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
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

- **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

Phase I  7-9 months
6 months
Phase II  7-9 months
24 months

Fast-Track review option

Phase I + Phase II
Simultaneous submission/review
7-9 months
6 months
Satisfactory Phase I Final Report
Phase II

7-9 months
NIH SBIR “FAST-TRACK”
Best Option For Everyone?

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

No!
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](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.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
SBIR CONTRACTS

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SBIR CONTRACTS

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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)
- Division of Clinical Neuroscience and Behavioral Research – Geetha Subramaniam, M.D. (subramaniamga@mail.nih.gov)
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