WRITING AN EFFECTIVE RESEARCH PROPOSAL

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The purpose of this handout is not to teach you how to design a research project. Rather it is to help you translate your research plans into an effective research proposal. A well-written proposal will ease the process of obtaining institutional and ethical approval and will increase your chances of obtaining funding for your project.

The writing of this booklet was guided by our experience writing proposals but also on our experiences as reviewers on institutional and granting agency review panels.

The booklet is designed for health sciences researchers conducting quantitative, clinical research. However, the general concepts are applicable to most areas of inquiry.

ELEMENTS OF A RESEARCH PROPOSAL

* Title

* Abstract

* Study Problem

* Rationale/Relevance of the Project

* Literature Review

* Specific Study Objectives

* Research Methods
    I. Study design
    II. Subjects
            Inclusion/exclusion criteria
            Sampling
            Recruitment plans
            Method of assignment to study groups
    III. Data collection
            Variables: outcomes, predictors, confounders
            Measures/instruments
            Procedures
    IV. Intervention
    V. Statistical considerations
            Sample size
            Data analysis

* Ethical Considerations
    Consent form
    Privacy of information

* Work Plan

* Budget

* Research team

* Dissemination Plan

KEYS TO SUCCESS TO WRITING A GOOD PROPOSAL

Overall Quality of the Study
* Good research question
* Appropriate research design
* Rigorous and feasible methods
* Qualified research team
* Research questions matches data collection/data analysis

Quality of the Proposal
* Informative title
* Self-sufficient and convincing abstract
* Clear research questions
* Scholarly and pertinent background and rationale
* Relevant previous work
* Appropriate population and sample
* Appropriate measurement and intervention methods
* Quality control
* Adequate sample size
* Sound analysis plan
* Ethical issues well addressed
* Tight budget
* Realistic timetable
* Identify strengths and limitations

Quality of the Presentation
* Clear, concise, well-organized
* Helpful table of contents and subheadings
* Good schematic diagrams and tables
* Neat and free of errors   Adapted from Hulley & Cummings

Types of Shortcomings in NIH Grant Applications for Clinical Research That Fared Poorly

Type of shortcoming	Number of applications
A. Research problem	
Hypothesis: ill-defined, lacking, faulty, diffuse, unwarranted	120
Significance: unimportant, unimaginative, unlikely to provide new info	77
B. Experimental Design	
Study group or control: inappropriate composition, number, characteristics	103
Technical methodology: questionable, unsuited, defective	168
Data collection procedures: confused, inappropriate	104
Data management & analysis: vague, unsophisticated	80
C. Investigator	
Inadequate expertise or unfamiliarity with literature, insufficient time	43
D. Resources	
Inadequate setting, support staff, lab, equipment. Restricted access to patient population	9
Total number of shortcomings	704
Number of applications	256

BEFORE YOU START

Developing a research proposal takes time. The process starts by identifying a general area or research and then developing a focused research question to be answered. Next a research protocol is created. The protocol needs to be appropriate to the research question, but also feasible in terms of time, resources and ethical considerations. The research proposal is the formal description of this process. The first part of the proposal will include the research question to be answered along with a statement of why the area of research is important and what is known already. The second part of the proposal is the methods section, where the plan for answering the research question is given. Depending on why the research proposal is being written (ethical approval, submission to funding agency), other sections may need to be included in the proposal.

When you are ready to start writing the research proposal, the first step is to carefully read over the guidelines of whatever agency you are submitting it to. These guidelines will give the deadlines for submission and instructions for the length, structure and format of the proposal. Proposals that are late or do not meet the agency's guidelines will usually be returned without being reviewed. Therefore, it is well worth the effort to obtain and carefully read the guidelines prior to writing your research proposal.

Title

Examples:

Preoperative Anxiety (too brief)

The effects of a counseling program by nurses on preoperative anxiety in children undergoing tonsillectomy. (concise but gives sufficient information)

Keys to Success
* Informative
* Succinct
* Interesting

STUDY PROBLEM AND GENERAL PURPOSES OF RESEARCH

Study Problem: Health care issue that is a concern or a problem.

Research Purpose: Broad statement indicating the goals of the project.

Different types of purposes include:
    Exploration
    Description
    Explanation
    Prediction/Control

Some agencies want to know what are the overall objectives of the research program (i.e. long-term goals) and what are the specific aims of the current project (i.e. what is hoped to be accomplished with this project). Some agencies require that research address specific areas or goals set by the agency.

Examples:

1. What are problems related to unplanned caesarean deliveries?

2. Is colonoscopy accessible to all Canadian health care consumers?

Keys to Success
* Relevant
* Clear
* Logically argued

Examples of Problems

> The purpose of this study is to determine the major concerns of women after a cesarean delivery.

> Which operative method of treating a fractured pelvis is better—the Miller procedure or the Morgan procedure?

> Does the administration of analgesic by nurses vs. by patients themselves affect how older patients feel during postoperative recovery?

WHY SHOULD THIS RESEARCH BE DONE?

