The self-paced training targets individuals new to research and who may have responsibilities in the conduct of research and focuses on information that may be helpful in understanding the tasks you are asked to carry out.

**PURPOSE AND OBJECTIVES**

The purpose of this training is to promote an understanding of basic research concepts for new research staff. The curriculum is intended for research staff who are involved in research, but who have received little to no formal training in this area.

The primary goal is to assist new research staff in developing an understanding of basic research concepts and an appreciation for the importance of conducting research in keeping with an approved plan. We hope this enhanced knowledge and understanding of research concepts and responsible practices will contribute to the integrity of the research and the value of the research results.

The training is self-paced and provides a brief introduction to basic research concepts that serve as a basis for conducting responsible and sound research. The topics introduce how research is designed and conducted as well as how actions in the conduct of research may influence the integrity of the research project. This training introduces ethical issues associated with the conduct of research and encourages novice research staff to make choices consistent with responsible research practices.

Topics covered were chosen by research methods experts from a variety of different fields. The topics presented are commonly found in academic research methods courses; however, the information has been written using non-technical terminology to appeal to individuals who may be less experienced with this topic.

At the end of the session, trainees will be able to define and/or describe:

1. key research terminology,
2. research practices with the potential to impair or enhance research integrity,
3. important concepts related to research data and management of the data.

**RATIONALE**

Novice research staff comprised of community members, college students and other lay professionals are often involved in the conduct of research. While developing a research ethics training program for novice Latino Community Health Workers (CHWs)/Promotores, we learned that while these individuals are involved in various aspects of a research study (e.g., participant recruitment, data collection and data management) they lacked a basic understanding of research design and methodology. In academic settings, faculty members routinely involve students in the conduct of research. These individuals may also lack prior training in basic research methodology since this type of information is traditionally provided in upper-level courses. Novice research staff may have the responsibilities to screen participants, collect data or enter and analyze research information. In most cases, these individuals have limited formal exposure to research design and the overarching concepts that determine and drive the conduct of research. A basic understanding of research methods is believed necessary for novice research staff to understand research and to conduct research responsibly.

The materials presented introduce basic research concepts to new research staff with little to no formal training in research methodology. This is not a comprehensive training in the subject of research methods. The content provides a basic overview and preliminary framework that should be supplemented by additional resources. These materials may also be used by research investigators as a supplement to training for a specific research activity.

**DEVELOPMENT PROCESS**

The topics covered and content of each session was determined through input from focus groups, interviews and surveys of members of the SDSU research community who involve new research staff (Community Health Workers as well as undergraduate and graduate students) in the conduct of research. The concepts that were identified as important to include in this training were drafted using a variety of research methods texts and feedback and editorial changes provided by research methods experts. Materials were pilot tested by potential end users to determine if the training resulted in increased knowledge of the basic research concepts presented. Findings from the pilot testing will be made available in January 2006.

**ACKNOWLEDGEMENTS**

This training module was developed through support from the Office of Research Integrity within the Office of the Secretary of Health and Human Services (OS) and SDSU’s Graduate and Research Affairs.
As project director, I would like to thank the faculty and staff of San Diego State University (SDSU), SDSU Research Foundation and the University of California, San Diego (UCSD) who provided valuable contributions and insight to the content as well as those who provided extensive feedback about the training during focus groups, expert review and during pilot testing.

Much appreciation to those who participated in the focus groups, surveys and interviews from SDSU including: Stuart Aitken, professor of geography, Marcie Bober, professor of educational technology, Audrey Hokoda, professor of child development, Susan Levy, professor of exercise and nutritional sciences, Robert Pozos, professor of biology and Susan Woodruff, research associate, public health. Very special thanks to Karen Coleman, SDSU professor of public health, Terry Conway, SDSU research professor of public health and Dena Plemmons, UCSD post doctoral fellow and SDSU lecturer of research ethics and responsible conduct in research, for their invaluable feedback and written contributions to complete the final product.

The web design and development is attributed to Padhmavathy Neelamegan, graduate student in the SDSU Computer Sciences degree program, who skillfully headed up our web programming.

To the core development team, thank you all as this was a very challenging project to tackle. My grandest “thank you” does little to acknowledge the contribution of Gayle Simon, SDSU Resource Specialist/Ethics Educator, who took the lead on coordinating every aspect of this project and created a methodical, orderly and manageable path of development which took us from beginning to end. My gratitude also goes to Michael Kalichman, Director of the UCSD Research Ethics Program, for his unrelenting commitment, focused contribution and good humor throughout all aspects of the development process. Lastly, special thanks to Wendy Bracken, SDSU regulatory analyst/ethics educator, who brought her interest in teaching and research and research ethics to help refine content and develop examples that could be managed and understood by our target audience.
HOW TO USE

The web-based format lends itself to a self-paced learning process. Links to glossary terms are embedded so that you can locate more complete definitions of terms to better understand the topic. To enhance the learning process, we have created case examples with subsequent discussion questions to help you critically think about the topics presented. You do not need to have a password or register to access the materials within this module.

TIME NEEDED

The time needed to complete the session is approximately 90 minutes, but may be longer depending on links to additional resources that are accessed and reviewed. This information may also complement training for a specific research project in which novice research staff are involved.
The purpose of this training is to promote an understanding of basic research concepts for new research staff. The curriculum is intended for research staff who are involved in research, but who have received little to no formal training in this area.

The primary goal is to assist new research staff in developing an understanding of basic research concepts and an appreciation for the importance of conducting research in keeping with an approved plan. We hope this enhanced knowledge and understanding of research concepts and responsible practices will contribute to the integrity of the research and the value of the research results.

To access the training, select a topic using the menu bar to the left. Each topic is intended to be reviewed in the order presented. Once you are in a section, use the arrows at the bottom of each page to move forward or back. Definitions to some of the more technical terms are easily found by putting your cursor over the highlighted term.

