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The Nature and Process of Research

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Chapter Outline

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Learning Objectives

After studying Chapter 1, the reader should be able to:

- Describe the different types of research objectives and their purpose
- Identify the key aspects of the scientific approach and describe how they contribute to obtaining valid results
- Apply theory to guide planning a study and interpreting results
- Describe the inference process
- Describe the major determinants of research validity
- Identify the major stages in the research process and describe how they are interrelated
- Develop a research plan to address a specific research question

Overview

The ultimate goal of health research is to develop and enhance evidence-based policy and practice to promote health and prevent illness and injury. Pursuing that goal requires seeking answers to challenging questions about how complex factors, such as lifestyle, aging, social context, and the physical environment, may influence individual and population

health. Moreover, health-related factors and health outcomes often vary substantially across individuals, populations, settings, conditions, and time. Health research seeks to describe, explain, and predict such variation. It does so by employing a systematic process comprising an integrated series of planning and activities to collect and analyze valid information.

The Nature of Research

Research Objectives

Each research study is focused on at least one specific objective determined by assessing the current state of scientific understanding of a problem and ascertaining how that understanding may be enhanced. Indeed, the first aspect of planning a research study is specifying the objective, which may range from an unstructured exploration of the fundamental

aspects of an emerging problem to a highly structured evaluation of an intervention. As depicted in Box 1.1, the course of studying a particular problem generally entails a progressive series of studies with different objectives. When investigating a new problem about which little is known, initial studies commonly are **exploratory** and descriptive, with an objective to gain a basic understanding of the problem's nature and scope. The results of such studies might provide a foundation for developing and implementing

an intervention strategy. If subsequent evaluations indicate an intervention is effective, further research might include developing a dissemination plan and proposing evidence-based policy and practice guidelines. Box 1.2 presents examples of research objectives for three different aspects of nutrition research.



Key Concept

Studying a particular problem generally entails a progressive series of studies with different objectives.

The Scientific Approach

Scientific research studies are guided by principles that distinguish them from the observations and conclusions people routinely make during the course of daily living. Deliberately and consistently applying those principles enhances the likelihood of deriving valid conclusions. Certainly, people making observations during the course of daily living also want to draw valid conclusions. However, those conclusions typically are not subjected

BOX 1.1: GENERAL PROGRESSION OF RESEARCH OBJECTIVES

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- Exploration
 - Description
 - Intervention development
 - Evaluation
 - Dissemination

BOX 1.2: EXAMPLES OF RESEARCH OBJECTIVES

Impact of Healthy Vending Machine Options in a Large Community Health Organization

Banner Health worked with its vending machine vendor to increase healthy vending options in 23 sites, including corporate, hospital, and other clinical settings, which provides [sic] vended food choices for employees and clients. We performed an evaluation of this organizational environmental change with the primary research question, “Did increasing the proportion of healthier ‘right choice’ (RC) options in vending machines at Banner Health corporate and patient-care sites decrease the amount of calories, fat, sugar, and sodium vended, while maintaining total sales revenue?”

Source: Grivios-Shah et al. (2018, p. 1426).

Prevalence and Implementation Practices of School Salad Bars Across Grade Levels

The purpose of this article is to report on the prevalence of salad bars in Arizona schools by grade level (elementary, middle, high, and K-12). In addition, we will describe characteristics of school salad bars including type, format, and foods served on the salad bars by grade level.

Source: Bruening, Adams, Ohri-Vachaspati, & Hurley (2018, p. 1376).

Physician Characteristics Associated With Sugar-Sweetened Beverage Counseling Practices

The objectives of this exploratory study were as follows:

1. To investigate what topics physicians discuss with patients who are overweight or have obesity when providing SSB-related counseling.
2. To examine the association between physicians’ personal and medical practice characteristics, including physician personal SSB intake, and their SSB-related counseling practices for patients who are overweight or have obesity.

Source: VanFrank, Park, Foltz, McGuire, & Harris (2018, p. 1366).

to the same scrutiny and standards as are applied to scientific research. Key components of the **scientific approach** are as follows:

- Objectivity
- Control
- Replication

Objectivity

To the extent possible, a research study should be conducted with **objectivity**, whereby researchers maintain an impartial posture, which sometimes is called *value neutrality*. The goal is to prevent **researcher bias** (also called “investigator bias” or “experimenter bias”)

whereby personal values might influence how researchers conduct a study and interpret its result. This threat to research validity especially is a serious concern in health research because it might lead to implementing an ineffective procedure or policy or even contribute to adverse health outcomes. It is not ethical to conduct a study or interpret its result deliberately in a biased manner. Nevertheless, researcher bias may be introduced inadvertently. Therefore, several strategies may be employed to guard against it.

Monitoring. Throughout the research process, it is important to monitor the research environment to identify potential sources of bias and employ appropriate countermeasures whenever feasible. There are two basic approaches to monitoring. One is **self-monitoring**, which involves routinely conducting self-reflective checks. Such checks are most effective when collaborating with colleagues who are committed to holding one another accountable. The other approach is **independent monitoring**, whereby by a third party (e.g., other researchers, practitioners, or community leaders) provide oversight for how a study is planned, conducted, and reported. This approach is more effective than self-monitoring because independent monitors have no vested interest in the research results. Such oversight may be exercised informally or semiformally, for example by sharing a research plan and progress reports in “brown bag seminar” presentations. Formal oversight typically involves convening an **advisory panel** of professional and/or lay experts that reviews plans and progress according to a predetermined protocol and schedule. Self-monitoring always should be employed. When feasible, the best practice is to employ both self- and independent monitoring.

Blinding. When evaluating an intervention, researcher bias might be introduced by favoring subjects in a **treatment group** that receives the intervention over ones in a **control group** that does not receive it. For example, as compared to control subjects, treatment subjects might be provided a more comfortable physical setting, or staff might communicate with them in a more supportive manner. Such actions may bias a study's result in favor of the treatment condition demonstrating a more positive outcome than the **control condition**. Consequently, a result might suggest an intervention is more effective than it actually is, or that it is effective when actually it is not.