STUDY RATIONALE

In this section, you are arguing why your study should be done. Granting agencies may have specific high priority areas. Be sure to explain how you study fits into those areas.

Ask yourself:
1. Will this study generate new knowledge?
2. Will the study benefit patients, advance understanding or influence policy?
3. Will the study fill gaps in existing knowledge or resolve current controversies?

Generally a study should do more than just generate new knowledge. The knowledge should in some way be useful, either by leading to a tangible benefit such as improved patient care, or a less tangible one such as addressing an area of controversy
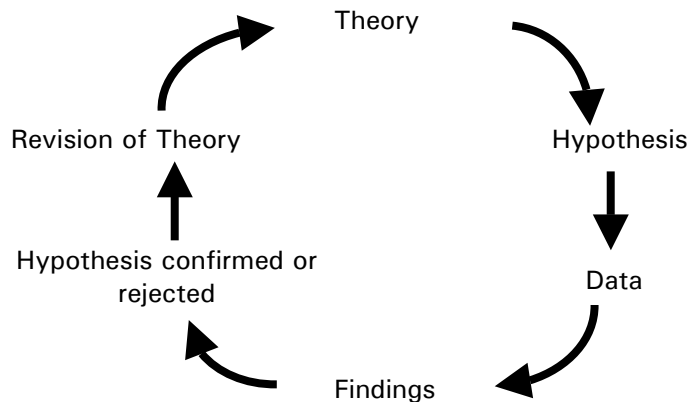
Keys to Success
* Positive answer to question 2 and/or 3 above
* Fits in the granting agency's terms of reference/mandate

LITERATURE REVIEW

A critical summary of research on a topic of interest, generally prepared to put a research problem in context or to identify gaps and weaknesses in prior studies so as to justify a new investigation.

Research tends to be a cyclical process – research findings lead to theory development, theory leads to further research. As a researcher, you can jump into this cycle at many places. In the literature review, you should show that you are jumping in at the appropriate place. If little is known in an area, then very basic descriptive studies designed to give a preliminary understanding about a phenomenon are appropriate. However, if the area is well advanced, that type of study will be inappropriate. When reading the literature review section, a reviewer will be looking to see whether you are sufficiently knowledgeable about the area and whether your proposed work is appropriate for the level of knowledge currently existing in that area.

Theory → Hypothesis → Data → Findings → Hypothesis confirmed or rejected → Revision of Theory → Theory

Keys to Success
∗ Thorough, complete and up to date, but not a recitation of every study ever conducted
∗ Logical
∗ Original research
∗ Primary sources
    Focus on original research and systematic reviews
∗ Well organized/synthesized
∗ Critical appraisal
∗ Build a case for a new study
    Describe any controversial areas objectively
        Include evidence for and against your position
    Identify any gaps in existing knowledge

OBJECTIVES/RESEARCH QUESTIONS/HYPOTHESES

Identifying the research problem and developing a question to be answered are the first steps in the research process. The research question will guide the remainder of the design process.

Research Objectives
A clear statement of the specific purposes of the study, which identifies the key study variables and their possible interrelationships and the nature of the population of interest.

Research Question
The specific purpose stated in the form of a question (descriptive/exploratory research).

Hypotheses
The specific purpose stated in terms of a tentative prediction or explanation of the relationship between two or more variables. A prediction of the answer to the research question (explanatory research).

Examples:
1. The purpose of this study is to determine the major physiologic, psychosocial and lifestyle concerns of women two weeks and eight weeks after an unplanned cesarean delivery.

2. Does the administration of analgesic by nurses vs. by patients themselves affect pain intensity during the first postoperative recovery day in older adults?

3. The objective of this study is to determine which operative method of treating a fractured pelvis is associated with a lower risk of postoperative infection—the Morgan procedure or the Miller procedure?

4. Patients resided in rural areas of Alberta are less likely than urban patients to undergo a colonoscopy within 18 months of a curative resection for colorectal cancer.

Functions
1. Provide reviewers with a clear picture of what you plan to accomplish.
2. Show the reviewers that you have a clear picture of what you want to accomplish.
3. Form the foundation for the rest of the proposal.

4. Will be used to assess the adequacy/appropriateness of the study's proposed methods.

Keys for Success

* Only one or two primary research questions or hypotheses: focus on the important question.
* Clear and consistent.
* Key concepts/constructs identified.
* Includes the independent and dependent variables (if applicable).
* Measurable.
* Hypotheses clearly predict a relationship between variables.
* Relevant or novel.

Examples of Problems

> The purpose of this study is to determine if there are differences in pain control with nurse versus patient administered analgesia following surgery.
>
> Research Question: Does the administration of analgesic by nurses vs. by patients themselves affect pain intensity during postoperative recovery in older adults?
>
> Hypothesis: Patients who self-administered narcotics will be more satisfied than patients who receive narcotics administered by nurses.
>
> Sample size: To achieve a power of 80% to detect a 20% difference in the total morphine dose in the first 24 hours surgery, 30 subjects in each group will be required.