Case examples are also provided in each section. The case example illustrates the topic and includes discussion questions to assist in understanding the concept. Please use these case examples to critically think about the topic presented and enhance your understanding of this information.
Research is a process to discover new knowledge. In the Code of Federal Regulations (45 CFR 46.102(d)) pertaining to the protection of human subjects research is defined as: “A systematic investigation (i.e., the gathering and analysis of information) designed to develop or contribute to generalizable knowledge.” The National Academy of Sciences states that the object of research is to “extend human knowledge of the physical, biological, or social world beyond what is already known.” Research is different than other forms of discovering knowledge (like reading a book) because it uses a systematic process called the Scientific Method.

The Scientific Method consists of observing the world around you and creating a hypothesis about relationships in the world. A hypothesis is an informed and educated prediction or explanation about something. Part of the research process involves testing the hypothesis, and then examining the results of these tests as they relate to both the hypothesis and the world around you. When a researcher forms a hypothesis, this acts like a map through the research study. It tells the researcher which factors are important to study and how they might be related to each other or caused by a manipulation that the researcher introduces (e.g. a program, treatment or change in the environment). With this map, the researcher can interpret the information he/she collects and can make sound conclusions about the results.

Research can be done with human beings, animals, plants, other organisms and inorganic matter. When research is done with human beings and animals, it must follow specific rules about the treatment of humans and animals that have been created by the U.S. Federal Government. This ensures that humans and animals are treated with dignity and respect, and that the research causes minimal harm.

No matter what topic is being studied, the value of the research depends on how well it is designed and done. Therefore, one of the most important considerations in doing good research is to follow the design or plan that is developed by an experienced researcher who is called the Principal Investigator (PI). The PI is in charge of all aspects of the research and creates what is called a protocol (the research plan) that all people doing the research must follow. By doing so, the PI and the public can be sure that the results of the research are real and useful to other scientists.
According to Trochim (2005), research design “provides the glue that holds the research project together. A design is used to structure the research, to show how all of the major parts of the research project work together to try to address the central research questions.” The research design is like a recipe. Just as a recipe provides a list of ingredients and the instructions for preparing a dish, the research design provides the components and the plan for successfully carrying out the study. The research design is the “backbone” of the research protocol.

Research studies are designed in a particular way to increase the chances of collecting the information needed to answer a particular question. The information collected during research is only useful if the research design is sound and follows the research protocol. Carefully following the procedures and techniques outlined in the research protocol will increase the chance that the results of the research will be accurate and meaningful to others. Following the research protocol and thus the design of the study is also important because the results can then be reproduced by other researchers. The more often results are reproduced, the more likely it is that researchers and the public will accept these findings as true. Additionally, the research design must make clear the procedures used to ensure the protection of research subjects, whether human or animal, and to maintain the integrity of the information collected in the study.

There are many ways to design a study to test a hypothesis. The research design that is chosen depends on the type of hypothesis (e.g. Does X cause Y? or How can I describe X and Y? or What is the relationship between X and Y?), how much time and money the study will cost, and whether or not it is possible to find participants. The PI has considered each of these points when designing the study and writing the research protocol.

There are many kinds of research, however, most of them fall into two categories: descriptive and experimental.
Descriptive Studies

A descriptive study is one in which information is collected without changing the environment (i.e., nothing is manipulated). Sometimes these are referred to as “correlational” or “observational” studies. The Office of Human Research Protections (OHRP) defines a descriptive study as “Any study that is not truly experimental.” In human research, a descriptive study can provide information about the naturally occurring health status, behavior, attitudes or other characteristics of a particular group. Descriptive studies are also conducted to demonstrate associations or relationships between things in the world around you.

Descriptive studies can involve a one-time interaction with groups of people (cross-sectional study) or a study might follow individuals over time (longitudinal study). Descriptive studies, in which the researcher interacts with the participant, may involve surveys or interviews to collect the necessary information. Descriptive studies in which the researcher does not interact with the participant include observational studies of people in an environment and studies involving data collection using existing records (e.g., medical record review).

Case example of a descriptive study

Descriptive studies are usually the best methods for collecting information that will demonstrate relationships and describe the world as it exists. These types of studies are often done before an experiment to know what specific things to manipulate and include in an experiment. Bickman and Rog (1998) suggest that descriptive studies can answer questions such as “what is” or “what was.” Experiments can typically answer “why” or “how.”
Experimental Studies

Unlike a descriptive study, an experiment is a study in which a treatment, procedure, or program is intentionally introduced and a result or outcome is observed. The American Heritage Dictionary of the English Language defines an experiment as “A test under controlled conditions that is made to demonstrate a known truth, to examine the validity of a hypothesis, or to determine the efficacy of something previously untried.”

True experiments have four elements: manipulation, control, random assignment, and random selection. The most important of these elements are manipulation and control. Manipulation means that something is purposefully changed by the researcher in the environment. Control is used to prevent outside factors from influencing the study outcome. When something is manipulated and controlled and then the outcome happens, it makes us more confident that the manipulation “caused” the outcome. In addition, experiments involve highly controlled and systematic procedures in an effort to minimize error and bias which also increases our confidence that the manipulation “caused” the outcome.

Another key element of a true experiment is random assignment. Random assignment means that if there are groups or treatments in the experiment, participants are assigned to these groups or treatments, or randomly (like the flip of a coin). This means that no matter who the participant is, he/she has an equal chance of getting into all of the groups or treatments in an experiment. This process helps to ensure that the groups or treatments are similar at the beginning of the study so that there is more confidence that the manipulation (group or treatment) “caused” the outcome. More information about random assignment may be found in section Random assignment.

Case example of an experiment
An understanding of the basic elements of research is essential for good research practices. Among the most important elements to be considered are variables, associations, sampling, random selection, random assignment, and blinding. For a more detailed explanation of other research concepts, please see the list of references provided at the end of this curriculum.
Variables

The purpose of all research is to describe and explain variance in the world. Variance is simply the difference; that is, variation that occurs naturally in the world or change that we create as a result of a manipulation. Variables are names that are given to the variance we wish to explain.

A variable is either a result of some force or is itself the force that causes a change in another variable. In experiments, these are called dependent and independent variables respectively. When a researcher gives an active drug to one group of people and a placebo, or inactive drug, to another group of people, the independent variable is the drug treatment. Each person’s response to the active drug or placebo is called the dependent variable. This could be many things depending upon what the drug is for, such as high blood pressure or muscle pain. Therefore in experiments, a researcher manipulates an independent variable to determine if it causes a change in the dependent variable.

