PREPARING A DEMONSTRATION GRANT PROPOSAL

Kathleen N. Lohr, David Draper

September 1986

N–2500–HCFA

The Health Care Financing Administration,
U.S. Department of Health and Human Services
The research described in this report was supported by the Health Care Financing Administration, U.S. Department of Health and Human Services, under Cooperative Agreement No. 18-C-98489/9-02.

The RAND Publication Series: The Report is the principal publication documenting and transmitting RAND's major research findings and final research results. The RAND Note reports other outputs of sponsored research for general distribution. Publications of The RAND Corporation do not necessarily reflect the opinions or policies of the sponsors of RAND research.

Published by The RAND Corporation
1700 Main Street, P.O. Box 2138, Santa Monica, CA 90406-2138
PREPARING A DEMONSTRATION GRANT PROPOSAL

Kathleen N. Lohr, David Draper

September 1986

N-2500-HCFA

The Health Care Financing Administration, U.S. Department of Health and Human Services
PREFACE

One of the early tasks undertaken by the RAND/UCLA Center for Health Care Financing Policy Research was the preparation of instructional materials to be included in the standard application kits distributed by the Office of Demonstrations and Evaluations, Office of Research and Demonstrations, Health Care Financing Administration (ODE/ORD/HCFA) to persons, government agencies, and institutions wishing to apply for funds or waivers to carry out a demonstration project. For one of these tasks, HCFA asked that the center develop a short, informal booklet that would explain the important attributes of a successful grant proposal, with specific attention to the "Project Narrative" portion of the application. The audience was assumed to be relatively unfamiliar with the basic principles of research, HCFA's program of demonstrations, and the general process of peer review of demonstration applications.

Although the resulting booklet is tailored for a HCFA proposal, its underlying themes and suggestions should be of interest to any individuals or institutions that wish to submit applications to the various governmental and private agencies and foundations that fund health services and health policy research. The project and the Center are supported through Cooperative Research Agreement 18-C-98489/9-02.
SUMMARY

Many individuals and institutions have good ideas for new ways to provide high quality health care, while containing costs, within two major publicly funded programs, Medicare and Medicaid. To obtain funding to demonstrate these ideas, people like you at institutions like yours may elect to submit an application to the Office of Research and Demonstrations of the Health Care Financing Administration (HCFA). To be successful in this search for financing or a waiver to conduct a demonstration project, you must develop a proposal that describes:

- What you propose to do;
- Why you propose to do it in the manner described;
- Why the enterprise is worthwhile, in its own right and to HCFA; and
- What new contributions your project offers (and how it is related to past or current work by you or others).

In developing a demonstration proposal, and especially the section known as the "Project Narrative" that describes the actual research you intend to carry out, it is important to keep in mind the main audience for which you are writing. This is the peer review panel, sometimes known as a study section, that reads, evaluates, and passes judgment on your proposed study. Your peer reviewers will look to see if you have identified the important effects or outcomes to study and if you have designed your study in a way that will let you detect those outcomes if they occur and determine the correct causal factors. In this brief booklet, we attempt to provide some guidance and reminders about what is or is not found in a successful proposal.

We describe and discuss the major elements of the project narrative section of a demonstration grant proposal, namely: Project Title and Objectives, Background and Importance, Research Questions and Methods, Evaluation and Analysis Plan, Work Plan, Project Staff, and Implementation Potential.
We concentrate on several topics that should receive special attention during your proposal-writing. These include hypotheses to be tested (or that might be tested in a follow-on study); study design issues such as experimental variables, population and samples to be studied; and plans and problems for data collection. We also offer some suggestions about the level of detail in your analysis plan and the importance of specifying any analytic pitfalls you can foresee. For instance, we argue that you need to make sure that you have no loose ends as regards the data you plan to collect and how you plan to use them in your final analyses. Finally, we have appended a highly selective bibliography on study design and analysis topics and a narrative glossary of scientific and statistical terms and synonyms that may be helpful.
ACKNOWLEDGMENTS

A number of colleagues at RAND contributed to this work through review and comments on a detailed preliminary outline and on an earlier version of the text of this booklet. They include Mary Anderson, James Chiesa, Paul Ginsburg, Thomas Glennan, Susan Marquis, Joseph Newhouse, Adele Palmer, and Peter Reuter. Sidney Trieger, our HCFA Project Officer, also gave helpful suggestions on the original outline and guidance about the full text. The authors also express their appreciation to Margaret Thomas of RAND for a careful review and apposite suggestions to improve the clarity and usefulness of the booklet.
## CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>I. PURPOSE OF HCFA DEMONSTRATION PROJECTS</strong></td>
<td>1</td>
</tr>
<tr>
<td><strong>II. PURPOSE, SCOPE, AND ORGANIZATION OF THIS BOOKLET</strong></td>
<td>1</td>
</tr>
<tr>
<td><strong>III. PURPOSE OF A PROPOSAL: COMMUNICATE TO REVIEWERS</strong></td>
<td>3</td>
</tr>
<tr>
<td><strong>IV. PROJECT NARRATIVE: KEY ELEMENTS</strong></td>
<td>5</td>
</tr>
<tr>
<td>A. Project Title and Objectives</td>
<td>5</td>
</tr>
<tr>
<td>B. Background and Importance</td>
<td>5</td>
</tr>
<tr>
<td>C. Research Questions and Methods</td>
<td>8</td>
</tr>
<tr>
<td>D. Evaluation and Analysis Plan</td>
<td>13</td>
</tr>
<tr>
<td>E. Work Plan</td>
<td>16</td>
</tr>
<tr>
<td>F. Project Staff</td>
<td>18</td>
</tr>
<tr>
<td>G. Implementation Potential</td>
<td>19</td>
</tr>
<tr>
<td><strong>V. FINAL POINTS</strong></td>
<td>20</td>
</tr>
<tr>
<td><strong>SELECTED REFERENCE PUBLICATIONS</strong></td>
<td>23</td>
</tr>
<tr>
<td><strong>SELECTED GLOSSARY OF RESEARCH AND DEMONSTRATION TERMS</strong></td>
<td>25</td>
</tr>
</tbody>
</table>
### TABLES

