	$280M
National Science Foundation (NSF)	$202.4M
National Aeronautics and Space Administration (NASA)	$198.0M
Agencies with Only SBIR Programs	**Approx. Budget**
Department of Agriculture (USDA)	$27.0M
Department of Homeland Security (DHS): Science and Technology Directorate (S&T) & Countering Weapons of Mass Destruction Office (CWMD)	$20.8M
Department of Commerce: National Oceanic and Atmospheric Administration (NOAA) & National Institute of Standards and Technology (NIST)	$14.2M
Department of Transportation (DOT)	$8.5M
Department of Education (ED)	$7.5M
Environmental Protection Agency (EPA)	$4.2M

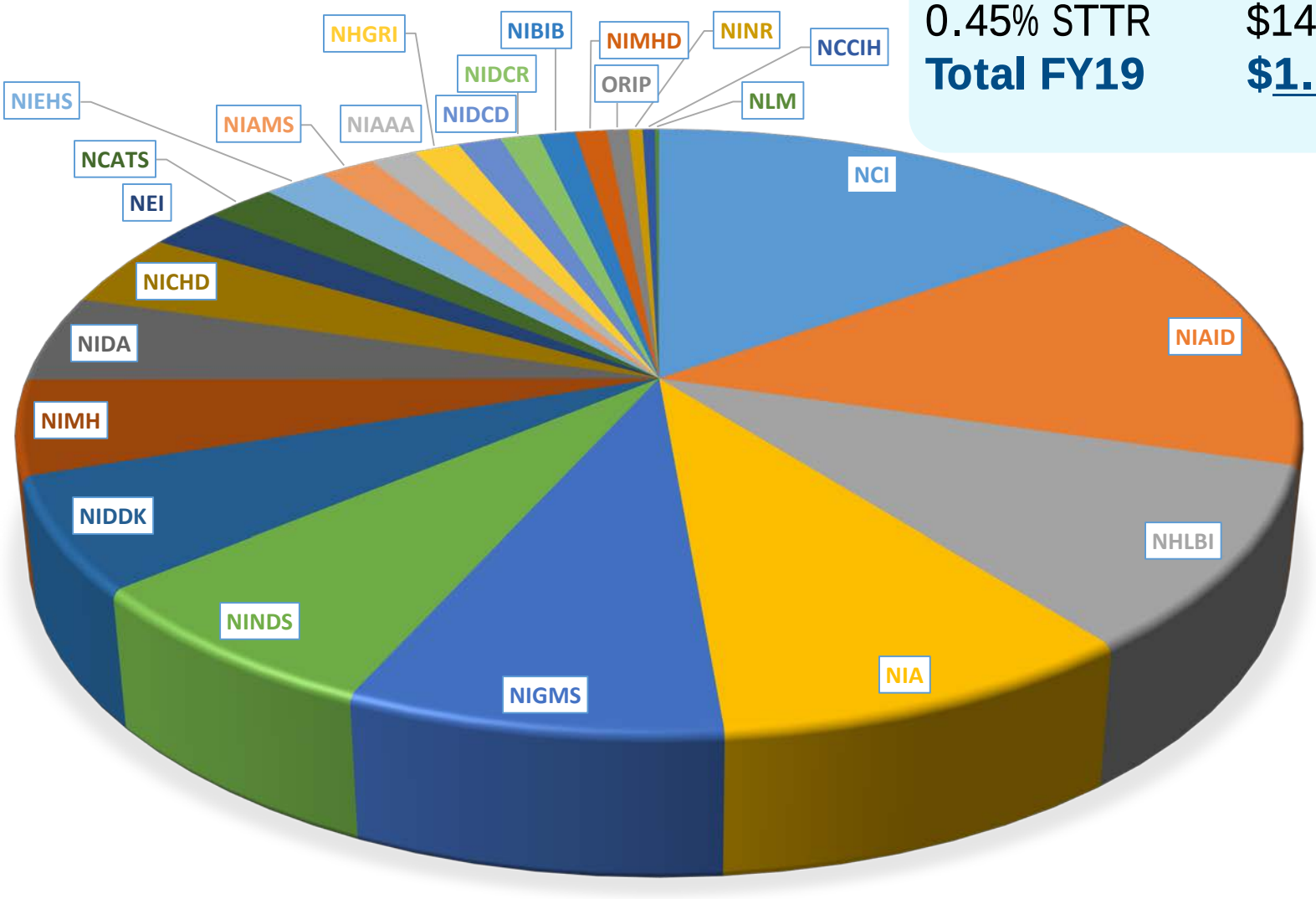
National Institutes of Health
Office of Extramural Research

