# TABLE OF CONTENTS

**INTRODUCTION** ........................................................................................................................................ 1

**INITIATING A RESEARCH PROJECT: GETTING STARTED & DEVELOPING YOUR IDEA** ......................................................... 2
  - Research Workbook ........................................................................................................................................... 2
**FORMULATING A QUESTION USING PICO** ............................................................................................................. 3
**LITERATURE SEARCH BASICS** ...................................................................................................................................... 4

**USING, SEARCHING & APPRAISING RESEARCH EVIDENCE** ........................................................................................................... 5
  - Critically Appraising a Research Article ........................................................................................................... 5
  - Managing Citations ........................................................................................................................................... 6
  - Referencing & Documentation Formats ........................................................................................................... 6
  - Research Terms & Glossary ................................................................................................................................ 6

**DEVELOP & REFINE THE PROJECT** ................................................................................................................................. 7
  - Finer Criteria ...................................................................................................................................................... 7

**RESEARCH DESIGN: UNDERSTANDING METHODOLOGICAL NUANCES** ............................................................... 8
  - Features of Qualitative & Quantitative Research ................................................................................................. 8
  - Levels of Evidence-Based Research: Quantitative ............................................................................................... 9
    - Systematic Review ............................................................................................................................................ 10
    - Randomized Control Trial (RCT) ..................................................................................................................... 11
    - Pragmatic Clinical Trial .................................................................................................................................. 12
    - Cohort ............................................................................................................................................................. 13
    - Case-Control ................................................................................................................................................... 15
    - Case Report / Case Series ............................................................................................................................. 16
    - Editorial / Expert Opinion ............................................................................................................................. 16
    - Common Quantitative Questions & Corresponding Research Designs .......................................................... 17
  - Levels of Evidence-Based Research: Qualitative ................................................................................................. 18
    - Survey ............................................................................................................................................................... 19
    - Face-to-face Interview / Questionnaire ........................................................................................................... 20
    - Focus Group(s) ................................................................................................................................................ 20

**CLINICAL PRACTICE GUIDELINES: APPRAISAL FOR RESEARCH & EVALUATION** ................................................. 21
  - AGREE Tool ....................................................................................................................................................... 21

**RESEARCH PLAN: DEVELOPING THE RESEARCH PROPOSAL** ...................................................................................... 22
  - Template for Research Proposal: Quantitative & Qualitative ................................................................................ 22
    - Introduction ..................................................................................................................................................... 22
    - Background (Review of the literature) ............................................................................................................. 22
    - Purpose & Objectives ....................................................................................................................................... 22
    - Methods (Quantitative; Qualitative) ................................................................................................................ 23
    - Anticipated Ethical Issues ................................................................................................................................ 24
    - Significance of the Study / Expected Outcomes ............................................................................................. 24
    - Knowledge Translation ................................................................................................................................... 24
    - Assessing the Applicability of Interventions ................................................................................................ 25
    - Writing the Abstract ....................................................................................................................................... 26
    - Common Pitfalls of Primary Research ........................................................................................................... 28

**CONSIDER FUNDING APPLICATIONS** ................................................................................................................... 29
  - Applying for Funding, Grants & Awards ............................................................................................................. 29
    - Helpful Hints on Writing a Successful Grant Application .............................................................................. 30
    - B.Sc. Medicine & Med II Summer Research Programs ............................................................................... 31
Primary Care Research Guide

Introduction:

Within family medicine, there is exceptional potential to contribute and become involved in research and scholarly activity. In fact, family medicine researchers have been at the forefront of several important research achievements, all of which have had a significant impact on primary care, clinical practice and health standards – both at the patient-level and reaching well beyond. Family medicine is recognized as a unique discipline as it spans a range of patients at all stages of the health spectrum and lifecycle.

The following guide can be used as a reference and is intended to serve as resource for DFM faculty, staff and others with an interest in research. A complimentary quick-reference guide is also available on the DFM website, which provides links and lists of resources available to University of Manitoba researchers, potential grant and funding opportunities, organizations and research networks relevant to primary care/family medicine, etc. Additionally, the department’s Research Facilitator is available to provide support and guidance on a variety of research-related topics and inquiries.

THE RESEARCH ROADMAP

Steps to Administering your Research – This handbook is meant to provide guidance as you navigate each step

- Develop the research question
- Review the literature
- Develop & refine the research proposal & design
- Consider funding applications
- Obtain necessary approvals
- Collect & collate data
- Analyze & interpret data
- Report & disseminate findings
Initiating a Research Project: Handbook for getting started

GETTING STARTED – DEVELOPING YOUR IDEA

Research Workbook: A simple, non-technical aid available for novice researchers as they begin to develop and refine a research project. This workbook follows through a series of questions to help encourage initial project development. While not intended to provide technical instruction, it is a useful exercise both to organize thoughts, and ensure important topics receive appropriate consideration. (Example excerpts provided below).

III. JUSTIFYING THE STUDY

Who cares about the answer?
How is present opinion divided?
How important is it to have the right answer?
What are the implications of various possible answers?

Write a paragraph justifying your study. Consider the questions above but feel free to modify or add to them.

XII. STATISTICAL ANALYSIS

Design and analysis are two sides of the same inferential coin. Always seek competent consultation in the design phase or there may never be any analysis worth doing.

You may begin to organize the analysis by listing below all of the variables considered in your design. Separate the variables into the three categories described.

A. Demographic variables which describe characteristics of subjects such as age, sex, race, previous hospitalizations, etc.

B. Variables of the study under the control of the investigator, such as type of instruction given, therapy options, duration of treatment, or other exposures or treatments to which the investigator can assign subjects.

C. Outcome variables or effects potentially related to or caused by A or B above, such as adherence to instructions, speed of recovery, or client satisfaction.

Formulating a Question Using PICO²

The **PICO framework** can be used to help build a question that will identify the patient *problem or population* (P), *intervention* (I), *comparison* (C) and *outcome(s)* (O).

NOTE: PICO is generally applicable to traditional *quantitative* research methods, and is not particularly relevant to *qualitative* research designs, which tend to explore the experiences/views of individuals and understand their actions, choices, etc.

The first step is to identify the patient **Problem or Population**. Describe either the primary complaint or generalize the patient's condition to a larger population. Therefore it is helpful to ask the following:

- How would you describe a group with a similar problem?
- How would you describe the patient to a colleague?
- What are the important characteristics of this patient?
  - Primary Problem
  - Patient's main concern or chief complaint
  - Disease or health status
  - Age, Race, Sex, Previous ailments, current medications
- What are the important characteristics that should be considered, or may have an impact?

Identifying the **Intervention** refers to what you plan to do for the patient. This may include the use of a specific diagnostic test, treatment, adjunctive therapy, medication or the recommendation to the patient to use a product or procedure.

The **Comparison**, or the alternative, should be specific and limited in order to facilitate an effective computerized search. Note: The Comparison is *an optional component* in PICO. It is possible to look at an intervention without exploring alternatives, and in some cases, there may not be an alternative.

The **Outcome** is the final aspect of the PICO question. It specifies the result(s) of what you plan to accomplish, improve or affect and should be measurable. Outcomes may consist of:

- relieving or eliminating specific symptoms
- improving or maintaining function or
- enhancing systems, procedures or effects.

Example of a PICO question: **For a patient with illnessX, will procedureY, as compared to procedureZ/standard care, decrease side-effects/improve outcomes/etc.?**

**LINKS to PICO Resources**

---

**Literature Search Basics**

With a potential research question in mind, an effective search of the relevant academic literature should follow to determine:

- a context for the research
- justification for the study
- whether the research has been done before
- where the research fits into the existing body of knowledge
- how the subject has been studied previously
- flaws in previous research
- gaps in previous research
- what the research will add to understanding and knowledge of the field/topic
- how or whether to refocus &/or change the topic, or objectives

The UMan librarians are an excellent resource when it comes to searching techniques and effectiveness. Helpful resources include contact information (listed both by primary library location—including the libraries located within clinics/hospitals—and area of expertise) along with research guide(s), which can be filtered by subject, librarian expertise, and provides information on current articles, search filters, useful links. Additionally, the library offers guides on how to evaluate various types of resources and literature.

For those who prefer to do their own literature review, it is useful to identify and record key concepts, determine relevant alternative terms and outline inclusion criteria (publication year, gender, age, language and other limits). Once relevant articles are found, it is a good idea to identify the type of question being asked and methodology to get a feel for what has been done, and where there are gaps remaining.

An effective literature search should accomplish the following:

1. be organized and related directly to the research question in development
2. synthesize results into a summary of what is and is not known
3. identify areas of debate/uncertainty in the literature
4. formulate questions that need further research

**Bottom line:** A literature search should help shape your research question, and ultimately, influence the ‘Background’ section of the formal research proposal. The most effective way to present literature findings is not to list, or summarize one study after another; rather, organize the literature review/background into sections and present themes, identify trends, including relevant theory, while discussing the relevant/supporting literature. Overall, instead of listing all material published, it is much more effective to synthesize and evaluate the literature according to the concept, purpose, or specific research question.

**Useful Reading:**

**LINKS to Searching Resources**
Also see: http://libguides.lib.umanitoba.ca/familymedicine

---

5 Information available from: http://www.usc.edu/hsc/ebnet/ebframe/Search.htm
University of Southern California.

4 Information available: http://library.queensu.ca/webedu/grad/Purpose_of_the_Literature_Review.pdf


6 Information available: http://www.writing.utoronto.ca/advice-specific-types-of-writing/literature-review
Using, Searching & Appraising Research Evidence:

Decision Tree for Using, Searching & Appraising Research Evidence:

Critically Appraising a Research Article:
A critique of the research evidence will differ slightly according to the type of study (e.g. systematic reviews, observational studies, cohort). Systematic reviews are a reliable source of evidence because they appraise and summarize numerous primary research studies; however, they are not always available. If a systematic review related to your potential research topic has not been conducted, other types of studies should be evaluated in order to find the best and most current available evidence. As such, the following questions can be used to help assess the quality of the article:

**IS THIS ARTICLE RELEVANT TO MY ISSUE AND SETTING?**

*Read the Abstract*
Use the information found in the abstract to answer the questions:
- Are your issues discussed there?
- What are the main findings of the research?
- Do you want to know more after reading the abstract?
- Was the research done in a similar or related setting to yours?
- Does it address a related question? (Note: research that covers your issue indirectly can be useful.)
- Are there reasons to doubt the findings (without even reading the whole article)?

*Read the Introduction & Discussion*
To further assess the relevance of a study, look to those sections of the research article that describe the objectives and context of the study in more detail. The Introduction and Discussion sections should help identify the key

---


consult the methods

the methods section will give you a step-by-step description of exactly how the study was carried out. some important features to note:

• where the study was done (on site, at home, administrative setting, etc.);
• from whom the data was collected (primary from staff, patients, families; or secondary from databases); and
• how the data was collected (interviews, focus groups, questionnaires, surveys, observations, etc.).

if what you have read about the article is both useful and reliable, then move on to evaluate the conclusions:

compare the abstract to the discussion section

the discussion section is more detailed and precise than the abstract, and will explain the limitations of the research and possible implications, which are not mentioned in the abstract.

compare data tables with results discussed in the conclusion

are the results reported in the conclusions consistent with what is reported in the tables? is the interpretation consistent with the actual findings?

are the results related or similar to other research on the same topic?

is there a review of how these results compare or contrast with prior research? if the report found something different, then it is important to closely evaluate the reliability of the findings.

managing citations:

reference tools are incredibly useful for storing articles and managing citations/references. additionally, these programs allow users to easily create bibliographies and/or reference lists. generally, the program automatically downloads references from the library databases and catalogues into your own database, as well as permits sharing information, which enhances collaboration amongst research team members. for example, refworks users can share references with members of their own institutions, and more globally (i.e., with any designate who has internet access).

the university of manitoba library provides useful information on refworks, which is the web-based content management software available to all university of manitoba students, staff, faculty and alumni. it also provides important details about other popular citation/reference tools (e.g., mendeley, endnote, zotero, papers, reference manager): http://libguides.lib.umanitoba.ca/content.php?pid=339895&sid=2778498

referencing & documentation format(s):

examples of common documentation styles/systems (e.g., apa, mla), indicating the kinds of information needed, details of punctuation, typeface, and indentation, can be found here: http://www.writing.utoronto.ca/advice/using-sources/documentation

the examples also demonstrate ways of introducing citations and commenting on sources.


research terms & glossary:

definitions of common terms relevant to primary care research: http://research.familymed.ubc.ca/files/2012/03/common_terms_relevant_to_primary_care_research9331.pdf

glossary – systematic review & research-related terms defined and explained: http://www.health evidencenetwork/tools.aspx

examples include: cohort study, confidence interval, incidence, number needed to treat, odds ratio, prevalence, p-value, quasi-experimental design, relative risk, systematic review
Develop & Refine the Project (FINER Criteria)\textsuperscript{9}

Once a research question has been developed, an evaluation of the potential and/or feasibility of the question and corresponding research project should be a next step. The FINER criteria can be used to assess a project’s potential.

FINER Criteria:
- Feasible
- Interesting
- Novel
- Ethical
- Relevant

Is it Feasible?
- Adequate number of subjects
- Appropriate equipment, data (available? accurate?)
- Available expertise or skills
- Sufficient time, money
- Manageable in scope

Is it Interesting?
- Interesting to you
- Interesting to others (e.g., researchers, funding agencies, practitioners, policy-makers)
- Will the results contribute to the literature (no matter what the results find)?
- Will it lead to subsequent questions, studies, etc.?
- What journals, or who would be interested in this information & why?

Is it Novel?
- Generate new information
- Confirm or refute previous findings
- Expands on available information, or questions (new population, new application, additional variables, etc)
- Addresses question from a primary care perspective (how is it different? What does it add?)

Is it Ethical?
- Risk/Benefit balance
- Informed consent (applicable?)
- Privacy/Confidentiality
- Conflicts of interest, Disclosures
- Ethics & other Approval Bodies/Organizational Review

Is it Relevant?
- To scientific theory & knowledge
- To clinical practice & patient care
- To health policy
- To education & training
- To quality improvement
- To future research & inquiry

Summary available: \url{http://www.usc.edu/hsc/ebnet/ebframe/Search.htm}
RESEARCH DESIGN: UNDERSTANDING METHODOLOGICAL NUANCES  
Features of Qualitative and Quantitative Research\textsuperscript{10}

<table>
<thead>
<tr>
<th>Qualitative</th>
<th>Quantitative</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;All research ultimately has a qualitative grounding&quot;</td>
<td>&quot;There's no such thing as qualitative data. Everything is either 1 or 0&quot;</td>
</tr>
<tr>
<td>- Donald Campbell</td>
<td>- Fred Kerlinger</td>
</tr>
<tr>
<td>The aim is a complete, detailed description.</td>
<td>The aim is to classify features, count them, and construct statistical models</td>
</tr>
<tr>
<td></td>
<td>in an attempt to explain what is observed.</td>
</tr>
<tr>
<td>Researcher may only know roughly in advance what he/she is looking for.</td>
<td>Researcher knows clearly in advance what he/she is looking for.</td>
</tr>
<tr>
<td>Recommended during earlier phases of research projects.</td>
<td>Recommended during latter phases of research projects.</td>
</tr>
<tr>
<td>The design emerges as the study unfolds.</td>
<td>All aspects of the study are carefully designed before data is collected.</td>
</tr>
<tr>
<td>Researcher is the data gathering instrument.</td>
<td>Researcher uses tools, such as questionnaires or equipment to collect</td>
</tr>
<tr>
<td></td>
<td>numerical data.</td>
</tr>
<tr>
<td>Data is in the form of words, pictures or objects.</td>
<td>Data is in the form of numbers and statistics.</td>
</tr>
<tr>
<td>Subjective - individuals interpretation of events is important, e.g., uses</td>
<td>Objective - seeks precise measurement &amp; analysis of target concepts, e.g.,</td>
</tr>
<tr>
<td>participant observation, in-depth interviews</td>
<td>uses surveys, quantifiable data.</td>
</tr>
<tr>
<td>Qualitative data is more 'rich', time consuming, and less generalizable.</td>
<td>Quantitative data is more efficient, able to test hypotheses, but may miss</td>
</tr>
<tr>
<td></td>
<td>contextual detail.</td>
</tr>
<tr>
<td>Researcher tends to become subjectively immersed in the subject matter.</td>
<td>Researcher tends to remain objectively separated from the subject matter.</td>
</tr>
</tbody>
</table>

\textsuperscript{10} Available at: [http://wilderdom.com/research/QualitativeVersusQuantitativeResearch.html](http://wilderdom.com/research/QualitativeVersusQuantitativeResearch.html)
Levels of Evidence-based Research: *Quantitative*

Distinguishing between strong and weak evidence, and determining which evidence is the most authoritative and why, is important. The diagram (below) illustrates very basic and general hierarchical levels of evidence for quantitative research design, based on *internal validity*. Internal validity refers to the extent to which the results of the research may be biased, and therefore is a measure of the strength of the cause-and-effect relationship between an intervention (independent variable) and its outcome (dependent variable).