Researcher bias may be prevented by employing a **researcher blind**, whereby researchers are not aware of which participants are assigned to which study condition/group. The underlying logic is that researchers and staff are likely to manage subjects and their data equitably if they do not know to which study condition subjects are assigned. Researcher **blinding** is implemented by engaging a third party to assign subjects to conditions using nondescript labels that do not disclose their assignment while a study is being conducted. The labels should be assigned using a random procedure to avoid a pattern, such as “Group A” always is treatment and “Group B” always is control. A **full blind** is applied at the time subjects are assigned to study groups, and the third party maintains custody of records regarding study condition assignments until all data are collected and analyzed. Thus, researchers may derive conclusions about differences in group outcomes while shielded from any potential influence associated with knowing to which conditions subjects were assigned.

Sometimes a full blind strategy is not possible. For example, if resources are not sufficient to employ independent health education staff, the researchers themselves might conduct educational sessions that are part of an intervention. Thus, they would know which subjects participate in those sessions. In such a situation, a **partial blind** might be applied, whereby the researchers are blinded to subject assignment during one or more parts of a study. For example, it might be feasible to apply a blind during data analysis by having a third party designate study conditions using nondescript labels that are disclosed only after data analysis is complete. Another example is data collection staff, such as interviewers,

might be blinded regarding the condition to which subjects are assigned. That strategy might protect against potential **interviewer bias**, such as differences in probing or asking leading questions owing to expectations of obtaining certain types of responses from treatment versus control subjects.

In addition, validity may be enhanced by employing a **subject blind**, whereby the subjects are not told to which study condition they are assigned until after an intervention is implemented and outcome data are collected. The goal is to prevent study outcomes from being influenced by subjects reacting to their condition assignment. For instance, subjects who know they are assigned to receive a new intervention might expect to experience change, which might lead them to overreport positive outcomes and/or underreport negative outcomes. An example is that smoking cessation program participants might be reluctant to admit failure and not report occasions when they smoke cigarettes postintervention. Consequently, researchers might overestimate positive outcomes attributable to the smoking cessation program. On the other hand, control group subjects who are disappointed at not being assigned to receive an intervention might independently seek an alternative treatment outside the research context. If such compensatory behavior decreases control group smoking prevalence, the smoking cessation program's effectiveness might be underestimated. The term **single blind** applies to situations when only members of the research team or only subjects are blinded. In a **double blind** protocol, both researchers and subjects are blinded.

Empirical assessment. Scientific research results are derived from analyzing data collected through systematic empirical observation (Chapter 15). Furthermore, to the extent possible, analytic procedures should be employed that yield the same result regardless of who performs the analysis. The strongest support for the validity of data analysis is obtained when data are made available for independent verification of results by other researchers.

Full disclosure. **Full disclosure** includes reporting results, it is essential to disclose all aspects of how a study was designed and conducted so others may evaluate its validity and replicate it. When limitations of publication space or presentation time restrict the detail that may be reported, such as for a complex sampling design, a long section of a questionnaire, or a complex coding protocol, supplemental information should be provided on request or at a website. Full disclosure includes reporting all significant unanticipated problems encountered while conducting a study (e.g., recruiting subjects, gaining access to sites, staff turnover, and travel conditions), describing how they were addressed, and assessing their potential impact on a study's result.

Peer review. Most research studies undergo **peer review**, whereby independent researchers review a study proposal and/or reports of results. Typically, the peer review process begins when a research proposal is submitted to a funding agency. The proposal is reviewed by other researchers who evaluate features such as the significance of the research problem, innovative aspects of the research approach, the potential to produce important new information, the appropriateness of the study design and procedures, and the research team's capacity to conduct the study (based on training, experience, and resources). When a study is completed, the most rigorous reporting venues are publication in professional journals and presentations at professional meetings that require independent peer review prior to accepting a proposed manuscript or presentation. In most cases, the reviewers (called "referees," hence the term *refereed publication*) are blinded to the identity of the authors to prevent potential conflicts of interest and reviewer bias. Further, the readership or audience may raise questions about the research report and challenge the interpretation of a result.

Control

Control refers to managing the conditions under which a study is conducted and employing systematic protocols throughout the research process to enhance the comparability of results across individuals, groups, populations, settings, and time.

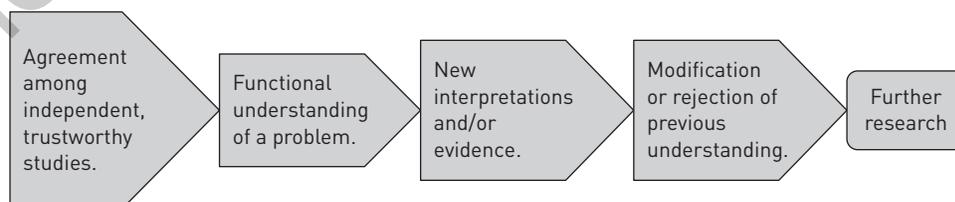
Conditions. Controlling conditions is a hallmark of **experimental research** (Chapter 6), whereby subjects are assigned to two or more **comparison groups**, such as treatment and control. Ensuring that all subjects experience the same conditions, except for intentional exposure to the treatment, enhances the validity of attributing an outcome difference to the treatment rather than to other differences in study conditions. If treatment exposure is the only substantial difference across groups, then treatment exposure is the most plausible explanation for different outcomes. Thus, alternative explanations may be ruled out.

Protocols. Employing systematic protocols reduces variation in activities such as recruiting subjects, exposing subjects to an experimental treatment, collecting data, and coding data in preparation for analysis. Such variation may influence the validity of a study's results. For example, suppose researchers studying stress related to conflict among coworkers give subjects the option to complete a self-administered questionnaire at the workplace or at home. The setting in which they complete the questionnaire might influence their responses. Those who complete it at the workplace, where they might discuss the questions with coworkers, might be inclined to enter responses that are more positive than those who complete the questionnaire in private at home.

Replication

In view of the various challenges to research validity, no study can be considered definitive. The body of scientific evidence about any problem derives validity from the collective results of multiple independent studies. As illustrated in Figure 1.1, when the preponderance of evidence from trustworthy studies converges on a particular answer to a research question, that answer is accepted as a functional understanding of the problem, pending convincing contradictory evidence. **Replication** refers to assessing whether consistent results are obtained from two or more studies using a design and procedures that are as similar as possible. While both the initial and replication studies may be conducted by the same researchers, the validity of replication results is enhanced if studies are conducted independently by different researchers, which controls for potential researcher bias that might enhance the similarity of results across studies.