HHS Program Funding

2019 Budget	SBIR	STTR
NIH	**$1B**	**$141M**
CDC	**~$12M**	N/A
ACL (NIDILRR)	**~$3M**	N/A
FDA	**~$1M**	N/A

NIH SBIR/STTR Budget Allocations FY2019

3.20% SBIR	$1**B**
0.45% STTR	$141M
Total FY19	**$1.141B**



NIH Small Business Innovation Research (SBIR)
Small Business Technology Transfer (STTR)

SBIR/STTR 2018
Success Rates by Funding

Fiscal Year	SBIR/STTR	Phase	Number of Applications Reviewed	Number of Applications Awarded	Success Rate	Total Funding
2018	SBIR	Phase I	3,607	665	18.4%	$164,092,776
2018	SBIR	Fast Track	730	147	20.1%	$41,420,240
2018	SBIR	Total Phase II	**619**	**258**	**41.7%**	**$214,967,591**
2018	SBIR	Regular Phase II	531	224	42.2%	$176,948,384
2018	SBIR	Phase IIB	84	32	38.1%	$36,023,223
2018	STTR	Phase I	1,011	211	20.9%	$52,320,567
2018	STTR	Fast Track	129	27	20.9%	$8,767,497
2018	STTR	Total Phase II	**79**	**27**	**34.2%**	**$20,972,412**
2018	STTR	Regular Phase II	78	27	34.6%	$20,972,412
2018	STTR	Phase IIB	1	0	0.0%	$0
2018	**FY TOTAL**		**6,177**	**1,337**	**21.6%**	**$504,146,584**

Success Rates Posted Online: https://sbir.nih.gov/statistics/award-data

NIH Small Business Innovation Research (SBIR)
Small Business Technology Transfer (STTR)

SBIR/STTR 3-Phase Program

Discovery

Phase I

Phase I Feasibility Study

Budget Guide: $150K for SBIR and STTR
Project Period: 6 months (SBIR); 1 year (STTR)

Development

Phase II

Phase II Full Research/R&D

$1M for SBIR and STTR, over two years

Phase IIB

Phase IIB Competing Renewal/R&D

Clinical R&D; Complex Instrumentation/to FDA
Many, but not all, IC's participate
Varies~$1M per year; up to 3 years

