# Handbook for Prospective Investigators

American Dental Hygienists' Association
Institute for Oral Health

**Prepared for the**

**American Dental Hygienists' Association**
**Institute for Oral Health**


by
**Kevin J. Lyons, Ph.D.**
Associate Dean and Director
Center for Collaborative Research

and

**Laura N. Gitlin, Ph.D.**
Associate Professor
Department of Occupational Therapy/
Assistant Director and Director of Research
Center for Collaborative Research
College of Allied Health Sciences
Thomas Jefferson University
Philadelphia, Pennsylvania




Revised Edition 1996
American Dental Hygienists' Association
Institute for Oral Health
444 North Michigan Avenue, Suite 3400
Chicago, Illinois 60611

## TABLE OF CONTENTS

# HANDBOOK FOR PROSPECTIVE INVESTIGATORS

## A. Introduction to the Purpose and Scope of the Handbook

The profession of dental hygiene is undergoing a period of growth and change. One area of emphasis involves expanding the research activities of dental hygienists to systematically build a knowledge base for the profession. As part of this building process, the ADHA Institute for Oral Health awards grants to help dental hygienists develop skills in conducting research to advance the research mission of the profession. The Institute has published a set of instructions that must be followed to submit a grant proposal. The purpose of this manual is to provide a resource to help dental hygienists write a competitive grant proposal to the ADHA Institute. The manual is designed to be a step-by-step practical guide to each section of the research proposal that is required by ADHA Institute. It contains a description of the material that must be included in each section and suggestions as to how to communicate this information effectively. The manual also presents strategies for developing competitive research ideas and a general set of guidelines for any grant proposal competition.

However, one must adhere to the specific requirements of each granting agency. This information is based on a manual commissioned by the Bureau of Health Professions on innovative strategies for grant writing and over 10 years of experience by the authors in working with allied health professionals in helping them improve their grant writing skills.

The manual focuses on writing a proposal for a quantitative research study and offers examples from proposals written in a similar fashion.

Writing a grant proposal is a very logical process. Each section of the proposal is intended to answer a specific question which, taken as a whole, paints a picture of what an investigator plans to do. Proposals are organized in such a way as to help answer these questions and to paint an attractive picture. This picture, if compelling, will enable a review panel to make an informed decision about funding.

Before we discuss each section of a proposal, we first introduce the unique vocabulary that is used by funding agencies and those writing proposals.

## B. Language of Grantsmanship

There is a specific language which is associated with the funding world. This language is important to know as you expand your research career and pursue funding from federal or foundation sources. Below are 12 common terms most often used.

- *Agency*
  The federal government is divided into a number of organizational units which consist of offices, centers, agencies, institutions, bureaus, divisions, and departments. Throughout this manual, we use the more general term "agency" to refer to any potential funding source including the ADHA Institute for Oral Health.

- *Call for proposals (or request for proposals)*
  A call for proposals (sometimes referred to as requests for proposals) is a notice of an opportunity to submit a proposal on a specific topic. Agencies often specify a particular issue that they want investigated and publish an announcement inviting interested parties to propose how they would investigate this issue. These announcements vary considerably in their specificity as to what should be investigated and how the investigation should be conducted. The ADHA Institute for Oral Health grant application is, in essence, a call for proposals.

- *Competition*
  The term "competition" simply refers to a particular grant program for which a call for competitive proposals has been issued.

- *Preferences, priorities and special considerations*
  Frequently, an agency may prefer to fund proposals that address a specific issue (e.g., minority health issues, women and AIDS). There are three ways in which an agency may choose to emphasize an issue: by initiating either a funding preference, funding priority or special consideration. Let's say your proposal is approved for funding by a review panel and you qualify for a *funding preference*. In this case, you will be awarded funding before other applicants who do not meet the preference. Let's say the agency establishes a *funding priority* for research on women and oral health care practices. If your application addresses this issue, your score will be adjusted by a certain point value, say 5 or 10 points, depending upon the agency. If, on the other hand, the agency establishes a *special consideration*, each reviewer may assign extra points to your proposal. When you apply to the federal government for a grant, and an agency offers one or more of these forms of "extra credit," you should try to qualify, since your proposal will be more competitive. The National Dental Hygiene Research Agenda included with the research grant application is an example of this "extra credit" approach. Although no extra points are given to applications, your proposal will be more competitive if it addresses an area within this agenda.

- *General instructions*
  All funding agencies publish a set of general instructions or guidelines to help prospective grant seekers write a proposal. While the guidelines vary in their level of specificity, they all provide information which is critical to the submission of a proposal. The research grant application form from the ADHA Institute for Oral Health is an example of a set of general instructions. It is very important to read all instructions carefully prior to developing a grant proposal.

- *Supplemental instructions*
  Some agencies modify their requirements for a specific competition and publish these changes as "supplemental instructions." These are very important to read because they may contain critical changes in the requirements from the general instructions.

- *Principal investigator/project director*
  A principal investigator is the person who directs a grant project. This title is used most often in research grants. A program director is the term applied to the person directing a training or educational grant or who is responsible on a research grant for the day-to-day research activities. In either case, there is one identified person who oversees the grant, assures the scientific integrity of the endeavor and is responsible for assuring that the grant is conducted in accordance with all conditions and regulations. This person may also be the key point of contact with the granting agency.

- *Program or project officer*
  A program or project officer in a federal agency or foundation provides leadership to a particular program of grant funding. A project officer is the person who supervises a specific set of funded projects or awarded grants.

- *Peer review panel*
  A peer review panel is a group of experts selected by an agency to evaluate grant proposals which have been submitted in response to a call for proposals. This panel follows a set of procedures established by the funding agency to evaluate proposals and make recommendations as to which should be funded. It is always important to learn how a funding agency reviews proposals and the evaluation criteria which are used by panelists.

- *"Pink sheets"*
  Pink sheets are written evaluations of proposals which are sent to the principal investigator. They are named, quite simply, for the color of the paper on which they are often printed. The pink sheet usually provides an in-depth narrative assessment of your proposal, including an overall summary of the strengths and weaknesses, the peer review panel's critique of each section, and recommendations or suggestions for improvement. Attached to this manual is a sample copy of the guidelines used by the review panel of the ADHA Institute for Oral Health. As you write your proposal, use these as a checklist to evaluate your proposal as you complete each section.

- *Direct and indirect costs*
  Direct costs are costs directly associated with implementing the grant proposal or project. They include project expenses such as salaries of project staff, fringe benefits, supplies, travel, trainee expenses and equipment. Indirect costs are costs associated with the general operation of your institution such as space to carry out the project, heating, telephone costs. The indirect costs are based on a rate which is usually negotiated between your institution and the funding agency or set by the agency at a fixed rate. The total cost of a project is calculated by adding the direct costs and the indirect cost based on the determined or allowable rate.

- *In-kind contribution*

This refers to the support your institution will provide or contribute to the project if you receive funding. Many agencies request that an institution contribute a portion of the expenses required to carry out a project, such as office supplies or secretarial time.

## C. **Plan of Attack for the Investigator**

1. *Developing a research idea*

The first place to begin in writing a research grant is to have a clear idea of your research question and how you want to carry it out. However, even the best ideas will not get funded if they are not of interest to a funding agency. Therefore, your great idea must be compatible with the interest of an agency. There are at least five major sources from which you can develop a competitive idea for funding. These are: the professional literature, clinical problems, professional association interests, legislative initiatives and collaboration with others.

a. *Professional literature*
As a professional, you should be reading the journals and other literature in your field. As you read, ask yourself: What are the major topics of the articles in the journals? Is there a trend in these topics? What are the major problems that are identified in the articles? These topics or problems can suggest areas for you to pursue in formulating a research topic because they reflect the important issues which are being examined in the field.

b. *Clinical problems*
As a dental hygienist, what are the major problems you see in your practice? What questions do you have about the clinical procedures you follow? Are there ways in which you can improve these procedures through systematic inquiry?

c. *Professional association interests*
The ADHA Institute has identified a number of areas that they believe are important to investigate. Attached to the grant application guidelines is a copy of the National Dental Hygiene Research Agenda. This agenda serves as a guideline for future directions in dental hygiene research and lists five general topic areas. A study to validate this research agenda was completed by the Center for Collaborative Research and the Department of Dental Hygiene at Thomas Jefferson University, in 1994, through funding by the Bureau of Health Professions. The study identified 37 research topics that leaders in the field of dental hygiene thought were important to investigate.

d. *Legislative initiatives*
Monitoring the progress of major legislation is an important way to anticipate future funding initiatives on the federal level. Congress appropriates money to all federal agencies with the expectation that it will be used to investigate concerns important to the American people. By monitoring legislation, you will learn about the major issues which are currently important to Congress. Since it can take six months to two years for legislation to be translated into a call for proposals, anticipating a potential funding opportunity may provide you sufficient lead time to think about a research proposal. One way to learn about pending legislation which is important to dental hygiene is to contact the ADHA. They monitor the activities on Capitol

Hill very closely.

e. *Collaboration with others*
Collaborating with professional colleagues is an excellent way to develop a competitive idea for research. Often, in discussions with others, common professional issues and new ideas which may be fundable can emerge.

