NIH Small Business Grant Programs

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Disclaimer

- My opinions do not necessarily represent those of NIH or HHS.
- Based on my experience
  - Academic faculty (30 years)
  - Biotechnology start-up
  - Manager of NIH basic AIDS extramural research and small business programs
  - Organizer of NIH Bioengineering Consortium (BECON) precursor to National Institute of Biomedical Imagining and Bioengineering
  - Board of Biotechnology Industry Organization's Council of Biotechnology Centers

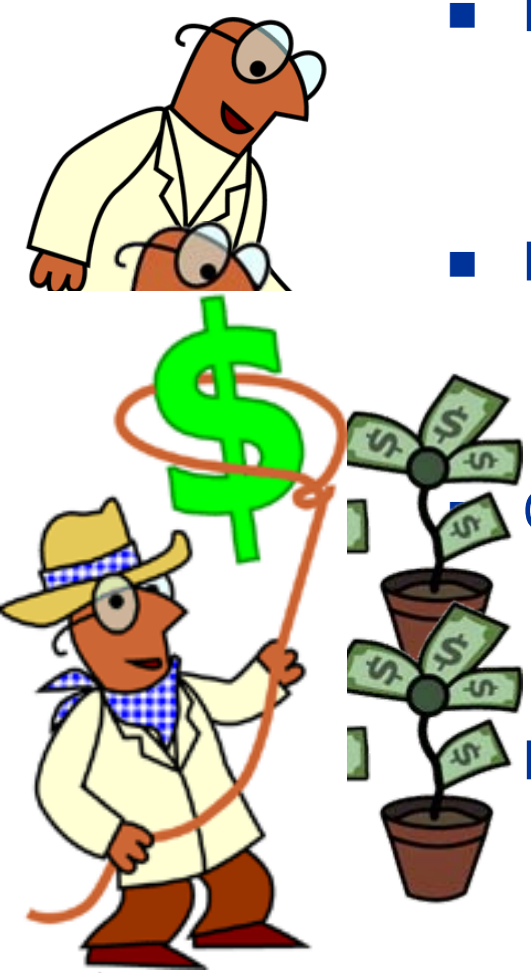
NIH Small Business Programs

- **SBIR - S**mall **B**usiness **I**nnovation **R**esearch funds support research by business.
  - First authorized in 1982, extended until 2008
  - 2.5% of all agencies extramural research budget
- **STTR - S**mall Business **T**echnology **T**ransfer **R**esearch funds support collaborative research by business and US research institutions.
  - First authorized in 1992, extended until 2009
  - 0.3% of all agencies extramural research budget
- Small Business Administration (SBA) responsible for SBIR and STTR oversight
- Small business programs serve **dual purposes**:
  - SBA – **economic development** (support small companies)
  - Agency mission (NIH) – (**translational research** to improve health)

Participating Federal Agencies

DOD	SBIR/STTR
HHS	**SBIR/STTR**
NASA	SBIR/STTR
DOE	SBIR/STTR
NSF	SBIR/STTR
DHS	SBIR
USDA	SBIR
DOC	SBIR
ED	SBIR
EPA	SBIR
DOT	SBIR

SBIR and STTR Are Three Phase Programs



- Phase I
  - Proof of feasibility
  - Funding for 1 yr, sometimes 2
  - Median NIH award $160K/yr
- Phase II
  - Major research and development
  - Funding for 2 yr, sometimes 3
  - Median NIH award $375K/yr
- Competing Continuation Phase II
  - For FDA related products
  - Compete with other Phase II applications
  - Award up to $1M/yr for 2 to 3 years
- Phase III
  - Remaining steps of commercialization
  - Not funded by government. Funded by other sources, e.g., angels, venture capital, etc.

