

## Lessons Learned from Grant Writing: Establishing a Track Record for Funding and Involving Community Providers in Implementation

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My career as a dental hygienist–scientist began in 1980 asking questions in unfunded pilot studies. In 1986, I began collaborating with established researchers on an epidemiology study of the oral and general health effects of smokeless tobacco among professional baseball players. After a while, they generously allowed me to conduct a qualitative pilot study of my own among some of their smokeless tobacco users to learn about reasons for use and experiences with trying to quit. Based on this work, in 1990, I successfully submitted an application for a large-scale community-based smokeless tobacco cessation intervention that involved dentists and dental hygienists in its delivery. With this funding, my research career was launched and my subsequent research has built on this initial work.

Over the years, I learned many lessons about grant writing from mentors and from professional development seminars offered at my University.<sup>1</sup> My goal today is to share with you some of those lessons. I will begin with my most important lesson: writing a clear, concise and focused grant application with good science is not enough. To be successful, the application must:

- Be tailored to the funding agency's public health mission
- Easy for reviewers to under-

stand the ideas, why the study is important and why it is reasonable and feasible

- Convince reviewers that I have the expertise to carry out the planned study and that I have the appropriate environment, equipment, collaborators and budget
- Address the NIH's review criteria of:
  - Significance
  - Approach
  - Innovation
  - Investigator
  - Environment

The following will briefly address lessons about these latter review criteria.

### Significance

Your study's significance must be made clear in direct language and answer questions such as:

- Does the study address an important problem from the funding agency's perspective?
- If the aims are achieved, how will scientific knowledge be advanced?
- What will be the effect of your study on the concepts or methods that drive the field?

### Approach

Your study's approach must answer such questions as:

- Are the conceptual framework, design, methods and analyses adequately developed, well-integrated and appropriate to the aims of the study?
- Are potential problem areas acknowledged and alternative tactics considered?

### Innovation

In addressing your study's innovation:

- State that you believe the research proposed is original and innovative, and offer examples
- Explain what your project does that challenges existing paradigms or requires developing

new methods, techniques or technologies

### Investigator

In addressing this criterion, be sure to answer the following questions:

- Are you appropriately trained and well suited to carry out this work?
- Is the work proposed appropriate to your experience level (and that of your collaborators)? Explain how the proposed study is similar to those you have already completed
- Does the investigative team bring complimentary expertise to the project?

### Environment

In addressing the environment criterion, answer such questions as:

- Does your scientific environment contribute to the probability of success?
- Does your study take advantage of the unique features of the scientific environment?
- Is there evidence of institutional support?

Other important lessons are:

- Do not make the reviewers "work hard." Make it easy for them to understand your ideas, to find things and to be your advocate
- Read the application instructions carefully and follow the instruction to the letter
- Be specific about what you want the reviewers to know and what they need to know
- Prepare a "reviewer friendly" application that is well organized and clear

I will use my remaining time to share lessons learned about the following grant application components.

### Abstract

The abstract, your research summary, may be the only part of your application reviewers read. For me, the best approach is to write it first

and revise it last when you know your final application content.

### **Specific Aims**

The Specific Aims, the most important section of the grant application, should be well focused, not overly ambitious and hypothesis-driven. It is critical to write them early, circulate them to your team of experts and incorporate their feedback before writing the rest of the proposal. Usually 2 to 4 aims are the norm.

The Specific Aims section typically includes 3 general sections:

1. The “set-up” paragraph, which explains the relationship between a pressing problem and your research theme. This paragraph should strongly persuade the reviewer that the topic is important and worthy of their attention
2. The “hypothesis” paragraph, which points to a specific problem or area and culminates in

- the statement of the hypothesis
3. The “specific aims” paragraph starts with a sentence like “The specific aims of the study are to...” and then lists the aims. Each aim should allude to the techniques used to achieve each one. In listing the specific aims use active verbs, rather than passive ones.

### **Background and Significance**

The background and significance section must establish 3 things: the project is important, the science is interesting and there is a high probability of success. This is not a literature review. Educate the reviewers to your way of thinking. Put the project into context by providing essential background information for the content area. Show how the proposed project builds on previous work and identify gaps in previous knowledge.