Case example of independent and dependent variables

As we learned earlier in a descriptive study, variables are not manipulated. They are observed as they naturally occur and then associations between variables are studied. In a way, all the variables in descriptive studies are dependent variables because they are studied in relation to all the other variables that exist in the setting where the research is taking place. However, in descriptive studies, variables are not discussed using the terms “independent” or “dependent.” Instead, the names of the variables are used when discussing the study. For example, there is more diabetes in people of Native American heritage than people who come from Eastern Europe. In a descriptive study, the researcher would examine how diabetes (a variable) is related to a person’s genetic heritage (another variable).

Case example of descriptive study variables

Variables are important to understand because they are the basic units of the information studied and interpreted in research studies. Researchers carefully analyze and interpret the value(s) of each variable to make sense of how things relate to each other in a descriptive study or what has happened in an experiment.
Associations and Cause and Effect

The term association means that two or more things are related or connected to one another like height and weight, cholesterol level and heart failure or exercise and weight loss. Associations can be positive or negative. Positive associations suggest that when one variable is increased, the value of another variable increases (e.g., as height increases, so does weight; as cholesterol level increases, so does the risk of heart failure). Negative associations mean that when a variable is increased, the value of another variable decreases (e.g., exercise is introduced (or increased) and weight decreases). Associations can be found in experimental or descriptive studies. Finding significant associations, either during descriptive or experimental studies, may lead to the development of programs or treatments to remedy a particular problem.

Case example of associations
Sampling

Sampling is the process of choosing participants for a research study. Sampling involves choosing a small group of participants that will represent a larger group. Sampling is used because it is difficult or impractical to include all members of a group (e.g., all Hispanic women in the United States; all male college athletes). However, research projects are designed to ensure that enough participants are recruited to generate useful information that can be generalized to or representative of the group represented.

Case example of sampling
Random selection

Random selection is a form of sampling where a representative group of research participants is selected from a larger group by chance. This can be done by identifying all of the possible candidates for study participation (e.g., people attending the County fair on a Tuesday) and randomly choosing a subset to participate (e.g., selecting every 10th person who comes through the gate). This allows for each person to have an equal chance of participating in the study.

Allowing each person in the group an equal chance to participate increases the chance that the smaller group possesses characteristics similar to the larger group. This produces findings that are more likely to be representative of and applicable to the larger group. Therefore, it is extremely important to adhere to this procedure if it is included in the research design. Ignoring or altering random selection procedures compromises the research design and subsequent results. For example, friends or relatives may be easier or more convenient to recruit into a research study, but selecting these individuals would not reflect a random selection of all of the possible participants. Similarly, it would be wrong to select only individuals who may potentially benefit from study participation rather than randomly selecting from the entire group of individuals being studied. Ignoring random selection procedures when they are called for in the research design reduces the quality of the information collected and decreases the usefulness of the study findings.
Random assignment

Random assignment is a procedure used in experiments to create multiple study groups that include participants with similar characteristics so that the groups are equivalent at the beginning of the study. The procedure involves assigning individuals to an experimental treatment or program at random, or by chance (like the flip of a coin). This means that each individual has an equal chance of being assigned to either group. Usually in studies that involve random assignment, participants will receive a new treatment or program, will receive nothing at all or will receive an existing treatment. When using random assignment, neither the researcher nor the participant can choose the group to which the participant is assigned.

The benefit of using random assignment is that it “evens the playing field.” This means that the groups will differ only in the program or treatment to which they are assigned. If both groups are equivalent except for the program or treatment that they receive, then any change that is observed after comparing information collected about individuals at the beginning of the study and again at the end of the study can be attributed to the program or treatment. This way, the researcher has more confidence that any changes that might have occurred are due to the treatment under study and not to the characteristics of the group.

A potential problem with random assignment is the temptation to ignore the random assignment procedures. For example, it may be tempting to assign an overweight participant to the treatment group that includes participation in a weight-loss program. Ignoring random assignment procedures in this study limits the ability to determine whether or not the weight loss program is effective because the groups will not be randomized. Research staff must follow random assignment protocol, if that is part of the study design, to maintain the integrity of the research. Failure to follow procedures used for random assignment prevents the study outcomes from being meaningful and applicable to the groups represented.

Case example of random assignment
Blinding

Blinding is a technique used to decrease bias on the part of the researcher or the participant. In some studies, the participant is not told to which group they have been assigned. This is called single blinding. There is another level of blinding called double blinding where neither the researcher nor the participant know which group the participant is in until this information is revealed at the end of the study. Blinding can reduce the temptation to ignore random assignment procedures and can reduce any expectations about the potential effectiveness of the treatment or program since group assignment remains unknown by the participant, the researcher or both the participant and researcher. The results are more likely to provide information about the true effect of the treatment or program being tested when blinding is used.

Case example of blinding
Research is designed to gather accurate information to explain concepts or events that are not well understood. Gathering accurate information is a critical part of research. Information gathered for research can be collected in many ways depending on the type of research design that is being used. The method used to gather information depends on the questions that the research will attempt to answer.
Examples of information collection methods

There are many ways to collect information in research. The method that is chosen by the researcher depends on the research question that is being asked. Examples of information collection methods include surveys, interviews, tests, physiological assessments, observations, existing record reviews and biological samples.

A survey is a set of questions for research participants to answer. Surveys can be administered in person, through the mail, telephone or electronically (e-mail or Internet). A survey can be administered to an individual or in a group setting. Surveys are used to gain information about many individuals and may include multiple/forced choice or open-ended questions (e.g., demographics, health, knowledge, opinions, beliefs, attitudes or skills).

An interview is an interaction that involves the researcher and the participant(s) in which questions are presented in person, over the telephone or even electronically (email or Internet). During an interview, questions are asked to obtain detailed information from the participant about the topic under study. The questions may be similar to those asked in a survey.