![Quantitative Research: Study design organized by the hierarchy of evidence](Available from: http://ebp.lib.uic.edu/nursing/node/)

**Quantitative Research Design**\(^\text{12}\):  
- Employs strategies of inquiry such as experiments, and collects data on predetermined instruments that yield statistical data.  
- Observes and measures information numerically

**Advantages:**\(^\text{13}\)  
- Typically involves a greater number of subjects, enhancing the generalizability of the results  
- Attempts to control bias and confounding variables, allowing for greater objectivity and accuracy  
- Employs prescribed procedures to ensure validity and reliability  
- Reproducible  
- Facilitates comparisons across categories and over time

**Disadvantages:**  
- Generally complex and costly  
- Results are limited to numerical descriptions, and information available to access for research purposes.  
- Research generally carried out in an unnatural, artificial environment, which may not always translate to applicability in the ‘real world’.  
- Preset answers or hypotheses may not cover the full breadth and depth of participants’ knowledge, feelings, or the issues at play.  
- Ethical considerations render some quantitative designs impracticable

---

\(^{11}\) (Available from: [http://ebp.lib.uic.edu/nursing/node/12](http://ebp.lib.uic.edu/nursing/node/12))  
\(^{12}\) John W. Creswell’s “Research Design: Qualitative, Quantitative & Mixed Methods Approaches”, 2\(^{\text{nd}}\) Ed  
\(^{13}\) (Available from: [http://learnhigher.ac.uk/analysethis/main/quantitative1.html](http://learnhigher.ac.uk/analysethis/main/quantitative1.html))
**Systematic Review**

A summary of the academic literature that uses explicit methods to perform a comprehensive literature search and critical appraisal of individual studies, often employing appropriate statistical techniques to combine the valid studies found.\(^\text{14}\)

- A comprehensive strategy to find all published research on a topic, which is then combined into a single analysis
- Follows clearly stated objectives, in which there are explicit and justified criteria for the inclusion or exclusion of any study.
- The characteristics of each study are summarized, and a critique of the methodological quality provided
- The review includes a comprehensive list of all studies excluded and justification for exclusion
- NOTE: Systematic reviews are different than a review of several articles; that is, systematic reviews are conducted to answer a specific clinical question and/or identify gaps in the literature, while a review is intended to provide a broad overview on a topic to answer background questions and/or build an argument for additional exploration, and does not attempt to find all existing knowledge on a topic.\(^\text{15}\)

**Advantages:**
- Identify areas for further development/study
- Inexpensive
- Information relatively accessible
- Not dependent on other factors (can be done at any time & under most circumstances)
- Ethical (ethics approval not a requirement because it summarizes knowledge that is already available and in the public domain, and are derived from studies that have already gone through ethics approval)

**Disadvantages:**
- Time commitment, consuming
- Documentation (must be precise, detailed and consistently captured)
- Difficult without some familiarity of the existing literature, terminology and/or field of interest

---


\(^{15}\) Margaliot, Zvi, Kevin C. Chung. Systematic Reviews: A Primer for Plastic Surgery Research. PRS Journal. 120/7 (2007)
**Randomized Controlled Trial (RCT)**

An experimental, prospective study in which "participants are randomly allocated into an experimental group or a control group and followed over time for the variables/outcomes of interest"\(^{16}\)

- Random assignment of individuals to an intervention, treatment, or to a control group. E.g., an individual is randomly assigned to an experimental group to receive a treatment such as surgery, or to a control group (the control group might receive nothing, placebo or standard-care).
- Minimizes confounding (known and unknown)
- Offers the most solid basis for an inference of cause and effect compared with results obtained via other study designs.

### Design of RCT\(^ {17}\)

Three basic methods for randomization: *Simple, Blocked, and Stratified.*

- **Simple** randomization is most often performed prior to participant enrollment using random number tables or computerized random number generators.
- **Block** randomization is a way to guarantee that treatment group sizes will be equal, or nearly so, by allocating treatments within groups of participants (e.g. every 3 subjects would comprise a block in a 3 arm study trial).
- **Stratified** randomization is utilized to provide even greater protection against confounding in trials with a small number of participants, by creating randomization blocks based on some key factor (i.e. potential confounder) such as age, for example.

**Advantages:**
- Unbiased distribution of confounders
- Blinding more likely
- Randomization facilitates statistical analysis.

**Disadvantages\(^ {18}\):**
- Expensive
- Time commitment (to set up, operationalize, ensure adequate participation, etc)
- Volunteer bias
- Ethically problematic at times (e.g., placebo)

---


\(^{18}\) Available at: [http://www.cebm.net/?o=1039](http://www.cebm.net/?o=1039) (Centre for Evidence-Based Medicine, University of Oxford)
One important limitation of the RCT design is that in limiting bias and effectively controlling for confounding effects, it creates an atmosphere in which results can be difficult to apply in clinical settings and broader patient populations. Thus, pragmatic clinical trials are intended to address practical questions in real-life routine practice conditions, and are designed to overcome many of the potential limitations of RCTs by including (1) use of active controls and clinically relevant comparisons, (2) broad study populations, (3) enrollment from diverse clinical environments, (4) evaluations of strategies of treatment rather than single drugs or devices, and (5) measurement of multiple health outcomes including those related to patient symptoms, quality of life, and costs.

- Minimal inclusion or exclusion criteria
- Practitioners are not constricted by guidelines on how to apply the experimental intervention
- Experimental intervention applied by many practitioners, to cover a wide spectrum of clinical settings
- Alternative/standard treatments are used for comparison, with no restrictions on its application
- Primary outcome is one that is clinically meaningful, and does not require extensive training to assess
- Analysis includes all participants.

Advantages:

- Applicable to clinical setting
- Inclusive of a broad patient population
- Patient-centered focus
- Results maximize applicability and generalizability

Disadvantages:

- Time commitment (to set up, coordinate, operationalize, etc.)
- Large samples and/or long follow-up required (to increase power to detect small effects)
- Not appropriate to assess complicated problems and/or tease out cause-effect relationships

Suggested Reading:


---

19 Patsopoulos, NA (2011). *A Pragmatic View on Pragmatic Trials*. Dialogues in Clinical Neuroscience, 13(2): 217-224. *Beyond the Randomized Clinical Trial*: [http://circ.ahajournals.org/content/118/12/1294.full](http://circ.ahajournals.org/content/118/12/1294.full)
Cohort

- Compare outcomes of individuals whose treatment differs “naturally” (i.e. not as the result of random assignment).
- Study participants are identified based on treatment or illness, and then outcomes are compared.
- Eligible participants not having experienced the outcome of interest at the time treatment groups are defined are used as the compare group.
- May be either prospective or retrospective depending on the time of study initiation.
  → Prospective cohort studies involve the ascertainment of treatment status at the outset with follow-up for outcome to occur in the future.
  ← Retrospective cohort studies are characterized by the treatment and outcome having already occurred at the time of study initiation, and looking back in time to see the events that may have contributed or may be associated with the treatment/outcome.

Cohort studies are observational and can establish a temporal relationship between the treatment and the outcome of interest (i.e., the treatment clearly precedes the outcome). However, cohort studies are vulnerable to bias/misleading results, since factors other than treatment alone (e.g., prognostic factors), can also unduly influence. Therefore, it is important to carefully identify and control – either by overestimating or underestimating the treatment effects – factors that may influence outcomes.

Prospective and retrospective cohort studies

<table>
<thead>
<tr>
<th>Identify study subjects</th>
<th>Classify prognostic factors</th>
<th>Factor present</th>
<th>Factor absent</th>
<th>Good outcome</th>
<th>Bad outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time</td>
<td>Prospective cohort study begins here</td>
<td>Retrospective cohort study begins here</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Cohort study designs (prospective & retrospective)²⁰

NOTE: While retrospective cohort studies tend to be cheaper and faster than prospective cohort studies, the retrospective nature of the study can introduce additional bias. Further, retrospective studies are by their very nature, limited to outcomes and prognostic factors that have already been collected and therefore, may not be appropriate/applicable to answer all aspects of the clinical question.

Cohort (continued)...

Advantages:
• Ethically safe
• Subjects can be matched
• Can establish timing and directionality of events
• Eligibility criteria and outcome assessments can be standardized
• Administratively easier & less expensive than RCT to set-up, implement, follow-up, etc.

Disadvantages:\(^{21}\):
• Controls may be difficult to identify
• Exposure may be linked to a hidden/unapparent confounder
• Blinding is difficult
• Randomization not present
• For rare or uncommon diseases, large sample sizes or long follow-up necessary

Suggested Reading:


\(^{21}\) Available at: http://www.cebm.net/?o=1039 [Centre for Evidence-Based Medicine, University of Oxford]
**Case-Control**

- Compares the frequency of past “exposure” between cases (individuals who develop the outcome of interest) and controls (individuals who do not).
- Controls are chosen to reflect the frequency of “exposure” in the underlying population at risk from which the cases arose.
- Study participants are identified based on outcome and then compared for presence of “exposure”, wherein “exposure” refers to a treatment or any other factor that may influence the outcome (e.g., severity, age). Determining a patient’s treatment status generally requires the use of one or more sources of information (e.g., medical records, interview or questionnaire data, individual measurements).
- Is important to clearly define the population from which the cases were identified, so as to identify an appropriate and comparable control group.

### Design of a case-control study

The case-control design is an alternative to the cohort design, when the outcome of interest is rare (i.e., a rate of less than 5% of treated subjects). A case-control study compares the odds of a past treatment or a suspected risk factor between cases (individuals with the outcome of interest) and controls (individuals, who are as similar to the cases as possible, without the outcome of interest).

**Advantages:**
- Not a large time commitment
- Relatively inexpensive
- Feasible for rare disorders or those with long lag between exposure/outcome
- Fewer subjects needed than cross-sectional studies.
- No loss to follow-up

**Disadvantages**:
- Reliance on information available (e.g., health records, recall) to determine exposure status
- Confounders
- Selection of control groups is difficult
- Potential bias: recall, selection.

**Suggested Reading:**

---


23 Available at: [http://www.cebm.net/?o=1039](http://www.cebm.net/?o=1039) (Centre for Evidence-Based Medicine, University of Oxford)
Case Report / Case Series

- Descriptive study of a single individual (case report) or small group (case series)
- Describes an atypical combination of signs and symptoms, experience with a novel treatment, or a sequence of events that may suggest previously unsuspected causal relationships.
- Association(s) between an observed effect and a specific environmental exposure is based on detailed clinical evaluations and histories of the individual(s).
- Most effective if the disease is uncommon and/or when it is suspected to be caused exclusively or almost exclusively by a single kind of exposure.

Advantages:
- Inexpensive
- Simple
- Not a big time commitment

Disadvantages:
- Not generalizable
- Privacy/confidentiality issues
- Only appropriate for rare or unusual circumstances

Editorial / Expert Opinion

Clinical experience, expertise, and judgment of healthcare professionals can play a role in scholarly activity. Situations may present wherein methodologically sound research to answer a clinical question is not possible, and expert opinion may be an important alternative. However, expert opinion, just as scientific research, should be assessed for its merit with specific attention to the selective use of evidence and other biases.

Advantages:
- Inexpensive
- Simple
- Not a big time commitment

Disadvantages:
- Subjective
- Bias susceptibility (selective use of evidence, personal or flawed assumptions, external influences)
- Problematic in terms of establishing internal and external validity

---

### Common Quantitative Questions and Corresponding Research Designs

<table>
<thead>
<tr>
<th>If your question is about</th>
<th>Look for the following study design(s)</th>
</tr>
</thead>
</table>
| The effectiveness of a prevention or treatment/therapy intervention | • Randomized Control Trial (RCT)  
  • Cohort-Analytic Study |
| The cause/etiology of a problem/condition/disease | • Randomized Control Trial (RCT)  
  • Cohort-Analytic Study (for rare exposure with common outcome)  
  • Case-Control Study (for rare outcome with common exposure)  
  • Cross-Sectional Study |
| The course/prognosis of a problem/condition/disease/situation | • Cohort Study  
  • Case-Control Study |

**Suggested Reading:**

---

25 From Yost, J. (2010). Online Learning Module: Research Designs. School of Nursing McMaster University, Hamilton, ON. Contact Jennifer Yost, jyost@mcmaster.ca, for additional information.
Cornell University, College of Veterinary Medicine (2010). *Study design tutorial: Comparing study designs.* Retrieved from http://www.vet.cornell.edu/imaging/tutorial/5review/table.html
Levels of Evidence-based Research: **Qualitative**

The hierarchy of qualitative research designs reflects the *reliability* of study *conclusions* for use in health policy and practice. Four levels are categorized and listed, wherein the least likely studies to produce applicable evidence-for-practice are single case studies, followed by descriptive studies. More weight is given to conceptual studies that analyze data according to conceptual themes, but even these may be limited by a lack of diversity in the sample. Generalizable studies, which utilize conceptual frameworks to derive a diverse sample with analysis accounting for all data, are considered to provide the best evidence-for-practice. NOTE: Unlike the hierarchy of evidence-based medicine (quantitative research, above), the levels here do not have specific, recognized names (e.g., cohort, randomized controlled trial).  

---

### Qualitative Research Design:

- Explores the subjective experiences of individuals, to understand their lives, experiences, choices, perceptions, attitudes, reasoning etc.
- Qualitative methodologies include direct observation, interviews/questionnaires, analysis of available information to explore behavior, actions, etc.

**Advantages:**

- Relatively inexpensive
- Identifies themes, concepts, attitudes, reasons, etc., that are not apparent/available from other sources of information.

**Disadvantages:**

- Potential time commitment (depending on method of recruitment, data collected, extent of analysis required, etc)
- Ethically problematic (depending on population, areas of interest)
- Subjective
- Bias susceptibility (recall, volunteer, interpreter)

---

Survey

- Provides a description (numerical, categorical) of trends, attitudes, or opinions of a population by studying a sample of the population
- Examines the relationship between diseases (or other health-related characteristics) and other variables of interest as they exist in a defined population at one particular time (i.e., cross-sectional), or with data collected over time (i.e., longitudinal).

Advantages:
- Cheap and simple (depending on method);
- Ethically safe (depending on recruitment methods);
- Development and organizational tools available on-line (e.g., Survey Monkey).

Disadvantages:
- Subjective
- Bias susceptibility (recall, volunteer)
- Confounders may be unequally distributed;
- Group sizes may be unequal.
- Low response rate

The questions below are for general reference, and can be used to guide survey development and design:

- Is the purpose of the survey design stated?
- Are the reasons for choosing the design clear? If not, indicate why a survey is the preferred method, and its advantages (e.g., economy of the design, relatively fast turnaround, data not available otherwise).
- Is the nature of the survey identified (cross-sectional – one point in time vs. longitudinal – collected over a period of time)?
- Are the population and size of the population projected?
- How many people will be in the research sample? Why was this size chosen?
- Will the population be stratified? If so, how?
- What will be the procedure for sampling these individuals? (e.g., random, convenience)
- What instrument will be used in the survey? Who developed the survey? (Consider whether the instrument was designed for this research? Modified or adapted? Is it an existing instrument that has been validated – keeping in mind the three types of validity – content, predictive, construct?)
- What are the content areas addressed in the survey? (e.g., demographics, attitudinal items, behavioral items, factual items) The scales? (e.g., continuous, categorical)
- What is the time-line for administering the survey? How will follow-up occur to enhance response rate?
- What are the key variables in the study?
- How do these variables cross-reference with the research questions and items on the survey?
- What specific steps will be taken in data analysis to:
  - Analyze returns?
  - Check for response bias?
  - Conduct a descriptive analysis?
  - Collapse items into scales?
  - Check for reliability of scales?
  - Run inferential statistics to answer the research questions?

---

28 John W. Creswell’s “Research Design: Qualitative, Quantitative & Mixed Methods Approaches”, 2nd Ed
Face-to-face interview/questionnaire

- Provides information that is filtered through the view(s) of participants, and allows the interviewer/researcher to direct the line of questioning and further explore developing themes (e.g., semi-structured format).  

Advantages:
- allows collection of complex information (not readily accessible elsewhere)
- high response rates
- ability to prompt/probe for missing information and/or developing themes

Disadvantages:
- Subjective
- Volunteer bias and/or researcher/interviewer presence may bias responses
- expensive;
- time commitment (recruitment, interview, analysis, follow-up, ensure sufficient sample size)
- Ethically problematic at times (e.g., depending on sensitivity of the topic/information or population to be explored, and ability to de-identify and/or preserve confidentiality of participants)

Focus Group(s)

- A group conversation – either structured or unstructured – amongst a group of individuals, which is arranged to discuss a particular topic.
- The primary aim is to describe the meanings and interpretations of a select group of people to gain an understanding of a specific issue from the perspective of the focus group participants.

Advantages:
- allows collection of complex information (not readily accessible elsewhere)
- relatively quick and convenient way to collect information from several people
- can be used with a wide range of people and groups in different settings
- ability to prompt/probe for missing information and/or developing themes

Disadvantages:
- Subjective
- Volunteer bias and/or the presence, or thoughts/attitudes of others may bias discussion
- Tendency for one or two people to dominate the conversation; an experienced moderator required to ensure equal participation and keep group on-track
- Variable (depending on group dynamics, moderator, and other extraneous circumstances)
- Ethically problematic at times (e.g., depending on sensitivity of the topic/information or population to be explored, ability to de-identify and/or preserve confidentiality of participants)

Suggested Reading:

29 John W. Creswell’s “Research Design: Qualitative, Quantitative & Mixed Methods Approaches”, 2nd Ed
30 Liamputtong, P. “Qualitative Research Design” (2009), 3rd Ed.
Clinical Practice Guidelines: Appraisal for Research & Evaluation

Clinical practice guidelines are systematically developed statements, which are intended to assist practitioners by providing concise recommendations for clinical decisions/practice. Scholarly work can be undertaken (and in fact, is encouraged by the CFPC) to review clinical practice guidelines for validity, scientific accuracy, practicality and adaptability at the outset of guideline development, at the implementation stage, or in light of new information, changes in policy, etc.

An internationally accepted standard to critique clinical practice guidelines was developed by the AGREE (Appraisal of Guidelines Research and Evaluation) collaboration\(^3\). The AGREE tool is available for use, and can be found at (you can download the AGREE tool as a PDF): http://www.agreetrust.org/resource-centre/agree-ii/

While the tool initially appears long and complex, it appears this way only because it offers thorough explanations for criterion and the scoring process. In actuality, most guidelines can be assessed in under an hour.

The tool is intended to be scored by an individual, but it can be adapted to a consensus process, wherein multiple raters discuss each rating. The tool alerts you to problems that may impact utilization, allowing one to evaluate whether the guideline is ‘flawed’ (leading evaluators reject or question it), and/or the extent of its limitations. For example, if the guideline fails to include a time for the next review or update, this is typically not considered a fatal flaw; whereas, if the guideline was not based on the appropriate and relevant literature, this would be considered a fatal flaw and, therefore, a solid reason to reject the guideline\(^3\).

The **purpose** of the AGREE tool, is to provide a framework to:
1. assess the quality of guidelines;
2. provide a methodological strategy for the development of guidelines; and
3. highlight what information and how information ought to be reported in guidelines.

The AGREE is **intended for use** by:
- Health care providers who wish to undertake their own assessment of a guideline before adopting its recommendations into their practice;
- Guideline developers to follow a structured and rigorous development methodology, to conduct an internal assessment to ensure that guidelines are sound, or to evaluate guidelines from other groups for potential adaptation to their own context;
- Policy makers to help decide which guidelines should be recommended for use in practice, or to inform policy decisions; and
- Educators to help enhance critical appraisal skills amongst health professionals and to teach core competencies in guideline development and reporting.

