

## Research Design/Research Approach

The research design is the master plan specifying the methods and procedures for collecting and analyzing the needed information.

Begin this section with a declarative statement telling the reader what your study design is. Examples would include: “This is a cross-sectional study of the prevalence of.....” “This study is a retrospective analysis of existing clinical data about.....” “This study is a randomized, double-blind, placebo-controlled clinical trial examining the question whether.....”

**Explain in detail** how you intend to conduct this study. This explanation will follow directly from your statement regarding the kind of study design you are proposing. This section should take the reader step-by-step through exactly what you intend to do.

- a. Include the duration and time frame of the study.
- b. If the study is a multi-center study, describe what other institutions are involved and what they are contributing to the research.
- c. Describe your proposed study population in detail. Address the issue of generalizability. Explain why this population is a good one to use in addressing your research question.
- d. Detail specific inclusion and exclusion criteria. Justify any exclusion.
- e. Be sure to consider the issue of a control group if it is pertinent to your study design.
- f. Explain how prospective study subjects will be identified and recruited.
- g. Explain all your methods, what materials you will use, what procedures will be carried out, what will happen to your subjects.
- h. If specific screening tools, validated instruments, questionnaires, flyers, advertisements, or brochures, etc. are to be used, include them as an appendix to your proposal.
- i. Describe the informed consent process. Who will conduct the informed consent process? How and where will it be done? What efforts will you make to promote understanding on the part of the prospective subject?
- j. If randomization is part of your study design, describe how it will be performed (i.e., computer generated, table of random numbers, etc.) Remember that randomization cannot occur until study subjects have consented to be in the study.
- k. If your study design involves blinding, explain how blinding will occur.
- l. How will you assure that participation is entirely voluntary? If you think that informed consent is not necessary, justify that position.
- m. Include how your methods will protect human subjects. Address assuring absence of coercion, protecting confidentiality, ensuring patient safety as appropriate.
- n. Detail what data points will be collected. Include data collection sheets as an appendix to your protocol.

- o. Explain how your data will be monitored for safety. Present any plans for interim analysis if appropriate. Present your medical monitor if you think your research is more than minimal risk.
- p. If you think your research is minimal risk, explain that position.
- q. Explain your anticipated statistical analysis based on the data points that you expect to collect. State what your dependent (outcome) and independent variables are. Explain what statistical tests will be used to analyze the variables. Seek statistical consultation as appropriate.
- r. Address sample size calculation including what assumptions you made to arrive at your proposed sample size. Seek statistical consultation for this section as appropriate.
- s. Explain how your study design will produce a credible answer to your research question. Explain the limitations of your study design. All designs have limitations.

### **Three traditional categories of research design:**

1. Exploratory
2. Descriptive
3. **causal**

The choice of the most appropriate design depends largely on the objectives of the research and how much is known about the problem and these objectives.

### **Basic Research Objectives and Research Design**

#### **Explanatory research**

Explanatory research focuses on why questions. For example, it is one thing to describe the crime rate in a country, to examine trends over time or to compare the rates in different countries. It is quite a different thing to develop explanations about why the crime rate is as high as it is, why some types of crime are increasing or why the rate is higher in some countries than in others.

The way in which researchers develop research designs is fundamentally affected by whether the research question is descriptive or explanatory. It affects what information is collected. For example, if we want to explain why some people are more likely to be apprehended and convicted of crimes we need to have hunches about why this is so. We may have many possibly incompatible hunches and will need to collect information that enables us to see which hunches work best empirically.

Answering the 'why' questions involves developing causal explanations. Causal explanations argue that phenomenon Y (e.g. income level) is affected by factor X (e.g. gender). Some causal explanations will be simple while others will be more complex. For example, we might argue that there is a direct effect of gender on income (i.e. simple gender discrimination). We might

argue for a causal chain, such as that gender affects choice of training which in turn affects occupational options, which are linked to opportunities for promotion, which in turn affect income level.

<b>Research Objective</b>	<b>Appropriate Design</b>
1. To gain background information, to define terms, to clarify Exploratory problems and develop hypotheses, 2. to establish research priorities, to develop questions to be answered	Exploratory
To describe and measure marketing phenomena at a point in time	Descriptive
To determine causality, test hypotheses, to make “if-then” statements, to answer questions	Causal

**Exploratory research** is most commonly unstructured, “informal” research that is undertaken to gain background information about the general nature of the research problem. Exploratory research is usually conducted when the researcher does not know much about the problem and needs additional information or desires new or more recent information. *Exploratory research is used in a number of situations:*

1. To gain background information
2. To define terms
3. To clarify problems and hypotheses
4. To establish research priorities

**A variety of methods are available to conduct exploratory research:**

1. Secondary Data Analysis
2. Experience Surveys
3. Case Analysis
4. Focus Groups
5. Projective Techniques

**Descriptive research** is undertaken to provide answers to questions of who, what, where, when, and how - but not why.

1. undertaken with the aim of determining the characteristics of a population or phenomenon
2. Previous knowledge of problem exists
3. High degree of precision or accuracy required

Descriptive Research is a fact finding investigation which is aimed at describing the characteristics of individual, situation or a group (or) describing the state of affairs as it exists at present

**Examples:**

1. Who are the main consumers of organic foods?
2. How many students read the prescribed course literature?
3. Where do most holiday-makers travelling overseas go?
4. When do petrol stations tend to raise their prices?

Two basic classifications:

- a. Cross-sectional studies
- b. Longitudinal studies

**Cross-sectional studies** measure units from a sample of the population at only one point in time. Sample surveys are cross-sectional studies whose samples are drawn in such a way as to be representative of a specific population. On-line survey research is being used to collect data for cross-sectional surveys at a faster rate of speed.

*Longitudinal studies repeatedly draw sample units of a population over time.* One method is to draw different units from the same sampling frame. A second method is to use a “panel” where the same people are asked to respond periodically. On-line survey research firms recruit panel members to respond to online queries

**Two types of panels:**

- a. Continuous panels ask panel members the same questions on each panel measurement.
- b. Discontinuous (Omnibus) panels vary questions from one time to the next.

**Causal Research**

Causality may be thought of as understanding a phenomenon in terms of conditional statements of the form “If x, then y.” Causal relationships are typically determined by the use of experiments, but other methods are also used.

**Experiments**

**An experiment** is defined as manipulating (changing values/situations) one or more independent variables to see how the dependent variable(s) is/are affected, while also controlling the affects of additional extraneous variables.

1. **Independent variables:** those over which the researcher has control and wishes to manipulate i.e. package size, ad copy, price.
2. **Dependent variables:** those over which the researcher has little to no direct control, but has a strong interest in testing i.e. sales, profit, market share.
3. **Extraneous variables:** those that may effect a dependent variable but are not independent variables.

**Two broad classes:**

1. **Laboratory experiments:** those in which the independent variable is manipulated and measures of the dependent variable are taken in a **contrived, artificial setting** for the purpose of controlling the many possible extraneous variables that may affect the dependent variable
2. **Field experiments:** those in which the independent variables are manipulated and measurements of the dependent variable are made on test units in their natural setting