



National Institutes of Health
Office of Extramural Research



Overview of the NIH SBIR/STTR Program

**Meet the Experts in NIH Peer Review
for Small Business Grant Applicants**

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Office of Extramural Research, NIH





2.9%

SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM

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

0.4%

SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAM

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





- Stimulate technological innovation
- Use small business to meet Federal R&D needs
- Foster and encourage participation by minorities and disadvantaged persons in technological innovation
- Increase private-sector commercialization innovations derived from Federal R&D

Small Business Innovation Development Act of 1982

P.L. 112-81 Re-Authorizes program through FY2017





- Stimulate and foster scientific and technological innovation through **cooperative research** and development carried out **between small business concerns** and **research institutions**
- Foster **technology transfer** between small business concerns and research institutions

Small Business Research and Development Enhancement Act of 1992

P.L. 112-81 Re-Authorizes program through FY2017





Overall Impact Score

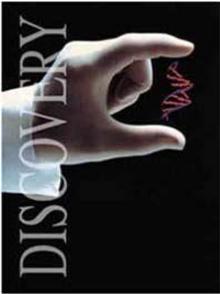
Scored Review Criteria (score 1-9)

- 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)

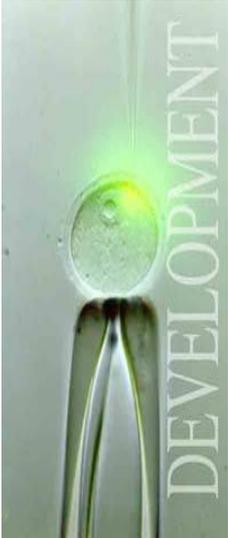
- Protection of Human Subjects
- Inclusion of Women, Minorities & Children
- Vertebrate Animals
- Biohazards





PHASE I Feasibility Study

- Budget Guide: \$150K (SBIR); \$150K (STTR) Total Costs
- Project Period: 6 months (SBIR); 1 year (STTR)

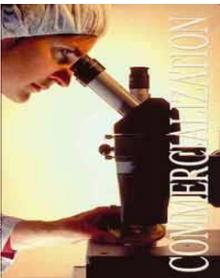


PHASE II Full Research/R&D

- \$1M (STTR), \$1M (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; 3 years



PHASE III Commercialization Stage

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



- Capital is in the form of grants and contracts
- Strategic Investment in Innovation
- Non-diluted funding:
 - No repayment
 - No debt service
 - No equity forfeiture
 - No IP forfeiture





SBIR Eligibility Criteria

From 1/28/2013 FOAs going forward



Organized as **for-profit** U.S. business



Small: **500** or fewer employees, including affiliates



PD/PI's **primary employment** must be with **small business concern** at time of award and for duration of project period



Greater than **50% U.S.- owned by individuals** and independently operated **or**

Greater than **50% owned and controlled by other business concern/s** that is/are greater than 50% owned and controlled by one or more **individuals** **OR**



Be a concern which is more than 50% owned by multiple venture capital operating companies, hedge funds, private equity firms, or any combination of these





Applicant is Small Business Concern



Formal Cooperative R&D Effort

Minimum 40% by small business

Minimum 30% by U.S. research institution



U.S. Research Institution

College or university; other non-profit research organization; Federal R&D center



Intellectual Property Agreement

Allocation of rights in IP and rights to carry out follow-on R&D and commercialization





- PD/PI is not required to be employed by SBC
- PD/PI at RI must establish contract between RI and SBC describing PD/PI's involvement
- PD/PI must commit a **minimum of 10% effort**
- PD/PI's "signature" on application is agreement to conforming to Solicitation requirements





- **Research Partner**

- SBIR: **Permits** partnering
33% Phase I and 50% Phase II
- STTR: **Requires** partnering with research institution.
Small business (40%) and U.S. research institution (30%)

