

Case Study Structure

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1. **Title:** make it descriptive; use your question as the title.
2. **Investigators:** complete name and contact information and titles for each. Please note that UH requires a "Responsible Investigator" (a faculty member or attending physician) if the PI is a resident, fellow or student.
3. **Background** of the Study. Explain to a naive colleague why this study is worth doing. This is the "who cares" section. This is generally one to two paragraphs..
4. **Past work.** What has previously done? Whose work are you building on? This is where you put your Literature Review. It shows that you are building on what has previously been done. Show how your work will further current work. If you have personally done any work in the area, highlight your work and demonstrate how this project will further your personal career. Reference this background if possible, but no more than 10 references
5. **Aims:** If you want to, you can write 1-3 sentences about what your overall goals /aims are. This is pretty general.
6. **Objectives** – very specific, answerable / refutable.
 - a. What is the primary question you wish to answer, and what response variables will allow you to answer it?
 - b. Secondary questions and response variables, if any
 - c. Do NOT put in more than 2 objectives.
 - d. **List** each of your variables; code them as independent (or predictive) variables or as dependent (or response) variables.
7. **IRB decision:** exempt or not exempt. (or expected response & plan)
8. **Sample size:** Estimate depending on a guess as to how much difference you expect to find in your dependent variable. Show your power calculation.
9. **Allocation strategy.** For us, this is usually a "convenience sample."
10. **Design** of the survey study.
 - a. Surveys can have several question types. They might include bivariate answers (true/false, yes/no, etc), multiple choice (either single answer or many answers permitted), response on a continuous scale (such as a visual Analog Scale or VAS), response on an ordinal scale with either neutral permitted or not permitted (Likert response, vs forced Likert) , or even free text. The analysis gets more complicated the more potential responses there are, if these are response variables.
 - b. Do you plan to analyze just one population, or do you plan to compare 2 populations (two different hospitals, before and after, etc). Justify your choice.
11. **Population.** What population do you plan to study? What is the comparison group if any? cohort, case control, or other: _____

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- a. Inclusion and Exclusion: Inclusion and exclusion criteria (may attach as appendix). Allocation strategy if any (describe)
- b. Also, sample size determination must be addressed.

12. Method

- a. How do you plan to perform your survey? On paper? Electronically?
 - i. Where do you plan to store your answers? And How long?
 - ii. What database do you plan to enter the answers into?
 - iii. How will you know that a given survey has been entered?
 - iv. How will you know that surveys haven't been double entered, or missed?
- b. Where do you plan to perform your survey?
- c. Enrollment of subjects: Assessment of eligibility: by whom, and how? What time frame?
 - i. Training of investigators / data collectors -- by whom, how?
 - ii. Data collection methods and recording forms. Please provide a copy of your proposed survey.
 - iii. Data monitoring and quality control. How will you assure adequate capture of potential subjects, and monitor the data collectors? Where will you store the answers?
 - iv. Termination policy. Under what circumstances will the study be stopped prematurely? Who will make the call, and by what criteria?

13. Planned Statistical Analysis

- a. Data analysis. Planned statistical treatment. What tests will be applied to the data?
- b. First is "Simple summary statistics will be applied to demographic data to characterize the sample and compare it to the proposed population."
- c. Then come the comparisons of the predictor to the outcome variables.

Boilerplate Statistical Analysis Blurbs

Example 1

Descriptive statistics will be used to examine the distribution of key outcome and predictor variables. Means and standard deviations will be computed for continuous variables and percentages for categorical variables. These data will be used to describe the study participants, address the descriptive research questions, and inform the statistical analysis.

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Example 2

Statistical evaluation

The association between provider-patient relational communication and patient quality of life, and association between provider-patient relational communication and patient understanding of his/her disease will be estimated by Pearson's correlation if those measurements are normally distributed or Spearman's correlation if the distributions are skewed for those measurements. The various scores, including relational communication, uncertainty, QOL, depression, hope, and association between the scores will be summarized using figures, such as box plot, bar plot or scatter plot.

Example 3

The survey (appendix A) will capture key descriptors of the project, including title, intended innovation, sample size, study design, population of interest, clinical outcomes, and outcomes of innovation/data. All data will be entered into SPSS 17.0 and analyzed using descriptive statistics. A list of secondary data sets will be provided to the steering committee to identify and prioritize possible research projects. A research team will be formed to quickly develop research questions, analyze data and draft a manuscript suitable for publication and/or to apply for additional funding. Because this is in part a feasibility study, the process of accomplish the above aims will be thoroughly documented by the clinical research facilitator, specifically focusing on factors that enabling or obstruct the use and collection of secondary data.

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