2. *Matching your idea to ADHA Institute interest*

Once you have identified an idea that is important to you, the next step is to make sure this idea matches the interests of the ADHA Institute (or any other agency from which you may wish to seek funding). There are two important sources of information to help you accomplish this task. The first source for information is the agency itself. As we mentioned earlier, the ADHA Institute has identified in writing, a number of areas they consider important. Although you might be interested in pursuing a topic not related to these areas, your proposal would be more competitive if you modified it to fit the areas identified by ADHA Institute. The second source of information is to call the agency and speak to a program officer or representative. For example, call the ADHA Institute for Oral Health and ask the executive administrator if she/he thinks your idea will be competitive. While interest in your idea from the ADHA Institute does not guarantee that it will be funded, it does indicate that you are on the right track and in keeping with the goals of the Institute. If you are pursuing funding from another agency, read any material which the agency distributes and then call a program officer. He or she may be able to provide advice as to how to develop your proposal.

**Table I presents seven steps to follow to help guide matching your idea to a funding source.**

TABLE 1
STEPS TO MATCH YOUR IDEA WITH A FUNDING AGENCY

1. Identify broad topic areas through literature searches, discussions with colleagues and others; Ask yourself:

    a. Is this idea stimulating and important to me?

    b. Does the idea reflect contemporary thinking in the field?

    c. Does this idea have long-term potential to be expanded and contribute to my career?

    d. What are the goals of my department, institution and profession and how do their goals fit with my topic of interest?

2. Develop a preliminary list of potential funding agencies, (using the Federal Register, Catalog of Domestic Assistance, discussions with program officers, the Foundation Directory or Other Sources described in Section 2).

3. Evaluate your resources: Ask yourself:

   a. What is my level of expertise, interest and comfort with this topic area?

   b. Are others available to serve as collaborators to complement my level of expertise?

4. In light of #2 and #3, narrow your area of interest;

5. Write an abstract which reflects your current thinking;

6. Contact program officers of identified competitions to discuss your ideas and determine if the idea fits the priorities of the funding agency;

7. Reshape your ideas based on these conversations and a further review of the literature.

## D. Overview: The ADHA Institute Grant Application Packet

A proposal is a very rational and logical document. In a proposal, you need to inform a review panel of the following: 1) what you will do, 2) why it is important to do, 3) how you will do it, 4) how you will analyze your results, 5) why you should be the one to do it, 6) how much it will cost, and 7) why it will cost what it does. The research grant application provides a set of directions you need to follow to develop a proposal that addresses the points above.
The ADHA Institute application packet contains detailed directions for developing a proposal which are reviewed here. Before you write anything, read these instructions very carefully. In fact, read these directions several times. Many mistakes which often lead to non-funding can be avoided by carefully reading and following the instructions. The first two pages of the ADHA Institute application packet contains general guidelines.

The general instructions (Part A) of the research grant application kit provide important procedural information that you should read carefully before beginning your proposal. These sections contain general administrative information such as the procedures which will be used to evaluate your proposal, the number of copies to submit and the deadline or due date for the proposal. These sections also contain a description of who may apply for funding and the topics of interest to the ADHA Institute. They also contain a description of the budget items that are allowable and those that are not.

Also, carefully read the sections on research involving human and animal subjects and the section on the publishing rights agreement and publication process. With regard to the first, it is very important that you give careful consideration of the procedures you will use to protect the rights of any human or animal subjects that is included in your research. Any invasive procedure must be carefully planned and monitored for safety and that in the case of human subjects, patients are fully informed about the study. Even for surveys or questionnaires, it is important that participants are informed about their involvement in the study. If you are at a college or university, contact the Institutional Review Board (IRB) to learn about their requirements for implementing a study and protecting subject rights.

The section on the publishing agreement notifies you that, by funding your research, the ADHA Institute retains publication rights to the information. This agreement must be read very carefully so that you understand your rights regarding the results of your research and your responsibility to acknowledge the financial assistance of the ADHA Institute.

## E. <u>Sections of the Narrative for an ADHA Institute Proposal</u>

Now that you have developed an important idea, are sure it meets the interest of the ADHA Institute, and have read all of the preliminary material, it is time to write the proposal. The next part of the Handbook presents a discussion of the material you should include in each section and provides recommendations as to how to approach the writing task.
Section IX, Part B of the application guidelines is a section that you must read carefully and follow diligently. In this part, the ADHA Institute specifies exactly the way you should organize your proposal and what you should include in each section. Be sure to follow these directions closely. What follows is a discussion of each of these sections.

1. *Title page*

The title page contains, obviously, the title of your proposed research. This title should be brief, but descriptive. The following are three examples of possible titles.

<u>Too Brief</u>:
"A study of curriculum in dental hygiene"

<u>Too long and convoluted</u>:
"A study of the manifestations of student anxiety regarding anatomy and physiology instruction given by master's degree prepared instructors in an associate degree dental hygiene program located in a two-year institution in the Northeastern United States"

<u>Just Right</u>:
"A study of student anxiety toward courses in anatomy and physiology in an associate degree dental hygiene program"

The title page should just contain the title. However, you also need to complete the <u>ADHA Institute for Oral Health Research Grant Program Application Form</u> which is included in the application packet.

2. *Table of contents*

The table of contents is the next page in the proposal. Copy the 11 sections and subsections presented in Section IX, Part B of the application packet and use this as a table of contents. This list will also act as a checklist by which to ensure that you have included all required sections in your proposal.

The table of contents and abstract are not part of the 30-page limitation, so number these pages with lower case roman numerals, i, ii, etc.

3. *Abstract*

The abstract is a brief, descriptive overview of your research idea and methodology. It must be no more than 300 words. You need to describe the purpose of your study, the research design and how you will analyze your data. Since you only have 300 words, you must be succinct. This is a very important section, since it is the first introduction to your idea that a reviewer will read. The abstract often leaves a reviewer with a lasting first impression. If a reviewer does not understand what you propose to do in the abstract, this first impression may influence how the entire proposal is evaluated. The abstract should be the last section you write in your proposal.

**EXAMPLE OF AN ABSTRACT**

The conduct of research is an important activity to advance the profession of dental hygiene. The ADHA Institute for Oral Health Research Program has recognized the importance of this process and has made available money to support research studies in dental hygiene. The purpose of this manual is to provide a resource to help dental hygienists write a competitive grant proposal to the ADHA Institute. The manual is designed to be a step-by-step practical guide to each section of the research proposal that is required by the ADHA Institute. It contains a description of the material that must be included in each section and suggestions about how to communicate this information effectively. It also provides suggestions about how to generate research ideas. This information is based on a manual commissioned by the Bureau of Health Professions on innovative strategies for grant writing and over 10 years of experience by the authors in working with allied health professionals in helping them improve their grant writing skills.

4. *Introduction*

The introduction to a proposal usually includes several components. It is here where you begin to build a case for funding. Begin this section with a clear statement as to the problem you plan to address in your research, and the significance of the project. Include the operational definitions of key concepts and the specific hypotheses or study objectives. In this section, you are explaining to a review panel what you are going to study, why it is important, how you define your terms and the specific research question you plan to answer. Let's examine each one of these components.

a. *Introduction to topic*

Before you write a formal statement of the problem, you need to introduce your topic. To do this, describe the subject matter of your study in a few paragraphs. For example, if you were to do a study on the effectiveness of computer assistive instruction in teaching dental hygiene students about oral pathology and their level of satisfaction with this instructional method, you could organize your approach as follows. Introduce the proposal with a discussion of traditional instructional approaches in dental hygiene programs. Then identify problems associated with traditional instructional approaches, particularly the lack of satisfaction which has been reported by students. Next, briefly describe approaches to computer assistive instruction. This discussion will provide the background or context by which to understand your study. The background statement should also identify the variables that you plan to study and their relationship. Tell the reviewer only those essential aspects that he or she needs to know, and not all the things that would be "nice" to know.

b. *Statement of the problem*

After you introduce the topic, then write your statement of the problem. The statement of the problem actually poses a question about the relationship among the variables described in your introductory remarks. For example, how is computer assistive instruction (variable #1), related to learning of oral pathology? (variable #2) and student satisfaction with this method? (variable #3). You also need to make sure that the problem is directly related to the mission and agenda of the ADHA Institute. The following are examples of acceptable problem statements:

<u>Example #1</u>
How effective is computer assistive instruction in advancing student knowledge of oral pathology and in increasing their level of satisfaction with the learning process?

