3rd Global Congress on Sickle Cell Disease

Grant Training Workshop

LARS RESEARCH INSTITUTE, INC.

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Designing a Competitive Grant Proposal

Workshop Highlights and Training Materials©

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I. Opening Remarks for 3rd Global Congress on SCD Grant Training Workshop

This grant writing workshop is organized thematically around several "key" essential activities required to proficiently write extramurally funded grants. During the Workshop, we combine presentations, discussion, and group problem solving projects with hands-on demonstration activities. The activities are intended to reveal the key active ingredients of writing effective grants; they are intended to be both "fun" and informative. The workshop reflects a compilation of personal and professional experiences that stem from years of writing, reviewing, and critiquing grants. The two main presenters have accumulated a rich professional acumen that involves producing, managing, and serving a leadership role on many different kinds of grants; research, demonstration, dissemination, and training. In addition, both presenters have amassed extensive experience reviewing grants for the National Institutes of Health (NIH), international funding agencies, charitable organizations, military contracts and other funding organizations.

II. Workshop Highlights

We appreciate that a number of participants attending the workshop hail from various academic disciplines and that represent many different walks of life. Some of the attendees may be medical professionals, physicians, allied healthcare providers, or researchers. In many cases, the "focus" of a clinically focused medical practitioner may be somewhat different from an applied researcher; however, when it comes to grants, the review processes are quite similar. Whether you place your emphasis on research with gene transfusion and finding ways to replenish sickle cells with healthy erythrocytes, or you are vested in developing and testing behavioral interventions to reduce the complications of pain, a grant is a grant is a grant. In this regard, if you are interested in discovering the underlying physiological basis for the neuromodulation of pain and your background is firmly rooted in biochemistry, physiology, or pharmacology, you should benefit from attending this workshop. Likewise, if you are an intervention scientist and your program of research emphasizes family-based models for disease management, you too can benefit from attending this workshop.

We would be remiss if we also did not recognize another group of individuals that can benefit from the workshop. Past experience reveals to us that we should not be surprised if one or two of the workshop participants also function in the workplace as administrators, or hold titles such as supervisor of "contract and grants," where they may perform services revolving around budgetary or administrative matters. Librarians and research personnel can also benefit from the workshop, as can junior researchers, and more senior faculty tasked with supervising the next generation of scientists and who wish to cull specifics detailing "*how to write grants*." Accordingly, we have formulated the contents of this workshop to fit these broad interests and be applicable to diverse professional backgrounds.

YOU SHOULD KNOW …

- The workshop is "*skills*" oriented rather than hitting on any one particular facet of behavioral or medical science.
- The workshop highlights "*strategies*" and thematically integrates these around developing, writing, and submitting grants.
- The workshop also addresses to some degree the "*philosophy of science*," which we think underscores the importance of scholarship and personal empowerment.

*I*n order to boost your power and provide you with the very latest in successful grant writing tips, we have included special sections in the workbook that detail:

- Budgets and administrative concerns.
- Small business innovative research grants (SBIR).

*W*e did this because you cannot conduct science using grant funding without putting a price tag on the work product. Also, there is so much emphasis today in "technology" and developing cures, interventions, remedial programs, and so forth using state-of-the-art interactive media and computer based programs. Therefore, attendees may benefit from learning about funding mechanisms in the USA that emphasize "technology + science."

*A*s with any good managerial training, the didactic portion of the workshop is complemented by hands-on presentations and activities that are intended to stimulate "*group think*" and impart special critical reasoning skills. While these activities are structured with the intent of having fun and developing insight, they also provide you with the type of perspective on what it takes to be a success *grant writer* and more importantly to garner success in other travels along the road.

III. The Value of a Story

*A*t the very outset, we offer a point of clarification about what makes a grant so special. This discussion resonates around the close fundamental relationship between constructing a grant and telling (or reading) a "*story*." All of us grow up on a rich tradition of folktales, whether we are from India or another country. In India, there are many useful and informative "stories" that are told as part of a rich tradition of *Jataka Buddhist, Hitopadesha, or Panchatantra* folktales. Many of these folktales take shape as short stories, some written in *Sanskrit or Pali,* and that provide life lessons on humanity, morality, and kindness. There is the *Hitopadesha* tale of the *Elephant and*

the Dog, teaching us about fidelity and friendship. Then there is the Panchatantra tale about the *Bird with Two Heads*, which weaves a story about Bharunda, a bird that has two necks but only one stomach. The profound story shows us that sharing good things brings rewards. The Panchatantra collection of folktales gave us the story of the *Two Headed Weaver*, which teaches us to develop our own wit, work hard of our own accord for life's rewards rather than trying to improve ourselves based on false pretenses.

In the U.S. or Europe we have comparable "folktales" like *Rumpelstiltskin, The Frog Prince, Hansel and Gretel, and Rapunzel*, to name a few of the more famous and remembered ones. One of the most endearing features of a story is the rapt attention paid by children to the way a story unfolds. The story identifies a setting usually in times way before, then portrays the dark and sinister features of an evil character, describes a beautiful damsel in distress, and relates the plight and heroics of the savior prince. Indian folktales vary somewhat and tell of morality, human kindness, friendship, self-sacrifice, honesty, happiness, and the different ways to achieve enlightenment. In this respect, all stories move sequentially from an introduction of characters, development of a plot, through a climax, and eventual end. Across the world, no matter what culture, regardless of how primitive or advanced, no matter how inaccessible their land territory, explorers have repeatedly found upon encountering different civilizations that children share a common experience. That is, all children yield their undivided attention to hear how a story unfolds.

Writing grants is like writing folktales or children's books, their structure shares the simple pleasures of a story and even though the "*sell*" inside the children's book is somewhat different then a grant, the reader (reviewer) looks for similar "story-like" events to unfold. The reader wants to know about characters (investigator), the plot (theory), the prince (new idea or innovation), and how the story will end (the research product). Workshops, like the one you are attending, teach us that the story of a grant has to include certain 'parts' and these parts make up the review criteria. For instance, reviewers of an NIH government grant in the US determine the merit of a grant based on certain evaluation criteria including the grant's significance, innovation, qualities of the investigator, environment, and approach. According to these criteria, grants that are well designed, historically relevant and theoretically rich, emphasizing an important scientific topic, written with logical clarity, involving an investigator with a productive scholarly track record, who works as part of a supportive environment will be designated competitive. As we learn from the "*secrets of peer review*," each of these components reverberates in the reviewers' mindset as essential components of the story.

To continue with this analogy between "stories" and "grants," reviewers want to see explicitly stated and well-articulated aims, well-developed research hypotheses, a methodologically rigorous research design, that is appropriately powered and backed by a strong, detailed analytic framework (with a logic model). They also want to read about the special features of the research group, develop a sense the environment is supportive and where there are any "weaknesses" how the investigative team reached out to secure the support of consultants. The grant must outline a

reasonable timeline for conducting research activities, be aware of the pitfalls of conducting research with human subjects (if needed a story about invertebrate animals and their protections) and the entire story should reek of significance, tapping into a public health vein that requires immediate, if not long-term, attention.

Knowing all of this helps us to recognize that there are even greater parallels between folktales (children's stories) and grants, but the important thing to realize is that when you write a story and feather this information inside your grant, you are writing it for the reviewer, just like a storyteller who spins his story or folktale for children. The grant reviewer gives you the same rapt attention as the child does to the storyteller, sitting patiently waiting for the story to unfold. Readers that need more advice on how to write a story should pick up a copy of Robert McKee's (1997) bestselling book that teaches you how to artfully spin a yarn.

IV. Workshop Objectives (Skills, Attitudes, and Knowledge)

The workshop includes content that will be useful to teaching and clinical faculty, junior investigators, senior researchers, grant writers, clinicians, behavioral scientists, medical practitioners, and university graduate students. The workshop offers "practical skills" needed for planning and writing grant proposals. Other interested parties can include those involved in the grant production process including staff researchers, librarians, and administrative personnel, the latter who are instrumental in constructing budgets and collating grant materials. No participant should feel that their area of expertise is being overlooked or special grant considerations not discussed. We welcome comments and thoughtful insight presented during the open discussion periods and encourage your participation in the group activities. Examples shown on slides or discussed during a particular presentation are meant to "illustrate" a process.

The specific learning objectives for the workshop are the following:

1. Obtain knowledge and skills in planning and writing grant proposals.
2. Become empowered to write grants as "*stories*" with a beginning, middle, and end.
3. Realize the importance of collaboration as a cornerstone feature of scholarly work.
4. Gain greater insight on what the essentials of grant writing entails.
5. Develop a keener sense of science and innovation.

V. Foundations of Grant Writing 101

Step One: Understanding the Mertonian sociology of science!

The basic currency of scientific reward is a mixture of "discovery" and "recognition." For discovery this means being the first person to come up with an idea and gaining notoriety. Recognition is the accolades of your colleagues, public honor, and respect. When you embark on a career in science, the vehicle to achieve recognition is through publication. Your colleagues will know of your work when you publish in reputable journals and gain market share. The thinking behind this statement is that nobody else can publish on the exact same topic without recognizing your seminal contribution. In this respect, your impetus as a scientist and the protection of your *work* revolves around publications that position your seminal thinking as frontrunners.

This means your publications must resonate with insight, express novelty, and be written with a scholarly flavor. This is exactly the same recipe for writing successful grants, which much reek of novelty, scholarship, and creative thinking. Unfortunately, with the current page limits on most grants, this often becomes a struggle for many investigators. In other words, finding balance in the grant to reflect the high quality of scholarship, innovation, creativity, and presentation of material that supports the required "science." In general, **creative thinking** is clearly a requirement for successful grant writing. It is important that you recognize that once you publish your findings in a public domain (journal or book), the ideas you hold dear are now open to the public both for scrutiny and sharing. This is why we can sit today and discuss Mendelian genetics, Heisenberg's Uncertainty Principle, Darwinian evolution, Einstein's quantum physics, Hubble's astronomy or Leakey's paleontology and discovery of hominid ancestral lines in Africa. Once ideas become available to the public as published books or peer review articles, it is hard to own them; they will become part of our intellectual heritage, shared and discussed forever.

One important distinction to realize is that publication should not become a surrogate for real recognition by your colleagues, rather it is the pathway to recognition; in essence it is the road upon which you will tread. You will get more points (respect) from your colleagues if you can eloquently expand on a publication at a seminar or presentation than if your prose is poetic. Publications are an important yardstick not only among your more immediate academic colleagues, but throughout the scientific community and among lay people as well. There are countless examples of current Television talk show hosts that possess an M.D. or Ph.D. degree in some specialty and that continue to publish trade books. Their effort to boost name recognition and fill an important gap in the literature fits an important scholarly paradigm. All of your efforts and resources should thus be marshaled toward working your own magic and with this important goal in mind. While science is in essence a social dialogue, it rests on the principles of discovery, creativity, and original thinking. The impression you need to come away with from this workshop is that **hard work will pay off in the end** (but recognize that the end may not be within sight),

you should focus on a few measurable, reasonable, obtainable goals (be the master of few not the king of many), and you should continue to pursue your own ideas with rigor and respect.

Step Two: Understanding how to showcase innovation in theory and approach.

One of the more difficult moments during any grant review is when two reviewers are diametrically opposed in their review of a grant, producing wildly different scores. One reviewing has given the grant the top score possible (1 in NIH terms) and the other reviewer carries a dour face and has given it a score of 7 (below the payline). The conversation between reviewers can go something along these lines:

Reviewer #1: "*I am not seeing the innovation in this grant.*"
Reviewer #2: "*This is a very creative and innovative grant, discussing an important and timely topic, rife with wonderful ideas. I really wish I had thought of this."*
Reviewer #1: *"I just don't get what they are doing, it is not clear what their intention is and what the final product will be. Can they even test this idea in the real world?"*
Reviewer #2: *"They have a very clear picture of the work product and they have detailed a very reasonable production timeframe to achieve their goals."*
Reviewer #1: *"This is just not a significant public health concern, the investigator fails to make clear the grant's innovation, and I have specific issues with their approach."*

For the purpose of this conversation, an important point to make is "Why do the reviewers differ so much when they are reading the same grant?" Also, what does each reviewer mean when they discuss a grant's "*innovation*?" In a later portion of the workshop we discuss "innovation"; making sure to provide examples and definitions that you can use to guide your own writing. Innovation is the core of scientific thinking. Put quite simply, innovation represents change, or departing from the "norm." Innovation is pushing the event horizon and doing something that has not been done before, or presenting normally occurring events in a very different and unique way. As an interesting sidebar, when we review grants, there are two competing forces; on the one hand, we are discussing innovation as a proxy for "change" and fighting the norm, when on the other hand, science, by definition, is slow to achieve distinction, slow to change, and extremely conservative in its motion. These competing forces should be resolved somewhat as you write your grant.