Commercialization

Phase III

Phase III Commercialization

NIH, generally, not the "customer"
Consider partnering and exit strategy early

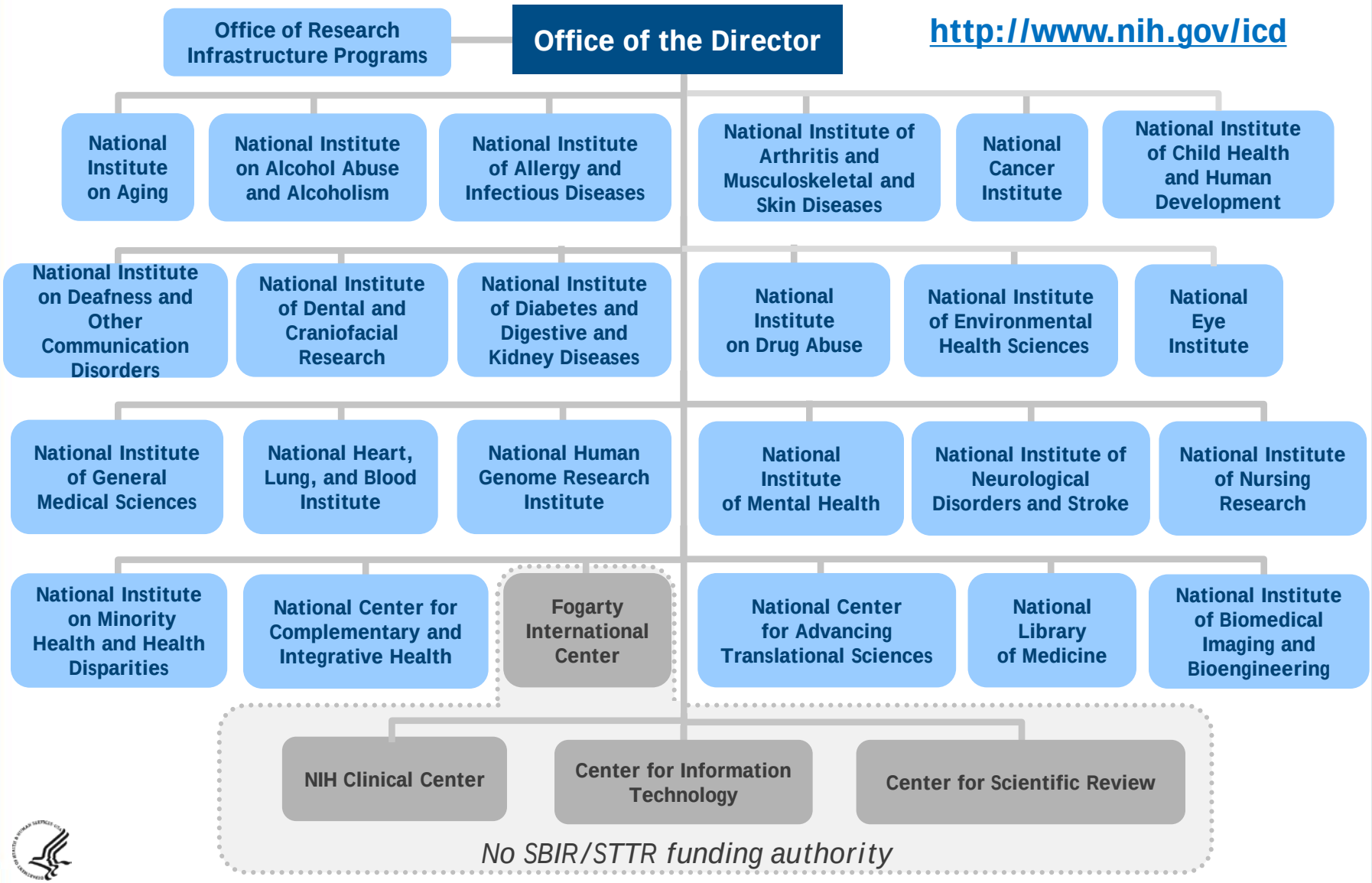
Mission

To seek fundamental knowledge about the nature and behavior of living systems and the ***application of that knowledge to enhance health, lengthen life, and reduce illness and disability****.*

Small Business Innovation Research (SBIR)
Small Business Technology Transfer (STTR)

National Institutes of Health

http://www.nih.gov/icd



SBIR/STTR Legislative Update

- SBIR/STTR programs authorized through FY22
- 4 pilot programs extended through FY22
  - **SBIR Direct Phase II** (some by 1/7/19, rest by 4/5/19)
    - Apply at Application Level for SBIR Direct Phase II (New)
    - NIH Only, not available for STTR by law
  - **Commercialization Readiness Pilot Program** (SB1 or other options targeting 4/5/19)
  - **3% Agency SBIR Admin funds** (more outreach, more commercialization assistance, etc.)
  - NIH Phase 0 Proof of Concept Centers (REACH – planning)

SBIR/STTR Legislative Update

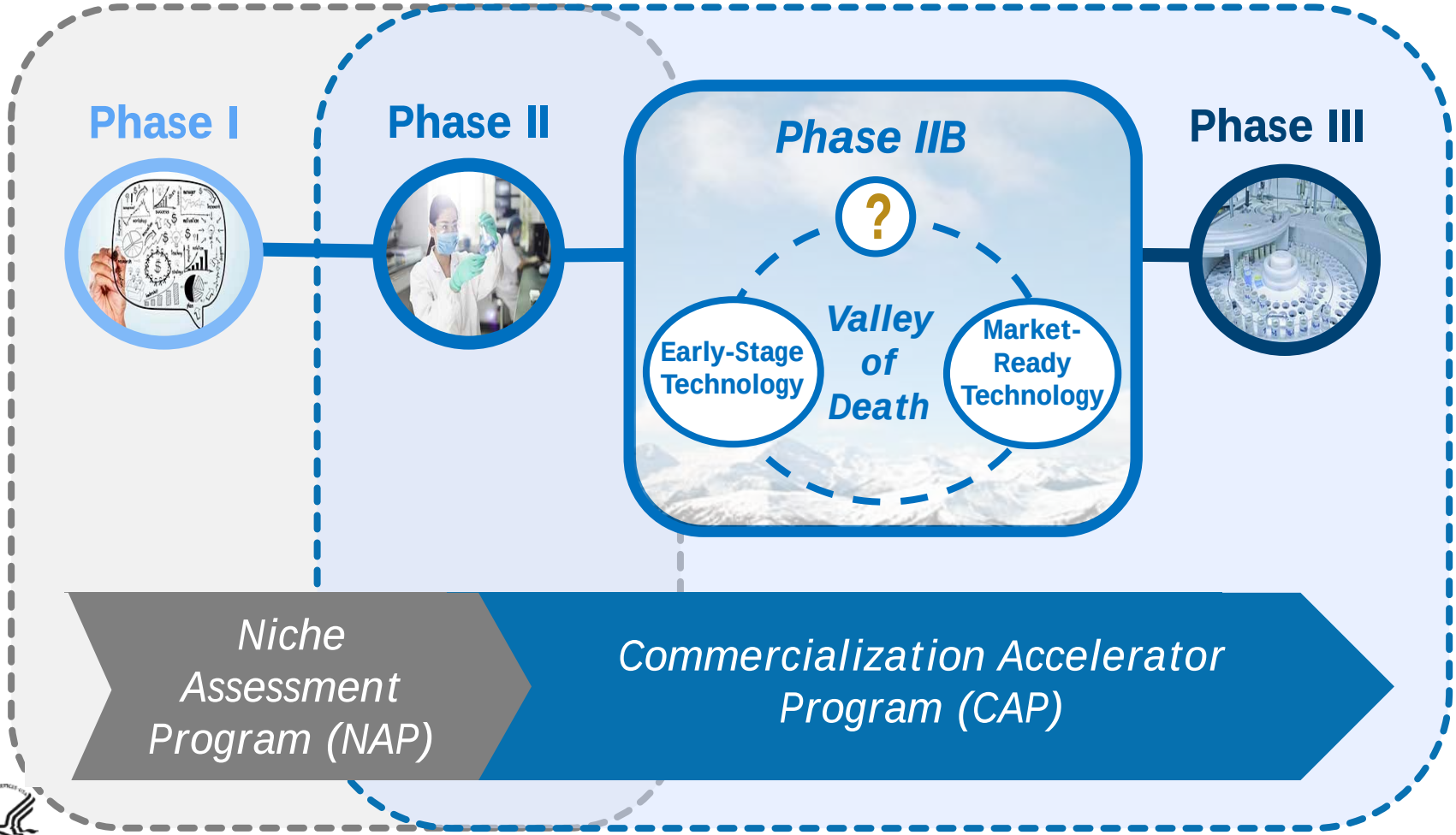
- Increase Technical and Business Assistance
  - Up to $6,500 per year per Phase I (up from $5K/year)
  - Up to $50,000 per Phase II project (up from $5K/year)
  - Request at time of APPLICATION
  - Request in F. Other Direct Costs lines 8-10 on SBC budget
  - Label as "Technical Assistance"