- **Principal Investigator**

- SBIR: Primary (>50%) employment **must** be with small business concern
- STTR: PI may be employed by either research institution or small business concern

**Award is always made
to Small Business Concern**

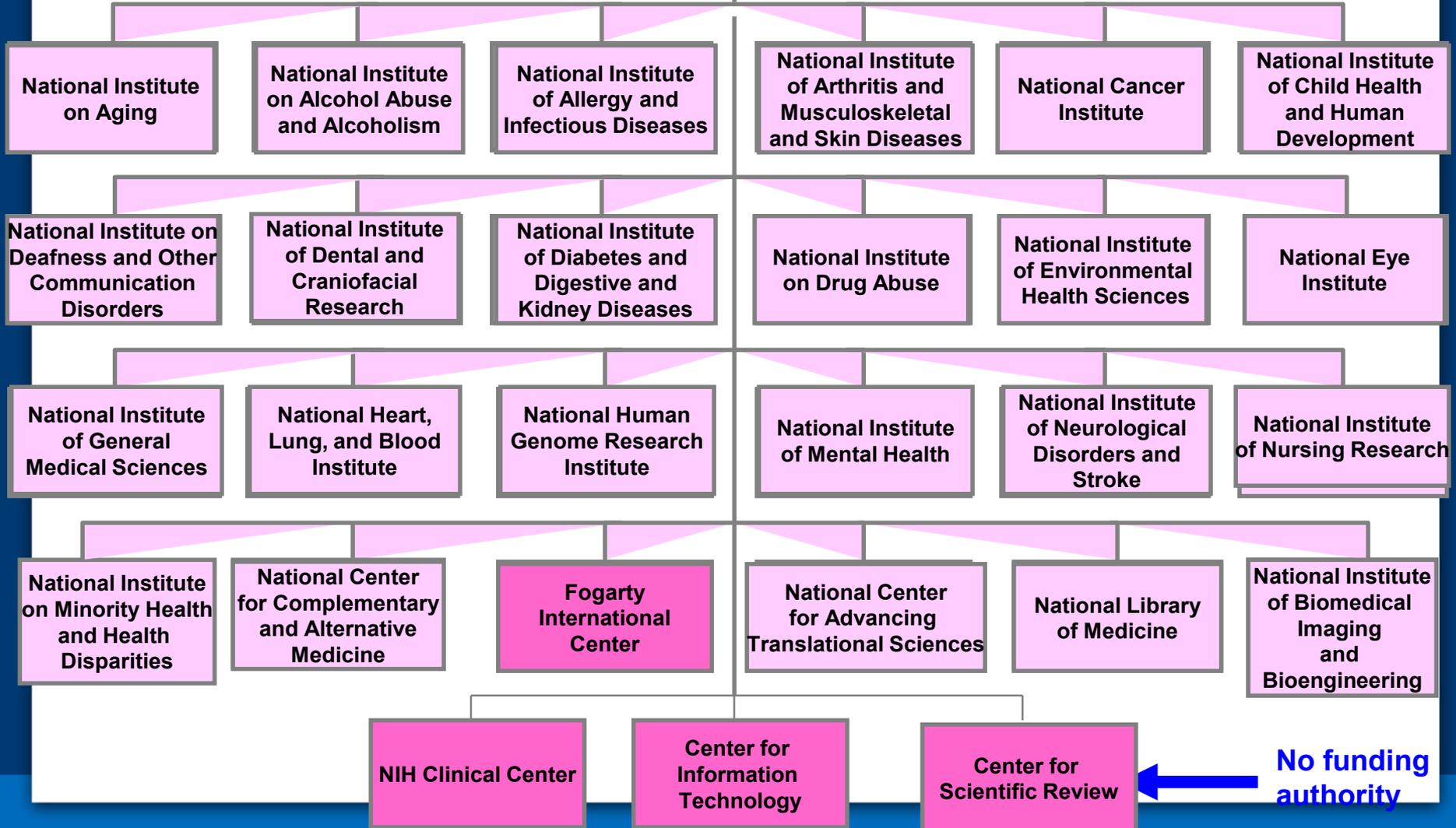




Office of Research
Infrastructure Programs

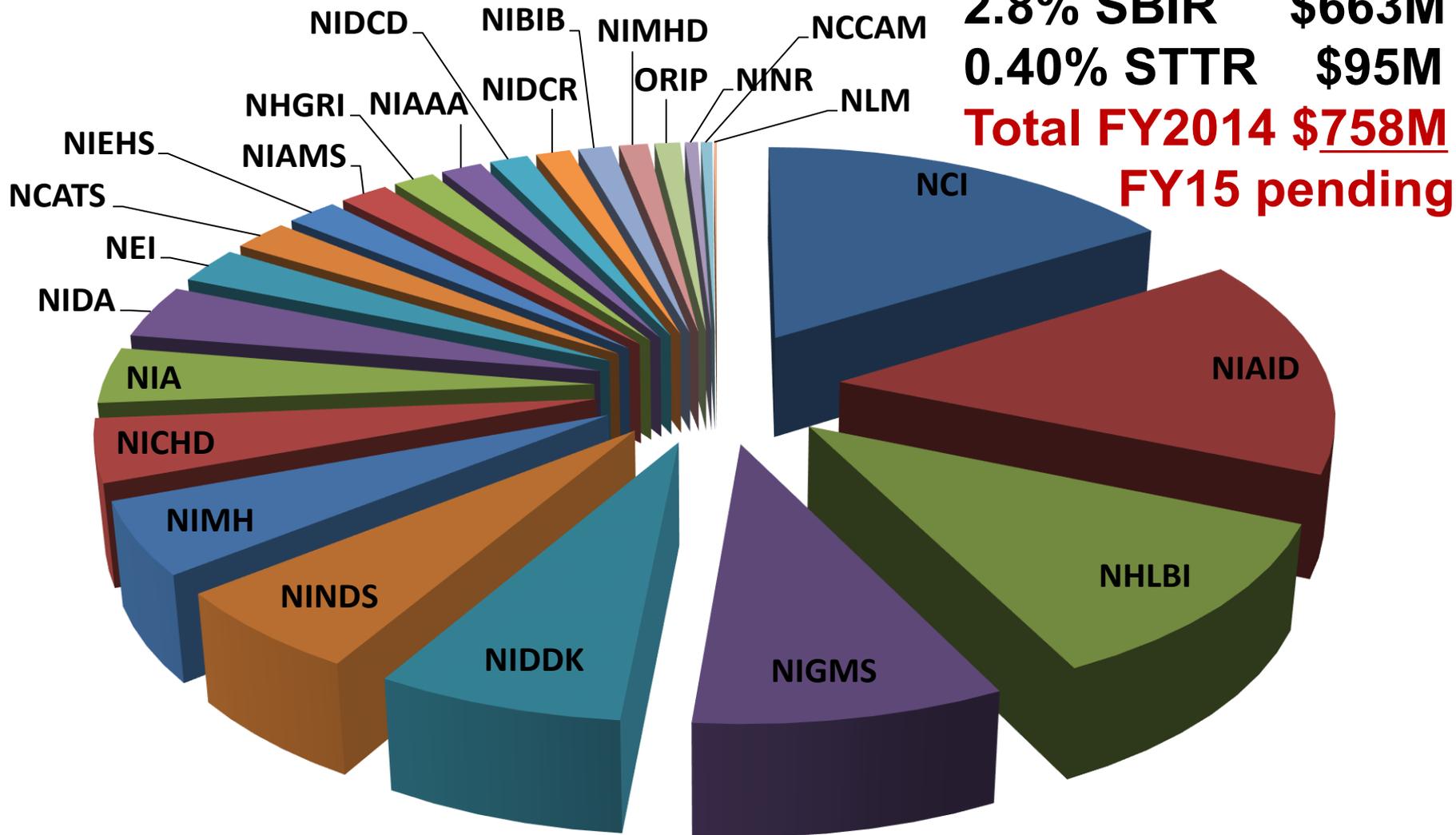
Office of the Director

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



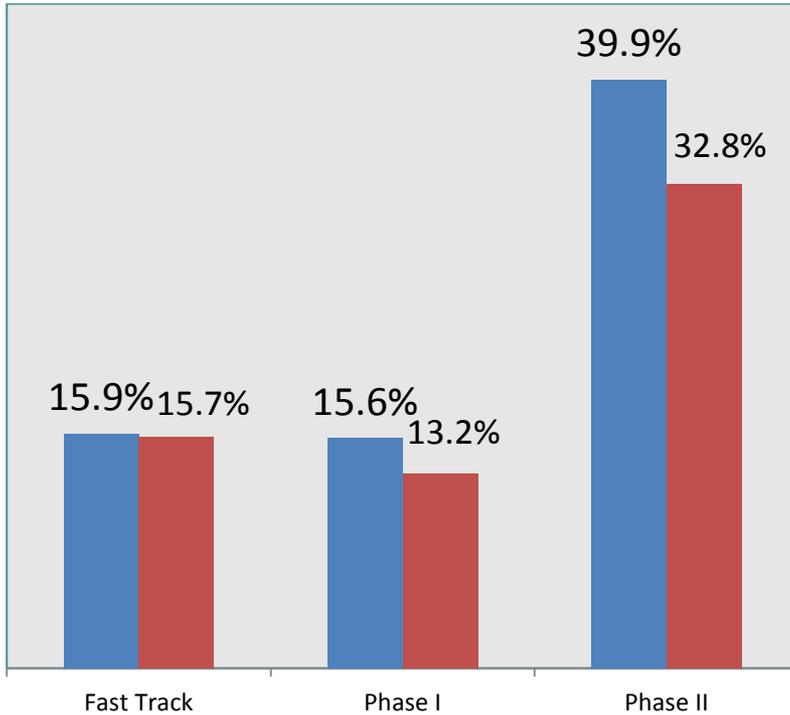
