

NIH SBIR Contracts Funding Webinar

September 18, 2014 12:30-2:00 pm ET

For audio, dial in: 240.276.6338

Meeting ID: 739 400 581

For Technical Support, call **866-229-3239** and choose **option 1**



Welcome
Christie Canaria

Overview of the NIH SBIR/STTR Programs
Jennifer Shieh

*The Contracts Process at NIH:
How are SBIR Contracts Different from Grants?*
Christie Canaria

FY2014 Contract Funding Opportunities at NIH
Christie Canaria

Q&A

Closing Remarks

Contract Topic Details:

<http://sbir.cancer.gov/funding/contracts>

<http://grants.nih.gov/grants/forms.htm#contracts>

Proposal Deadline:

November 5, 2014 at 4:30PM Eastern Time

Send Your Questions

- Please submit your questions at any time via the Q&A box on the right-hand side of your screen.
- If you do not see the Q&A box, you can expand it by hovering over the **green bar** at the top of your screen and clicking the Q&A button.



Welcome
Christie Canaria

Overview of the NIH SBIR/STTR Programs
Jennifer Shieh

*The Contracts Process at NIH:
How are SBIR Contracts Different from Grants?*
Christie Canaria

FY2014 Contract Funding Opportunities at NIH
Christie Canaria

Q&A

Closing Remarks

Overview of the NIH SBIR/STTR Programs



Jennifer C. Shieh, PhD

Small Business Coordinator

Office of Translational Alliances & Coordination
National Heart, Lung, and Blood Institute



