Outline of a Study Protocol

*(Note. Questions are included to guide you in what goes where, not to be repeated in the actual protocol!)*

Title

Investigator(s) and Residency Program

**Introduction (Background and Rationale)**

Based on the relevant scientific literature, write the background for your study. What do we know about your question? What do we not know? This sets the stage for your research question and/or hypothesis. Make sure to cite the relevant literature from your literature search.

Include citations as appropriate (North, West, and South 2002) and add to Reference list

**Research Question**:

What question will the study address? The question(s) should be specific, not vague.

*Say this:* Does enrollment in a tobacco quit line increase smoking quit rates in new Moms during the first three months after delivery?

***Not** this:* What is our experience with tobacco quit lines?

**Hypothesis Statement**:

A hypothesis is an educated guess. If your study is exploratory or descriptive, you may have only a research question and no hypotheses. If you are making comparisons, you likely will have hypotheses. The hypotheses are simply the research questions rephrased in a format that can be tested using statistics.

The hypothesis is always stated as a NULL hypothesis and is always accompanied by an alternate hypothesis. This format is used because, using statistics, we cannot prove something to be true, we can only disprove it. Our goal is to disprove the null hypothesis.

*Example*:

$H_0$: There is no association between carotid plaque as measured by ultrasound and coronary plaque as measured by CTA.

$H_A$: There is an association between carotid plaque as measured by ultrasound and coronary plaque as measured by CTA.

*Try to write your hypotheses so that two-sided statistical tests can be done—so use the words "no difference" vs. "a difference" instead of "no difference" vs. "better" or "worse" (one-sided statistical tests).*

**Methods & Materials**

Study Design (How will the question be approached?)

Who are the patients who will participate (inclusion and exclusion criteria)

What is the time frame?

What information are you collecting? How you will get it? (interview, records review, etc)

Any other pertinent info you are collecting (Patient #, date of surgery)

If a prospective study, how will the patients be assigned? (Randomly)

If it is a treatment study, how will you insure blinding of subjects and medical personnel?

How will you insure patient anonymity and confidentiality of records?

Draft of data collection form is included

**Data quality:**

How will you assure the quality of the data? Data abstraction and entry errors are common.

If there is one person collecting data, then a random sample of about 10% of the cases should be re-abstracted. The re-abstracted data should be compared to the original data to determine the number of errors, type of errors and to create a plan for error reduction.

If there are multiple people collecting data, you should:

1. Clearly define what each data element means (create a data dictionary);
2. Define where the data should be collected from (for example, collect blood pressure data from the "flowsheet" tab in eCare);
3. Conduct a training session with the other investigators or individuals collecting data;
4. Prior to the start of the study, have all individuals who are collecting data abstract several of the same charts and compare results. Determine where the mistakes are occurring and how to avoid them;
5. Develop an audit plan, for example, where 10% of the data are re-abstracted by the principal investigator to look for routine errors.

***Talk with your medical researcher to help design the data quality process that is suitable for your project.***

*Power analysis*

How many subjects will you need to include to find a statistically significant difference if it truly exists? A sample size analysis with the alpha error rate set at 0.05 and beta error rate of 0.1-0.2 (corresponding to 80-90% power) is required. **Your medical researcher will help you with the sample size calculation—you are not expected to know how to do this step.**

*Statistical Analysis*

Describe how you will analyze the data to answer your research questions or hypotheses. Explain what descriptive statistics you will use and what inferential analyses you will do. **Your medical researcher will help you to write this section—you are not expected to know how to do this step. Your medical researcher will also perform the statistical analysis when your data are collected.**

*HIPAA/Patient Confidentiality*

Describe what measures you will take to protect patient data and confidentiality.

**References**

Note: If you are using EndNote or other reference management software, choose the **Vancouver** style.

**In the text**, references should be cited as they are mentioned, usually at the end of the sentence. The first authors' last names should be followed by the year, as follows:

single author - (Franklin, 1776)
dual authors - (Franklin and Washington, 1776)
three authors - (Jefferson, Franklin and Washington, 1776)
four or more authors - (Hamilton et al., 1777)

Mentioning the first author by name to attribute an aspect directly should be handled as:

Franklin (1776) was the first to report the electrifying properties of lightening.

**At the end of the article, a list of references** should be included that is alphabetized by the first author's last name. Complete guidelines for reference types are available from the National Library of Medicine NLM via the library's Web site (http://www.nlm.nih.gov/). Below is the citation format that the Research Director recommends for protocols.

**Standard journal article:**

Vega KJ, Pina I, Krevsky B. Heart transplantation is associated with an increased risk for pancreatobiliary disease. Ann Intern Med 1996;124:980-3.

For more than six authors, list the first 6 followed by et al.:

Parkin DM, Clayton D, Black RJ, Masuyer E, Friedl HP, Ivanov E, et al. Childhood--leukaemia in Europe after Chernobyl: 5-year follow-up. Br J Cancer 1996;73:1006-12.

(From Uniform Requirements for Manuscripts Submitted to Biomedical Journals. International Committee of Medical Journal Editors, March 19, 1997.)

**Budget**

A list of the items/paid assistance to be used to acquire or enter data, and their costs.
(What will you need to do the study properly? What will it cost for those items?)

Example: A study comparing BMI and Body Fat in a study group and a control group

| Item | Unit Cost | Number | Total Cost |
|---|---|---|---|
| Hand-held body habitus measurement devices | $200 | 4 | $800.00 |
| Diet and exercise handouts for study group | $3.00 | 200 | $600.00 |
| General dietary information handouts for control group | $0.50 | 200 | $100.00 |
| Study Incentive $5 Target gift card | $5.00 | 400 | $2000.00 |
| Total | | | $3500.00 |

**Budget Justification**

One or two sentences per line item in budget to explain why you need that item. If cost is unusual, explain how you reached that price.