1. Summary of Characteristics of HCFA Demonstration Categories ......................................................... 2

2. Sample Project Narrative Outline for HCFA Demonstration/ Evaluation Grant Proposals .......................... 6
I. PURPOSE OF HCFA DEMONSTRATION PROJECTS

The Office of Research and Demonstrations (ORD) of the Health Care Financing Administration (HCFA) directs several hundred research, evaluation, and demonstration projects. These projects are used to test new ways to provide high quality health care, while containing costs, within two major health programs, Medicare and Medicaid. Such projects often provide a basis for decisions about critical health policy issues, and they frequently advance the state of knowledge about measuring health care practices and behaviors of providers and program beneficiaries. This booklet is intended as an aid to individuals and institutions who wish to secure HCFA funding for demonstration projects.

II. PURPOSE, SCOPE, AND ORGANIZATION OF THIS BOOKLET

You have in mind a good idea "to demonstrate" and you believe that it corresponds to HCFA's concerns and research priorities. That is a long way, however, from a successful proposal that will gain approval during the review process and, ultimately, gain funding or a waiver from HCFA. This booklet attempts to provide some guidance and reminders about what is and is not found in a successful proposal.

The Office of Demonstrations and Evaluations (ODE) within ORD funds, manages, and evaluates projects or studies that assess new and innovative ways of delivering and financing Medicare's and Medicaid's services. ODE defines three types of demonstrations, which are briefly described in Table 1. Briefly, demonstration studies can be controlled experiments in which the investigator manipulates treatment variables and randomly assigns participants to groups, observational studies in which the investigator manipulates treatment variables but cannot control who goes into which groups, or descriptive studies in which the investigator examines new or existing programs or groups to see how well they operate or how feasible they are to expand.

You are expected to designate your proposal as belonging to one of these categories, and this booklet provides proposal-writing suggestions applicable to all three. However, many of the Category I proposals, generically considered experiments (randomized controlled trials), will be written by researchers with considerable experience, so much of this
Table 1
SUMMARY OF CHARACTERISTICS OF HCFA DEMONSTRATION CATEGORIES

<table>
<thead>
<tr>
<th>Characteristic or Requirement</th>
<th>Type of HCFA Demonstration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Category I</td>
</tr>
<tr>
<td>Type of Research Design</td>
<td>Experimental (controlled experiment)</td>
</tr>
<tr>
<td>Major Characteristics and Subtypes</td>
<td>Investigator manipulates treatment variables</td>
</tr>
<tr>
<td>Randomization of study participants into experimental and control group(s)</td>
<td>No randomization of study participants</td>
</tr>
<tr>
<td>HCFA Evaluation Plan Requirements</td>
<td>Research and evaluation plan are the same</td>
</tr>
<tr>
<td>Applicants conduct evaluation or designate evaluator</td>
<td>Applicants must include evaluation component (HCFA may still do an independent evaluation)</td>
</tr>
<tr>
<td>Relative Importance of Design Issues</td>
<td>Critical</td>
</tr>
<tr>
<td>Relative Importance of Evaluation Issues</td>
<td>Critical (but builds directly from design)</td>
</tr>
</tbody>
</table>
booklet is addressed to persons or agencies who may have less expertise in this area and who may be more likely to propose Category II or III studies.

We focus here on the description you will give of your research project, especially in the section of the proposal called "Project Narrative." We are not concerned with how one estimates or prepares a budget or develops waiver cost estimates for projects that need them.¹ The remainder of the booklet treats the purpose of your proposal, important parts of your proposal, and key elements of the project narrative. In addition, we have appended both a highly selective bibliography of reference publications that you may find helpful and a glossary that explains more fully some of the terms contained in this booklet.

III. PURPOSE OF A PROPOSAL: COMMUNICATE TO REVIEWERS

The first and most important audience you need to reach is the peer review panel, which will read, evaluate, and pass judgment on your proposed study. Thus, the basic purpose of your proposal is to communicate your ideas to this panel, thoroughly yet crisply. If you cannot successfully outline your objectives, explain your study methods, or argue for the importance of your project, your proposal will quite probably be disapproved on scientific and technical grounds.

Announcements of the demonstration program, typically appearing in the Federal Register, give due dates for applications, and peer review panels are usually convened about a month or two after these closing dates. The panels consist of experts--"peers"--from HCFA, other federal

¹Advice on completing the budget forms can be found in the HCFA brochure entitled "Research & Demonstrations Grant Application Guide," which is included in this grant application kit; instructions about waiver cost estimates are given in the HCFA document "Guidelines for the Preparation of Demonstration Project Waiver Cost Estimates," OMB #09380408, which is also enclosed in the application kit. You should take care to fill out all required forms completely.
health agencies, and (mainly) from academic and research institutions around the country. These peers represent a range of disciplines from economics and statistics to psychology and sociology to medicine and health policy. Always assume that at least one member of a review panel is knowledgeable about the topics you want to investigate and the methods you propose to use in your investigation; panel members who have this knowledge may well be assigned as the primary reviewers of your proposal. But remember also that you must communicate with the entire review panel and that many panel members may not have specialized knowledge in your particular area.