@NHLBI_SBIR
@NCIsbir
@NIHsbir



National Institutes of Health
Turning Discovery Into Health



National Institutes of Health
Turning Discovery Into Health

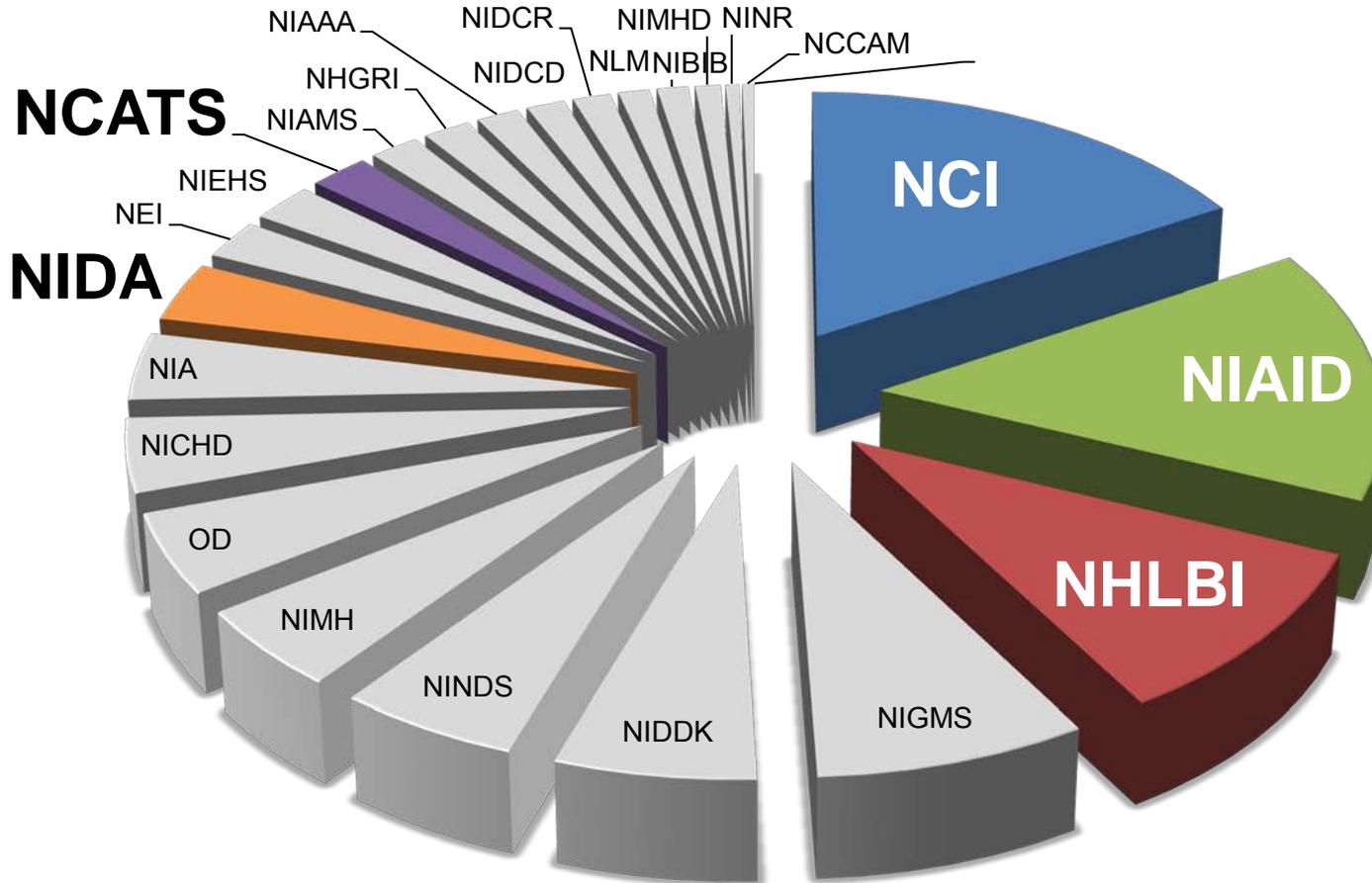
\$30 Billion

Basic and applied biomedical science

\$758 Million

Non-dilutive funding just for small businesses

NIH FY2014 Small Business Funding



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

	SBIR	STTR
Program Size	2.8% set aside	0.4% set aside
Partnering Requirement	Permits partnering	Requires a non-profit research institution partner
Principal Investigator	Primary employment (>50%) must be with the small business	PI may be employed by either the research institution partner or small business
Work Requirement	Guidelines: May outsource up to 33% (Phase I), 50% (Phase II)	Minimum Work Requirements: 40% Small Business 30% Research Institution Partner

Grant Funding Opportunities (SBIR/STTR)

Investigator-Initiated Due April 5, August 5, December 5

- Omnibus Solicitations (Phase I, Phase II, FastTrack)
 - [PA-14-071](#) (SBIR) and [PA-14-072](#) (STTR)
- Direct to Phase II Solicitation
 - [PAR-14-088](#) (SBIR only)

Targeted Release dates, topics, and receipt dates vary

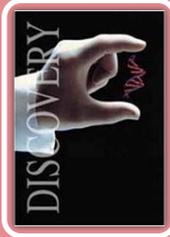
- <http://sbir.nih.gov/funding/individual-announcements>
- Check the NIH Guide: <http://grants.nih.gov/grants/guide>
- Check your relevant IC's website
- Sign up for your relevant IC's listserv

Contract Solicitation for NIH & CDC (SBIR Only)

- Only 1 per year
- Targeted, milestone-driven topics
- Different application & award process from grants
- Questions must be submitted by **September 19**
- **Proposals due November 5, 2014 at 4:30 pm ET**

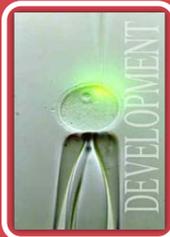
<http://1.usa.gov/1l98jHM>

Phased Development



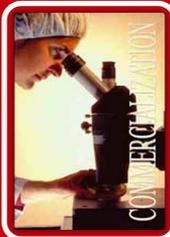
PHASE I

- Feasibility Study
- \$150K for 6 months



PHASE II

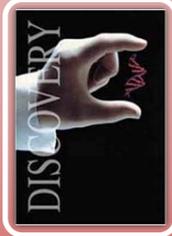
- Full Research/R&D
- \$1M for 2 years
- Commercialization plan required



PHASE III

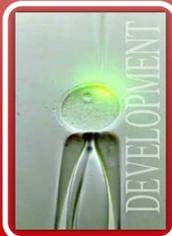
- Commercialization Stage
- Use of non-SBIR/STTR Funds
- Not generally funded by NIH

Fast Track (NIH Only)



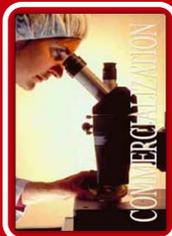
PHASE I

- Feasibility Study
- \$150K for 6 months



PHASE II

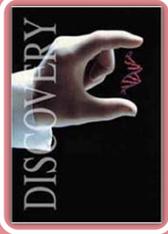
- Full Research/R&D
- \$1M for 2 years
- Commercialization plan required