FIGURE 1.1 ● Building a Body of Scientific Evidence

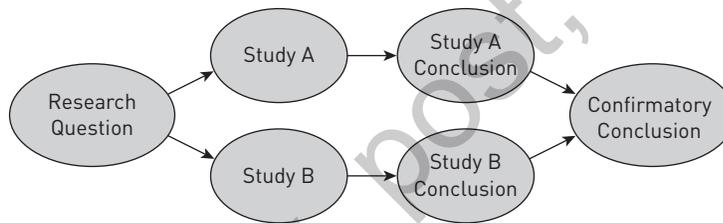


Sequential studies. Most often, replication studies are conducted sequentially. Exact replication across sequential studies is impossible because they are conducted in different time-related contexts. The more time that elapses between studies, the more likely their results will differ, for example owing to changes in social or political factors. Moreover, replication

studies typically are conducted with different subjects and at different sites (e.g., different clinics, schools, or workplaces). Therefore, it is essential to take into account the potential that such factors might influence the comparability of results.

Simultaneous studies. A stronger replication approach is conducting simultaneous studies, as depicted in Figure 1.2. The most effective strategy for this approach is to divide an initial sample or pool of subjects randomly into **subsamples** of equal size so statistical power for analyzing results from the studies will be the same. Most often, it is not feasible to conduct simultaneous studies in the same setting owing to concern about contamination across studies. Instead, settings must be selected to be as similar as possible in terms of key characteristics that might be associated with the studies' results, such as high schools in the same geographic area with similar sociodemographic and academic profiles. Although replication across simultaneous studies may be conducted by the same research team, the best practice is for independent teams to conduct the replication studies. In comparison with sequential studies, an advantage of the simultaneous approach is it controls for potential differences in time-related contextual factors. However, an advantage of the sequential approach is it assesses the time invariance of results. Overall, the strongest replication evidence is derived when similar results are obtained from both approaches.

FIGURE 1.2 • Replication Across Simultaneous Studies



The Role of Theory

A **theory** is a conceptual model (sometimes called a **conceptual framework**) that identifies and defines key factors and describes relationships among them. Accordingly, it guides specifying the factors to measure and the factors to manipulate experimentally, planning data analysis, and interpreting results. Frequently used models of health behavior are the Health Belief Model (Rosenstock, Strecher, & Becker, 1988), the Theory of Planned Behavior (Ajzen, 1991), Social Cognitive Theory (Bandura, 2001), and the Social Ecological Model (McLeroy, Bibeau, Steckler, & Glanz, 1988). Although there are similarities among them, they differ in the factors and relationships they comprise. Some models emphasize individual cognitive factors (e.g., Health Belief Model and Theory of Planned Behavior), while others emphasize social structural factors (e.g., Social Ecological Model). It is essential to be well acquainted with the various theoretical approaches that pertain to a particular problem in order to choose among them appropriately.

For example, suppose the Health Belief Model is chosen to guide developing and evaluating an intervention to increase the rate of mammography screening among a particular

Key Concept

A theory is a conceptual model that identifies and defines key factors and describes relationships among them.

group of immigrant women. It would be posited that a woman is likely to obtain a mammogram if she perceives any of the following:

- She is susceptible to getting breast cancer (perceived susceptibility).
- Getting breast cancer will have a serious impact on her life situation (perceived seriousness/severity).
- Mammography is effective in detecting breast cancer early in its development (perceived benefits).
- She has access to obtain a mammogram (perceived barriers).
- She is capable of obtaining a mammogram (self-efficacy).

Therefore, each of those factors should be measured. Moreover, the intervention should be developed with the goal of influencing one or more of those factors in order to increase the likelihood that women who are exposed to it will get a mammogram.

Reasoning

Inductive reasoning

Inductive reasoning proceeds from empirical observations of specific instances to general conclusions. From an inductive perspective, the general research question may be stated as “What are the key factors that influence this problem, and how are they related?” Results from an inductive research approach may contribute to developing or modifying theories to guide further research, interventions, and policies. The term **grounded theory** refers to theory derived from interpreting empirical observations, rather than having been generated by speculation (Glaser & Strauss, 1967).

Most often, conducting research from an inductive perspective entails employing a fairly unstructured protocol to explore all aspects of a problem in a natural context. Such studies primarily collect **qualitative data** because there is insufficient understanding of the problem to guide collecting **quantitative data** (Chapter 13). For example, a study seeking to identify the key factors and relationships contributing to adolescent obesity might conduct unstructured individual interviews and/or focus groups with adolescents to explore their perceptions about various potential sources of influence on their food choices, such as peer pressure, body image, and the impact of obesity on health. Also, observations might be made of food choices and eating behavior in school lunchrooms.

Deductive reasoning

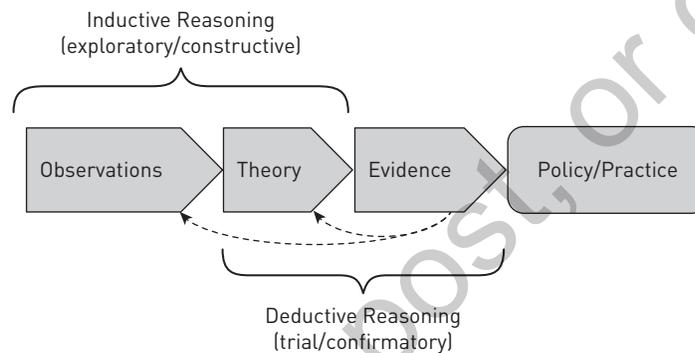
Deductive reasoning proceeds from general postulations derived from theory to specific predictions. From a deductive perspective, the general research question may be stated as “When certain factors are introduced or modified, do other factors that are expected to be related to them change in predictable ways?” A common application of deductive reasoning is evaluating an intervention or a policy. Conducting research from a deductive perspective typically entails employing a structured research protocol and collecting primarily quantitative data to test theory-based expectations (Chapter 15). Using a structured approach optimizes the validity of conclusions by controlling the data collection process and facilitating a standardized analysis. For example, the Theory of Planned Behavior might guide evaluating an intervention to prevent adolescent obesity by promoting healthy food choices in school lunchrooms. According to that theory, an effective intervention would be expected to promote positive attitudes toward eating healthy food to prevent obesity,

promote a peer environment supportive of eating healthy food to prevent obesity, and enhance perceptions of behavioral control over food choices to prevent obesity.