No funding authority

NIH SBIR/STTR Budget Allocations FY2014

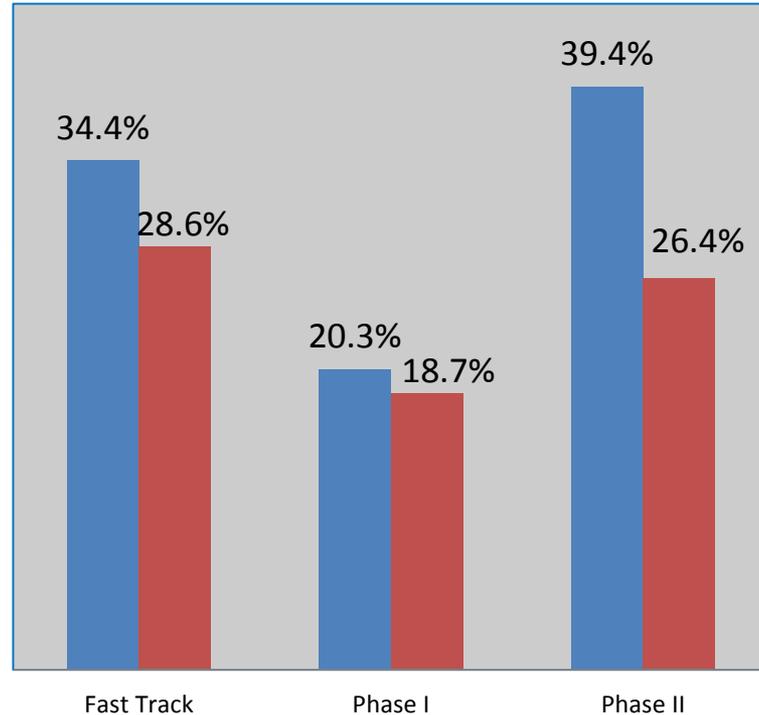




SBIR



STTR



■ 2012
■ 2013







SBIR/STTR HOME

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New to SBIR/STTR
WHERE TO START