An Example of Innovation

The discussion over innovation can be readily seen in the work of American astronomer Edwin Powell Hubble, who, working from his Mt. Wilson observatory in Pasadena, California, suggested the universe is expanding equally in all directions and with no ultimate horizon. He based his theory (i.e., the volume of space in our universe) on observations of galactic shift using the most rudimentary telescopes and high-resolution photometric and spectral measurements. However, later when astronomer's tools became more precise, Hubble and those that followed

in his footsteps would be able to resolve, quantitatively, the inflation rate of the universe. The important take home message here is that, given the historical context of his discovery, and the rudimentary tools available to him at the time, Hubble's work in galactic and planetary movement was innovative by definition.

Step Three: Understanding how to highlight your unique professional skills.

Applicants for NIH fellowship (F) or career (K) awards are seeking ways to stimulate their careers. However, these scientists may be skeptical about highlighting their professional acumen on the grounds that this section of their application is "*paper thin.*" With so few publications and so few "discoveries" they feel this will reduce the chances of netting a promising review. However, keep in mind that all of the competition for the same piece of the pie (funding dollars) faces the same yardstick with few exceptions. If your publication track record is not substantial, highlight other features of your training including mentorship, active work in the field, and presentations at conferences, specialized training, and anything that reinforces the building blocks of a scholarly career. At some point, we are all equal in our publication track record (we all start with "0") and any distinctions in this regard come from the hard work mentioned above. In some cases, a very thorough explanation of mentoring experience with extra attention paid to seminars, hands-on training, exposure to specialized laboratory techniques, cross-laboratory training, summer internships, and the like will alert reviewers to the 'extra ounce' of scholarship. It goes without saying that the reviewer is looking for some special feature of your training program that merits recognition and reward.

Step Four: Understanding how to collaborate: The essential nature of team science.

Most of what we consider "*modern day physics*" was penned by Sir Isaac Newton in 1687 as part of his major opus titled "***Philosophia Naturalis and Principia Mathematica***." It is without question that the durability of his ideas have influenced physics, mathematics, astronomy, even cosmology. His seminal work laid the foundation for calculus, optics, gravitation, the laws of motion and classical mechanics (how things work in the physical universe). The long trail of ideas penned by Newton and his disciples fosters the realization that ultimately the best of science rests with a long tradition of sharing ideas, pushing innovation, and penning these ideas in an acceptable format (journals and books). Names like Locke, Voltaire, Galileo, and Leibniz have to be considered contemporaries of Newton who inspired the thinking of that time. For India we recognize important scientists that have made contributions in physics, mathematics, chemistry, medicine, and natural sciences. Counted among these are Salim Ali the great ornithologist, C.V. Raman who won the Nobel in 1930, Jagadish Chandra Bose who advanced thinking in radio and microwave optics, the 1968 Nobel winner, Har Gobind Khorana for his work understanding how nucleotides in nucleic acid aided protein synthesis, the 1983 Nobel winner, Subrahmanyan Chandrasekhar for his discovery of the evolutionary stages of massive stars, and my own favorite, Prasanta Chandra Mahalanobis, a physicist and mathematician known for his groundbreaking work in multivariate statistics (countless other names decorate the halls of Indian science).

Step Five: Building capacity: Implementing and sustaining change.

In 1985 noted business consultant and author Rossabeth Moss Cantor wrote a book called *The Change Masters.* In this book she artfully outlined several instrumental steps to create, foster, and sustain workplace change. The bottom line in her book is that change is a psychological *manifestation of beliefs.* In no uncertain terms, she wrote that the role of business leaders is to sustain these beliefs as a means of improving technology, instituting innovation, and improving the work ethic of employees. The problem is that very few of us recognize the need for these types of *mastery* beliefs in our scientific lives. We rarely discuss what we mean by innovation, we rarely get together and review new technology that might improve our own scientific endeavors (e.g., changes in the way survey researchers gather data using online web platforms as opposed to the old fashioned paper-and-pencil surveys), we rarely discuss our career goals openly, and we rarely discuss how to improve or strengthen the nature of our professional collaborations.

How often do we attend required faculty or laboratory meetings and walk away disgruntled that "precious" time was wasted? Increasingly we find these meetings bothersome and over time we contribute less and less of our energy and resources. As we mature into our profession, only a few of us attend workshops or summer institutes and while we can glean very important information from these opportunities, the larger core of investigators, researchers, teaching faculty do not have the time or resources to attend "trainings." For those among us that want to continue to grow, sew our intellectual seeds, and reap the benefits of collegial conversations, we need help to sustain our "learning curve." We can get this help by using technological innovations that are available in the workplace. Some of the changes that may provide more fertile grant collaborations include:

- Have regular monthly (routine) staff meetings to discuss new innovations
- Use the phone regularly to contact potential collaborators
- Talk with experts that may consult on your grant
- Reach out and create the next event horizon on your own
- Build your own technical assistance and support mechanism from inside out
- Work closely with local CBOs to promote your own research agenda
- Find creative people and discuss new ways to collect data
- Use VoIP technology to routinely meet with distant colleagues
- Always find ways to engage in refreshing conversations

Researchers, particularly young investigators, take a long time to learn the lessons we outlined above. It is very important that you realize to be an "expert" in any one field requires tremendous intellectual powers, fantastic resources, loads of time, and a tremendous capacity to wed many different types of expertise under a single roof. Consider that routinely, the different components of science (applied, behavioral, or otherwise) can include the following expertise:

• Power (sample size calculations) • Sampling and recruitment • Randomization (cluster designs) • Instrument development • Statistical analysis • Psychometrics (lab measures) • Survey construction • Substantive expertise (e.g., biochemistry, physiology, pain studies, family processes)	• Field-work • Clinical trial experience • Intervention methodology • Evaluation • Research design • Hypothesis construction • Administrative planning • Budgetary matters (costing science) • Program design (implementation)

This is tremendous coverage in research skills (M.D. or Ph.D.) if you can engage all of these skills under one skin. The better tactics, which we cover in this workshop involve:

- Build a collaborative support network of expert consultants
- Find in-house colleagues and staff
- Develop the necessary administrative infrastructure
- Seek mentoring experiences
- Develop support systems to review grants in-house (Red Team)
- Invest in developing younger faculty (mentoring)

Step 6: Knowing who you are and what you are capable of doing.

The social psychologist Albert Bandura, who fathered the concept of "self-efficacy," gave a talk at the *Nebraska Symposium on Motivation.* In the published version of his speech, he wrote:

> "The emerging evidence indicates that the achievers, the innovators, the sociable, the nonanxious, the nondespondent, and the social reformers take an optimistic view of their personal efficacy to exercise influence over events that affect their lives. If not unrealistically exaggerated, such self-beliefs sustain the motivation needed for personal and social accomplishments" (1991, p. 96).

Other quotable phrases worth mentioning from his talk include:

> "Simply adopting a goal, whether an easy or a challenging one, without knowing how one is doing, or knowing how one is doing in the absence of a goal, has not lasting motivational impact" (p. 81).

> "Perceived self-efficacy is another cognitive factor that plays an influential role in the exercise of personal control over motivation. It is partly based on their self-belief or efficacy that people choose what challenges to undertake, how much effort to expend in the endeavor, how long to persevere in the face of difficulties, and how much stress and despondency they experience in the face of difficulties and failures" (p. 82).

> Those who harbor self-doubt about their capabilities are easily dissuaded by failure" (p. 83).

Let's review for a minute now that you have had a chance to reflect on these quotes from a leading *expert on mastery and motivation*. First, you will write grants as part of a larger ambition to be a successful scientist, professor, colleague, breadwinner, and hopefully knowledge maker. But the real issue is what will keep you going? In other words, when you have too much on your plate, too many classes to teach, too many article revisions, too many committees, and too many pressures to deliver your 'academic product,' what will keep you writing grants to succeed in obtaining independent funding? This is the critical question that you need to ask yourself, but you may also want to pose this question to your colleagues, mentors, and any successful scientists that you interact with routinely. While I would not expect there to be one single answer from all these disparate sources, consider that most of those you encounter will talk about reaching some "bar," about setting some standard or some "goal" to achieve and never giving up.

Second, you will write grants that you think are the best piece of scientific work you have done, the culmination of your career to date, the most exemplary piece of writing and thinking that has jumped from your mind to the page. And lo' and behold your grant will not fare well during review, given such a low priority score that it is sent home packing. Again, read carefully through the quotes from Bandura about motivation, about your sense of personal self-efficacy, and about what efficacy does in terms of perseverance, about sticking to your guns, and how efficacy can help you overcome doubt and failure.

It is fitting then, that we end this section of the workbook with another quote from Bandura, in which he said:

> "There is a growing body of evidence that human accomplishment and positive well-being require an optimistic and resilient sense of personal efficacy. This is because ordinary social realities are usually fraught with difficulties. They are full of impediments, adversities, failures, setbacks, frustrations, and inequities. Success usually comes through renewed effort following failed attempts" (p. 94).

And that is why we persevere, sometime feel downtrodden, pick ourselves up, dust ourselves, off, revise and resubmit.

VII. Ten Tips for Writing Effective and Successful Grants

Some of the tips listed below are taken from The Complete Writing Guide to NIH Behavioral Science Grants, L. M. Scheier, & W. L. Dewey (Eds.), 2008 Oxford University Press, 506p.

Tip #1: Remember that synthesis (cross-fertilization) is sometimes as valuable as creating *de novo*. Some of the best programs available (e.g., basic or applied science) are hybrids of existing theories or blends of logic models that are carefully crafted to work in new situations, with different populations, and that have been slightly "tweaked."

Tip #2: When you are done writing your grant, take the time to review the grant's content. Make sure that whatever you wrote in the abstract should be a beacon that sheds light on your grant as the remaining grant material unfolds. Ask yourself, "Is there a story and how well is it told?"

Tip #3: Whatever you wrote down in your aims, make sure you revisit them in the research hypotheses, statistical analysis, and the overall significance and importance of your research.

Tip #4: Whatever you state as your research study aims, make sure you carefully delineate analyses that will address these aims (one-by-one). If you have a logic model, make it shine!

Tip #5: Whatever you do, don't leave any detail out; thus match your budget's dollar figures to the actual science and execution of the grant. These details can make your grant sink or swim.

Tip #6: Whatever you do, don't assume. If you are not sure then call your project officer or the funding agency and ask questions. Find a "lifeline" in a colleague that has experience writing grants, and ask for a definitive answer. The web can also be helpful to find answers.

Tip #7: Whatever you do, at the end of your writing day, make sure there is a sense of cogency, completeness, and consistency (i.e., the logical train of thought).

Tip #8: Whatever you do, make sure your grants spins a story, with a beginning, middle, and an end, with characters that make sense to the reader; and that it is "*exciting*." Don't bore.

Tip #9: Don't think that any one section of the grant is less important than another one. Reviewers have a tendency to look for fault everywhere and anywhere.

Tip #10: Remember and apply "Occam's Rule or Okham's Razor." William of Occam was a 14th century Franciscan friar who extolled the virtues of simplicity. Philosophers resort to Occam's razor as a neat and tidy explanation of simplicity. The Latin phrase "*entia non sunt multiplicanda praeter necessitatem*," translates to "entities should not be multiplied beyond necessity." Read your grant with this ***Razor*** sharp idea in mind; don't write in an obfuscating manner, parsimonious models are better for the field than overly complicated models with poor semantic and axiomatic connections.

