

# Research Opportunities for Small Businesses

*SMALL BUSINESS INNOVATION RESEARCH  
(SBIR) PROGRAM*

*SMALL BUSINESS TECHNOLOGY TRANSFER  
(STTR) PROGRAM*

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**SBIR/STTR Programs:  
for small businesses to  
develop marketable  
products**

# Program Descriptions

- **Small Business Innovation Research (SBIR) – 2.5%**  
Set-aside program for small business concerns to engage in federal R&D– with potential for commercialization.
- **Small Business Technology Transfer (STTR) – 0.3%**  
Set-aside program to facilitate cooperative R&D between small business concerns and U.S. research institutions – with potential for commercialization.

# SBIR PROGRAM

## *Goals*

- Stimulate technological innovation in the private sector
- Strengthen the role of small business in meeting Federal research or research and development needs
- Increase the commercial application of Federally-supported research results
- Foster and encourage participation by socially and economically disadvantaged small business concerns and women-owned business concerns in the SBIR program

# STTR PROGRAM

## *Goals*

- 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

# SBIR AND STTR PROGRAMS

## *CRITICAL DIFFERENCES*

- Research Partner
  - SBIR: **Permits** research institution partners
    - [Outsource ~ 33% Phase I and 50% Phase II R&D]
  - STTR: **Requires** research institution partners (e.g. universities)
    - [40% small business concern (for-profit) and 30% U.S. research institution (non-profit)]
- AWARD IS ALWAYS MADE TO THE SMALL BUSINESS

# SBIR AND STTR PROGRAMS

## *CRITICAL DIFFERENCES*

- Principal Investigator
  - SBIR: Primary (>50%) employment **must** be with small business concern
  - STTR: Primary employment **not stipulated** [PI can be from research institution and/or from small business concern]

# SBIR PROGRAM

## ELIGIBILITY CHECKPOINTS

- Organized for-profit business
- At least 51% U.S.-owned and independently operated
- 500 or fewer employees
- P.I.'s primary employment with small business during project



# STTR PROGRAM

## ELIGIBILITY CHECKPOINTS

- Applicant is Small Business Concern
- Formal Cooperate 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

# SBIR/STTR GRANTS

- Phase I – R43 and R41
  - Establish technical feasibility and potential for commercialization of the project
  - Determine quality of performance of the small business
  - 6 months
  - \$100K

# SBIR/STTR GRANTS

- Phase II – R44 and R42
  - Continue projects initiated in Phase I
  - More extensive R&D to further develop scientific merit and commercial potential
  - 2 years
  - \$750K

# *Phase II Competing Continuations*

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- **Goal:** Provide additional research funds to move already identified drugs or devices requiring regulatory approval into clinical trials
- **Stipulations:**
  - Available only to Phase II grantees preparing for clinical trials
  - Focus -- Diagnostics, devices, tissue engineering, drug development
  - Funding level: \$750K to \$1M per year for maximum of 3 years
  - Available for grantees involved in advanced stage development of pharmacological treatment agents for drug and nicotine abuse and addiction

# SBIR/STTR GRANTS

- 3 submission dates/year – April 5, August 5, December 5
- Review conducted by CSR
- FY09 ~ \$16,214,000 – SBIR Grants
  - ~ \$ 2,666,000 - STTR Grants
  - ~ \$ 6,000,000 – SBIR Contracts
- Success rate in FY09:
  - R43 - 21% of applications were funded
  - R44 – 30% of applications were funded
  - R44 – Fast Track – 25% of applications were funded
  - R41 - 60% of applications were funded
  - R42 – 0% of applications were funded

# ***REVIEW CRITERIA***

## ***Phase I***

- Significance (Real Problem/Real People)
- Approach (Research Design, Feasible)
- Innovation (New or Improved?)
- Investigators (PI and team)
- Environment (Facilities/Resources)
  - ... Protection of Human Subjects
  - ... Animal Welfare
  - ... Budget

