Preparing a Health Research Proposal

"Opportunities Unlimited"

References:

- Verhoef MJ, Boon HS, Mutasingwa DH. The scope of practice of naturopathic medicine in Canada: An emerging profession. Soc Sci Med 2006; 63; 409-417
- Robert M, Ross S, Brasher P, Fischer B, Jacobs P. Surgical Management of Stress Incontinence in Women: Randomized Trial of Trans-Obturator Tape versus Tension- free Vaginal Tape http://www.obgyn.ucalgary.ca/Documents/TOTv%5B1%5D.TVT.pdf

Acknowledgements:

The Centre for Advancement of Health, 602 South Tower, 1403 29th Street NW, Calgary AB

HEALTH RESEARCH PROPOSAL WRITING

Research Proposals are intended to demonstrate:

- That your project should be done and how
- Specifically what you intend to accomplish and how you will do it
- A work-plan that demonstrates you have thought through all of the elements of your project

Potential Audience:

Academic Institutes,Funders, committees overseeing institutional approval (science, ethics), thesis committees etc.

Keys to Success in Writing a Good Proposal

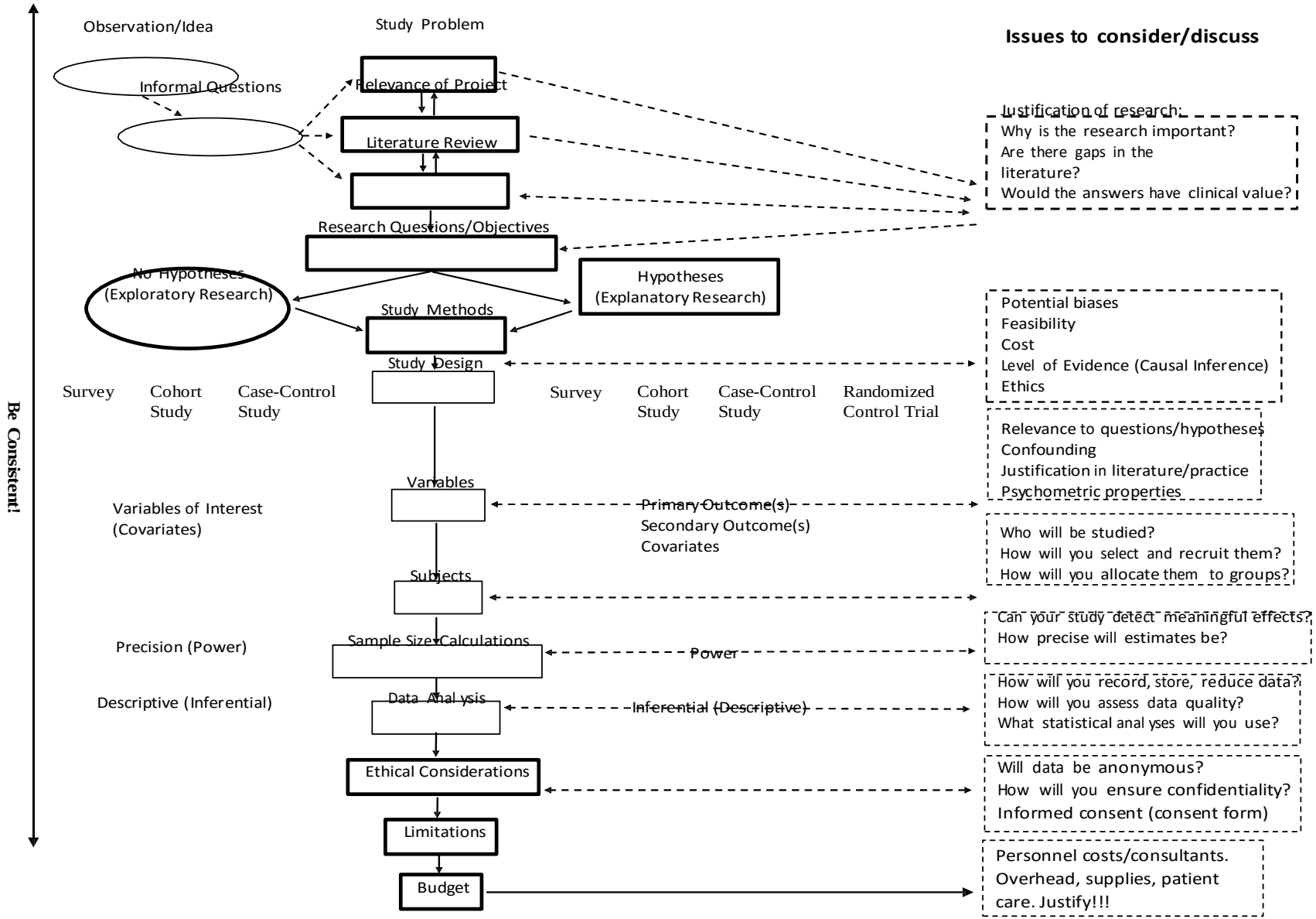
Overall Quality of the Study

- Good research question (relevant, justified)
- Appropriate research design
- Rigorous, feasible, and ethical methods
- Qualified research team

Quality of the Proposal

- Informative title
- Clear research questions
- Thorough and relevant background
- Convincing rationale/significance
- Clearly defined (and measurable) research objectives
- Appropriate population and sample
- Appropriate measurement and intervention methods
- Adequate sample size
- Sound analysis plan
- Ethical issues well addressed
- Tight budget
- Realistic timelines

(Adapted from Hulley & Cummings)


Observation/Idea
Study Problem
Issues to consider/discuss
Informal Questions
Relevance of Project
Literature Review
Justification of research:
Why is the research important?
Are there gaps in the literature?
Would the answers have clinical value?
Research Questions/Objectives
No Hypotheses (Exploratory Research)
Hypotheses (Explanatory Research)
Study Methods
Potential biases
Feasibility
Cost
Level of Evidence (Causal Inference)
Ethics
Study Design
Survey
Cohort Study
Case-Control Study
Survey
Cohort Study
Case-Control Study
Randomized Control Trial
Relevance to questions/hypotheses
Confounding
Justification in literature/practice
Psychometric properties
Variables
Variables of Interest (Covariates)
Primary Outcome(s)
Secondary Outcome(s)
Covariates
Who will be studied?
How will you select and recruit them?
How will you allocate them to groups?