F. Other Direct Costs	Funds Requested ($)
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8.	
9.	
10.	
Total Other Direct Costs	

Subaward/Consortium/Contractual Costs are not pre-populated. Include both Direct and Indirect costs.

Technical Assistance Programs

Helping companies cross the *"Valley of Death"*



Technical Assistance Programs

Niche Assessment Program – *Foresight Science & Technology*

(Phase I Awardees)

https://sbir.nih.gov/nap

- Helps jump start commercialization efforts
- Determines competitive advantages
- Develops market entry strategy

Commercialization Accelerator Program - *Larta, Inc.*

(Phase II Awardees)

https://sbir.nih.gov/cap

- Technical Assistance/Training in:
  - Strategic/business planning
  - FDA requirements
  - Technology evaluation
  - Manufacturing issues
  - Patent and licensing issues
- Helps build strategic alliances
- Facilitates investor partnerships
- Individualized mentoring/consulting

Multi-IC Technology Development Programs

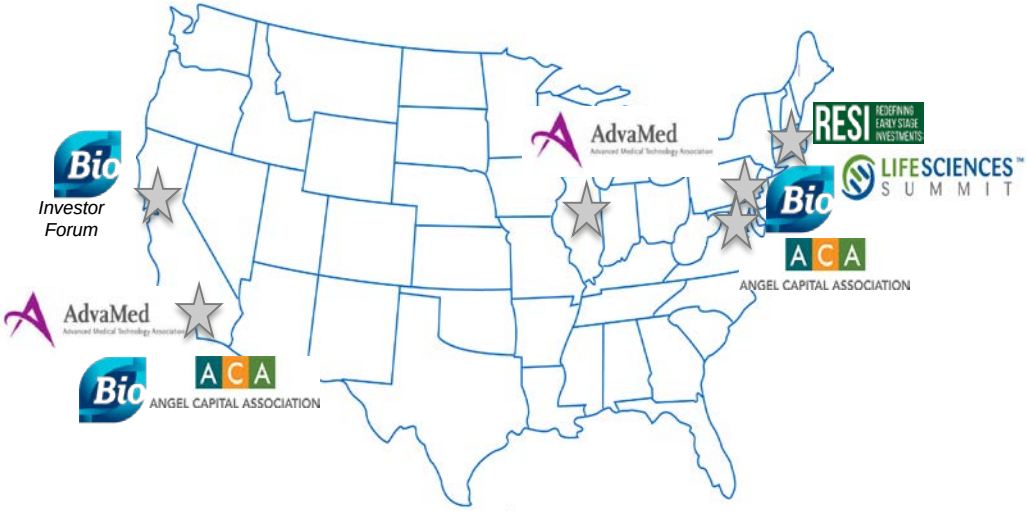
(open to eligible Awardees from participating ICs)