### **Preliminary Studies**

The preliminary studies section should convince reviewers that you know what you are doing. Show that the work is feasible and that suitable groundwork has been done by you.

In conclusion, never forget that your application is a work of persuasion. It is not merely a description of the work you want to do. Rather you are making an argument that it is work that needs to be done and that you are the right person to do it.<sup>2</sup>

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## Research Priorities from the Behavioral and Social Sciences Research Program at the NIDCR

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### Overview of the Program

The purpose of this talk is to highlight the funding opportunities and priorities of the Behavioral and Social Sciences (BSS) Research Program at the National Institute of Dental and Craniofacial Research (NIDCR). The BSS program supports basic and applied BSS research to promote oral health, to prevent oral diseases and related disabilities and to improve management of craniofacial conditions, disorders and injury. The BSS research program views oral health as one component of a larger system of health and well-being, and encourages both basic and applied research that incorporates other aspects of health and well-being that contribute to oral health. This view of oral health as a component of general health builds on the Surgeon General's report on oral health in America (2000), and on the 2007 report of the Office of Behavioral and Social Sciences Research (OBSSR).

### Multidisciplinary and Team Science

The program aims to draw on the expertise of researchers from multiple fields of study, including those with a focus on basic and clinical oral health and those from other fields whose research might be applicable to oral health. Depending on the research questions of interest, projects may draw from the theories, measures and methods of a single scientific discipline or from those of multiple scientific disciplines.

### Methodologies

The BSS research program encourages the use of a variety of methodologies, depending on the research questions of interest. For example, studies may utilize randomized clinical trials methodology, or may utilize other methods such as single-case, within-subjects, historical control, microanalytic change process and other designs. Studies are strongly encouraged to utilize methods that allow for a test of mechanisms of action. Mechanisms of action are causal explanations for behavior. These are distinguished from correlates, predictors, mediators, moderators, risk and protective factors, etc., which may be candidate mechanisms, but have not been demonstrated as having a causal link with the outcome(s) of interest.

### Basic Behavioral and Social Sciences Research

NIDCR supports basic BSS research that identifies the mechanisms by which behavioral and social factors contribute to oral health. Exploratory research to generate hypotheses and confirmatory research to test hypotheses are both encouraged. Basic BSS research may involve qualitative and/or quantitative research methods, and may occur in a variety of settings (e.g., research laboratory, clinic, school, community, etc.). Basic BSS research at NIDCR focuses on human populations – basic BSS studies of animal models are not supported.

### Applied Behavioral and Social Sciences Research

NIDCR supports applied BSS research that develops and tests interventions to promote or improve oral health. These interventions may target individuals, families, groups, communities and others. Investigators are encouraged to consider following intervention-development models described in one of several recent NIH Program Announce-

ments. These include a 3-stage model of intervention development outlined in a joint National Institute on Alcoholism and Alcohol Abuse/National Institute on Drug Abuse Program Announcement (please see: <http://grants.nih.gov/grants/guide/pa-files/PA-07-111.html>) and a Program Announcement on Community Participation in Research (please see: <http://grants.nih.gov/grants/guide/pa-files/PA-08-074.html>). These encourage community-based participatory research on health promotion, disease prevention and health disparities that communities and researchers jointly conduct, along with dissemination and implementation research that focuses on sustainability of interventions in community settings (please see the materials and archived video presentations of an National Institute of Mental Health sponsored workshop entitled, "Building the Science of Dissemination and Implementation in the Service of Public Health," 9/10/07 – 9/11/07, <http://obsr.od.nih.gov/di2007/agenda.html>).

### Health Behaviors Research

Basic health behaviors research clarifies how health behaviors, including oral health behaviors, develop and are maintained across the lifespan. Applied health behaviors research develops and tests interventions that promote oral health. Interventions may target prevention of oral disease or appropriate treatment for an existing oral or craniofacial condition, disease or injury. Interventions may target a general, specific or clinical population. Development and testing of community-wide or public health interventions to promote health and oral health are also encouraged.