---

\(^3\) Access via: http://www.agreetrust.org

RESEARCH PLAN: DEVELOPING THE RESEARCH PROPOSAL

Template for Research Proposal (Quantitative & Qualitative)*:

*Note: there are slight differences in the methods section for quantitative versus qualitative research

Generally, a research proposal should be relatively detailed and complete, yet readable (i.e., avoid excessive jargon or technical language in favor of simple, concise descriptions). For example, the proposal should be clear enough that someone who does not have expertise in the topic of interest can still clearly understand the overall proposal (i.e., the who, what, where and why of the study). As such, the proposal should include the following:

Introduction:

- This section should build an argument for your study and why it is important. Ideally, the introduction should serve as a brief synopsis of the study overall and touch on the following:
  - Statement of the problem
  - Purpose of the study
  - Theoretical perspective (not always required)
  - Research question(s) & hypotheses
  - Definition of terms
  - Delimitations and limitations

Key questions to answer: What do you propose to study and why is it important? What activities and/or exposure led you to ask this question? Why do you want to do the study? What do you intend to accomplish? How will this new knowledge be applied? Who/What will benefit from the new knowledge generated?

Background (Review of the literature):

- This should be used to provide the appropriate context (with appropriate references from the available literature) so the reader understands the issues clearly, and understands how your research will add to the body of literature/scholarly knowledge.

Key questions to answer: What do we need to better understand your topic? What do we know (critically review, build a case using the highest quality evidence, point out gaps in knowledge)? What are some of the deficiencies & strengths of prior research? Why is the study unique, original, and/or the next logical step (e.g., corrects flaws in previous work, expands study and/or study sample, includes more covariates)?

Purpose & Objectives:

- This section should clearly and concisely state the overall purpose and specific aims of the study. Note that bullets listing the specific objectives are acceptable, and many times preferred. This section should be a natural progression or follow-up from the issues discussed in the ‘Background’ and the review of the literature. The Purpose & Objectives should include the following:
  - Statement of the problem
  - Overall purpose or aim(s)
  - Specific research objectives or questions (include only one idea per objective, and each objective should be feasible and evidently relevant to the purpose)
  - Theoretical perspective (not always required)
  - Hypotheses (clear and testable, derived from specific objectives)
  - Definition of terms
Methods (Quantitative):

- Research design (descriptive, cohort, case-control, RCT)
- Sample, population and participants
  - Inclusion/Exclusion criteria (defines generalizability, clear, replicable)
  - Sampling scheme (how is the sample selected, how is bias minimized)
  - Sample size (power calculations, describe sources of baseline, define clinically important differences in outcome)
- Data collection process/procedures, instruments, variables and materials
  - Type of measurement, what is the current gold-standard, discuss restrictions and limitations, accuracy
  - Sources of data, who will collect it, and how (e.g., form, videotape, electronic)?
  - Data entry
- Data analysis procedures
  - Describe the protocol (methods of recruitment, allocation to groups, obtaining consent)
  - Measure of association, statistical tests, control of confounders
- Outcomes (primary & secondary) and strategies for validating findings (if applicable)

Key questions to answer: What is the setting or people that you will plan to study? What methods do you plan to use, and why? How will you obtain your data, and why is it the best approach? How and why are these methods adequate (e.g., are there other studies that have employed these techniques, have the tools been validated?) How will you analyze the data? How will you validate your findings?

Methods (Qualitative):

- Research design (focus groups, unstructured or semi-structured interviews, participant observation, participatory action research)
- Sample, population and participants
  - Inclusion/Exclusion criteria
  - Sampling framework (how is the sample selected & why)
    - Convenience (volunteer, snowball or network sampling)
    - Quota
    - Purposive or theoretical sampling (maximum variation, extreme or typical case)
    - Community of interest
  - Sample size (estimates, calculations, data saturation)
- Data collection process/procedures, instruments, variables and materials
  - Discuss restrictions and limitations
  - Sources of data, who will collect it, how (tape recording, field notes, transcription), and from where (site)?
- Data analysis procedures
  - Describe the protocol (methods of recruitment, obtaining consent, process for analysis of transcripts/data)
- Strategies for validating findings (triangulation, member checking)

Key questions to answer: What is the setting or people that you will plan to study? What methods do you plan to use, and why? How will you obtain your data, and why is this the best approach? How and why are these methods adequate (e.g., are there other studies that have employed these techniques, have the tools been validated?) How will you analyze the data? How will you validate your findings?
Anticipated Ethical Issues

- Declare any researcher biases upfront.
- Include discussion around any anticipated controversies in the study design, recruitment methods, privacy/confidentiality of information and participants, potential or real conflicts of interest.
- The **Tri-Council Policy Statement 2 (TCPS2)** is the guideline used by the research ethics board (REB) to assess ethical issues and can be a resource to researchers to provide guidance if there is uncertainty. For example, some of the key concepts discussed pertain to issues around informed consent (when it is/is not necessary), ethical issues that are specific to qualitative or clinical trials research, etc.

*Key questions to answer: What ethical issues does your study present? How will you account for or minimize real/potential harms? Are the study methods in line with the TCPS2 guidelines?*

Significance of the Study and/or expected outcomes

- Include discussion as to why the proposed study is required, it’s feasibility, potential results and intent overall (i.e., there has to be some thought as to what will be done with the results – a study should not be undertaken unless there is some real intent to make a contribution).

*Key questions to answer: Does the current literature hint at what you should find in your results? What is the practicability and value of the proposed study? How do you anticipate results will be used? How will this study/results add to the literature/scholarly discourse (e.g., improve policy? Improve practice?)*

**Appendixes:** Instruments (questionnaire, surveys), documentation (consent forms, recruitment posters), timeline, budget, as applicable.

**NOTE:** Knowledge Exchange or Knowledge Translation (KT) is an important aspect of the study design, and should be considered at the outset. In addition to providing some indication of how a population, group, and/or system will benefit from the research findings, the proposal should also include some consideration as to how research findings will be distributed or translated into practice, policy, etc., to ensure this occurs.

Some key questions to consider in knowledge exchange / translation:

- **What (is the message)?** How can I/we translate or transform the research findings into an actionable message.
- **To Whom (the audience)?** Who needs to get the message (be specific)? Who will make the decisions?
- **By Whom (the messenger)?** Is the messenger credible? Is there a chance for the audience to partner with the messenger(s)?
- **How (transfer method)?** What is the budget? What transfer method will we use? (In other words, how will we share this new information?) Have we asked our audience how they prefer to learn new information? Is the transfer method we selected evidence-based? Is the intervention tailored to overcome the audience’s identified barriers?
- **With what expected impact (evaluation)?** What does the knowledge translation project hope to change?

---

34 A tool is available that helps you use these questions to prepare a knowledge transfer strategy. You can use this tool ([http://www.iwh.on.ca/from-research-to-practice](http://www.iwh.on.ca/from-research-to-practice)) to work through the questions above.

John Lavis and colleagues (2003, 2004)

Assessing the Applicability of Interventions:
The table below highlights items to consider when assessing applicability (feasibility) and transferability (generalizability) of evidence for public health, practice, & policy\textsuperscript{35}, and can be used in thinking about KT:

<table>
<thead>
<tr>
<th>Construct</th>
<th>Factors</th>
<th>Questions to Ask</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Applicability (feasibility)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Political acceptability</td>
<td>• Will the intervention be allowed or supported in current political climate?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Will there be public relations benefit for local government?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Will this program enhance the stature of the organization?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Will the public and target groups accept and support the intervention in its current format?</td>
<td></td>
</tr>
<tr>
<td>Social acceptability</td>
<td>• Will the target population be interested in the intervention? Is it ethical? Does it marginalize?</td>
<td></td>
</tr>
<tr>
<td>Available essential resources</td>
<td>• Who and what is available and/or essential for the local implementation?</td>
<td></td>
</tr>
<tr>
<td>(personnel and financial)</td>
<td>• Are they adequately trained? If not, is training available and affordable?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• What is needed to tailor the intervention locally?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• What are the full costs (supplies, systems, space requirements for staff, training, technology &amp; infrastructure, administrative supports) per unit of expected outcome?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Are the health benefits worth the costs of the intervention?</td>
<td></td>
</tr>
<tr>
<td>Organizational expertise and</td>
<td>• Is the current strategic plan in alignment with the intervention to be offered?</td>
<td></td>
</tr>
<tr>
<td>capacity</td>
<td>• Does this intervention fit with its mission and local priorities?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Does it conform to existing legislation or regulations (either local or provincial?) Does it overlap with existing programs?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Any organizational barriers/structural issues or approval processes to be addressed?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Is the organization motivated?</td>
<td></td>
</tr>
<tr>
<td><strong>Transferability (generalizability)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Magnitude of health issue in</td>
<td>• Does the need exist?</td>
<td></td>
</tr>
<tr>
<td>local setting</td>
<td>• What is the baseline prevalence of the health issue locally?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• What is the difference in prevalence of the health issue (risk status) between the study and local settings?</td>
<td></td>
</tr>
<tr>
<td>Magnitude of the “reach” and</td>
<td>• Will the intervention broadly “cover” the target population?</td>
<td></td>
</tr>
<tr>
<td>cost effectiveness of the</td>
<td></td>
<td></td>
</tr>
<tr>
<td>intervention</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Target population characteristics</td>
<td>• Are they comparable to the study population?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Will any difference in characteristics (ethnicity, socio-demographic variables, number of persons affected, supports available) impact intervention effectiveness locally?</td>
<td></td>
</tr>
</tbody>
</table>

\textsuperscript{35} Table: Buffett et al, 2007, \url{http://www.nccmt.ca/pubs/2007_12_AT_tool_v_nov2007_ENG.pdf}
Writing the Abstract:
An abstract is a brief summary, which provides the argument and all the essential information of a paper or project. The abstract should allow the reader to quickly understand the contents of a document, project, etc. in order to decide whether to learn more and/or continue reading. While an abstract is typically dense with information, it also should be readable, well-organized, brief and self-contained.

The following are things to keep in mind, when drafting an abstract:

1. Write the abstract last
   The abstract should be drafted once the paper is complete. It is much easier to incorporate important take-away points from completed paper/project. Abstracts written at the outset tend to be vague and uninformative – both of which should be avoided.

2. Follow any guidelines provided
   Journals, granting agencies, as well as conferences will have strict guidelines that you must strictly adhere to. For example, if an abstract is required to be under 200 words, do not submit an abstract that contains 205 words.

3. Be accurate
   Be sure that the abstract only contains information provided in the paper (i.e., no new information should be introduced in the abstract), and that the body of it closely reflects the language, concepts, and content of the larger paper.

4. Be self-contained
   The reader should be able to understand the contents of your abstract without having to read the full article. As such, ensure that acronyms are defined, and unique terms are comprehensible.

5. Be clear, concise and specific
   Each sentence should be as informative and simple as possible (i.e., stick to the facts). Keep sentences brief; particularly, since an abstract is information-dense, it is easier to read/understand concise sentences. Do not repeat, or state unnecessary information (e.g., the project title, use digits instead of writing numbers).

6. Use signals
   Common phrases used to signal various sections of the proposal/paper:

<table>
<thead>
<tr>
<th>Your question:</th>
<th>We asked whether X inhibits Y...</th>
</tr>
</thead>
<tbody>
<tr>
<td>Your method:</td>
<td>We hypothesized that X inhibits Y...</td>
</tr>
<tr>
<td>To answer this question, we used...</td>
<td></td>
</tr>
<tr>
<td>To test the hypothesis that..., we conducted two trials...</td>
<td></td>
</tr>
<tr>
<td>Your results:</td>
<td>We found that...</td>
</tr>
<tr>
<td>Your analysis:</td>
<td>Descriptive statistics were used to analyze...</td>
</tr>
<tr>
<td>Your answer:</td>
<td>We conclude that X inhibits Y...</td>
</tr>
<tr>
<td>Therefore,...</td>
<td></td>
</tr>
<tr>
<td>Your implications:</td>
<td>We suggest that X may play a role...</td>
</tr>
<tr>
<td>Your recommendations:</td>
<td>We recommend that X should be administered...</td>
</tr>
</tbody>
</table>

What grammatical tense should be used where, when:
-- use present tense for the topic/problem/question
-- use past tense to describe your method, results and analysis
-- use a cautious present tense for implications (e.g., may mediate, can improve) and recommendations (e.g., should be administered)
-- use simple future tense in a proposal (e.g., I will measure..., This exploratory study will investigate...)

Available at:

36
7. Emphasize points in proportion to the emphasis they receive in the paper
   If the overall paper/proposal has several sections (e.g., background, methods) that are fairly equal, then generally, those proportions should be mirrored in the abstract. If you are reporting on research, the amount of space devoted to results should reflect their importance and level of complexity.

8. Select key indexing terms
   Choose key words and phrases that will allow your paper to be readily searchable, and that accurately reflect the content/objective(s) of your paper. As a useful tip, consider how you (or ask a colleague) would select terms to ‘find’ and/or describe your paper.

Generally, an abstract is ~100-250 words, though a thesis or conference abstract could be up to 400 words. The required format of an abstract can vary; however, the most commonly used formats are: paragraph style, headings style, and mixed 37.

For a research paper, an abstract typically answers these questions:
Purpose: What is the nature of your topic/study and why did you do it?
Methods: What did you do, and how?
Results: What were your most important findings?
Conclusions: What can you logically conclude through analysis of your data?
Relevance: How do your findings relate to the theory or practice of your field, or to future research? Do you have any recommendations?

For a methods paper, an abstract typically answers these questions:
Name: What is the name or category of the method, apparatus, or material? If this is an improved version of an existing method, say so.
Purpose: What is the major reason for developing this method? State the purpose in the form “for doing X” or “to do X.”
Features: What are its key features, how does it work, or both?
Relevance: Why is this method needed?
Tests: How was it tested?
Evaluation: How well did it work?

**Sample abstracts, with critiques & notes available at: http://hswriting.library.utoronto.ca/index.php/hswriting/article/view/3322/1447

---

37 Information available: http://hswriting.library.utoronto.ca/index.php/hswriting/article/view/3322/1447
Common Pitfalls of Primary Research: 38

The following are some of the most common issues to be aware of, and avoid:

Over generalizing results
It is impossible to make sweeping generalizations about groups of people based solely on a few interviews, observations, or surveys – a representative sample size should always be the goal. And, while you may discover general patterns or trends, don’t necessarily assume that what has been found is what exists or what will always exist. In fact, caution should be used when making concrete generalizations about any occurrence that relates to people because people themselves are dynamic, and situations are always changing.

Biased methodology
If you create a biased survey or ask biased questions (e.g., leading questions), then you’ll get biased results; therefore, seek out instruments that have been tested, or validated, if available.

Mistaking correlation for causation
Remember that discovering a relationship between results or variables does not necessarily mean that one causes another to occur. For example, although video games and violent behaviors are shown to have a link, it has not been proven that video games cause violent behavior (instead, there could be other factors or variables at play – e.g., it could be that individuals who are predisposed toward violent activity are drawn to violent video games).

Not considering other factors
It is very difficult to explore all factors that relate to a specific group of people, event, or occurrence. Even so, if you do not include certain factors within your research, they should still be considered when you begin to analyze your data, or at least provide comment as to why they have been left out. For example, if you are studying parking issues on campus and look at the amount of cars being parked on campus vs. the student population, you are omitting other factors like the amount of commuter students, the number of faculty who drive, accessibility of public transportation and others. If you are unable to explore all factors, acknowledging and accounting for them will add credibility to your project and provide some understanding for the narrow focus.

Failing to monitor study data and progress
There are several reasons why participants may provide inaccurate answers or engage in purposely uncharacteristic behaviors. While this phenomenon is more common with surveys that individuals complete on their own, it can also occur during interviews or even with observations. Such findings can lead to inaccurate information, and consequently discount your research. Thus, it is important to monitor data for this type of erroneous information, and include ways to validate the information into your research design.

Reported behavior vs. actual behavior
An individual’s report or recollection of their behavior might not always be accurate or correct. In general, individuals will often report their own behavior in a more positive light than it may actually be. For example, if you are surveying college students about their study habits, they may report that they study for more hours than they actually do.

Suggested Reading:

38 (Contributors: Dana Lynn Driscoll, Allen Brizee via http://owl.english.purdue.edu/owl/owlprint/559/)
CONSIDER FUNDING APPLICATIONS

Applying for Funding, Grants & Awards

An external organisation will invest in your research only if it is clear to them that your ideas are relevant to their priorities, and that your research will contribute real added value. These concepts are best conveyed via the research proposal, and in that respect, there is no substitute for preparation. The research proposal is your chance to show potential funders that you know your academic field, what research is being done (or has been done) by others, and how your research plans would add to this in an innovative way. That is, provide a compelling argument for why your idea is worth funding, why it is worth funding now, and clearly indicate who will benefit from your research and how.

Also remember that some of the best research proposals grow from exchange, dialogue, and exposing ideas to critique and discussion. As such, generate opportunities to share your early ideas – whether formal or informally – with colleagues, peers and even potential collaborators/funding organizations. Collaboration with others is important in research, and particularly when it comes to securing larger grants for research funding. Therefore, consider with whom you could collaborate to improve the quality, scope or impact of your research proposal. If you are unsure of collaborators who would be a good fit, the University of Manitoba has several Research Facilitators who will assist faculty in fostering links with potential collaborators across academic units, and promote dynamic research partnerships throughout the University.

The DFM website (under the Research Guide) lists and provides links to potential sources of funding and awards that are most relevant to primary care/family medicine. A more comprehensive listing of current Research Award opportunities can be found on the University of Manitoba’s website: http://umanitoba.ca/research/awards.htm

The UMan does have some institutional requirements (subsequently discussed), in addition to the specific requirements of each funding agency. The requirements of the funding agency are typically outlined in the “How to Apply” section of the funding opportunity, or organization website. Submission requirements can vary among funding programs in the same agency, so it is important to understand the requirements of the specific opportunity to which you are applying.

Note that while REB approval is necessary prior to commencing a research project, in most cases one can submit the research proposal for consideration of award/grant/funds even if REB approval has not yet been obtained. However, note that the funder will often make REB approval a condition of receiving funds, so REB approval should be sought as soon as possible. Further, the REB prefers to review projects wherein funding has been secured, so if you are in the process of submitting for an award, grant, etc, this should be indicated on the REB submission form.

