****If you already have a study protocol that has been approved by your funder (federal, state, corporate, etc.) then please submit that document in lieu of this template. CMS prefers to see the funder-approved protocol when available. However, if a formal protocol was not prepared (i.e. internal funding), then please complete this Study Protocol Template.*

Requesting Institution (see Item 1 of DUA): Click here to enter text.
DUA User name and title (see Item 16 of DUA): Click here to enter text.
PI (if different from DUA User): Click here to enter text.
Study Title: Click here to enter text.
Funding source: Click here to enter text.
Funding period:Click here to enter text.

CMS Data files/years requested (if requesting reuse of data, include DUA# to be reused)(see Item 5 of DUA):

List requested data files and years here (justification not required). If reusing data from an existing DUA then please specify reuse and provide the DUA number.

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.

Study Objectives/Research Questions:

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.
Click here to enter text.

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.

Describe the sample population to be studied and the method to be used to select or identify the study population in the data files.
Click here to enter text.

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.
Click here to enter text.

Table 1. Description of CMS data files and key variables needed for analysis.*

Please fill out this table. You don't need to justify every variable, but please include the major aspects of each data file that are needed for your study/analysis.

Study objective/measure	Data variable(s)	CMS data file(s) needed

* Note: With the exception of the assessment data and the Part D Event file, all files are distributed as full-record files.

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.
Click here to enter text.

If relevant, discuss the project's cross-sectional aspects (comparisons in one time period) and longitudinal aspects (comparisons over time).
Click here to enter text.

If the requested CMS data files are to be linked to other non-RIF CMS data files or non-CMS data sources, specify these additional data files in Table 2 below. Per section 10 of the DUA, the requestor cannot link CMS data files without noting this request in the study protocol.

Table 2. Description of additional files and purpose for linking to CMS RIF data.

Name of additional files	Purpose for linking to RIF data

Data Limitations:

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. Also, note that for the most part, CMS data do NOT include information for beneficiaries enrolled in a Medicare managed care plan. 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.