A holistic perspective

The body of scientific evidence about any problem comprises contributions from both inductive and deductive perspectives. Moreover, a study may include aspects of both approaches, although typically one approach is emphasized. Figure 1.3 illustrates the general roles of inductive and deductive perspectives in research. Operating from the inductive perspective, observations are collected to explore a new problem or new aspects of an existing problem, which might lead to constructing a new or revised theory. Operating from the deductive perspective, observations are collected to test the validity of theory-based expectations about relationships or outcomes, which might lead to proposing policy/practice guidelines and directions for further research and/or theory development.

FIGURE 1.3 • Inductive and Deductive Reasoning in Research

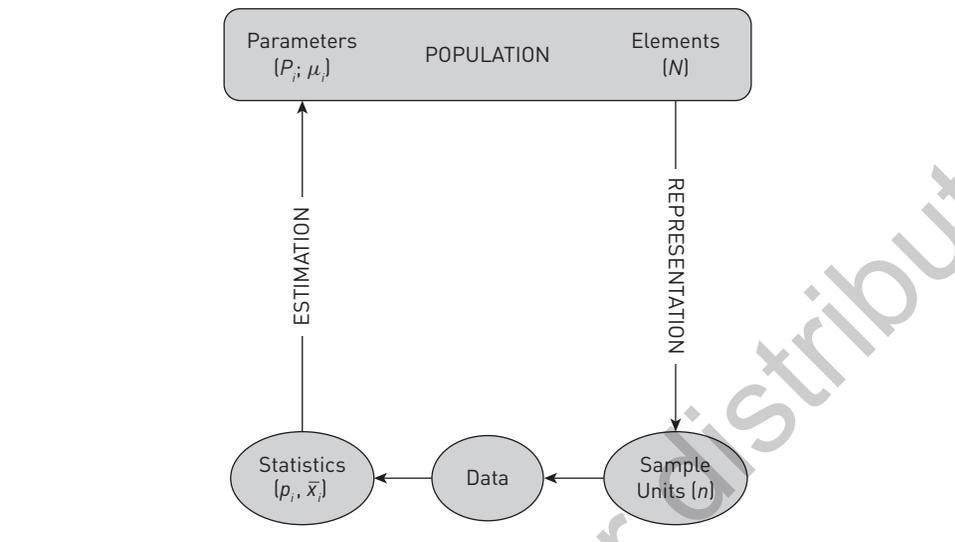


Inference

Most research studies do not include all members of a target population as subjects because doing so generally is prohibitively expensive, time-consuming, and logistically not feasible. For instance, it would not be reasonable to include all members of a population that includes hundreds of thousands or even millions of people, such as all high school students in a large city, all women age 50 or older in an urban county, or all adult cigarette smokers in the United States. Instead, most often research subjects are drawn in a sample, which is a subgroup selected to represent the target population (Chapter 7). Results from studying a sample are analyzed to draw inferences about what the results likely would have been had all members of the target population been studied. Figure 1.4 illustrates the **inference process** and introduces some key terms.

The set of entities targeted for a study is called a **population**. The individual entities in a population are called **elements**, which in most studies are individual people. However, other types of population elements may be studied, such as households, schools, and health clinics. Common notation uses capital Roman or Greek letters to designate population features. For example, N designates the number of population elements. Aggregate population characteristics are called **parameters**. For example, P_i (pronounced “P-sub-i”) designates a population proportion with a particular characteristic (e.g., the proportion of middle school students participating in a school lunch program), and μ (Greek “mu”) designates the population mean (i.e., arithmetic average) for a characteristic, such as the mean

FIGURE 1.4 ● The Inference Process



number of fruit servings consumed per week by middle school lunch program participants. The subscript i indicates a proportion (P_i) or mean (μ_i) may be derived for more than one parameter. For example, for a population of middle school students, (P_1) might indicate the proportion participating in a school lunch program, (P_2) might indicate the proportion that is overweight, and (P_3) might indicate the proportion that is physically active.

Whenever possible, random sampling procedures (Chapter 7) generally are preferred for selecting a representative sample from a target population. The population elements to be included in a sample are called **sampling units**, which might be individual people, households, schools, or other entities, according to how the population elements are specified. While N designates the **population size**, n designates the **sample size**, the number of sampling units selected in a sample. Data are collected from or about the sampling units, and analyses are conducted to describe a sample's characteristics, called **statistics**, which are used to estimate corresponding population parameters.

The term *statistics* commonly is used to refer to analytical procedures, such as Student's t test (to assess differences between two means) (Chapter 15). However, technically those procedures are applied to data about sample characteristics (i.e., statistics), from which the generalized application of the term *statistics* to the analytical procedures is derived. According to common notation, lowercase Roman letters designate sample features. Accordingly, p_i designates the sample proportion with a particular characteristic and \bar{x}_i (pronounced "x-bar sub-i") designates the sample mean for a characteristic. Thus, for example, the sample proportion of middle school students participating in a school lunch program (a statistic) would be used to estimate the proportion of middle school students participating in a school lunch program in the target population (a parameter).

For example, as shown in Table 1.1, if 40% of middle school students in a sample participate in a school lunch program, it would be estimated that approximately 40% of the population of middle school students participate in a school lunch program. Similarly, if the mean number of fruit servings consumed per middle school lunch program participant in a sample is 2.6 servings per week, then it would be estimated that the mean number of fruit servings consumed in the population of middle school students is approximately 2.6 servings per week. As described in Chapter 7, another aspect of making such inferences

TABLE 1.1 • Inferences From Sample Statistics to Population Parameter Estimates

| Variable | Sample Statistic | Inference Direction | Population Parameter Estimate ^a |
|---|-------------------------------|---------------------|--|
| Proportion of middle school students participating in a school lunch program | $p = .40$ (40%) | → | $\hat{p} = .40$ (40%) |
| Mean number of fruit servings consumed per week per middle school lunch program participant | $\bar{x}_i = 2.6$ | → | $\hat{\mu} = 2.6$ |
| Difference in mean number of fruit servings consumed per week by middle school lunch program participants (1) vs. nonparticipants (2) | $\bar{x}_1 - \bar{x}_2 = 0.7$ | → | $\hat{\mu}_1 - \hat{\mu}_2 = 0.7$ |
| Correlation between number of fruit servings consumed per week and body mass index (BMI) among middle school lunch program participants | $r = .35$ | → | $\hat{r} = .35$ |

Note: The ^ symbol above a character representing a population parameter indicates the value is an estimate rather than the parameter's true value, which typically is not known when conducting a research study.

is computing confidence intervals for parameter estimates to account for variation in the random sampling process. Table 1.1 also illustrates that the inference process may be used to estimate a group difference and a correlation between variables.