STUDY VARIABLES

Variables: Characteristic or quality that takes on different values.

In Research Identify:
∗ Dependent or outcome variables (the presumed effect).

∗ Independent or predictor variables (the presumed cause).

>   Note: Variables are not inherently independent or dependent.
>   In descriptive and exploratory studies, this distinction is not made.

∗ Confounding variables
>   A confounding variable is an extraneous variable that:
>   1) is a risk factor for the outcome variable.
>   2) is associated with the predictor variable.

> *Example*
>
> Dependent variable: undergoing colonoscopy.
> Independent variable: residing in urban or rural area.
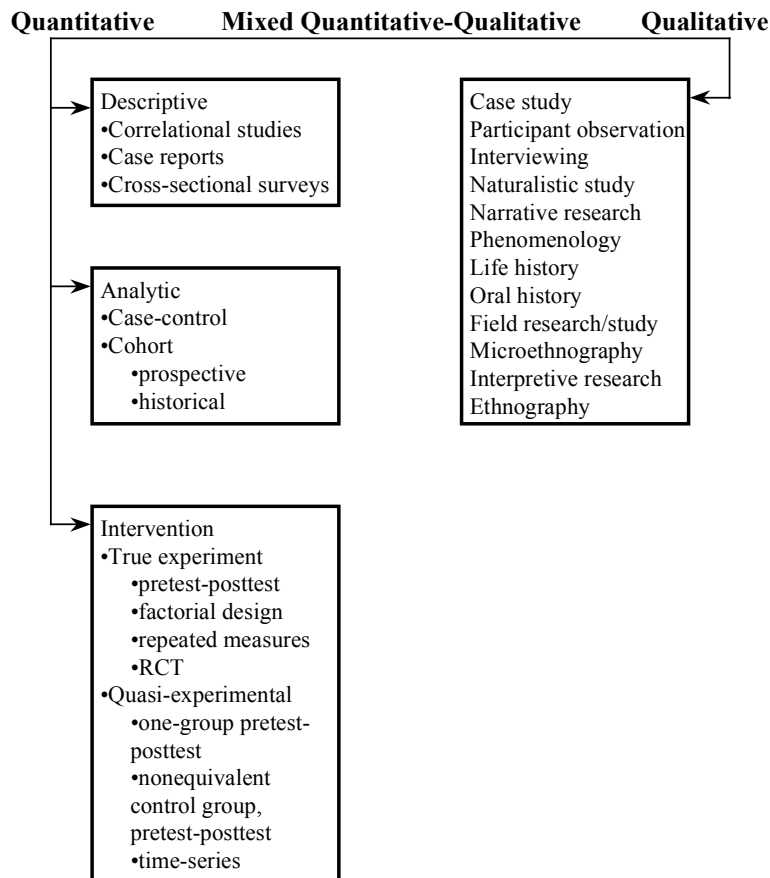> Confounding variable: degree of specialization of physicians.

Keys to Success
∗ Clearly identify study variables and their role in the study
∗ Select only variables that are measurable

RESEARCH/STUDY DESIGNS

The overall plan for obtaining an answer to the research question or for testing the research hypothesis.

Overview of Study Designs

Quantitative	Mixed Quantitative-Qualitative	Qualitative

Descriptive
•Correlational studies
•Case reports
•Cross-sectional surveys

Case study
Participant observation
Interviewing
Naturalistic study
Narrative research
Phenomenology
Life history
Oral history
Field research/study
Microethnography
Interpretive research
Ethnography

Analytic
•Case-control
•Cohort
    •prospective
    •historical

Intervention
•True experiment
    •pretest-posttest
    •factorial design
    •repeated measures
    •RCT
•Quasi-experimental
    •one-group pretest-
    posttest
    •nonequivalent
    control group,
    pretest-posttest
    •time-series

Will have been chosen based on:
1. Research question/hypothesis.
2. Strengths and weaknesses of alternative designs.
3. Feasibility, resources, time frame, ethical considerations.

Examples:

1. The purpose of this study is to determine the major physiologic, psychosocial and lifestyle concerns of women two weeks and eight weeks after an unplanned cesarean delivery.

Methods
We will use a descriptive survey design in which all patients at weeks two and eight following an unplanned cesarean delivery will be mailed a questionnaire designed to assess physiologic, psychosocial and lifestyle concerns.

Example:

2. Patients residing in rural areas of Alberta are less likely than urban patients to undergo a colonoscopy within 18 months of a curative resection for colorectal cancer.

Methods
This will be a cross-sectional survey. Patients with a diagnosis of colorectal cancer who underwent a curative resection will be mailed a questionnaire 18 months following surgery asking about diagnostic tests performed since surgery.

or

This will be a historical cohort-study. Patients with a diagnosis of colorectal cancer will be identified using the Alberta Cancer Registry and divided into two groups based on place of residence. Subsequent colonoscopies will be detected by linkage to the Alberta Health Insurance Claims Database for the 18 months following surgery.

Example:

3. Does the administration of analgesic by nurses vs. by patients themselves affect pain intensity during postoperative recovery in older adults?