A study of the level of knowledge of nursing assistants regarding the oral health care needs of the elderly might have a problem statement that looks like this:

<u>Example #2</u>
To what extent does nursing assistants' knowledge of the oral health care needs of the elderly who reside in nursing homes lead to the identification of potential oral health problems?

c. S*ignificance of the problem*

Now that you have introduced a topic and written a problem statement, you need to explain the importance of your area of research. Although its importance may be very apparent to you, you need to convince a panel of your peers, the reviewers, of its significance. The significance section of a proposal addresses the "so what" question.  That is, you need to present a clear argument as to what is important, innovative or unique about your research.  Will it produce new knowledge that improves patient care?  How does it advance knowledge building in dental hygiene?  To build a logical argument and demonstrate the potential impact of your research findings, draw on published literature or pilot research you have conducted.  For example, let's say you want to demonstrate the significance of computer assistive instruction for dental hygiene students.

First, look for documentation which suggests that low achievement and student dissatisfaction with courses in oral pathology is common.  Consider reports of national board test scores and do not limit yourself to the dental hygiene literature.  You might find evidence of poor performance in similar types of courses reported in the literature of other professions such as education, occupational therapy, nursing or dentistry.  Demonstrate the prevalence of the problem, the significance of finding a solution, and the broad impact of your research.

Once you complete a draft of this section, ask yourself a series of questions as a way of checking the clarity, accuracy and completeness of your presentation.  The self-study questions posed below are those that are also used by the reviewers on an ADHA Institute panel to evaluate this section of your proposal.

**Self-Study Questions**

1. Is the statement of the problem clearly stated?

2. Is the statement of the problem relevant to the ADHA Institute mission/research agenda?

3. Is the significance of the problem clearly stated?

4. Is the significance of the problem relevant to the ADHA Institute mission/research agenda?

5. Does the significance of the problem show how the research project will advance current knowledge or improve current techniques?

d. *Operational definitions*

An operational definition provides an explanation of exactly how you will define and measure each variable, including independent, dependent, and control variables.  For example, in a study of student anxiety, anxiety might be defined conceptually as "a painful or apprehensive uneasiness of mind that is temporal."  Based on this concept, you would seek a measure that assessed anxiety as a state-like or temporal dimension such as Spielberg's 20-item State Anxiety Scale.  In addition to defining the term "anxiety," your operational definition should include a statement of how you intend to measure anxiety, for example, "Anxiety is a score of 40 or below on The Spielberg State Anxiety Scale (range is 20 to 80)."  Be sure to cite a reference if referring to a previously published instrument.

e. *Hypothesis/objective*
A hypothesis is a potential answer to your research question, or in this case, your statement of the problem. For example, in the statement of the problem cited above; "How effective is computer assistive technology in advancing student understanding of oral pathology and in increasing their level of satisfaction with the learning process?" the hypothesis would be:

> "Dental hygiene students who are taught anatomy using a computer assistive instructional program will perform significantly better on a standardized knowledge examination than students who are taught anatomy using a lecture format."

When you set a hypothesis, you will also have to test it against what is called a null hypothesis. This is a statement that simply says that there will be no difference between the two methods. The rationale for this procedure is found in many introductory statistics and research books, and will not be discussed here. The important point is that in your proposal you should state both forms of a hypothesis.

Objectives are different than hypotheses. If you are not doing an experimental or correlational study, a hypothesis may not be appropriate. In this case you would state your objective for doing the study. For example, if you were to do a study to assess a particular curriculum, your objective might be stated like this.

**EXAMPLE OF AN OBJECTIVE**

"The objective of this proposed study will be to determine if the curriculum guidelines developed by the American Dental Hygienists' Association are consistent with the competencies measured by the licensing board."

Upon completion of a draft of this section, ask yourself the following questions as a way of reflecting on your work.

**SELF-STUDY QUESTIONS**

1. Are the independent/dependent variables operationally defined?

2. Are the key concepts/constructs defined?

3. Are the definitions valid indicators of the independent/dependent variables?

4. Is the terminology used for the operational definitions consistent with the oral health professions?

5. Are the hypotheses/objectives stated in observable/measurable terms?

| | |
|---|---|
| 6. | Do the hypotheses clearly predict a relationship between variables? |
| 7. | Are the hypotheses based on a sound theoretical framework? |

5. *Review of the related literature*

The review of literature should be comprehensive and support the research problem statement. However, only the most pertinent or related and current works should be reviewed and cited. Since you have 30 pages of narrative, the literature review must be a comprehensive description of the existing research literature related to your problem area. Design your presentation in a logical manner to demonstrate your command of a scientific body of knowledge and how your study fits into a broader context. There are four major reasons why you need to review the literature.

a. The first is to determine what previous research has been conducted on your topic. If your research question has been studied, you may either want to replicate a study or modify the research design and take a slightly different approach.
b. The second reason is to use the literature to identify and describe your theoretical foundation or framework that will guide your study.
c. The third reason to review literature is to determine the relevance of a body of knowledge to your research idea. As you review and discuss the literature, indicate how your study will build on or test current knowledge.
d. Finally, it is important to review the literature to develop a rationale for your research strategy. Draw on the literature to justify the way you have chosen to pose your research question and develop your design and set of procedures.

There are several different ways of conducting a literature review and writing it up. Do a literature search in your library for articles or research studies which are directly related to the concepts and constructs of your study. A good rule of thumb is to review literature which has been published within the past five years unless there is an older “classic” article. Also, be sure to consider literature in fields other than dental hygiene. Review the abstracts of the articles and organize them into four categories:

1. Those that appear highly relevant and are absolutely essential for you to read for your proposal;

2. Those that are somewhat relevant and will probably be used;

3. Those that are relevant and you might use;

4. Those that are not relevant.

Start by critically reviewing the “most relevant” articles. Write down a very brief description of the article or study. If it is a research article, write a 4-5 sentence introduction in which you identify what was studied, how it was studied, what was found and what conclusions were drawn. Also, discuss any recommendations for future research in these articles which support your own proposed study. If it is not a research article, briefly summarize the major points of the article that are related to your topic. Once you have completed the pile of the most relevant articles, do the same with the articles in your “relevant” category. If, at the end of these two categories, you find that the conclusions of these articles are similar, or there does not appear to be any new information, it is probably time to stop searching for new articles.

When you write the literature review for your proposal, there are at least two forms that it can take. You can present the articles chronologically or you can group the articles for common themes that are related to your topic. For example, in the illustration of the study on the effectiveness of computer assistive technology in teaching anatomy, you might arrange the articles of the literature review in the following categories.

1. articles or studies discussing the need for new ways of teaching components of dental hygiene curriculum;
2. articles describing the components of computer assistive technology;
3. learning theory;
4. effectiveness of computer assistive technology;
5. effective methods of teaching anatomy;
6. studies of computer assistive technology in dental hygiene.

In this example, it would be very important to search for literature outside of dental hygiene. For example, computer assistive instruction has been investigated and written about in the educational literature in recent years. This body of literature will be very important in helping you develop your study.

If the topic area in which you are interested is one that has not been discussed or studied very much, your literature review may not be very long. You can then cite this point as a reason for conducting your study, as long as you have demonstrated the significance of your topic. However, don’t ignore the fact that even if there are no studies, there may be theoretical models, in dental hygiene or in other fields, that help inform your topic. If this is the case, include such literature in your review.

Another important aspect of the review is that you must always use what are called primary sources. For example, always read and cite original articles. Do not discuss a research article as described or presented by another author.

At the conclusion of the literature review you should summarize your analysis of the articles. In this concluding section, discuss the major findings from the review and how these findings support your background, significance, research question, hypotheses, and design. Be critical and identify gaps in knowledge, methodological flaws or other design related issues.

Once you write this section of your proposal, ask yourself the following questions.

**Self-Study Questions**

1. Does the literature review present the background to the present proposal?
2. Does the literature review critically evaluate and synthesize existing knowledge?
3. Are the gaps in knowledge which this study will address identified?
4. Does the review provide a basis of support for the hypotheses and/or research questions?
5. Has the need for this particular study been documented?
6. Does the literature review appear complete and up-to-date?
7. Is the literature review free of errors in logic or misinterpretation of information?
8. Is the literature logically developed?

6. *Methods and materials*

This section provides a comprehensive description of your research design and includes a discussion of the sampling plan, subject recruitment strategies, the desired sample size, data collection procedures, instrumentation and data analytic strategies you plan to implement. You must present a detailed discussion of your plan of action and demonstrate the scientific validity of your approach. This discussion should be detailed enough so that another investigator could conduct your study by reading the proposal. The research methods which you present will be evaluated for their logic, systematic organization, thoroughness and the extent to which the procedures can be expected to accomplish the specific aims of your research project.

A description of methods and materials is the most critical component of any research proposal. It may, therefore, be necessary to obtain consultation from a statistician or someone familiar with research design to assure that your design and analyses are scientifically sound and appropriate for your research question.