PHASE III

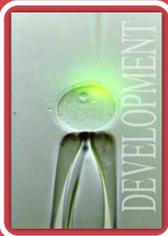
- Commercialization Stage
- Use of non-SBIR/STTR Funds
- Not generally funded by NIH

Direct to Phase II (NIH Only)



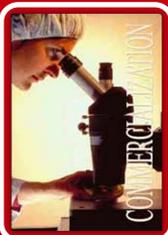
PHASE I Equivalence

- Proof-of-Concept data
- No SBIR/STTR money



PHASE II

- Full Research/R&D
- \$1M for 2 years
- Commercialization plan required



PHASE III

- Commercialization Stage
- Use of non-SBIR/STTR Funds
- Not generally funded by NIH

Visit the New sbir.nih.gov

The screenshot shows the homepage of the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs. At the top, there is a navigation bar with links for OER HOME, ABOUT GRANTS, FUNDING, FORMS & DEADLINES, GRANTS POLICY, ERA, NEWS & EVENTS, and ABOUT OER. Below this is a search bar and a printer-friendly option. The main content area features a large blue banner with the text "Electronic Submission Process" and a sub-headline "Understand the electronic registration process so you can successfully submit an application". To the left of this banner is a vertical menu with links for SBIR/STTR HOME, ABOUT, FUNDING, APPLY, REVIEW, POLICY, TECHNICAL ASSISTANCE, RESOURCES, STATISTICS AND SUCCESSES, and ENGAGE AND CONNECT. Below the banner is a row of six icons representing different program areas: TECHNICAL ASSISTANCE PROGRAMS, FUNDING, ELECTRONIC SUBMISSION PROCESS (highlighted in black), SUCCESS STORIES, CONTACT US, and ENGAGE AND CONNECT. At the bottom, there is a section titled "What are SBIR and STTR Programs?" and a "NEWS" section with a link to "The NIH/CDC SBIR Contract Solicitation PHS 2015-1 Has".

<http://sbir.nih.gov>

16th Annual NIH SBIR/STTR Conference

LAND OF ACHIEVEMENT

Extending the Reach of Science with the SBIR/STTR Programs

Albuquerque, New Mexico

October 21-23, 2014

16th Annual NIH SBIR/STTR Conference

October 21 – 23, 2014

Albuquerque, New Mexico

Hosted by University of New Mexico Health Sciences Center

sbir2014.com



National Institutes of Health
Turning Discovery Into Health

Welcome
Christie Canaria

Overview of the NIH SBIR/STTR Programs
Jennifer Shieh

***The Contracts Process at NIH:
How are SBIR Contracts Different from Grants?***
Christie Canaria

FY2014 Contract Funding Opportunities at NIH
Christie Canaria

Q&A

Closing Remarks

The Contracts Process at NIH: How are SBIR Contracts Different from Grants?