Methods
This will be a two-group randomized clinical trial. Preoperatively patients will be randomized to nurse-administered or patient administered post-operative analgesia.

Keys to Success
* Clearly identify and label study design using standard terminology.
    * Quantitative/qualitative
    * Intervention/descriptive
    * Cross-sectional/longitudinal
    * Prospective/retrospective
    * True Experiment/Quasi-Experiment

* Must specify the major elements of the design
    * Variables, instruments
    * Subjects: sampling frame, sample size, selection procedures
    * Timing of testing/intervention

* Use a diagram if needed

* Must be consistent with objectives/hypotheses.

* Must justify choice of design:
    * appropriate choice to answer question
    * lack of bias/validity
    * precision/power
    * feasible
    * ethical

Examples of Problems in Describing Research Designs

A randomized quasi-experimental design.   (quasi-experimental studies are not randomized)

The primary objective is to determine if coffee drinking causes pancreatic cancer.

A case-control study will be conducted.   (case-control studies can determine associations but not causation)

1. Who will be studied?
2. How will they be recruited?
3. How will they be allocated to study groups? (if appropriate)

1. Who Will be Studied

A. Specify eligible subjects
* Target population: clinical & demographic characteristics
* Accessible population: temporal & geographic characteristics
   ⇒ Inclusion/Exclusion Criteria

Examples

Women following an unplanned cesarean delivery at the Foothills hospital between January 1 and March 30, 1997.

Inclusion Criteria:
1. Age > 16
2. English-speaking
3. Calgary resident

Exclusion Criteria:
1. Refuse to give informed consent
2. Concomitant severe medical problem preventing   participation

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All patients undergoing elective orthopedic surgery of the knee, ankle or shoulder at the Peter Lougheed Centre.

Inclusion Criteria:
Age > 18
Able to understand instructions

Exclusion Criteria:
Allergy to study medications
Drug/alcohol dependence
Surgery completed after 2000H
Refuse to give informed consent

B. How will they be selected

Sampling: the process of selecting a portion of the population to represent the entire population of interest (target population).

Types of Sampling

1. Probability: each element in the population has an equal, independent chance of being selected. The goal is to obtain a sample representative of the target population. Nonprobability samples may differ in important ways from the target population because of how they were selected (selection bias). This is of greatest concern when the study is defining the characteristics of a population (i.e. a survey).

> Examples:
> * Simple random sampling
> * Stratified random sampling
> * Cluster sampling

2. Nonprobability
> * Consecutive sampling: commonly used in intervention studies.
> * Convenience sampling
> * Purposive sampling: commonly used in qualitative research.

Keys to Success
* Clear description of study population.
* Appropriate inclusion/exclusion criteria.
* Justification of study population and sampling method (bias).
* Clear description of sampling methods.

Examples

1. Consecutive patients admitted to the Peter Lougheed Hospital for orthopedic surgery.

2. The survey will be mailed to a random sample of 100 women who underwent a Cesarean section from January 1 to December 31, 1996. Sampling will be stratified based on the hospital where they delivered.

3. All patients who underwent curative surgery for colorectal cancer between April 1, 1985 and March 30, 1994 in the Province of Alberta.

4. We will recruit a convenience sample of 25 patients attending the prenatal clinic.

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2. How Will They Be Recruited?

Describe what methods will be used to recruit subjects. Important to document that the study will be feasible and that there will be no ethical problems.

Examples

1. Patients admitted for orthopedic surgery will be asked by their attending surgeon for permission to be contacted about the study. Those who agree will be seen by the study nurse who will explain the nature of the study to the patient and assess eligibility for the study. Willing patients will then be seen by the principal investigator and informed consent obtained.

2. A poster will be placed in the prenatal clinics requesting people who are interested in participating in a research study to complete and return a stamped, self-addressed card.

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3. How Will They Be Allocated To Study Groups?

Random Allocation: The assignment of subjects to treatment conditions in a manner determined by chance alone.

Goal of Randomization: to maximize the probability that groups receiving differing interventions will be comparable.

Goals of the Randomization Technique
* True random allocation
* Tamperproof
* Allocation concealment

Methods of randomization
* Drawn from a hat
* Random number table
* Computer generated

Methods that are NOT Random
Alternate days of the week
Alternate patients

In the protocol:
∗   Describe the randomization technique in detail
∗   Justify any special techniques used
      stratification
      blocking
      disproportionate randomization

Example

Subjects will be allocated to study groups using simple randomization performed using a computer-generated randomization list and sequentially-number, sealed, opaque envelopes. After a subject has signed informed consent, the next envelope will be opened to determine which treatment the subject will receive.

Subjects will be allocated to active treatment or placebo in a 2:1 ratio. It is believed that this ratio will increase the likelihood that patients will be willing to participate in the study and therefore increase recruitment rates.