VIII. Art versus Science: How History Dictates What We Think

If any of you are familiar with the tenets of dialectical materialism (the writings of philosophers Karl Marx or Georg Hegel) these individuals suggests a tacit recognition that man is concerned with his power of reasoning. These philosophers and others of the same "genre" (Kant, Leibniz, Spinoza, and Heidegger, to name a few) emphasized "where does thought come from?" Some of these individuals were concerned with the factors that shape thought, in particular those historical influences that culture thought over time. Although these philosophers proposed slightly different tenets, most believed that man was responsible for his own thinking and that history was a significant contributor to the development of ideas. In fact, history was the best way to monitor the flow of ideas across people, places, and time. History, to paraphrase Hegel, has this uncanny ability to look back as much as it can foreshadow the future. In this respect, a good scientist realizes that his or her ideas are not created inside a vacuum or without some tacit reference to standing on someone else's shoulders, shoulders that bear the brunt of discovery and prior rumination.

The work of science is laborious, conservative, methodical, and repetitive. We spend loads of precious time connecting ideas, like dots as we formulate pictures (ideas). It is important to make

those connections through historical reasoning, theoretical proofs, and other ways that make it possible to connect the dots of reality with our everyday experiences. Essentially, as the picture of ideas unfolds, we come to realize there is an element of "art" to science. Young investigators should keep in mind that many great minds that came before you made it possible to start where you start today, with the ideas you hold current. In fact, you should always keep in mind, the questions those individuals asked, no matter how primitive their tools, were no less important than the ones we address today.

The currency of a grant, its *touchstone* value has a lot to do with how directly the grant ties in with history and draws from the theoretical strengths of previous thinkers. These are the connections you draw out for reviewers, enabling them to see where you came from and where you are headed. This type of thinking and reasoning should not be buried or hidden in the grant's significance section. Rather it is essential that a grant writer continually refreshes the reader on the importance of their topic, its relevance to current public health agendas, its role in stimulating change, and its immediate application to rectify a problem. While we are not preaching the virtues of being historically accurate to the point of forgetting newer and more novel techniques, we do need to reinforce the importance of remembering scientific lineage.

IX. Philosophy and Science: The Interface between Knowing and Knowledge

All of us are at some level familiar with the difference between induction and deduction. The use of inductive logic is what makes the wheels of science go round and this is coupled with deductive thinking that helps science smooth the rough edges of our knowledge. We gather information and use this information to fuel our own epistemological growth. Scientific thinking is after all, an attempt to explain the known from the unknown. Scientific thinking has, after all, a certain style, modus operandi, and purity of thinking that paves the way for mankind to acquire greater information about the universe we inhabit, the reasons we are here, and the ultimate suggestion there is a purpose in our existence. Science is best described as a search for the truth; it is part of the quest of understanding our world, the universe, and our knowledge of these relations. With the promise of scientific thinking comes a certain "buy-in" to a style of reasoning and this reasoning is based on inductive and deductive logic. Many of us, in our own innocent manner, wait too long to realize what the buy-in entails, and we are slow to give credence to the dispassionate ways of science and we are even slower to accept the terms of scientific inquiry (i.e., the methods of empirical inquiry). Many of us forget that science did not appear on our intellectual horizon yesterday, but rather is a reflection of centuries of thinking and rationalization about how man can learn more about the world, the universe, and our role in procuring knowledge about both. It is only when we can grasp bits and pieces of this history of scientific thinking that we can be better grant writers, because once this occurs we can then accept the premise that science is the right way (i.e., the best method) to find the truth.

In his book *Conjectures and Refutation,* philosopher Karl Popper (1963) laid bare the essentials of critical rationalism and the way to structure theory. Popper suggested that we can never truly find the truth, but we can at least discard or rule out poor or weak explanations. In essence, we can never really "know" or prove something right, because there will always be alternative explanations, considerations that did not come to mind, and ways to conceptualize the problem using information outside the framework of our current thinking. However, with our scientific methods at hand, we can at least pare away the bad explanations that do not suffice and withstand empirical scrutiny (i.e., corroboration). In an earlier treatise, *The Logic of Scientific Discovery* (1959), Popper discussed the patterns in our thinking and the path toward scientific progress that manifest our need to accumulate more knowledge. These two books alone are must "reads" for young investigators. Both books provide ample suggestions that help investigators shape their aims and hypotheses and yield a sense of the value of science, as a method of inquiry and as the harbinger of our collective knowledge. Because Popper was a firm believer that science must invest equally in discovery as it does in refutation all scientists must think long and hard (before you write your grant) how another individual, with a slightly different perspective, would refute or try to disarm your theoretical position. For instance, if you fastidiously claim that self-efficacy is a major component of why certain behavioral interventions work, remember that someone out there, a potential reviewer, is not a firm believer that self-efficacy exists or that it can be measured. Even more eventful, this same reviewer does not believe self-efficacy is amenable to modification through strategic interventions. Thus, a major focus of your application, your modus operandi, should be to convince the reader that you have given a lot of thought to the principles you wrote down on how you will assess self-efficacy, how self-efficacy functions, and how the program you are designing will change self-efficacy. Remember the reviewer is not always on your side.

Another way of thinking about your purpose in a grant application is not to regale the *quid facti* (emphasis on facts) but to regale the *quid juris* (justification or validity) of your research aims. In this respect, your grant is based more on explicating the logical dependence of any specified relations, the testability of your study, the formulations or constructions of your ideas (many grants get trashed on this note alone), and technical applications. At this point deduction kicks in and you base your thinking on the specified theory. What would happen if the theory is correct? In other words, if you are a behavioral scientist and self-efficacy theory is the basis of your application, what are the predictions that would arise if the theory was correct? This premise is no different if you are managing a pharmacological drug trial. If the psychotherapeutic regimen works and the theory of cellular physiology is correct (the specified ligand or liposome bonding), what are the predictions regarding patient recovery that you can make given the explanatory theoretical framework.

Popper talked about the situation when a theory passes detailed and "severe" tests and proves its mettle. In *Conjectures and Refutation*, he detailed his *falsification hypothesis* and made transparently clear that the goal of scientific thinking is to rule out what doesn't work. Your grant must embody this type of thinking and lay bare the inner working of your thinking. Grants that get

funded are noticed by reviewers because they attend substantially to several key indicators including highlighting their promise (innovation), detailing in precise terms the investigator's acumen, specifying the strength of the environment (and not just listing laboratory equipment), and paying serious attention to logical dependence, what we all *approach* and the methods used to explicate the science. The best piece of advice a mentor can provide is to be highly critical of your own writing in this regard.

X. Editing Guidelines

It is incredibly important to consider what editing process you will implement in your grant construction. For instance, will you as the lead investigator, be the only set of *eyes* that sees the proposal before submission. Will there be a team of supportive personnel that helps you edit the proposal in the final stages prior to submission? Many investigators assume the individuals in contracts and grants (or research development offices) will read the proposal and check it for grammatical clarity and logical consistency. Bet not. The sole responsibility for making sure the proposal reads smoothly is with the principal investigator. Therefore, it is prudent to consider how you will approach this task, particularly if the writing of the proposal largely reflects your own effort and another set of *eyes* has not glanced at the work.

It is generally considered very prudent and favorable to circulate your preliminary proposal to a colleague or group of faculty members that have time to conduct a thorough review. The value of this process should not be underestimated. Being able to share insight and review the proposal prior to submission can help an investigator "*head bad things off at the pass*." The benefits of such an "*internal*" review are very striking and bode well for any institution that has already established such a policy and protocol. It is much better, for instance, to find out a week before the proposal deadline that you have not addressed the RFA or RPF as specifically as you might have or that you are missing critical ingredients of the proposal that will ensure a low (and fundable) priority score. Another way to think about this process is that many of your colleagues have conducted reviews, may have chaired reviews or been ad hoc members and they can provide valuable insight to the science of your proposal, innovation and the overall sales "*job*" you performed through your writing. Having another pair of eyes read the proposal will find errant peccadillos (typos), missing references, poorly constructed sentences, grammatical and syntax problems, absent materials, and budgetary issues you may not have considered.

In light of this, some outfits use the "*Red Team*" approach, a group of designated writers or scientists who review proposals for their grammatical soundness and logical consistency. The team is usually comprised of individuals with extensive writing backgrounds (maybe even a person with advanced graduate training in English composition) and other investigators who have a keen eye toward review procedures and protocols. It behooves any institute to assure the success of "*all*" of the investigators and not only a select handful of seasoned veterans. The more junior investigators

that can obtain funding, the larger the critical mass of investigators that can be cobbled together for a larger collaborative multisite trial or center proposal.

Every institute should develop a critical *crib* notebook that determines the writing and presentation style of the organization. The worst-case scenario is when two or more investigators collaborate on a proposal and the writing gets mangled because of overwrites and rewrites all in the hope of obtaining a consistent style. That *style* should be available to each investigator as part of the laboratories overarching research *zeitgeist* or modus operandi. The absence of a *Turabian* stylebook will hinder any new investigators when they submit their proposal for review by senior investigators. The senior person will have fashioned a particular style and use this to *edit* the junior person's work. This will result in a manuscript or proposal going back and forth several times until the *personality* writing conflict is resolved. Some institutes use a *passive* writing style (e.g., "the fact that no rats were able to solve the maze was reported" vs. "the investigator reported that no rats were able to solve the maze"). Reviewers get accustomed to the different styles and usually don't evaluate the proposal based on style points as much as grammar and presentation. Sloppy proposals are often a point of discussion because every reviewer has their moments and become testy when a proposal is difficult to read, does not track well, and has many grammatical soft points.

The stylebook should outline specifically language conventions, word usage (tense), abbreviations and acronyms (e.g., many labs use LCM [latent curve modeling] while others use LGM [latent growth modeling] while others use GM [growth modeling] to capture "*latent growth modeling*"), capitalization, compound words, hyphens and dashes, numbers, punctuations, references, and citations. The issue of citations is inherently important because the page limitations of grants and contracts often *strangle* investigators looking for ways to shorten the text. One suggestion is that the investigator makes a choice at the get-go and follows their lead. If space is a consideration, using the Vancouver reference style can only help in this case (e.g., "the authors[23] reported that all the rats could solve the maze" vs. "Smith and Jones (1965) reported that some of the rats could solve the maze").

This type of *quality control process* should be built from ground up with certain individuals given responsibility to learn the different options for producing scientific works. Grants are not the only consideration when it comes to production concerns. Papers, journal articles, contracts, books, presentations all fall under this rubric and help make the laboratory a team that works collectively toward a goal. The goal of any group should be to develop the highest quality product given their resources. If the team lacks a person talented in power analysis, someone has to find this individual to complete the grant application. Power is essential to determine whether the study will have scientific validity and be applicable to real world settings. The same goes for writing and style editing. If the team lacks an individual with these skills, go out and find someone who can give the time and resources to make sure the proposal is state-of-the-art and reflects the highest quality effort.

XI. Small Business Innovative Research Grants (SBIR)

SBIR grants are an offshoot of the government's need to have grants funded that can bring products to market more quickly than research grants. SBIR grants therefore include a stage that emphasizes commercialization and product marketing in addition to any grant components that identify pure science as an aim. Readers interested in gaining the upper hand on this type of funding mechanism (R44) are encouraged to read a chapter by Jeffrey Hoffman, Susanna Nemes, and William Hansen (2008), titled "SBIR Funding: A Unique Opportunity for the Entrepreneurial Researcher" that appears in *The Complete Writing Guide to NIH Behavioral Science Grants* (Oxford University Press).

The purpose of this section of the workbook is to provide you with experience formulating research questions, hypotheses, and specific aims and developing them into an SBIR. The exercises below will walk you through the process of creating a theory driven and empirically sound SBIR grant.

Introduction

- The Small Business Innovation Research (SBIR) program represents a unique Federal funding program that, as of 2005, has been awarding over $2 billion of grants and contracts annually. Federal agencies with extramural research budgets of over $100 million are required to administer SBIR programs using an annual set-aside of 2.5% for small businesses. The intent is to stimulate research and development of innovative products or services that have the potential for commercialization and public benefit. Small businesses are defined as for-profit companies with less than 500 employees.
- Currently, 11 Federal agencies participate in the SBIR program: the Departments of Health and Human Services (DHHS), Agriculture (USDA), Commerce (DOC), Defense (DOD), Education (Deed), Energy (DOE), Homeland Security, and Transportation (DOT), the Environmental Protection Agency (EPA), the National Aeronautics and Space Administration (NASA), and the National Science Foundation (NSF).
- The Small Business Technology Transfer (STTR) program is a related set-aside program to facilitate cooperative research and development (R&D) between small businesses and U.S. universities or non-profit research institutions funded by Federal agencies with extramural R&D budgets of over $1 billion, using 0.30% of their budget. Currently, five Federal agencies participate in the STTR program: DOD, DOE, DHHS (NIH), NASA, and NSF. The intent of both the SBIR and STTR programs is to use small businesses to facilitate research and development of innovative products and transfer this technology from the research setting into the commercial marketplace.