I-Corps™ at NIH

An intensive *Entrepreneurial Immersion* course for scientists

12 Participating ICs + CDC

Facilitating Partnerships



NIH Small Business Innovation Research (SBIR)
Small Business Technology Transfer (STTR)

SBIR/STTR 3-Phase Program

Discovery
Phase I

Feasibility

Development
Phase II

Full R/D

Competing Renewal Award
Phase IIB

$3M for up to 3 years

Commercialization
Phase III

Phase I → ***Phase II***

Fast-Track

Direct to Phase II

Congressional authority back!
Re-implemented fall/winter

Commercialization Readiness Pilot (CRP)
Congressional authority back!
Re-implemented winter/spring
$3M for up to 3 years

Only Some ICs Participate

NIH Small Business Innovation Research (SBIR)
Small Business Technology Transfer (STTR)

SBIR/STTR Fast-Track

Discovery
Phase I

Feasibility

Development
Phase II

Full R/D

Competing Renewal Award
Phase IIB

$3M for up to 3 years

Additional R/D

Commercialization
Phase III

Phase I → ***Phase II***

Fast-Track

Direct to Phase II

- Simultaneous submission and review of Phase I and II
- Phase I is awarded
- Milestones/aims of Phase I are assessed by program staff BEFORE Phase II is awarded

NIH Small Business Innovation Research (SBIR)
Small Business Technology Transfer (STTR)

SBIR/STTR
Direct to Phase II

Discovery
Phase I

Feasibility

Development
Phase II

Full R/D

Competing Renewal Award
Phase IIB

$3M for up to 3 years

Additional R/D

Commercialization
Phase III

Phase I → ***Phase II***

Fast-Track

Direct to Phase II

- SBIR only
- Bypass Phase I grant
- Congressional authority is BACK!

NIH Small Business Innovation Research (SBIR)
Small Business Technology Transfer (STTR)

Phase IIB Competing Renewal Award

- SBIR/STTR Phase II awardee
- Technologies that require extraordinary time/effort to develop, and often require FDA regulatory approval
- Awards up to **$1M/year for up to 3 years**
- IC must accept Competing Renewal applications (NIA, NIAAA, NIAID, NICHD, NIDA, NIDCD, NIDDK, NEI, NIGMS NHLBI, NIMH, NINDS, NCATS, ORIP, NCI, NHLBI, NINDS)

Contact NIH Program Staff to discuss!

Funding Opportunities Announcements (FOAs)

a publicly available document by which a federal agency makes known its intentions to award discretionary grants or cooperative agreements, usually as a result of competition for funds.

https://sbir.nih.gov/funding

Omnibus vs Targeted FOAs

	Omnibus	Targeted
Due Dates	Standard Due Dates	Standard or Customized Due Dates
Review	SBIR/STTR panels at CSR	SBIR/STTR panels at CSR <OR> SBIR/STTR panel at IC
Application Instructions	Follow SF424 R&R SBIR/STTR Application Guide & Annotated Form Set	Follow SF424 R&R SBIR/STTR Application Guide & Annotated Form Set <AND> any additional instructions in FOA

Read FOA very carefully!

NIH, CDC, FDA, & SBIR/STTR Grant Solicitation "Parent" FOAs:

Clinical Trial Not Allowed

SBIR: PA-18-574 **STTR: PA-18-575**

Clinical Trial Required

SBIR: PA-18-573 **STTR: PA-18-576**

Release: January 16, 2018
Standard Due Dates: **April 5th**, September 5th, January 5th

YOUR Ideas: Investigator-initiated R&D

- Research projects related to the NIH mission
- "Other" areas of research within the mission of an awarding component

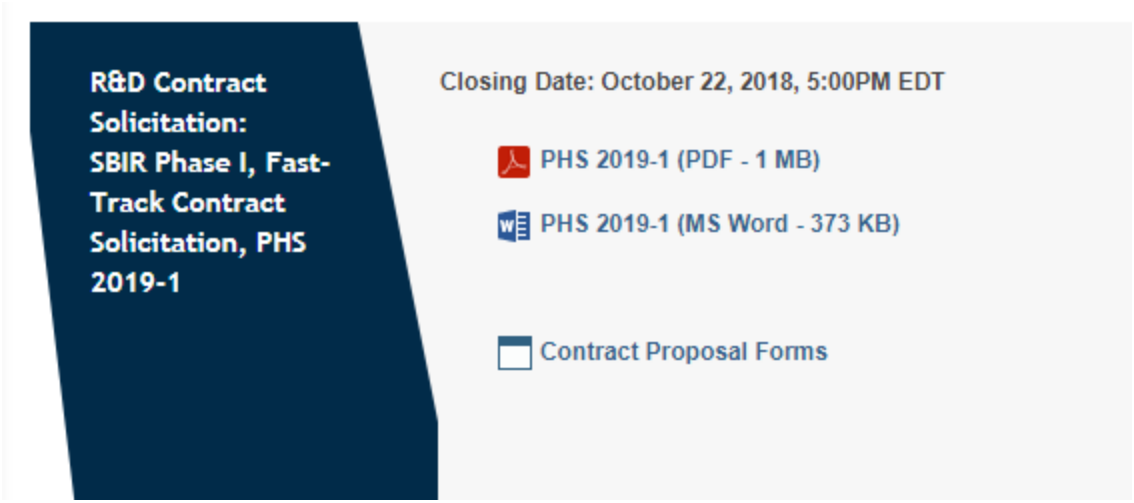
Keyword Search the Solicitation
Ctrl + F