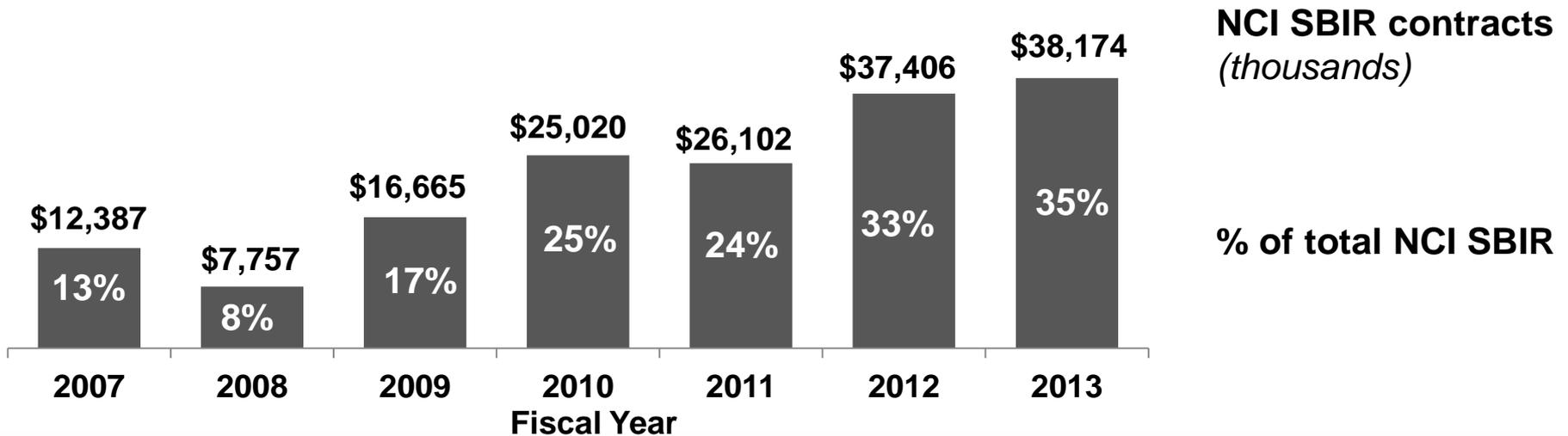
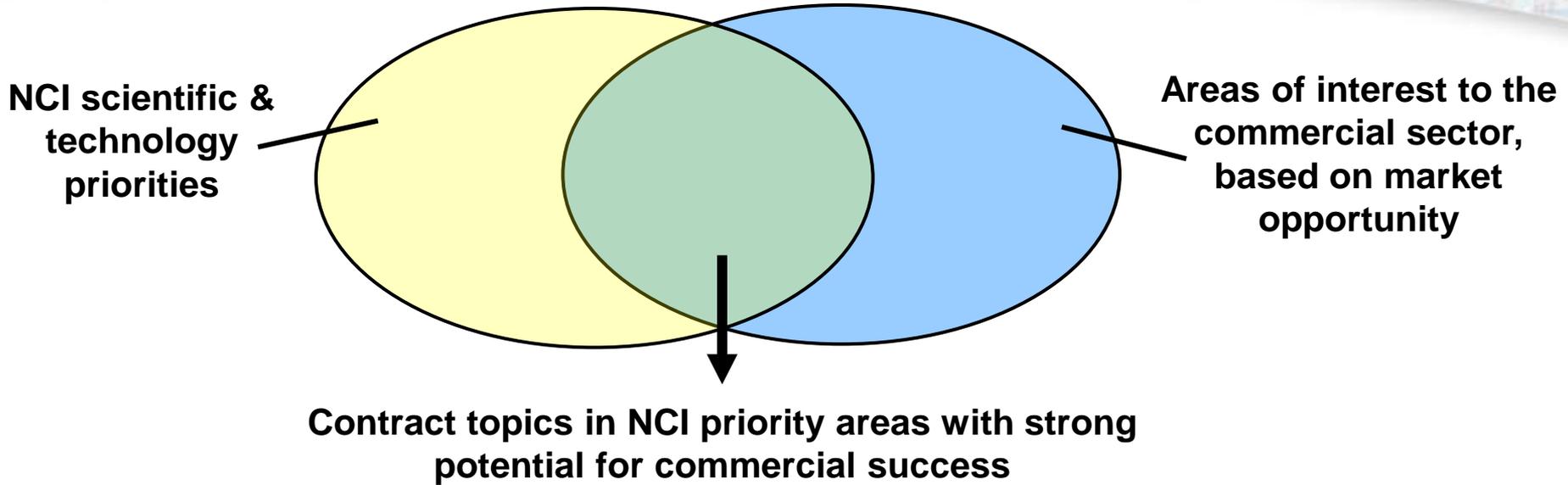
<http://sbir.cancer.gov/funding/contracts>