A test is a form or a physical or mental task for which a normal standard has been determined or for which there are correct answers. A participant’s performance on the test is then compared to these standards and/or correct answers. Tests are used in research to determine a participant’s aptitude, skill, knowledge, health, or mental status as compared to the general population. Tests can be administered in person or through a paper or electronic medium. An example would be students taking a standardized test for academic achievement (e.g., SAT, MCAT, GRE).

Physiological assessments are measurements in which a participant’s physical characteristics are evaluated such as blood pressure, heart rate, or physical strength. In health-related research, physiological assessment may be used to determine the participant’s health status prior to, during, or after the completion of the study. An example would be older adults touching their toes to assess flexibility and reach.

Observations are recordings that are taken of the participant without requiring interaction. These recordings are made while participants are engaged in routine behaviors and are used as an indicator of what participants actually do rather than relying completely on self-reports of participants’ behaviors. An example would be a researcher observing an ongoing lesson plan used in a classroom by a public school teacher.

Record reviews take place when the researcher examines and extracts information from documents that include information about the participant. Records that are reviewed in research may be either public or private. An example would be a researcher collecting information about a disease from patient medical records.

Biological samples are substances (blood, urine, saliva) that are taken from an individual and used to measure physiological information. An example would be drawing blood to assess the sugar content in a diabetic patient.

No matter what kind of information is collected in a research study or how it is collected, it is extremely important to carry out the collection of the information with precision (i.e., reliability), accuracy (i.e., validity), and minimal error. The integrity and usefulness of the research may be compromised if the study measurements are not carried out correctly. Factors that contribute to effective information gathering are discussed in the next few sections.
Factors in effective information gathering

Three major concepts are important to understand in order to collect useful and valuable research information: precision (i.e., reliability), accuracy (i.e., validity), and error.
Factors in effective information gathering

**Precision (i.e., Reliability)**

It is very important to make sure the information gathering methods are *precise* (i.e., reliable). This means that a method measures the same thing every time you use the method.

There are many things that can affect an instrument's or a method's precision (i.e., reliability). This includes the form of the instrument (e.g. oral or written), the environment in which it is administered, how the staff administers it, the difference in participants from group to group and across time, and the time of the day it is administered (among many others). The researcher can also influence precision (i.e., reliability) by either overtly or inadvertently praising, complimenting or admonishing the participant. The principal investigator is responsible for providing proper training and "spot checks" for how instruments or methods are administered to ensure that the research study is conducted with precision.

Research studies are often criticized because they did not use precise methods to gather data. Precision (i.e., reliability) helps to promote research that is of greater value because you can be more confident that the findings are real.

**Case example of precision (i.e., reliability)**
Accuracy (i.e., Validity)

It is also very important to make sure the information gathering methods are accurate (i.e., valid). Accuracy (i.e., validity) refers to whether or not an instrument or method truly measures what you think it measures. Researchers want accurate or valid study procedures so that study results are useful and meaningful.

There are many things that affect the accuracy (i.e., validity) of an instrument or method. These include the cultural appropriateness, the theoretical constructs used to develop the instrument or method, and the appropriateness of the testing method or form of the instrument for the participants' abilities (among many others).

To demonstrate that study measures are accurate, researchers will sometimes collect different kinds of information to measure the same thing. They then look to see if all of the methods or instruments provide the same or similar conclusions. If they do, the researcher can be confident that what they have found actually represents what they intended to study.

Along with lack of precision (i.e., reliability), research studies are often criticized because of the use of inaccurate methods to gather information. Measurement accuracy (i.e., validity) is essential in order to guarantee the quality and integrity of the research findings.

Case example of accuracy (i.e., validity)
Factors in effective information gathering

Error

When we measure something or collect information, there are many reasons that our findings might be wrong. The most obvious reason is that we could simply make a mistake in writing something down. This kind of mistake is how we might usually think about error. However, there are other kinds of errors that we might not see unless we knew to look for them. These errors are not mistakes in the sense that we have done something wrong. These types of errors can decrease the reliability or accuracy of what we do, but often because of things that we cannot control.

One of these is called Random Error. An error is considered random if the value of what is being measured sometimes goes up or sometimes goes down. A very simple example is our blood pressure. Even if someone is healthy, it is normal that their blood pressure does not remain exactly the same every time it is measured. If several measurements of blood pressure were taken over time, some would be higher and some would be lower. The reason for this random error is to be expected because of variation in normal processes in the body and in the way that the measuring device works. If error is truly random, and if we take enough measurements, then it is still possible to get a good estimate of what we are measuring. However, if random error is large, then our measurements will be unpredictable, inconsistent and they will not represent the true value of what we are measuring.

The second type of error is called Systematic Error. An error is considered systematic if it consistently changes in the same direction. For example, this could happen with blood pressure measurements if, just before the measurements were to be made, something always or often caused the blood pressure to go up. Or this could happen because our device for measuring blood pressure was defective so that it always gave a result higher, or always gave a result lower, than the true value. In these cases, even if our measurements were predictable and consistent, the results would still not be accurate.

Case example of systematic error and random error
This section includes a brief overview of some issues related to responsibly handling information collected in research. To maintain the confidentiality and accuracy (i.e., validity) of the information collected during research, any information collected about an individual should be handled with care through proper documentation and secure storage. Failure to properly handle research information may result in wasting resources, violating confidentiality, and failing to answer the research question(s) (i.e., adding unknown (random) error to the study). To avoid these serious consequences, research information should be properly documented and stored and the information provided by a research participant should never be changed or altered.
Security and Storage

The ethical conduct of research, with human subjects especially, depends in part on protecting the confidentiality of sensitive information such as name, age, occupation, income level, education level, job title, health status, family history, photographic images, survey answers, and interview responses. Even biological samples may reveal information about an individual that could be very sensitive (such as a positive HIV test). Carefully handling information according to the research design will help to ensure that sensitive information collected for research will remain private.

Research information should always be stored in a secure location. Forms and other study materials that include confidential information (e.g., blood or tissue samples, audio/video-tapes, informed consent forms) should be stored in a locked facility to which only authorized personnel have a key. Computers should be password protected and the user should log-off when the computer is not in use.