Peer review panels, sometimes known as study sections, receive applications to be reviewed in advance and then meet for (usually) a day or two; in that time, they may discuss, critique, and vote on 10 to 25 or more proposals. This means that, often, proposals are read and reviews written under great time constraints. Thus, all that you can do to make your proposal as clear and concise as possible, consistent with telling the full story about your intended project, will pay immense rewards.

In particular, you must find balance: Communicate enough, but not too much. Reviewers should be able to understand all of the following:

- *What* you propose to do;
- *Why* you propose to do it *in the manner described*;
- *Why* the enterprise is *worthwhile*, in its own right and to HCFA; and
- *What new contributions* your project offers (and how it is related to past or current work by you or others).

Reviewers should not be confronted with extraneous material, excessively long literature reviews, or unsubstantiated claims about the project's relevance or importance. Within some reasonable length, you want to convince the reviewer that your topic is worth investigation and that you can handle the task.

A completed demonstration application will have five main parts: the "Front Sheet," the "Project Approval Information Sheet," the "Budget Information and Justification," the "Project Narrative," and the "Waiver
Cost Estimate." (See your application kit for these forms.) All are eventually important in final funding decisions. The most critical is the Project Narrative, because it is the heart of your proposal and as such is given the most scrutiny by the review panel.

Over the years, conventions have emerged about the structure of research applications, including standard outlines. The Project Narrative is no exception. Although the outline suggested in Table 2 is not an absolute requirement, it is a commonly used guide for HCFA proposals. Thus, it is used here as the format for discussing the major points about preparing a good proposal. If you believe you have good reason to depart from this outline, do so. Remember, however, that your reviewers will expect something much like this structure, and you lighten their task when you follow it.

IV. PROJECT NARRATIVE: KEY ELEMENTS
A. Project Title and Objectives

Be succinct in titling your project, and be accurate. Find the key words, phrases, or descriptors that will highlight the population of interest, the medical problems of concern, and the health policy issues of importance, and then stop.

Your objectives should pinpoint what you plan to do and what you expect to achieve. They should be relatively few in number and listed in approximate order of priority or importance. Remember that what you state as your objectives sets the framework and the tone for judging the rest of the proposal. Underscore the major elements of your work that you believe are achievable: Do not promise to study the world or to answer all the crucial questions in the area.

B. Background and Importance

B.1. Background to the Project

This is in all likelihood where you will put your literature review. It need not be lengthy, but it should be reasonably comprehensive and up-to-date. Basically, your task is to highlight, succinctly, where the gaps in knowledge or practice are that your project will help correct. You must show that you understand the important studies that form the foundation for your proposal and
Table 2
SAMPLE PROJECT NARRATIVE OUTLINE FOR HCFA
DEMONSTRATION/EVALUATION GRANT PROPOSALS

(Part I. Front Sheet)  
(Part II. Project Approval Information Sheet)  
(Part III. Budget Information and Justification)

Part IV. Project Narrative

Table of Contents Page

Executive Summary

A. Project Title and Objectives
B. Background and Importance
C. Research Questions and Methods
   1. Hypotheses
   2. Study Design
D. Evaluation and Analysis Plan
E. Work Plan
   1. Description of Tasks
   2. Time Schedule
   3. Level of Effort of Personnel
F. Project Staff
   1. Qualifications of Key Staff
   2. Organizational Chart
G. Implementation Potential
References
Appendices

(Part V. Waiver Cost Estimate)

indicate how your project will go beyond them. You are not expected to review all the relevant literature in great detail; if you are conversant with other bibliographies or literature reviews, go ahead and cite them.
Again, assume that at least one reviewer will know this literature well; he or she will speak up during the panel meeting if the proposal shows no familiarity with existing work. If there is no literature or body of knowledge in the area you want to study, say so up front—but be sure you are right. Rarely does a project start *de novo*, so to be safe you may still be better off briefly considering the research closest to your proposed work.

For demonstration proposals, it is important to show familiarity with HCFA-sponsored work. Your literature review will presumably pick up relevant published articles or reports. For on-going projects, you might double-check the HCFA publication called *Health Care Financing Status Report*, which appears annually. Indicate where your proposed work builds on earlier or current projects or addresses new problems not yet investigated through HCFA funding. This often provides a lead-in to the next subsection, on "Importance of the Project."

Finally, there are two other scholarly points: Cite the references completely and correctly, and be sure everything has a citation in the reference list. You can be sure that if you omit something from the list, *that* will be the reference your reviewers will want to know about. Of course, you will not cite anything that you have not used in the literature review or in later parts of the proposal.

**B.2. Importance of the Project**

You need to make two main points here: the *significance of the question or issue* you are proposing to investigate and the *significance of your particular project*. As to the former, HCFA occasionally publishes a grant solicitation in the *Federal Register*. Recent ones (e.g., that of January 30, 1985) highlight priority areas for HCFA-sponsored research. If your topic fits in one of the areas specifically mentioned in such a solicitation, say so, because proposals in these areas receive priority for funding. This also assures that your proposal is reviewed by the appropriate review panel.