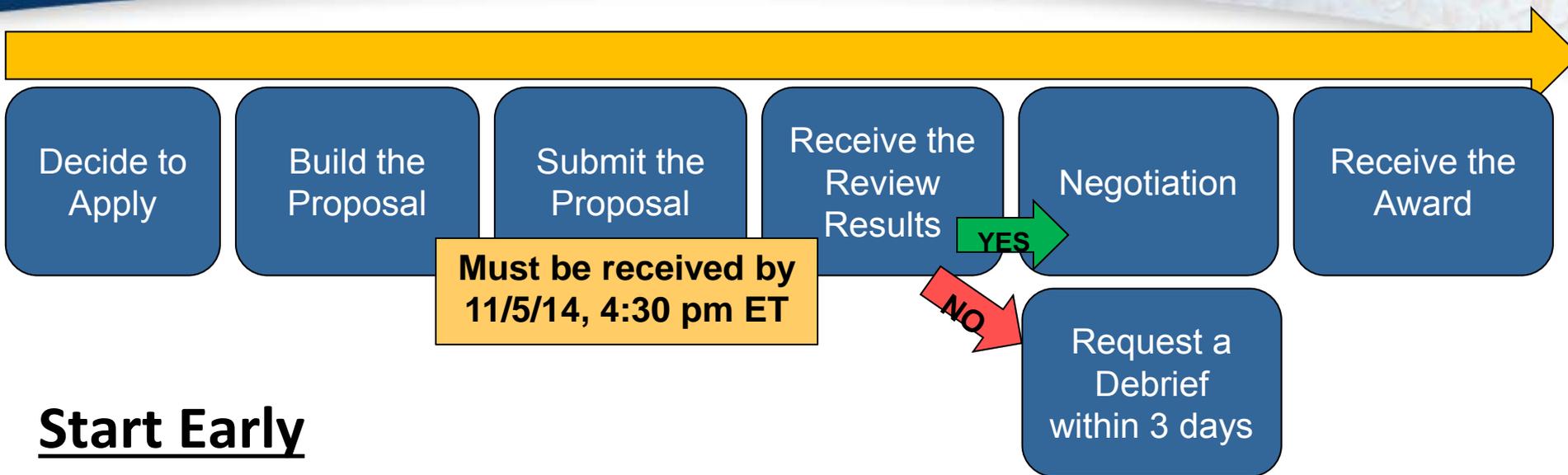
Christie Canaria, PhD
NCI SBIR Development Center



NCI SBIR Targeted Contract Solicitations



Understand the Proposal Process



Start Early

- Strong proposals take time to develop
- **Take care of the administrative registrations**
 - SAM.gov, SBA Company Registry
- Carefully Read the Solicitation
- Need time to fill the gaps
 - Assemble a strong scientific team
 - Get access to equipment and other resources
 - Get letters of support

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS), THE
NATIONAL INSTITUTES OF HEALTH (NIH) AND THE CENTERS FOR
DISEASE CONTROL AND PREVENTION (CDC) SMALL BUSINESS
INNOVATIVE RESEARCH (SBIR) PROGRAM**

PROGRAM SOLICITATION PHS 2015-1 - Amendment 1

Closing Date: November 5, 2014, 4:30PM Eastern Time

Participating HHS Components:

- The National Institutes of Health (NIH)
- The Centers for Disease Control and Prevention (CDC)

IMPORTANT

Deadline for Receipt: Proposals must be submitted by November 5, 2014, 4:30PM Eastern Time

Solicitation Changes:

As a result of program reauthorization, the solicitation has been EXTENSIVELY rewritten and follows the changes of the SBIR/STTR reauthorization. Please read the entire solicitation carefully prior to submitting your proposal.

Please go to <http://www.sbir.gov/about/sbir-policy-directive> to read the SBIR/STTR Policy Directive issued by the Small Business Administration.

Contact the contracting officer

- National Cancer Institute (NCI)
Ms. Victoria Cunningham
Email: ncioasbir@mail.nih.gov
- National Center for Advancing Translational Sciences (NCATS)
Mr. Sean Dalenberg
Email: sean.dalenberg@nih.gov
- National Heart, Lung, and Blood Institute (NHLBI)
Mr. John Taylor
Email: taylorjc@nhlbi.nih.gov
- National Institute of Allergy and Infectious Diseases (NIAID)
Eileen Webster-Cissel
Email: webstere@niaid.nih.gov
- National Institute on Drug Abuse (NIDA)
Mr. Brian O’Laughlin
Email: bo50d@nih.gov
- Centers For Disease Control And Prevention (CDC)
Sean David Griffiths, M.P.H.
Email: SGriffiths@cdc.gov

Questions must be
received by
September 19.

SBIR Contracts vs. Grants

	SBIR Grants	SBIR Contracts
Scope of the proposal	Investigator-defined within the mission of NIH	Defined (narrowly) by the NIH
Questions during solicitation period?	May speak with any Program Officer	MUST contact the contracting officer [See Solicitation]
Receipt Dates	3 times/year for Omnibus	Only ONCE per year
Reporting	One final report (Phase I); Annual reports (Phase II)	Kickoff presentation, quarterly progress reports, final report, commercialization plan
Set-aside funds for particular areas?	No	Yes
Program Staff Involvement	Low	High

SBIR Contracts vs. Grants

	SBIR Grants	SBIR Contracts
<i>Peer Review Locus</i>	NIH Center for Scientific Review (CSR)	At each IC
<i>Review Sections</i>	Sections review applications for different programs in similar topic areas	Specific sections for each single topic
<i>Basis for Award</i>	Peer review score Program assessment	Peer review score Program relevance & balance Negotiation of technical deliverables Budget

- I am working on a topic that fits well with what is being requested in the contract topic → **CONTRACT**
- Differences
 - Review sections are only for the specific topic under consideration
 - Because it is more specific, there may be less competition
 - Fast-Track – possibility of splitting up Ph I and Ph II in a contract
- You **cannot** submit both a contract proposal and a grant application for *essentially the same project*. If the contract proposal has been evaluated, you can submit a grant application after it is no longer being considered for award.