Importantly, please be aware that all research grant applications and contract proposals must be reviewed by the UMan Office of Research Services staff prior to submission to the funding/awards committee. As such, it is important to consult the University of Manitoba Office of Research Services website for internal grant deadlines (typically at least two weeks prior to the official award deadline).

A Funding Application Approval Form (FAAF) must accompany all grant submissions to the Office of Research Services. A link to the form can be found here. Additional information relating to the FAAF process and guidelines can be found here. Note that the FAAF requires signatures from the appropriate Department Head, and Principle Investigator’s Dean or Director, so some advanced planning/coordination will be required to complete this form.

For applications to the major funding agencies (CIHR, SSHRC, NSERC), the ORS has also established Research Facilitators to assist researchers in identifying internal and external funding sources, reviewing proposals, facilitating the submission of large interdisciplinary team grant applications and assisting with knowledge translation, community engagement and exchange activities.
NOTE: Industry or Privately sponsored grants/contracts are subject to additional processing requirements by the UMan Office of Research Services, and specifically, Contracts & Agreements. Discussions should be initiated at the outset to ensure compliance with UMan policies, and the formal submission to the ORS to review the contract would include a detailed study proposal, budget, Funding Application Approval Form (FAAF), and a copy of the contract from the proposed funder. The ORS website provides two sample contract templates 1) Collaborative Research Agreement Template, and 2) Sponsored Research Agreement Template, which are both accessible via the link provided above. In addition to those items, a Research Contract Questionnaire is also a requirement. As for the process of review, the above items would be reviewed by the ORS, and then sent to UMan legal for review and/or approval. Generally Industry/Privately sponsored grants/contracts take longer to review, so factor in some additional time (~3 months) for this process to be finalized. Additionally, industry sponsored projects should factor, or build in, an extra 30% overhead to the project budget for costs relating to all the additional processes and review requirements.

Helpful Tips on Writing a Successful Grant Application

Do

- Start early — it takes many months to put together an application, and allow time for reiteration and feedback from Co-Investigators. Get the application guide and other materials together well in advance of the closing date for applications.
- Think the project through, anticipating questions and objections to your hypotheses, theoretical approach, research plan, and budget allocations.
- Find out who is on the adjudication committee to which you will be applying. The composition of last competition's adjudication committees, two-thirds of whom usually continue to the next competition, is usually published in the council/agency's annual report.
- Remember that you have three audiences to convince: the council/agency program officer, the external evaluator (a specialist in your field or topic), and the members of the adjudication committee (not all of whom will be specialists in your field).
- Pay special attention to the preparation of the one-page summary of the project. Unlike the detailed project description, all members of the adjudication committee will read this.
- Justify in writing every major category of expenditure that is listed in the summary budget. Pay special attention to the research time stipend section, if you are applying for release time; however, this will be evaluated by the officials of your own university and by external assessors, but not necessarily by the adjudication committee.
- Write the project summary, detailed project description, and budget justification as clearly and simply as you can and where possible, include preliminary data, or letters of support (e.g., from data custodians) to show feasibility.
- Have an experienced colleague or two look over the application. Inquire who among faculty in your area has had experience on an adjudication committee recently. Ask an experienced adjudicator to read over your application and provide brief comment(s).
- Remember that the Internet extends the range and number of experienced colleagues who potentially can help you fashion a persuasive application. Lead-time is especially important if you are applying for a research time stipend.
- Enlist the support of an expert as a collaborator or co-applicant if you do not have the required expertise in an approach that you plan to use and that is critical to the project's success. Or if

you are a novice researcher, consider involving an experienced research mentor as you develop and carry through with your project.

- Get the application completed in good time to secure the necessary signatures from University officials without undue hassle for you and/or them.
- Sit back, relax, and prepare yourself for the receipt of good news.

\textbf{Don't}

- Leave preparation of the application until the last few weeks before the deadline.
- Forget to leave adequate time for review of the application, by you and other experienced applicants, including University/Department-specific processes (e.g., submission to the Office of Research Services, review by the Department Head).
- Ignore the "state of the art" in your application. You're writing to persuade informed people that you know what you are going to do and why you are going to do it.
- Use jargon or obscure or esoteric language. Your application might go to an adjudication committee containing some people who are not specialists in your field. Remember, too, that your application might be read by scholars whose first 'language' is not yours.
- Inflate your budget. Adjudication committees sometimes act like forensic auditors. A budget that is judged non-credible could render the whole application suspect.
- Ignore help that is available to you: program officers, experienced colleagues, Office of Research Services.
- Pretend it's a new application if it's a re-application.
- Ignore the criticisms made on an earlier application if it's a re-application for the same project.
- Give up.

\textbf{Bachelor of Science in Medicine (B.Sc. Med) \\ & Med II Summer Research Programs}

For smaller-scale projects, consider the B.Sc Med, or the Med II Summer Research Programs as an opportunity to conduct your research project with the help of an enthusiastic trainee to assist in the project's development and completion.

Further information can be found on the Program website (links provided below), or from:

Kimberley Ormiston  
Undergraduate Medical Research Program Coordinator  
Office of the Associate Dean, Research  
A108 Chown Building  
Ph: 789-3558  
E: kim.ormiston@umanitoba.ca

\textbf{Bachelor of Science in Medicine (B.Sc. Med) Program}

The B.Sc. (Med.) program in the Faculty of Medicine gives medical students an opportunity to engage in original research, either basic or clinical, under the supervision of a member of the Faculty of Health Sciences. The specific aim is to develop skills in experimental design, hypothesis testing, critical evaluation of data and effective communication of results. Students who successfully complete the program will be awarded the B.Sc.(Med) degree upon receipt of the M.D. degree.
The program runs during the summer break between Years I and II and Years II and III. The first term consists of 12 weeks (which shall include a two week vacation period); the 2nd Year BScMed consists of 13 weeks (which shall include a two week vacation period). E.g., For the 2015 Term: 1st year BScMed June 1st - August 21st (2nd Year BScMed starts May 25th). Students in the program receive stipendiary support for each term (covered by the B.Sc. Med Program).

A call for B.Sc.Med research program proposals (i.e., abstracts) is sent to all UMan Medicine academics in late August. A standardized template/fillable form used, and can be found on the Program website. The deadline for abstract submissions is generally October 1st. Following this, students review projects available and contact the prospective supervisor. Once both a student and supervisor agree, there is a series of requirements that follow (e.g., develop and submit the full proposal and application for approval by the Program committee, obtain ethics approval); a comprehensive list, as well as suggested timelines are provided on the Program website.

**Med II Summer Research Program**

The Med II Summer Research program gives medical students an opportunity to engage in research, under the supervision of a College of Medicine supervisor who is based at the University of Manitoba. The specific aim of the program is to develop skills in experimental design, hypothesis testing, critical evaluation of data and effective communication of results. This is a non-degree course; however, participation in the program is recorded on the student’s transcript.

The program currently can accommodate a maximum of 20 positions; therefore, not every project will be approved. Students accepted to the program complete the 13 week program, producing a written and oral report at the end. The program runs for 13 weeks during the summer recess between Year II and Year III, and a two-week vacation period should be accommodated within this time-frame. The chosen project must be feasible within this time frame. All students receive stipendiary support for the summer (paid by the Med II program); however, any research costs are born by the supervisor, from either research grants or departmental funds.

*A call for applications is circulated annually in the Fall.*

**Creating a Budget**

The budget quantifies the research plan in terms of personnel, materials, supplies and other requirements. It is essential that the link between the research proposal and the budget is clear, and therefore, that the duties assistants will perform, how materials and equipment will be used, etc. is detailed. All budget items listed must be essential to the conduct of the research project and a brief, clear justification for each budget item must be provided.

For the most part, costs that can be included in the budget normally include:

- Consumable costs of carrying out research/operating equipment
- Service contracts for equipment
- Specific lab services e.g. safety services, specific lab waste services.
- Building services for major new-build projects (heating, uniformed staff, cleaning, maintenance))
- If secretarial/administrative staff salaries are not included in the staffing of the proposal, costs for support may be included in the overhead or may be allowable as direct costs. Wherever possible include as direct costs.
The following general categories can be used as a guideline to structure the study budget:

**Personnel (student, technical, secretarial, professional)**
The details regarding the nature of the tasks to be carried out, the level of responsibility, the period of employment and the proposed rate of pay (hourly, monthly, annually) must be specified. Benefits and payroll levy must be included in the calculation of salaries for research personnel.
Note that if you are requesting secretarial support, a case must be made as to why departmental secretarial services are insufficient or unavailable.

**Materials and Supplies**
It is assumed that standard office and laboratory supplies (including photocopying) are covered by the PI's University department or faculty. When this is not the case, or when unusual items or large quantities are requested, a complete justification must be provided.

**Equipment**
When requesting essential research equipment costing over $500 per item, the applicant must confirm that he/she has made efforts to determine if the needed equipment is owned by the University and, if so, whether it is available for use. The budget must also comment on the extent to which the requested equipment will be made available for use by other university researchers, and on the likely extent/utility of this use. For items over $500, formal quotations must be provided.

**Travel**
The specific details regarding the purpose of the trip, destination and length, mode and cost of travel, must be provided. When travel is proposed for the purpose of research collaboration, the need for such collaboration in lieu of mail, telephone, FAX, and electronic mail/correspondence must be clearly demonstrated. Similarly, when proposing travel to consult library or archival materials, a justification for this travel in lieu of reviewing or purchasing materials through inter-library loan, document delivery, etc. must be provided.

**Post-doctoral support**
Typically, a budget would at most, provide only partial support for the salary of a post-doctoral fellow. Therefore, the budget must provide details on the Tri-Agency funding source (e.g., CIHR, NSERC, SSHER). Applicants are reminded that the salary of any individual supported under this program must meet the University minimum (for more information on minimum requirements, please consult the Office of the Vice-President (Research and International) at 474-9488 for the current support levels).

The SickKids Hospital for Children provides a budget checklist to assist investigators in budget preparation. The example template is found on their [website](#) (downloadable in a MS Word file), and can be used for reference.
**Timelines**

Although tedious, it is a good idea to break down the study into stages (pre-study preparations, data collection, and analysis) and assess what aspects need to be accomplished, assigning tentative time-lines for each. Additionally, grant applications typically require timelines to be defined upfront to ensure that projects stay on target.

The following diagram is a very general example of a timeline for a prospective study lasting 3 years from initiation to study close-out. Note that there may be other factors to consider (e.g., institutional review(s)/approval(s)/requirements) that can also add to the timeline and/or delay the study from starting on time. Typically, it is best to allot at least two months to submit your proposal to ethics and allow for additional correspondence and clarification(s). Most other institutional approvals/reviews can be submitted concurrently, but will likely remain conditional upon receiving full ethics approval.

Example time table for a 3-year prospective study (e.g. RTC or cohort study)

<table>
<thead>
<tr>
<th></th>
<th>2</th>
<th>4</th>
<th>6</th>
<th>8</th>
<th>10</th>
<th>12</th>
<th>14</th>
<th>16</th>
<th>18</th>
<th>20</th>
<th>22</th>
<th>24</th>
<th>26</th>
<th>28</th>
<th>30</th>
<th>32</th>
<th>34</th>
<th>36</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB approval</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study enrollment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Follow-up questionnaires</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Data entry</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Data analysis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Documentation of results</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Example time table (3-year prospective study [e.g. RCT, cohort study])\(^40\)

Managing a research project in addition to other requirements of your workload/responsibilities can be challenging (particularly if you are unfamiliar with these tasks), but also rewarding. As such, it is a good idea to consider the workload implications of taking on a research activity (e.g., workload conflicts, important deadlines, research milestones) in order to prepare clinic manager(s) and colleagues of competing demands, and inquire as to whether there are options to acquire dedicated time to devote to research activity. In some cases, consider asking a colleague or research mentor about the time management strategies they use, or have negotiated within their academic appointment. Equally, faculty development often puts on training sessions, many of which are aimed at time/workload management and strategies.

---

RESEARCH PROJECT REVIEW – ETHICS, REVIEW COMMITTEE(S) & OTHER REQUIREMENTS
Researchers must be aware of the University requirements for research and scholarly activity, which entails submitting your research project for peer review (ethics, UMan Office of Research Services, and other research review committees). Please be aware that the process of submitting your project for review and/or approval/signature/etc, can be time-consuming and therefore, adequate time should be allotted for this important step. Familiarizing yourself with the requirements of your academic unit, the University, and the funding agency will also help to ensure all necessary requirements are met.

Research Ethics Board (REB) Review
University of Manitoba Office of Research Ethics & Compliance

All research projects involving humans conducted at, or under the auspices of the University of Manitoba (UMan), require prior ethics review and approval by a Research Ethics Board (REB).

There are 5 Research Ethics Boards at the UMan. Applications to the Education/Nursing, Psychology/Sociology and Joint-Faculty REBs are administered through the Fort Garry Campus Human Ethics Office. Applications to the Health and Biomedical REBs are administered through the Bannatyne Campus Research Ethics Board Office, and this will be mostly likely the board to which you submit. Members of the Faculties of Medicine, Dentistry, and Pharmacy, the affiliated teaching hospitals, their associated research foundations and the School of Medical Rehabilitation submit their protocols to the appropriate REB at the Bannatyne campus.

There are two Research Ethics Boards (REBs) at the Bannatyne Campus:
(1) Biomedical Research Ethics Board (BREB) – the BREB reviews all research ethics protocols involving clinical trials and other biomedical research interventions.
(2) Health Research Ethics Board (HREB) – the HREB reviews research from the Bannatyne campus involving the behavioral sciences, surveys, examinations of medical records and protocols of generally lesser risk.

The following link will take you to the REB Submission Requirements and Forms for the (Bannatyne Campus), and the full Bannatyne Research Ethics website.

Contact Information: Bannatyne Campus REB
Location: P126 - 770 Bannatyne Avenue, Pathology Building
Winnipeg, MB  R3E 0W3
T: (204) 789-3255
F: (204) 789-3414
E: http://umanitoba.ca/faculties/health_sciences/medicine/ethics/

NOTE: The Bannatyne Campus REB website is a good resource and provides templates for consent forms, as well as upcoming deadlines for submission and useful links. Typically the REB meets once a month, except for the month of July.

Hours of Operation:
Monday - Friday 8:30 a.m. - 4:30 p.m.
*Summer Hours: (May 20 - September 2, 2014)
   Monday - Friday 8 a.m. - 4 p.m.
Research Ethics Board (REB) Review: Purpose

The goal of an REB is to represent the interests of participants by assessing the foreseeable risks, ethical implications, and potential benefits of each proposal they review. The REB Committee will be most interested in some of the processes and/or logistical details of the project; for example, specifically how/by whom/where will potential participants be approached for research participation? How/by whom/where/under what circumstances will consent to participate be obtained? Etc.

The Tri-Council Policy Statement 2 (TCPS2) is the guideline used by the REB to assess ethical issues and can be a resource to researchers to provide guidance if there is uncertainty. For example, some of the key concepts discussed in the TCPS 2 pertain to issues around informed consent (when it is/is not necessary), privacy & confidentiality, conflict of interest, research involving First Nations, Inuit and Metis peoples of Canada, ethical issues that are specific to qualitative or clinical trials research, etc.

The following questions can be used as a general guide when considering ethical concerns in advance of ethical review:

- Is there a power relationship between the researcher and the research participants (e.g. doctor/patient, teacher/student, supervisor/assistant)? If yes, what can be done to minimize, or eliminate this dynamic?
- Are there any cultural norms or practices that need to be factored into the recruitment, consent, or debriefing process (e.g., OCAP principles)? If so, specifically indicate this, as well as how your approach will attempt to mitigate these factors.
- What are the economic circumstances of the prospective participants? This is an important consideration when determining what is/is not an appropriate incentive for participation, and/or whether remuneration for participation will be offered.
- Could there be any social repercussions of participation in this project? If so, what are they? Will participants be compensated? How will participants be made aware of this possibility?
- How can the privacy and confidentiality of participants be protected? Specifically indicate the security measures, as well as how other relevant data protection issues will be handled to prevent privacy/confidentiality breach (e.g., what are the physical, technical and administrative controls/safeguards in place).

NOTE: Researchers can consult with REB staff at the design phase of their project, while they are preparing their application for REB review, or following the review process, if issues are identified, or there is uncertainty as to the best way to proceed.

Specific REB submission requirements can be found on the REB website. Note that there are slight differences in the submission requirements, depending on whether a project will be considered for full board review, delegated review, or a retrospective chart/records review process – the REB website clearly outlines each category, and provides a checklist of the documents required for each. In addition to this, the following requirements (in addition to the project-specific documentation) are required:

- Curriculum vitae (CV) - Required of the Principal Investigator (PI). CVs should be up-to-date, and are required to be submitted with the first submission to the REB and annually; templates are available on the REB website.
- TCPS 2: Course on Research Ethics (CORE) Certificate – The PI Must complete this course (available online: http://www.ethics.gc.ca/eng/education/tutorial-didacticiel/) and include a copy of the certificate with all submissions. Once the course has been fully completed, there is no need to update.
- Approvals from other Organization(s) – Not applicable in all cases, but if for example, you require access to information for research purposes wherein the WRHA is the Trustee (e.g., hospital charts/records), then you will be required to get approval from the WRHA Research Review
Committee (RRIC). In most cases, such approvals can be sought concordantly with REB approval; however, please note that the REB will likely consider final approval conditional until receipt of other approval(s) is received.

- Signed submission form – This must be signed and dated by the PI, as well as the Department Head (in order to vouch for scientific merit of the study). Please be mindful of this when preparing the submission ahead of the deadline. **NOTE:** In the Department of Family Medicine, either the Department Head OR the Family Medicine Research Director can act as the signatory.
- Study Protocol (this is in addition to the REB submission form) – A complete scientifically-structured protocol is required.
- Study budget and/or funding letter to show that funds are available and adequate to cover costs, as applicable. While this is not always a requirement, if available, this letter provides the REB with a sense of who is funding the project (e.g., granting agency versus private sponsor), and whether there is the potential for conflict of interest/bias.
- Draft consent form(s), survey/questionnaire, etc., as applicable.