As to the significance of your proposed work: This is the place to make as strong a case as possible for the importance of your particular project! It may add to the general body of knowledge about a problem; it may expand the possible ways to organize and deliver health services
to meet a particular human need; it may do both. The point is to
marshall a credible, straightforward argument for the important
contributions your work will make.

C. Research Questions and Methods

Together with the subsection "Evaluation and Analysis Plan," this
is the heart of the Project Narrative. These sections will be read more
carefully than any others, because ultimately this is what HCFA is
buying.

Hence, your peer reviewers will look to see if you have

- Identified the important effects or outcomes to study; and
- Designed your study in a way that will let you detect those
effects if they occur and determine the correct causal factors.

C.1. Hypotheses

If you have hypotheses to test, state them explicitly. Category I
and II demonstrations probably will have them. Category III
demonstrations may not have precise, testable hypotheses, as they are
usually descriptive studies, but you should at least allude to the
issues that prompted you to undertake the project. In some cases, a
Category III study is seen as a precursor to a larger, more controlled
experiment. In this case, it may be useful to indicate what hypotheses
would be tested in a larger study in the event your first study
indicates that a followup would be worthwhile.

C.2. Study Design

Your basic objective here is to describe how your demonstration
project will operate. In part, you could try to discuss how your
demonstration activities are similar to or different from what occurs
now in the programs, Medicare or Medicaid, for instance, that you are
trying to study.

The research methods will come under close scrutiny in any review.
They may be more critical, the more like a Category I study your project
is, but in all cases they should be thought out. It is crucial that the
timing and sequence of your project be clear in the reviewers' minds;
you may find that inserting a simple descriptive diagram at this point
that makes the timeline clear will prove very helpful.
Illustrative questions that should be addressed directly in the proposal are briefly noted below, but they do not necessarily exhaust the important dimensions to study design that may be pertinent in your particular case.

**Treatment or experimental variables.** In some ways, the key part of your study will be the activities or services you undertake to study—that is, the *treatment* or *experimental* actions that are under your control. This might be a single line of action, such as providing a particular nursing service on an ambulatory basis; or, it may be a range of related activities of varying intensity (such as providing only "usual medical care," "usual care plus homemaker services," or "usual care plus homemaker and visiting nurse services"). In any event, you must make sure you have described these as fully as possible.

**Population to be studied.** What is the population from which your study's participants and subjects will be drawn? Is it truly appropriate to the topic you want to examine and the program you want to demonstrate? What will be your unit of observation? For instance, are you studying individuals, organizations, or communities?

**Sample to be used.** Rarely will a demonstration project study everybody in a population or community; typically, you will use a sample drawn from a larger group. In either case, you should explain as much as you can about how you will determine the size of your sample and how you will *select* it, how you will *assign* your study participants to different groups, and how you will deal with *sample loss*. It is often helpful to present a summary table giving information about the initial sample size, the likely number of subjects lost from the sample for various reasons, and the target numbers of subjects in each group.

Regarding sample size and generalizability: How many people will you be studying? How representative are they of the population of interest (e.g., Medicaid or Medicare beneficiaries)? How many will be in your *experimental* or *treatment* groups and how many in the *control* or *comparison* groups? Will these numbers be sufficient to let you detect differences of a magnitude relevant to health policy decisions? These questions relate to the important issue of the *precision* or *power* of your study and the strength of its eventual conclusions, so you should
indicate here (or in an appendix) whatever power calculations you might have done to justify your sample sizes. Will your sample let you generalize accurately to larger populations?

If this is a true experiment (Category I), how will you randomly assign participants to groups? Do you face any ethical or practical problems in this assignment process? If this is a quasi-experiment (Category II and possibly Category III), how will you match experimental to comparison groups or otherwise find a suitable external comparison? In this latter case, you should take on directly the question of why you rejected a full randomized design.

As for sample loss, what will you do if people drop out of your study? That is, what if some individuals leave the area, become disenchanted with your project, become too ill to continue to participate, or die? Do you have some idea how large these losses might be? Have you built enough subjects into your total sample to withstand such sample losses? What provisions have you made for dealing with bias arising from these losses (systematic differences between the subjects who drop out and those who remain)?

Data collection plans. Describing fully your plans for gathering information is critical. You should provide as much detail as you can at this point to answer the following: What pieces of information are you planning to collect? Precisely from whom? How often? By what techniques? Are there alternative data collection methods or sources of information that you have considered but rejected? If so, explain why, especially if the ones you dismissed might be less costly.

Uppermost in the reviewers' minds may be the question of how each piece of information relates to the hypotheses you are testing or the program you are trying to demonstrate. Think of it as a chain of reasoning that must be internally consistent—an unbroken set of links, so to speak. These links are critical, and you can make the points best if you try to accomplish the following here:

- Give a good, specific description of the match between what you say you are investigating and the particular data you plan to collect.
• Clarify what your dependent (or response) variables are, what your independent (or treatment or explanatory) variables are, and what factors you may need to measure or account for because they might otherwise confound your analyses.

• If relevant, discuss your project's cross-sectional aspects (comparisons in one time period) and longitudinal aspects (comparisons over time).

• Avoid left-overs! It should be clear by the end of this section that you will not collect data for which you have no obvious use in this study and that you will have obtained pertinent data for all the topics you propose to address.