Phase I Technical Evaluation Criteria	Weight
1. The soundness and technical merit of the proposed approach based on: a. Clear measurable goals (milestones) that have a reasonable chance of meeting the topic objective in Phase I; b. The approach is innovative and not routine, c. Offeror's ability to implement technical approach	40%
2. The qualifications of the proposed PDs/PIs	20%
3. The potential of the proposed research for technological innovation .	15%
4. The potential of the proposed research for commercial application . The commercial potential of a proposal will be assessed using the following criteria: a. Whether the outcome of the proposed research activity will likely lead to a marketable product or process. b. The offeror's discussion of the potential barriers to entry and the competitive market landscape as well as method to overcome.	15%
5. The adequacy and suitability of the facilities and research environment	10%

See pg. 28 of PHS2015-1 for more details about the evaluation process

For Fast-Track or Direct to Phase II applications: Phase II Technical Evaluation Criteria	Weight
1. The soundness and technical merit of the proposed approach based on: <ul style="list-style-type: none">a. Clear measureable goals (milestones) that have a reasonable chance of meeting the topic objective in Phase II;b. The approach is innovative and not routine,c. Offeror's ability to implement technical approach	30%
2. The potential of the proposed research for commercial application , as documented in the Commercialization Plan and evidenced by: <ul style="list-style-type: none">a. Offeror's record of successfully commercializing prior SBIR/STTR or other research projectsb. Commitments of additional investment during Ph I & Ph III from private sector or other non-SBIR funding sourcesc. Other indicators of commercial potential for the proposed research	30%
3. The qualifications of the proposed PDs/PIs , supporting staff and consultants.	25%
4. The adequacy and suitability of the facilities and research environment	15%

See pg. 28 of PHS2015-1 for more details about the evaluation process

FY 2015 NIH and CDC SBIR Contract Solicitation

<http://sbir.cancer.gov/funding/contracts>



- **PHS-2015-1 “HHS, NIH, and CDC SBIR Program Solicitation”**
- **ONE application receipt date per year:**
 - Published August 15, 2014
- **Questions must be received by **September 19****

Receipt Date: November 5, 2014, 4:30 PM ET

- **RFP can be found at:**
 - <http://grants.nih.gov/grants/funding/SBIRContract/PHS2015-1.pdf>
- **Amendment 1 published 9/11/14:**
 - <http://sbir.nih.gov/sites/default/files/PHS2015-1-AmendmentOne.pdf>

<http://sbir.cancer.gov/funding/contracts>

Advancing Cancer Research

- 334 Vacutubes to Preserve the Viability of Circulating Tumor Cells
- 335 Development of Advanced Culture Systems for Expansion of Cancer Stem Cells

Therapy & Diagnosis

- 336 Development of Novel Therapeutic Agents That Target Cancer Stem Cells
- 337 Cell-Free Nucleic Acid-Based Assay Development for Cancer Diagnosis
- 338 Predictive Biomarkers of Adverse Reactions to Radiation Treatment
- 339 Systemic Targeted Radionuclide Therapy For Cancer Treatment

Health IT

- 340 Validation of Mobile Technologies for Clinical Assessment, Monitoring, and Intervention

NHLBI Contract Topics for FY2015

- 087 Transcatheter Cerclage Mitral Annuloplasty (SBIR-TT)
- 088 Closure Devices for Transcaval Access to the Abdominal Aorta
- 089 In-bore Defibrillation for Invasive MRI Cardiology Procedures
- 090 Devices to Close Ductus Arteriosus in Premature Infants
- 091 Therapeutic Delivery of ADP-ribosylarginine Hydrolase
- 092 Selective Silencing of Stat3 Signaling to Treat Relapsed Disease after Transplantation
- 093 Cellular Immunotherapy after Stem Cell Transplantation

