

General Retrospective Protocol Template

A. Title

Descriptive title of your project
Principal Investigator
Co-investigator(s)
Other study personnel

B. Table of Contents (if >10 pages)

C. List of Abbreviations

D. Brief Summary/Abstract

Key elements and expected outcomes
Long term objectives

E. Specific Aims/Objectives

Aims and Hypotheses

F. Background and Significance

Previous significant research

G. Study Design

Case series, case control, etc.
Who, what, where, when, and how the research will be accomplished
Study time frame, population, and inclusion and exclusion criteria.

H. Medical Record Requirements

Sources of data (patient charts, databases, etc.)
Number of records required for sample size

I. Data Collection Plan and Sources of Data

Describe data collection tools
Databases and data fields
Software, hardware and data security

J. Statistical Methods

How analysis will be done, statistical significance
a. Power/Sample Size Considerations Calculation (assumptions, power level, alpha level, etc.)
b. Statistical Analysis Plan Describe the statistical methods to be used

K. Publication and Presentation Plan Planned meetings, conferences, journal publications

L. Timeline When you expect to complete the study, include key milestones

Attachments and Appendices

Budget Page

Curriculum Vitae of Principal Investigator

Roles of Personnel

References

Data Guardian Approval

Data Collection Forms