Numerous issues arise with respect to data collection instruments and people. If, for instance, you are using or adapting existing self-reported measures such as questionnaires that patients or care-givers complete, can you document that they are known to be reliable? (That is, is there evidence that they will assess patient characteristics or attributes the same way if used more than once or if administered in different ways?) Further, can you document that they are known to be valid? (That is, do they really assess the factors or variables they purport to assess and not something else?)

If your data collection instruments already exist in some form, consider including them (or at least a subset) as an appendix. If you are going to get help from persons knowledgeable about these instruments, such as the original developers, say so.

If you are developing your own measures or instruments, indicate how you will establish their reliability and validity. In this instance, you should give at least some idea of what such forms might look like or what elements (e.g., individual illustrative questions) they might contain. As with most research projects, developing data collection instruments usually does not start completely from scratch, so if you have examples of materials on which you might base your own forms, include them and indicate how you expect to modify, update, or improve them.
If you are using interviewers, medical record abstractors, or other data collection personnel, you should give some description of how they will be selected and trained. How will you ensure that they all do things in pretty much the same way, so that in the end you have comparable data across all your study participants?

Your will probably need to get informed consent from potential subjects to participate in your demonstration, unless you will be collecting only anonymous data. This section is as good a place as any to describe how you will carry out the informed consent procedures.²

Finally, this section would be a good place to distinguish between two types of data you may collect in your study: primary (gathered directly by you from your subjects) and secondary (drawn from sources external to your own direct data-gathering). Secondary data are often useful, but their value may be limited by a lack of comparability between your own subjects and those on which the secondary data were based. Thus, if you plan to draw on secondary data sources you should discuss both their advantages and limitations for your project.

Data collection problems. If you foresee special data collection problems, indicate what they are and how you will try to overcome them. For instance, might you have difficulty gaining access to medical records in local hospitals or physicians' offices, or in obtaining information on the total amounts of medical services study participants use during the project? Or, what will you do if certain individuals, or types of study participants, do not respond to your surveys? It is better to show that you know where the problems are and that you have given them some thought than to have reviewers assume that you were not aware difficulties might arise.³

²Informed consent is part of a larger concern for protecting human subjects—that is, what steps have been taken, such as getting approval from an Institutional Review Board, to safeguard the rights and welfare of your study subjects. This is typically done on a separate HCFA or DHHS form (see the application kit). Explicit requirements can be found in the Code of Federal Regulations, Title 45 on Public Welfare, Section 46 on Protection of Human Subjects. The Office of Protection from Research Risks of the National Institutes of Health in Bethesda, Maryland, publishes an "OPRR Report" containing the relevant regulations.

³If you are doing a project for which federal funding is requested (a project that is not a waiver-only demonstration), or if you expect
Data base management. The larger your proposed project, the greater the amount of information you will amass. Regardless of the size of your project, however, the quantity of data you eventually collect will probably be larger than you expect. Thus, no matter how large your study, you should comment explicitly on how your data will be held, managed, and processed.

For instance, who will have the main responsibility for organizing, storing, and archiving completed questionnaires? Who will maintain computer data tapes and make needed workfiles available to those who will analyze the data? How will the privacy of information on study participants be guarded and guaranteed?

D. Evaluation and Analysis Plan

D.1. General Points

In an ODE demonstration project, the plans you have for analyzing your data form your evaluation plan, and they should be discussed here. The reasoning is essentially as follows: You are mounting a demonstration to explore the feasibility and practicality of some program or to test some hypotheses about that program, be it a new service to Medicare beneficiaries or a different way of making care available to mothers or children eligible for Medicaid. To know if your demonstration has been successful, you will have to evaluate it.\(^4\) That is, you will have to carry out a series of specific analysis tasks, either throughout the demonstration or near its conclusion, that will permit you to conclude something about the feasibility and possible generalizability of the program or about the degree to which your hypotheses have been supported or rejected.

\(^4\)In funding demonstration projects, ODE assumes that the analysis or evaluation plan you provide in the proposal could be done by you. However, the agency does reserve the right to pull out the analysis plan and have it done by others.
The elements of an evaluation plan differ according to the three categories of demonstrations. In Category I projects, the evaluation plan is built directly into your experimental research design, so in some sense a separate plan by which the project can be evaluated is unnecessary. You will discuss what parts of the analysis are directed at each hypothesis stated at the outset.

For Category II projects, you are required to give a separate plan by which your project can be evaluated. It should cover in detail what aspects of the demonstration need to be evaluated, how you propose to judge them, and by what criteria. You should be trying to answer the questions: "How well did what we tried to do work?" and "What did we learn from the project?" Finally, for Category III projects you should discuss the relevant evaluation issues as noted for Category II and describe a general framework for evaluation. Category III projects are likely to be less complex than the other types of projects, but because they may have a weaker design (experimentally speaking) it is all the more important that the analysis be well thought out.

D.2. Analysis Plan

This is the section where you explain, as clearly as possible, how you will use the data you have collected. These data will presumably allow you to test the hypotheses you set out earlier, to examine how practical your program is, or to determine how applicable your services might be for wider populations. This section should convince reviewers that your methods are consistent with the questions you have asked and the data you have collected, and it should persuade them that the quality and nature of the data will support the level of analysis you have in mind.