2015 NCATS Contract Funding Opportunities

- **NCATS 009***: Exploring the Potential of CRISPR/CAS Genome-editing Tools
- **NCATS 010***: Assay Development for High-Throughput Screening of Chemicals of Toxicological Concern
- **NCATS 011***: Simple and Robust Reaction Progress Analyzer
- **NCATS 012***: Online Real Time Metals Analysis at Low ppm

*Topic numbers updated in Amendment 1 issued 9/11/14

NIAID Contract Topics for FY15

- **029 Development of Novel Influenza Antivirals**
- **030 Methods of Clinical Sample Preparation for Rapid Detection of Bacterial Pathogens**
- **031 Inhaled Delivery of Clofazimine (CFZ) – An Important Anti-tuberculosis Drug**
- **032* Simple, Inexpensive Unit for Removing Cells from Small Amounts of Blood in Resource-Limited Settings**

All questions related to NIAID contracts, please contact:

Eileen Webster-Cissel
Chief, AIDS Research Contracts Branch
Office of Acquisitions, DEA
webstere@niaid.nih.gov

*Topic number updated in Amendment 1 issued 9/11/14

- 157 Mobile Technologies Extending Reach of Primary Care for Substance-Use-Disorders

CENTER FOR GLOBAL HEALTH (CGH)

- 007 Diagnostic Tools to Support the Elimination and Control of Neglected Tropical Diseases

NATIONAL CENTER FOR CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION (NCCDPHP)

- 037 Optical Character Recognition Software for Scanning Nutrition Facts Panel

NATIONAL CENTER FOR EMERGING ZONOTIC AND INFECTIOUS DISEASES (NCEZID)

- 011 Development of Nanoparticle Dengue Diagnostic Tests

NATIONAL CENTER FOR HIV/AIDS, VIRAL HEPATITIS, STD, AND TB PREVENTION (NCHHSTP)

- 043 Yeast-derived Candidate of Hepatitis E Virus Vaccine
- 044* Multiplex Assay for Simultaneous Detection of Hepatitis and Other Viruses
- 045* Improved Antibody Preparation for Post-Exposure Prophylaxis Against Hepatitis A

NATIONAL CENTER FOR IMMUNIZATION AND RESPIRATORY DISEASES (NCIRD)

- 029* Thermostable Dry Vaccine Formulation for Microneedle Administration
- 030* Thermostable Oral Vaccines to Combat Enteric Diseases

**Topic numbers updated in Amendment 1 issued 9/11/14*

Contact the contracting officer

- National Cancer Institute (NCI)
Ms. Victoria Cunningham
Email: ncioasbir@mail.nih.gov
- National Center for Advancing Translational Sciences (NCATS)
Mr. Sean Dalenberg
Email: sean.dalenberg@nih.gov
- National Heart, Lung, and Blood Institute (NHLBI)
Mr. John Taylor
Email: taylorjc@nhlbi.nih.gov
- National Institute of Allergy and Infectious Diseases (NIAID)
Eileen Webster-Cissel
Email: webstere@niaid.nih.gov
- National Institute on Drug Abuse (NIDA)
Mr. Brian O’Laughlin
Email: bo50d@nih.gov
- Centers For Disease Control And Prevention (CDC)
Sean David Griffiths, M.P.H.
Email: SGriffiths@cdc.gov

Questions must be
received by
September 19.

Send Your Questions

- Please submit your questions at any time via the Q&A box on the right-hand side of your screen.
- If you do not see the Q&A box, you can expand it by hovering over the **green bar** at the top of your screen and clicking the Q&A button.



THANK YOU!

Please provide your feedback:
bit.ly/NCIsbirFeedback



[@NCIsbir](https://twitter.com/NCIsbir) [@NHLBI_SBIR](https://twitter.com/NHLBI_SBIR) [@NIHsbir](https://twitter.com/NIHsbir)

NCI SBIR Development Center

NCIsbir@mail.nih.gov

Phone: 240.276.5300

<http://sbir.cancer.gov>

Sign up for updates!

On LinkedIn

<http://www.linkedin.com/company/nci-sbir-development-center>

NHLBI Office of Translational Alliances & Coordination

nhlbi_sbir@mail.nih.gov

Phone: 301.496.2149

Sign up for updates!

<http://bit.ly/NHLBI-SBIR-list>

<http://www.nhlbi.nih.gov/funding/sbir/index.htm>