Subjects
Can your study detect meaningful effects?
How precise will estimates be?
Precision (Power)
Sample Size Calculations
Power
How will you record, store, reduce data?
How will you assess data quality?
What statistical analyses will you use?
Descriptive (Inferential)
Data Analysis
Inferential (Descriptive)
Will data be anonymous?
How will you ensure confidentiality?
Informed consent (consent form)
Ethical Considerations
Limitations
Personnel costs/consultants.
Overhead, supplies, patient care. Justify!!!
Budget
Be Consistent!

HEALTH RESEARCH PROPOSAL WRITING

Title

The title should be informative, succinct and interesting. It should include the population of interest and the condition/issue being investigated.

Example 1

Title: ***"The Scope of Naturopathic Practice: An Emerging Profession"***

Reference*: Verhoef MJ, Boon HS, Mutasingwa DH. The scope of practice of naturopathic medicine in Canada: An emerging profession. Soc Sci Med 2006; 63; 409-417*

Example 2

Title: "*Surgical Management of Stress Incontinence in Women: Randomized Controlled Trial of Trans-Obturator Tape Versus Tension-Free Vaginal Tape*"

Reference*: Robert M, Ross S, Brasher P, Fischer B, Jacobs P. Surgical Management of Stress Incontinence in Women: Randomized Trial of Trans-Obturator Tape versus Tension-free Vaginal Tape* http://www.obgyn.ucalgary.ca/Documents/TOTv%5B1%5D.TVT.pdf

- Common Mistakes
  - A title that is too brief or too long
  - Use of incorrect terminology
  - Not specifying the population of interest

Introduction

- Introduce what your topic is about
  - Define Terms
  - What is already known about this ?
  - What research has been done about it / related areas? (Locally/ regionally/Internationally)

Study Problem / Purpose

- A broad statement indicating the goals of the project.
  - *Eg*. exploration, description, explanation, prediction (hypothesis testing)

Keys to success:

- Relevant
- Clear
- Logically argued

~~Example 1:~~ ***Naturopathic Practice***

The purpose of the study is to describe naturopathic practitioners' perception of their current scope of practice, and of the quality of the training they receive. These perceptions will be compared with current regulations governing naturopathic practice in the four regulated provinces.

~~Example 2:~~ ***Surgical Management of Stress Incontinence***

The purpose of this study is to compare outcome up to one year following surgery for stress incontinence using Trans-Obdurator Tape (TOT) versus Tension-free Vaginal Tape (TVT).