Please contact FM **Research Facilitator** for assistance in finalizing ethics applications prior to submission:

**Other Committee Review (applying for approval/access in addition to the REB):**
There are often other approvals that researchers will need to seek prior to commencing a research project. For the most part, there isn’t one standard process to follow as most approvals will depend on what kind of data you are accessing (e.g., patient hospital charts), who is the trustee of the data (e.g., WRHA, Manitoba Health), where you are accessing the data (e.g., SBGH, MCHP), and in what form (e.g., patient records, survey). The list below outlines the various committees (listed in alphabetical order) where approval may be required, and the conditions under which seeking approval would be appropriate.

**CancerCare Manitoba Research Resource Impact Committee (CCMB RRIC)**
All studies conducted at CCMB or by CCMB staff must be submitted to the CCMB RRIC for review and approval. These include (but are not limited to):

- a. studies which involve CCMB data or Cancer Registry data;
- b. studies which involve any type of contact with CCMB patients (including questionnaires or surveys) and/or collection of any materials (e.g., tissues, body fluids) from CCMB patients;
- c. studies which involve CCMB staff (as research subjects);
- d. studies which have an impact on CCMB resources.
- e. quality assurance projects, with potential publication of the findings.

The CCMB RRIC form can be found [here](#), and inquiries, questions, etc. can be directed to: E: RRIC.Coordinator@cancercare.mb.ca, or Ph: (204) 787-4170

Additionally, knowledgeable staff from the CCMB Epidemiology and Cancer Registry are available to assist in study design, plans for data analysis, and in determining the number of patients and/or charts that would meet the eligibility criteria for a given study. It is highly recommended that those unfamiliar with CCMB data and processes initiate contact and seek help at the outset of their project planning. To request assistance, please email epi.cancerregistry@cancercare.mb.ca.

Workstations in Health Records (ON 2092) are available to accommodate researchers’ review of electronic and hard copy patient charts on approved research studies. The workstations are available Monday to Friday 08:00 - 17:00 hrs. To book a workstation, please contact the File Control Clerk at 204-787-4017.
Health Information Privacy Committee (HIPC):
Intent to access and/or link with information held by the Government of Manitoba (e.g., DPIN, Hospital abstracts, medical claims) for population-based research requires a submission to the Health Information Privacy Committee (HIPC) for approval.

The goal of HIPC review is to ensure that research requesting access to personal health information (to which the Manitoba Government is the trustee) is of sufficient importance and merit to outweigh the disclosure of that information. The Committee’s response to the research request will be framed within the context of the conditions under which the Committee may grant/refuse approval (see the Personal Health Information Act (PHIA), Sect. 24(3)); however, the HIPC will be most interested in understanding the specifics of what information is requested, how it relates to the study objectives, as well as how the information will be safeguarded to eliminate the risk of privacy/confidentiality breach.

HIPC Review & Considerations: The HIPC will evaluate a research project submission based on the following:
* Value of Research
  - Does the value of the research outweigh the intrusion?
* Level of Intrusion
  - Is the scope of the project clear?
  - Does the data request fit with the research objectives?
  - Can the research be accomplished with less than is requested?
* Safeguards
  - Are there adequate protection (physical, technical and administrative security) measures in place to prevent a privacy breach?
  - Are safeguards and processes for data linkage and/or transfer clearly described?
* Destruction of Data
  - Are there adequate measures in place to ensure the proper destruction or return of protected data post-research?

The HIPC website is frequently updated and includes the following resources:
- HIPC meeting dates & submission deadlines
- Submission requirements
- HIPC submission form & guidelines to complete the form*
  *An aid for researchers as they work through and answer the questions in the submission form
- Links to Manitoba’s PHIA and Regulation
- HIPC Coordinator contact information

NOTE: When accessing data via the Manitoba Centre for Health Policy (MCHP), please be aware that the MCHP has a feasibility & cost-assessment process that is requirement of all applicants. In addition to this, all researchers are required to complete an accreditation session. Details and more information can be found on the MCHP website:
http://umanitoba.ca/faculties/medicine/units/community_health_sciences/departmental_units/mchp/resources/repository/index.html
**Health Sciences Centre Research Impact Committee (HSC RIC)**

Individual hospital approval is a requirement when you are using patients records (e.g., hospital charts) or approaching staff (e.g., to help in recruitment) *within* the hospital. The HSC RIC will evaluate the impact the study will have on HSC resources, staff time, patient needs and/or care.

*Contact Information:*
MS7—820 Sherbrook Street
Winnipeg, Manitoba R3A 1R9
Ph: (204) 787-4831; (204) 787-4968
F: (204) 787-4547

**St. Boniface Hospital Research Review Committee (SBH RRC)**

The intent of the SBH RRC review process is to ensure that clinical research conducted at SBH is adequately funded, has received appropriate SBH departmental approval, meets the applicable regulatory, ethical, and good clinical practice guidelines and has received appropriate peer review. The SBH RRC submission form can be accessed [here](#) (‘Form D’, available also for download through the website link).

*Contact Information:*
N1004—409 Tache Avenue
Winnipeg, Manitoba R2H 2A6
Ph: (204) 235-3623
F: (204) 237-9860

Any research study that involves human subjects (clinical research) associated with SBH and/or access to personal health information for research purposes must be approved by the SBH RRC. However, the RRC does *not* need to review:

- Chart review studies and chart audits that are not related to research projects.
- Journal articles and publications arising from chart audits and chart reviews.

Where access is required to SBH health records, proposals (REB Form, RRC Form, and a copy of the protocol) must be submitted to SBH Health Records Department along with a completed [Request for Access to Health Records and / or Statistical Data](#) form.

If you need assistance in identifying health record numbers or preparation of statistical data, you will need to also complete a [St-Boniface Hospital Study / Data Request Form](#). For information on [Research Retrieval Fees](#) or additional information can be obtained by calling 237-2405.

**WRHA Research Review Committee (WRHA RRIC)**

The WRHA RRIC reviews all research proposal for research conducted at or with WRHA sites, programs, services and/or will access/link with information wherein the WRHA is the trustee. This includes research done at WRHA Corporate Office, and spans even indirect operations such as Public Health, Home Care, Community Mental Health, Community Development, Primary Care, Pan Am Clinic, Breast Health Centre, Access Centres.

**WRHA RRIC Review & Considerations:** The WRHA RRIC will evaluate a research project based on the following:

- **Impact on the WRHA**
  - Will the study have an impact on WRHA resources, including costs (explicit or in-kind), staff time, patient needs or care?
**Compliance with WHRA policies**
- The PI must indicate how the research project will be in compliance with WRHA policies relating to the collection and/or access of personal health information (PHI), privacy/confidentiality, ongoing protection, as well as the security and storage of the information
- Does the data request fit with the research objectives?
- Can the research be accomplished with less than is requested?

**Safeguards**
- Are there adequate protection (physical, technical and administrative security) measures in place to prevent a privacy breach?
- Are safeguards and processes for data linkage and/or transfer clearly described?

**Destruction of Data**
- Are there adequate measures in place to ensure the proper destruction or return of protected data post-research?

**Contact Information:**
Please contact Judy Dyrland at jdyrland2@wrha.mb.ca for an electronic copy of the Research Application Form.

*NOTE: The WRHA RRIC website is a good resource and provides research application procedures and guidelines, as well as upcoming deadlines for submission and useful links. Typically the Committee meets once a month.*

**Assembly of Manitoba Chiefs (AMC)**
If your research will focus on First Nations (FN) and/or will stratify results based on First Nations/non-FN, then seeking AMC review and input would be appropriate.
For more information, contact Kathi Avery Kinew (kathiaverykinew@manitobachiefs.com) to either direct you through the process, or direct you to someone who can assist you.
METHODOLOGY: DATA COLLECTION & ANALYSIS

Reference & tutorials
Reusable learning objectives and tutorials are available on select topics, and help to walk learners through concepts such as incidence, prevalence, power & sample size, etc.

Sample Size
Consideration of sample size is essential. A sample that is too large can lead to unnecessary expenses (both time and money), and one that is too small will lack sufficient power detect differences in treatment effectiveness, yielding statistically non-significant results and inadequate information\(^{41}\). Further, the initial proposal should describe sample size calculations in order to justify the recruitment goals and demonstrate due diligence in terms of research design and methodology.

When determining appropriate sample size, it is important to consider several factors: variability of the population, method of sampling, size of the population, anticipated level of non-response/withdrawal. Secondary factors, which tend to be more practical in nature, include things such as costs, available funding and operational constraints, should also be considered.

Variability of characteristics of the population:
- greater the variability amongst units means that a larger sample size will be needed to achieve certain levels of precision and representation
- variability of the population is difficult to determine and therefore, must be approximated (based on previous literature, results of pilot studies, known demographics, etc.).
- if variability is difficult to determine, use maximum variability (e.g., a 50/50 split in a public opinion poll)\(^{42}\).

Method of sampling:
- Probability sampling methods: simple random, systematic, stratified, cluster, multi-stage\(^{43}\)
  - Simple random – all individuals of the population of interest are eligible, and each has an equal probability of being selected from the population (ensuring the sample will be representative of the population of interest).
  - Systematic – A method that employs an arithmetic progression, wherein the difference between any two consecutive numbers is the same. (e.g., There are 100 patients total in a clinic; pick an integer that is less than the total number of the population (e.g., 3), and this will be your first subject. Select another integer, which will be the number of individuals between subjects. Thus, if this number is 5, then your subjects will be patients 3, 8, 13, 18, 23, and so on.)
  - Stratified – Participants are initially grouped into different classifications such as age, socioeconomic status or gender, and individuals are randomly selected from the different strata.
  - Cluster – Used when simple random sampling is not plausible (due to size of the population). In order to accomplish this, the researcher first needs to identify boundaries or parameters within the population. From this, a random selection of identified areas/parameters should be chosen, wherein all areas within the population have an equal chance of being selected.
  - Multi-stage – A combination of two or more sampling techniques (described above).
- Non-probability sampling methods: convenience, volunteer, quota, purposive, snowball\(^{44}\)
  - Convenience – Sample is selected out of convenience (i.e., accessible and available to the researcher).

\(^{43}\) Available: https://explorable.com/probability-sampling

- Volunteer – Individuals volunteer their services for the study (e.g., pharmaceutical trials (drug testing) are often volunteer, as it is both difficult and unethical to enlist random participants from the general public for these types of studies).
- Quota – Equal or proportionate representation of subjects is chosen, depending on which trait is considered the basis of the quota. The bases of the quota are usually age, gender, education, race, religion and socioeconomic status. (e.g., if basis of the quota is college year level and the researcher needs equal representation, with a sample size of 100, he must select 25 1st year students, another 25 2nd year students, 25 3rd year and 25 4th year students.)
- Purposive – Subjects are chosen to be part of the sample with a specific purpose in mind (e.g., there might be some subjects that are a ‘better’ fit for the research/topic as compared to others).
- Snowball – This technique is typically used when there is a very small population size, the population is unknown/unfamiliar, or difficult to reach. Here, the researcher asks the initial subject to identify other potential subject(s) who meets the criteria of the research, and recruitment follows along with this pattern.

- Formulas to calculate sample size are based on simple random sampling, and typically do not apply to non-probability sampling methods
- As compared to simpler designs (e.g., random), complex sampling designs (e.g., multi-stage) lend to higher variances in survey estimates and therefore, one should increase the sample size to take additional complexities into account.

Size of the population:
- the size of the sample does not increase in direct proportion to the size of the population
- the gains from sampling are greatest with large populations (e.g., a random sample of 100 from a population of 5,000,000 provides essentially the same precision – assuming the variability among the units is comparable – as a random sample of 100 from a population of 5,000.
- sample size depends on how frequently the outcome of interest occurs (e.g., if the rate at which an outcome occurs is 1%, then a study that includes 1000 patients will yield only 10 patients with that outcome; in this case, 1000 patients would not be enough).
- Web-based and other programs for download are available that will calculate sample size requirements. Such programs will permit users to either calculate a sample size estimate from a given level of power, or calculate power for a given sample size. However, calculating for a range of estimates is preferable to limit reliance on a single value.45

The table below illustrates the effect of population on sample size. The table is based on the case maximum variability (when the estimate of the population proportion is 0.50), and on the requirement that the margin of error is to be within ± 0.05, 19 times out of 20 (i.e., 95% of all possible samples)46.

<table>
<thead>
<tr>
<th>Population size</th>
<th>Sample size</th>
</tr>
</thead>
<tbody>
<tr>
<td>50</td>
<td>40</td>
</tr>
<tr>
<td>100</td>
<td>80</td>
</tr>
<tr>
<td>200</td>
<td>133</td>
</tr>
<tr>
<td>500</td>
<td>222</td>
</tr>
<tr>
<td>1,000</td>
<td>286</td>
</tr>
<tr>
<td>5,000</td>
<td>370</td>
</tr>
<tr>
<td>10,000</td>
<td>385</td>
</tr>
<tr>
<td>100,000</td>
<td>398</td>
</tr>
<tr>
<td>1,000,000</td>
<td>400</td>
</tr>
<tr>
<td>10,000,000</td>
<td>400</td>
</tr>
<tr>
<td>100,000,000</td>
<td>400</td>
</tr>
</tbody>
</table>

Confidence level reflects error due to sampling. The 95% and 90% confidence are those most commonly used in research; survey researchers tend to choose a 95% confidence level, while clinical researchers and epidemiologists generally choose a 99% confidence level.

Nonresponse/Withdrawal:
- Consideration of potential nonresponse/withdrawal can serve to reduce sampling variability and ensure the desired precision of the sample size estimates.
- Existing literature on similar studies/results can be used to estimate response rates, and therefore provide a rationale for aiming for a larger initial sample size in order to compensate.

EXAMPLES

Sample Size Table:

95% Confidence Level

<table>
<thead>
<tr>
<th>POPULATION SIZE</th>
<th>Margin of Error</th>
<th>±3%</th>
<th>±5%</th>
<th>±7%</th>
<th>±10%</th>
</tr>
</thead>
<tbody>
<tr>
<td>25</td>
<td></td>
<td>24</td>
<td>24</td>
<td>22</td>
<td>20</td>
</tr>
<tr>
<td>50</td>
<td></td>
<td>48</td>
<td>44</td>
<td>40</td>
<td>33</td>
</tr>
<tr>
<td>75</td>
<td></td>
<td>70</td>
<td>63</td>
<td>55</td>
<td>43</td>
</tr>
<tr>
<td>100</td>
<td></td>
<td>92</td>
<td>80</td>
<td>67</td>
<td>50</td>
</tr>
<tr>
<td>150</td>
<td></td>
<td>132</td>
<td>109</td>
<td>86</td>
<td>60</td>
</tr>
<tr>
<td>200</td>
<td></td>
<td>169</td>
<td>133</td>
<td>101</td>
<td>67</td>
</tr>
<tr>
<td>250</td>
<td></td>
<td>204</td>
<td>154</td>
<td>112</td>
<td>71</td>
</tr>
<tr>
<td>300</td>
<td></td>
<td>236</td>
<td>171</td>
<td>121</td>
<td>75</td>
</tr>
<tr>
<td>350</td>
<td></td>
<td>266</td>
<td>187</td>
<td>129</td>
<td>78</td>
</tr>
<tr>
<td>400</td>
<td></td>
<td>294</td>
<td>200</td>
<td>135</td>
<td>80</td>
</tr>
<tr>
<td>500</td>
<td></td>
<td>345</td>
<td>222</td>
<td>145</td>
<td>83</td>
</tr>
<tr>
<td>600</td>
<td></td>
<td>390</td>
<td>240</td>
<td>152</td>
<td>86</td>
</tr>
<tr>
<td>800</td>
<td></td>
<td>465</td>
<td>267</td>
<td>163</td>
<td>89</td>
</tr>
<tr>
<td>1,000</td>
<td></td>
<td>526</td>
<td>286</td>
<td>169</td>
<td>91</td>
</tr>
<tr>
<td>1,500</td>
<td></td>
<td>638</td>
<td>316</td>
<td>180</td>
<td>94</td>
</tr>
<tr>
<td>2,500</td>
<td></td>
<td>769</td>
<td>345</td>
<td>189</td>
<td>96</td>
</tr>
<tr>
<td>5,000</td>
<td></td>
<td>909</td>
<td>370</td>
<td>196</td>
<td>98</td>
</tr>
<tr>
<td>10,000</td>
<td></td>
<td>1,000</td>
<td>385</td>
<td>200</td>
<td>99</td>
</tr>
<tr>
<td>25,000</td>
<td></td>
<td>1,064</td>
<td>394</td>
<td>202</td>
<td>100</td>
</tr>
<tr>
<td>100,000</td>
<td></td>
<td>1,099</td>
<td>398</td>
<td>204</td>
<td>100</td>
</tr>
<tr>
<td>500,000 &amp; over</td>
<td></td>
<td>1,110</td>
<td>400</td>
<td>204</td>
<td>100</td>
</tr>
</tbody>
</table>

Note: This table is based on simple random sampling and a 100% response rate. For example, if the response rate is expected to be 50%, then the sample size should be doubled.
### Sample Size Table:

90% Confidence Level

Preliminary estimate of the proportion = 0.50

<table>
<thead>
<tr>
<th>POPULATION SIZE</th>
<th>Margin of Error</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>±3%</td>
</tr>
<tr>
<td>25</td>
<td>24</td>
</tr>
<tr>
<td>50</td>
<td>47</td>
</tr>
<tr>
<td>75</td>
<td>68</td>
</tr>
<tr>
<td>100</td>
<td>88</td>
</tr>
<tr>
<td>150</td>
<td>125</td>
</tr>
<tr>
<td>200</td>
<td>158</td>
</tr>
<tr>
<td>250</td>
<td>188</td>
</tr>
<tr>
<td>300</td>
<td>214</td>
</tr>
<tr>
<td>350</td>
<td>239</td>
</tr>
<tr>
<td>400</td>
<td>261</td>
</tr>
<tr>
<td>500</td>
<td>300</td>
</tr>
<tr>
<td>600</td>
<td>334</td>
</tr>
<tr>
<td>800</td>
<td>388</td>
</tr>
<tr>
<td>1,000</td>
<td>429</td>
</tr>
<tr>
<td>1,500</td>
<td>501</td>
</tr>
<tr>
<td>2,500</td>
<td>578</td>
</tr>
<tr>
<td>5,000</td>
<td>653</td>
</tr>
<tr>
<td>10,000</td>
<td>699</td>
</tr>
<tr>
<td>25,000</td>
<td>730</td>
</tr>
<tr>
<td>100,000</td>
<td>746</td>
</tr>
<tr>
<td>500,000 &amp; over</td>
<td>752</td>
</tr>
</tbody>
</table>

**Note:** This table is based on simple random sampling and a 100% response rate. For example, if the response rate is expected to be 50%, then the sample size should be doubled.
Statistical Significance vs. Clinical Significance:

- **Statistical significance** relates to how likely the observed effect is due to chance (i.e., sampling variation).
- **Clinical significance** relates to the magnitude of the observed effect.

