DEMYSTIFYING THE SBIR-STTR FUNDING PROGRAM AND NEW COMPANY FORMATION

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SBIR and STTR Grant Program Definitions

- **SBIR** – **Small Business Innovation Research Grant Program** Submitted and largely driven by a "small business concern" (LLC, C corp, S corp) with 500 or fewer employees where the principal investigator (PI) is a key member of the company that devotes 51% or more effort to the company
- **STTR** – **Small Technology Transfer Research Grant Program**– Submitted by a newly forming small business concern in collaboration with the university institution that it is emerging from – same size of company and % effort rules apply

NOTE: Inventors that stay within the University can still derive some significant monies from both types of Small Business grants *– subcontracts or budget monies back to the inventor's laboratory to perform key tasks or experiments is absolutely allowable – this strategy maximizes value for the University of origin and it allows access to said grant monies for University investigators and labs*

SBIR-STTR Program Reauthorization

- The US Congress reauthorized the SBIR-STTR program formally at the end of 2011 with a 'rider' on the Defense Act (funding for the wars in Iraq and Afghanistan) in a bipartisan effort
- The % of monies dedicated to SBIRs and STTRs in every government agency is set to increase by 0.1% per year from 2011 through 2017 – by 2017, 3.2% of the extramural funding budget is mandated for SBIRs and 1.2% for STTRs
- The reauthorization was delayed by the late federal budget efforts and the government shutdown but it kicked into place in 2013
- A recent presentation by a National Cancer Institute SBIR-STTR Program Official stated that NCI had monies left over last year that it needed to devote to SBIRs and STTRs so that more awards with lower priority scores became funded
- The downside is 'robbing' of monies from the R01/R21 pool

US Governmental Agencies Involved in SBIR/STTR

- **National Institutes of Health (NIH)** – All Institutes and Centers participate and they often also have special Requests for Applications (RFAs) and Program Announcements (PAs) geared toward small business concerns (SBCs)
- **NSF** and the **FDA** also participate, although the award amounts are smaller…**USDA** and many other agencies participate too…
- **DARPA** and **BARDA** within the Department of Defense have their own configurations
- There are also both SBIR/STTR grants and SBIR contracts – DBM reviews the SBIR/STTR grant mechanisms (*NIH Guide to Grants and Contracts*) routinely and also receives the SBIR contract solicitations

Note: Small Business Concerns are also eligible for R01s, R21s, and other types of grant mechanisms (P and U awards)…DBM does not actively apply to these as a matter of principle but has been involved in a P30 award.

SBIR/STTR Submission, Scoring and Funding Odds

- **Deadlines for Omnibus SBIR/STTR have shifted recently** – April 5/6 is the next deadline but future deadlines are September 5, January 5 and May 5 and this sequence will maintain going forward *(but special deadlines can be set for special RFA and PA solicitations)*
- **SBIRs and STTRs receive a priority score or they are 'not discussed'** – They are not 'percentiled' like R01s or R21s – Funding is determined by a priority score payline only (latest examples: NIAID 32/33; NHLBI 28/28; NCI 30s/30s in 2014)
- **Odds at obtaining funding** – DBM batting average has been improving as we have begun focusing on our 3 major R&D programs (a few years ago it was 10-20%; it is now 1 in 3) – The DBM batting average for Phase 2 renewal of funded Phase 1 SBIR programs is 50% *(if a Phase 1 SBIR or STTR-funded program hits all of its goals and milestones, its chances for progression to later and more monies in Phase 2 are good)*

Critical Small Business Concern Requirements

- **Tax ID number –** granted when one forms the SBC
- **DUNS number –** need to apply for one from Grants.gov
- **Separate NIH Commons account (for NIH SBIRs and STTRs) –** for those who still have a University-based account
- **System for Awards Management (SAM) registration** – critical, needs to be renewed annually, and **SBA registration**
- **Grants.gov Account** – need to have an account for the SBC

- Discussion of Real versus Virtual Companies and SBIR/STTR Submission
  - Better to be real than virtual with a real location and beginning or established business practices and business and laboratory infrastructure
  - Reviewers have many ways of 'sniffing out' the difference

SBIR/STTR Strategy Intangibles

- **SBIR or STTR** – How to choose...???!!! Discussion…, including:
  - Status of the small business concern: Forming or formed?
  - How much work still required from within the University in the inventor's laboratory?
  - Status of IP ownership and term sheet/licensing with a Tech Transfer office
  - How easy is it to work with your Grants and Contracts office?
  - Are you planning on submitting for one core piece of technology or are you planning to fund multiple programs or technologies with this mechanism?