Significance / Justification

- Why should the research be done?
  - Why is the research important?
  - Has it been done before?
  - Will the study benefit patients, increase knowledge and/or influence policy?
  - Will research resolve controversies?
  - Would the answers have clinical value?

- **Keys to success**
  - Lead reviewers to answer the above questions.
  - Should be reasonable given the proposed study
  - Literature review will demonstrate that the research is justified
  - Granting agencies may have specific priority areas, be sure to explain how your study fits into those areas.

Example 1: ***Naturopathic Practice***

Relevance / Rationale

The results of this study will identify the degree of variation in naturopaths' practices, as well as the potential degree of overlap with other practitioners' scope of practice. This information is important in the debate about the profession's identity, its role in the Canadian health care system and the development of new health care professions. The study results will also generate important information with respect to evaluating and further developing national training programs. This study will allow collection of baseline data that can be used to track the development of naturopathic medicine as a profession over the coming years.

Example 2: ***Surgical Management of Stress Incontinence***

Literature Review

A critical summary of research on a topic of interest, generally prepared to put a research problem in context or to identify gaps and weaknesses in prior studies so as to justify a new investigation. Generally starts off broadly addressing the problem then becoming more narrow and leading to your specific research question(s).

- This is your chance to build a case for doing your study!
- Justify the statements that you have made in your Relevance/Rationale section.
- Reviewers will be looking to see whether your proposed work is appropriate for the level of knowledge currently existing in that area.

- **Keys to success**:
  - Identify gaps in knowledge or controversies
  - Focused on and leading naturally to your research questions/objectives
  - Be thorough, relevant, and up-to-date
  - Use primary sources of original research
  - Synthesize and be critical
  - Provide local background

Research Objectives / Research Questions

- Explicitly state what you propose to study.
- Form the foundation for the rest of the proposal.
- Will be used to assess the adequacy/appropriateness of the study's proposed methods.
  - Testable
  - Logically derived from the literature review

- Often includes:
  - Population of interest (person, place, time)
  - Variables (independent and dependent)
  - Relationship between variables being investigated

- **Keys to success**:
  - Be clear and consistent
  - Generally have only one or two primary research objectives
  - Include the independent and dependent variables, if applicable
  - Your objectives must be measurable.
  - Objectives must be Relevant or novel (as you've established in the literature review!).
  - If it is a pilot study, state clearly the pilot objectives (e.g., testing the feasibility of the study procedures, patient adherence to the study protocol, drop-out rates etc.).

Example 1: ***Naturopathic Practice***

Research Objectives:

1. **To describe naturopathic practitioners' perceptions of their scope of practice**
2. **To determine naturopathic practitioners' opinion about their current scope of practice**
3. **To examine naturopathic practitioners' satisfaction with their training and how well it prepared them for their current scope of practice.**
4. **To compare naturopathic medicine's scope of practice as identified by federal and provincial governing authorities with practitioners' perceptions.**

METHODS

Study Design

- Issues to consider in design
  - Accuracy of results and generalizability
  - Potential biases that may emerge
  - Feasibility (logistics)
  - Cost
  - Level of evidence, limitations
  - Ethics

Types of Designs:

- Descriptive (Survey, cross-sectional, correlational)

- Observational/analytic
  - Cohort studies
    - Prospective
    - Retrospective
  - Case-control studies

- Interventional
  - Quasi-experimental
  - Randomized controlled trials

- **Keys to success**:
  - Clearly identify the type of design and justify your choice
  - Describe using standard terminology
  - Make sure what you have named your study fits with what will be done

- Ensure the proposed design is appropriate to address study objectives
- Address any design issues in the literature review and limitations sections

Example 1: ***Naturopathic Practice***

Study Design

The study design will consist of two components: ***1)*** *a survey of licensed Canadian naturopathic practitioners; and* ***2)*** *an analysis of pertinent national and provincial documents in the public domain.*

SURVEY: Data will be collected by means of a standardized questionnaire, which will be mailed to all practitioners in the study group. Questionnaires will be numbered to identify those who have responded and, thus, to facilitate follow-up. A reminder will be sent 2 weeks after the initial mail out. Non-responders will be sent a second questionnaire 4 weeks after the initial mailing. Practitioners who have not responded 6 weeks after the initial mail-out will be contacted by phone and asked whether they would be willing to participate in a brief telephone interview to assess selected socio- demographic and practice characteristics, two brief questions assessing opinion about scope of practice, and the reason for not responding. This information will assist in assessing whether the sample of respondents is similar to the target group. The questionnaire will include……

DOCUMENT COMPARISON: The document analysis will include the collection of documents in the public domain that address issues around the scope of practice of naturopathic medicine.