Contracts

SBIR Contract Solicitation (NIH, CDC) - CLOSED

Closing Date: October 22, 2018 5:00PM EDT

Program Solicitation PHS 2019-1 (SBIR Only)



NIH Guide Notice: **NOT-OD-18-209**

NIH Guide for Grants and Contracts

Release: Weekly receipt dates specified in each FOA

Clinical Trials Changes

Determine if Your Study is an NIH-defined Clinical Trial

Does your study…

1. Involve one or more **human participants**?
2. **Prospectively assign** human participant(s) to intervention(s)?
3. Intend to **evaluate the effect of an intervention** on human participants
4. Have a **health-related biomedical or behavioral outcome?**

If "yes" to ALL of these questions, your study is considered a clinical trial

Clinical Trial Interactive Decision Tree: https://grants.nih.gov/ct-decision/index.htm

Clinical Trials Changes

Public Website on Clinical Trial Requirements

National Institutes of Health
Office of Extramural Research

Grants & Funding
NIH's Central Resource for Grants and Funding Information

HOME | ABOUT GRANTS | FUNDING | POLICY & COMPLIANCE | NE

Home » Policy & Compliance » Clinical Trial Requirements for Grants and Contracts

Policy & Compliance

- NIH Grants Policy Statement
- Notices of Policy Changes
- Compliance & Oversight

Select Policy Topics

- Animal Welfare
- Application Submission Policies
- Clinical Trial Requirements
  - Clinical Trial Definition
  - Why the Changes
  - Good Clinical Practice
  - Specific Funding Opportunities
  - New Form
  - Single IRB Policy
  - Protocol Template
  - Registration and Reporting

Clinical Trial Requirements for Grants and Contracts

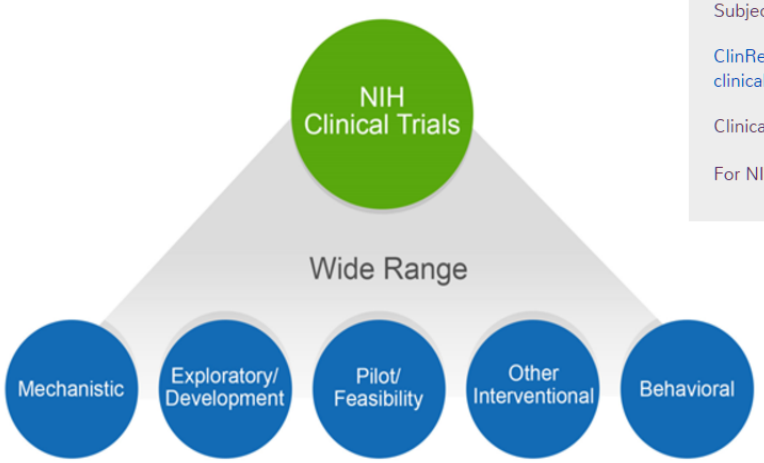
NIH is launching a series of initiatives that are rolling out in 2017-2018 to enhance the accountability and transparency of clinical research. These initiatives target key points along the whole clinical trial lifecycle from concept to results reporting. Learn more about these changes and how they will affect your research.

NIH Definition of a Clinical Trial

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. Learn more

Your human subjects study may meet the NIH definition of a clinical trial.

FIND OUT HERE



Relate
FAQs
Training
Research Subjects
ClinRegs clinical tri
Clinicaltri
For NIH

https://grants.nih.gov/policy/clinical-trials.htm

Electronic Submission

SBIR/STTR grant applications **and** SBIR contract proposals must be submitted **electronically**.

Registrations are required!!!