### Stress and Health Research

Basic stress research clarifies how behavioral and social factors influence inflammation, wound healing, immunity to infection and

other health and oral health outcomes. Applied stress research develops and tests interventions to improve wound healing, immunity to infection and other health outcomes relevant to oral health.

### **Pain Research**

Basic pain research clarifies the mechanisms linking psychosocial processes (e.g., cognitive, emotional, behavioral and social processes) and the experience of acute and/or chronic pain. Applied pain research develops and tests interventions to prevent or manage acute and/or chronic pain conditions.

### **Health Communication Research**

Basic health communication research clarifies the role of health communication in oral health, including communication between patients and oral health care professionals, communication between

oral health and other health care professionals, oral health literacy (i.e., an individual's ability to utilize oral health care), diffusion and dissemination of health information, etc. Applied health communication research develops and tests interventions to improve oral health by improving oral health communication among patients, communities and oral health care professionals.

### **Research on Managing Serious and/or Chronic Illness**

Basic research clarifies the mechanisms by which serious and/or chronic craniofacial illnesses (e.g., temporomandibular joint disorders, craniofacial anomalies and injuries, oral, head or neck cancers, oral complications of HIV infection, etc.) are related to patient, family and social functioning. Basic research also clarifies the barriers to better oral health for individuals with serious

and/or chronic illnesses (e.g., those with congenital or acquired cognitive, neurological or psychiatric conditions, those with cancers, HIV or AIDS, diabetes, etc.). Applied research develops and tests interventions to support patients, families and others in the social environment in managing serious and/or chronic craniofacial conditions or illness, including temporomandibular joint disorders, craniofacial anomalies and injuries, oral, head or neck cancers, oral complications of HIV infection and others. Applied research also develops and tests interventions to eliminate barriers to better oral health for individuals with serious and/or chronic illnesses (e.g., those with congenital or acquired cognitive, neurological or psychiatric conditions, or those with cancers, HIV or AIDS, diabetes, etc.).

## Research Priorities in Women's Health

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Research related to women's health is sponsored by all of the individual institutes of the National Institutes of Health (NIH). Coordination is provided by the Office of Research on Women's Health (ORWH). ORWH works in partnership with NIH institutes and centers to ensure that women's health research is part of the scientific framework at NIH and throughout the scientific community.

### Overview of the Office of Research on Women's Health (see <http://orwh.od.nih.gov/>)

The ORWH was established in September 1990. Dr. Vivian Pinn is the NIH Associate Director for Research on Women's Health and Director at the ORWH.

#### ORWH:

- Promotes, stimulates and supports efforts to improve the health of women through biomedical and behavioral research on the roles of sex (biological characteristics of being female or male) and gender (social influences based on sex) in health and disease
- Works in partnership with NIH institutes and centers to ensure that women's health research is part of the scientific framework at NIH and throughout the scientific community
- Advises the NIH Director and staff on matters relating to research on women's health
- Strengthens and enhances research related to diseases, disorders and conditions that affect women

- Ensures that research conducted and supported by NIH adequately addresses issues regarding women's health
- Ensures that women are appropriately represented in biomedical and biobehavioral research studies supported by NIH
- Develops opportunities for and supports recruitment, retention, re-entry and advancement of women in biomedical careers
- Supports research on women's health issues

In 2009, ORWH is holding 4 regional scientific workshops and public hearings to update the women's health research agenda. The overarching theme of this ORWH strategic planning initiative is "*Moving Into the Future: New Dimensions and Strategies for Women's Health Research for the National Institutes of Health.*" These meetings will be held in St. Louis, San Francisco, Providence and Chicago. The goal of the ORWH strategic planning effort is to look ahead for the next 10 years to ensure that women's health research continues to be scientifically relevant, anticipates new approaches to research on women's health or modifies existing research to apply to women's health research and employs the most advanced techniques and methodologies in new and creative ways. Ideas and recommendations from regional workshops will be integrated, with further input from the NIH. The final strategic plan will be presented to the NIH, Department of Health and Human Services and Congress in September, 2010.