Surrogates of SBIR/STTR Program Value

- Leverage – Venture capital raised by SBIR/STTR companies
- Patents – Comparison with academic institutions
- Financial health – Membership in Biotechnology Industry Organization (BIO)

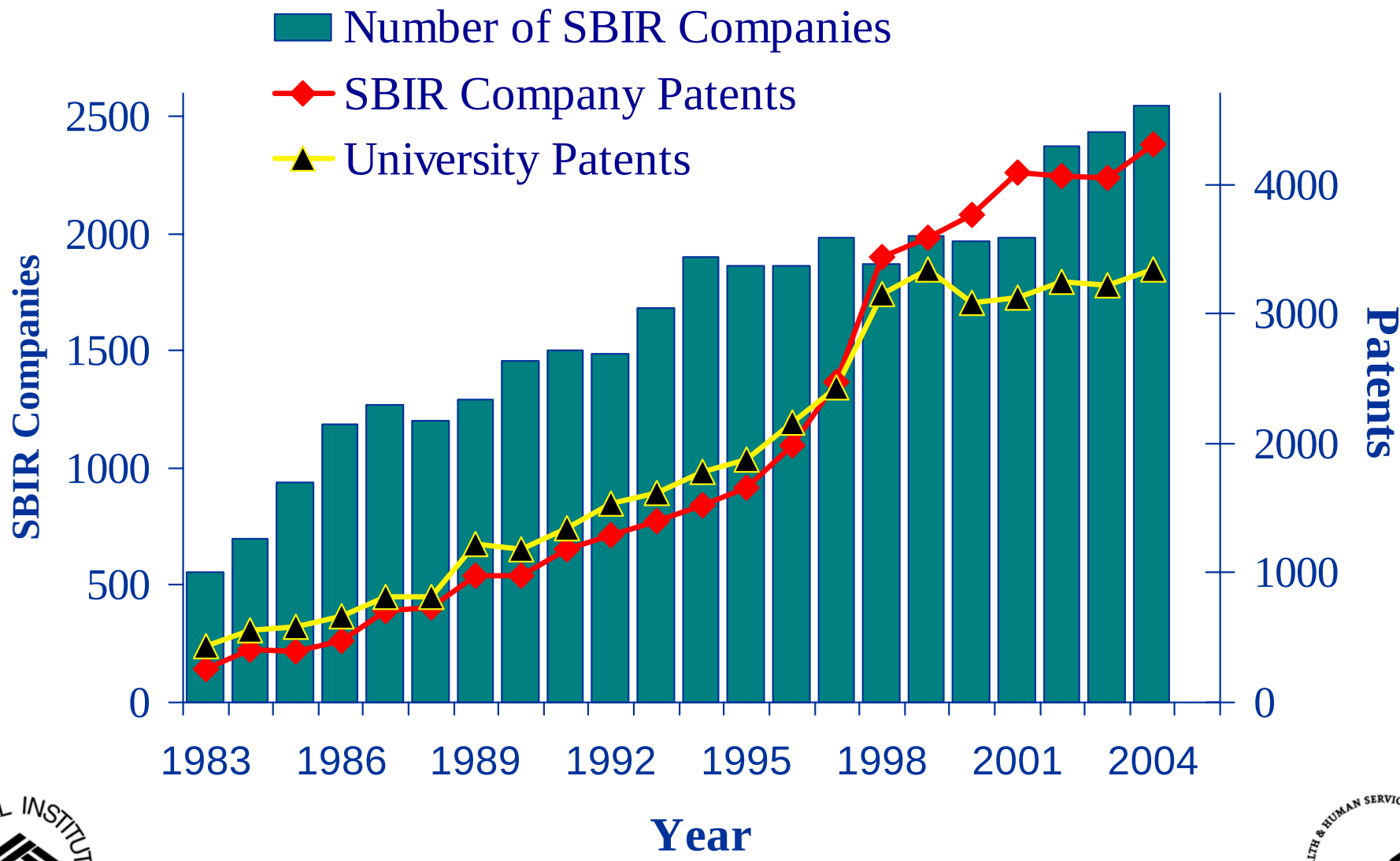
Venture Capital (VC) Attracted by SBIR Companies– 2000 to Present*

SBIR Source	Number of Companies	Attracted VC Funds	Percent VC Funds
All 50 States			
All Sources	7713	824	10.7
NIH	3008	528	17.6
Others	4705	296	6.3
California			
All Sources	1584	247	15.6
NIH	601	166	27.6
Others	883	81	9.2

Leverage: VC Funds to SBIR Funds – 2000 to Present*

All 50 States			
SBIR Source	SBIR Funds	VC Funds	Ratio VC/SBIR
All Sources	$2.14B	$20.21B	9.43
NIH	$1.56B	$13.74B	8.78
California			
All Sources	$466M	$8.79B	18.9
NIH	$339M	$6.01B	17.8

Patents Awarded



BIO Membership Data – March 10, 2005

- 1148 BIO members
- 187 or 16.3% received NIH SBIR or STTR grants between 1999 and 2004
- Over 50% of BIO members were ineligible for SBIR or STTR awards.
- Estimate that between 30% and 50% of eligible BIO members received NIH SBIR or STTR awards.