Common mistakes made by applicants in this section include the lack of detail, inadequate justification of procedures, poor integration of ideas, or a fatal flaw in the design. A fatal flaw represents a fundamental problem with the design which cannot be remedied. It requires that you rethink the entire project idea or set of procedures. For example, the following are comments from a review panel that illustrates a fatal flaw in a proposal.

**EXAMPLE OF A FATAL FLAW**

This research design cannot be accomplished without random assignment of patients to experimental and control groups. It does not appear that this is possible since to do so would compromise patient treatment plans at this facility. Without random assignment, however, it is difficult to see how the study outcomes can be interpreted and treatment effectiveness determined.

Let's examine each subcomponent of the methodology section.

a. *Research design*

A research design is the "blueprint" or plan which specifies how the study will be organized, the variables which will be measured and the data collection and analytic processes that will be followed. In this subsection of the proposal, it is important for you to provide a clear and concise description of your study design, and its major components. Also, you must explain why this design is appropriate for your study. This discussion provides an overview or framework from which each subsequent subsection on methodology logically flows.

First, be sure to identify and label your design correctly (e.g., a two-group randomized experimental design; correlational, prospective design; a 2 X 2 X 3 factorial design; mail survey). Make sure that the design you choose is appropriate to control for variance or extraneous variables and threats to validity.

Second, identify the major elements of the design such as the independent and dependent variables, the subject pool, sample size, and the number of testing occasions. Be specific in your description. For example, specify the independent and dependent variables as well as their proposed relationship in the study (causal, explanatory, mediator, predictive, etc). Indicate who or what is being studied and the sample size which is required.

The following are two examples of design statements.

**EXAMPLE #1 DESIGN STATEMENT**

This study is designed to evaluate the level of knowledge of nursing assistants concerning the oral health care needs in the elderly who reside in nursing homes. A descriptive survey design is proposed by which 100 nursing assistants from 10 nursing homes in the state of Pennsylvania will be randomly selected to participate in a telephone survey. A telephone survey will assure that nursing assistants will respond to knowledge questions without the assistance from other health professionals. An investigator designed survey will consist of basic demographic information, questions which assess knowledge of oral health issues in the elderly, and a case vignette to determine the ability of respondents to recognize signs and symptoms of oral health problems.

**EXAMPLE #2 DESIGN STATEMENT**

The research design chosen for this study is a two-group randomized experimental design to test the effectiveness of computer assistive instruction in increasing the knowledge of oral pathology of 50 dental hygiene students.

Students in their second year of study at Thomas Jefferson University will be randomly assigned to either an experimental or control group. Students in the experimental group will receive instruction using a newly developed computer assistive instructional program while those in the control group will participate in the traditional lecture discussion approach. The outcome or dependent variables in this study include knowledge level of oral pathology and student satisfaction with the learning experience. The advantage of randomization and a two-group experimental design in educational research has been well documented and includes the ability to control for differences in student backgrounds and learning styles, and other extraneous sources of variation.

After completing a draft of your design statement, ask yourself these questions.

**Self-Study Questions**

1. Is the research design appropriate to study the research problem?

2. Does the research design control for extraneous variables and threats to validity?

b. *Sample description and selection*

In this subsection, describe the sample and the procedures by which subjects will be selected to enter your study. Five basic points should be included. These are:

1. the characteristics of the participants in the study and the extent to which these are representative of the population to which you plan to generalize;
2. criteria for inclusion and exclusion of subjects and the reason for selecting these criteria;
3. procedures which will be followed to recruit and select the sample;
4. the sample size and a justification for its adequacy;
5. assurance of the feasibility of obtaining the required sample.

**EXAMPLE #1 SAMPLE DESCRIPTION**

Participants in this study will consist of a convenience sample of 50 dental hygiene students in their second year of the program. Students with previous course work in oral pathology or exposure to a computer assistive program will be ineligible for participation. The sample size of 50 is adequate to detect outcomes and is based on a power analysis, with power set at .80, alpha at .05 and an anticipated moderate effect size. No difficulty is anticipated in obtaining a sample of 50 students in that the average enrollment is 60 to 70 students each year.

**EXAMPLE #2 SAMPLE DESCRIPTION**

This study will be comprised of a convenience sample of 20 HIV positive patients with intraoral lesions who are seen at the oral health clinic and who volunteer for study participation. Criteria for eligibility include evidence of an HIV positive test, one or more intraoral lesions which may occur on any oral site, and at least one lesion which is rated as moderate to severe by an experienced clinician.

Currently, the oral health clinic has an active patient pool of 50 individuals who have been tested as HIV positive. Subject recruitment will occur in two stages. In the first stage, a letter will be sent to each active patient which describes the purpose of the study and invites participation. Patients will also be informed of the study during their regularly scheduled visits at the clinic. Those who contact the clinic to inquire about study participation will be screened over the telephone to determine initial eligibility.

In stage two of the recruitment process, those who are eligible based on the initial telephone screen will be asked to visit the clinic for an oral examination. A final determination of eligibility will be made by the dental hygienist.

Once you have a good draft of this section, ask yourself these questions.

**SELF-STUDY QUESTIONS**

1. Is the sample representative of the population of interest?
2. Is the sample size adequate?
3. Is the description of how the sample was derived clearly stated?
4. Is the sampling procedure appropriate (free of sampling error or bias)?
5. Are the procedures described in detail to allow for replication?
6. Is the assignment of subjects to groups/treatments appropriate?

c. *Procedures, materials, data collection instruments*

This subsection should include a discussion of three elements of the design: study procedures, data collection instruments and the protection of human subjects.

First, provide a detailed description of the procedures you intend to follow to collect data. One way to approach writing this part of the subsection is to think about what you need to do if your grant is approved for funding and you are due to start implementing it tomorrow. Then describe each step in detail.

**EXAMPLE #1 DISCUSSION OF PROCEDURES**

Following notification of grant approval and funding, a letter will be mailed to administrators of participating nursing homes. This letter will explain the purpose of the study and its procedures and the importance of participation of the nursing assistants. The letter will be followed by a telephone call to the administrator to determine an appropriate time to arrange for a 20-minute telephone survey with each nursing assistant. Each participating nursing home will be requested to provide a quiet office setting from which the nursing assistant can participate in the telephone survey.

**EXAMPLE #2 DISCUSSION OF PROCEDURES**

Cultures will be obtained from 20 HIV positive patients and identified and quantified on a weekly basis until the infection has been controlled. Thereafter, cultures will be taken monthly for a maximum of 12 months. Treatments will be administered to control the clinical signs and symptoms.

Second, discuss the materials that are necessary or the data collection instruments that will be used for the study. In describing an instrument, discuss its domains (e.g., demographic information, job satisfaction, psychological stress, etc.), the measurement level of a scale, and its validity and reliability. If you intend to design a data collection instrument, discuss a plan for examining its reliability and obtaining at least face or content validity.

A discussion of the reliability and validity of the data collection instruments that you plan to use in very important. The reliability of an instrument refers to the extent to which it measures the same phenomenon consistently or over repeated occasions. Validity refers to whether the instrument measures what it is supposed to measure (please see Appendix E for a more thorough discussion of reliability and validity). You must assure the review panel that the measuring instruments you have selected are reliable and valid so that they will yield the information required to answer your research question. Even the most sophisticated research question or design will not get funded if the instruments you choose are not adequate.

It is NOT sufficient to say that reliability and validity will be obtained by the usual methods. You must describe the known reliability and validity of the measures. If you intend to design your own data collection instrument, you must discuss your plan for examining its reliability and obtaining at least face or content validity. If you significantly modify an established instrument you will need to re-examine its reliability and validity. Once you have modified an instrument, you cannot be sure that it is still reliable and valid. Therefore, you must develop a plan to determine its reliability and validity and describe that plan in detail in the proposal.

**EXAMPLE #1 DISCUSSION OF INSTRUMENTATION**

The telephone survey will be developed by the investigators and consist of three primary domains: demographic information; items which assess knowledge of oral pathology in the elderly; and a case vignette with questions to determine the ability to recognize signs and symptoms. The survey will be reviewed by five individuals with expertise in oral health care of the elderly. This panel of experts will independently review the survey for its face and content validity. Modifications to the survey instrument will be made based on the panel’s review and the survey will be pilot tested with five nursing assistants.

**EXAMPLE #2 DISCUSSION OF INSTRUMENTATION**

The instrument we plan to use in this study is the Dumas Depression Inventory. This instrument has known reliability and validity. Heller (1993) used this instrument in a study of 256 dental hygienists in the state of Minnesota. She assessed its internal consistency as one measure of its reliability by using Cronbach's Coefficient Alpha and found it to be 83. Both concurrent and construct validity were also assessed. Concurrent validity was assessed by comparing the result of this questionnaire with the Beck Depression Inventory, an instrument that has been used in numerous studies. A significant correlation was found between the total scores of the two instruments. Construct validity was assessed using factor analysis. The factor analysis yielded three subscales, all with eigne values greater than 1.0.

