

Statistical Studies: Statistical Investigations

III.A Student Activity Sheet 2: Treatment of Subjects



There are two ways to categorize data according to its source—as **primary data** or **secondary data**.

Primary data are data that you collect directly. Sources of this type of data include the following:

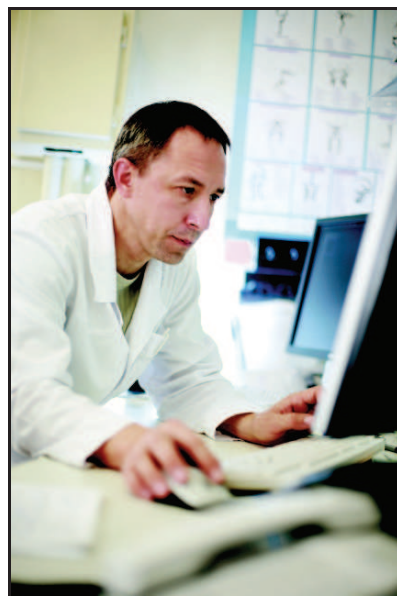
- experiments,
- survey instruments, and
- observation instruments.

When collecting primary data, most researchers run a **pilot study** first. This is a small-scale version of the research plan. What are some reasons to run a pilot study?

Secondary data are data that have been collected by someone else and are available to the researcher. The following are examples of this type of data:

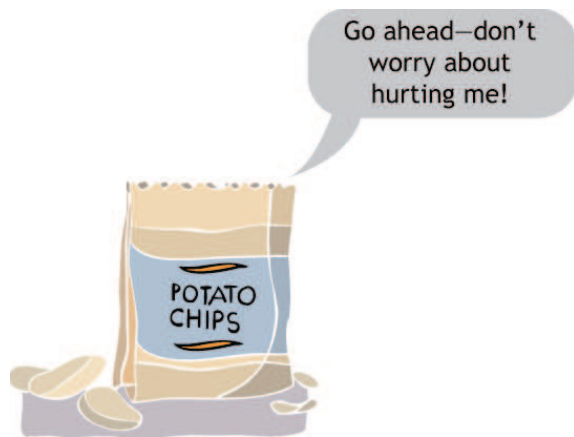
- the Internet, including websites such as the U.S. Census Bureau and other government sites;
- printed materials, such as books, almanacs, newspapers, and magazines; and
- historical documents.

When using secondary data, part of the research plan must include ensuring that the data are reliable. When collecting primary data, you are responsible for doing everything possible to ensure that your participants are well informed and safe.



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One nice thing about a potato chip study is that researchers do not have to worry about hurting the chips, and the chips' permission is not needed! With human participants, you have to be more careful.

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was created by the 1974 enactment of the National Research Act. Its purpose is "to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with these principles." (from Office of Human Subjects Research on the National Institutes of Health website: ohsr.od.nih.gov/guidelines/belmont.html)

The commission developed the following guidelines:

- A. Ethical Principles and Guidelines for Research Involving Human Subjects
- B. Boundaries Between Practice and Research
- C. Basic Ethical Principles
 - 1. Respect for Persons
 - 2. Beneficence
 - 3. Justice
- D. Applications
 - 1. Informed Consent
 - 2. Assessment of Risk and Benefits
 - 3. Selection of Subjects

Issues related to these guidelines include the protection of "vulnerable subjects," recruiting volunteers, payment for volunteers, and so on. To ensure that researchers follow these guidelines, research facilities have **Institutional Review Boards (IRBs)** that must approve all study design plans. If a facility does not have its own IRB, it must contract with an outside source.

The U.S. Department of Health and Human Services' Food and Drug Administration performs inspections of IRBs to ensure that they are working effectively.

(from Food and Drug Administration document at www.fda.gov/oc/ohrt/irbs/reviewboard.pdf)

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You will explore the guidelines further through a class share activity. Discuss the following questions and record your responses.

1. Describe why special classes of human subjects need special protection. Select your choices from the following list: fetuses, women, children/minors, cognitively impaired persons, prisoners, traumatized or comatose patients, terminally ill patients, elderly/aged persons, minorities, students, or employees.
2. Could excluding classes of people from research studies be dangerous?
3. How could a survey or questionnaire be dangerous to participants?
4. Why is *informed consent* of human subjects important to a researcher?
5. What factors should a researcher consider in deciding whether to pay volunteers to participate in a study?
6. **REFLECTION:** How well do you think the 1974 National Research Act protects the rights and privacy of individuals? In what ways does it support or interfere with the goals of researchers in answering important questions?
7. **EXTENSION:** Find out about the Institutional Review Board at a research university in your area or online. Do the IRB's guidelines reflect the provisions of law? Do they go further? Interview a researcher to get his or her perspective on the IRB's provisions.