Research information is often stored for several years after the study is completed. This is done for several reasons. First, long term storage may be necessary to comply with professional standards, institutional requirements, or federal law. For example, federal regulations require that informed consent documents be stored for at least three years. Second, researchers may want to keep raw data to prove the accuracy (i.e., validity) and precision (i.e., reliability) of the information they collected during a study. Third, samples or other information such as interview transcripts may be kept for future analyses. When data are kept in a digitized form, there should be at least one additional place where the information is kept in case the original data source is lost or damaged.

Case example of security storage of research information
Handling Information

Documentation

The ethical conduct of research is also measured by the degree to which the information collected is accurate and precise. Information should be recorded and documented carefully according to the research design so that the potential for error is reduced. Documentation is the act of recording, summarizing and/or coding information for future use.

Documentation must be accurate so that the records of research activity represent what actually occurred during testing/participation. Accurate documentation also allows others to more easily detect any errors that may be included in the information collected. If information is recorded inaccurately, the results of the study may not be useful.

Documentation should be completed as the research occurs, not at a later time. Information is likely to be more accurate when recorded as soon as possible rather than recalling information from memory which can be mistaken.

Case example of documentation

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The [productId] documentation is also measured by the degree to which the information collected is accurate and precise. Information should be recorded and documented carefully according to the research design so that the potential for error is reduced. Documentation is the act of recording, summarizing and/or coding information for future use.

Documentation must be accurate so that the records of research activity represent what actually occurred during testing/participation. Accurate documentation also allows others to more easily detect any errors that may be included in the information collected. If information is recorded inaccurately, the results of the study may not be useful.

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Excluding and changing information

At times, it may be appropriate to exclude or omit information from the research record. For example, if the participant discloses information that is unrelated to the study, this information can be excluded. Another example is when a participant writes in a response on a multiple-choice survey that is not one of the multiple-choice options. This information may also be excluded from the final data set (Link to example of this). However, the decision to exclude or omit information should always be made with the full knowledge and understanding of the Principal Investigator and disclosed in any public presentation of the results of the study such as a presentation at a conference or a published paper.

Changing or altering information about a research participant or changing information that the research participant provides is never appropriate. Changing study information can seriously damage the credibility of the results.

Case example of appropriate and inappropriate exclusion of information
Glossary

This section includes definitions for the terms found in the text of this curriculum and additional terms that are relevant to the conduct of research.

Links to additional resources

This section includes links to other references and resources related to Basic Research Concepts.
This section includes definitions for the terms found in the text of this curriculum and additional terms that are relevant to the conduct of research.

Words that are highlighted in this list correspond with a green highlighted word in the text. When a user places their cursor over the highlighted word, a floating text box should appear that includes the definition of the word. There are also words that are included here in this glossary that do not appear in the text but are important research terms.

- **Analysis**: The process of evaluating research results through the use of statistical or other procedures to make sense of the information collected during a research study.

- **Association**: A connection or relationship between things.

- **Bias**: Something that happens during the course of a study that is not part of the research protocol and which alters the results.

- **Control group**: A group in an experimental study, which serves as a comparison group. The experimental treatment, procedure or program is not given to those in the control group, leaving these participants to either receive the usual available care, or an alternative, such as a placebo.

- **Controlled condition**: a highly regulated or restrained situation.

- **Cross sectional**: A research study in which information is collected at one point in time.

- **Demographics**: Personal information collected about an individual such as name, country of origin, birth date, race/ethnicity, occupation, education level and income level.

- **Dependent variable**: "The outcomes that are measured in an experiment. Dependent variables are expected to change as a result of an experimental manipulation of the independent variable(s)." (Penslar and Porter, 2001).

- **Error**: In a research study, this means anything that interferes with making a confident conclusion.

- **Ethical**: In accordance with what is widely accepted as "right" or "wrong." In this curriculum, this applies to practices and standards of research conduct.

- **Focus group**: A meeting with individuals in which a structured, group interview is conducted and information obtained from the interview is recorded and analyzed for research purposes.

- **Generalizable**: This means that research results or patterns found in a sample population will also be found in the wider population which the sample represents.

- **Human subjects**: "Individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project. Under the federal regulations, human subjects are defined as: 'living individual(s) about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information [Federal Policy §__.102(f)].'" (Penslar and Porter, 2001).

- **Hypothesis**: A prediction or explanation about future data based on previously collected data.

- **Incentives**: A motivation or inducement (inducement may be too complex), often monetary, that is provided to participants to encourage involvement in a research project.

- **Independent variable**: "The condition of an experiment that is systematically manipulated by the investigator." (Penslar and Porter, 2001).

- **Informed consent process**: The process of providing information about the research study to an individual so that he or she can make an informed decision about whether or not to participate in research. This is a process which occurs throughout the length of the research study, beginning with recruitment and occurring periodically throughout the study.

- **Longitudinal**: A research study that takes place over a significant period of time. Should we include that data collection occurs at multiple time points to help clarify how this is different from cross sectional?

- **Multiple-choice survey**: A form with questions in which an individual is provided with various options to choose as his/her response to the question.

- **Principal Investigator (PI)**: The lead researcher responsible for all aspects of a research study.

- **Open ended**: A free-flowing, non-directed, detailed response to a question.

- **Random assignment**: "Assignment of subjects to different treatments, interventions, or conditions according to chance rather than systematically (e.g., as dictated by the standard or usual response to their condition, history, or prognosis, or according to demographic characteristics). Random assignment of subjects to conditions is an essential element of experimental research
because it makes more likely the probability that differences observed between subject groups are the result of the experimental intervention.” (Penslar and Porter, 2001).

- **Randomly** : "Of or relating to an event in which all outcomes are equally likely.” (The American Heritage® Dictionary of the English Language, Fourth Edition Copyright © 2000 by Houghton Mifflin Company.)

- **Raw data** : Information collected from individuals in a research study that is in its original form; this might include audiotapes of interviews, completed survey sheets or measurements (like blood samples?).

- **Reliable** : A term used in research to describe the consistency or precision of the information provided by a participant or of the measure used to document study information.