Statistical significance depends on three parameters:

- Sample size (the larger the sample size, the easier to demonstrate statistical significance)
- Variability in patient response, either by chance or by non-random factors (the smaller the variability, the easier to demonstrate statistical significance)
- Effect size, or the magnitude of the observed effect between group (the greater the size of the effect, the easier to demonstrate statistical significance)

Clinical significance reports on the size of the effect, and is typically presented as:

- **relative risk (RR)** – The rate (risk) of poor outcomes in the intervention group divided by the rate of poor outcomes in the control group. (e.g., if the rate of poor outcomes is 20% in the intervention group and 30% in the control group, then the RR is 0.67 = 20% divided by 30%. The RR is 1 when the intervention has no effect, below 1 when it does good, and above 1 when it does harm.
- **relative risk reduction (RRR)** – The extent to which the risk of a poor outcome is reduced by an intervention. In the example given for RR (above), the RRR, expressed as a percentage is 33% (1-0.67 = 0.33)
- **risk difference (RD), or absolute risk reduction (ARR)** – e.g., an RCT found that 20% of the control group developed bad outcomes, compared with only 12% of the treatment group. In this example, the RD is 8% (20%-12% = 8%). This means that if 100 people were treated, 8 would be prevented from developing bad outcomes. Another way to express this is the number needed to treat (NNT), wherein if 8 out of 100 benefit from treatment, then NNT for one person to benefit is ~13 (100÷8 = 12.5).

The above values are given as a single number and therefore, are referred to as “point estimates”. A range of values around the point estimates can be calculated, which gives us an “interval estimate”. The interval estimate is also known as the “confidence interval” (CI). The CI provides an idea of how confident one can be about a study’s estimate of a treatment effect. A 95% confidence interval tells us that an experiment conducted 100 times would result in the point estimate falling inside the confidence interval 95 times. For example, if the RRR = 0.45 and its 95% confidence interval = 0.35 – 0.55, that means that a repeat of the experiment conducted 100 times would yield a RRR somewhere between 0.35 and 0.55 ninety-five times. The narrower the range, the more precise the study’s estimates, and the more confident one can be that it is a ‘real’ finding (i.e., not due to chance).

If the confidence interval does not include the number “one” for RR (or the number “zero” for RRR), then the point estimate will be statistically significant. As an example, consider a case that x occurred in 14 of 100 cases receiving y, and 26 of 100 cases in those receiving z.

- The RR would be 0.54, and the 95% confidence interval would be 0.30 to 0.97. Here, the confidence interval excludes “1.0” and this tells us that the p-value will be significant at the 0.05 level; in fact, in this example, p=.038, telling us that the point estimate of 0.54 is statistically significant.
- Now take a look to see what happens when we change the rate in the z group slightly from 26 of 100 cases of x to 24 of 100 cases. The RR would be 0.58 and the 95% confidence interval would be slightly wider, 0.32 to 1.06, p=0.07. Here, the number “1.0” is included in the confidence interval telling us that the point estimate of 0.58 is not statistically significant.
- As you can see, the confidence interval is closely related to the p-value.

With the use of confidence intervals, you can use your clinical experience to judge if the size of the effect is large enough to be important clinically.

---

Analysis (Quantitative)\textsuperscript{50}

Questions to ask and clarify prior to statistical analysis

Q: What type(s) of data?
A: Basic data collected could be either quantitative (numerical) data or qualitative (categorical) data, both of them having subtypes.

The quantitative (numerical) data could be:

Discrete (discontinuous) numerical data — if there are only a finite number of values possible (e.g., the results of rolling two dice), or if there is a space on the number line between each 2 possible values (e.g. records from an obsolete mercury based thermometer).

Continuous data — This type of data is usually associated with some sort of advanced measurement technique or instruments (e.g., height, weight, finish time in a race).

Interval data — Does not have an absolute zero; therefore, it does not make sense to say that one level represents twice as much as another level, if divided by two. E.g., although temperature measured on the Celsius scale has equal intervals between degrees, it has no absolute zero. The zero on the Celsius scale represents the freezing point of water, not the total absence of temperature. Therefore, it does not make sense to say that a temperature of 10 on the Celsius scale is twice as hot as 5.

Ratio data — ratio data has an absolute zero. E.g., when measuring length, zero means no length, and 10 meters is twice as long as 5 meters.

*Both interval and ratio data can be used in parametric tests.

The qualitative (categorical) data could be:

Binary (logical) data — Basic type of categorical data (e.g. positive/negative; present/absent)

Nominal data — Nominal data is made up of values that are distinguished by name only; there is no standard ordering scheme to this data (e.g. Romanian, Hungarian, and Croatian, as groups of people).

Ordinal (ranked) data — Ordinal data are similar to nominal data, in that the data are distinguished by name, but different than nominal level data because there is an ordering scheme (e.g. low, medium and high level smokers).

Q: How should data be organized, before starting a statistical analysis?
A: "Raw data" is a term used to describe data which has not been subjected to processing or any other manipulation (i.e., primary data). Therefore, the primary data collected during scientific investigation needs to be transformed into a format that allows interpretation and analysis. Typically, data are collected using a database management system (Microsoft Access, Oracle, MySQL or dedicated e-health record systems) or spreadsheet software (e.g., Microsoft Excel). In both cases, data should be exported to a program that allows analysis. Data must be organized in a tabular (spreadsheet-like) manner using tables with an appropriate number of rows and columns, a format used by the majority of statistical packages.

Numerical data can be organized in two ways, depending of the requirements of the statistical software:

1. Indexed data – when we will have at least two columns. A column will contain the numbers recorded during the experiment and another column will contain the “grouping variable”. Using only two columns of a table, we may record data for a large number of samples. This approach is used in popular and powerful statistical software, such as SPSS, and in free software (e.g., Epiinfo (developed by Center for Disease Control - http://www.cdc.gov/epiinfo/downloads.htm), OpenStat (developed by Bill Miller, http://statpages.org/miller/openstat/)).

2. Raw data – when data are organized using a specific column (row) for every sample we may have. This approach is used by a relative small number of statistical software (e.g. MS Excel Statistics Add-in, OpenOffice Statistics, Graphpad Instat and Prism).

Qualitative (categorical) data should be aggregated in a contingency table. A contingency table is essentially a display format used to analyze and record the relationship between two or more categorical variables.

**Q**: How many samples?

**A**: Depending on the research/study design, we may have any of these situations: one sample; two samples; three or more samples.

If there is only one sample, we may ask a pertinent question: what statistical inference could be made, if no obvious comparison terms seem available? In this case, there is still some statistical analysis that can be done. E.g., if a drug is administered to one sample group, we still may be able to make some comparisons, such as looking at the mean of body temperature recorded during the experiment and a “normal” value, in order to demonstrate if the difference between those values has “statistical significance” and to conclude if the drug has some effect.

If there are two samples involved in the research, then inferential statistics can be used to make the comparisons between samples.

When more than two samples are involved, the analysis is a little more complicated; however, there are statistical tests available that are capable of dealing with this scenario. For example, to compare the means of all samples in one instance, use the analysis of variance (ANOVA test).

**Q**: Is it dependent or independent samples/paired or unpaired groups?

**A**: Generally, whenever a subject in one group (sample) is related to a subject in the other group (sample), the samples are defined as “paired”.

For example, in a study of mothers and daughters, the samples are paired, a mother with her daughter. Subjects in the two samples are not independent of each other. For independent samples, the probability of a member of the population being selected is completely independent of any other subject being selected, either in the subject’s own group, or in any other group in the study.

Paired data may be defined as values, which fall normally into pairs and can therefore be expected to vary more between pairs than within pairs. If such conditions aren’t met, we will have to deal with unpaired or independent samples.

The above considerations are important because there are many statistical tests that have different versions for paired/unpaired samples, with a different mathematical approach which may lead to different results. For example, a well-known statistical test, the t-test used for comparison of means between two samples, has different versions for paired/unpaired samples: paired (dependent) samples t-test and unpaired (independent) samples t-test. Thus, choosing a paired test (test for dependent samples) instead of an unpaired test (test for independent sample) is incorrect, and will lead to inaccurate results/conclusions in the statistical inference process.
Choose a paired test when the experiment follows one of these designs:
- when a variable is measured before and after an intervention in each subject;
- when subjects are recruited as pairs, matched for variables such as age, ethnic group or disease severity; one of the pair gets one treatment – the other gets an alternative treatment;
- when a laboratory experiment is run several times, each time with a control and treated preparation handled in parallel;
- when an outcome variable is measured in child/parent pairs (or any other type of related pairs).

Whenever we expect a value in one sample to be closer to a particular value in the other sample, than to a randomly selected value in the other sample, choose a paired test; otherwise, it is an independent samples test.

**Q: Are the data sampled from a normal (Gaussian) distribution?**

**A: Based on the normality of distributions, we chose parametric or nonparametric tests.**

Many statistical tests (e.g. t-tests, ANOVA and its variants), assume data will follow a normal (i.e., bell-shaped) distribution. Tests that follow this assumption are called parametric tests and the branch of statistical science that uses such tests is called parametric statistics.

Parametric statistics assume that data come from a type of probability distribution (e.g. normal distribution) and make inferences about the parameters of the distribution. However, many populations from which data are measured - and biological data are often in this category - never follow a normal distribution precisely. A normal distribution extends infinitely in both directions and so includes both infinitely low negative numbers and infinitely high positive numbers, whereas biological data are often naturally limited in range. Still, many kinds of biological data do follow a bell-shape that is approximately normal. ANOVA tests, t-tests and other statistical tests work well, even if the distribution is only approximately normal (especially with large samples, e.g. > 100 subjects) and these tests are used routinely in many fields of science.

In some situations, for example when we have to deal with small samples (e.g. < 10) or have as an outcome variable a medical score (e.g. Apgar Score), applying such a test that assumes that the population follows a normal distribution, without a proper knowledge of the phenomena, could result in a P-value that is misleading. As such, nonparametric statistics, which propose distribution-free methods and tests that do not rely on assumptions (that the data follow a normal distribution) are also available. Such tests are named nonparametric statistical tests.

To understand the difference between these two types of tests, it helps to understand two basic concepts in statistics: robustness and power of a statistical test.

A robust statistical test is one that performs well, even if assumptions are somewhat violated. In this respect, nonparametric tests tends to be more robust than their parametric equivalents, and are able to deal with very small samples, where data are far from being normally distributed.

The power of a statistical test is the probability that the test will reject the null hypothesis when the alternative hypothesis is true (e.g. that it will not make a type II error). A Type II error is also known as an “error of the second kind”, a β error, or a “false negative” and is defined as the error of failing to reject a null hypothesis when it is in fact not true. As power increases, the chances of a Type II error decrease. Nonparametric tests tend to be more robust, but usually they have less power. In other words, a larger sample size can be required to draw conclusions with the same degree of confidence.
Q: Choose one-tailed or two-tailed tests?
A: Two different types of tests that can be performed:
A one-tailed test looks only for an increase or a decrease (a one-way change) in the parameter whereas a two-tailed test looks for any change in the parameter (which can be any change - increase or decrease).

E.g., To understand this concept we have to define the critical region of a hypothesis test (i.e., the set of all outcomes which, if they occur, will lead us to decide to reject the null hypothesis in favor of the alternative hypothesis). In a one-tailed test, the critical region will have just one part (the grey area in the figure below). If our sample value lies in this region, we reject the null hypothesis in favor of the alternative one. In a two-tailed test, we are looking for either an increase or a decrease.

![Figure 3. Critical regions in one-tailed and two-tailed tests](image)

When comparing two groups, we must distinguish between one- and two-tail P-values.

The two-tail P-value answers this question: Assuming the null hypothesis is true, what is the chance that randomly selected samples would have means as far apart (or further) as we observed in this experiment with either group having the larger mean?

To interpret a one-tail P-value, we must predict which group will have the larger mean before collecting any data. The one-tail P-value answers this question: Assuming the null hypothesis is true, what is the chance that randomly selected samples would have means as far apart (or further) as observed in this experiment with the specified group having the larger mean?

A one-tail P-value is appropriate only when previous data, physical limitations or common sense tell us that a difference, if any, can only go in one direction. Or alternatively, we may be interested in a result only in one direction. For example, if a new drug has been developed to treat a condition for which an older drug exists. Clearly, researchers are only interested in continuing research on the new drug if it performs better than the old drug. The null hypothesis will be accepted if the new drug performs the same or worse than the older drug. So, the real issue here is whether we have sufficient knowledge of the experimental situation to know that differences can occur in only one direction, or we are interested only in group differences in both directions.
Q: What is the goal of the statistical analysis?
A: When using basic statistical analysis, there are three potential main goals:
1. To compare means (or medians) of the one, two or more groups/samples (e.g. is blood pressure higher in control than treated group(s)).
2. To make some correlation, to look at how one or more independent variable(s) and one dependent variable relate to each other (e.g. how do weight and/or age affect blood pressure).
3. To measure association between one or more independent variables (e.g. epidemiological risk factors) and one or more dependent variables (e.g. diseases). This is analysis of contingency tables, where we may look at how independent variable(s) (e.g. smoke or higher levels of smoking) are associated with one or more dependent variable(s) (e.g. lung cancer and its various forms).

### Statistical tests that compare the means (medians) for one, two, three or more groups/samples

<table>
<thead>
<tr>
<th>How many samples?</th>
<th>Paired/ Unpaired</th>
<th>All sample(s) are drawn from a normal distribution? / Parametric (P) or non-parametric test (NP)?</th>
<th>Name of the statistical test</th>
<th>Observations</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 sample</td>
<td>One sample only</td>
<td>Yes/P</td>
<td>One sample t-test</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>No/NP</td>
<td>Wilcoxon rank sum test, One Sample Chi-Square test</td>
<td></td>
</tr>
<tr>
<td>Paired</td>
<td>Yes/P</td>
<td>Independent samples t-test</td>
<td>Paired t-test</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No/NP</td>
<td>Wilcoxon matched pairs test</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 samples</td>
<td>Unpaired</td>
<td>Yes/P</td>
<td>Independent samples t-test</td>
<td>It assumes that the two samples have equal variance (in other words that the difference between the variance of the two samples has not statistical significance). The F test may be used to prove this assumption.</td>
</tr>
<tr>
<td></td>
<td>No/NP</td>
<td>Welch's corrected unpaired t-test</td>
<td></td>
<td>It assumes that those two samples have unequal variance. The F test may be used to prove this assumption.</td>
</tr>
<tr>
<td>3 or more samples</td>
<td>Paired</td>
<td>Yes/P</td>
<td>Repeated-measures one-way ANOVA</td>
<td>We will present here only the simple form of analysis of variance (ANOVA), not the two-way or multifactorial ANOVA. Some post hoc tests are available, able to make comparison between each and every pair of samples from the experiment.</td>
</tr>
<tr>
<td></td>
<td>No/NP</td>
<td>Friedman's test</td>
<td>Post hoc tests are available, able to make comparison between each and every pair of samples from the experiment.</td>
<td></td>
</tr>
<tr>
<td>Unpaired</td>
<td>Yes/P</td>
<td>One-way ANOVA</td>
<td>Post hoc tests are available</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No/NP</td>
<td>Kruskal-Wallis test</td>
<td>Post hoc tests are available</td>
<td></td>
</tr>
</tbody>
</table>

---

### Types of statistical tests

There are a wide range of statistical tests. The table (below) provides a simple, general guideline; however, it is a guideline only, as often data can be analyzed in multiple ways:

<table>
<thead>
<tr>
<th>Type of Test:</th>
<th>Use:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Correlational</strong></td>
<td>These tests look for an association between variables</td>
</tr>
<tr>
<td><strong>Pearson correlation</strong></td>
<td>Tests for the strength of the association between two continuous variables</td>
</tr>
<tr>
<td><strong>Spearman correlation</strong></td>
<td>Tests for the strength of the association between two ordinal variables (does not rely on the assumption of normal distributed data)</td>
</tr>
<tr>
<td><strong>Chi-square</strong></td>
<td>Tests for the strength of the association between two categorical variables</td>
</tr>
</tbody>
</table>

**Comparison of Means: look for the difference between the means of variables**

<table>
<thead>
<tr>
<th>Type of Test:</th>
<th>Use:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Paired T-test</strong></td>
<td>Tests for difference between two related variables</td>
</tr>
<tr>
<td><strong>Independent T-test</strong></td>
<td>Tests for difference between two independent variables</td>
</tr>
<tr>
<td><strong>ANOVA</strong></td>
<td>Tests the difference between group means after any other variance in the outcome variable is accounted for</td>
</tr>
</tbody>
</table>

**Regression: assess if change in one variable predicts change in another variable**

<table>
<thead>
<tr>
<th>Type of Test:</th>
<th>Use:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Simple regression</strong></td>
<td>Tests how change in the predictor variable predicts the level of change in the outcome variable</td>
</tr>
<tr>
<td><strong>Multiple regression</strong></td>
<td>Tests how change in the combination of two or more predictor variables predict the level of change in the outcome variable</td>
</tr>
</tbody>
</table>

**Non-parametric: are used when the data does not meet assumptions required for parametric tests**

<table>
<thead>
<tr>
<th>Type of Test:</th>
<th>Use:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Wilcoxon rank-sum test</strong></td>
<td>Tests for difference between two independent variables - takes into account magnitude and direction of difference</td>
</tr>
<tr>
<td><strong>Wilcoxon sign-rank test</strong></td>
<td>Tests for difference between two related variables - takes into account magnitude and direction of difference</td>
</tr>
<tr>
<td><strong>Sign test</strong></td>
<td>Tests if two related variables are different – ignores magnitude of change, only takes into account direction</td>
</tr>
</tbody>
</table>

**Suggested Reading:**

In addition to analyzing data and being aware of the types of statistical tests available, it is important to also understand the underlying principles of common statistical tests – whether statistical tests have been applied in the right way, at the right time, with the right data:


---

52 Available via: [https://cyfernetsearch.org/ilm_6_7](https://cyfernetsearch.org/ilm_6_7)
Tests of Difference:
Tests of difference ask the question, "are the differences observed between the categories of the independent variable (IV) with respect to the dependent variable (DV) due to chance or are they real differences?"

