

## General Retrospective Protocol Guidelines

### A. Title

Descriptive title of your project

*For example: Mortality rates following acute myocardial infarction among ethnicity groups at a large hospital in Hawaii.*

Principal Investigator(s)

Co-investigator(s)

Other study personnel (e.g. biostatistician, clinical study personnel)

### B. Table of Contents (if >10 pages)

### C. List of Abbreviations

A list of abbreviations used in the protocol.

### D. Brief Summary/Abstract

Briefly discuss the overall rationale for the study, the key elements, expected outcomes, and the long-term objectives of your research.

*For example: This research is being done to study in-hospital mortality among patients admitted to The Queen's Medical Center (QMC) with myocardial infarction by ethnicity. We hypothesize that patients of Polynesian heritage have a higher mortality rate than other ethnicity groups. This may have a long-term impact on our ability to provide emergency care with better outcomes.*

### E. Specific Aims/Objectives

List the specific aims and hypotheses of your study, usually in numbered paragraphs. Describe what your research intends to accomplish. Relate the specific aims to your long-term objectives.

*For example:*

*Aim 1: Evaluate the in-hospital mortality rate by ethnicity in patients admitted to QMC with a primary diagnosis of acute myocardial infarction.*

*Hypothesis: The Polynesian ethnicity group will have a higher mortality rate.*

*The long term objective will be to design a future protocol to study why Polynesian patients have higher mortality.*

### F. Background and Significance

Describe the prior research that has been done on your topic. Provide a critical evaluation of previous research, identify the gaps in knowledge about your topic, and explain how your study will fill a gap in the current understanding of your topic. Include reference citations.

### G. Study Design

Describe the study design (case series, case control, etc.) and procedures (who, what, where, when, and how the research will be carried out). Provide sufficient detail to allow reviewers to evaluate the proposed research methods. Define the study time frame, population, and list of inclusion and exclusion criteria.

*For example: This study is a case series study consisting of a retrospective medical chart review of patients admitted to The Queen's Medical Center with a primary diagnosis of acute myocardial infarction (ICD9 code 410) from January 1, 2005 to December 31, 2005. Study subjects will be identified from the Medical Center database by research personnel and categorized by ethnicity. Charts will be requested from the Department of Medical Records and reviewed by investigators and research associates. Data will be transcribed to a form, and then into a database for analysis to determine if there are significant differences in mortality among the ethnicity groups.*

*Inclusion criteria:*

- 1. Adult > 18 years of age*
- 2. Subject had acute myocardial infarction*

*Exclusion criteria:*

- 1. History of CHF, ACS, or known cardiac birth defect*

## **H. Medical Record Requirements**

Describe the sources of data (patient charts, databases, etc.) and the number of records that you will require. Explain who will do the records review, and if a non-Care\*Link database will be used, state that you have obtained written approval from the Data Guardian of the respective database. The approval or agreement letter should be included in Appendix E. Discuss the issue of HIPAA defined protected health information use, either through the manual review of medical records, Care\*Link or other electronic medical records, or programmatic extraction or reporting of data to be used in the research. *For example; An accounting of subjects for which HIPAA defined protected health information is used will be kept by the PI and automatically registered in the Quick Disclosure sub-system of Care\*Link.*

## **I. Data Collection Plan and Sources of Data**

Describe the overall data collection plan. Define the types of data collection instruments that will be used, and list which data fields will be collected. Data collection forms should be included in Appendix F. Specify if a computerized database will be used. If known, describe what hardware and software will be used (e.g. data will be entered into an Excel spreadsheet on a laptop computer). Explain precautionary steps taken to assure data security and integrity.

## **J. Statistical Analysis Considerations**

Provide evidence that you have considered the statistical aspects of your study, such as the sample size, how you will analyze your data, and what constitutes statistical significance (e.g. p-value<0.05).

### **a. Power/Sample Size Considerations**

Provide details of the sample size calculation (assumptions, power level, alpha level, etc.). The assumptions used in the calculations should correspond to existing knowledge as stated in the Background and Significance.

### **b. Statistical Analysis Plan**

Describe the statistical methods to be used for addressing each specific aim (e.g. descriptive statistics will be produced, chi-square test will be used for comparing proportions, and t-test for comparing means). Also list the computer software that will be used for the analysis.

## **K. Publication and Presentation Plans**

List any meetings or conferences where you plan to present the results. If possible, list any journals you are planning to submit to for publication.

## **L. Timeline**

Write a short paragraph stating when you expect to complete the study. Include certain milestones (e.g. subjects identified within 1 month, data collection completed within six months, analysis will be completed within one month after data collection ends, publication 2 months thereafter, completing the study by June 2007).

## **Attachments and Appendices**

**A. Budget Page** - Brief description of fees (i.e. chart archives fee may be imposed @ \$3 per chart, researcher hourly fee @ \$10 per hour, etc.), or attach a balance/work sheet

**B. Curriculum Vitae of Principal Investigator**

**C. Roles of Personnel** - Also specify any privileges that will be needed (i.e. Allied Health Professionals credentialing, Care\*Link training and access required)

**D. References** - List only the literature cited within your Protocol's text.

Use the NIH format: names of all authors, title, book or journal, volume, page, and year.

**E. Data Guardian Approval** - Approval from Data Guardian(s), signed agreement letter should be attached.

**F. Data Collection Forms** - Data collection tools, forms, or screen prints.

## Sample Data Collection Form

Medical Record #: \_\_\_\_\_

Account #: \_\_\_\_\_

Subject Name: \_\_\_\_\_

Was patient enrolled in study:  1=No, 2=Yes

If No, specify why:  1) **Subject ≤ 18 yrs old**  
 2) **Subjects had a history CHF, ACS, or known cardiac birth defect**  
 3) **Other, specify:**

\_\_\_\_\_.

Age:  Years

Gender:  1=M, 2=F

Ethnicity:  1=White, 2=Black, 3=Hispanic, 4=Japanese, 5=Native Hawaiian, 6=Chinese, 7=Filipino, 8=Other

Primary diagnosis ICD-9 code:  ie. 410 Description \_\_\_\_\_.

MI Onset date/time:  mm/dd/yyyy hh:mm

Admission date/time:  mm/dd/yyyy hh:mm

Discharge date/time:  mm/dd/yyyy hh:mm

Discharge status:  1=Alive, 2=Expired

Any concurrent illnesses:  1=No, 2=Yes If Yes, specify: \_\_\_\_\_.

\_\_\_\_\_.