Take Home Message

- Federal SBIR and STTR programs seem to be effective ways to leverage government investments to promote:
  - Translational research
  - Economic development
- NIH small business funding of California companies was matched about 6-fold by venture capital funding.
- SBIR companies are awarded more patents than universities.
- A high percent of biotechnology companies who can afford to belong to BIO were awarded NIH SBIR or STTR grants.

Inventions Resulting from U.S. Government Supported Research

- The Bayh-Dole Act specifies invention reporting compliance responsibilities and timelines.
- A grantee institution must report an invention to the U.S. funding agency within 2 months of learning about it from the inventor.
- The grantee institution must pursue a patent application on the invention.
- The granting agency (NIH) may pursue a patent application (march in rights) if the grantee institution elects not to.
- The inventor may pursue a patent application if he or she requests it and both the grantee institution and granting agency elect not to pursue it.
- The granting agency has the right to a royalty free license to practice the invention for its own use but NIH never has.
- Products should be produced in U.S.

Small Business Requirements

- Business = For-profit.
- Principal place of business in U.S.
- SBIR/STTR funded research must be conducted entirely in the U.S.
- A reasonable portion of the research must be conducted by the company in company controlled facilities.
- Small = 500 or fewer employees in the small business and its affiliates.
- Owned by individual U.S. citizens, not venture capital organizations.

Innovation and Research Requirements

- Innovation
  - New technologies.
  - Significant improvement of existing technologies.
  - New applications for existing technologies.
- Research
  - Collection and analysis of data
  - Validation of product, e.g., safety and efficacy.
- Not Development

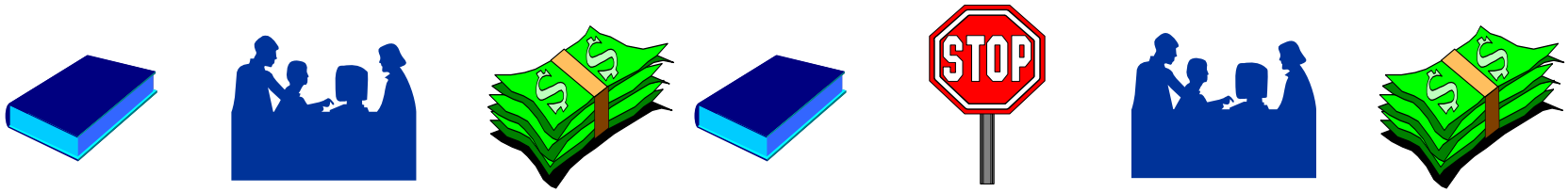
Comparisons Between SBIR and STTR

		SBIR	STTR
Agency research budget		2.5%	0.3%
Award guidelines	Phase I	$100K 6 mo.	$100K 12 mo.
	Phase II	$750K 2 yr.	$750K 2 yr.
Research institution partner required		no	yes*
Max. outsource	Phase I	33%	60%*
	Phase II	50%	60%*
Min. company effort	Phase I	67%	40%*
	Phase II	50%	40%*
Min. research inst. effort	Phase I & II	0%	30%*
PI Company employed over 50% time		yes*	no