- DUNS Number (Company)
- System for Award Management (SAM)
- Grants.gov (Company)
- eRA Commons (Company and all PD/PIs)
- SBA Company Registry at SBIR.gov

- Helpful NIH Grants Registration Infographic
- For contracts, submit proposals with electronic Contract Proposal Submission (eCPS) website

NIH Small Business Innovation Research (SBIR)
Small Business Technology Transfer (STTR)

Timeline: New Applications

Due Date	Scientific Review	Council Review	Award Date *(earliest)*
April 5th	**May/June**	**Aug/Sept**	**October**
Sept 5th	**Oct/Nov**	**Jan/Feb**	**March**
Jan. 5th	**Feb/Mar**	**May/June**	**July**

Review Criteria

Overall Impact Score:

Scored Review Criteria (score 1-9)

- Significance (Real Problem/Commercial Potential)
- Investigators (PI and team)
- Innovation (New or Improved?)
- Approach (Research Design, Feasible)
- Environment (Facilities/Resources)

Additional Review Criteria (not scored individually)

- Protection of Human Subjects
- Inclusion of Women, Minorities & Children
- Vertebrate Animals
- Biohazards

Efforts in Diversity

Administrative Supplements to Promote Diversity in Research and Development Small Businesses-SBIR/STTR

NIH will now offer funding for SBIR/STTR awardees to recruit and compensate **students**, **postdoctorates**, and **eligible investigators from underrepresented groups** to participate in SBIR research projects.

Institutes/Centers Currently Participating

- National Cancer Institute (NCI)
- National Eye Institute (NEI)
- National Human Genome Research Institute (NHGRI)
- National Institute on Aging (NIA)
- National Institute on Alcohol Abuse and Alcoholism (NIAAA)
- National Institute of Allergy and Infectious Diseases (NIAID)
- National Institute of Biomedical Imaging and Bioengineering (NIBIB)
- National Institute of Dental and Craniofacial Research (NIDCR)
- National Institute on Drug Abuse (NIDA)
- National Institute of General Medical Sciences (NIGMS)
- National Institute of Neurological Disorders and Stroke (NINDS)
- National Institute of Nursing Research (NINR)
- National Institute on Minority Health and Health Disparities (NIMHD)
- National Center for Complementary and Integrative Health (NCCIH)
- National Center for Advancing Translational Sciences (NCATS)
- National Heart, Lung, and Blood Institute (NHLBI)

https://grants.nih.gov/grants/guide/pa-files/PA-18-837.html

When is SBIR/STTR appropriate?

Lift Labs

- Develops new technologies to provide proactive care for people with essential tremor and Parkinson's Disease
- Acquired by Google in September 2014

Anupam Pathak, Ph.D.
Founder & CEO
NINDS SBIR Awardee

http://www.liftlabsdesign.com/

continued . . .

SenesTech

- Limits rodent fertility in a non-lethal and environmentally-friendly way
- Works with NYC Subway System, and Chicago Transit Authority

Loretta Mayer, Ph.D.
Founder & CSO
NIEHS SBIR Awardee

SenesTech

http://senestech.com/

Be Prepared to Resubmit!

REESSI
RESEARCH, EVALUATION & SOCIAL SOLUTIONS, INC.
INFORMATION...KNOWLEDGE...ACTION...POWER

"[SBIR] has been a long, trying, but worthwhile journey...from multiple submissions that were not discussed...to applications that scored below the funding levels...to concurrent applications (one Phase II and a Phase I) emerging from the rigorous peer review process with impact scores in the "Excellent" range."

Laverne Morrow Carter, Ph.D.

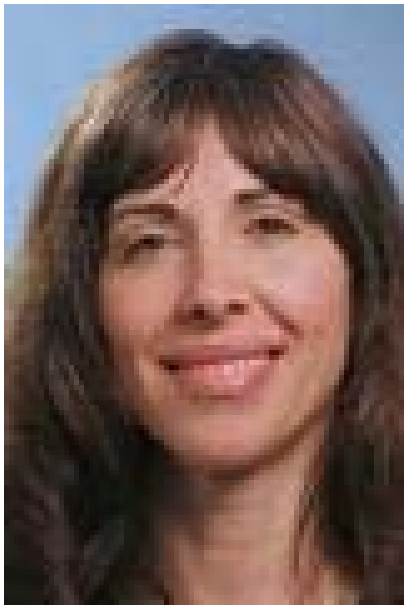
Founder & President, REESSI
NIMHD SBIR Awardee

http://www.reessi.com

continued . . .

irisEd®

"As a native Spanish-speaking curriculum designer with a background in literary and performing arts, I work as a principal investigator on a number of NIH-funded projects. The SBIR and STTR programs allow me to translate evidence-based practices into web-based multimedia programs that offer skill-building tools for improving health and educational outcomes among Latino audiences."