SBIR Phases

- The SBIR funding program is organized in three performance phases. Phase I is intended to establish the technical merit and feasibility of a proposed product or service. Phase I is generally awarded for a six-month period with a funding ceiling of roughly $150,000. Requests for funds exceeding this amount, or a time period longer than six months need to be well justified. During Phase I, some type of prototype is generally developed and evaluated using pilot studies to determine the feasibility of proceeding to Phase II.
- Phase II generally entails the full development of a product over a period of up to two years with a budget of up to $1,000,000. A longer time period and/or additional funds can be requested, but will require a clear justification. During Phase II a prototype is fully developed a tested using a more rigorous evaluation (i.e., RCT). These are general guidelines but the specific requirements are determined by agency and exceptions are also allowed with permission from the agency. In most cases, both Phase I and Phase II projects can receive no-cost extensions.
- Phase III is the commercialization phase and entails the commercial marketing and distribution of the product by the small business. Some agencies provide some minimal support or technical assistance for Phase III. Generally, the small business is responsible for the funding of this Phase but may seek other external sources of capital or business partnerships for this commercialization phase.
- Another variation of the application process for some agencies including NIH is the Fast-Track mechanism. This mechanism allows applicants to submit the Phase I and Phase II applications simultaneously, along with a more detailed commercialization plan. The purpose of the Fast Track mechanism is to reduce the period of time between Phase I and Phase II. The time period between the two phases can be at least a year, and possibly longer if reapplication for funding is necessary and especially if the Phase II application is submitted only after the Phase I component is completed. Because Phase I captures information regarding feasibility, many SBIR applicants tend to hold off their Phase II application until Phase I is completed. The Fast Track mechanism should be considered when a product has high potential for commercialization, an evaluation plan has been fully developed, is poised for implementation, partners have been aligned for both Phases, and a long delay between Phase I and II could be detrimental to the project. However, Fast Track applications generally receive rigorous attention by reviewers and we would advise that this mechanism should not be utilized until the small business has demonstrated some record of success within the SBIR/STTR program. It is important to include a section in the Fast-Track proposals where you specifically justify the need for continuous funding through the Fast Track mechanism.
- In the case of most SBIR grants, supplemental funds can be requested once a grant is awarded. In general, the supplemental funds can be up to 25% of the grant award amount. The availability of supplemental funds is largely determined by how much funding in an agency's set-aside is left unspent at the end of the fiscal year. Supplemental funds can be requested to complete additional related work that would

enhance the viability or success of a project. Funding supplements should be requested as early as possible once a grant is awarded, mainly because the scope of work outlined in the supplement request will need to be completed at the same time as the parent SBIR grant. A supplement will not be awarded if requested during an extension period of the parent grant. Therefore, for Phase I grants, requests for supplements should be in the first month of the grant or not too long after. This provides sufficient time for the supplement request to be processed and for the proposed work to be completed. For Phase II grants, requests for supplements should be made during the first year of the grant. Earlier is always better when requesting an SBIR supplement. It is advised that the PI discuss these issues with the assigned Project Officer prior to any such requests. The application process is simple, consisting of a letter describing the need for the additional product, the steps that will be taken to complete the product and a budget. The supplement application is in essence, a 3-4 page mini-proposal.

Developing your SBIR

Exercise 1: Developing Your Research Question

Often, we have a vague notion of what we are interested in studying – an idea that we encounter through reading or based on experience. Often, we begin with the simple premise "why does a particular process occur, what induces a particular outcome, or what makes an intervention work or produce a particular outcome?" Part of the process of developing our initial ideas also comes from noticing a "*gap*" or a "*hole*" in the literature. We can address this "gap" by creating a "bridge" that stretches across this gap. For an SBIR, your goal is to devise a new treatment or intervention and to rigorously evaluate this new product. Therefore, your research question should be clearly delineated before beginning the grant writing process. Let's go through the three most basic steps of forming a research question.

Step 1 – Your idea. When reading journal articles, attending conferences, or conversing with your professional colleagues, a thought or idea may have popped into your head concerning future directions your research could take. What was that original thought or idea?

I think …

Step 2 – The 5 W's. Now it's time to turn that original thought into a research question. Recall the 5 W's – Who? What? Where? When? Why? and sometimes How? Consider how each of these questions pertains to your thought or idea and answer the questions below.

Who?
_____
_____

What?
_____
_____

Where?
_____
_____

When?
_____
_____

Why?
_____
_____

How?
_____
_____

You may not think each of these questions is applicable to your original idea; however, the more you expound upon these questions, then the greater detail you will have that support your hypotheses and help delineate your specific aims.

Quick Tip: State your research question clearly and succinctly upfront. A simple sentence in the opening paragraph or section of your proposal will start your proposal off on the right foot.

Step 3 – Composing the research question. Now that you have answered the questions above, try composing your research question below.

My research question …

Taking a Step Back
Have I coherently articulated the issue or problem I wish to address?
Sometimes it helps to run your research question by others working in the field such as your colleagues, mentors, or supervisors. Now turn to the person next to you and read them your research question. In what ways could your research question be clarified or improved upon?

Exercise 2: Hypotheses and Specific Aims

Once you have devised your research question, you can move forward to create your hypotheses. Many times our original idea has hypotheses built into it. Take a moment to revisit your initial idea above, and then reread your research question. Contemplate these questions:

What hypotheses are included in your original idea?
_____
_____

What do you think will happen if your research question is true?

_____
_____

What are you trying to prove/disprove?
_____
_____

Does more than one hypothesis come to mind? What are they?
_____
_____

*H*ypotheses frequently take the form of "if/then" statements; that is "if this sequence occurs, then I expect this outcome." Or, in the case of hypotheses stated in a statistical form, they may be phrased as the null and alternative hypotheses. Try spelling out your hypotheses in the space below.

Hypothesis 1:
_____
_____

Hypothesis 2:
_____
_____

Hypothesis 3:
_____
_____

The specific aims of your research state the overall goals and specific program objectives of the study. Because the overarching goal of your research is to test your hypotheses, it logically follows that your specific aims should stem directly from your hypotheses. Specific aims are not simply a restatement of your hypotheses, but an extension of your hypotheses. Here you answer the question: How do I intend to address my hypotheses? Review your hypotheses and devise your specific aims based on these hypotheses below.

Quick Tip: Highlight your specific aims. Consider bulleting your points, placing them in a textbox, or bolding or italicizing them. Doing this makes your specific aims stand out to the reviewers by illuminating your points.

Specific Aim 1:

_____

_____

_____

Specific Aim 2:

_____

_____

_____

Specific Aim 3:

_____

_____

_____

Taking a Step Back

Do my hypotheses logically follow from my research question?
Are my specific aims plausible?
Can the specific aims be achieved given the constraints of the funding mechanism?
Again, here, a second set of eyes may be helpful. Ask a colleague to review your hypotheses and specific aims. Do the hypotheses and specific aims make sense given the research question?

Exercise 3: Background and Significance

In background and significance section of your proposal you demonstrate your familiarity with the literature and research related to your research question. Here, also, you will describe the technical or social problem your research will address, and state the significance of your

project for the target population, and/or society at large. Additionally, you will describe any theoretical underpinnings to your approach. Think about the questions below and answer each.

What is the extent of the problem/issue that I wish to address?

To whom does my research/product apply?

What has been accomplished in the past in this field/area or for this population?

What is the theory behind my research?

Does this study/product address an important problem?

Taking a Step Back
Is the argument supporting the need for this research clearly made?
Conduct an "in-house" review. Have a trusted colleague read and critique your proposal. The feedback will be invaluable.

Exercise 4: The Research Design and Timeline

The previous exercises have led you down the path to designing a formidable research plan. Research questions bring about hypotheses → hypotheses produce specific aims → and specific

aims are what you will accomplish through your research design. The approach section of your proposal should provide a detailed description of the research design, methods, and protocols used to evaluate your hypotheses, and should follow the rigorous academic standards for conducting research in your field. Note the specific aims you created above and state how you will measure them below.

Your research design may involve potential confounding factors and potential challenges (i.e., threats to internal validity). This section of your proposal should address these issues and provide a justification for why you have selected the proposed design. Is randomization possible, necessary, the only route? There is propensity scoring and other weighting methods to consider. You're your "control" or treatment as usual group make for a good comparison or are you stacking the results toward the intervention group? Weighing the pros and cons of your research design and laying out the potential limitations may help you tackle any issues that may arise before you begin writing. This information should be included throughout your work plan, although you can create a table for yourself like the one below to think through these concerns. It is helpful to include examples from other work you have done, in which you have solved similar challenges.

Possible Challenges	**Actions Taken to Address the Challenges**
1.	
2.	
3.	
4.	
5.	
6.	

In conjunction with your research design, you should provide a description of the sequence of activities and a timetable for the study. It is important to outline what specific aims will be accomplished in what time frame by whom and with what outcome. Your aims may be broken down into smaller goals that are achievable in pre-specified periods of time by assigned members of the research team. Complete the table[1] below. Consider what the outcome or milestone will be for each goal.

[1] A table similar to the one above can be included in your SBIR proposal (or any R funding mechanism).

Table 1. Consortium/Contractual Task Assignments				
Task	Title	Entities	Month(s)	Description
Phase I				
D.1.1.	Kickoff meeting	GRP1	1	Initial organization meeting with all consultants
D.1.2.	Game logic & architectural plan	GRP1 & GRP2	1-6	Specify the game logic, underlying algorithms and create the wireframe schematic
D.1.3.	Story board #1	GRP3	5-6	Draft initial graphics and provide story boards for focus group meetings

Phase II				
Task	Title	Entities	Month(s)	Description
D.2.1	Virtual Reality game programming	GRP3 & GRP1	13-22	Complete game programming
D.2.2.	Functional validation trial recruitment	GRP2	20-21	Identify CBOs and secure commitment for shakedown trial
D.2.3.	Functional validation trial	GRP1 & GRP2	23	Trial consisting of 100 to 150 SCD patients
D.2.4.	Game programming	GRP2	24	Final game programming for RCT trial

Taking a Step Back
Is the work plan reasonable in the available amount of time?
Is the timeline well structured?
Are the study goals realistic or overly ambitious?
Are the milestones and evaluation approaches appropriate?
Can the aims be accomplished with the proposed plan?

SBIR Commercialization

There are many challenges to the commercialization goals of the SBIR program, especially within the public health sector supported by NIH grants. If a product or service truly possesses significant commercial potential, it is unlikely that you would want to choose the SBIR program as your first source of funding because of the very slow bureaucratic process (including review time) and length of time it can take to obtain the funding and actually conduct the research. Therefore, most of the types of products and services developed under the SBIR program

address unique or specialized public health needs where private sector funding is generally not available. This type of niche marketing can be useful to product developers and help them focus exclusively on an identified market. In addition, commercialization schemes for many types of public health products or services target small markets, making it difficult to find sufficient start-up capital to market or sell these products. Finally, oftentimes the government is also working to address similar public health needs and likewise is developing similar products and services that are offered to the public for free – and it is difficult to compete with free. Nevertheless, there have been breakthrough products funded by the SBIR program (e.g., Norton Antivirus) and there are some useful tips and strategies that should enhance your opportunities for successful commercialization or increase societal benefits.