** Mandatory, no wiggle room*

Fast-Track and Normal Timelines

Normal application, review, award process



Submit Phase I — Apr 1

Review 7-9 Months — ~Jul

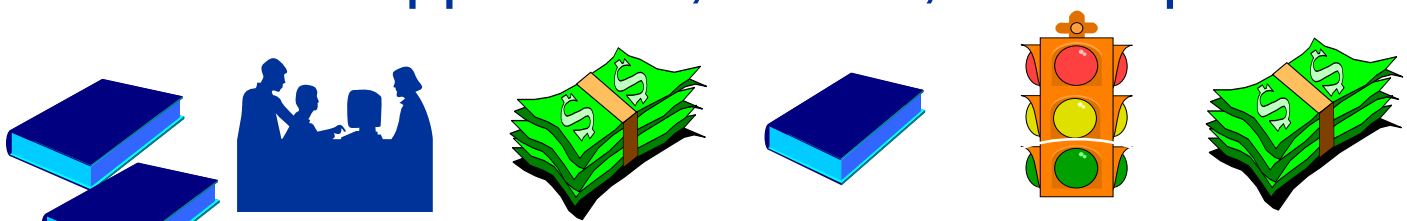
Award 6 months — ~Nov

Prepare & Submit Phase II — ~Apr

Review 7-9 Months — ~Jul

Award 24 months — ~Nov

Fast-Track application, review, award process



Submit Phase I & Phase II

Review 7-9 Months

Award 6 months

Phase I Progress Report

Program Review 1 Month

Award 24 months

>7 months earlier

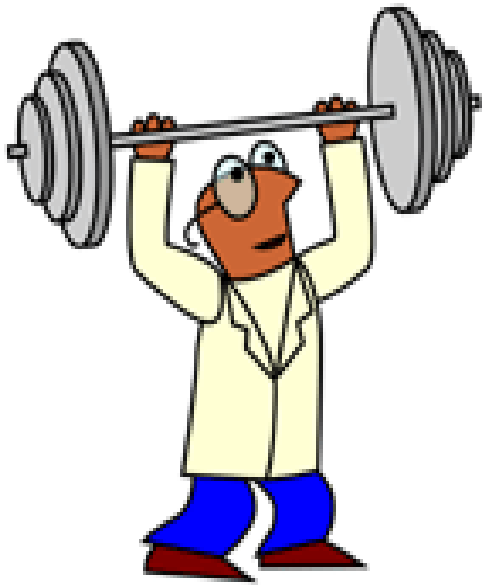
Advantages of SBIR over STTR

- No research institution partner necessary.
  - Fewer agreements, fewer lawyers, less cost.
  - Company controls all funds.
  - Less or no academic overhead.
- More flexible percent effort than STTR.

