**RESEARCH PROJECT OUTLINE**

TITLE

Descriptive title of the research project; keep it succinct and clear.

You can use the PICO format:

Patient/Population – Who or What?

Intervention/Comparison – How?

Control – What is the main alternative? (If Appropriate)

Outcome – What are you trying to accomplish, measure, improve, effect?

INVESTIGATORS / KEY PERSONNEL

Include a list of all study personnel (include name, credentials, affiliation):

RESEARCH QUESTION / HYPOTHESES

Identify the specific aims for your study.

Write your study purpose, rationale, or hypotheses.

Specific Aim(s):

1.

2.

3.

SIGNIFICANCE / BACKGROUND

Using the literature, establish any previous work related to your research question. This section should describe the gaping hole in the literature and how your specific aims will attempt to address it. Remember to cite your references throughout your proposal! Pick a style from your favorite journal. Most people use numbered superscripts. The main thing is to be consistent.

-Find 3 – 5 relevant articles [request assistance from the Advocate Medical Sciences Library Network Librarians for literature search, go to: [http://libraryonline.advocatehealth.com/page.cfm?id=1](http://libraryonline.advocatehealth.com/page.cfm?id=1%20) [located on Advocate Online)]

 -To evaluate your articles, use the Oxford Center for EBM Critical Appraisal Sheets at the following website: <http://www.cebm.net/index.aspx?o=1157>

 -Supply e-copies of the two (2) best articles to the research consultant(s) for their review

METHODS

The next five sections encompass the methods. Traditionally, this grouping has been headed “Methods” or “Materials and Methods” but studies involving human subjects usually label this section “Patients and Methods”.

DESIGN

What research design will be used to address your specific aims? Examples include: case series, case-control, retrospective cohort, cross-sectional, survey, and observational. Just a reminder that “retrospective chart review” is not a study design. You probably really mean a case series or retrospective cohort study.

SUBJECTS

If your study is a clinical study, you will need to provide information concerning your subjects. You should describe where you will obtain your subjects, over what time period and the specific inclusion and exclusion criteria you will use.

 -Inclusion Criteria

 -Exclusion Criteria

PROCEDURES / VARIABLES / DEFINITIONS

This section basically describes your study group(s), your methods of obtaining data and a description of your variables. Provide information about your primary outcome variable as well as all secondary outcome variables. At times it will be necessary to define these variables, so be precise.

 -Include a Data Form (see below)

 -Surveys or Questionnaires should be taken from previously published literature with validation methods cited

SAMPLE SIZE CALCULATION / POWER ANALYSIS

This section should include a write up of how many subjects you will need in your study group(s) to achieve an 80% power of detecting a difference based on the magnitude of the difference given from published literature, pilot data or expert clinical opinion.

DATA ANALYSES

Use this section to provide a thorough description of the statistical tests planned, and your criterion for significance (e.g., p < 0.05).

REFERENCES

Use this section to provide all of the references used throughout your study. Pick a format from your favorite journal and use it consistently.

DATA FORM / CASE REPORT FORM

This form is used to capture the data. The form should be constructed so that most of the information can be recorded as a short answer or a check-box. Most likely, in this day and age, a lot of the actual data accrual will be recorded directly to a computerized database, spreadsheet or electronic case report form. Nevertheless, for the purposes of thinking through your study, and for the IRB, you will need to have your data in document form.

BUDGET / RESOURCES UTILIZED

This is an important part of the planning for your study and while it seldom ends up in the final reporting of your results, it is just as important to consider these aspects of your study as statistics or number of participants.

TIMELINE

Use this section to include timeframes for project milestones. Often, this information is presented in a chart or table of some kind.

SITE MONITORING PLAN

If applicable, describe the action plan for the site monitoring plan. On-site monitoring is an in-person evaluation carried out by an independent representative(s) at the site(s) at which the clinical investigation is being conducted. On-site monitoring can identify data entry errors (e.g., discrepancies between source records and Data Forms / Case Report Forms (CRFs) and missing data in source records or CRFs; provide assurance that project documentation exists; assess the familiarity of the site’s project staff with the protocol and required procedures and assess compliance with the protocol.