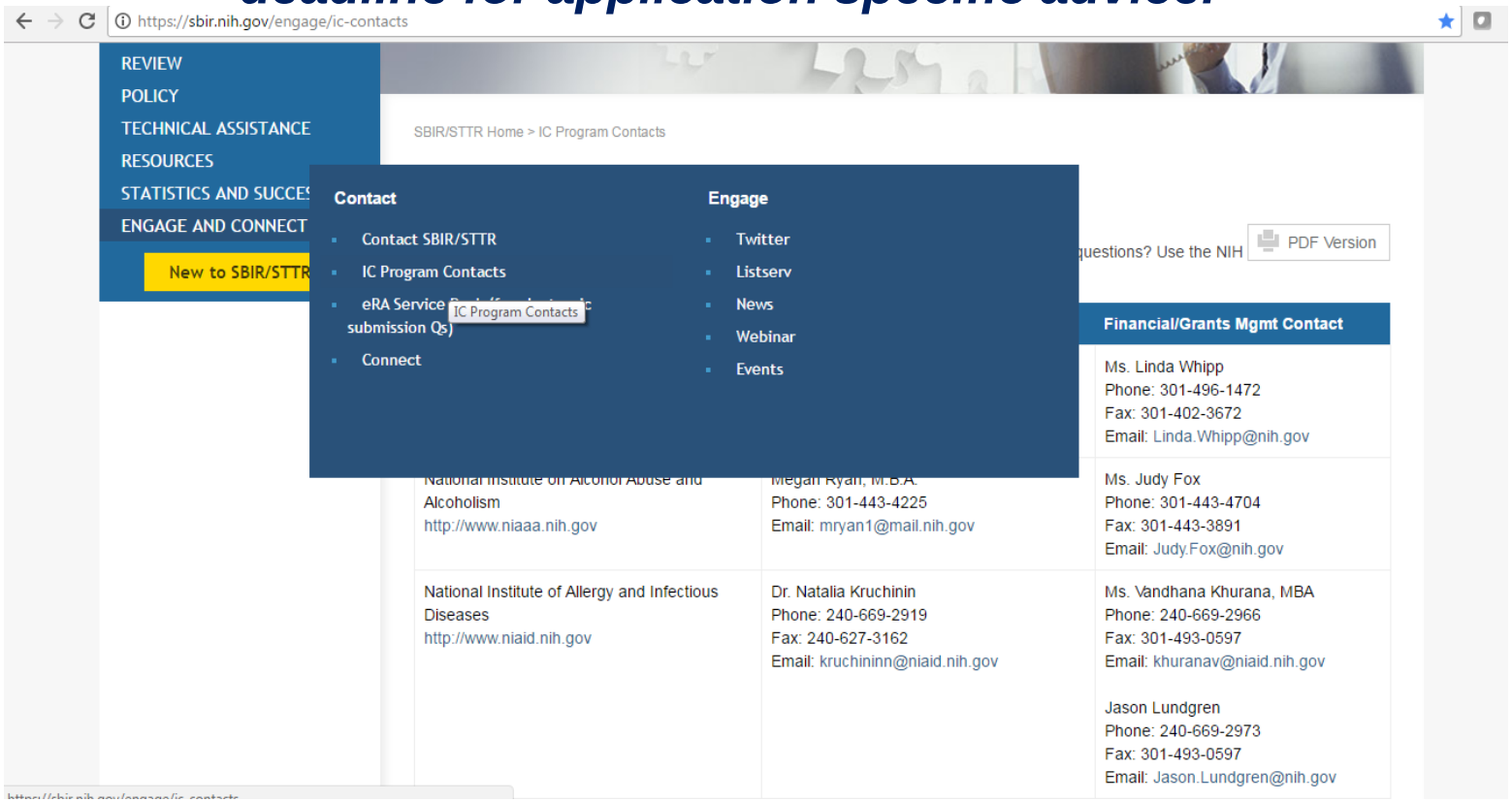


Jessie Marquez
Instructional Designer at
IRIS Educational Media

http://www.irised.com/

Most Important Piece of Advice

"Talk to a HHS Program Officer at least 6-8 weeks before a deadline for application specific advice."



Click here for the list of HHS SBIR Program Managers

Not sure who to contact? Email sbir@od.nih.gov

NIH Small Business Innovation Research (SBIR)
Small Business Technology Transfer (STTR)

HAMPTON UNIVERSITY

SAVE THE DATE!

21st Annual HHS SBIR/STTR Conference

October 28 – October 30, 2019
Virginia Beach, VA

Stay connected for updates!
@NIHsbir | https://sbir.nih.gov/

More Information

Get Connected!

- Subscribe to the SBIR/STTR Listserv:
  - Email LISTSERV@LIST.NIH.GOV with the following text in the message body: **subscribe SBIR-STTR your name**
- NIH Guide for Grants and Contracts (weekly notification)
- Follow us on Twitter: @NIHsbir
- Read our NIH SBIR/STTR Success Stories
- Connect with Us
- Email: sbir@od.nih.gov

For More Information

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