First, it is essential that you gain a good understanding of the potential market for your product or service. Identify who will buy it. Develop a surefire plan for sales and distribution. Conduct market analyses to find out whether certain demographics support your marketing strategy. A good question, and that should be addressed right in the beginning of the development process is whether the target audience has the resources to purchase the product. Many times, a product developer with good intentions, will target CBOs or community groups and then find they lack sufficient resources to afford the product. Develop a specific marketing plan that identifies the end users. Amortize the marketing plan back on the costs of marketing and sales to ensure the product is priced accordingly and will net a positive cash flow. These are only a few of the many essential questions that need to be asked and evaluated as part of the business plan. Once you have an understanding of the market, you have to decide the best way to reach the target audience. Oftentimes, the market plan is developed by outside parties. Most companies that have the ability to win an SBIR grant and conduct the research required do not possess the financial resources or skills to market, sell, and distribute a product. It is often best to form strategic partnerships with third party licensing companies for these purposes. Licensing can be handled by publishers, distributors, manufacturers, and marketing companies. Large professional organizations that may be possible end users may also team up for distribution. Another useful tactic involves affiliating with national organizations that address the unique health or social needs of specific target populations. If you are planning to market the product yourself, be prepared to invest substantial resources into marketing, sales, and fulfillment (e.g., using PayPal for online purchases) in a competitive market.

Exercise 5. Commercialization

Think through the following points. You want to submit an SBIR Fast Track or Phase II grant, it is your first one, and you know that you have to develop a commercialization plan. You have very little background in business, indeed science and scientific thinking is your strength. Think through your commercialization strategy, including who is the target audience, how large is the market, how will you reach this market, who is your competition in this market, who will your partners be for licensing or product distribution, what are potential side markets, how many "widgets" do you expect to sell and at what price (do you have hard cold facts that defend your

pricing structure?), what percent of the market do you think you can reach, what is your overall outreach and marketing strategy? Present this information to a larger "venture capital" group for feedback and discussion. You can find these capital investment groups, which consist of bankers, VC experts, local business and civic leaders, and commercial enterprises usually meet regularly in the community. They are looking for networking or lucrative financial opportunities and hold meetings to shakedown possible investment opportunities.

Review Criteria

There are specific review criteria, similar to those used for other NIH grants, but for SBIR/STTR also specifically emphasizing innovation and commercialization. Before you submit, you should make sure you address all of the following key areas. You should write your proposal from the ground up keeping these review criteria in mind. You should also ask a couple of colleagues to review your grant using this outline as a guide. Be open to the feedback you receive and revise appropriately. It is always better to get feedback, even if negative, from a colleague before you submit, then later, from the NIH reviewers. The section below includes a brief overview of the main areas for criteria for review and evaluation:

1. Significance:
-Does the study address an important problem? (Public health need?)
-Is the argument for the need for this product/project made clearly/well?
-Does the proposed project have commercial potential?
-Is the proposed product and improvement over what is already available?
-How does the proposed product compare to similar products? Was this addressed in the application?

2. Approach:
-Is the proposed plan a sound approach for establishing technical and commercial feasibility?
-Is the work plan doable in the available amount of time? Is the timeline reasonable? Too ambitious?
-Will the study likely lead to a sound scientific conclusion in the time allotted? (Rigor)
-Does the applicant acknowledge potential problems and consider alternative strategies (is there a limitations section)?
-Are the milestones and evaluation approaches appropriate?
-Can the aims be accomplished with the proposed plan?
-At the end of Phase I, will be team be able to show that their product does what they want it to do?
-Will the target audience be reached with the proposed product/approach?

3. Innovation:
-Are the aims or product original and innovative?

-Does the project employ novel technologies, approaches, or methodologies?
-How is the proposed product different from what already exists in the field?
-Is the proposed innovation appropriate for the target audience?

4. Investigator:
-Is the Principal Investigator capable of coordinating and managing the proposed project?
-Is the work proposed appropriate to the experience level of the PI and other researchers?
-Does the PI have experience doing this type of project? Executing SBIRs?
-Is there a description of the consultants- and are they appropriate? Do they cover any areas of expertise not covered by the research team? Are there letters of support from the consultants?
-Is the PI devoting sufficient time to this project? Will logistics be a concern?

5. Environment:
-Is there sufficient access to resources (e.g. equipment, facilities) to complete the project?
-Does the environment contribute to the probability of success?
-Are there collaborative arrangements that will increase the likelihood of success? Will the collaborative arrangements assist in areas that the small business needs support (such as recruiting, conducting pilot study, etc.)?
-Are there letters of support from the collaborators? Are the letters supportive?

Overall Evaluation:
-Brief summary of strengths and weaknesses

6. Protection of Human Subjects: Will human subjects be appropriately protected? Consents obtained? Risks/benefits described? How will this be done? Are the risks reasonable compared to the benefits?

Data and Safety Monitoring Plan: Only required for Phase II or Fast Track if there is a clinical trial. Does it define the general structure of the monitoring entity and mechanisms for reporting adverse events to the NIH and or IRB?

Inclusion of Women Plan: Will females be included? Why or why not? What is the percent of women in the study? How many and how will women be recruited? Is the recruitment strategy to enroll women scientifically acceptable?

Inclusion of Minorities Plan: Will minorities be included? Why or why not? What is the percent of minorities projected to be in the study? How many and how will minorities be recruited? The recruitment mechanisms should be sound and grounded in the community where the research will be conducted or if nationally, a representative plan should be put forth. Is the recruitment strategy scientifically acceptable and will hold up upon deeper scrutiny?

Inclusion of Children Plan: Will those under 18 be included? Why or why not? How many and how will they be recruited? Is the recruitment strategy to include children or exclude children scientifically acceptable? Does the team have expertise working with children? Note that NIH changed its definition of children from 21 years of age to 18 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-010.html).

Table of targeted enrollment including gender and race: Is an enrollment plan included? Is it reasonable? Does it match what was described in other sections of the proposal?

Additional Criteria for Phase II Applications (include review comments from Phase I if possible for review)

-Did the applicant meet the Phase I goals? Did they demonstrate feasibility? Did the application produce what the investigators said they would produce? If not, did they explain why? Is there a solid foundation for Phase II?
-Is the commercial potential addressed in detail- plan, competition, market analysis, sales of similar products, partners for marketing, etc.?
-Are there solid letters of support from partners? Is there a high degree of commercial potential?
-Is there a detailed Product Development Plan?
-Is there a Data and Safety Monitoring plan- if necessary?

Additional Criteria for Fast Track Applications

-Are there clear criteria for meeting Phase I goals before moving to Phase II?
-Is there a reasonable justification for doing a Fast Track?
-Does the team have experience with SBIRs? Have they been successful in completing these types of grants in the past?
-Have they done similar projects? Included lessons learned that can help with this new project?
-Is there a detailed Product Development Plan? (also called an Architectural Plan)
-Is the commercial potential addressed in detail?
-Did they include materials that show recognition of the competition, market analysis, sales of similar products, partners for marketing, licensing outlets, distribution channels, ROI information, some awareness of production costs, etc.?
-Did they applicant include letters of support from potential business or licensing partners?
-Is there a high degree of commercial potential?
-Is there a Data and Safety Monitoring plan- if necessary?

Additional Criteria for Resubmits (include previous reviewer comments with the new proposal)

-Did the applicant address reviewer comments adequately? In a respectful manner?
-Do the changes improve the revised application?
-Are there any new areas of concern that now need to be addressed?

Top Ten Tips for Writing an SBIR

1. **Keep it Simple:** Keep your project small in scope. Don't be overly ambitious. Make sure the project has a reasonable timeframe and appropriate budget. Most importantly, your application should propose a project that can be completed successfully within the milestones and specific aims set forth.

2. **Commercialization is Key:** It is essential that you gain a good understanding of the potential market for your product or service. Identify who will need it, use it, and buy it. Develop a surefire plan for marketing, sales, and distribution. Conduct market analyses to find out whether demographics support your marketing strategy. Form strategic partnerships with third party companies to market, sell, and distribute a product. Affiliate with national organizations that address the unique health or social needs of your target population and can sustain licensing.

3. **Innovate, Innovate, Innovate:** Make sure the product is unique and innovative – that is offers something new from what already exists in the marketplace. Whether the product uses new technology, renders considerable advances in science, or supplies much needed creative development, ensure that the product takes the field a step forward in innovation.

4. **Conduct Rigorous Research:** A successful SBIR application has to include a sound research platform – both in the development of the application and the implementation. Make sure the application adequately addresses any relevant research already completed, proposes a robust research design, and the collective staff maintains strong, credible research capabilities with a system of accountability.

5. **Budget Wisely:** Make sure the project is within the allowable cost limits and that the budget matches your technical proposal. The percent effort allotted to personnel should be reasonable to accomplish the work to be done. It is important to make sure

staff are not covered more than 100% on government grants and contracts. Carefully consider who is listed as "key personnel" as this cannot be changed. Establish an indirect rate for your company. It is generally recommended to use a 20-25% rate of total direct costs.

6. **Avoid Common Pitfalls:** There are numerous pitfalls associated with SBIR grant applications. Some of the more common problems are: 1) overly ambitious and unrealistic applications; 2) lack of innovation; 3) poor research design; 4) inadequate knowledge of the literature; 5) lack of evidence of potential commercialization or social impact; 6) inadequate sampling frame, 7) questionable recruitment methods, 8) lack of support for true collaboration, 9) major design flaws, and 10) failure to address threats to internal validity (design). Added to this short list, many applications also fail miserably because of not following the grant application instructions carefully.

7. **Consider the Fast-Track Mechanism:** The Fast-Track mechanism allows applicants to submit the Phase I and Phase II applications simultaneously and is designed to reduce the period of time between phases. It should be considered when the product has high potential for commercialization. Warning: Fast-Track applications receive thorough attention by reviewers!

8. **Apply for Supplemental Funds:** Supplemental funds can be requested once a grant is awarded for up to 25% of the grant award. They allow you to complete additional work that would enhance the viability or success of a project. The application process is simple, consisting of a letter describing the need for the additional product, the steps that will be taken to complete the product and a budget. It's a 3 to 4 page mini proposal!

9. **SBIR v. STTR:** There are several factors to consider when determining whether to apply for an SBIR or STTR: 1) There is more funding for SBIRs than for STTRs; 2) Fewer agencies use the STTR program; 3) Phase II funding for STTRs is limited; and 4) As relationship can be established between the PI/key personnel and a university or non-profit, but requires a complex contractual agreement between the company and the university or non-profit.

10. **SBIR Contracts:** The contract mechanism has many of the same eligibility requirements as SBIR grants. Contract solicitations detail the type of product or services the government wants developed. This funding mechanism is highly competitive and it's critical to follow the solicitation guidelines and evaluation criteria to the fullest extent possible. It is best to consult with the appropriate agency prior to submission.

XII. The Financing and Cost Accounting of Science: Budgets and Budget Administration

"The best approach to constructing budget's for grant applications submitted to the NIH and other Public Health Service (PHS) agencies involves the technique of "cost accounting the science," an approach that emulates or parallels the methods and experimental procedures outlined in the grant proposal" (Lewis, 2008).

Budgets are Easy

Preparing a budget for research is similar to the plant-growing process. "*Funny*" you say, because if I had said, "preparing budgets for research is similar to keeping track of the stock market," most of you would throw your hands up in disgust and say, "*Now I know for certain that I will never be able to prepare a budget for my research!"* By no means is it my intention to disparage the complexity and *art* of preparing budgets for research by comparing it to a plant. On the contrary, if the research is complicated, like non-modular categorical NIH grant applications (Lewis, 2008); the budget will more than likely also be detailed and complicated. On the other hand, if the research is simple and straightforward, like modular non-categorical NIH grant's (Lewis, 2008), (in most instances), the budget will be simple and far less complicated (p. 356-360). Fortunately, all grant agencies provide guidelines and/or general application instructions, which should be the first point of reference before writing the grant and most certainly before preparing a budget.

There are some instances where the science (i.e., soil) contains key elements that are appealing to the reviewers, but for some reason you may have not substantiated this in the budget. In some cases, your project (plant) will be fortunate enough to get funded but your ability to fully execute all of the specific aims stated in the proposed research will prove to be difficult. Your lack of funding (or adequate time) may hamper execution of the project and the project may not be successful in the end (and the plant might die). Just as a plant will thrive given the right conditions, the success of the project can be tenuous if the cost to finance it was not well thought-out in the beginning stages of the grant writing process. For example, (as zany as it may seem) you are

proposing to conduct a school-based survey to evaluate whether teenagers abuse certain recreational drugs. The study calls for the students to take a web-based survey and give an on-site blood sample to substantiate their responses to the survey.