### Women's Health Research Sponsored by the National Institute of Dental and Craniofacial Research

The mission of the National Institute of Dental and Craniofacial Research (NIDCR) is to promote the general health of the American people by improving craniofacial, oral and dental health through research.

This includes funding clinical and basic research to understand, prevent and treat oral and craniofacial diseases that disproportionately or solely affect women. These diseases include orofacial pain, diseases of the temporomandibular joint and muscles (TMJMD), osteoporosis of the craniofacial complex, salivary gland diseases, autoimmune diseases and oral diseases of pregnant women.

Clinical initiatives sponsored by the NIDCR include large cohort studies designed to identify risk factors and to characterize diseases impacting women. One study is following over 3,000 young women to identify those who develop TMJMDs. Two groups supported by the NIDCR continue to characterize individuals with Sjögren's syndrome, an autoimmune disease that severely impacts oral health. Over 90% of patients with Sjögren's syndrome are female.

Other recent studies sponsored by the NIDCR investigated the benefits of adjunctive therapies for treatment of periodontal disease in osteopenic women, treatments for severe TMJ and the effect that treatment of periodontal disease during pregnancy has on the incidence of preterm birth and associated growth restriction. Other studies of poor inner city women helped define factors that make them more susceptible to oral diseases.

The NIDCR also supports basic science studies examining growth and development of teeth, cartilage and bone. These studies have led to advances in biomaterials research and to the emerging field of tissue engineering and biomimetics, fields that use the body's own cellular and molecular processes to repair and regenerate tissues and organs. These include in-depth studies of the characteristics of the TMJ disk at the cellular level.

Recognizing the importance of gene-to-gene, gene-environment and behavioral interactions, the

NIDCR has long emphasized the importance of genetic, behavioral, social science and epidemiological research. Researchers supported by the NIDCR have defined genes associated with primary Sjögren's syndrome, cleft lip and palate and characterized features of women more likely to develop chronic pain. On-going studies hope to define susceptibility genes for TMJMD and other genes associated with craniofacial diseases. Complete re-

ports covering women's health research sponsored by NIH are available at [http://orwh.od.nih.gov/pubs/pubs\\_reports.html](http://orwh.od.nih.gov/pubs/pubs_reports.html).

### **Grants and Funding**

NIDCR is the nation's leading funder of oral, dental and craniofacial research. Approximately 75% of NIDCR's budget goes to the support of grantees at universities, dental schools and medical schools across the country and around the

world. Research grant applications are solicited through Funding Opportunity Announcements (FOAs) that are posted on the NIDCR Web site at <http://www.nidcr.nih.gov/GrantsAndFunding/>. General guidelines, including electronic grant application forms, application instructions and deadline information, are found at <http://grants.nih.gov/grants/oer.htm>.

## Tobacco Control Research Priorities at the National Cancer Institute

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The health effects and the economic burden of tobacco use are well known. Enormous progress has been made in decreasing the use of tobacco by both adults and youth in this country. Since the 1964 Surgeon's General report which highlighted cigarette smoking as a health hazard, the prevalence of smoking in the U.S. has decreased from approximately 42% in 1965 to 20% in 2007 for adults and approximately 37% in 1975 to 23% in 2005 for youth.<sup>1,2</sup> Currently, approximately 45.1 million adult Americans are smokers.<sup>1</sup> In 2006, overall cancer rates dropped for the first time in a century, a milestone attributed to the significant reductions in smoking.<sup>3</sup>