- **Sample** : A selection of a smaller group of individuals who have been chosen to participate in a research study because they represent the characteristics of the larger group.

- **Systematic** : A systematic investigation means that a careful plan is followed to gather information. The Office of Human Research Protections offers this explanation of the systematic process of research: “Systematic observations are obtained under clearly specified, and, where possible, controlled conditions that can be measured and evaluated.”

- **Treatment group** : The group which receives the treatment or intervention or service that is being studied/tested.” Also known as “experimental group.”

- **Valid** : Accurate, factual, correct or true.

- **Validity** : The accuracy or correctness of a study measure used in research.

- **Survey** : A set of questions for research participants to answer.

- **Test** : A form or a physical or mental task for which a normal standard has been determined or for which there are correct answers.

- **Physiological assessments** : Measurements in which a participant’s physical characteristics are evaluated such as blood pressure, heart rate, or physical strength.

- **Observations** : Recordings that are taken of the participant without requiring interaction.

- **Interview** : An interaction that involves the researcher and the participant(s) in which questions are presented in person, over the telephone or even electronically (email or Internet).

- **Precise** : In research, precise refers to a method that measures the same thing every time.

- **Manipulation** : A controlled change that is introduced by the research such as an alteration of the environment, a program or a treatment.

- **Protocol** : The research plan developed by the researcher that should be followed when carrying out the study.

- **Control** : An important element of a true experiment that prevents outside factors from influencing the results of the study.

- **Random selection** : A form of sampling where a representative group of research participants is selected from a larger group by chance.

- **Variance** : The difference or the variation that occurs naturally in the world or change that is created as a result of a manipulation during an experiment.

- **Placebo** : An inactive drug that may be used in research
References and Resources

Congratulations, you have reached the end of the session!

Please provide feedback if you have comments or questions that you would like to pass on so that we can improve the training. If you want to test your knowledge of the materials, please take the quiz (coming soon).
Case example for Accuracy (i.e., Validity)

**Definition:** Accuracy (i.e., validity) refers to whether or not an instrument or method truly measures what you think it measures. Here is an example to illustrate the importance of accuracy in research:

In a study involving a weight loss program, the researcher weighs participants to determine if the program is effective in helping individuals lose weight. To accurately measure weight, the scale must be working properly. To check the accuracy of the scale, a 25 pound weight is placed on a digital scale three times to make sure that a 25 pound reading is found each time.

In another study, researchers want to determine whether participants have reduced their smoking. To find out, the researcher asks the individual a series of questions on a survey about their smoking habits over the last two weeks. To verify the accuracy of the survey responses, the researcher also does a test to measure chemicals in saliva that increase with smoking.

**Discussion questions**

1. What would happen in each of the previous examples if an accuracy check was not conducted?
2. What are some other ways to check for accuracy in these studies?
3. Why is it important to use accurate methods to collect research information?
Case example for Associations and cause and effect

**Definition**: The term association means that two or more things are related or connected to one another. Here are some examples of associations:

One example of an association is seen with aspirin use and prevention of heart attacks. The more aspirin that a former heart-attack patient takes, the less likely it is that he/she will have another heart attack (American Heart Association, “Aspirin in Heart Attack and Stroke Prevention” Available: [http://www.americanheart.org/presenter.jhtml?identifier=4456](http://www.americanheart.org/presenter.jhtml?identifier=4456), Accessed on February 15, 2005).

Here are some examples of positive and negative associations:

<table>
<thead>
<tr>
<th>Variable 1</th>
<th>Variable 2</th>
<th>Direction of association</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Education level</td>
<td>Income level</td>
<td>Positive</td>
<td>As education level increases, so does income level.</td>
</tr>
<tr>
<td>Exercise</td>
<td>Weight</td>
<td>Negative</td>
<td>As exercise increases, weight decreases</td>
</tr>
<tr>
<td>Study time</td>
<td>Test score</td>
<td>Positive</td>
<td>As study time increases, test score increases</td>
</tr>
<tr>
<td>Sick days</td>
<td>Work productivity</td>
<td>Negative</td>
<td>As number of sick days increases, work productivity decreases</td>
</tr>
</tbody>
</table>
Case example for Blinding

Definition: Blinding is a technique used to decrease bias on the part of the researcher or the participant in which the participant or both the researcher and the participant are not told to which group they have been assigned.

In a study investigating the effects of a new anti-itch cream, participants with minor skin rashes were randomly divided into one of three groups. In the first group, participants received a new anti-itch cream that contained 3% hydrocortisone. In the second group, the participants received the standard cream available over-the-counter which contains 1% hydrocortisone. The third and final group members received a cream that contained 0% hydrocortisone. The participants did not know to which group they were assigned. Participants used the cream for three days to relieve itching symptoms caused by the rash. After three days, each participant’s rash was examined to determine if itching symptoms subsided. If this was not the case, the participant was provided with the standard treatment which is known to relieve itching.

Discussion questions

1. Why are participants not told (blind to) their group assignment?
2. Is this a single or double blind study?
3. Do you think knowledge of group assignment (no blinding) would affect the results? Why or why not?
4. Do you think that the researcher’s knowledge of group assignment would affect the results? Why or why not?
Case example for Descriptive Studies

**Definition**: A descriptive study is one in which information is collected without changing the environment (i.e., nothing is manipulated).

Here is an example of a descriptive study:

A researcher wants to know why individuals in Community A have a higher rate of a rare form of cancer when compared to those living in Community B. To find out the reasons for the differences in cancer rates in these two communities, the investigator surveyed residents about their lifestyle, noted the types of businesses that were present in the community and searched medical records. The researcher found that the headquarters for the Toxico Chemical Plant is located in Community A, there is a higher rate of cigarette smoking in this community and residents tended to delay or skip going to the doctor for an annual checkup. In Community B, the largest employer was a department store and on average, residents did not smoke as much as residents from Community A. However, like individuals from Community A, Community B residents tended to delay or skip their annual checkup with their doctor.