Analytic methods. In particular, you should indicate here what analytic methods you expect to use to address which questions. For instance, you may want to rely on detailed narrative descriptions to show how the implementation of your program in several sites was similar or different across those sites. Your reviewers may then look for some indication or listing of the topics you expect to discuss in that narrative.
For other parts of the analysis, however, you may plan to employ such statistical techniques as multi-level contingency tables, analysis of variance, and/or linear regression. Reviewers may want to see some general statement (a model) of what variables you expect to be associated with the program outcomes you are studying; you might display this as an equation or as a flow diagram. For these more technical analyses, you should give some idea of the tests you will apply to see if differences between groups or changes over time in program outcomes are statistically significant.

It is often helpful to give examples of your analyses or to show what you think your final tables of results might look like. Often, discussing hypothetical findings based on likely values of the data you will eventually collect is a useful device for making the analysis plan seem less abstract. In essence, you are trying to aid reviewers in visualizing the data set you will compile, so that they can think along with you about what methods of analyses seem appropriate and reasonable to answer the questions you have set out to answer.

Analytic pitfalls. As with data collection efforts, it is better to acknowledge possible problems with your analysis and conclusions drawn from it, and to indicate how you would overcome those that seem most troublesome, than to ignore such issues altogether. For instance, will you run the risk of a Hawthorne effect, in which special attention to some study subjects may either mask or enhance the effects you are actually trying to measure? An example of such an effect would be doing several interviews of elderly participants who are otherwise relatively isolated; just the attention being paid to them may have some unanticipated influence on their responses or activities. As another example of analytic pitfalls, if you are going to identify for additional or repeat analyses some special group, who may score high or low on some measure of interest, will you be able to account for the possible regression to the mean phenomenon? This says simply that, just by chance alone, people who are very high (low) at one time are likely to go down (up) the next time they are studied.
There are many other standard analytic pitfalls, some of which will be relevant to your study and some of which will not be; you may already know about many of them, and you can examine some of the books in the bibliography for details about others. It is a good idea to consult a statistician, econometrician, or some other person well acquainted with basic research methodology when you are planning the design and analysis of your demonstration; your proposal will likely be strengthened substantially by discussions with such people.

D.3. Phase-Down Plan

All demonstration proposals must include a section that describes how your project will wind down, and this can be discussed as part of the evaluation plan. That is, you need to say how you will make a smooth transition from the end of a demonstration to whatever would come next (typically, no longer giving the services directly through the project). You should indicate how and when you will inform program beneficiaries that the project is coming to an end; for instance, you may plan to tell your participants three months ahead of time "... to remember that starting on such-and-such a date, we will no longer be providing such-and-such services." Although this may be of greater importance to ODE staff than to your peer reviewers, the latter will appreciate your attempt to minimize disruption in your study participants' lives.

E. Work Plan

E.1. Description of Tasks

Your work should be sufficiently well planned that you can specify a set of tasks that will cover all the activities needed to complete the project. There are no hard-and-fast rules here, although a general guideline might be that a multi-year Category I proposal could have 30 or so discrete tasks to describe. For instance, assume that part of your work calls for you (1) to adapt an existing patient questionnaire on health status for use in your demonstration, (2) to administer it once as you enroll people into the demonstration, and (3) to administer it again at the end. Then you probably have (at least) three separate tasks for which to account. It helps to number the tasks.
The aim is to cover all the things you promised to do in Sections C and D regarding study design and analysis. In addition, note that one task will probably involve producing a final report. This is a good spot to check that you have no loose ends. Every task noted here should have some corresponding description in the methods to show how it will be accomplished; every major activity you promised to do should have a corresponding task.

E.2. Time Schedule

You should provide a Gantt chart or some other diagram to illustrate when the tasks just outlined will be done, in what order, and how long they are expected to take. This is commonly done in terms of elapsed months (e.g., for a two-year study, months 0 through 24 would be one axis of your chart), but if some other timeframe seems more appropriate for you, use it. It is helpful to adopt some conventional symbols, such as an asterisk or triangle, to show when specific milestones are to be achieved.

Working out the time schedule may seem burdensome, but it helps you avoid awkward problems that your reviewers may well detect. For example, you do not want to say that you will follow your study participants for three years and analyze data on all participants, and then show that data analysis is over at the end of the third year.

E.3. Level of Effort of Personnel

This section is commonly shown as a table, in which you list the key individuals (by name or by role in the demonstration) and the number of days they will devote to each task. That is, what you expect your personnel to do should be tied to the tasks you previously described.

For multi-year demonstrations, you should show total days in each year. Total days per year should be equivalent to whatever percentage of time you show for these individuals in your budget document.

This is one more chance to make sure that what you propose to do looks possible. Reviewers pay attention to these figures. Too little time for key personnel suggests you may have an unrealistically optimistic view of what you can accomplish.
F. Project Staff

F.1. Qualifications of Key Staff

To the extent possible, persons you believe are crucial to a successful demonstration project should be known to you and named in this section. Even very good projects will look dubious to reviewers if the principal investigator or critical staff are "to be named."

You should briefly discuss the qualifications of key personnel named in this section. Probably a paragraph or two per person will do, as you need indicate only what in their background and experience is most pertinent to this demonstration. (You will append to the proposal full curricula vitae on all these individuals.)

This or a parallel section could also be used to describe any experience your organization has had in conducting similar demonstrations, especially insofar as that experience will be available as backup and support for the key staff.

If you have special data collection or analytic needs, this is the place to indicate that you have the right personnel for the job. Often, these individuals can be consultants rather than project staff. For instance, you may need a physician or psychologist for certain tasks and a statistician or economist for other tasks. To the degree you can, indicate who these people are or say what types of individuals you will later recruit.