Tests of difference are always used with research questions or hypotheses looking at differences between groups, therefore the independent variable is always categorical in nature, meaning it is nominal (and sometimes ordinal), and the dependent variable is always continuous (interval or ratio).

Which difference test you run depends on the number of independent variables you have and how many levels there are for your independent variable (if you only have one). The chart below should help in choosing the most appropriate difference test for your difference research question/hypothesis.

**DECISION FLOW-CHART FOR DIFFERENCE TEST CHOICE**

<table>
<thead>
<tr>
<th>Are all the variables being studied nominal or categorical?</th>
</tr>
</thead>
<tbody>
<tr>
<td>No - just the independent variable is nominal.</td>
</tr>
<tr>
<td>Do you have more than one IV?</td>
</tr>
<tr>
<td>Yes - then you use a two-way or factorial ANOVA.</td>
</tr>
<tr>
<td>Is at least one of your IVs repeated in any way (e.g., pre-posttest)?</td>
</tr>
</tbody>
</table>

Info available via: [http://www.uni.edu/commstudies/researchmethods/chapterfour2.html](http://www.uni.edu/commstudies/researchmethods/chapterfour2.html)
**T-Test:** T-tests are used to test the significance of differences between the means of TWO groups or populations on some dependent variable. There are two overall types of t-tests: (a) the t-test for independent samples, and (b) the paired samples t-test. The basic difference between these two tests is whether the two groups being compared are related in some way.

**Analysis of Variance (ANOVA):** ANOVA is used when testing for the significance of differences between means among groups/populations with one of the following conditions:
- a single categorical/nominal IV with THREE or more levels (e.g., home vs. public vs. private schooling), or
- two or more categorical IVs (e.g., type of schooling & biological sex).

The reason these tests are called analysis of variance is because there are two possible sources of variability – there are differences between the groups being compared, and that is called "between-groups variance," and there are differences within each group, and that is called "within-groups variance" (sometimes also called "error" or differences within the groups occurring just by chance).

**One-Way ANOVA:** A one-way ANOVA has one categorical IV, with more than two levels, and one continuous dependent variable.

**Two-Way & Factorial ANOVA:** A two-way ANOVA has two independent categorical variables and one continuous dependent variable. Two-way and above ANOVAs are also called factorial ANOVAs, because they have multiple "factors" or independent variables. While you could also have three-way (with three independent variables), four-way (with four independent variables) ANOVAs, etc., it is easier to call anything above a two-way ANOVA a factorial ANOVA.

**Chi Square:** The chi-square test is used with categorical (usually nominal) variables only. It is specifically used to test whether the actual frequency of occurrence of responses in a particular set of categories differs from what might be expected or what might occur by chance. It uses frequency data rather than means, since you are dealing with nominal or categorical data. Often a chi-square test will be performed when the data involves frequency counts (e.g., content analysis data).

**Goodness of Fit Chi Square:** There are two different types of chi-square analyses you can do. The first one is the "goodness of fit" chi-square in which you only have one variable you are testing for significance, i.e., only one group of frequencies. The "goodness of fit" chi-square allows you to see if the frequencies for each theme were significantly different than what would be expected by chance. It tests to see if the expected frequencies (usually the same number per category) are the same as the observed frequencies.

**Test of Independence:** The second type of chi-square test is the test of independence, and involves a categorical independent variable and a categorical dependent variable. This differs from the ANOVA and t-test procedures because the dependent variable is not continuous in nature, as is required by the ANOVA and t-test statistics.

**Tests of Association or Relationship**: Tests of association or relationship do not look for differences between groups, as the tests of difference do. Rather, they are used with research questions/hypotheses of association/relationship. You use these types of tests when you are exploring or testing the relationship between two or more variables. Typically, the variables used in these types of tests are all continuous in nature.

Often the independent variables are called "predictor" variables in these types of tests, and the dependent variables are called "criterion" or "outcome" variables.

---

54 Info available via: [http://www.uni.edu/commstudies/researchmethods/chapterfour2.html](http://www.uni.edu/commstudies/researchmethods/chapterfour2.html)
Correlation: When you want to see if two or more variables covary or change with each other, then you are looking for a relationship between these variables.

For each correlation done, for each person or group, their independent and dependent variable scores are matched. Often researchers will plot matches on what is called a "scatterplot," to be able to visually see if there is a relationship between the two variables. The closer the dots are to a line that can be drawn through the data, the greater the relationship or correlation is between the two variables.

The measure for a test of relationship/association for interval/ratio variables is Pearson's r (Pearson's product-moment correlation), and it can range from a "-1" to "+1." The size of the number (correlation coefficient) indicates how large or small the relationship is, and the sign indicates the direction of the relationship (positive or negative). If the relationship between the variables is positive, as the value of one variable goes up, then the value of the other variable goes up. If it is negative, that means that as the value of one variable goes up, the value of the other variable goes down.

How large the relationship is (i.e., as the correlation coefficient, r, gets closer to 1 or -1) helps explain how much predictive power one variable has for another variable. This predictive power is specifically measured by squaring the r value to get "R-squared" or the "coefficient of determination." This value tells the researcher how much of the variance of one variable is accounted for by the other variable.

NOTE: Even though we can use the coefficient of determination or R-squared to account for variance in one variable by the other variable, we cannot prove causation by correlational data.

Regression: If you wish to go further than correlation and actually try to predict a person's score on a dependent variable by knowing their score on an independent variable, you should use regression. Regression attempts to find the "line of best fit" for the data, and is used in any professions to try to predict a person's future behavior.

Regression tests look at:
(1) whether a predictor variable (IV) can "predict" some outcome/criterion variable (DV), or
(2) which predictor variables (IVs) best "predict" the level of an outcome/criterion variable (DV).
The first type of scenario above is called "simple linear regression," and the second is called "multiple regression".

Simple Linear Regression: When you have only one predictor or independent variable and one criterion/outcome/dependent variable, then you have simple linear regression. It uses the notion of plotting the scores on both variables in an attempt to predict what a person's score might be on the other variable, using a "line of best fit" regression equation.

Multiple Regression: Most often researchers choose to enter several possible predictor variables into their regression equation, especially if they have found these independent/predictor variables to be already correlated with the dependent/criterion/outcome variable. Using more than one predictor variable (multiple variables) makes the study a "multiple" regression study. There are many decisions researchers can make when doing a multiple regression, and most of them have to do with how they order or group the predictor variables (e.g., hierarchical multiple regression, logistic multiple regression, step-wise regression, etc. For definitions and further explanation, see: Multiple Regression Methods.
**Statistical Software**

There are several software programs that can help manage and analyze data. Below are some of the more popular options:

<table>
<thead>
<tr>
<th>Software</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excel</td>
<td>Part of the Microsoft Office software package, relatively easy to use program for basic data management and analysis, provides users with basic descriptive statistical functions, useful for an evaluation plan that does not include a rigorous experimental design. Click here for more information on Microsoft Office products, including Excel.</td>
</tr>
<tr>
<td>Access</td>
<td>Part of the Microsoft Office software package, can analyze multiple fields at a time, can perform a variety of functions, including descriptive statistics and t-tests. Click here for more information on Microsoft Office products, including Access.</td>
</tr>
<tr>
<td>SPSS</td>
<td>Statistical Package for the Social Sciences (SPSS) is designed specifically for social science statistical analysis, is an advanced program that may require training, can be used to store large amounts of data, ability to perform complex statistical functions including regression analysis, as well as correlation and variance analysis, suitable for experimental, longitudinal designs, or basic evaluation needs. Click here for more information on SPSS.</td>
</tr>
<tr>
<td>SAS</td>
<td>SAS is a statistical program designed specifically for social science statistical analysis, advanced statistical program with a wide range of functions, similar to SPSS, includes survey data analysis, regression analysis, and categorical data analysis. Click here for more information on SAS.</td>
</tr>
<tr>
<td>STATA</td>
<td>Statistical software used by medical researchers, biostatisticians, epidemiologists, social scientists, and other research professionals to analyze data, useful for analyzing large, longitudinal datasets; able to analyze datasets with numerous variables, easy statistical analysis, but less flexible than SAS in terms of data manipulation. Click here for more information on STATA.</td>
</tr>
</tbody>
</table>

As a useful resource, the following table provides a guide for choosing a statistical analysis/test, as well as information (and links) showing how to do such tests using SAS, STATA and SPSS.

Additionally, there are free resources that explain how to use statistical software, such as SPSS, as well as YouTube videos. The ones listed, below, will guide you as you enter, "clean", and run the necessary statistics (to answer your research question/s or test your hypothesis/es):

- **Website Links:** [SPSS On-Line Training Workshop](https://www.spss.com/training), [SPSS Tutorial](https://www.spss.com/tutorials)
- **YouTube Videos** (Type in "SPSS tutorial" into YouTube, and you will find helpful videos such as the following): [Intro to SPSS](https://www.youtube.com/watch?v=Q7Z4g0Z1H7Q), [SPSS 1 Quickstart: Extracting Data](https://www.youtube.com/watch?v=Q7Z4g0Z1H7Q)

**The UCLA Statistical Consulting Group** offers various workshops and seminars online. This resource covers introductions to SAS, STATA, SPSS, as well as tutorials on analyzing results from online questionnaires, power analysis and more.

**G*Power** is another tool that can be used to compute statistical power analyses for many different t tests, and is available for download for free (available to both Mac and Windows applications).

---

55 Available at: [https://cyfernetsearch.org/ilm_6_8](https://cyfernetsearch.org/ilm_6_8)
Centre for Health Care Innovation (CHI): REDCap Program
REDCap (Research Electronic Data Capture) is a secure, web application designed to support data capture for research studies. CHI has implemented REDCap, at the UMan, to provide researchers with a highly secure, centralized, audited environment to store manage and analyze research data. REDCap provides users with multiple features such as multi-site data entry, real-time data entry validation, audit trails and the ability to set up a calendar to schedule and track critical study events such as blood-draws, participant visits, etc. It is also highly adaptable; data collection is customized for each study or clinical trial by the research team. CHI’s team will support researchers by providing guidance on the development of collection tools along with crucial statistical analysis and support.

Advantages of REDCap
- Designed to comply with PHIA & FIPPA regulations to provide highest standards of security to protect data against loss, destruction or unauthorized access and use
- Provides user-friendly web-based Case Report Forms (CRFs),
- Allows users to assign different levels of access to member of the research team
- Research investigators and their research staff have secure, controlled access to individual project databases
- Provides a range export procedures for seamless data downloads to various file formats and common statistical packages such as SAS, R, SPSS, Stata
- Provides a powerful tool for creating and managing web based surveys (e.g., it allows researchers to collect anonymous responses or track and identify responses from survey participants).

Biostatistical Consulting Unit (BCU)
The BCU serves as a resource of statistical expertise for researchers and students across the University of Manitoba environment. The BCU operates on a cost recovery model; however, there are accommodations for students and faculty who do not have funds to support their research.

UMan Library
The UMan library provides Data Library Services to assist individuals in identifying and accessing data, including aggregate, survey, and spatial data. In addition to these services, the Uman library website offers a guide to statistics and data, providing information about, and access to, a wide variety of data resources.

The University of Manitoba Libraries subscribes to many sources of aggregate statistical data, with many more sources being freely available. The guide outlined on the UMan libraries webpage outlines the databases available, and provides descriptions of some of the more popular sources, as well as supports to both find and cite data sources.

Suggested Reading & Research Reference:
- http://www.statswhisperer.com/ Provides formal training and free webinars to assists individuals in understanding the fundamentals of quantitative & qualitative research methods and application.
**Analysis (Qualitative)**

**Types of Qualitative Questions**

The *what, why* and *how* questions work well for qualitative methods:

- *What* are the dynamics of the student/resident/fellow/staff team in the Emergency Department?
- *Why* is there brand loyalty to antibiotics?
- *How* does the learner gain confidence in procedures done rarely? (Note confidence is a feeling rather than a skill.)

If your research question requires you to learn about people’s view, assess a process (to which there is little or no numerical data available) over time, develop theories from participant perspectives or learn more detailed information from a smaller number of people, then it is appropriate to use qualitative methods. Note that the ‘*how many / how often*’ questions tend to be less suited to qualitative methods, as are comparisons among groups (although there are exceptions) and interventional questions, and are therefore typically answered using quantitative measures/analysis.

**Qualitative Approaches**

**Biography:** The study of an individual and her or his experience as told to the researcher or found in the documents and archival material. – Can be autobiographical. Includes history, influences, pivotal life changing event(s), impact of events

**Phenomenology:**

- Describes and interprets the meaning of everyday experiences, concepts and phenomena from the perspective of several individuals. Examples include:
  - The physician – nurse relationship in acute care
  - Meanings of spirituality in palliative care
  - Skateboarders’ experience of risk and injury
- Data sources can be interviews, focus groups, observation, photographs
- The focus of data analysis is lived experience, and the meanings associated with those experiences (i.e., you as the researcher are interpreting the participants’ presented interpretation of their experience)
- Also known as circular hermeneutics

**Grounded Theory:**

- Seeks to understand and describe human behaviour
- Generates theory that explores social processes – how people interact, take action in response to a particular phenomenon
- Theory is generate from the “ground” up
- Often medical/nursing literature portrays this approach as a more “objective” form of qualitative research because it attempts to remove the researchers’ opinions and interpretation. Although even if results appear to come out of the data, ultimately the end result will be affected by the researchers’ background, assumptions and/or combined analyses.
- Data sources include interviews, observations, focus groups, literature
- Need to be conversant in the relevant literature, topic

**Ethnography:**

- Seeks to understand human behaviour in the cultural context in which it is embedded.
- Requires observation of learned patterns of behaviour, language, customs, interactions and ways of life.
- Involves prolonged cultural immersion and understanding from the insider’s point of view. The researcher is often an outsider looking in – unless it is an auto-ethnography in which the researcher is part of the examined culture – e.g. pediatric emergency doctor looking at the culture of communication within the Pediatric Emergency
- Institutional ethnography looks at the culture of institutions – such as health care, and how groups or individuals interact with that culture – within or as outsiders – e.g. marginalized populations accessing medical care
- Sources of data include interviews, field notes, observations, policies, documents, cultural artifacts.

---

56 Patton: Qualitative Research and Evaluation Methods, 3rd edition, p 132-133.
Also available at: [http://research.familymed.ubc.ca/files/2012/03/StudyDesignsIII21715.pdf](http://research.familymed.ubc.ca/files/2012/03/StudyDesignsIII21715.pdf)
Case Study:

- An exploration of a bounded system (defined) or a case (or multiple cases) over time through detailed, in-depth data collection involving multiple sources of information rich in context
- A case or bounded system may be a person, group, episode, process, community, hospital, society
- Data is collected about the nature of the case, its historical background, other contexts (economical, political, legal), other cases through which the case is recognized, those informants through which the case can be known
- Sources of data include interviews, observations, documents, letters, diaries, texts, policies

Participatory Action Research

- “Action research...aims to contribute both to the practical concerns of people in an immediate problematic situation and to further the goals of social science simultaneously. Thus, there is a dual commitment in action research to study a system and concurrently to collaborate with members of the system in changing it in what is together regarded as a desirable direction. Accomplishing this twin goal requires the active collaboration of researcher and client, and thus it stresses the importance of co-learning as a primary aspect of the research process.”
  - [Thomas Gilmore, Jim Krantz and Rafael Ramirez, “Action Based Modes of Inquiry and the Host-Researcher Relationship,” Consultation 5.3 (Fall 1986): 161]
- The researcher studies the problem systematically and ensures the intervention is informed by theoretical considerations.
- Much of the researcher’s time is spent on refining the methodological tools to suit the exigencies of the situation, and on collecting, analyzing, and presenting data on an ongoing, cyclical basis.”

Data Collection

Triangulation:

Triangulation is the technique of using more than one method of data collection within a study to give more credibility to the results. For example, if the same discoveries are made through observation as through interview and focus groups, the results are much more convincing.

Observations:

Observation is the process of gathering first-hand information by observing people and places at a research site. Observers can be participant observers, or non-participant observers. The location can be public or require specific access. It is advised that this type of research should collect multiple observations in the same site to gain enough information to be able to adequately describe the phenomena under investigation. Typically, field notes are taken during observation (so the research is not relying on recall, or memory alone).

Interviews & Surveys:

Interviews or surveys – in person, self-administered, by telephone, email, etc. – use questions to allow the participant to create options for responding, and voice their experiences and/or perspectives. Such approaches, often involves some form of questionnaire or survey, whether it is executed individually or in a group setting (e.g., focus group). As such, it is important to develop the interview guide, either from existing research/tools available, or anew, and to test/validate questions prior to implementation. Pilot testing is a good option to consider in determining whether your questions are asking what you want to know, what kinds of probes are helpful to get the information you need, whether questions are appropriate to the intended audience, etc.

Tips for generating questions:

- General before specific
- Do not use value-laden phrasing, or language
- Question should be genuinely exploratory, not leading
- It may be helpful to use/generate probes (either to expand discussion, or help participants understand
- As a last question: Anything important we haven’t talked about?

---

Focus groups:
Essentially, focus groups are group interviews that facilitate the exchange of ideas. An experienced focus group facilitator is important to recognize group dynamics, engage all participants, and keep the group focused on the issues. Focus groups can be a good option if the topic of interest involves marginalized or minority groups (including youth and children), as often such individuals will feel more at ease, or willing to participate collectively, rather than a one-on-one interview format.

Limitations: It may be more challenging to broach difficult, sensitive or opposing views in a group setting; a limited number of questions can be asked due to groups size, dynamics and time constraints; Participants must understand the importance of confidentiality, and all should complete a PHIA orientation and confidentiality agreement.

Analysis & Assessing Rigor
Qualitative analysis is no less rigorous, systematic and/or procedural in its approach than quantitative analysis. While the most appropriate approach to qualitative analysis depends on the methodology followed; generally, each approach attempts to describe, interpret and derive meaning from the data. Some of the more common approaches include: content analysis, constant comparison analysis, phenomenologic analysis, and grounded theory analysis.