Research Validity

In the research context, validity refers to the extent to which there is confidence in drawing conclusions based on research results. Validity is of the utmost importance in health research, where results may have a substantial impact on the health and well-being of many people. **Research validity** is a function of all aspects of how a study is designed, conducted, and analyzed. In general, the main factors that affect a study's validity are the following:

- Fit of the research design to the research problem
- Number and types of study groups
- Number and timing of observation points
- Number and types of subjects who participate
- Cooperation of subjects with a study protocol
- Setting(s) where a study is conducted
- Measurement instruments and procedures
- Analytical procedures

There is no definitive approach to assessing research validity. Thus, it is imperative to understand the research process and the factors that may influence validity.

Ultimately, a study's strengths are weighed against its weaknesses and limitations. All studies have weaknesses of some kind. Common examples are procedural variations (e.g., not implementing a data collection protocol consistently from one setting to another) and unavoidable, unanticipated problems (e.g., not being able to contact some subjects due to inclement weather). Moreover, virtually all studies have one or more limitations in the research plan. For example, instead of studying all schoolchildren in the United States, a study might be limited to those attending public schools and/or schools within a certain geographic area.

CHECK YOUR UNDERSTANDING 1.1

- List and briefly describe the major research objectives and their purpose.
- Identify the key aspects of the scientific approach and describe how they contribute to obtaining valid results.
- Describe the role of theory in planning a study and interpreting results.
- Describe the two types of reasoning and their role in research.
- Identify the inference process components and describe how they are related.
- Describe the major determinants of research validity.

The Research Process

Figure 1.5 depicts the general process for planning and conducting a study. Research results often lead to specifying new research questions to be addressed in subsequent studies. Consequently, most studies are conducted in a context whereby they are preceded by other studies about the same or a related problem. Thus, the **research process** is a cyclical approach to building a valid body of scientific evidence about a particular problem.

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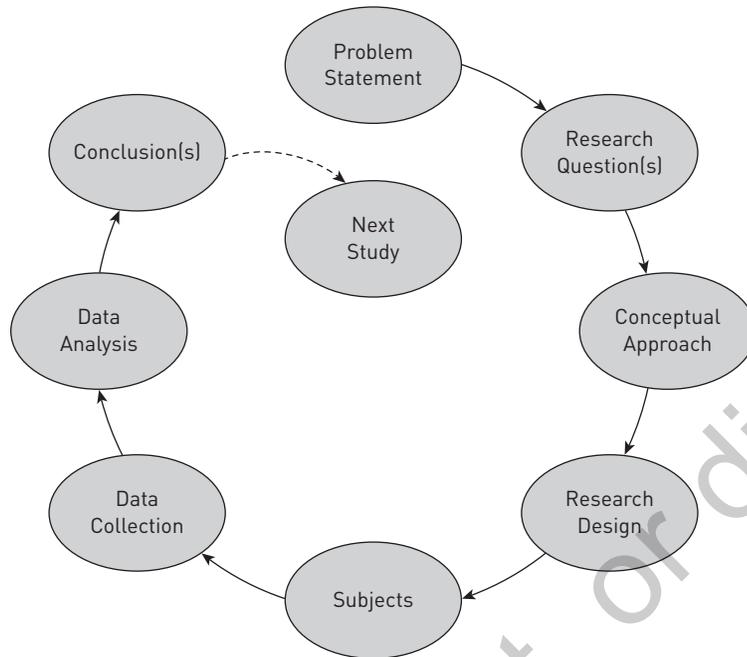
Key Concept

A body of valid scientific evidence is developed by cycling through the research process.

Problem Statement

A study starts a **problem statement** identifying what is to be investigated. The more specifically the problem is stated, the better it provides guidance for the rest of the process. For example, Box 1.3 presents two statements about the same general problem. Statement A is an inadequate guide for planning a study because it does not specify the nature of the racial disparity in mammography screening rates or among which U.S. women the disparity is present. In contrast, statement B is more useful because it specifies three key aspects of the problem: (1) It focuses on women in a certain age group (50–74), (2) it identifies Asians as the main racial group of concern, and (3) it specifies the outcome criterion as the rate of self-reporting having a mammogram within the past two years.

Specifying a problem statement typically draws on a variety of sources. The process might begin with informal observation, such as noticing matters regarding health issues experienced professionally or personally, and reports in the news media (e.g., about an outbreak of gun violence). The most familiar source is a **literature review** to understand the current state of scientific understanding about a particular problem. A literature review might reveal important gaps or limitations in previous studies, such as populations that have not been represented adequately, or at all. Also, it might reveal contradictory results

FIGURE 1.5 • The Research Process**BOX 1.3: PROBLEM STATEMENTS****Problem Statement A**

There is a racial disparity in mammography screening rates among women in the United States.

Problem Statement B

Among women aged 50–74 in the United States, Asian women have the lowest percentage who report having a mammogram within the past two years (Centers for Disease Control and Prevention, 2012).

that should be reconciled. Although most attention is given to publications in professional journals, it is important not to overlook presentations at professional conferences and reports from government and nonprofit agencies. Another valuable resource for specifying a research problem is consulting experts of various types. These include colleagues who are conducting research on the same or related issues, practicing health and social services professionals, and members of the prospective target population.

Research Question

The **research question** specifies the purpose and focus of a study. As such, it is the foundation for planning all the subsequent aspects of the research process. While typically there are multiple facets of virtually any problem, the research question specifies which



Key Concept

The research question is the foundation for all the subsequent aspects of the research process.

one(s) will be the focus for a particular study. Therefore, it is essential to state a research question clearly and specifically to guide developing and implementing a research plan.

Box 1.4 presents a research question corresponding to problem statement B from Box 1.3, specifying that a study will seek to identify the primary factors (rather than all factors) that account for the racial disparity in mammography screening. Also, it indi-

cates the study will be exploratory in nature rather than one that will evaluate an intervention, for example. However, it does not specify the potential factors about which data should be collected. The next stage of the research process, specifying a conceptual approach, provides that guidance.