Third, provide a discussion of the protection of human subjects. This discussion should include: a) your plans to assure confidentiality of the information or data that you obtain from human subjects, b) how consent from study participants will be obtained, c) the potential benefits and risks associated with participation for a subject, and d) the risk benefit ratio. Be sure to indicate whether you have either initiated the process of obtaining IRB approval for your protocol and consent form or have obtained such approval.

Although not required, the ADHA Institute for Oral Health strongly encourages you to have secured IRB approval prior to proposal submission. However, final approval **is** dependent upon this provision being met.

**EXAMPLE DISCUSSION OF HUMAN SUBJECTS**

This research is descriptive and involves a telephone survey. Participation in the study will be voluntary and by responding to the telephone survey, respondents will be giving their informed consent to participate. Subject confidentiality will be assured by the use of identification numbers on data sheets. Subject names and other identifying information will be kept in a locked filing cabinet in the office of the investigator and will be kept separate from the information provided by subjects in response to the survey questions. Information will be reported in aggregate form only and no participant will be identified.

There are no potential risks to participants. There are no direct personal benefits except for personal satisfaction obtained in participating in research and contributing to building a body of knowledge.

d. *Validity and reliability*

In this section you need to address the validity and reliability of your design. Just as reliability and validity are important in determining the adequacy of data collection instruments, they are also important considerations for assessing the appropriateness of your research design. Validity refers to whether a design and its procedures are appropriate and will yield information to answer the research question. Research findings are always vulnerable to alternative explanations. In other words, the results you obtain may be due either to the variables under study, or some other extraneous variables that you did not control for or consider. The effects of extraneous variables are referred to as threats to internal validity. The classic work in this area for experimental designs has been done by Campbell and Stanley (1963). You should refer to their work as you plan you design, and show how your design addresses the threats to validity identified by Campbell and Stanley.

**EXAMPLE OF A STATEMENT ON VALIDITY**

The approach used in this study is a randomized, pretest-posttest control group design. As a true experimental design, it controls for all but one of the threats to internal validity. The threats of history, maturation, regression to the mean and testing are controlled for by use of a control group. The possibility of subject selection bias is controlled for through the use of randomization in sample selection. While subject mortality is not controlled for, the sample size has been increased by 15% over the number required by the power analysis. Past studies in this area have reported subject attrition rates that are 10% or less. Randomized selection of subjects in the sample allows for generalizability of the results, increasing external validity of the study.

You also need to consider the reliability of your approach to data collection and analysis. Consider the specific design features you have established which assure consistency of data collection. Also, think about whether another investigator could replicate your study and would obtain similar data and draw the same statistical conclusions. A detailed description of the decision rules that will be implemented in your study increases its ability to be replicated. Finally, consider the procedures you plan to implement to assure that data is collected consistently and entered accurately.

**EXAMPLE OF RELIABILITY STATEMENT**

Following notification of grant approval and funding, a letter will be mailed to administrators of participating nursing homes. This letter, a copy of which is found in Appendix A, will explain the purpose of the study and its procedures and the importance of participation of the nursing assistants. The letter will also request the administrator to provide a list of the names of the nursing assistants at the site. The letter will be followed by a telephone call to the administrator to confirm participation and to determine the most convenient times to conduct a 20-minute telephone survey with the nursing assistants. Each participating nursing home will be requested to provide a quiet office setting from which the nursing assistant can participate in the telephone survey. Once the list of nursing assistants has been obtained from the administrators, 9 will be randomly selected from each site using a table of random numbers. Those identified will be contacted within 7 days. The principal investigator will explain the purpose of the study, ask for his/her participation and arrange a specific time for the telephone interview. If a nursing assistant is not able to participate in an interview, a replacement will be randomly selected from the list. If an interview has to be interrupted for any reason, arrangements will be made to complete the interview within a five day period.

Three interviewers will be trained to use the telephone interview protocol. Once training is complete, inter-rater reliability will be attained by having each interviewer conduct a mock interview with 5 volunteer nursing assistants and their responses correlated. Once a satisfactory level of inter-rater reliability is achieved, each interviewer will be assigned to interview 3 nursing assistants at each site. The principal investigator will randomly select one out of each 10 interviews to observe to assure adherence to the interview procedures. All interviews will be checked twice for completeness and accuracy.

Completed interview protocols will be coded to identify the nursing home, the nursing assistant being interviewed and the interviewer. The responses to the interview will then be entered on standard coding sheets, and entered by a data entry program using double verification procedures. Once data are cleaned, the completed interviews and coding sheets will be placed in a locked filing cabinet. All personal identification information will be kept separate from the interviews in a locked cabinet by the principal investigator.

e. *Assumptions, limitations and boundaries of the study*

In this section your discussion must focus on the underlying assumptions of your design, its specific limitations and the boundaries of the study.

First, think about the underlying premise of your study design. Every design is based on certain assumptions. For example, let's say you have designed a mail survey. One assumption of survey research is that respondents answer questions honestly and without assistance from other individuals. Another assumption might be that those who are sampled are representative of a larger population. Or, in an experimental design, a basic assumption is that randomization will assure equivalence between the experimental and control group condition.

Second, discuss the limitations of your study design. Every study has limitations. These may include possible sources of bias, potential for contamination of experimental and control group subjects, or inability to control variance. For example, let's say you are conducting a Delphi study, one limitation of this study design is the possibility that some respondents may discuss their opinions with others who they may know are participants in the study. This reflects a possible limitation which is inherent in the Delphi technique.

Third, identify the boundaries of your study. Every study design has boundaries which may include the persons studied, the settings analyzed or the selection of specific variables for study at the exclusion of others. In your discussion, indicate who will be studied and the extent to which you will be able to generalize your study findings to other persons, settings or situations.

To check this stage of your proposal, use the following self-study questions.

**Self-Study Questions**

1. Are the instruments used valid for the purpose of the study and the sample?
2. Is reliability accurately represented in relation to the instruments used?
3. Is reliability accurately represented in relation to the examiners gathering data?

f. *Time table*

The earliest possible funding date for your proposal will be May 30. Therefore, base your start-up date on July 1 and outline the length of time which you will require to accomplish the major activities of your study. Provide a table which summarizes these major activities and the time frame for their completion.

Here are two examples of how this material can be presented.

**EXAMPLE #1 TIME TABLE**

| | ACTIVITY | TIME FRAME |
|---|---|---|
| 1. | Questionnaire development | Months 1-3 |
| 2. | Pilot testing of instruments | Months 4 |
| 3. | Subject recruitment | Months 5-8 |
| 4. | Subject interviewing | Months 5-10 |
| 5. | Data entry, data cleaning | Months 10-12 |
| 6. | Data analysis | Months 12-15 |
| 7. | Report generation | Months 15-18 |

| EXAMPLE #2 TIME TABLE | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **ACTIVITY** | | | | **TIME LINE** | | | | |
| | July | Aug. | Sept. | Oct. | Nov. | Dec. | Jan. | Feb. |
| Instrument Development | | | | | | | | |
| Pilot Test of Protocol | | | | | | | | |
| Sampling | | | | | | | | |
| Mail Survey Sent | | | | | | | | |
| Reminder Notice | | | | | | | | |
| Second Reminder Notice | | | | | | | | |
| Data Entry Analysis | | | | | | | | |
| Report Writing and Dissemination | | | | | | | | |

After you finish the time line, ask yourself the following question.

**Self-Study Question**

1. Is there a feasible time line for completion of the study which reflects the major requirements of the study?

7. *Statistical analysis*

This section involves a discussion of your analytic approach and the statistical procedures you plan to use. In your discussion, it is helpful to restate the hypotheses of your study and demonstrate the specific statistical analyses you intend to use to test them. Also, provide a brief rationale for your choice of a statistical test and the significance level or alpha which will be used to determine statistical significance.

Be sure that the analyses you select fit the measurement level of your data. For example, if your data is categorical or ordinal, then a descriptive and non-parametric statistical approach would be the most appropriate. Also, indicate how you plan to report your data such as by using frequency tables involving distribution of percentages or using measures of central tendency such as means, medians or modes.

You may need to consult with a statistician to determine the best analytic approach for your study. Keep in mind that the analyses you choose are an extension of your study design and must be appropriate and capable of providing an answer to the research question.

**EXAMPLE #1 DISCUSSION OF STATISTICAL ANALYSIS**

The major hypothesis which will be tested in this study is that students who participate in a computer assistive learning experience will demonstrate greater knowledge of oral pathology and greater satisfaction with their educational experience than students who participate in a traditional educational experience. Analysis of covariance (ANCOVA) will be used as the primary statistical analytic strategy to determine experimental effect on the two dependent variables (knowledge of oral pathology and student satisfaction). ANCOVA is the statistical test typically used in a two-group experimental design involving pre- and post-test data.