Subcontracting for very specialized work, such as abstracting medical records or conducting a survey, may be an option for you. In these instances, if the subcontractor arrangement has not already been settled, you should be explicit about whom you have in mind or what criteria you would use to select a subcontractor.

F.2. Organizational Chart

In a complex project, you should state who is responsible for what sets of activities and how those individuals relate to one another and to the principal investigator and/or project director. For multi-site projects, you should also say who acts as the liaison across the sites. For projects involving subcontractors (such as the organization that does just the survey work or provides the particular services), you should show which individual(s) are responsible for those
subcontractors. It should be possible to indicate all this in a single organizational chart.

G. Implementation Potential

This is not a long section, typically, but it is an important one. It is where you discuss the expected use, generalizability, applicability, and dissemination of your work. That is, what do you see as the likely application or dispersion of the program or innovation you have been studying to other settings or facilities, or to other parts of the country, or by other researchers?

If you can foresee possible obstacles to implementation of your work elsewhere, you probably should mention them; reviewers will see them, too. Indicate why they may be less troublesome than customarily expected or how they might be gotten around. Conversely, if there are factors that facilitate implementation, note them also.

Other Parts of the Project Narrative

By now you may have a long, but one hopes not overly long, proposal, and the question arises as to what else you might do to make the proposal clearer and to ease the reviewers' burden. Remember that some reviewers will be traveling to the peer review panel meeting, carrying numerous and lengthy documents with them!

First, a Table of Contents for the Project Narrative section (including its appendices) is a big favor to your reviewers. Implicitly, then, it is helpful to everyone to number your pages. Second, successful proposals often contain an Executive Summary, which should be short and yet should cover the critical points of what you aim to do. That is, it would summarize Parts A through D above.

Third, examples of data collection instruments and letters of support and commitment from professional organizations, local health facilities, or possible consultants can all be included as appendices. Be sure that appendix designations (by letter or numeral) correspond to those you have used in the Project Narrative text. Technical appendices on design or sampling issues, such as any power calculations you have done, can be helpful; reviewers who want to go over such details can do so and reviewers who will not check such materials can ignore the appendix.
You should probably forgo putting some things into any appendix. These include reprints of other work you have done and reprints of articles that other investigators have written. Presumably you have covered this material and experience in the literature review, so unless such information is critical to understanding your present demonstration or substitutes for a technical appendix, leave it out.

Finally, make sure your references are complete, accurate, and match what you have cited throughout the entire document. For publications cited in technical appendices, you can either have a separate reference list directly following the appendix or incorporate the citations into your main list.

V. FINAL POINTS

If you are uncomfortable, at this stage of reading this brief guide, with any aspects of the proposal you intend to write, get help. For instance, as mentioned in the analysis plan section above, successful applicants often call on statistical consultants (perhaps from a local university) for assistance during the proposal-writing stage. Such experts may also be involved for a portion of their time throughout your project. You may also wish to contact ORD if you have specific questions.

Successful proposals also seem to benefit from a few other techniques. Perhaps the least obvious, but often most rewarding, is to ask someone not on the proposal-writing team to read through a draft and tell you where the problems are!

Use enough "road signs" to help your reviewers understand where you are heading and how you got there. Subheadings are important; you might try an outline numbering system for all levels of headings (remembering that the Project Narrative is Part IV). Long, dense pages of text are daunting, so divide lengthy paragraphs into smaller ones.

We have concentrated on the Project Narrative section of the proposal, but one point about budget remains. Make sure that your budget matches up with tasks and personnel named in Sections E and F above. For instance, are the key people named above covered in the budget for the time you said it would take them to do all their assigned tasks?
Your proposal does not have to be fancy in appearance, but it should be neat and attractive. Check for consistency, spelling, and other such details enough ahead of time that you can make corrections. Try to write in as lively and active a way as possible; it will shorten your proposal and convey enthusiasm and confidence about your proposed work. With those attributes, a clear statement of objectives, a consistent plan for data collection and analysis, and appropriate personnel, you are well on your way to a proposal reviewers will applaud and recommend for approval.
SELECTED REFERENCE PUBLICATIONS

Research Reviewing


Study Design and Sampling


Statistics


Epidemiology


Cost Studies--Economics


Program Evaluation

SELECTED GLOSSARY OF RESEARCH AND DEMONSTRATION TERMS

Bias: The systematic tendency to over- or underestimate the true value of some quantity of interest, often arising from the use of nonrepresentative sampling schemes or from a reliance on noncomparable treatment and control groups (see comparison group). For example, using 55- to 64-year-olds in a control group of a study of the impact of the Prospective Payment System (PPS) on quality of health care for 65-and-over Medicare patients would certainly bias the results against the treatment (PPS) unless steps were taken in the analysis to adjust for prior health status (a potential confounding factor); the first group will be systematically healthier than those in the PPS group, just because they are younger and will therefore exhibit fewer negative outcomes (deaths, hospital readmissions, and so on) than the treatment group, even if PPS has no effect.