BOX 1.4: A RESEARCH QUESTION

What are the primary factors that account for Asian women aged 50–74 years in the United States having a lower percentage who report having a mammogram within the past two years than women of the same age in other racial groups in the United States?

Conceptual Approach

The **conceptual approach** specifies the key factors that will be studied and describes expected relationships among them. Thus, it guides identifying the variables to measure, developing a data collection plan, and developing a data analysis plan. Moreover, by specifying how key factors are expected to relate to one another, it guides interpreting a study's result, formulating conclusions, and proposing recommendations for policy, practice, and subsequent research.

A conceptual approach is derived by reviewing theories relevant to the research problem. Then, based on logic and previous research, the one that appears most appropriate for addressing the research question is selected. For example, to investigate a racial disparity in mammography screening among women in the United States, a theory would be considered that may be applied to understanding the process of engaging in health screening behavior, such as the Health Belief Model (Rosenstock et al., 1988) or the Theory of Planned Behavior (Ajzen, 1991). Although there are similarities among these theories, as summarized in Box 1.5, they differ in their key concepts and relationships. When conducting an exploratory study, it is wise to collect data about as many potentially key variables as is feasible to avoid overlooking them. Accordingly, a study to identify the primary factors that account for a racial disparity in mammography screening might collect data about the key factors specified by both the Health Belief Model and the Theory of Planned Behavior, and then assess which theory best fits the data.

Research Design

The **research design** specifies the pattern for how a study will be conducted. In general, a design comprises two main elements: the number and types of study groups and the number and timing of observation points. Research designs are discussed in detail in Chapters 4–6.

BOX 1.5: TWO CONCEPTUAL APPROACHES FOR ADDRESSING THE SAME RESEARCH PROBLEM AND RESEARCH QUESTION

| Health Belief Model | Theory of Planned Behavior |
|---|--|
| Perceived susceptibility for getting breast cancer | Expectation about the outcome of getting a mammogram to detect breast cancer early |
| Perceived seriousness of getting breast cancer | Value of detecting breast cancer early |
| Perceived benefits of detecting breast cancer early | Perceptions of others' beliefs about getting a mammogram |
| Perceived barriers to obtaining a mammogram | Motivation to comply with others' beliefs |
| Self-efficacy to obtain a mammogram | Perceived control to perform the behavior of obtaining a mammogram |

Subjects

The next stage in the research process involves specifying who will be the subjects and how they will be selected (Chapter 7). This stage involves specifying five key characteristics about subjects:

- Target population
- Units of study
- Inclusion/exclusion criteria
- Selection procedure
- Sample size

Target population

The **target population** is the set of entities (people or other elements) for which a study will seek to answer the research question. For example, to address the research question about a racial disparity in mammography screening, a study must include subjects who are Asian women in the United States aged 50–74. However, if only subjects with those characteristics were included, a study would not be able to identify effectively the primary factors that account for the racial discrepancy. That is because it would not be able to distinguish how Asian women differ from women in other racial groups in terms of the factors the conceptual approach posits might be related to mammography screening. Therefore, it would be essential also to include subjects who are women in the United States aged 50–74 but not Asian.

The most comprehensive approach would include women from all other racial groups, specifying the target population as all women in the United States aged 50–74. However, the more diverse the target population, the more challenging and expensive it likely will be to study. Greater diversity (i.e., variance) among the target population requires a larger sample size (Chapter 7). Also, it might require employing multiple strategies for selecting and recruiting subjects and collecting data. Finally, a more complex data analysis plan is necessary to assess differences across multiple groups. An alternative approach would be to focus on comparing only the two groups for which the disparity in mammography screening

rates is highest: Asian and Black/African American women (Centers for Disease Control and Prevention, 2012). That approach would simplify the research plan, be more feasible to implement, and provide a more sensitive contrast. Accordingly, the target population would be specified as Asian and Black/African American women in the United States aged 50–74.

Units of study

The **units of study** are the entities in the target population about which a study will collect and analyze data. For instance, in a study about a racial disparity in mammography screening, the units of study likely will be individual women. However, the units of study also may be entities in which individuals are clustered, such as families, schools, workplaces, or health clinics. As will be discussed regarding cluster sampling design in Chapter 7, the most challenging situation is when the units of study are nested within other units. For example, a study of elementary school students might first select a sample of school districts, then schools within districts, then classes within schools, and finally individual students.

Inclusion/exclusion criteria

Every study must specify subject eligibility criteria. **Inclusion criteria** are characteristics target population members must meet to be eligible as subjects. **Exclusion criteria** are characteristics that disqualify target population members as subjects. Inclusion and exclusion criteria may be based on a variety of factors, including personal attributes (e.g., age, gender, race, health status, health history), behavior (e.g., use of certain services, alcohol consumption, tobacco use), and ability to participate (e.g., availability during the study time period, language proficiency, availability via a particular technological mode such as the internet). Typically, they include several factors in combination.

All target population members should be included unless there is a compelling reason for excluding them. Therefore, the rationale for invoking exclusion criteria must be considered carefully because they restrict the population to which results may be applied. Moreover, an important ethical concern (Chapter 2) is to avoid an inequitable exclusion of target population members. Generally, it is best to specify inclusion criteria first to ensure including as many target population members as possible and then specify exclusion criteria as appropriate. For example, to study a racial disparity in mammography screening among all women in the United States aged 50–74, inclusion criteria might be specified simply by reflecting the research problem and the research question: being women, residing in the United States, and being 50–74 years old.

Exclusion criteria should specify conditions other than those that do not meet the inclusion criteria and thus are redundant (e.g., not being a woman). A common reason for invoking an exclusion criterion is it would be inappropriate to include certain target population members. For example, to study a racial disparity in mammography screening, it would be reasonable to exclude women who already have been diagnosed with breast cancer. Also, in view of the research question's focus on having a mammogram within the past two years, it would be appropriate to exclude women who have not resided in the United States for at least two years.

Other exclusion criteria may be based on logistic factors, such as the data collection mode that will be employed. For instance, if data will be collected conducting in-person interviews, which are expensive and time-consuming, resource limitations might require excluding target population members who reside outside a prescribed geographic area to keep travel expenses and time manageable. Another common exclusion criterion is if subjects are not capable of participating in the study, such as not being sufficiently proficient in the language(s) that will be employed to collect data. Box 1.6 presents an example of inclusion and exclusion criteria for a study of a racial disparity in mammography screening among women in the United States aged 50–74. The criteria are based on the examples in the preceding paragraphs.