Advantages of STTR over SBIR

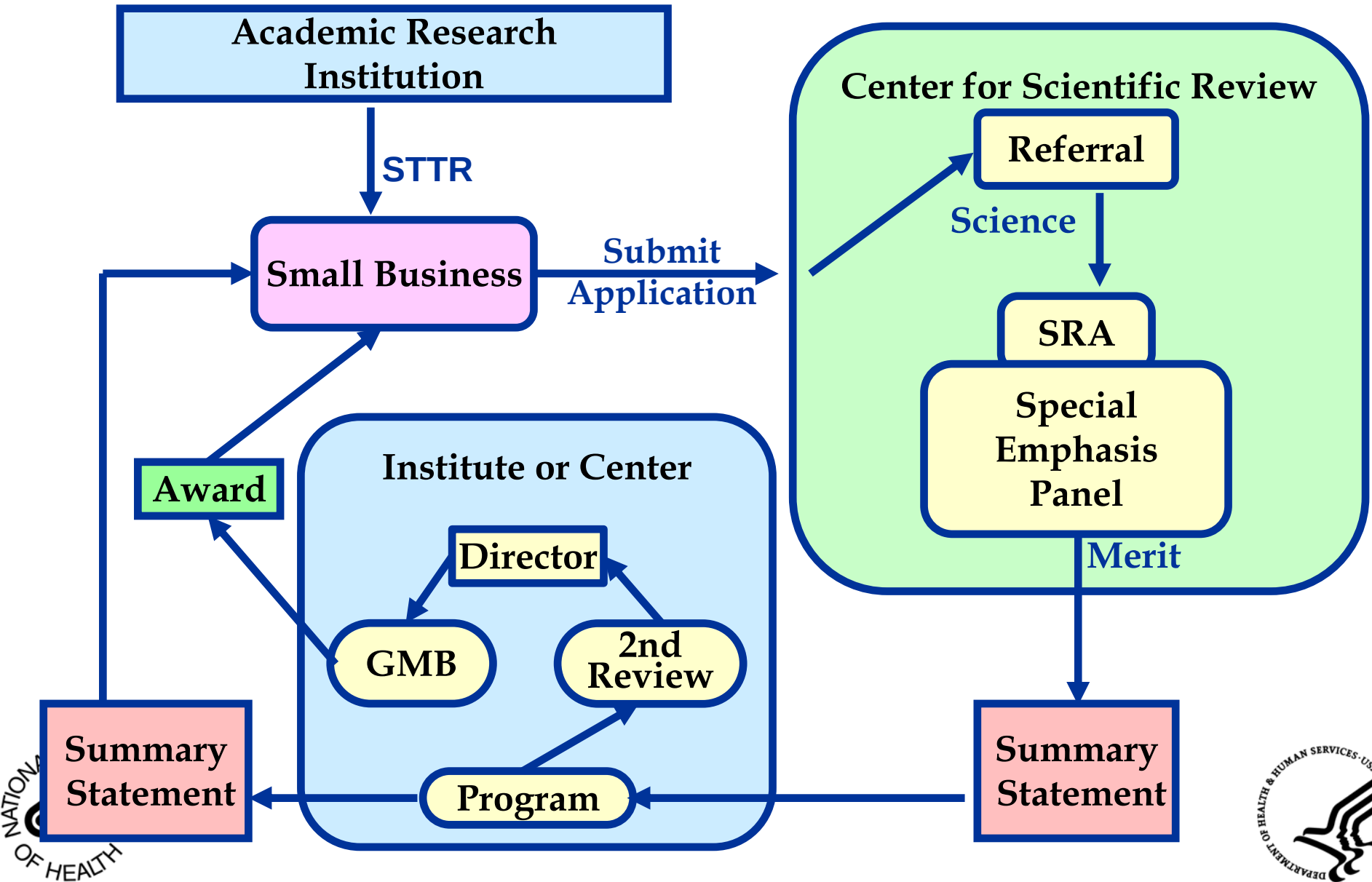
- Company may lack credible PI, e.g.,
  - Scientist with expertise in area of application.
  - Clinician with access to medical setting.
- PI role essential to collaborating academic scientist.
  - Promotion, etc.
  - May be easier to avoid conflict of interest.
- Potentially better access to academic facilities, intellectual property, support, e.g., IRB and animal welfare committee.
- Higher percent subcontract possible.
- Higher percent of applications may be funded.

STTR Applications Require Extra Effort



- Both company and research institution partner must sign an intellectual property agreement.
- Certification of cooperative R&D arrangement between business and research institution is required prior to award.
- Virtual companies do not qualify – a company's research facilities is carefully scrutinized.
- Extra care is required to avoid conflict of interest.
- Cannot switch between STTR and SBIR tracks.