NOTE: SBIR or STTR are non-dilutive monies but they are also 'slow monies' and 'budget-capped monies' and 'scripted by year monies' and 'often delayed monies' – One can also be stricken with what is known as "SBIR Dependency Disorder"; companies that are 100% dependent on such funds can be viewed upon unfavorably by future investors in specific cases

Avoid Saturation Bombing for SBIRs/STTRs

- **As a reviewer of SBIRs and STTRs, some helpful hints of things to avoid**:
  - Avoid having multiple SBIR or STTR applications land in the same Special Emphasis Panel and in the same review cycle (this is never said in the comments but it is viewed as greedy)
  - Avoid the "why not" rationale for submission of SBIR or STTR applications
  - Avoid 'saturation bombing' of Special Emphasis Panels with SBIRs and STTRs from the same company and same PI name (in the last panel that I participated in in July, there were 3 applications in the same panel for a single company and another different 3 in the same panel from a single company with the same PI name)

NOTE: There are a handful of small business concerns that do this in the drug discovery and development space and they become known to reviewers and Chairs of SEPs

EMS and DBM: SBIR Applicant and Reviewer

- **DBM and EMS submitted our first Phase 1 SBIR grant application on December 5, 2007** – We have rarely missed these 3 deadlines each year in our history
- **EMS began reviewing for SEPs in Respiratory, Nephrology and Metabolic in 2010/2011 and reviews one or more times every cycle** – This practice has helped tremendously for our own applications because one sees the full spectrum of what reviewers on SEPs are looking for in a competitive application
- **SEPs for SBIRs and STTRs are populated by experts from academia, clinical medicine, small biotech, larger industry and by consultants in specific fields** – Every SEP is a mix and you need to write the application with that full spectrum in mind and try to keep every type of reviewer happy and engaged with your application and program

Types of SBIR and STTR Awards

- **Phase 1** – Pilot grant…6 months to 1 year in duration…$225,000 total cost cap but can go beyond the cap with proper budget justification…Preliminary data not required <u>but strongly encouraged</u>
- **Phase 2** – Renewal grant…2 years…$1.5 M total cost cap but can go beyond the cap with proper budget justification…Best to wait to submit until Phase 1 goals and milestones accomplished
- **Direct Phase 2** – New mechanism – Can submit directly as a Phase 2 application if you have ample Phase 1-like preliminary data
- **Phase 1/Phase 2 'Fast Track"** – Can submit an application that spans 2.5 to 3 years that covers a full program from proof-of-concept through significant development (reviewed with greater scrutiny)
- **Phase 2B SBIR –** If one holds a Phase 2 award and if there is an RFA out that will fund this, one can apply for a 3-year $3M award but it requires a partial or full match from a third party

Choice of Principal Investigators

- **Young Investigators Populating Small Business Concerns or Young Scientists Being Mentored at DBM**
  - EMS still believes that this is the best paradigm for UAB or any University going forward and for multiple reasons discussed in the last 2 sessions
  - This is a 'double-edged' sword, however, because you can then get the comment that the PI does not have a track record of NIH or SBIR/STTR funding
  - This can be mitigated by having dual PIs
    - A younger DBM investigator paired with EMS
    - Dual DBM younger investigators as PIs with EMS in collaborative support
    - A newly minted MBA or Ph.D. student and/or postdoctoral fellow as PI of the main grant with the faculty mentor still in academia as PI of a subcontract

Questions and Discussion and Break

- **No such thing as a dumb or stupid question, ask away…**

SBIR/STTR Templates and Helpful Hints

- **Goals and Milestones page –** The most critical page in the ap…

This is similar to the Specific Aims page where a Hypothesis and Specific Experimental Aims are declared in an R01 or R21 application

EMS uses a Goal statement, guiding Milestone statements and Specific Experimental Aims statements under each Milestone

- *Reviewers often turn to this page first to get an overall picture about the outline of the program or the Critical Path of product ID and/or development (it is 1 page max)*
- *This is also supplemented by a Project Summary Abstract and a Public Health Relevance statement (together, these can add up to 1 page max) – EMS uses these sections to make complementary key points to what appears on the G&M page – often, other applicants do not use this space wisely or they simply repeat themselves 2 to 3 times over – neither practice is wise*
- *If the application is a revised application, the Introduction (response to reviewers comments is also very key (it is also 1 page max)*