During the budget process, however, you failed to cost account for several important items. For instance, you fail to include the cost to hire a full-time lab technician in the data collection years to conduct the blood draw, process the assays, and to travel to the sites. Furthermore, you forgot to include costs to purchase the laptops for the field coordinators to administer the surveys because you thought that you could reserve computers in the library at the target schools. However, you were unaware that the school districts put restrictions on the use of internet service, which is vital to conduct the web-based surveys. Even under expanded authorities, you do not have enough money in the other budget categories to re-budget in order to cover these costs. Changing the scope of work to adjust for these oversights will require permission from the granting agency and the changes may not be favorable to the Program Officer who can decide whether to continue to finance the project.

On the other hand, if the science (soil) does not provide the infrastructure and key elements needed to support the specific aims and the research design, you will likely not get funded (or worse the grant may be unscored) even if you've prepared a stellar budget. Reviewers are very savvy to the expenses of certain things including longitudinal tracking and laboratory techniques.

The "What" Factor in Preparing Budgets

Budget preparation for grant applications is equally as important as writing the research plan. In order to finance and cost account science for research however; there are certain core questions investigators must be able to answer. **These core questions remain the same no matter how simple or complex the proposed research and accompanying budget**. Having the wherewithal to evoke these core questions is what renders budget preparation (and grant writing) easy for some investigators and difficult for others.

When drafting a budget for research, it is important for the PI to invest time to think about *what* resources, *what* infrastructure, *what* staffing, *what* supplies and most importantly, *what* costs are needed to conduct their research. The investigator should lend equal focus to comprehending *what* information the sponsor requires on the budget and what expenditures are allowed against their research dollars (e.g., such as the guidance provided by OMB Circular A-21, the RFA, or within the body of the grant application). Sponsors typically provide applicants with a list of budget items that are allowable (particularly if the funding is restricted). If you are unsure whether an item you intend to budget is allowable and the written guidance is not clear, the sponsors are always more than happy to receive your calls or e-mails of inquiry for clarification on budgetary guidelines.

Additionally, the sponsors' budget guidelines generally include a list of unallowable costs (e.g., membership dues) or restrictions to certain budget categories (e.g., sponsor cannot pay more than 11% for indirect costs). Strictly adhering to the guidance provided by the sponsor and that of your university's office of sponsored research will save you a lot of time in the end. If you find yourself in the position of making your own interpretation of the guidelines because they are vague, it is always best to call the sponsor.

➢ Budget Should Always Reflect the Sponsors Expectations

When reading the sponsor's guidelines it is important to look out for language that provides a directive to the applicant regarding their expectations. For example, does the sponsor set a cap at the total direct cost dollars requested? Does the sponsor require that the PI devote a specific amount of effort to the project? Does the sponsor require cost sharing and/or cost matching and what are the terms of the cost sharing/matching? Does the budget follow the format required by the agency? Submitting a budget and/or grant application that contradicts (or outright omits) the sponsor's expectations or guidance demonstrates a lack of due diligence on the part of the PI. This can leave the foundation or agency with a poor impression of the applicant. In a worst case scenario, the applicant can be denied funding based on a technicality.

This strategy of thinking about the budget beforehand is just as important as writing the research plan. This is because you need to have a cost-conscience plan for allocating resources within the parameters set by the grant sponsor while taking into consideration the requirements of your institution. As many before us have stated, the science (i.e., specific aims, scope of work, research design and project timeline) dictates the budget. For example, let us say that the sponsor guidelines state that the maximum total direct cost dollars allowable per year is $100,000/yr. with no more than two years of funding. You write the grant so that all data collection will take place in year one and data analysis and dissemination of research findings will occur in year two. The consulting biostatistician you hired to calculate the power analysis determines that you need to recruit at least N = 1,000 research subjects in order to achieve adequate statistical power. You write the proposal opting to recruit all 1,000 research subjects in Year 01. You should already begin to see a problem. There are too many research subjects for the type of funding! After you factor in the costs of hiring and training RAs, hiring focus group facilitators, travel to recruitment sites, design and reproduction of assessment instruments, focus group expenses (recruitment flyers, moderator, audio-transcription, incentives), and incentives for the research subjects, there will not be enough money in the budget to cover the cost of the PI's salary much less any other investigator or consultants. Furthermore, it is highly ambitious to think that you will recruit 1,000 research subjects in the first year of the project. Therefore, it may be wise to re-think the scope of the project.

➢ Tools: What Do I Need to Prepare a Budget?

A good way to think about writing grants is that they are like houseplants, they need nurturing periodically, some vitamins (acid food if the leaves are yellow), fresh soil with vermiculite, routine watering, and even transplanting when they outgrow the pot. In this regard, it is not as important to question, "*How* will I take care of this plant?" as opposed to asking, "*What* resources will I need in order for this plant to thrive and survive?" As you write the research plan, continuously ask yourself what resources will I need (i.e., personnel, consultants, materials and supplies, services, travel costs, equipment, to name a few) in order to execute this project properly? The answer to these questions will bring to life the first of many drafts of your research budget.

If you think about the basic resources a plant needs for survival in comparison to what an investigator needs to prepare a budget for research; the similarities are uncanny. The *soil* of a plant provides plant nutrients and is required for successful plant growth. The diligence, creativity, depth of the research hypothesis, and quality of the investigative team are the "soil" of the grant budget. If the science does not make sense, neither will the budget. Consider a situation where a budget person is working with a junior investigator who drafted a budget for a small pilot study she was submitting to a foundation. The budget included several categories, which were self-explanatory and required no further inquiry. However, two entries were "hot" flash points for the budget person. First, the budget included a line to purchase snacks for "research assistants" (RA) and included a line labeled "unforeseen expenses" of $1,000 that was not justified. The personnel section of the budget did not include a line for hiring RAs, nor did the science make mention of the use of RAs to conduct the study. Furthermore, the foundations grant guidelines did not explicitly state that food would be an allowable expense and mentioned nothing regarding the fact that "unforeseen expenses" was acceptable.

A careful review of this particular budget should raise some alarm. The budget person has to sit down with the PI and go over each and every expense looking for connections to the research plan. For instance, the budget person should ask, "*Why is there no mention of the RAs on the budget or in the research plan?"* In this particular case, the investigator replied, "*Oh, they are not RAs, they will be student volunteers."* After some additional prodding the budget person learned that these student volunteers were going to be responsible for facilitating focus groups and data collection and were thus very important to the study design. Clarification of their omission will only help to strengthen the application when the research plan is brought in line with the staffing needs.

Not mentioning this important fact anywhere in the application (and most especially in the budget) could have been fatal to the review. Any individual(s) devoting effort to your research project must be listed on the budget regardless of whether a salary is requested. Particularly if the individual(s) role in the study design is significant. This type of oversight can demonstrate to the reviewers that the investigator does not have a complete grasp of their research or the aptitude to comprehend

what is required to execute the study properly. This is what Lewis meant by the "synergy between the science and the budget is vital to cost account a grant" (2008, p. 348).

- Core questions: Answers to these core questions will facilitate the first of many drafts of your research budget

When preparing budgets for research, it is important to contemplate some basic questions regarding your proposal. Should an investigator approaches the process of budget preparation with a genuine intellectual curiosity about the research they are pursuing, it will make the process of preparing budgets for research increasingly inherent. Upon answering the core questions below, you will have completed the first draft of your research budget.

1. **How many years will I need to request agency funding to achieve my stated research objectives? Is this project timeline consistent with the funding mechanism of which I am applying? What does the sponsor's guidelines state?**

Think: Seek out several funding sources and determine which agency is better suited to support your research agenda and objectives. Upon deciding which agency to submit, download the RFA (read this carefully!), the sponsor application (SF424 R&R for NIH) and funder guidelines.

Plan: You have decided to submit a secondary data analysis grant application to the NIH in response to a specific RFA. Budgets for direct costs of up to $125,000 per year and a project duration of up to two years may be requested for a maximum of $250,000 direct costs over a two-year project period. You will submit the application to the NIH electronically using the modular NIH format.

Please note, for illustrative purposes, the sample budget provided in **Figure 1** is being used to illustrate the basic information needed to construct a budget while thinking about the core questions provided in this section of the workbook. **Modular NIH grant applications do not require any of the detail provided in the sample budget in Figure 1**; however, it is still a good practice to work out the details of the costs for your project in order to ascertain its cost-feasibility.

NIH or Federal Websites that contain Budget Information:

Develop your budget:
https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/develop-your-budget.htm

Federal Cost Principles:
https://grants.nih.gov/grants/policy/nihgps/HTML5/section_7/7.2_the_cost_principles.htm

Calculation of Person Months:
https://grants.nih.gov/grants/policy/person_months_faqs.htm

Allowable Costs (Fringe):
https://grants.nih.gov/grants/policy/nihgps/HTML5/section_12/12.8_allowable_and_unallowable_costs.htm?Highlight=fringe%20benefits#Salaries

Federal Travel Regulations:
http://www.gsa.gov/federaltravelregulation

Federal Allowable Costs (entertainment, incentives):
https://grants.nih.gov/grants/policy/nihgps/HTML5/section_7/7_cost_consideration.htm

Common Application Mistakes:
http://www.nimh.nih.gov/funding/grant-writing-and-application-process/common-mistakes-in-writing-applications.shtml

Figure 1: Sample (modular) budget with detail:

	YEAR 1			YEAR 2			TOTAL
PERSONNEL	% effort	calendar months	SALARY	% effort	calendar months	SALARY	
C. CHARLES, PI	50%	6.00	$48,555	50%	6.00	$50,493	
J. JACOBS, Co-Investigator	20%	2.40	$21,117	20%	2.40	$21,960	
L. LYONS, Statistician	5%	0.60	$9,565	5%	0.60	$9,565	
S. SIMMONS, Research Coord.	10%	1.20	$7,626	10%	1.20	$7,931	
TOTAL SALARY			$86,863			$89,948	$176,811
FRINGE (29%)			$25,190			$26,085	$51,275
TOTAL PERSONNEL			$112,054			$116,033	$228,087
	BASE YR 1 (12/1/08 - 11/30/09)			BASE YR 2 (12/1/09 - 11/30/10)			
INSTITUTIONAL BASE SALARIES (prorated)	SALARY AS OF_	12/08 - 6/09	7/09 - 11/09	SALARY AS OF_	12/09 - 6/10	7/10 - 11/10	
	CHARLES	$95,500	$99,320	CHARLES	$99,320	$103,293	
	JACOBS	$103,834	$107,987	JACOBS	$107,987	$112,306	
	LYONS	$191,300	$191,300	LYONS	$191,300	$191,300	
	SIMMONS	$75,000	$78,000	SIMMONS	$78,000	$81,120	
CONSULTANTS							
Janice Johnson, M.D.			$1,000			$1,000	
Michelle Lawry, Ph.D.			$3,000			$1,000	
TOTAL CONSULTANTS			$4,000			$2,000	$6,000
SUPPLIES							
Research Supplies			$550			$550	
ABC National Dataset			$400			$0	
XYZ National Dataset			$0			$475	
SAS license			$600			$600	
SPSS license			$600			$600	
TOTAL SUPPLIES			$2,150			$2,225	$4,375
TRAVEL							
PI Travel to conferences			$3,200			$3,200	
TOTAL TRAVEL			$3,200			$3,200	$6,400
OTHER EXPENSES							
Postage & Fedex			$500			$500	
Duplicating			$300			$300	
Books			$700			$700	
TOTAL OTHER EXPENSES			$1,500			$1,500	$3,000
TOTAL DIRECT COST:			$122,904			$124,958	$247,862
MODULAR DIRECT REQUESTED:			$125,000			$125,000	$250,000
F&A COST RATE 1			68%			68%	
MTDC Base			$125,000			$125,000	
F&A COST			$85,000			$85,000	$170,000
TOTAL COST			$210,000			$210,000	$420,000

2. **Has the NIH funded similar research in the past? (You can look this up on the NIH Reporter at https://projectreporter.nih.gov/). What makes the approach innovative and is there a cost benefit to my approach? Are the budget costs accurate and adequately justified for the decision-makers to compare the cost of your project with its benefit? The cost of your project versus another with similar objectives? The cost of alternative methods of reaching a specified goal?**

Think: Have any of my colleagues (or my mentor) submitted applications in the past to investigate a similar research hypothesis? How is my application different and am I considering an alternative method of reaching my research objective that differs from my predecessors while adding a cost-benefit to the research? Will the reviewers be able to compare the cost of the project with its benefit to research?