Content analysis: provides a descriptive record and an initial level of interpretation.
Constant comparison analysis: involves comparing incidents and applying/sorting by category, integrating categories and their properties, defining the theory and/or phenomenon and writing the theory.
Phenomenologic analysis: depends heavily on individual quotations to illustrate analytic points. As such, the research must immerse themselves in the data to understand the individual’s perspective, try to make sense of the experience, and answer the research question.
Grounded theory analysis: organizes data into concepts and categories, which are developed into theory (i.e., the theory should rise from the data). Analysis tends to starts soon after data collection begins, which then shapes the data collection that will follow. This approach typically uses “saturation” as an end point to data collection (i.e., when no new ideas are emerging from the data).

Assessing the rigor of qualitative research processes and data is important, and therefore documenting the research approach can help others assess the quality of the research process and potential transferability of the results. As such, there are some general tactics that can help to promote credibility – the degree of match between the realities of participants and realities/findings presented by the researcher – of findings:
• Prolonged engagement with participants, phenomena, etc.
• Persistent observation
• Peer debriefing, and member checks to see if one’s analysis resonates
• Researcher reflexivity – attempting to understand one’s own values, assumptions, characteristics and motivations and how it impacts on interpretation and presentation of research findings.
• Thick description of time, place, context
• Accurate documentation of why and how decisions were made (e.g., categories chosen) and/or factors that led to the final interpretations of data.

58 The College of Family Physicians of Canada. What we want: Checklist for Quantitative Research Articles.
Qualitative Software
There are several software programs available to manage, organize and analyze qualitative data. The following link provides a comprehensive listing of resources available for qualitative research, including links to the software website.

Suggested Reading & Research Reference:
- Qualitative Research Glossary: Qualitative research terms compiled by the King’s College, London libraries.
- Qualitative Case Study Methodology: Study Design and Implementation for Novice Researchers. (Open Access Article)
REPORTING & DISSEMINATING FINDINGS

Publication:
Publication is an important piece of any project’s successful completion. Most medical journals expect authors to follow a standard manuscript structure, and include the following elements:\textsuperscript{59, 60}:

\textit{Title page} – This page should include general information pertaining to the article title, author information (including contact information), any disclaimers/conflicts of interest, sources of funding/support, word count, and, as applicable, the number of tables and figures.

\textit{Abstract} – The format and/or structure requirements of the abstract may vary slightly amongst journals; therefore, the author should consult the journal requirements directly. Nonetheless, most journals expect the abstract to briefly provide the context of the study, including the purpose, basic procedures, main findings, and key conclusions. The abstract should emphasize new and/or important contributions of the study, but should not introduce new concepts or ideas that are not adequately developed in the full article. Note that funding sources should be listed separately, following the abstract, to facilitate proper acknowledgement and transparency.

\textit{Introduction} – Provide the context and/or background for the study, elaborating on the nature of the problem, its significance, building the platform for why this study is important and/or the gap it fills. State the purpose, specific objectives, and as applicable, hypothesis to be tested. Cite only direct and pertinent references.

In sum, ensure the introduction addresses the following:\textsuperscript{61}:
- Current state of knowledge is indicated
- Context of the study is given
- Key references are provided
- Study question is clearly outlined
- What is new or important about this study is stated clearly

\textit{Methods} – This section should seek to provide clarity regarding details of how and why the study was conducted.

- \textit{Selection & description of participants}: Describe the selection of participants, exclusion/inclusion criteria, and a description of the source population. Include more detail regarding important characteristics (sex, age) and demographics, as it relates to the study, as well as how variables were measured and/or defined.

- \textit{Technical information}: Specify the main and secondary outcomes, as well as describe methods, equipment, statistics, etc employed, including why it was used, limitations, and references.

- \textit{Statistics}: Describe statistical methods in sufficient detail so that readers may assess the appropriateness of the chosen method(s). Emphasize and summarize the most substantive findings, and quantify findings, presenting appropriate indicators of measurement error or uncertainty (e.g., confidence interval). Explain any exploratory or sub-group analyses performed. Specify the statistical software package used, including the version.

In sum, ensure the methods address the following:\textsuperscript{62}:
- Setting is presented
- Sample frame is described
- Inclusion/Exclusion criteria are listed
- Intervention or issue is described
- Outcome stated

\textsuperscript{59} ICMJE (December 2013). \textit{Recommendations for the Conduct, Reporting, Editing, & Publication of Scholarly Work in Medical Journals}: 1-17.


\textsuperscript{61} The College of Family Physicians of Canada. \textit{What we want: Checklist for Quantitative Research Articles}.

\textsuperscript{62} The College of Family Physicians of Canada. \textit{What we want: Checklist for Quantitative Research Articles}.

• Measurement instruments validity and reliability are reported (Quantitative)
• Statistical testing / Analytic approach is described
• Is the framework adequate in view of the aim of the study (Qualitative)
• Sample size computations are described / justified
• Design is appropriate to the question
• Ethics approval is indicated for studies with human subjects

Results – Present results in a logical sequence, detailing the most important findings first; do not repeat all data presented in tables or figures, instead, summarize and emphasize only important observations. It is a good idea to explain results as both derivatives (percentages) and absolute numbers, and refrain from using technical terms in statistics (e.g., “random”, which implies a formal randomizing device or technique) to describe nontechnical situations or circumstances.

In sum, ensure the results address the following 63:
• Response rate is satisfactory
• Results are presented clearly in text and tables without overlap
• Results relate to the research question
• Statistics / Results given are appropriate to study question, design and numbers (Quantitative)
• Findings / Data presented adequately support and enrich the researcher’s position, or synopsis of the issue (Qualitative)
• Confidence intervals are used whenever possible (Quantitative)
• Strategies used to validate results are presented (Qualitative)

Discussion – Emphasize new and important findings from the study, and the conclusions that follow with attention to potential mechanisms or explanations for the end results. Findings should be compared/contrasted with other relevant literature and research as applicable. Implications for future research and clinical practice should also be suggested. Note that while it is important to link conclusions with the objectives of the study, avoid unqualified statements and conclusions not supported by the data (e.g., avoid making statements regarding economic benefits and costs, unless the manuscript includes appropriate economic data and corresponding analyses).

In sum, ensure the conclusion and discussion addresses the following 64:
• Clinical and statistical significance is described
• How results compare with the literature is described
• Possible explanations for results are provided
• Speculation is reasonable
• Future directions for research are indicated
• Results are discussed
• Limitations/Strengths of the study are accounted for and briefly discussed
• Conclusions are supported by the data found/findings in the study
• Conclusions answer, or follow from, the research question

References – It is important to include original research sources in addition to review articles. Avoid referencing conference abstracts, as well as citing “personal communication”, unless it provides essential information not available from any other public source. Reference to papers accepted, but not yet published should be referred to as “in press”, or “forthcoming”; reference to manuscripts submitted, but not accepted should be cited in the text as “unpublished observations” with written permission from the source.

In sum, ensure the following\textsuperscript{65}:

- References are relevant, current, complete and accurate.

**NOTE:** Different journals may have differing requirements with respect to citation and formats, so it is recommended that authors consult with the journal to which they plan to submit in order to understand specific requirements. Please also see earlier sections: Managing Citations, Referencing & Documentation

Tables, illustrations, figures (as applicable) – Most journals will have specific requirements for tables, illustrations, etc., which will allow for simple import into the journal’s publication software. Please check requirements specific to the journal to which you are applying.

--Tables: Including data in tables rather than text often makes it possible to reduce the length of the text to fit word limitations. In general, explanatory information should be outlined in the footnotes, rather than the heading/title and, tables should be consecutively ordered, according to the order listed/cited in the text.

--Illustrations & Figures: In general, figures should be professional quality to ensure adequate quality of images for print. Figures should be consecutively ordered, according to the order listed/cited in the text. In general, legends for illustrations should be detailed on a separate page.

Abbreviations & symbols (as applicable) – Use only standard abbreviations, and avoid abbreviations in the title of the manuscript. Before utilizing an abbreviation, the complete word/title/etc. should be articulated on the first mention in the manuscript, followed by the abbreviation in parenthesis.

The overarching theme of any manuscript should be cohesiveness; ideas and items for discussion should follow from the objectives and/or overall purpose of the paper. Be mindful of redundancy; do not repeat in detail information provided in other sections of the manuscript. As outlined, the manuscript should be organized into sections (and subsections), and heading titles should be clear, contain no acronyms, and ideally summarize the point you plan to make in each section. Generally, manuscripts should not exceed 20 pages (double-spaced, one-inch margins, 12pt font, including figures, tables and references); although, shorter manuscripts tend to have a slightly better chance of being accepted for publication.

Lastly, there is no harm in being generous with acknowledgements, so be sure to thank all individuals/organizations/etc, who played a part – big or small – in helping you accomplish your research. Acknowledgements generally are not a part of the body of the manuscript, so excessive reference to the work of colleagues/mentors is unnecessary (unless it is completely relevant to the current project).

When submitting a manuscript, most journals provide a pre-submission checklist to ensure all required components are included. It is a good idea to check the website of the journal to which you will be submitting, to ensure compliance.

It is important to note that there are associated publication costs to submit to open access journals. Ideally, such costs should be anticipated and factored in to the original study budget and/or grant request.

\textsuperscript{65} The College of Family Physicians of Canada. *What we want: Checklist for Quantitative Research Articles.*
The following template (micro-article) can be used to help develop a clear focus when beginning to draft a manuscript or article intended for formal publication:

![Micro-article template image](http://fr.slideshare.net/lichtfouse/scientific-writing-for-impact-factor-journals)

66(via: http://fr.slideshare.net/lichtfouse/scientific-writing-for-impact-factor-journals)
Medical Journal Lists & Indices:
There are several resources that list academic medical journals, and provide their ranking (e.g., impact factor, influence, citation/referenced).

The following site provides a list, including ranking of medical journals:
http://www.journalranking.com/ranking/listCommonRanking.html?citingStartYear=1901&externalCitationWeight=1&journalListId=370&selfCitationWeight=1

Also see: http://www.med.uottawa.ca/aime/eng/journals.html, which provides a list of journals that publish medical education work, each journal’s impact factor rating, along with links to the home-page.

Another good resource is the U of Saskatchewan’s index of journals for publication, which focuses on journals that have the most applicability to primary care/family medicine:
http://www.medicine.usask.ca/family/research/index-of-journals-for-publication-rev.html

The UMan Libraries periodically provides information sessions throughout the academic year that focus on the publishing and specifically, journals you should consider, new journals that may be of interest, how to assess impact factor, and other resources to assist researchers in this regard. Further, a guide to Impact Factor and other Citation Metrics is available via the UMan libraries website. Additionally, the UMan Library Guide provides information relevant to the Health Sciences, including toolkits specific to Family Medicine, amongst other specialties. These toolkits provide access to a variety of information topics, including core journals, clinical guidelines, topics that are of most interest to Family Medicine, education and learning guides, etc.

Posters & Presentations:
Presenting work – whether it is work that is proposed, in-progress or complete – is an essential part of research project development and knowledge translation. Posters and oral presentations present another forum to engage colleagues in dialogue, encourage interest, and connect with others.

The University of Toronto provides a concise and helpful guide to poster design and presentation.

The DFM website provides the UMan poster template, along with some useful tips; however, the more you can display information using info-graphics and rather than text, the better. Info-graphics and other visuals are ideal, but often require a lot of skill and thought to bring it together (please see example) and create something meaningful. Additionally, the Centre for Healthcare Innovation can provide this service, and should be contacted for more information.

Suggested Reading & Research Reference:

In some cases, the information you will be presenting will not yet be complete, and the focus of the poster/presentation will be a bit different. As such, Johns Hopkins provides some useful tips for making the most of a talk or poster presenting research-in-progress.

Additionally, Duke University offers some general guidelines for converting a written paper into a presentation, and incorporating appropriate visual material.
PRIMARY CARE-SPECIFIC DATA

Canadian Primary Care Sentinel Surveillance Network (CPCSSN)
The Canadian Primary Care Sentinel Surveillance Network (CPCSSN) is a network of networks initially funded by the Public Health Agency of Canada (PHAC). The CPCSSN uses routinely collected EMR information from primary care practices for surveillance of chronic diseases, research and practice quality improvement. It is the only pan-Canadian primary care information system that collects de-identified EMR data from consenting family physicians and other primary care providers. In Manitoba, the Manitoba Primary Care Research Network (MaPCReN) serves as the local contributing network to CPCSSN. CPCSSN supports the only pan-Canadian central data source for primary care EMR data through a robust infrastructure to ensure secure, accessible and accurate longitudinal data collection.

Manitoba Primary Care Research Network (MaPCReN)
The MaPCReN data includes health problems, billing information, medications, laboratory results, risk factors, biological information, referrals and procedures. Currently, it includes many (but not all) primary care clinics in Manitoba, including those operated by the Winnipeg Regional Health Authority (WRHA), and represents just over 150,000 patient records (and there are plans to expand into more areas in rural and Northern Manitoba). MaPCReN extracts the EMR data quarterly, which provides the opportunity for nearly real-time data access and a timely representation of real-world settings. While the MaPCReN data is provincial in scope, its connection to the larger CPCSSN network and national team of data managers, provides expertise in the science of data extraction, aggregation and categorization directly related to primary care. Thus, one of the strengths of MaPCReN lies in the successful algorithms developed over the past 5 years by a national team of data managers each with complimentary and unique skills, and the ongoing refinement of these, and new, algorithms.

CPCSSN/MaPCReN data can be used for a variety of purposes/objectives, which to date have included projects validating case definitions and case finding algorithms, providing insight into the context of chronic disease epidemiology and management, and identifying patterns in primary and integrated models of care. Some of the more recent research that MaPCReN has contributed to relates to anticoagulation use and antibiotic stewardship, and several other initiatives, including work related to the Choosing Wisely program, collaboration with the CIHR-funded immune mediated-inflammatory diseases (IMID) group, evaluation of the Family Medicine resident clinical experience, documentation of alcohol use in primary care, and family medicine resident-led projects, one focusing on primary prevention and cardiovascular disease.

Accessing MaPCReN Data
To access MaPCReN data, contact the regional CPCSSN Director (Dr. Alexander Singer) to obtain the MaPCReN data access form. The form requires Investigators/Students to briefly outline the project details, including the data that is anticipated for use and where data access/analysis will occur. Any use of MaPCReN for research purposes must be approved by the MaPCReN Regional Director.

References:
To access CPCSSN data, a more formal process is required. Please consult the CPCSSN website and/or your local regional network director for more information.

Note that the use of Electronic Medical Records (EMR) information for research purposes accessed via MaPCReN, may have additional benefits that researchers should be aware of, and emphasize at the time of REB review:

- If the intention is to only use MaPCReN data, then this is considered a Retrospective Database Review, and would be eligible for Delegated Research Ethics Review (UMan, Bannatyne Campus REB).
- Even if the study only utilizes MaPCReN data, it is worth noting the connection to the original CPCSSN study & approval(s). That is, CPCSSN has received ethics approval to collect electronic medical record (EMR) information from participating primary care practices in Manitoba (Ethics #: HS11382 (H2009:134)). In addition to UMan HREB approval, CPCSSN has national ethics approval from Health Canada.
- In terms of consent, projects utilizing MaPCReN data most often will involve secondary analysis of de-identified data files (where identifiers have been removed and/or scrambled); therefore, it is impractical/impossible to obtain consent. All linkages should be made via computerized files. The record linkage will not be used for purposes that can be detrimental to the individuals involved, and benefits to be derived from such a linkage are clearly in the public interest.

Further, given that this project will focus on the Manitoba population, consent is impractical given the number of records that will be included. Note RE: CPCSSN Data: In order for electronic medical records (EMR) information to become a part of CPCSSN, primary care physicians must first sign a consent form. Individual primary care physicians are under no obligation to participate in CPCSSN. Patient consent is not individually obtained, but patients are informed of the opportunity to have their health information excluded. This process has received approval from the research ethics board (both UMan HREB (Ethics #: HS11382 (H2009:134), and Health Canada), and is consistent with the Personal Health Act (PHIA) in Manitoba.
- MaPCReN data has been integrated into the Population Health Research Data Repository housed at the Manitoba Centre for Health Policy (MCHP), which provides additional depth and breadth to the Repository in the area of primary care. See the MCHP website regarding accessing Repository data.

Suggested Reading & Research Reference:

DFM RESEARCH COMMITTEE: TERMS OF REFERENCE

The DFM has established a Research Committee, which typically meets every 2-3 months. Please direct any items for discussion, questions regarding the Committee, its activities, current membership, etc. to the **DFM research section**. The details of the Committee and the terms of reference are listed below.

**Purpose:**
The purpose of this committee is to provide guidance to the department with regard to the research vision and implementation of that vision.

**Reports to:**
Executive Management Committee, Department of Family Medicine

**Functions:**
The Research Committee shall:
1. Periodically, develop a strategic plan for research within the Department of Family Medicine and use this plan as the basis for setting goals for research in the Department.
2. Advise on the utilization of resources available for research and make recommendations for additional resources.
3. Determine faculty development priorities related to research and organize relevant continuing professional development to address these priorities.
4. Propose requirements for resident training in research and scholarly activity to the Department’s Postgraduate Education Committee.
5. Establish and update research policies for the Department of Family Medicine.
6. Identify opportunities for cooperation and collaboration with the WRHA Family Medicine with respect to research and/or program evaluation.

**Membership:**
Director, Research (Chair)
Research Associate
Research Facilitator(s)
Two Family Physician Faculty
Two Inter-Professional Faculty
One Family Medicine Resident
Head, Department of Family Medicine
Administrative Director
Program Evaluation Officer

At the discretion of the Chair, membership may be extended to additional individuals.

Committee members are selected by the Research Director from among faculty who have expressed interest and have research training and/or experience. The physician faculty and inter-professional faculty members shall serve three year terms. Under ordinary circumstances, the turnover of faculty committee members should not exceed one per year.

The family medicine resident representative shall serve a one year term, and shall be selected by the group of family medicine residents. The position will begin in January and end at the end of December.

**Meetings:**
The Research Committee will be chaired by the Director, Research.

The Committee shall meet at least three times per year, but may meet more frequently at the call of the Chair. Meeting dates will be set at the outset of the academic year and a schedule provided to all members.
Minutes will be taken by the Family Medicine Office Assistant assigned to Research. Agendas shall be sent out in advance of the meeting, accompanied by minutes of the previous meeting.

**Quorum:**
Since it seems that this group isn’t a decision-making body, no quorum is needed.

**Review:**
Terms of Reference shall be reviewed every 5 years by the Research Committee and approved by Executive Management Committee.