Example of Problems in Describing Allocation to Study Groups

We will randomize 50 patients to either treatment or control group. During the 4 weeks of the study, it is anticipated that approximately 60 patients will be eligible. Therefore, a random sample of fifty will be chosen.   (mixing up creating a random sample and random allocation. Must randomized control trials recruit consecutive patients who are then randomly allocated to the different study groups.)

INTERVENTION

In experimental research, the experimental treatment or manipulation. The literature review should have provided a justification for the use of this application, including information on dosing, expected benefits and the risk of side effects. In the methods section, how intervention should be described in terms of when and how it will be administered, dosing, etc.

Keys to Success
∗   Careful description of intervention including potential risks

Be aware of unintended interventions

DATA COLLECTION

Measurement: The assignment of numbers to objects according to specified rules to characterize quantities of some attribute. This can range from a very simple relationship between variables and number (i.e. age) to a very complex relationship (i.e. satisfaction, quality of life).

Scale: A composite measure of an attribute, consisting of several items that have a logical or empirical relationship to each other; involves the assignment of a score to place subjects on a continuum with respect to the attribute.

i.e.   Quality of Life, Patient Satisfaction, General Well Being, Social Support

Criteria for Instrument Selection
* Objective of the study
* Definitions of concept and measuring model
* Reliability: degree of consistency with which an instrument or rater measures a variable (i.e., internal consistency, test-retest reproducibility, inter-observer reliability).
* Validity: degree to which an instrument measures what it is intended to measure (i.e., content validity, concurrent validity and construct validity).
* Sensitivity: ability to detect change.
* Interpretability: the degree to which one can assign qualitative meaning to an instrument's quantitative scores.
* Burden

Questionnaire: A method of gathering self-report information from respondents through self-administration of questions in a paper and pencil format. Often questionnaires include scales.

<u>Keys to Success</u>
* Are the words simple, direct and familiar to all?
* Is the question as clear and specific as possible?
* Is it double question?
* Does the question have a double negative?
* Is the question too demanding?
* Are the questions leading or biased?
* Is the question applicable to all respondents?
* Can the item be shortened with no loss of meaning?
* Will the answers be influenced by response styles?

* Have you assumed too much knowledge?
* Is an appropriate time referent provided?
* Does the question have several possible meanings?
* Are the response alternatives clear and mutually exclusive (and exhaustive)?
* Always pretest questionnaires.
    * Be specific about the purpose of the pretest.
* Use colleagues, potential participants, experts and potential users of the data.

Methods of Collecting Data

1. Personal Interview

Advantages
* Flexible
* High response rates
* Control over who is the respondent and over sequence of questions
* No systematic exclusion of illiterate or physically handicapped people
* Clarification and probing possible by interviewers
* Spontaneous responses may be obtained

Disadvantages
* Expensive
* Possibility of interviewer cheating
* Bias due to socially acceptable answers by respondents
* Age, race or sex of interviewer may introduce bias

2. Telephone Surveys

Advantages
* Less expensive than personal interviewer
* Control over interviewer bias better than in personal interviews
* Higher response rates than mail-out questionnaires
* Fast
* Interviewer can encourage respondent to participate, can probe for incomplete answers and can clarify answers.

Disadvantages
* Non-telephone owners (and possibly those with unlisted numbers) cannot be reached
* May be perceived as a sales pitch
* Certain techniques cannot be used (the use of cards)

* Limit to length of interview
* Interviewer voice may cause bias

3. Mailed Surveys

Advantages
* Inexpensive
* Respondents may be more frank and honest on sensitive issues
* No interviewer bias
* Certain segments of the population may be reached more readily by mail
* Respondents can take time to think about responses

Disadvantages
* Low response rates
* Sequence of question cannot be controlled
* Mail-out questionnaires should be short
* Question with no answer difficult to interpret (i.e., deliberately or accidentally)
* No probing and clarification possible
* Not clear who has completed the questionnaire

Example of Problems

The primary objective is to determine the degree of satisfaction patients have with outpatient surgery. A questionnaire will be mailed to patients that asks about their degree of satisfaction with their hospital stay.

DATA ANALYSIS

Procedures for
1. recording, storing and reducing data
2. assessing data quality
3. statistical analysis

Step 1: Descriptive statistics
* Describe the shape, central tendency and variability
* Looking at variables one at a time: mean, median, range, proportion

Purposes
* Summarize important features of numerical data

* Pick up data entry errors: i.e. 3 genders, age 150
* Characterize subjects
* Determine distribution of variables
* Assess assumptions for statistical tests: i.e. normality

Step 2: Analytic/inferential statistics
* Looking at associations among two or more variables

Purposes
* Estimate pattern and strength of associations among variables
* Test hypotheses

Example

The distribution of the ages of patients undergoing and not undergoing colonoscopy will be examined with descriptive statistics (median, mean, standard deviation) and boxplots. If the normality and equal variance assumptions are satisfied, the difference in mean age in the two groups will be tested using a *t* test. If the assumptions are not met, a non-parametric test will be used (Wilcoxon rank-sum test). All statistical tests will be two-sided. A *P* value of ≤ 0.05 will be considered statistically significant.