**Discussion questions**

1. **What makes this a descriptive study?**

2. **Why did the researcher collect information about the lifestyle of community residents? What about the type of businesses present in each community? Medical records?**

3. **Can the investigator establish that the chemical plant and cigarette smoking are the cause for the higher rate of cancer among those in Community A?**

4. **Can the investigator establish that lower smoking rates and the absence of a chemical factory explains the lower rate of cancer among those in Community B?**
Case example for Descriptive study variables

**Definition**: Variables are characteristics studied in research that can take on different values (e.g., weight, height, exposure to a substance, demographics i.e., where you live, your ethnicity, how much income you have, medical background). See if you can identify the variables that are under investigation in the following descriptive study:

Many children who live in the Bronx, a borough of New York City, are developing asthma. In a descriptive study investigating this problem, parents whose children have asthma are asked about whether they smoke around their child, whether they live near a freeway, whether their child regularly sees a healthcare provider, their family income level and also if there is a history in their family of asthma. Prior research has shown that these factors may have an influence on the development of asthma in children.

**Discussion questions**

1. *What are the variables that are under investigation in this study?*

2. *If you were the researcher, what other variables would you study to see if it may contribute to developing asthma? Why?*

3. *Given the variables presented in the example and the variables that you thought of, why would these variables be useful to the researcher?*
Case example for Documentation

**Definition**: Documentation is “the collation, synopsizing, and coding of printed material for future reference” (American Heritage Dictionary of the English Languages). Here is an example illustrating the importance of documentation in research:

In a weight loss study, the research assistant failed to measure the participant's weight at the beginning of the study. Later, when it was time to review the results of the study, the assistant realized that he did not have the weight for the participant.

**Discussion questions**

1. How does this type of situation affect the integrity of the study?
2. What should you do if you forget to document important information in the beginning of the study?
3. Why is it important to accurately document research information?
Case example for Systematic and Random Error

**Definition:** Error in research is anything that interferes with making a confident conclusion about the study. The following examples illustrate both systematic error and random error in research:

**Systematic error**

In a study on weight loss, researchers determined at the end of the study that the scale that was used to measure participant’s weight was inaccurate. The scale added 10 pounds to the person’s actual weight every time the scale was used. Because the researcher realized that the scale consistently added ten pounds to each participant’s weight, they adjusted for this problem when analyzing the results.

**Discussion questions**

1. If you were the researcher, how would you handle this problem if you found out about it at the end of the study?
2. What are some things the researcher should have done in the first place to avoid this problem?
3. Is systematic error problematic in research in general if it can be corrected? What if the researcher doesn’t know about the systematic error?

**Random error**

In a study on weight loss, a scale was used that added a few pounds more or a few pounds less each time the scale was used. The researcher did not know that the scale did not measure the participant’s exact weight. Because the researcher did not realize this, the researcher could not adjust for this problem when analyzing the results. This caused the study results to include some error.

**Discussion questions**

1. Are the results of this study accurate? Why or why not?
2. Does the use of a slightly inaccurate scale cause serious problems with the study results?
3. Is there anything that the researcher should have done to avoid this problem?
4. Which do you think is a more serious problem in research - systematic or random error?
5. Which type of error - random or systematic - is easier to control?
Case example for Excluding and changing information

Here are two examples about when it is appropriate to exclude or change research information:

Excluding information

In a study on improving literacy skills, researchers developed a tutoring program at a public library. The researchers want to determine whether the tutoring helps the participants to obtain a job. Since the research is conducted at a public library, however, the researchers are required to offer the program to all individuals regardless of their employment status. Since the researchers are only interested in the effect of this program on unemployed individuals, the information collected from employed individuals is excluded.

Discussion questions

1. Why did the researchers exclude information about employed individuals?
2. What other situations can you think of when it would be appropriate to exclude information collected for research purposes?
3. How would the results be affected if the information from all participants was included?

Changing information

A research assistant is responsible for recruiting families with children ages 12 to 24 months old for a study of language and learning. She is having trouble finding families who are interested in participating. However, she finds a family who are willing to participate with 27 month-old twins. So that she can include the twins in the study, she records their age as 24 months instead of their real age. The twins are enrolled in the study and the Principal Investigator publishes information on the normal development of 24 month olds based on the data collected from these older children. This information is used to affect recommendations for parents on how to stimulate their child’s learning and language development.

Discussion questions

1. How do the research assistant’s actions affect the integrity of the study?
2. What should you do if you are having trouble recruiting participants who meet the study eligibility requirements?
3. Why is it important to adhere to the study eligibility requirements when recruiting participants?
Case example for Experimental Studies

**Definition**: An experiment is a study in which a treatment, procedure, or program is intentionally introduced and a result or outcome is observed.

**Experimental studies - Example 1**

An investigator wants to evaluate whether a new technique to teach math to elementary school students is more effective than the standard teaching method. Using an experimental design, the investigator divides the class randomly (by chance) into two groups and calls them “group A” and “group B.” The students cannot choose their own group. The random assignment process results in two groups that should share equal characteristics at the beginning of the experiment. In group A, the teacher uses a new teaching method to teach the math lesson. In group B, the teacher uses a standard teaching method to teach the math lesson. The investigator compares test scores at the end of the semester to evaluate the success of the new teaching method compared to the standard teaching method. At the end of the study, the results indicated that the students in the new teaching method group scored significantly higher on their final exam than the students in the standard teaching group.

**Experimental studies - Example 2**

A fitness instructor wants to test the effectiveness of a performance-enhancing herbal supplement on students in her exercise class. To create experimental groups that are similar at the beginning of the study, the students are assigned into two groups at random (they cannot choose which group they are in). Students in both groups are given a pill to take every day, but they do not know whether the pill is a placebo (sugar pill) or the herbal supplement. The instructor gives Group A the herbal supplement and Group B receives the placebo (sugar pill). The students’ fitness level is compared before and after six weeks of consuming the supplement or the sugar pill. No differences in performance ability were found between the two groups suggesting that the herbal supplement was not effective.

**Discussion questions**

1. What makes both of these studies experimental?

2. What type of information might the investigator collect in these two studies to see if the treatment (e.g. new teaching method or herbal supplement) is effective?