Population / Subjects

- Who will you study? Why?
- Specify eligible subjects
  - Target population: clinical & demographic characteristics
  - Accessible population: temporal & geographic characteristics
- **Keys to success**:
  - Clearly describe the study population
  - Provide appropriate inclusion/exclusion criteria
  - Justify the use of the study population and the sampling method (consider potential bias, generalizability)
  - Provide all details of the sampling and recruitment methods (including any barriers to recruitment specific to the population and strategies you will use to address these - e.g., cultural barriers)
  - Do not confuse randomization with random selection

~~**Example 1:**~~ ***Naturopathic Practice***

Study Subjects

SURVEY*:* The study group will consist of all licensed naturopathic practitioners (approximately 400) in Canada. Addresses will be obtained from a database maintained by the Canadian College of Naturopathic Medicine. Letters of support have been obtained from the Canadian Naturopathic Association and the Canadian College of Naturopathic Medicine.

Variables / Data Collection

Identify the:

- Independent variable (exposure, intervention…)
- Dependent variable (outcome)
- Covariates
- Where will the information come from (data sources)?

In descriptive and exploratory studies, this distinction is not mad

Exactly how will the information be collected (data collection methods)?

- **Keys to success**:
  - Indicate relevance to research questions/objectives
  - Describe the variables in detail
    Primary, secondary, covariates
  - Discuss psychometric properties (for measurement instruments, scales)
  - Provide justification for use (gold standards, other research, clinical practice).
  - Include letters of agreement if you will get data from a third party

Example 1: *Naturopathic Practice*

Data Collection

1) SURVEY:
Primary Variables (what will be measured):

- Scope of practice (treatment modalities, types of health conditions treated, referral practices)

Other Relevant Variables:

- Sociodemographic information (age, gender, marital status, membership of professional organization, and license status)
- Practice Characteristics (number of years in practice, location of practice, involvement in teaching/research, number of patients seen each week)
- Education

Measurement Tool:

The questionnaire was developed by the research team and has used valuable information by Boon (5) in qualitative interviews with Canadian Naturopaths. A draft copy of the questionnaire is included for review, along with discussion of the psychometric properties. The questionnaire will be pre-tested using a number of naturopaths, as well as independent assessors representing medicine, research, a wide range of other health professions, and government.

2) DOCUMENT COMPARISON: The document comparison will include legislation from the regulated provinces, the CAN Code of Ethics and CAN Standards of Practice.

Variables to be assessed include:

- Treatment modalities and health conditions seen as part of naturopathic medicine's scope of practice
- Referral policies
- Rationale and philosophy underlying scope of practice.

Data Collection - Common Pitfall
'The Unknown Instrument'
The primary objective is to determine the degree of satisfaction patients have with outpatient surgery. A questionnaire will be mailed to patients asking about their degree of satisfaction with their hospital stay.

- Where did the questionnaire come from?

Note about Questionnaires

- A questionnaire is a data collection instrument
- What reviewers are looking for:
  - How was the questionnaire developed (and by whom)?
  - Are you using a Standardized Instrument?
  - Has it been tested for
    Reliability
    Validity
  - Has the questionnaire been pre-tested among the patient population being studied?
  - How will the questionnaire be administered?

Statistical Analyses and Sample Size

In many proposals, the sample size section precedes the data analysis section. However, it is advisable to consider the analysis section first, as the sample size calculation should be based on the analysis of the primary research question.

Data Analysis Section

- A detailed plan for handling and analyzing data, including procedures for:
  - Recording, storing and reducing data
  - Assessing data quality
  - Statistical analyses
- **Keys to success**
  - Indicate how you will test assumptions
  - Provide reasonable detail
  - Make sure you have described the analysis for each stated objective

Tips for the Data Analysis Section

- Make sure your objectives are clear, simple and testable.
- Think carefully about your outcome measure.
  - What constitutes clinical relevance?
  - Is it appropriate, relevant and measurable?
- Be concrete and explicit.

Turn your research question into something testable.
Take the essential features of your problem and turn it into something measurable.