Plan: Once you have answered the questions above, you will have already completed or nearly completed the design to your research, the next step involves specifying the budget.

3. **Who will be the personnel (investigative team) on the grant and how do their functions and roles on the project influence the budget and most importantly the scope of work? How much time will each person need to devote to the project to facilitate the work proposed? How are the person months (based on percentages of effort), for the key personnel, determined and are they reasonable given the individual's other commitments? This is always an area for review criticism that you need more "time" to devote to your research and the execution of your study.**

Think: What type of ground floor expertise is necessary for me to carry out the objectives of this proposal?

Situation#1: The RFA specifically requires that I have a strong data analytic and data management team.

Situation#2: The investigative team is comprised of a multi-disciplinary team of scientists.

Both situations carry different demands. A strong analytic team may require a biostatistician, a quantitative methodologist, or an individual with a particular strength, for instance, modeling missing data in a longitudinal study. If this is the case, then the personnel budget should include not only effort for statisticians, but carry a broader selection of individuals who can lend their specific professional expertise to the grant.

Also, often times PIs believe that because they are an "expert" or highly trained in a particular subject matter that including a colleague with a similar expertise is overkill. For a junior faculty member, this may not necessarily be the case. Especially if your colleague may bring more years of experience in that subject area to the project, or he/she may have years of publishing peer-reviewed articles or he/she may have a track-record of acquiring grants or consulting in that subject. Including a more senior-level person on the grant can only serve to make your proposal more marketable. Whom you select and what percent effort they devote to the project should always be determined by asking yourself "What will this person add to the project? Could this proposal be successful without their active input/participation?"

Think: Given the funding restrictions (i.e., $125K/yr. for two years) and the agency requirements (i.e., biostatistics and data management) you have to keep in mind that this secondary data analysis grant does not need full-time effort of any one of the key personnel. Since all of the data has already been collected, and the instruments (i.e., surveys) used are already designed, the investigative team will be devoted to re-evaluating the data with the new variables in comparison to two national samples. A core group of biostatisticians and research assistants can plough through the data.

Tip#1: The level of percent effort devoted by the key personnel to the project will be determined by considering three factors:

a) What work they will be contributing to the research project and how much time will it take per week/day/month to complete?
b) Is it more advantageous to the project to put them on the grant as a consultant or would a consortium agreement be more suitable?
c) What other commitments outside of this project is he/she obligated to and can he/she feasibly allocate the proposed effort?

Tip#2: Never select a random level of effort for an investigator because the number sounds strong. All personnel involved in the project should have a say in what effort they can or are willing to devote to the project. If the project involves investigator(s) outside of your department or institution, the signing official (or a compliance officer from their institution) will be able to ascertain whether their effort on your project is going to over-commit their investigator. It is always more diligent to resolve potential over-commitment issues prior to submitting an application to the NIH or any other agency. More often than necessary, awards for newly funded grants will be delayed by the NIH for weeks up to several months while the institution is trying to prepare a statement or the other support page to address the resolution of potential overlap by the grantee institution investigator(s). These delays can cause projects to start late, have adverse implications on data collection (particularly for school-based studies), and can cause internal (institutional) delays with setting up the grant account, subcontracts, consortium agreements, etc.

On average, personnel costs make up anywhere from 55% to 75% of the direct costs on a grant budget. Therefore, more time and writing space is needed to explain this section.

4. **What is the population being evaluated/examined in the proposed research and how will their participation influence the budget? Why is the proposed budget expenditure important to the project, and how does it contribute to the overall goals of the study? Are all of the non-personnel items budgeted (i.e., consultant costs, equipment, supplies, travel, other expenses, etc.) supported by the science?**

Think: What does my project timeline say about the intervention? How many research subjects do I need to recruit in order to achieve statistical power? Will I offer incentives? How much will

each incentive really cost (gifts or movie vouchers) and how many should I budget to purchase? Do I purchase incentives for teachers and the schools to boost participation rates? Are there certain costs that should be built into the cost of the grant but not necessarily be budgeted every year?

Situation #1: The proposed project will not require re-consenting the research subjects because this is a secondary data analysis study. Therefore, it would be odd to include costs for paying incentives to the research subjects for their participation. Now, if the study called for re-consenting a subset of the original group of research subjects it would make sense to include incentives or costs to mail and or duplicate the consent forms.

Plan: The budget presented in Figure 1 has study-specific costs built-in for purchasing research supplies, datasets, and licenses for statistical software (under the "supplies" category). Notice that the PI only budgeted to purchase the ABC National Dataset in year 1. The PI must have decided that he only needs to purchase this dataset in year 1 because he will be evaluating the second dataset from XYZ National Dataset in year 2 for comparative reasons. Additionally, the PI has budgeted for the purchase three SPSS licenses at $200 per team member (excluding the statistician who already has access to these software) in years 1 and 2 because data analysis will be ongoing for both project years (same for the purchase of the SAS licenses). The PI also budgeted to purchase consumable research supplies (i.e., paper for data reports, toner, highlighters, USB flash drives, etc. in both years of requested support). Don't assume that many of these costs will be borne by the institution as part of F&A, or at least check with the budget administrative officer.

5. **Where does the project take place and what resources are required to facilitate the needs of the study? If resources available are inadequate, does the sponsor permit the use of grant funds towards purchasing capital equipment, or construction to upgrade laboratory space, etc.?**

Think: What institutional resources are available to me in order to carry out this project (if any)? If my institution does not have the required infrastructure in place for me to carry out this project here, how much of the project-related work will be farmed out? What would be the most cost-effective way to manage these research needs?

Plan: Notice in the sample budget provided in Figure 1 that there is no budget for purchasing a computer or laptop. It is certainly correct to include this cost in the budget if it was necessary in order to conduct the project; however, the PI and his team has access to computers in their offices (provided by the institution) and do not project this unnecessary cost on the budget. This is probably a wise move. Laptops, computers, and other types of equipment create a 'hard sell' to a funding agency (particularly small foundations) and an even harder sell to an auditor if they choose to question the computer purchase and its intended purpose. If you intend to purchase a computer or laptop(s) on a grant provide a very detail explanation in the budget justification. While

explaining “why” the laptop is necessary to carry out the objectives of the project it would also be wise to explain that the computer (or printer) will be used exclusively for the project.
In the sample budget provided, the investigators have access to computers with all of the necessary components and state this information in the “Resources” section of the grant application. In some instances, if the sponsor did not allow the purchase of computers on the grant, you could indicate other institutional sources would be used to purchase laptops for the study and this alternative would be a form of cost sharing which should be disclosed to the sponsor in the application.

6. Does synergy exist between the budget, scope of work, research design, and the project timeline?

As depicted in Figure 2, a synergistic relationship between the science and the budget is important to cost account a grant during its basic construction and various phases of grant development. Any expenditure(s) proposed in the budget, that is not fully supported by the scope of work proposed in the aforementioned sections will raise a red flag to reviewers. Red flags over budgetary issues are less common during review; however, they can be as damaging as human subject concerns. In other words, these types of comments during review raise the specter that the PI does not fully grasp the project design or is unaware (e.g., junior faculty) of the resources needed to achieve the specific aims (goals) of the study. If it becomes evident to a review committee that a possible disconnect exist between the budget and project design, reviewers may lose enthusiasm even for the very best designed studies.

Figure 2: Synergistic Components of a Grant Budget

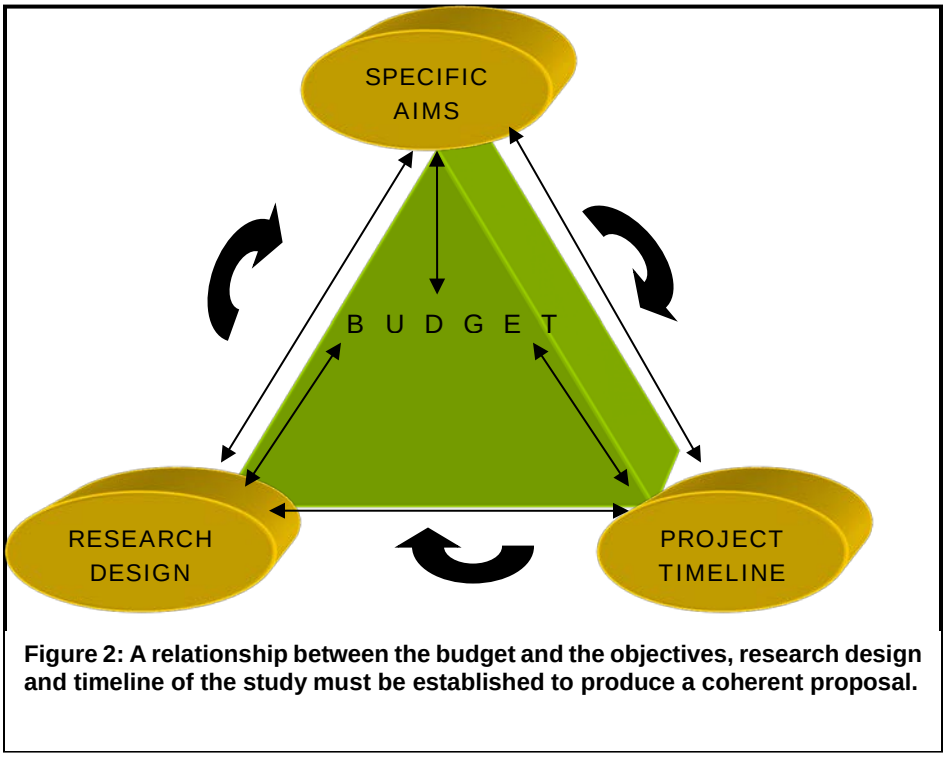

Figure 2: A relationship between the budget and the objectives, research design and timeline of the study must be established to produce a coherent proposal.

Think: In situation 1, we proposed to conduct a secondary data analysis study on existing data and compare the results to two national samples. Is the science adequately justified on the budget?

Tip#1: Read through each **specific aim** in the proposal and ask, "What do I need to achieve this aim and is there an actual cost or level of effort required to achieve it?" Is the number of specific aims commensurate with the level of effort that the PI proposes to commit to the project? For example, if you are proposing 15 specific aims, will 10% effort be enough to commit to the project?

Tip#2: Read through the **research design** and simultaneously create your **project timeline** and ask, "What type of infrastructure or personnel is required to implement the design?" For example, is it appropriate to state that the field coordinator will devote 100% effort to the project in all years of requested funding given that data collection only occurs in year two?

Plan: Continuously reconcile your **project timeline** with the budget. If your study requires that you achieve a certain level of statistical power and in order to achieve it you must recruit a certain number of research subjects, will it be feasible to conduct this study in two years, or might you need to add a third or fourth year to the study? How will this change in the project timeline affect the budget? Will the sponsor look favorably on a three-year study to conduct retrospective data analysis?

7. Does the budget provide sufficient flexibility to cover unanticipated costs?

Think: When budgeting for personnel, how do I account for inflation?

Plan: First, always consult with your grants and contracts office for guidance about this matter. However, if the sponsor sets a limit on the percent of inflation (which is rare) then only include a rate consistent with their guidelines.

Let's say for example that every July 1st, it is expected that your staff will receive an increase in their institutional base salary of 4% this should be reflected in the budget. By not accounting for inflation, you run the risk of overspending on the budget. While for smaller grant budgets the amount overspent might be insignificant, for larger P50 center grants, failure to prorate the salary to be consistent with your institutions fiscal year can be very costly to a project. In Figure 1, rows 16-21 you will see that a section of the internal budget provided show the detail for prorating the salaries for the personnel on the grant. In this scenario, it's assumed that the faculty salaries will increase by 4% every July 1st. The salary requested amount is a formula derived at calculating the IBS at the current rate for 7 months and adding to that the IBS at the new rate for the remaining five months.