BOX 1.6: EXAMPLE OF INCLUSION AND EXCLUSION CRITERIA FOR A STUDY OF A RACIAL DISPARITY IN MAMMOGRAPHY SCREENING

| Inclusion Criteria | Exclusion Criteria |
|--|---|
| <ul style="list-style-type: none"> • Woman • U.S. resident • Aged 50–74 | <ul style="list-style-type: none"> • Diagnosed with breast cancer • U.S. resident for less than two years • Not proficient speaking English or Spanish |

Selection procedure

The main subject selection decision is whether to use a random or nonrandom procedure. In general, random selection provides more reliable target population inferences than nonrandom selection (Chapter 7). Nevertheless, there are situations where nonrandom selection not only is acceptable but might be preferred over random selection, such as when conducting exploratory research using primarily qualitative data collection methods (Chapter 13). Moreover, there are some situations where it is impossible, or nearly impossible, to select a sample randomly.

Sample size

Finally, the number of subjects to include must be specified. Specific strategies for determining sample size are discussed in Chapter 7. The main issue that must be addressed regarding sample size is determining the number of subjects sufficient to provide a trustworthy answer to the research question.

Data Collection

The **data collection** stage of the research process is particularly critical because it provides the information to answer the research question. Moreover, it typically involves the largest investment of resources and often is a point of no return. If serious problems are encountered after data collection is well under way, in most instances a study is not likely to have sufficient unexpended resources available to restart data collection with a revised protocol.

Key variables

It is essential to collect data about all the key variables specified by the research question and the conceptual approach. In addition, data should be collected about relevant background and contextual variables that might enhance understanding relationships among key variables. Care should be taken not to divert a study's focus and resources from the key variables at the expense of collecting data about variables that may be tangentially relevant to the research question.

Subjects

The data collection plan must be appropriate for the target population to secure constructive participation in a study. The first factor to consider is whether the intended subjects will be *able* to participate in the data collection process. For example, if a study will ask subjects to complete a questionnaire online (i.e., a web survey), target population members without internet access will not be able to participate. A second factor is whether the

subjects will be *willing* to participate in the data collection process. For instance, some might decline an invitation to participate in a web survey if they do not think it is worth the investment of their time and effort.

Method

Many data collection methods (also referred to as “modes”) are available. Taking resources into consideration, in general, a study should employ the data collection method that will provide the most valid and reliable measures (Chapter 8) of the key variables. The most substantial distinction among data collection methods is whether the type of data they typically collect is primarily qualitative or quantitative. No single method generally is best in all situations. Indeed, it is becoming increasingly common to employ mixed methods (Chapter 13), such as conducting focus groups in conjunction with a survey.

Data Analysis

Although data analysis is the last stage in the research process prior to drawing conclusions, it is vital to consider the analysis plan throughout the research process. Not attending to the analysis plan until data collection is complete introduces a serious risk of not being able to conduct the analysis that most effectively addresses the research question. Such a situation might occur owing to factors such as an avoidable deficiency in the research design, an unnecessary limitation in the subject selection plan, failing to collect data about a key variable, or not employing the most effective measurement strategy. It is too late to change such aspects of a study when data collection is complete.

“

Key Concept

Consider the data analysis plan throughout the research process.

Before implementing a research plan, it is useful to review it in reverse order. Using that approach, first the data necessary to conduct an appropriate analysis is specified. Next, each preceding stage in the research process is reviewed to ensure the plan for that stage will lead to obtaining the necessary data. For instance, one may assess whether the data collection plan effectively will measure the key variables, the types of

subjects are relevant for addressing the research question, and the research design is appropriate for conducting the planned analysis.

Conclusions

It might appear it is not possible to plan for the conclusions of a study until it is virtually complete. However, conclusions often may be anticipated based on theory and previous research. When planning a study, it is helpful to consider whether anticipated conclusions coincide with the problem statement and research question to ensure the research plan is focused appropriately. Also, consideration may be given to how a study’s conclusions might guide planning a next study.

Next Study

After completing a study, consideration should be given to what might be the focus of a next study about the research problem and what subsequent research question(s) might be addressed. For example, when addressing the research question in Box 1.4, suppose results indicate social support is a primary factor for a disparity in mammography screening. In that case, the next research question might be “Are 50- to 74-year-old Asian women in the United States who participate in a program to enhance social support for obtaining

a mammogram more likely to obtain a mammogram within the next two years?" Four questions generally are useful to ask when considering the focus of a next study:

- What was learned from the completed study that is trustworthy?
- What results from the completed study are questionable (e.g., do not fit the conceptual approach, appear counterintuitive, or contradict other results)?
- What aspects of the research problem merit further investigation?
- What new information would advance understanding the research problem?

Pilot Study

A **pilot study** is a small-scale, developmental study that may be conducted to assess the feasibility of and plan a larger-scale study. Box 1.7 presents four sets of common pilot study conditions and goals.

| BOX 1.7: PILOT STUDY CONDITIONS AND GOALS | |
|---|---|
| Conditions | Goals |
| Exploring a problem | Explore the nature and scope of an emergent problem Explore a new aspect of an existing problem Specify/refine research questions |
| Developing/refining an intervention | Assess potential effectiveness Develop/refine subject recruitment strategy Explore media alternatives Assess/refine delivery protocol Assess target population acceptance Assess feasibility of venues |
| Developing/refining a research method | Develop/refine subject selection strategy Develop/refine data collection protocol Develop/refine measurement instrument Develop/refine data processing/analysis strategy |
| Planning a large, complex study | Demonstrate potential significance Demonstrate feasibility Gain experience and demonstrate competence Specify administrative components |

Plan and design

Sometimes a pilot study may be a complete study. Other times it may focus on developing and assessing one or more components of a research plan. Examples of such situations

include assessing potential sites, negotiating access to and assessing the quality of records, estimating the number of eligible potential subjects in a target population, and developing a measurement instrument.

Subjects

When feasible, pilot study subjects should be selected from the future study target population. The best practice is *not* to include pilot study subjects also as subjects in the future study to avoid bias owing to participating in the pilot study. Sometimes the target population is small, such that selecting pilot study subjects from it would deplete the pool of subjects for a subsequent study. In that situation, pilot study subjects might be selected from another population, such as from another community with similar characteristics in the same city. The number of pilot study subjects typically ranges from about 30 to 100. However, more subjects may be included when planning a large, complex study, such as a nationwide interview survey.