3. Can the researcher establish cause and effect in either or both of these two studies?

4. What would happen if the researcher allowed the students to study together or talk about the different methods that were being used to teach the math lesson? Would this be a good or a bad idea? How would this influence the study results?

5. What if the fitness instructor allowed participants to take other herbal supplements in addition to the supplements being tested? Would this be a good or a bad idea? How would this influence the study results?
Case example for Independent and Dependent variables

Definition: A variable is either a result of some force or it is the force that causes a change in another variable. In experiments, these are called dependent and independent variables respectively.

In an experimental study looking at classical music exposure and reading ability in children, the researcher divided the children into two groups (Groups A and B). In Group A, the children listened to Mozart for one hour every day for one month. In Group B, parents were instructed to refrain from playing classical music around the child for one month. At the end of the month, all children were given a reading comprehension test. Those who listened to Mozart daily (Group A) scored significantly higher on the reading test. In this case, the reading comprehension test score is the dependent variable and exposure to Mozart's music is the independent variable. This is because the test score is dependent on whether or not the child listens to Mozart's music. The independent variable, exposure to Mozart's music, is independent because it is something that can be manipulated or changed by the researcher.

In a study with a similar design as the previous example, researchers looked at the effects of nutrition on reading ability. In Group A, children ate at least three ounces of dark green vegetables every day for one month. In Group B, children were fed their regular diet. At the end of the month, the children took a reading comprehension test. Those who ate the green vegetables every day for one month (Group A) did not vary in their test scores when compared to Group B.

Discussion questions

1. In the second example what is the independent variable? Why?
2. In the second example, what is the dependent variable? Why?
3. Identify which variables are independent and dependent in the following examples:

   - Positive feedback and self confidence
   - Headache and aspirin
   - Muscle mass and weight-training
   - Calcium consumption and bone density
   - Blood pressure and salt intake
**Case example for Precision (i.e., Reliability)**

**Definition**: Precision (i.e., reliability) means that a method measures the same thing every time you use the method. Here are some examples illustrating the importance of precision (i.e., reliability) in research:

A study is designed to see if a new anti-hypertension drug is effective in reducing blood pressure. Participants in the study have their blood pressure measure to see if the drug has an effect on lowering blood pressure. The study design requires that blood pressure is taken when the individual is in a quiet location using a digital blood pressure monitor.

**Discussion questions**

1. **Imagine that the researcher decides to take the participant's blood pressure after he or she has completed a vigorous exercise routine. Would this be consistent with the research design? Why or why not?**

2. **In another situation, the researcher takes an individual's blood pressure in a noisy household where many young children are playing in the same room. Would this be consistent with the research design? Why or why not?**

3. **A researcher accidentally breaks the digital blood pressure monitor and decides to use a manual blood pressure cuff like a nurse would use during a routine check up. Would this be consistent with the research design? Why or why not?**
Case example for Random Assignment

**Definition:** Random assignment is a procedure used in experiments to create study groups with similar characteristics so that the groups are equivalent at the beginning of the study.

In a study to help individuals quit smoking, investigators randomly assigned participants to one of two groups. In Group A, participants took a class to quit smoking. The classes took place each week for 10-weeks and included information about the benefits of quitting smoking. In addition, participants in the class received strong social support from mentors or “buddies.” In the Group B, participants read a 3-page pamphlet created by the American Cancer Association that explains the benefits of quitting smoking. The investigator randomly assigned participants to one of the two groups. It was found that those who participated in the class and received support from their buddies were more likely to quit smoking compared to those in the other group that received only the pamphlet.

Discussion questions

1. *Why do you think random assignment was used in this study?*

2. *What would happen if the participants were allowed to choose their own group? What if the same results were found as in the case where individuals were randomly assigned?*

3. *If the participants could choose their own group, would the researchers feel as confident about the results as they would if random assignment were used? Why or why not?*
Case example for Random selection

**Definition**: Random selection is the process of selecting a smaller group of individuals from a larger group to be participants in a study. Every person has an equal chance of being selected which allows each of the individuals in the group the same chance of participating. Here is an example of random selection:

The investigator selects 200 names from a list of 50,000 Hispanic women by placing all of their names in a hat. Each name is put on a separate piece of paper and names are drawn until 200 names have been picked. This procedure to select names at random can also be done by using special computer programs. A computer program would probably be used for this process when there are hundreds of participants to randomly choose.

**Discussion questions**

1. Do the women included on this list represent the larger group?
2. Would you choose participants differently if this was your study? If so, how would you do it?
3. What if the researcher decided to ignore the random selection procedures as described in this example (e.g. pulling names from a hat, using a computer program to generate random numbers)? How would this affect the results of the study?
Case example for Sampling

**Definition**: Sampling is defined as the method by which some members of a larger group are selected. The usual goal is to sample those members so that they are representative of the group as a whole.

Here is an example of sampling:

An investigator will be studying nutrition among Hispanic women. To find participants to interview, she requested a list of names and contact information for all Hispanic women from a community clinic. These women had already provided consent and had agreed to be contacted about participating in future research studies. The list included 1,000 names of potential participants for the nutrition study. The investigator chose 200 of the women from this list to contact for possible inclusion in the study.

**Discussion questions**

1. **What is the purpose of selecting a smaller group of participants from a larger group?**
2. **Do the women included on this list represent the larger group?**
3. **Would you choose participants differently if this was your study? If so, how would you do it?**
4. **What would happen if the investigator chose individuals from the list that she knew? Would this affect the results of the study?**
Case example for Security and storage

**Definition:** Research information should always be stored in a secure location. Here is an example illustrating the importance of proper storage of research information:

In a needs assessment study on helping a clinic reach individuals without health insurance, the study forms included sensitive health information along with the person’s name and phone number. Before returning to the research office, the staff member left the information at home on her kitchen counter. That night, some of her friends came over for dinner, saw through the papers, and recognized the names of some of the individuals in the study.

**Discussion questions**

1. *What is the harm of her friends seeing this research information?*
2. *How could this type of situation be avoided?*
3. *How does this type of situation affect the integrity of the study? How does this type of situation affect the participants?*
4. *Why is it important to securely store research information?*