Comparison group: The point of most demonstrations is to estimate the causal effect of a program, or treatment, on one or more outcomes, or responses, or dependent variables of interest. In the PPS example above, the treatment is receiving care under PPS, and the outcomes are measures of the quality of health care such as rates of hospital readmission and postdischarge mortality. The goal is to estimate the difference between how things came out for a group of people who receive the treatment (the treatment group or experimental group) and how things would have come out for those people if they had not received the treatment. Sometimes it is possible to get a fairly direct idea of the latter by measuring the same people twice, once before they receive the treatment and then again afterward; this is an example of a pre-post (before-after) design, in which subjects serve as their own controls, and the analysis focuses on the differences for each subject between the pre and the post values of the outcomes (a paired comparison). But sometimes this is not possible; then it is necessary to use information from a second group of people who do not receive the treatment, the comparison or control group, as a proxy for how the treated people would have responded if they had not been given the treatment. The analysis is then based on the differences in the outcomes of interest between treatment and control subjects (a two-sample comparison).

Control group: See comparison group.

Controlled experiment: An experiment conducted under conditions in which the experimenters exercise control over who goes into the treatment and comparison groups, as contrasted with an observational study, in which no such control is exercised. A study on the efficacy of home health care in preventing institutionalization among Medicare patients could be conducted as a controlled experiment, since presumably it would be possible to assign eligible Medicare patients to a group receiving home health aide intervention or to a group not receiving such care. However, a study looking into the relationship
between smoking and lung cancer would have to be observational, because ethically no one can be forced to smoke just to find out if his or her chance of getting lung cancer would increase.

**Covariate:** See potential confounding factor.

**Dependent variable:** See outcome variable and comparison group.

**Experimental group:** See comparison group.

**Independent variable:** A variable that is useful in predicting the values of the outcome measures, also called an experimental or predictor variable. Typically these variables are under direct control of the researcher, as for instance the treatment-control distinction for each subject in a controlled experiment. Variables that are useful predictors but are not under experimenter control are often referred to as covariates or potential confounding factors.

**Informed consent:** The process by which you will fully explain to potential enrollees or participants (or their proxies) the study's purposes and activities, and the rights and obligations of both participants and investigators, and obtain their agreement to participate. It is in this context, for instance, that you will pledge to protect the privacy and confidentiality of any information you may obtain from participants.

**Observational study:** See controlled experiment.

**Outcome variable(s):** One or more variables that are of principal interest or value in assessing the effect of a program or treatment; see comparison group.

**Population:** The collection of people or things to which you wish to generalize on the basis of your sample.

**Potential confounding factor:** Demonstrating that treatment and control groups differ noticeably on the outcome variables (in other words, showing an association between the treatment and response variables) is not enough to prove that the treatment caused the difference observed. The two groups may differ in other important ways than just the treatment-control distinction, and until shown otherwise these sources of noncomparability could cause the outcome differences just as well as the treatment could. If a twofold argument can be made about a variable--namely, that the variable is likely to take on systematically different values in the treatment and control groups, and that the outcome measure is associated with the variable--then the variable is called a potential confounding factor. In a study relating use of the contraceptive pill to hypertension in women between 18 and 45, for instance, age would be a clear potential confounding factor, since older women use the pill less and also have higher blood pressure on average. When noncomparabilities between treatment and control groups are evident at analysis time, it is often possible to reduce the bias arising from such noncomparabilities by
means of a modeling technique known as analysis of covariance or covariate adjustment. Thus, potential confounding factors are also sometimes referred to as covariates.

**Power:** The chance of finding a difference in the outcome measures between the treatment and control people, if a difference is there to be found. The power of a statistical procedure to find differences depends on several things, mainly the size of the difference (bigger differences are easier to find) and the sample size (smaller differences can be found with more data). It is important at the time an experiment is designed to make sure that its resources are well matched to its needs—that is, to go through a process of sample size determination. This usually requires one or more power calculations. In calculations of this type, some thought is put into what magnitudes of differences on the outcome measures are worth detecting from a policy point of view; then, the sample sizes needed to have a reasonable chance of finding differences of that size (if they are there to be found) are computed.

**Randomization:** The standard way of achieving at least approximate comparability of comparison groups in controlled experiments is to assign subjects to treatment and control at random. This ensures exact comparability with respect to all potential confounding factors in a long-run-average sense; on average, across independent replications of the experiment, all the ways in which the treatment and control subjects might be different will balance out. Randomization cannot be relied on to achieve exact comparability each time it is employed, but particularly with fairly large single sites it can be expected to give rough comparability on most or all variables in any given performance of the experiment.

**Reliability:** The extent to which a measuring instrument like a survey produces the same answers when given to the same subjects under somewhat different conditions, for instance when administered by different people or when presented to the same people at two points in time. The issue being addressed by the question "How reliable is this survey?" is essentially the following: How much do extraneous factors (such as who administers the instrument, or how the person filling out the questionnaire happens to feel at the time) affect the results of the survey? As contrasted with validity.

**Response variable:** See outcome variable and comparison group.

**Sample:** The subset of the population of interest on which your inference is to be based; see population.

**Treatment effect:** Another name for the (adjusted or unadjusted) average difference on the outcome variable scale between the pre and post values in a pre-post design or between the treatment and control values in a two-sample comparison; see comparison group.
Treatment variable: See independent variable.

Validity: The extent to which a measuring instrument, such as a battery of questions in a survey, actually measures what it purports to measure. Do you have some items that you think measure aptitude, when in fact what they really measure is achievement? If so, you have a validity problem. As contrasted with reliability.

Waiver: As used by HCFA/ORD, approval by HCFA to deviate from the requirements of Title XVIII or Title XIX of the Social Security Amendments (Medicare and Medicaid, respectively) and their implementing regulations, to conduct a time-limited demonstration.