Also, demographic data obtained from this study will be tabulated using crosstab frequency distributions and measures of central tendency. All tests of significance will be reported at the .05 level.

**EXAMPLE #2 DISCUSSION OF STATISTICAL ANALYSIS**

A combination of statistical methods will be used to compare the characteristics of dental hygienists who participate in the mail survey questionnaire. Comparisons of the two groups (novice and experienced dental hygienists) on continuous variables will be based on analysis of variance (ANOVA). Significant ANOVA's will be followed up with Tukey's HSD (Honestly Significant Difference) test for multiple comparisons. Analysis of categorical variables will involve crosstab frequency distributions with chi-square statistics. To determine statistical significance, alpha will be set at .01 to control for Type I error and all statistical tests will be based on a two-tailed distribution.

Use these questions to check this part of the proposal.

**SELF-STUDY QUESTIONS**

1. Are the statistical analyses appropriate to answer the research question and test the proposed hypotheses?

2. Are the statistical analyses appropriate for the measurement level of the data which will be collected?

3. Are the variables identified for statistical analysis?

8. *Budget and budget justification*

In developing a budget, think about each project task and the costs associated with its accomplishment. Then develop a budget that is realistic in that it will provide the financial support which is required to conduct the study. As you prepare the budget, pay attention to the resources you may need as well as the policies and requirements of the agency. For example, the ADHA Institute **does not** provide grant funds to support the following activities:

- travel to professional meetings
- honoraria, salary or tuition for the investigators
- graduate student tuition
- fees or stipends
- equipment
- new facilities, renovation of existing facilities
- planning projects

The ADHA Institute **will** provide grant funds to support:

- secretarial assistance
- research assistants
- statistical consultation
- computer time
- travel related to the research study
- research supplies
- remuneration to patients

There are usually three major components of a proposal budget: 1) direct costs, 2) indirect cost allowances, and 3) institutional commitments. Each of these are discussed here in detail.

1. *Direct costs*:
   Direct costs are those expenses which are necessary to carry out your project and include salaries and benefits, consultant fees, supplies, travel and "other" expenses.

   a. *Personnel* - This category refers to the salary support that is requested for members of the project team (e.g., principal investigator, project director, interviewers, research assistant, secretary, or other personnel). Starting with the principal investigator, list the names and identify the roles of all personnel involved on the project during the budget period who are employees of your institution. To determine the cost of their salaries, it is first necessary to estimate the amount of time each person will spend on the project. Usually this time is calculated as the percent effort of a person's full time load. This percentage is multiplied by an individual's institutional base annual salary. If the person is on a nine or 10-month employment contract and is asked to work on your grant during the summer, you will need to make a separate calculation for this summer salary.

The next step is to compute the cost of fringe benefits which are attributable to this salary. This rate is determined by your university. The following table provides an example of how you would compute salary costs for individuals on your grant.

| **EXAMPLE** | | |
|---|---|---|
| Step #1 | 30% Effort x Base Salary = | Cost to Grant or Institutional Contribution |
| | .30 X 48,000 = | 14,400 |
| Step #2 | Requested Salary x Fringe Benefits = | Cost to Grant or Institutional Contribution |
| | 14,400 x .265 = | 3,816 |

b. *Consultant* - Consultants are those experts who are not university employees but who will perform a discrete task on your project. For example, you might require the assistance of a statistician to work with you on data analysis. You will need to negotiate the compensation for these individuals and report it in a non-salary section of the budget. Since these individuals are not university employees, fringe benefits are not calculated for consultants.

c. *Supplies* - These include daily office needs such as stationery, audiotapes, postage, laboratory supplies such as reagents and chemicals which are necessary for your project. Estimate the cost of all the materials you will need and ask for that amount.

d. *Travel* - Travel costs must be associated with the specific research tasks of your project. It may include costs associated with travel to interviews, research meetings at multi-sites, or consultant travel. As in each budget category, you should request only clearly justifiable travel expenses and provide an estimate of the costs. Also, each institution uses an adjusted government rate for reimbursing car travel. For example, the current government rate is $0.32 a mile. Be sure to inquire as to the rate used in your own institution.

e. *Other* - This category includes costs which are not covered in the above categories. These costs may involve data entry and computer file management and costs associated with advertising to recruit subjects.

2. *Indirect costs:* Indirect cost allowances are used to reimburse your institution for the fixed, continuing administrative and physical plant costs incurred in the course of "doing business." These costs include building maintenance, utilities, insurance and other general administrative expenses. An allowance for indirect or overhead expenses is based on a set rate or pre-negotiated percentage of certain direct costs of the grant.

3. *Institutional commitments:* Your institution can contribute to the financing of your project in a number of ways. First, an institution can contribute time for the principal and co-principal investigators of your project team. For example, if you estimate that a 30% effort is required by the principal investigator, your institution may agree to donate your effort. Another way to demonstrate institutional commitment is through the donation of supplies, mailing, telephone or duplicating expenses. A way to demonstrate university commitment with federal agencies is through a waiver of a portion of the indirect cost recovery allowance. If your university has a negotiated indirect cost rate of 67% with an agency, you might request a lower rate, such as 50% and show the difference (17%) as a university contribution. If you are applying to an agency in which there is no negotiated indirect cost rate, you could still use the 67% rate as a baseline to demonstrate an in-kind contribution.

   In developing a budget, be certain that your institution is agreeable to an in-kind commitment and the costs of your project. The following is an example of a final budget.

**SAMPLE OF A BUDGET**

**PERSONNEL**

| Position Requested | % Effort | Salary per Individual | Fringe Benefits (Salary x .265) | In-kind | Total Requested Funds |
|---|---|---|---|---|---|
| Investigator | 30% | $14,400 | $3,816 | $18,216 | 0 |
| Research Assistant | 10% | $ 1,800 | $ 477 | | $2,277 |
| Secretary | 10% | $ 2,000 | $ 530 | | $2,530 |
| Total Salary Costs | | $18,200 | $4,823 | $18,216 | $**4,807** |

| | | |
|---|---|---|
| **NON-SALARY COSTS** | | |
| **Consultants** | | |
| Questionnaire design (10 hrs. x $40) | | $ 400 |
| Statistical support (5 hrs. X $ 40) | | $ 200 |
| **Supplies** | | |
| Business envelopes (50 x 4 mailings .01) | | $ 2 |
| Diskettes | | $ 20 |
| Postage, printing costs, duplication | | $1,000 |
| **Travel** | | |
| Parking for meetings at collaborative sites | | $ 100 |
| **Other** | | |
| Entry and computer costs | | $ 500 |
| **Total Non-Salary Costs** | | **$2,222** |

| | | |
|---|---|---|
| **TOTAL COSTS** | **$18,216** | **$6,029** |

**BUDGET JUSTIFICATION**

You are also required to provide a detailed justification for each expense. A budget justification involves a brief explanation and rationale for each line item in the budget. Start with "Personnel" and identify each person's roles and responsibilities on the project and provide a rationale for their percent effort. Explain each line item and demonstrate how each cost has been derived.

> **EXAMPLE OF A BUDGET JUSTIFICATION FOR PERSONNEL**
>
> Personnel: The university will provide in-kind support in the form of salary and benefit support for the investigator who will commit 30% effort to this project. Grant funds are being requested for a project secretary who will provide clerical support and coordinate the printing and mailings of the survey. This individual will devote 10% effort to this project. Funds are also requested for a research assistant who will devote 10% effort to this project.

Ask yourself the questions below as a self-evaluation of this section.

**SELF-STUDY QUESTIONS**

1. Is my budget practical and realistic for the tasks I plan to accomplish?

2. Is my budget appropriate for the tasks I need to accomplish, my level of resources and the costs allowable by the ADHA Institute?

3. Are the grant funds I am requesting sufficient to offset the costs of my project?

ADHA Institute reviewers will ask:

**Self-Study Questions**

1. Does the budget seem realistic for the work to be done?

2. Is each entry in the budget justified as to how the amount was determined?

3. Do budget requests comply with ADHA Institute for Oral Health policies?

9. *Appendices*

The appendices include information that supplements the narrative. For the ADHA Institute, the appendices are not considered part of the 30-page limitation. However, you should be judicious in what you choose to include. Some agencies do not consider appendices materials included in page limitations so be sure to read the instructions closely. For example, appendix material may include tables, charts and graphs which support the text. Also, you must include your survey instruments or sample questionnaires along with the letters or instructions that will accompany their use.

Other materials you may want to include in the appendices are: the complete curriculum vita of key members of the project team, pertinent articles that you have published that relate to the project, and letters of support from consultants, leaders in your profession, or your senators and congressmen.

Label each appendix with an alphabetic letter and use a cover sheet to indicate its title. Also, include a list of the appendices in the table of contents.