Sites

In general, it is best to conduct a pilot study at the same site(s) that will be included in the future study. It is especially important for a pilot study to include sites with which there is little or no experience, or that might present a particular challenge. However, it is best not to include the same sites in a pilot study and in a future study if the pilot study might cause them to change in a way that is relevant to the research question. For example, conducting a pilot test of an intervention might change the way clinic staff subsequently interact with all patients of a certain type. Consequently, subjects assigned to a control condition for a future study might receive some or all aspects of an intervention that is being assessed. When feasible, that threat to validity may be avoided by conducting a pilot study at one or more alternative sites with similar characteristics (e.g., size, type, and location) as the future study site(s). If the future study will include multiple sites, an alternative strategy is to include only a representative sample of sites in the pilot study. When analyzing results from the main study, it should be assessed whether there are any systematic differences between pilot study sites and those that are included only in the main study. If such differences are detected, they should be taken into account when interpreting a study's result.

Data

The best practice is *not* to merge pilot study data with the future study data. When the number of future study subjects will be large, little is gained in analytic power by merging data from the typically small number of pilot study subjects with the future study data. Moreover, pilot study data and the future study data often may not be compatible for several reasons:

- A pilot study might not be a complete study.
- All aspects of a pilot study are not necessarily implemented in a manner identical with the future study plan.
- The time frame and conditions under which a pilot study is conducted will be different than for the future study.
- Based on the pilot study experience, the future study plan is likely to be revised.

Assessment

When assessing pilot study outcomes, it is common to seek answers to three questions:

- Is a future study worthwhile?
- How can a future study be conducted most effectively?
- How can a future study be conducted most efficiently?

First, the potential significance and return on investment for a future study should be assessed. In doing so, it is important to be mindful that owing to a smaller size a pilot study will not demonstrate outcomes at the same level of statistical significance as a larger study (Chapter 15). Second, potential factors that might threaten a future study's validity should be identified and strategies developed to address them in a future study. Examples are refining an intervention protocol and assessing alternative data collection strategies. Also, pilot study data may be used to estimate variance for key variables or the size of a treatment effect, which are important components for estimating sample size and statistical power for a future study (Chapter 7).

Third, a pilot study may provide valuable experience for refining logistic aspects that will affect the efficiency of a future, large-scale study, such as strategies for gaining access to sites, procedures for selecting and recruiting subjects, coordinating with external collaborators, and supervising data collection staff. Moreover, pilot study data provide a foundation for developing or refining an analysis plan, such as devising a coding scheme for administrative records, identifying potential confounding variables, planning subgroup analyses, or developing a preliminary multiple regression model. Finally, a valuable pilot study outcome is it provides an experiential foundation for refining budget and time schedule estimates.

CHECK YOUR UNDERSTANDING 1.2

- List and briefly describe the stages of the research process.
- Describe how the research process stages are interrelated.
- Describe the general characteristics and purposes for conducting a pilot study.

Key Points

The Nature of Research

Research Objectives

The course of studying a particular problem generally entails a progressive series of studies with different objectives.

The Scientific Approach

Research seeks to derive valid conclusions by following certain principles throughout the research process: objectivity, control, and replication.

The Role of Theory

A theory is a conceptual model that identifies and defines key factors and describes relationships among them.

Reasoning

Inductive reasoning proceeds from empirical observations of specific instances to general conclusions.

Deductive reasoning proceeds from general theoretical postulations to specific predictions about a particular problem.

Inference

Most often, a study focuses on a sample selected from a target population. A sample's characteristics (statistics) are analyzed to draw inferences about the population's characteristics (parameters).

Research Validity

Research validity is the extent to which there is confidence in drawing conclusions based on research results. It is a function of all aspects of how a study is designed, conducted, analyzed, and reported.

The Research Process

The research process is a cyclical approach to building a valid body of scientific evidence about a particular problem. It comprises the following major stages:

- Problem statement
- Research question
- Conceptual approach
- Research design
- Subjects
- Data collection
- Data analysis
- Conclusions
- Next study
- Pilot study (optional)

Review and Apply

Identify a health-related problem that interests you or choose one from U.S. Department of Health and Human Services, *Healthy People 2020 Leading Health Indicators: Progress Update*, available at <https://www.healthypeople.gov/2020/leading-health-indicators/Healthy-People-2020-Leading-Health-Indicators%3A-Progress-Update>.

1. Write a problem statement.
2. Conduct a brief search of the research literature about the problem and describe why it is important.
3. Choose a theory you consider appropriate to guide research about the problem, identify its key factors, and describe how they are related.

4. Write a research question to address the problem.
5. If you were to plan a study to address your research question:
 - a. What key variables would you measure?
 - b. How many and what types of study groups would your research design include?
 - c. Would you collect data at one observation point or more than one?
 - d. What would be the target population and the units of study?
 - e. What inclusion and exclusion criteria would you specify?
 - f. Would you collect qualitative, quantitative, or both kinds of data?
 - g. Without getting into technical statistical aspects, what general type of analysis would be appropriate to answer your research question?
 - h. Review your research plan in reverse order, beginning at the data analysis stage. Did you make any changes in your research plan? If so, why?
6. How might your research plan benefit from conducting a pilot study? Be specific in identifying aspects of your research plan that you might assess in a pilot study.

Study Further

Fink, A. G. (2014). *Conducting research literature reviews: From the internet to paper* (4th ed.). Thousand Oaks, CA: Sage.

Glanz, K., Rimer, B. K., & Viswanath, K. (2015). Theory, research, and practice in health behavior. In K. Glanz, B. K. Rimer, & K. Viswanath (Eds.), *Health behavior: Theory, research, and practice* (5th ed., pp. 23–42). San Francisco, CA: Jossey-Bass.

Rychetnik, L., & Frommer, M. A. (2002). *A schema for evaluating evidence on public health interventions* (version 4).

Melbourne, Australia: National Public Health Partnership. Retrieved from <http://www.health.vic.gov.au/archive/archive2014/nphp/publications/phpractice/schemaV4.pdf>

U.S. Department of Health and Human Services. (2018, last updated March 8). *Definitions of criteria and considerations for research project grant (RPG/X01/R01/R03/R21/R33/R34) critiques*. Retrieved from https://grants.nih.gov/grants/peer/critiques/rpg_D.htm