Your Research Proposal

The previous pages provided you with some starting points as well as things to consider when planning your research project. You are now ready to put together your research project proposal.

Answers to the following questions will form the outline for your research project:

- What is my research question?
- Why is it significant?
- What will I measure to support my hypothesis?
- Who will participate?
- How many participants do I need?
- How will I analyze the data?

The answers to questions like these will give you your research project outline and this information needs to be included in your research proposal. Once the proposal is written this process will be much clearer and provide you with a step by step approach to finishing your project. Parts of the research design include: hypothesis, background, and methods.

Your Question, your Hypothesis

You already have an idea in mind, the question you want to study and research. Now you need to turn this into a specific hypothesis. A hypothesis is an “educated” guess. They are phrased as statements and are attempts to explain observed patterns or predict the outcome of experiments. Conceptually, your hypothesis is your destination that all research roads must lead to.

A hypothesis is:

- Testable: Variables are operationalized and accessible so it can be tested
- Falsifiable: Should be able to be proven false

The following examples are taken from an NIH website. They provide more detail (http://funding.niaid.nih.gov/researchfunding/newsletter/2010/pages/1027.aspx#f01) and examples of good and bad hypotheses.

Your hypothesis triggers everything you plan to do. Conceptually, think of it as your destination, determining the course of your research and the terminal point of all its pathways.
Choose a hypothesis that is well-focused and testable, and that your experimental results will be able to prove or disprove. Here are examples of EFFECTIVE hypotheses:

From Jacques Banchereau, Ph.D., Baylor University:

- Systemic lupus erythmatosus patients with active disease display considerable alterations in their CD8+ T cell compartments, including effector CD28+ CTLs and suppressor CD28- subsets. We surmise that an excess of killer cells in lupus results in the characteristic tissue damage and explains an excess of dying cells that are considered as key factors in this disease.

From Volker Briken, Ph.D., University of Maryland College Park:

- This proposal seeks to test the hypothesis that the capacity of Mycobacterium tuberculosis to inhibit infection-induced apoptosis of macrophages is a major pathway of the bacteria to avoid the host’s innate and adaptive immune response.

And here are examples of hypotheses that are POORLY focused:

- Understanding the strategies of Escherichia coli to subvert host cells will allow for improved ways of preventing and treating E. coli -related diseases.

- Rheumatoid arthritis patients with active disease show many alterations in their immune profile.

- A wide range of molecules can inhibit HIV infection.

When writing the hypothesis you need to keep in mind the earlier recommendations of FINER. Is this Feasible, Interesting, Novel, Ethical, and Relevant? These are questions which should have been considered earlier but come back at every step and most definitely when you are deciding how to test your hypothesis and how to measure the variables you have identified.

Methods – What and How to Measure

You have your question; you now need to decide what your outcomes are and how they will be measured. If your question is, “What effect does osteopathic manipulation have on the management of knee osteoarthritis?” you need to establish some outcome. This can be a daily pain scale, a quality of life
questionnaire, or the amount of medication taken. These are only a couple of examples of possible outcome variables.

Picking a good outcome variable is important and might be determined by what is used in the clinical setting, what you have easy access to, etc. Keep in mind however that precision in the outcome measure and the nature of the outcome measure determines the types of statistical tests you will be able to use and also determine the precision you have in your findings and is linked to how large a sample size you will need.

For example you can ask the question whether or not there was a change in medication (Yes/No question, a dichotomous variable) or you can look at the amount of medication which was taken (continuous variable). Dichotomous variables provide much less detail and information and will require larger sample sizes to achieve a certain level of statistical power. Continuous outcome variables give more precision and can achieve a greater power with a smaller sample size when compared to dichotomous data.

More detailed information about study design and selection of variables is beyond the scope of this section. There will be plenty of opportunity to delve into this in a more detailed fashion during workshops. However, it is strongly recommended that you use measurement tools (survey, scale, event) which have been well studied and have proven their validity, accuracy, and precision.

**Methods – Subject Participation: who, where and how long?**

Determining your sample size is important. The bottom line is that when you have too few participants your data will lack power and when you have too many participants your study is inefficient. There is a balance point when after a certain sample size is reached any increase in power no longer outweighs the efforts. Certainly there are instances, rare conditions and specific chart reviews where you can only take all patients seen during a certain period of time and you may be dealing with very small sample sizes or case studies. The research support team and statistical help on campus can help you with issues related to sample size selection. This is something which you should do very early on in the design phase of the study.

**Who?**

Deciding who your study participants are is of great importance. How these will be selected and recruited is important. You can access databases at hospitals, medical offices, or public health agencies with appropriate approval. You can use
patients seen in outpatient clinics, inpatient settings and/or nursing homes. Whichever method you choose to recruit your study participants from has advantages and disadvantages.

The inclusion and exclusion criteria you use for your research project should be similar to published studies. This allows for greater ease of comparing your data.

Your research question also leads you to who the population is that you want to generalize the study findings/results to. This brings you to the question of the clinical/practical significance of the study. Who will be affected by the results? How do the results contribute to our medical understanding or changes in public health policy? The more exclusion criteria, the less generalized the study findings may be.

How Long?

There are several practical issues to consider. One is that your research project is limited by your graduation date. You need to keep a goal in mind of finishing this project in approximately 12 months, start to finish. If you are conducting an experiment this implies that you have 12 months to recruit/obtain participants, conduct the study, collect data, analyze the data and complete the paper. If you are conducting a prospective study and collect data at different time intervals you also need to keep in mind this 12 month window of time. This all assumes prior IRB approval which also can take a couple of months.

If you are joining an ongoing research project you need to determine if during your 12 month window of time there will be sufficient data for you to analyze and if a midpoint analysis makes sense.

Methods – Data Collection and Analysis

The kind of data you collect will determine which analyses you can perform. Unless you have experience in this area you will want to find someone to assist you. Help should be provided by your mentor but for more difficult studies is available through MWU’s Office of Research and Sponsored Programs and more specifically from our manager of Bio/Clinical Statistics Dr. Kamilar. You should have already established a good working relationship with either one of them when deciding on research topic, selection of sample, etc.

You also need a plan as to how and where you will store the collected data and how long you will keep the collected records. It is important to ensure patient confidentiality. Information should be kept in a locked cabinet in locked offices
and a specific plan regarding recordkeeping is needed for your IRB submission. You will also want to design some kind of computerized data base for electronic storage of the collected information. This can be done in an excel spreadsheet or in special statistical software. This also is a question to ask your research support group or statistician about early on in the process.

**Submitting Your Research Proposal**

At this point you are ready to submit your research proposal for approval. Having completed all the steps described in the previous sections should enable you to complete a 2-5 page research proposal describing your research topic and submit this for approval to your faculty research mentor. This document also needs to be reviewed by your Program Director. This document should include: title, background, hypothesis, specific aims and methods. A research proposal template can be found in Appendix 6. Your research proposal will also serve as the backbone for your application for IRB approval (if needed).

**First Steps:**

- A firm question in mind
- A preliminary literature search completed
- A faculty research mentor committed to working with you
- Completion of Human Protection in Research Online Compliance Training and obtained certificate
- Submitted your project proposal and obtained approval for your research idea.

**Steps Prior to Approval of Research Proposal**

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