Despite this enormous progress, it is unlikely that the Healthy People 2010 objectives of reducing smoking prevalence to 12% or less in adults and 16% or less in youth will be reached on schedule. Though adolescent smoking rates steadily declined from 1997 to 2005, this downward trend is now flattening. Furthermore, rates of adult smoking held relatively steady from 2004 to 2006, after declining steadily for 8 years.<sup>1</sup> Though the vast majority of smokers wish to quit, less than 5% are successful in any year. Certain racial, ethnic and population groups are disproportionately at risk to tobacco-related cancers because of factors related to disparities in tobacco-use and access to effective interventions. The recent epidemiological data on the stabilization of adult and youth smoking rates underscore the need for vigorous research. To-

bacco control research across the discovery and delivery continuum, which includes genetics, gene-environmental interactions, bioinformatics and health informatics, disparities and disproportionate risk and prevention and treatment, needs to be accelerated in order to reduce the disease burden caused by cancer.<sup>4</sup> In addition, scientists need to respond to the dynamic landscape. Tobacco use changes among populations (e.g., initiation by youth and young adults, established smokers and disproportionate use), tobacco control resources (e.g., funding, research capacity) and the tobacco industry (e.g., new products such as snus and water pipe use, evolution of existing tobacco products, marketing and advertising).

The mission of the Tobacco Control Research Branch (TCRB) of the National Cancer Institute (NCI) is to "lead and collaborate on research and to disseminate evidence-based findings to prevent, treat and control tobacco use." As such, TCRB funds a large portfolio of grants and contracts. For example, over the past 10 years TCRB has funded or co-funded specific research initiatives in the following areas: youth tobacco prevention and cessation, transdisciplinary tobacco use, international tobacco intervention research, analysis of tobacco industry documents, research on tobacco products and state and community interventions. Because some tobacco products are marketed with claims that imply reduced harm, NCI currently funds a research and development contract to develop methods and measures for product testing in order to advance scientific knowledge about the toxic and addictive properties of these products.

Several conferences and reports highlight and prioritize important tobacco control research questions. Such reports include the 2006 National Institutes of Health (NIH) State-of-the-Science Conference on Tobacco Control report "Tobac-

co Use: Prevention, Cessation and Control," the 2006-2007 President's Cancer Panel report "Promoting Health Lifestyles," the 2006 NCI-designated Cancer Center Directors report "Accelerating Successes Against Cancer" and the 2007 Institute of Medicine's report "Ending the Tobacco Problem: A Blueprint for the Nation." Using these reports as input, TCRB recently developed 3 research initiatives:

1. "Improving Effectiveness of Smoking Cessation Interventions and Programs in Low Income Adult Populations"
2. "Measures and Determinants of Smokeless Tobacco Use, Prevention and Cessation"
3. "State and Community Tobacco Control Media and Policy Research"

The first 2 funding opportunities are closed to applications and will be funded by September, 2009. The latter research initiative is slated for announcement in June, 2009 with funding by September, 2010. These 3 research initiatives combined represent an investment of almost \$100 million over 6 years to address these high priority research areas.

TCRB funds research to prevent and control tobacco use and tobacco-related cancers through a variety of means. They generate new information about the factors that influence tobacco use and addiction, second-hand smoke (SHS) exposure and tobacco-related cancers, they create and evaluate tools and interventions for tobacco use, addiction and SHS and apply, promote, and disseminate evidence-based interventions in clinical and public health practice and policy development. Research is funded primarily through request for announcements (RFAs), with approved set-aside funds for a specific initiative or investigator-initiated research using a variety of mechanisms to support worthy research ideas with funds from a common budget or "pool." Most research within TCRB is funded

via the common pool 3 times a year using the following mechanisms: small grants (R03), behavioral exploratory and developmental grants (R21), traditional research grants (R01) and program projects (P01). All of these grant mechanisms could be appropriate for dental hygiene research addressing tobacco depending on the training and experience of the principal investigator and research team and the type of research project. If dental hygienist researchers have any questions about funding opportunities or the grant process, please contact a member of the TCRB staff. Information about TCRB and how to reach us,

research initiatives, funding opportunities and other resources can be found at our Web site: <http://www.tobaccocontrol.cancer.gov>. Weekly information about all NIH funding opportunities can be found at <http://grants.nih.gov/grants/guide/> and information about cancer control funding opportunities can be found at <http://cancercontrol.cancer.gov/funding.html>.