- Think carefully about your outcome measure.

  What constitutes clinical relevance?
  Is the outcome measure appropriate? Select an appropriate analysis tool.
- Think about how you would present your final results.
  - What convincing evidence would you present?
  - What could you measure and report that would demonstrate clinical/economic impact?

- Make table shells (these do not need to be included in the proposal).
  How will you present the data from your study?
  What features of your patients would you need to describe in a manuscript?
  - How will tests of significance or models be presented? Comparison of means? Comparison of rates or proportions?

Sample Size Estimates: Inference

- Inference
  - In research, we usually can't measure everyone.
  - Forced to make inferences regarding "true" or underlying characteristics of a population on the basis of data collected from a sample.
  - The more subjects we use or measure, the more accurate our estimates will be.
  - If we measure too many, we will waste resources. If we measure too few, we won't be able to detect effects of interest.

Sample Size Calculations

- Keys to success:
  - If possible, consult a biostatistician (there are also some online sample size calculators available)
  - Justify the elements that you put into your calculation. For example:

    …control group is expected to have this response based on literature (eg. meta-analysis)"
    ….we'd like to detect this response in the intervention group based on previous literature and clinical significance
    …..the standard deviation around the change is based on the literature…

  - Base the sample size on the <u>primary objective</u>(s) and on the test of significance that will be used to test your primary study hypothesis.
  - If you have a fixed sample size, do a power calculation.
  - If you are estimating a prevalence or mean score in a cohort study or survey, justify the sample size on the widths of confidence

intervals (e.g. for prevalence, number of subjects needed to obtain 95% confidence intervals of +/- 10%.).

- Account for anticipated dropout rates and or non-response rates in the sample size estimate.

~~**Example 1:**~~ ***Naturopathic Practice***

Analysis Plan

SURVEY: The data analysis will be mainly descriptive. Frequencies and summary measures will be selected according to the level of measurement for each of the key variables of interest (components of scope of practice, satisfaction with scope of practice and training and preparedness for practice). If numbers are sufficient, contingency analyses will be conducted to identify whether socio-demographic, education and practice characteristics are associated with the key variables of interest. Depending on the level of measurement Chi-squared (discrete data, difference in proportions), t-test (continuous data) or one-way ANOVA will be used. Data will be analyzed using SPSS software.

DOCUMENT COMPARISON: Treatment modalities and health conditions will be assessed using quantitative content analysis where possible. Quantitative content analysis is "a research technique for the objective, systematic and quantitative description of the manifest content of communication" (9). The analysis consists primarily of counting occurrences in each identified category (eg. Scope of practice). The remaining variables will be analyzed using qualitative content analysis. This involves analyzing the content of the narrative to determine themes or patterns. A theme is a recurring regularity emerging from an analysis of qualitative data and may be a phrase, sentence or paragraph embodying ideas or making an assertion about a topic. The distinction between quantitative and qualitative content analysis is often more a mater of degree than a clear dichotomy.

The quantitative results of the document analysis will be compared with the survey participants' responses in terms of descriptive summary measures. Where required (ie. when documents reveal major differences across provinces), the responses of the survey participants will be stratified by province.

Ethical Consideration

- Keys to success
  - Describe the recruitment procedures
  - Describe procedures for maintaining subject privacy
  - Follow the guidelines for your organisation (consent form templates)
  - Describe harms and benefits
  - Describe alternatives to study participation
  - If asking for a waiver of consent, justify explicitly why you cannot get consent (HIA)
  - If using a placebo group, make sure it fits into the TCPS guidelines

Example 1: ***Naturopathic Practice***

Ethical Considerations

An introductory letter will be included with the questionnaire and will describe the purpose of the study, the research team, and confidentiality of the data (see Appendix X). Follow-up letters are also included in Appendix X. Return of the questionnaire is considered to be consent. Practitioners who do not respond to the questionnaire 6 weeks after two reminder letters will be telephoned and asked for a brief telephone interview. A script outlining how practitioners will be approached is included in Appendix Y.

Limitations

- Be upfront about the limitations of your study.
- This is one of the most important sections of the proposal (shows reviewers you have thought through all aspects of your study)
- Be clear about why you are not able to overcome these limitations *a priori.*
- How might these impact the findings?
- If there are clear issues, better to talk about them than leave them open.
- Put a positive spin on any limitations

Other Possible Sections

- Budget
- Timelines
- Plans for dissemination