Research Strategy and Commercialization Plan

- **Phase 1** – Research Strategy is 6 pages… No Commercialization Plan is required
- **Phase 2** – Research Strategy is 12 pages…Commercialization Plan is 10 pages
- **Direct Phase 2** – Research Strategy is 12 pages… Commercialization Plan is 10 pages
- **Phase 1/Phase 2 'Fast Track"** – Research Strategy is 12 pages… Commercialization Plan is 10 pages (unless they require additional information and extend the limit)
- **Phase 2B SBIR –** Research Strategy is 12 pages… Commercialization Plan is 10 pages (unless they require additional information and extend the limit)

EMS is glad to provide such templates electronically…

Research Strategy - Commercialization Plan 2

- **Research Strategy** specifics:
  - Significance (0.5-1 page)…Innovation (0.5-1 page)…Approach (5-10 pages)
  - Goals and Milestones outline serves as an outline for the Approach section – easiest to organize that section that way

- **Commercialization Plan** specifics:
  - There is a specific outline provided for this Plan that must be followed
  - In special cases, there are added sections to the outline that must be included in the plan

Other SBIR/STTR Application Intangibles 1

- **Letters of Support –** critical that they are ALL well done and compiled – if engaging with CROs helping with the program, can get a letter and a quote and methods and string it all together because there is no length limit here – can also present things here that you cannot fit into the research strategy
- **Budget and Budget Justification** – EMS finds the budget pages that one reviews from an electronic application to be useless – thus, DBM and EMS do a detailed budget by year of the SBIR that delineates salaries/benefits, equipment costs (if any), consultant costs, supplies costs (detailed) – DBM uses an Indirect Cost Rate of 20% for Phase 1 awards and 40% for Phase 2 awards – an SBC can ask for up to 40% as an Indirect Cost Rate without having to negotiate a fixed one with the NIH
- **Introduction**– Very critical in a revision – if EMS has reviewed the original application, I go there first along with reading the G&M page to jog my memory and to determine if the applicants were receptive to previous comments, etc.

Other SBIR/STTR Application Intangibles 2

- **Multiple PI Leadership Plan –** one can use this vehicle to include principals from both the SBC and academia – one can tout or 'talk up' the attributes of each principal here again

- **Contracts, Consortia and Collaborators** – one can use this section to make additional key points about everyone involved, especially collaborators (academics, clinicians, CROs), and also present how they are all tied together and become synergistic

<u>Note:</u> One might argue that this is redundant because these issues have been addressed in other parts of the application; however, EMS and DBM have found that presenting key points 2X or even 3X can be wise so that the key point is not missed by reviewers

IP Protection Status and Licensing Status with Technology Transfer Office and SBIRs/STTRs

- **It is fine and sometimes preferred that IP protection is in progress –** certainly acceptable in Phase 1 if it is in progress with a provisional patent application just submitted
- **More solid IP protection can help solidify later SBIR or STTR awards –** Phase 2 applications where Commercialization Plans are required are made better if a list of existing patents is provided
- **STTR is the way to go if the Term Sheet and Licensing negotiation is on-going for a piece of technology or a research program –** one can simply have a letter provided and included that the Technology Transfer office supports this application and that this effort is in progress (but if it looks like it will be awarded, it is best to pick up that pace and get it done)
- **SBIR is the better bet if the IP Licensing is done –** SBC is free of University entanglements and ready to go – often seen as a position of much greater strength

Discovery BioMed

A Thought for UAB to Realize SBIR/STTR Access

- **Grant a sabbatical and/or a leave of absence (without revoking or imperiling tenured status) for a faculty member to start an SBC and write for such SBIRs and STTRs**
  - Can garner such awards and then hand them off
  - Can garner such awards and subcontract monies back to his/her academic laboratory
  - Can garner such awards, hand them off to capable trainees and head back into the academic halls
- **Best that the SBC is real rather than virtual**
- **Entrepreneurial-friendly institutions have and foster such flexible structures and paths –** They are just not advertised or broadcast – one sees them as an SBIR/STTR reviewer and I saw them recently in a reviewer of NIH REACH Hub entrepreneurial program applications from Universities and state-wide University networks recently – multiple such constructs are possible at UAB