➢ Facilities and Administrative Costs (F&A)

The federal government goes into significant detail regarding the calculation of F&A costs (also referred to as "indirect costs" or IDC). Several very "hefty" documents outline legitimate IDC costs:

https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/develop-your-budget.htm

https://grants.nih.gov/grants/policy/nihgps/HTML5/section_7/7.3_direct_costs_and_facilities_and_administrative_costs.htm

For the purposes of this workbook however, it is important to note these tips:

Tip#1: Always involve your parent institution in any discussion regarding renegotiation of indirect costs. Some funding agencies have modified IDC rates (i.e., foundations support rates ranging between 8-15% rates).

Tip#2: Many Universities don't adhere to the traditional FAS distinction between Direct and Indirect Costs. Be sure to speak with the administration about their position before you cast your budget in stone. Items like copiers, phones, new computers, and machinery can be open for negotiation or held to a different standard from government accounting methods (see OMB Circular A-21 and Circular A-110 for further information).

XIII. Activity #1 (Ball Activity)

Activity No. #1 presents a problem that requires team science in order to forge a solution. The solution will require "collective input" from each of the group's members, who traditionally represent the "partners" you will need to execute a program of research. If you are invested in developing outreach activities involving health or training, you will need "partners" that come from local hospitals, clinics, schools or community-based organizations. As part of your "capacity building" efforts you will probably be required to have meetings with local health experts, other scientists and medical practitioners invested in the project, perhaps you will need to create inroads with major healthcare partners from the community, nursing organizations for training, and support from the community health workers that meet with parents/patients routinely at clinics.

Activity #1 consists of ten round balls. We begin with one ball for the purpose of demonstration and then progressively include more balls after we gained proficiency and can master the simpler steps. The rules of this activity are quite simple: ***Order must be maintained and sequence is important***. We start off with one person as the keystone (the stone that links all the other stones over a door or archway). The keystone individual throws the ball directly to one person. The person who receives the ball then throws the ball to another person (but not the first!) until each and every member of the group has touched the first ball. The final person to receive a ball then throws the ball back to the keystone person.

Stage two broadens our horizons (grant resources) and we add another ball, and there after we add more balls until all ten round balls (pieces of the organization) are being used. At this point in time, we introduce the concept of "*time*." That is, we want to speed up the process, take a peek (small look) at the groups' decision-making processes, and inspect leadership and division of labor concerns. Once time is factored into the equation, we begin to see groups take shape as a "*dynamic process*." Behavioral interventions, applied science laboratories, medical research units, and grant writing activities all take shape in a very similar fashion, where individual components (pieces) begin to build toward the more complete whole, complete with a richer set of ideas and concerns. Remember that as scientists meet to discuss their concerns over the progress of a research program, so too may the hospital administration, nurses, doctors, or teachers meet to discuss their concerns over the conductance of science in the real world.

Once "*time*" is factored into the equation, we set a standard for completion of the project, say, 2 seconds. Wow, 10-12 people, ten round balls that must move around a group, and only 2 seconds of time! If we have 10 people in each group, how is it possible that 10 people touch 10 balls, while maintaining **order** and **sequence** in just 2 seconds? This task seems almost impossible, but we ask that you trust us, accepting the fact that there is a solution. Hopefully, one or more groups can creatively solve this problem.

XIV. Activity #2 (Indian Mime Activity)

Activity No. #2, like the previous activity, also serves the purpose of *culture building*. Culture building is a major component of developing grant-writing resources and involves bringing colleagues and collaborators together with a unified mission. You won't believe how many times a young and somewhat inexperienced researcher approaches a more senior faculty or experienced grant writer inquiring about why a particular grant that he or she had written and submitted did not fare well during review. As the young researcher and more senior person sit down to review the grant and read the critiques (between the lines), a conversation ensues that goes like this:

Senior Person: "Who helped you to design the study?"
Junior Person: "I designed the study myself, sir."
Senior Person: "Who did your power analyses?"
Junior Person: "I ran my own power analyses, they are not really complicated."
Senior Person: "How did you come up with the intervention design?"
Junior Person: "I came up with this design based on my initial read of the literature."
Senior Person: "Did you have any help on the budget?"
Junior person: "Well, I really didn't have hard and fast costs, but I made up some dollar (rupee) numbers to make the budget work."
Senior Person: "Did you develop a logic model that incorporates your preliminary findings?"
Junior person: "Well, not really, I proposed a few new ideas, but they are not fully tested yet."

These are only a handful of the important questions one could ask, with additional inquiry probing even deeper into the composition of the "team" that developed the grant. The point here is that without a doubt, 99% of the time, the young researcher searching for support says "*I did it all*."

Indeed, a more elaborate and more complete answer would look like this: "I developed the analysis portion, I computed the power, I developed the intervention, I drafted the Human Subjects, I computed the budget, and I never asked any colleagues for help or to review my work." Hopefully, you can see from this brief example, there was no "culture building" that supported the grant's development and, as the reviewers saw, it contained serious flaws, failing to curry favor during review. Here, we can see the importance of "collaboration" and sharing resources when developing and writing grants. It is no wonder that the average age of a first R01 grant at NIH is still 44 years.

History of Activity

To continue developing our discussion of collaboration and "culture" building we have structured a second group activity. **Activity #2** takes shape as a Mime activity, where participants will be responsible for developing a five-minute skit that uses Mime. Mime (or pantomime) is an old form of communication that may have predated speech, as we know it today. Mime, which is also called the "*language of gestures*," involves story telling without talking. It is a theatrical art, a form of entertainment and information exchange. Mime finds its historical roots in Greek dance and theatre and has been a staple part of numerous religious ceremonies. Ancient records show that the legendary dancer Telestes (467 B.C.) used mime in a play by Aeschylus "*Seven against Thebes*" to depict the action sang by the chorus with rhythmic step and gesture. Anyone who has seen an Egyptian belly dancer can sense the distinctive component of mime that augments the dance routines. In modern times, Marcel Marceau (1923 - 2007) was one of the world's greatest mime artists.

Description of Activity

The country of India is well noted for its different religions, artistic endeavors, architecture, delicious foods including rare spices, colorful celebrations and festivities, and varying cultural beliefs spread across a wide and beautiful expanse of land. In the ***Mime Activity***, the objective is for each group to develop a short skit that shows a special cultural feature of India. Each group will have ten minutes to organize their Mime skit, select the mime actors, and develop their theme and content. Groups are encouraged to involve every participant and will be asked if a certain member of the group does not participate. After all the groups have developed their Mime skit, the entire audience will evaluate and rate the skits using a **Mime Evaluation Scale System** (MESS).

One of the strong features of this activity is that it combines the presentation on "innovation" with the art of grant writing. In grant writing there are many different responsibilities linked to production of grants and each individual member of your team will have a specific role. The **Mime Activity** helps you to learn quickly how to work as a group, find a creative idea, and bring this idea to fruition (innovation). One of the highlights of the **Mime Activity** is that we are at work, but heavily engaged in play.

XV. Workshop Presenters

Betty S. Pace, M.D. is Professor of Pediatrics and Biochemistry and Molecular Biology, Division Chief of Pediatrics Hematology/Oncology and Francis J. Tedesco Distinguished Chair at the Medical College of Georgia at Augusta University. Dr. Pace has dedicated her career to serving people with sickle cell disease (SCD) by rending clinical care, conducting laboratory research, and training the next generation of young scientists, to ensure discovery of new treatments and cures. Dr. Pace received her MD degree from the Medical College of Wisconsin followed by a Pediatric Hematology/Oncology fellowship at the University of Colorado, Health Sciences Center. After faculty appointments at the University of South Alabama and University of Texas at Dallas, Dr. Pace joined the faculty at Augusta University as a Professor of Pediatrics and active member of the Sickle Cell Center. She maintains a highly successful NIH-funded research laboratory to developing new drug therapies for SCD and direct training programs for junior faculty with a desire to conduct SCD research. Dr. Pace is fully engaged as the Director of the Pediatric Comprehensive Sickle Cell Program. She participates in national and international efforts to support SCD as Scientific Chair of the 2017, Foundation for Sickle Cell Disease Research Symposium and member of the National Heart Lung and Blood Institute-Sickle Cell Advisory Committee. She also tackles global SCD efforts with collaborators at the University of Nigeria.

Lawrence M. Scheier, Ph.D. is President of LARS Research Institute, a 501(c)(3) non-profit company engaged in program development, evaluation, and behavioral science technology transfer. LARS offers a full range of strategic services including formulating research design and conducting program evaluation using state-of-the-art statistical analysis, survey methodology, sampling and recruitment, and applying well-tested participant tracking methods. LARS specializes in developing interactive multimedia health technology (eHealth and mHealth) geared toward using e-learning for self-management training, health promotion, and professional education programs. Our program evaluation expertise includes examining regional and national youth anti-drug media campaigns, community health promotion and disease prevention programs. Our program development work emphasizes chronic disease management, health promotion, adolescent drug and violence prevention, positive health and resilience with the military, and professional training for community-health workers and medical practitioners addressing racial disparities in healthcare. LARS engages in dissemination activities including publishing in peer review scholarly journals, conference proceedings, and a quarterly eNEWS bulletin available at www.larsri.org.

XVI. Source Materials on Grant Writing

Handbooks:
Office of Sponsored Projects, University of Utah, Research Handbook. Salt Lake City, Utah. Get your free copy from the Office of Sponsored Projects at: http://www.osp.utah.edu/researchhandbook.html

Sample Grant Support Websites:
Cornell http://www.parenting.cit.cornell.edu/funding_prop.html

University of Pittsburgh
http://www.pitt.edu/~offres/proposal/propwriting/websites.html

University of Wisconsin:
http://grants.library.wisc.edu/organizations/proposalwebsites.html

University of North Carolina
http://research.unc.edu/grantsource/proposal_writing.php

Ohio State University
http://library.osu.edu/sites/education/grants.php

Missouri State University
http://www.srp.missouristate.edu/5165.htm

References:

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Popper, K. (1963). *Conjectures and refutations: The growth of scientific knowledge*. London: Routledge Classics.

Suggested Readings - Grant Writing

Coley, S. M., & Scheinberg, C. A. (2002). *Proposal writing*, Newbury Park, CA: Sage Publications.

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Delamont, S., & Atkinson, P. (2004). *Successful research careers: A practical guide*. New York, NY: McGraw Hill.

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Hayes, L. (Ed.). (1999). *Winning strategies for developing grant proposals.* Thomson Publishers: Tampa, FL.

Hoffman, J., Nemes, S., & Hansen, W. (2008). SBIR funding: A unique opportunity for the entrepreneurial researcher. In L. M. Scheier & W. L. Dewey (Eds.), *The complete writing guide to NIH behavioral science grants* (pp. 287-313). New York, NY: Oxford University Press.

Koch, D. S. (2009). *How to say it: Grantwriting.* New York, NY: Prentice Hall Press.

Lauffer, A. (1997). *Grants, etc*. Thousand Oaks, CA: Sage.

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Locke, L. F., Waneen, W. S., & Silverman, S. J. (2007). *Proposals that work: A guide for planning dissertations and grant proposals*. Thousand Oaks, CA: Sage.

Miller, P. W. (2002). *Grant writing: Strategies for developing winning proposals, 2nd Edition*, Munster, IN: Patrick W. Miller & Associates Publishers.

Punch, K. F. (2000). *Developing effective research proposals*. London: Sage Publications.

Ries, J. B., & Leukefeld, C. (1995). *Applying for research funding: Getting started and getting funded*. Thousand Oaks, CA: Sage Publications.

Roberts, B. (2007). *Getting the most out of the research experience: What every researcher needs to know*. London: Sage Publications Ltd.

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Smith, N. B., & Works, E. G. (2012). *The complete book of grant writing: Learn to write grants like a professional (2nd Ed.).* Chicago, IL: Sourcebooks, Inc.

Unrau, Y. A., Gabor, P. A., & Grinnell, R. M. (2006). *Evaluation in social work: The art and science of practice*. New York, NY: Oxford University Press.

Yang, O. O (2005). *Guide to effective grant writing: How to write an effective NIH grant application*. New York, NY: Kluwer Academic/Plenum Publishers.

Resources for Management Training Activities

Jackson, P. Z. (2003). *58½ ways to improvise in training: Improvisation games and activities for workshops, courses and team meetings*. Williston, VT: Crown House Publishing.