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## Behavioral and Integrative Treatment Development Program

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The National Institute on Drug Abuse supports an ongoing program of research on behavioral and integrative treatments for drug abuse, including nicotine dependence. The term “behavioral treatments” is used in a broad sense and includes various forms of psychotherapy, behavior therapy, cognitive therapy, family therapy, couples and marital therapy, group therapy, skills training, meditation and counseling. “Integrative treatments” refers to treatments that combine behavioral interventions with other treatments, including other behavioral therapies, medications or complementary/alternative therapies. Behavioral and integrative treatment research has been conceptualized, for the purpose of this program, to consist of 3 stages.

Stage I, or early treatment development, involves research on the development, refinement, and pilot testing of behavioral and integrative interventions. Stage I may include translational research that incorporates concepts, methods or findings from other disciplines (e.g., neuroscience) into the development of behavioral and integrative treatments. Stage Ia can be viewed as the most exploratory part of the treatment development process, in which theories of behavior change are tested, and the critical therapy development groundwork is laid. Late Stage I or Stage Ib, although still exploratory, can be viewed as the phase of Stage I in which theory-relevant data continues to be obtained, and the treatment undergoes pilot testing to determine whether or not a Stage II (or Stage III) study is warranted. Stage I may also include research to develop or adapt treatments to become

more community-friendly. When evidence-based treatments need to be adapted to be delivered by community treatment providers, such as in medical or dental settings, that adaptation is considered to be early treatment development. Such Stage I research may be conducted with research therapists or community treatment providers and may focus on developing technology-assisted treatment and training or modifying treatments to be briefer, less complex and/or less intensive. Stage I also involves testing the theory upon which a treatment is based to understand the mechanisms and principles of behavior change.

Stage II involves testing treatments that show promise. Stage II studies may include examinations of the components of treatments, dose-response and individual differences in treatment response. Stage II provides unique opportunities to further test the principles and mechanisms underlying behavioral change associated with treatment. If results are robust, Stage II studies may progress to Stage III. However, information obtained from Stage II studies may also be used to inform future Stage I studies. For example, if it is shown that a treatment works for some people, but not for others, a Stage II study may lay the groundwork for a Stage I proposal aimed at developing a treatment (or modifying the treatment) so that it works on the patients who were unresponsive to the initial treatment.

Stage III is research aimed at determining if and how efficacious behavioral treatments may be applied to community settings. Stage III may include studies that test treatments in community settings with community therapists. Stage III may also include studies that develop or test methods of training treatment providers to administer treatments.

The ultimate goal of treatment development is to produce treatments that work, and continue to

work when used in the community. Stage III research is aimed at obtaining knowledge and methods to ensure that an evidence-based treatment will retain its potency when delivered by community treatment providers. One question relevant to Stage III research is: “Does this treatment work when administered by community treatment providers?” Another question relevant to Stage III research asks: “How can this treatment be made to work when administered by community treatment providers?” Examination of the mechanism of action of treatments and/or training procedures is considered to be an integral part of Stage III. As is the case for Stage II, information obtained from Stage III studies may also be used to inform future Stage I studies. For example, if it is shown in Stage III that a treatment works for some people, but not for others, a Stage III study may lay the groundwork for a Stage I proposal aimed at developing a treatment (or modifying the treatment) so that it works on the patients who were unresponsive to the initial treatment.

Behavioral treatments play a critical role in most evidence-based drug abuse treatments, and often constitute the entire treatment. This program is intended to promote all of the necessary stages of behavioral and integrative treatment research so that better treatments are developed as advancements in science are made, and so that evidence-based treatments may be readily transported to the community. Over the past 2 decades, numerous evidence-based behavioral and integrative treatments for drug abuse and addiction have been created. With recent advances in science, particularly in neuroscience, it is evident that more can be done to incorporate new scientific discoveries into behavioral treatment development in order to improve treatment effects. In addition, as more is known about mechanism

of action of treatment, and as new technologies are developed, it is clear that more can be done to make treatments more easily transportable to community settings.

It is NIDA's objective to ensure sufficient emphasis and support for all stages of behavioral and integrative treatment research, so that scientific knowledge can readily be incorporated into newer and better behavioral interventions and treatments, and so that treatments can be effectively transported from research to the community.