SBIR and STTR Review and Award Process



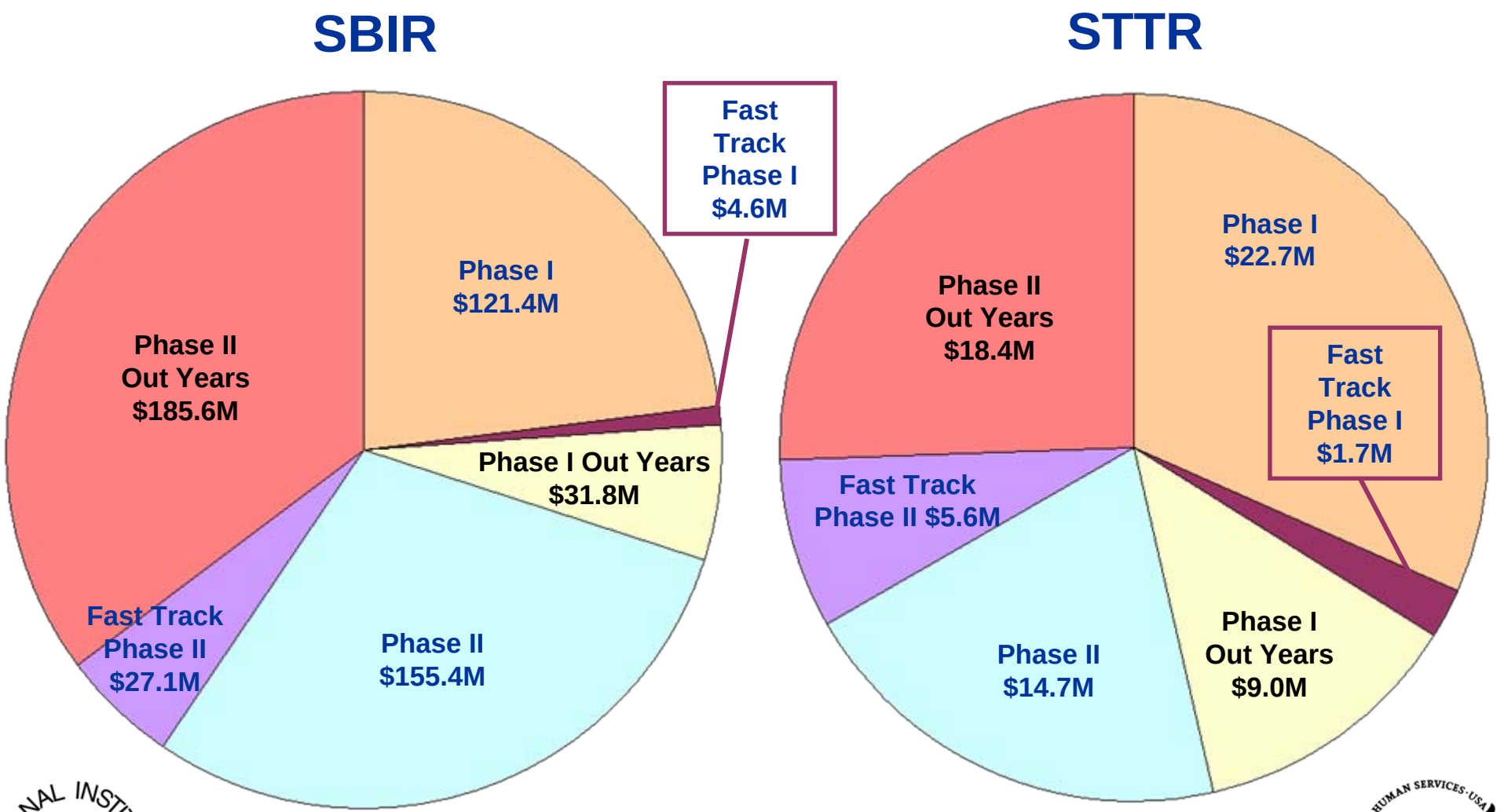
NIH Review Criteria

- **Significance:** Does the study address an important problem and have commercial potential? Will scientific knowledge be advanced and/or enabling technologies created?
- **Approach:** Are design and methods well-developed and appropriate? Are problem areas addressed?
- **Innovation:** Are there novel concepts or approaches? Are the aims original and innovative?
- **Investigator:** Is the investigator appropriately trained and capable of managing the project?
- **Environment:** Does the scientific environment contribute to the probability of success? Are there unique features of the scientific environment?

FY2005 NIH Applications

Type	Received	Funded	Award Rate
Phase I			
SBIR	4700	757	16.1%
STTR	692	136	19.7%
Fast Track			
SBIR	199	29	14.6%
STTR	44	11	25.0%
Phase II			
SBIR	955	295	30.9%
STTR	76	31	40.8%

FY2005 SBIR and STTR Awards



Points to Consider for CIRM Small Business Programs

- SBIR and STTR mechanisms?
- Percent of CIRM budget?
- Application receipt dates?
- Review and award policies and procedures?
- Phase I and II time and annual award amounts?
- Fast-Track permitted?
- Small company definition?
- Definition of research and development?
- Allow VC company ownership?
- Require principal place of business in CA?
- Require research funds used totally in CA?
- Require minimum percent effort by company?
- Require products be produced in CA?
- March-in rights?
- CIRM intellectual property agreements and licenses? Royalty free?

Potential Topics for Another Time

- Lessons learned in developing an NIH AIDS Reagent Program that may be applicable to a Stem Cell Reagent Program.
- Lessons learned in developing the NIH Centers for AIDS Research that may be applicable to developing Centers for Stem Cell Research.

CONTACT INFORMATION

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