Keys to Success
* The analysis section should correspond to the specific objectives: describe the planned analysis for the primary study objective first and then for any secondary objectives.
* Describe the exact statistical methods that will be used.

SAMPLE SIZE

Purpose: To make a rough estimate of how many subjects required to answer the research question. During the design of the study, the sample size calculation will indicate whether the study is feasible. During the review phase, it will reassure the reviewers that not only is the study feasible, but that resources are not being wasted by recruiting more subjects than is necessary.

Two basic methods of sample size estimation
1. Hypothesis-based
2. Confidence interval-based

Keys to Success
* Always justify the sample size
* Provide data necessary to calculate sample size
* State how the estimates were obtained

Example
The sample size estimates were based on the primary hypothesis: Patients who self-administer narcotics post-operatively will have a smaller mean total dose of drug used than patients who receive there analgesia by nurses. From a review of nurse-administered narcotic doses, we estimate that the mean dose of narcotics in this group will be 100 mg with a standard deviation of 40 mg. To achieve a 90% power to detect a 20% difference in the mean narcotic dose, with an alpha of 0.05 using a two-sided test, we estimate that 63 subjects in each group will be required.

Brief Overview of Sample Size Calculations
<u>Hypothesis-based sample sizes</u> indicate the number of subjects necessary to reasonably test the primary study hypothesis. Hypotheses can be shown to be wrong, but they can never be proven correct. This is because the investigator cannot test all people in the world with the condition of interest. The investigator attempts to test the research hypothesis through a sample of the larger target population.

From the data collected, inferences are made about the larger population. For example, if 80% of patients self-administering analgesia report good pain control, whereas only 40% of patients receiving nurse-administered analgesia report good pain control, one would conclude that there is a difference between the two methods and that self-administered analgesia is superior. However, there is always a possibility that since we have only used a sample of all possible patients, there may, in fact, be no difference between the two but the results have just occurred due to chance To test this formally, a statistical test would be done. In this case

the P value is 0.03. This P value means that the probability of obtaining these results or results even more extreme, if in truth there is no difference between the two methods, is no more than 3%. Therefore, either self-administered analgesia is better than nurse-administered analgesia or a very unusual event has occurred. When there is truly no difference between two interventions, but the results of our study suggest there is a difference, a type 1 error has occurred. Generally, studies will accept a 5% risk (α level) of making a type 1 error. The calculated P value is the probability that we may have made a type 1 error.

A type 2 error occurs when we conclude there is no evidence of a difference between two groups, when in truth there is. Most investigators accept a greater risk of making a type 2 error, usually 10% or 20% (β level).

		Truth in the Population	
		Association between predictor and outcome: there is a difference	No association between predictor and outcome: there is no difference
Results in the	Reject null hypothesis: there is a difference	Correct	Type 1 error
study sample	Fail to reject null hypothesis: there is no difference	Type 2 error	Correct

The risk that an investigator is willing to take in making a type 1 or type 2 error are important in determining the sample size. The less willing one is to make an error the more subjects that will be required.
The two other important factors in estimating the sample size is the magnitude of the difference in the outcome (effect size) that the investigator wishes to be able to detect and the amount of variation that is seen between subjects. The smaller the effect size or the larger the variation, the more subjects that will be required. For example, if one wished to detect at least a 20 mg/dl difference in serum cholesterol between two treatment groups, more patients would be needed than if a 40 mg/dl difference was the smallest difference one wished to be able to detect.

Components of the Hypothesis-based Sample Size Calculation
1. Type 1 error (α): falsely rejects null hypothesis
   * Usual risk 0.05
2. Type 2 error (β): falsely accepts null hypothesis
   * Usual risk 0.1 - 0.2
   * Study's power = 1-β

3. Effect size: magnitude of the association in the target population
4. Variability: variability of the outcome variable among the subjects
5. One/Two-tailed tests
6. Type of statistical test: test of means, proportions, etc.

Example
Study Hypothesis: There will be a difference in mean analgesic use of at least 20mg difference between nurse-administered and patient-administered analgesic groups.
Null Hypothesis: There will be no difference.
Effect size = 20mg   Estimate mean for nurse-administered group will be 100mg
Variability: Standard deviation = 40mg
α=0.05 β=0.10
Two-sided test

Computer output
```
. sampsi 100 80, power(.9) sd1(40) alpha(.05)

Estimated sample size for two-sample comparison of means
Test Ho: m1 = m2, where m1 is the mean in population 1
                  and m2 is the mean in population 2
Assumptions:
        alpha =   0.0500   (two-sided)
        power =   0.8000
           m1 =      100
           m2 =       80
          sd1 =       40
          sd2 =       40
        n2/n1 =     1.00

Estimated required sample sizes:
           n1 =       63
           n2 =       63
```

Therefore, necessary sample size: 63 in each group

Confidence interval-based sample size calculations are more applicable to surveys. For example, the investigator may be interested in determining what proportion of a population has undergone has a specific characteristic. This characteristic could be a risk factor (i.e. cigarette smoking), a disease or a history of having undergone a certain health care intervention (i.e. colonoscopy). Since the investigator determine whether or not every person in the population has the characteristic, the investigator must rely on obtaining an estimate of the true population proportion by examining a random sample of the population. How accurate this estimate is will depend in part on the size of the sample. The larger the sample the more closer it is likely to be to the true proportion. In determining how large of a sample is required, the investigator must consider what magnitude of the difference he wishes to tolerate between the sample and the population proportions. For example, is being within ± 10% good enough or is this too large?