**EXAMPLE OF COVER SHEET FOR AN APPENDIX**

APPENDIX A

Cover Letter and Sample of Telephone Questionnaire

10. *References*

As in all scientific work, a reference of your sources of information is required. If the agency does not specify a reference style, then use the American Psychological Association (APA). In all cases, be sure to use a uniform style and be consistent in the presentation of references.

Although there are no page limitations to this section, only include those references which are cited in the proposal.

11. *Supplemental required information*

a. Assurance of protection of human subjects
If your study involves the participation of human subjects, you must submit with the application, documentation that the research has received approval or exemption from your institutional committee charged with assuring compliance with federal, state and local law concerning the conduct of research involving human subjects.

b. Assurance of humane care and use of animals
If your study involves the participation of animals, you must submit with the application, documentation that the research has received approval or exemption from your institutional committee charged with assuring compliance with federal, state and local law concerning the conduct of research involving animals.

For this section, ADHA Institute reviewers will ask the following.

**SELF-STUDY QUESTIONS**

1. Are the characteristics of the subject population appropriate for this study?
2. Have the inclusion and exclusion criteria been identified and are they appropriate?
3. Do the plans for the recruitment of subjects meet ethical standards?
4. Does the informed consent form describe the risks and procedures for protecting the subjects from risk?
5. Are the risks identified reasonable in relation to the benefits?
6. Has Institutional Review Board approval been obtained?

Now that you have finished writing your proposal, check closely to make sure that all required material has been included, that you have the necessary signatures and that you have followed all of the requirements as specified by the ADHA Institute for Oral Health (use appendix as a final checklist). Duplicate the required number of copies, mail the proposal and wait for a response. Good luck.

References


1. Campbell, T., & Stanley, J.C. (1963). Experimental and quasi-experimental designs for research. Chicago: Rand McNally & Co.

2. Carmines, E.G. & Zeller, R.A. (1988). Reliability and Validity Assessment, Beverly Hills: Sage.

3. DePoy, E. & Gitlin, L.N. (1994). Introduction to research: Multiple strategies for health and human services, Philadelphia: Mosby.

4. DeVellis, R. F. (1991). Scale development: Theory and applications, 26, Newbury Park: Sage.

5. Findley, T.M. (1989). The conceptual review of the literature or how to read more articles than you ever wanted to see in your entire LIFE, Am J Phys Med Rehabil, 68:97-102.

6. Kerlinger, F.N. (1973). Foundations of Behavioral Research, (3rd ed.). New York: Saunders.

7. Silva, F. (1993). Psychometric Foundations and Behavioral Assessment, Newbury Park: Sage.

Appendix A

**TIPS FOR GETTING STARTED**

1. Read all materials and directions for proposal submission provided by the ADHA Institute.
2. Type each heading and use this as your outline for proposal development and writing (this should also form the basis for your table of contents).
3. Read all materials and directions for proposal submission provided by the ADHA Institute again.
4. Develop a time line for writing the proposal and if others are involved, assign writing responsibilities and due dates.
5. Read all materials and directions for proposal submission provided by the ADHA Institute **AGAIN**.
6. Leave sufficient time prior to the due date (January 30) to allow a colleague to critically review your proposal.
7. Identify who in your institution is required to sign the title page and approve the proposal prior to its submission to the ADHA Institute.
8. If human subjects are involved, submit the required forms to your Institutional Review Board prior to your proposal submission.

Appendix B

**WRITING TIPS**

1. Set aside a block of uninterrupted time to write.
2. Start the grant application by outlining the major sections of the proposal. Then begin writing the section with which you are most comfortable.
3. Expect to write between four to six drafts of each section. Do not expect your first draft to be perfect.
4. Once you complete a draft of a section, try to get some distance from it.
5. Try to revisit your work as if you were a reviewer examining someone else's proposal.
6. Read your draft aloud.
7. Do not clutter the narrative.
   - stay away from jargon
   - stay away from words that are "trendy"
   - avoid colloquialisms
   - do not try to sound intellectual
   - do not try to cut corners by using "etc."

Appendix C

Use this list as a final check prior to submitting your proposal.

**CHECKLIST FOR SUBMISSION OF PROPOSAL**:

_____ Six copies of proposal:

_____ Submission of Institutional Review Board Forms (if applicable).

_____ Narrative does not exceed 30 pages (Introduction through Budget and Budget Justification).

_____ Signature of institutional official on cover sheet.

APPENDIX D

**ADHA Institute for Oral Health Research Grant Reviewer Rating Form***

**TITLE: ____________________________________________________________**

**REVIEWER: _________________________________________________________**

**Instructions to Reviewer**

This grant should be reviewed in terms of the adequacy of the proposed research to yield valid results significant to dental hygiene. You are requested to read the proposal carefully, check off the quality rating phrase that best describes your impression of each section of the proposal and to supplement your indicated evaluation with comments. The comments are sought by the Research Grant Review Committee to not only aid in reaching a decision about funding, but also to supply helpful feedback to the applicant. The comments will be collated and transmitted anonymously to the applicant.

**Review of the Preliminary Matter**

| | | | |
|---|---|---|---|
| 1. | Is the principal investigator a licensed dental hygienist or a student pursuing a dental hygiene degree? | Yes | No |
| 2. | Does the proposal legitimately address the Mission of the ADHA Institute or the National Dental Hygiene Research Agenda? | Yes | No |
| 3. | Does the title of the proposal accurately represent the research project? | Yes | No |
| 4. | Is the abstract within the 250-300 word limit? | Yes | No |
| 5. | Does the abstract clearly describe the: | | |
| | purpose | Yes | No |
| | research design | Yes | No |
| | statistical analysis | Yes | No |

Comments:

* This is a **sample** ratings document, and is not to be used when submitting a proposal to the ADHA Institute for Oral Health Research Grant Review Program.

**Review of the Research Plan**

In reviewing the Research Plan, choose a quality rating phrase that best describes the particular aspect of the proposal and provide comments in the spaces provided. The following definitions should be used to decide on choice of quality rating phrase:

| | |
|---|---|
| S = Satisfactory | No modification or minor changes are indicated to strengthen the proposal. Suggested changes are described in the comments. |
| M = Marginal | Revision is needed before the proposal could be re-reviewed for possible acceptance. Your specific suggestions for revision should be included in the comment section. |
| U = Unsatisfactory | Does not meet minimal standards. This could apply to the conceptualization of the plan and/or the organization and expression of the ideas. Your comments should specifically state the reasons for making this judgement. |
| NA = Not Applicable | This criterion does not apply to the proposal. |

**A. Introduction**

**To What Extent:**

| | | S | M | U |
|---|---|---|---|---|
| 1. | Is the statement of the problem clearly stated? | S | M | U |
| 2. | Is the statement of the problem relevant to the ADHA Institute mission/research agenda? | S | M | U |
| 3. | Is the significance of the problem clearly stated? | S | M | U |
| 4. | Is the significance of the problem relevant to the ADHA Institute mission/research agenda? | S | M | U |
| 5. | Does the significance of the problem show how the research project will advance current knowledge or improve current techniques? | S | M | U |
| 6. | Are the independent/dependent variables operationally defined? | S | M | U |
| 7. | Are the key concepts/constructs defined? | S | M | U |
| 8. | Are the definitions valid indicators of the independent/dependent variables? | S | M | U |
| 9. | Is the terminology used for the operational definitions consistent with the oral health professions? | S | M | U |
| 10. | Are the hypotheses/objectives stated in observable/measurable terms? | S | M | U |
| 11. | Do the hypotheses clearly predict a relationship between variables? | S | M | U |
| 12. | Are the hypotheses based on a sound theoretical framework? | S | M | U |

Comments:

**B. Review of the Literature**

**To What Extent:**

| | | S | M | U |
|---|---|---|---|---|
| 1. | Does the literature review present the background to the present proposal? | S | M | U |
| 2. | Does the literature review critically evaluate and synthesize existing knowledge? | S | M | U |
| 3. | Are the gaps in knowledge which this study will address identified? | S | M | U |
| 4. | Does the review provide a basis of support for the hypotheses and/or research questions? | S | M | U |
| 5. | Has the need for this particular study been documented? | S | M | U |
| 6. | Does the literature review appear complete and up to date? | S | M | U |
| 7. | Is the literature review free of misinterpretation of information? | S | M | U |
| 8. | Is the literature logically developed? | S | M | U |

Comments:

