EXECUTIVE SUMMARY

The Executive Summary is a one page summary that includes a highly condensed version of the study objectives, background, importance, and design (including requested data files). This summary will be the cover page of the research protocol and should be detailed enough to allow any CMS representative reviewing the executive summary to understand the study being proposed. Although the Executive Summary should be submitted as the cover page, it may be beneficial to complete the summary after finishing the final protocol.

Additionally, the Executive Summary should *briefly* address each of the following:

1. How the study has the potential to improve the quality of life for Medicare beneficiaries or Medicaid recipients, or improve the administration of the CMS programs.
2. The measures to be taken to ensure that the use of these data involves no more than minimal risk to individuals. A more comprehensive overview may be presented in the Database Management section of the protocol.
3. Could the research be conducted without individual level authorization? Explain.
4. Could the research be conducted without access to these individually identifiable data? Explain.

INTRODUCTION

Title:

The researcher should be succinct in titling their project. Use keywords, phrases, or descriptors that will highlight the population of interest, the medical problems of concern, and the health policy issues of importance.

Objectives:

The objectives should pinpoint what the researcher plans to do and expects to achieve. The number of objectives should be relatively few and listed in approximate order of priority or importance. The objectives listed should underscore the major elements of work that are realistically achievable.

Background:

The background should succinctly highlight gaps in the current knowledge or practice in the field of study. The researcher must show that he or she understands the important studies that form the foundation for the protocol and indicate how the project will go beyond them. Please include a literature review. The literature review need not be lengthy, but it should be reasonably comprehensive and up-to-date. The researcher is not expected to review all the relevant literature in great detail; if he or she is conversant with other bibliographies or literature reviews, they should be cited. If there is no literature or body of knowledge in the area proposed for study, this should be stated.

Importance:

There are two main points that should be addressed here: the significance of the question or study issue proposed and the significance of the researcher's particular project. This is the place to make a strong case for the importance of the project being proposed. For example, the proposed study may add to the general body of knowledge, expand the possible ways to organize and deliver health services to meet a particular human need, or it may do both. The point is to deliver a credible, straightforward argument for the contributions that the work will make.

RESEARCH QUESTIONS AND METHODS

Hypotheses/Study Issues:

If there are hypotheses to test, they should be stated explicitly. If there are no specific hypotheses, the application should discuss the issues that prompted the researcher to undertake the project.

Study Design:

The basic objective is to describe how the project will operate. In some studies, Medicare or Medicaid data will be used to supplement other data. In this instance, the researcher should briefly state the design of the overall project and then describe in detail how the CMS data being requested will be used in the study. Uppermost in the reviewers' minds are the questions of how each piece of information relates to the hypotheses to be tested, issues to be studied, or program(s) to be demonstrated. It is a good idea to consult an epidemiologist, statistician, econometrician, or some other person well acquainted with basic research methodology when planning the design and analysis of the project. The study design must present a solid chain of reasoning. The study design, at a minimum, should:

- Describe the sample population to be studied and the method to be used to select or identify the study population in the data files;
- Discuss the issue of precision or power of the study and the strength of its eventual conclusions. If applicable, indicate whatever power calculations might have been done to justify the sample size and comment whether the sample size will permit accurate generalization to larger populations;
- Give a specific description of the match between what is to be investigated and the data files and variables to be used in the analysis;
- Briefly state the dependant (or response) variables, the independent (treatment or explanatory) variables, and the factors that may need to be measured or accounted for because they might otherwise confound the analyses;
- If relevant, discuss the project's cross-sectional aspects (comparisons in one time period) and longitudinal aspects (comparisons over time).

Data Limitations:

It is important to note potential limitations of the data in relation to the proposed study and to identify the efforts that will be made to address those issues. For example, noting that the data does not contain information regarding services not covered by, or billed to, Medicare and how that might affect the results. It is better to show that consideration has been given to what the potential limitations are rather than have reviewers assume that the researcher was not aware any existed.

Database Management:

The protocol should explicitly address how the data files will be held, managed, and processed. For example, who will have the main responsibility for organizing, storing, and archiving the data? Who will maintain computer data tapes and make needed work files available to those who will analyze the data? How will the privacy of information of beneficiaries in the files be guarded and guaranteed?

EVALUATION AND ANALYSIS PLAN

Analysis Plan:

In this section, the application should explain, as clearly as possible, how the data would be analyzed. This section should convince reviewers that the proposed methods are consistent with the hypotheses/issues to be studied and the data to be collected, and it should persuade them that the data will support the level of analysis planned.

Analytic Methods:

This section should discuss specifically what analytic methods are expected to be used to address which questions. It is often helpful to give examples of the analyses or to show what the tables of results might look like. Often, discussing hypothetical findings based on likely values of the data which will eventually be collected is a useful device for making the analysis plan seem less abstract. The goal is to try to aid reviewers in visualizing the data set that will be compiled, so that they can think along with the researcher about what methods of analyses seem appropriate and reasonable to address the hypotheses/issues to be studied.

WORK PLAN

Description of Tasks:

The proposed work should be sufficiently well planned that the researcher can specify a set of tasks that will cover all the activities needed to complete the project. The aim is to identify all the tasks to be accomplished regarding study design and analysis. In addition, note that one task will probably involve producing a final report. Every task noted here should have some corresponding description in the study design and/or analysis plan section(s) to show how it will be accomplished; every major activity targeted for completion should have a corresponding task.

Time Schedule:

The application should provide a Gantt chart or some other diagram to illustrate when the tasks outlined above will be completed, in what order, and how long they are expected to take. This is commonly done in terms of elapsed months (e.g., for a 2-year study, months 0 through 24 would be one axis of your chart). It is helpful to adopt some conventional symbols, such as an asterisk or triangle, to show when specific milestones are to be achieved.

Level of Effort of Personnel:

This section is commonly shown as a table, in which the researcher lists the key individuals (by name or by task) and the number of days they will devote to each task.

For multi-year projects, the researcher should show total days in each year. Total days per year should be equivalent to whatever percentage of time is shown for these individuals in the budget document. Note that reviewers pay attention to these figures. Too little time for key personnel suggests that the researcher may have an unrealistically optimistic view of what can be accomplished.

QUALIFICATIONS OF KEY STAFF

To the extent possible, persons the researcher believes are crucial to a successful project should be named in this section. Even very good projects will look dubious to reviewers if the principal investigator or critical staff are "to be named." The qualifications of key personnel named in this section should be discussed. A paragraph or two per person describing their background and experience most pertinent to this project will suffice.

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

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

IMPLEMENTATION POTENTIAL

This is not a long section, typically, but it is an important one. It is where the researcher discusses the expected use, generalizability, applicability, and dissemination of the work.