For example, an investigator may wish to estimate the proportion of a patients with colorectal cancer that have undergone a colonoscopy within 18 months of surgery. The investigator specifies the maximum discrepancy between the sample and population proportion of ± 5%.

To determine the sample size, the investigator would use the formula

$$n = (z/p)^2 \pi(1\text{-}\pi),$$

> n = the required sample size
> p = the desired maximum discrepancy (i.e. ± 5%)
> π = the population proportion
> z = corresponds to the appropriate z value from the normal
>   distribution for the desired confidence interval,
>   for 95% confidence interval = 1.96
>   for 99% confidence interval = 2.58

Since the population proportion (π) is not know some estimate or range of estimates is required.

So if believe population proportion is about 50% and wish 95% confidence intervals which will be no more than ± 5% of true population proportion,

$$n = (1.96/0.05)^2 0.5(1\text{-}0.5) = 384$$

The required sample size will increase if more precise estimates are required (i.e. ± 2% would require 2401 subjects) or if a 99% confidence interval is desired. The sample size will also change depending on the population proportion as shown in the table below.

	Sample Size Required for ± 5%	
Population Proportion	**95% Confidence Interval**	**99% Confidence Interval**
0.01	15 !!	
0.1	138	239
0.25	288	499
0.5	384	666
0.75	288	499
0.9	138	239

Two things can be seen from the table. First is that the sample size will be largest when the estimated population proportion is closest to 50%. Second is that the formula does not work for very small (or very large) proportions. As a general rule

of thumb, the sample size multiplied by the estimated population proportion should be at least 5. If it is smaller than advice from a statistician should be sought for calculating the necessary sample size. For example, 15 * 0.01 = 0.15.

In the sample size section, the investigator should provide the numbers that were used in calculating the sample size.

Examples of Problems in the Analysis Section

The data will be analyzed with appropriate parametric and nonparametric tests using SPSS for Windows, Version 7.

The data will be analyzed using means, standard deviations, t tests, chi-square tests, correlation coefficients and analysis of variance.

(Neither of these statements indicates how the investigators will actually conduct their statistical analysis. It is often useful to describe how each objective will be addressed or hypothesis tested.)

ETHICAL CONSIDERATIONS

Ethical Principles
* Respect for persons (autonomy)
* Non-maleficence (do not harm)
* Beneficence (do good)
* Justice (exclusion)

Ethical Considerations
1. Scientific validity
2. Recruitment
3. Informed consent
   - Study purpose
   * What does participation involve?
   * What are the alternatives to participation?
   * What are the potential harms and benefits?

Most Institutional Ethics Committees will provide you will be able to provide you with guidance, including a copy of a sample consent form and/or guidelines for questionnaires and telephone surveys

Keys to Success
* Follow guidelines on sample consent form
* Describe recruitment procedures in the proposal

BUDGET

Getting funded is the primary reason for submitting a grant application.

Keys to Success
* Read instructions (i.e., overhead, issues not covered, if in doubt call the person in charge of the grants)
* Itemization of costs
    - Personnel (salary and benefits)
    - Consultants (salary)
    - Equipment
    - Supplies (be complete, include cost per item)
    - Travel
    - Patient care costs
    - Other expenses
    - Indirect costs
* Do not inflate the costs
* Justify the budget
* Enquire about the granting agency's range

GRANTING AGENCIES

Major Variation in Application Forms
* Sections in application form
* Overall amount of detail required
* Components and structure of proposal content
* Personal information
* Budget

Helpful Hints
⇒ Review a successful application
⇒ Start early, pay attention to instructions/criteria
⇒ Carefully develop research team
⇒ Justify decisions (in particular those that reviewers might question)
⇒ Have others review your proposal (Centre for Advancement of Health)

WORK PLAN

* Personnel (include hiring and training)
* Tasks
* Timeline

Example

Principal Investigator	Jan	Feb	Mar	Apr	May	Jun	Jul
Hire personnel	X	X					
Recruit subjects			X				
Train personnel			X				
Supervise personnel				X	X	X	X
Write research report							X
Research Assistant							
Administer treatment				X			
Collect data				X	X		
Enter data					X	X	
Analyze data						X	

COMMON PITFALLS

Pitfall #1

Example:
In this innovative study, we will elucidate, categorize, and illustrate the myriad of characteristics that typify the consumers of emergency health care services. Previous researchers have done a lousy job in view of the fact that their methods were bad. We also had a notion to study this problem. The findings from our pilot study were great. After a thorough search of the literature, we firmly and honestly believe that an in-depth study which generates a large body of useful information will, in the final analysis, allow better management of emergency room resources in view of the fact that health care resources are stretched thin.