**C. Research Design and Methods**

**To What Extent*:***

| | | | | | |
|---|---|---|---|---|---|
| 1. | Is the research design appropriate to study the research problem? | S | M | U | NA |
| 2. | Does the research design control for extraneous variables and threats to validity? | S | M | U | NA |
| 3. | Is the sample representative of the population of interest? | S | M | U | NA |
| 4. | Is the sample size adequate? | S | M | U | NA |
| 5. | Is the description of how the sample was derived clearly stated? | S | M | U | NA |
| 6. | Is the sampling procedure appropriate (free of sampling error or bias)? | S | M | U | NA |
| 7. | Are the procedures described in detail to allow for replication? | S | M | U | NA |
| 8. | Is the assignment of subjects to groups/treatments appropriate? | S | M | U | NA |
| 9. | Are the instruments used valid for the purpose of the study and the sample? | S | M | U | NA |
| 10. | Is reliability accurately represented in relation to the instruments used? | S | M | U | NA |
| 11. | Is reliability accurately represented in relation to the examiners gathering data? | S | M | U | NA |
| 12. | Are the assumptions clearly identified? | S | M | U | |
| 13. | Are potential difficulties and limitations anticipated and addressed? | S | M | U | |
| 14. | Has the researcher submitted a feasible time line for completion of the study? | S | M | U | |
| 15. | Are the variables identified for statistical analysis? | S | M | U | |
| 16. | Is the statistical analysis appropriate to test the hypotheses? | S | M | U | |

Comments:

**D. Budget and Budget Justification**

**To What Extent:**

| | | | | |
|---|---|---|---|---|
| 1. | Does the budget seem realistic for the work to be done? | S | M | U |
| 2. | Is each entry in the budget justified as to how the amount was determined? | S | M | U |
| 3. | Do budget requests comply with ADHA Institute for Oral Health policies? | S | M | U |

Comments:

**E. Human Subjects (only rate if applicable)**

**To What Extent:**

| | | | | | |
|---|---|---|---|---|---|
| 1. | Are the characteristics of the subject population appropriate for this study? | S | M | U | NA |
| 2. | Have the inclusion and exclusion criteria been identified and are they appropriate? | S | M | U | NA |
| 3. | Do the plans of the recruitment of subjects meet ethical standards? | S | M | U | NA |
| 4. | Does the informed consent form describe the risks and procedures for protecting the subjects from risk? | S | M | U | NA |
| 5. | Are the risks identified reasonable in relation to the benefits? | S | M | U | NA |
| 6. | Has Institutional Review Board approval been obtained? | S | M | U | NA |

Comments:

**F. Animal Subjects (only rate if applicable)**
**To What Extent:**

| | | S | M | U | NA |
|---|---|---|---|---|---|
| 1. | Has the principal investigator described his/her qualification and training pertaining to the specific animal model and procedures involved in this protocol? | S | M | U | NA |
| 2. | Has the qualification and training of the personnel who will have direct animal and/or tissue contact in this protocol been described? | S | M | U | NA |
| 3. | Does the research, if it involves any of the following, been described?<br><br>Antibody production, blood/tissue collection, breeding colony, behavioral studies, field studies, surgical procedures, prolonged restraint, radioactive materials, other hazardous agents. | S | M | U | NA |
| 4. | Does the primary investigator explain why the species selected are the most appropriate for this study? | S | M | U | NA |

Comments:

**G. Recommendations**

_____ Approval for amount requested

_____ Approval for reduced funds (explain below)

_____ Approval for increased funds (explain below)

_____ Conditional approval (state conditions below)

_____ Recommend resubmission (summarize suggested changes below)

_____ Disapprove (summarize reasons below)

Comments:

Reviewer's Signature_______________________________________________
Date: ________________________________

# APPENDIX E

A Brief Discussion of Reliability and Validity

## RELIABILITY

Reliability of design:
The purpose of a study design is to allow you to interpret the results of your study accurately. If you cannot rely on measuring variables precisely, or if your research design is not well planned, then you cannot be sure that the results you attain are accurate. Therefore, you need to be sure that your design is reliable. Reliability refers to the accuracy or precision of a design. For a design to be reliable, it must be planned and executed in such a way that if repeated under the same circumstances, it would yield the same results each time. This means that procedures are in place to assure consistency in carrying out the study and that the study can be replicated by another researcher. To attain reliability, you must describe procedures such as how interviewers will be trained and monitored, how data will be examined for missing data and accuracy. That is, your description must be in sufficient detail so that it is clear to others that your operations, measurement instruments, quality control procedures and data analytic strategies are consistent and appropriate to the research question. You also need to describe the design in sufficient detail so that someone else could use this description and conduct the study the same way that you did.

Reliability of Measures:
For a data collection instrument to be reliable, it means that, all other things being equal, an individual would receive the same score each time he/she completed it. The two most common ways that reliability of a data collection instrument is assessed are through tests of homogeneity and tests of equivalence.

Tests of homogeneity measure the extent to which items on the instrument are internally consistent. A correlation coefficient is used to assess this consistency. The usual procedure is to randomly divide the instrument in half after it has been completed by a group of subjects. Each individual will then have two scores. If the test is internally consistent, the correlation between the two halves computed by correlating all the combinations of items, would be approximately the same. The statistical tests of reliability used most often are Cronbach's coefficient Alpha and the Kuder-Richardson test.

Tests of equivalence are also used to assess reliability. There are two approaches that are commonly used. The first is a comparison of alternate forms of an instrument. Alternate forms tests require the comparisons of two versions of the same instrument. A sample of individuals are given both forms to complete at one sitting. The scores from each form are then correlated. The second method is used to assess the reliability of observation or interview instruments. This method is called inter-rater reliability. Two observers measure the same event and their independent measures are then correlated (in some cases the same rater can make two observations at different times).

## VALIDITY

Validity of design:
The validity of a research design refers to the extent to which ones findings are accurate or reflect the underlying purpose of the study (DePoy & Gitlin, 1994: Kerlinger, 1973). In your proposal, describe the methodological limitations or issues posed by your design and how you plan to address them. In doing so, consider the classic work by Campbell and Stanley (1963). Campbell and Stanley identify four types of validity applicable to experimental-type research designs. These are internal validity, external validity, statistical conclusion validity, and construct validity.

*External validity* refers to the ability of the design to accurately answer the research question. In other words, can you be sure that your results are the consequence of the relationship between your dependent and independent variables rather than some extraneous factor. Campbell and Stanley have identified 11 potential threats to internal validity and ways in which these threats can be overcome.
*External validity* refers to your capacity to generalize the findings obtained from you sample to the population from which it was taken. Primary emphasis in maximizing the external validity of your study is usually placed on adequate sampling procedures.

*Statistical conclusion validity* refers to the ability of your statistical techniques to draw accurate conclusions from your data. In other words, our choice of statistical technique must be appropriate to the questions you ask. For example, if you are looking for causality, you would not select a correlation statistic or, if you were comparing three groups you would use an F test as opposed to a T test.

*Construct validity* refers to the fit between the constructs of your study and how they are operationalized. You must be sure that you accurately define the constructs in your study and select measures that they reflect.

Validity of measures:
you must consider the validity of the data collection instruments you will use in your study. There are four basic types of validity.

1. Face validity is the most basic and elemental approach for demonstrating the validity of a data collection instrument. It indicates that an instrument appears to measure what it is supposed to measure. To establish face validity, you must develop a clear definition of the concept you wish to measure and assess whether the instrument contains items that seem to explain the elements of this definition. This is usually done by the investigator who is developing the instrument. This approach is very subjective and, unfortunately, there is no standard or objective computation to determine how accurate the judgment is.

2. Content validity is also a subjective approach, although the process is more systematic than face validity. Content validity refers to the adequacy with which an instrument measures all of the basic content of the phenomena you wish to measure (DePoy & Gitlin, 1994). The first step in establishing content validity is to conduct a thorough literature search to identify the full domain of a construct. The second step is to use the findings from this review to construct items to represent these domains. The third step is to have these items evaluated by a panel of content experts and modify the items based on their review. This review provides a more systematic evaluation of the instrument in that each item is evaluated in terms of the definition of the construct and the specific objectives of the data collection instrument. As in face validity, there are no standard or statistical computations to determine the adequacy to which the instrument represents the underlying construct. Nevertheless, content validity is an important step in the validation process of an instrument.

3. Criterion-related validity - There are two forms of criterion-related validity. These are known as concurrent and predictive validity. They are determined by comparing the results of an instrument with criteria that are known to measure the same attribute contained in the instrument. Concurrent validity compares the results of an instrument with another known instrument. For example, if you have developed a test for depression, you would conduct a pilot study using your instrument and another depression scale which has know validity. If your test has concurrent

validity, subjects should score similarly on both scales. If you were to assess predictive validity for your depression instrument, you might give it to a sample of subjects and from the results predict which of the subjects would show signs of depression. You would then check the medical records of these individuals to see how accurate your predictions were.

4. Construct validity refers to how well a data collection instrument actually measures the theoretical construct that it is supposed to measure. For example, if an instrument is designed to measure the construct motivation, the question would be whether it really measured motivation or some other construct. To assess construct validity, you would hypothesize that individuals who are motivated, would have different characteristics than people who are not motivated. You would identify external criteria that are known to be related to motivation, such as better grades in college or a higher level of professional activity. If individuals with high scores on the motivation scale also had high scores on the criteria, and those with low scores on the motivation scale did not, you could claim a high level of construct validity.