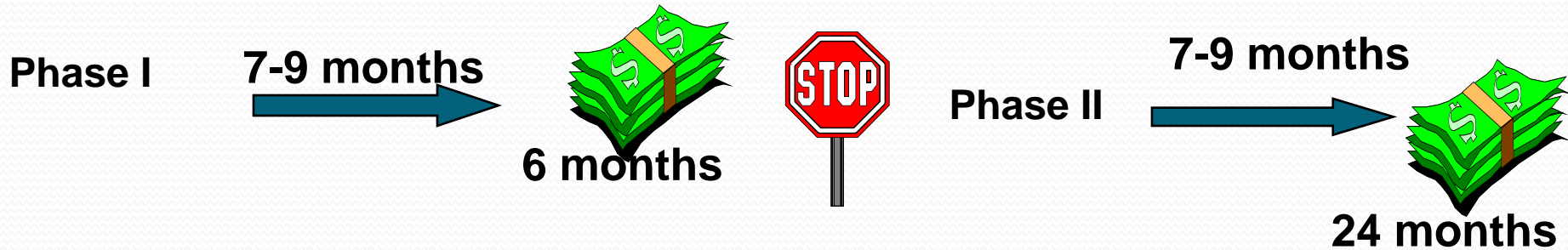
# ***REVIEW CRITERIA***

## ***Phase II***

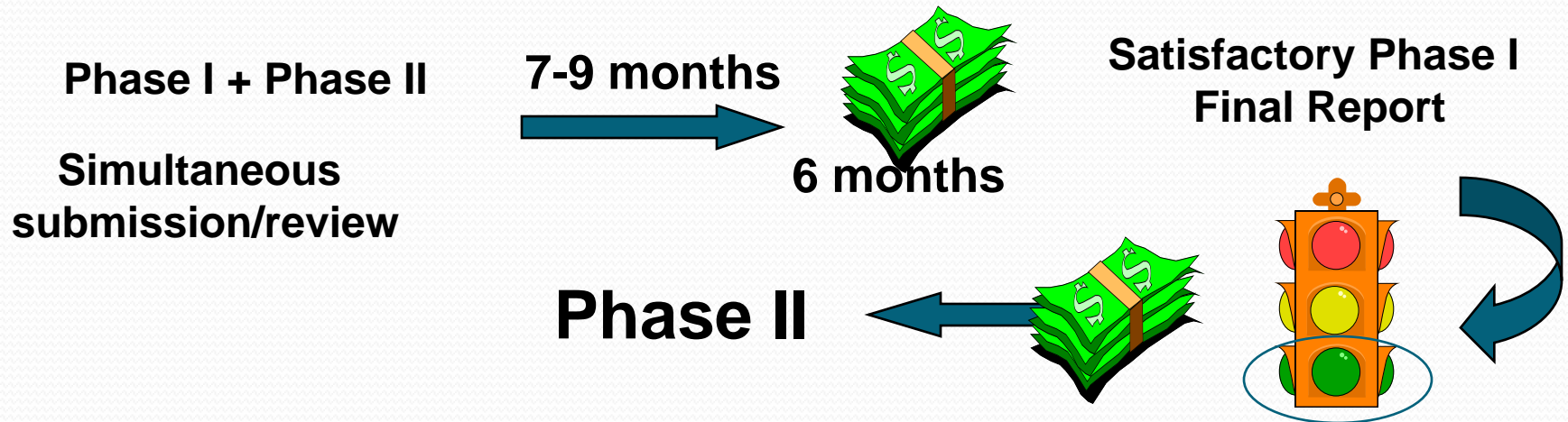
- Same as Phase I
- Demonstrated Feasibility in Phase I
- Commercialization Plan
- High Degree of Commercial Potential Based on Plan
  - ... Protection of Human Subjects
  - ... Animal Welfare
  - ... Budget

# SBIR "FAST-TRACK"

## Standard application, review, award process



## Fast-Track review option





# NIH SBIR “FAST-TRACK”

Best Option For Everyone?



No!

- 
- **Convincing preliminary data?**
  - **Clear, measurable, achievable milestones?**
  - **Well-conceived Commercialization Plan?**
  - **Letters of Phase III support/interest?**
  - **Track record for commercializing?**

# SBIR/STTR Omnibus Grant Solicitation

- NIH publishes a listing of each ICs program areas of interest in the omnibus solicitation.
- The current omnibus solicitation can be found at: <http://grants.nih.gov/funding/sbir.htm>
- NIDA's program areas of interest are listed in this.
- Potential grantees who are interested in a topic that isn't included in the solicitation can still apply.
- Applicants can include a cover letter requesting a NIDA assignment

# SBIR/STTR RFAs and PAs

- In addition to the omnibus solicitation, NIDA is currently on numerous program announcements and request for applications under the SBIR/STTR program
- These can be found at <http://grants.nih.gov/grants/funding/sbir.htm>
- [http://grants.nih.gov/grants/funding/sbir\\_announcements.htm#recovery](http://grants.nih.gov/grants/funding/sbir_announcements.htm#recovery)

# ***SBIR CONTRACTS***

- ~ \$6,000,000/year of NIDA's SBIR budget/year is spent on contracts (phase I & II)
- NIDA funds 10-14 new phase I contracts/year
- The solicitation is usually released in August
- One submission date/year – usually early November
- Same eligibility requirements as grant program
- Contract solicitations are generally more specific than grant solicitations

# ***SBIR CONTRACTS***

- SBIR Contract proposals are reviewed by NIDA, not CSR
- Unlike grants, NIDA program CANNOT communicate with applicants about the SBIR Contract Solicitation
- All questions must go through our contracts office
- At most, NIDA awards 1 contract/solicitation
- NIDA DOES NOT retain ownership of the product

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# ***SBIR CONTRACTS***

- FY09
  - 9 phase I contracts awarded
  - 11 phase II contracts awarded
- FY10 ~ 10 phase I contracts will be awarded – solicitation is now closed
- FY11 – contract solicitation will open late summer/early fall



# REAUTHORIZATION BILLS

- SBIR program is under a continuing resolution
- H.R. 2965
  - Increases the award level to \$250,000 for phase I and \$2 million for phase II
  - No increase in the amount agencies must put into the SBIR/STTR program
- S. 1233
  - Increases the award level to \$150,000 for phase I and \$1 million for phase II
  - Limits awards from exceeding 50% above recommended levels
  - Increases the SBIR set-aside to 3.5% over the period FY 2011-2020 and STTR set-aside from 0.3% to 0.6% from FY2011-2015

# ***NIDA SBIR/STTR CONTACTS***

- Division of Epidemiology Prevention and Services Research – **Augie Diana, Ph.D. ([dianaa@mail.nih.gov](mailto:dianaa@mail.nih.gov))**
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