"Canada has 2—and only 2—official languages: English and French, so do not write in any other language, such as Medicalese, Psychologese, or Nursing Theory"
DL Streiner, 1996

Keys to Effective Writing
* Simplicity
* Clarity
* Parsimony

Important Rules
1. Avoid jargon.
2. Avoid trendy words
3. Avoid abbreviations
4. Avoid colloquialisms
5. Do not try to sound "intellectual"
6. Avoid redundant phrases
7. Avoid overused phrases

For example:
in view of the fact that	because
utilize	use
elucidate, categorize, and illustrate	describe
an in-depth study	a study
audible to the ear	audible

Other Keys to Success
* Read and reread the grant's guidelines and instructions carefully.
* Always follow formatting instructions: margin size, font size, number of pages.
* Have someone read the proposal.

Pitfall #2:

> The purpose of this study is to determine the major concerns of women after a cesarean delivery.

Unclear: immediately after delivery, a year after delivery?
Concepts not identified: what kind of concerns?

> Which operative method of treating a fractured pelvis is better—the Miller procedure or the Morgan procedure?

Unclear: better what? functional results? fewer complications? shorter length of stay?

> Does the administration of analgesic by nurses vs. by patients themselves affect how older patients feel during postoperative recovery?

Constructs not defined: feel
Unmeasurable: feel

Be as specific as possible:

Does the administration of narcotic analgesics by nurses versus patient self-administration affect pain intensity, as measured by the McGill pain scale, 24 hours following laparoscopic surgery.

Pitfall #3:

> The purpose of this study is to determine if there are differences in pain control with nurse versus patient administered analgesia following surgery.
>
> Research Question: Does the administration of analgesic by nurses vs. by patients themselves affect pain intensity during postoperative recovery in older adults?
>
> Hypothesis: Patients who self-administered narcotics will be more satisfied than patients who receive narcotics administered by nurses.
>
> Sample size: To achieve a power of 80% to detect a 20% difference in the total morphine dose in the first 24 hours surgery, 30 subjects in each group will be required.

What is the primary objective? Do the researchers know?

Pitfall #4:

> A randomized quasi-experimental design.

Pitfall #5:

> The primary objective is to determine if coffee drinking causes pancreatic cancer.
>
> A case-control study will be conducted.

> *Better:*
> The primary objective of this study is to determine if there is an associated between coffee consumption and pancreatic cancer.

Pitfall #6:

> We will randomize 50 patients to either treatment or control group. During the 4 weeks of the study, it is anticipated that approximately 60 patients will be eligible. Therefore, a random sample of fifty will be chosen.

* How will random allocation be performed?

* Why and how will a random sample be obtained?

Pitfall #7:

> The primary objective is to determine the degree of satisfaction patients have with outpatient surgery. A questionnaire will be mailed to patients that asks about their degree of satisfaction with their hospital stay.

Where did the questionnaire come from?
How was it developed?
What does it consist of?
Has it been pretested?
Is it a reliable and valid measure of patient satisfaction.

> *Better:*
> The primary objective is to determine the degree of satisfaction patients have with outpatient surgery. We will use the Patients Satisfaction Scale. This instrument was developed to determine patient satisfaction with outpatient surgery. It is a 15-item self-administered questionnaire. On repeat testing two weeks a part, it had a test-retest reliability of 0.76.

Pitfall #8:

> The data will be analyzed with appropriate parametric and nonparametric tests using SPSS for Windows, Version 7.
>
>   *or in other words*
>
> I do not have the foggiest idea about what I will be doing.
>
>
> The data will be analyzed using means, standard deviations, *t* tests, chi-square tests, correlation coefficients and analysis of variance.
>
>   *or in other words*
>
> The data will be beaten with a bunch of statistical tests in hopes that it will talk.

* Devise an analysis plan not a statistical shopping list.
* Descriptive analysis first.
* Analytic tests second which address specific research questions.

> **Better**
> The mean 24-hour total morphine dose and standard deviation for each study group will be computed. Difference in the mean morphine dose between the two groups will be tested using a *t* test.

Pitfall #9:

> **Example:**
> Statistical analysis will be conducted with the aid of a statistician.

* Name the statistician
* Consultant (?fee) or Co-Investigator
* Attach a letter of support
* Describe the statistician's role

Dr. R. Fisher from the Department of Community Health Sciences will act as a statistical consultant. He has calculated the estimated sample size and will aid in the analysis of the data.

or

Dr. R. Fisher from the Department of Community Health Sciences will be hired to conduct the statistical analysis.

or

Dr. R. Fisher from the Department of Community Health Sciences will be a co-investigator in this study. He has participated in the design of the study and has written the sample size and data analysis sections of the protocol. He will be responsible for creation of the study database, performing validity checks on the data, and for conducting the data analysis.

Pitfall #10: Missing Items

* Signatures
* Budget items
* Sections: sample size

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