Funding Opportunity Announcements (FOAs)

NIH's SBIR and an STTR Omnibus grant solicitations allow small businesses to submit researcher-initiated projects that are within NIH's mission. For the additional NIH SBIR/STTR FOAs, please view the Funding page.

- [SBIR Omnibus FOA \(PA-14-071\)](#)
- [STTR Omnibus FOA \(PA-14-072\)](#)



TECHNICAL ASSISTANCE PROGRAMS



FUNDING



ELECTRONIC SUBMISSION PROCESS



SUCCESS STORIES



CONTACT US



ENGAGE AND CONNECT

What are SBIR and STTR Programs?

The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs are one of the largest sources of early-stage capital for innovative small companies in the United States. These programs allow US-owned and operated small businesses to engage in federal research and development (R&D) that has a strong potential for commercialization.

In Fiscal Year 2014, NIH's SBIR and STTR programs will invest over 750 million dollars into early-stage, health and life science companies that are creating a wide range of innovative technologies that align with NIH's mission to improve health and save lives. A key objective of this work is translating promising technologies to the private sector through strategic public and private partnerships, so that life-saving innovations reach consumer markets.

We invite you to explore our website to learn more about [NIH's SBIR & STTR programs](#), or get started

NEWS

Early Bird Registration Has Been Extended until September 5th - Register Now to Save **NEW**
September 5, 2014

Now Posted: 2015 Omnibus NIH/CDC SBIR Contract Solicitation PHS 2015-1
Aug 15, 2014

One Week Left for the Early Bird Registration Discount for the NIH SBIR/STTR Conference>
Aug 15, 2014

Register Today for NIAID's Small Business SBIR/STTR





- **NIH, CDC, FDA, & ACF SBIR/STTR Grant Solicitation ****

Omnibus FOAs: **SBIR:** [PA-14-071](#) **STTR:** [PA-14-072](#)

New SBIR Direct to Phase II FOA [PAR-14-088](#)

Release: January

Standard Due Dates: April 5, Aug 5, **Dec 5**

(AIDS/AIDS-related: May 7, Sept 7, **Jan 7**)

- **SBIR Contract Solicitation (NIH, CDC)**

Release: August 15 November **5** close date

- **NIH Guide for Grants and Contracts**

Release: Weekly Receipt dates specified in each FOA

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





See <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-048.html> for details.

- 1. NIH SBIR and STTR applicants may now switch programs at Phase II or Phase IIB.**
 - a) Phase I STTR Awardees may apply for NIH SBIR or STTR Phase II.
 - b) Phase I SBIR Awardees may apply for NIH SBIR or STTR Phase II.
 - c) Phase II STTR Awardees may apply for NIH SBIR or STTR Phase IIB.
 - d) Phase II SBIR Awardees may apply for NIH SBIR or STTR Phase IIB.





- 2. NIH has issued a Pilot SBIR Direct to Phase II solicitation, [PAR-14-088](#).**
- 3. VC-backed companies (VCOC, Hedge fund, private equity firm) CAN apply to NIH SBIR FOAs (since May 2013).**
- 4. SBA Company registry at SBIR.gov required for all submissions.**





- **NIH Guide for Grants and Contracts (weekly notification)**

<http://grants.nih.gov/grants/guide/listserv.htm>

- **NIH SBIR/STTR Notification**

Send email to LISTSERV@LIST.NIH.GOV with the following text in the message body:

subscribe SBIR-STTR your name.





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- **NIH Guide for Grants and Contracts** (weekly notification)
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