Research Design and Ethics

Most of the research we do includes people. And, many of the topics we study can be sensitive and/or include those factors that cannot be manipulated for the sake of experimental study. Consider your reaction if someone you met for the first time said *hello*, introduced her- or himself, and then asked you the number and types of sexual behaviors you engaged in within the last month. Let's assume a few of you actually provide answers. What would happen if the person then created a Facebook page, without your knowledge, posted your name and answers, and then friended your family members and closest friends to see the types of reactionary comments they would make. Or, what if the same person asked you to take an experimental drug that would make you fail this class so s/he could learn how failing a class impacts college students' studying habits the semester following receiving an F, or better yet, s/he just put the drug in your food without your knowledge and followed you around after you received the F to observe your behavior. Finally, what would happen if this drug actually would help you earn an A? But, the data on which this claim was based came from only one study and the researcher made up the results of that study so they could get a major financial contract with a pharmaceutical company. Our guess is that most of you would run the other way and maybe even file a lawsuit.

Historically, there have been many events (e.g., Tuskegee Syphilis Study, Nazi medical experiments on concentration camp victims) that led to the establishment of research ethics. From the examples, it should be clear that researchers must consider how to protect people who participate in research, the data we get from them, the integrity of the research process, whether benefits outweigh risks, and what we do with the data once we obtain it. These are some of the core ethical principles (informed consent, confidentiality/anonymity, voluntary participation, deception, risk of harm, accuracy in analysis and reporting) that must be considered and planned for when designing and carrying out studies. As new researchers, the ethical considerations for studies you develop likely will not be as obvious as those above so additional care is needed. Universities, colleges, and many organizations have Institutional Review Boards (IRBs) comprised of experienced researchers with advanced training and knowledge in research ethics and the regulations governing them. IRBs review all research proposals to ensure adherence to ethics, and, above all, protection of human subjects. Data collection can begin only after IRB approval. To not delay the project, you should spend a great amount of time planning it,

discussing it with others to gain outside perspectives, and submitting IRB applications as early as possible. It is quite common that IRBs will send feedback to researchers and request they make revisions and resubmit it for reconsideration. This process can easily take over a month, and much longer when revisions are needed, so the more detailed work done before submission the less likely your project will be delayed.

To get you on the right path we have listed several tips and questions to ask yourself below. Do not get too overwhelmed by these; simply begin to get a sense of things to think about and do, and remember to come back to the table throughout the research process. Eventually, these considerations will become second nature. The best place to start is to always ask yourself if you would let your closest relative participate in the study you are planning. We do caution students that not every ethical procedure is detailed in published articles because of space limitations, and it is becoming more customary to assume some ethical practices as long as a researcher documents IRB approval. As an exercise, you might wish to pick a research article and align the information in that methods section with the columns in Web Table 1.1.

Web Table 1.1.

Ethical Principles, Questions to Consider, and Tips

Ethical Principle	Questions to Consider	Tips
Informed consent	Is there an IRB template for informed consent (there often is)? Do participants know the purpose of the study? Do they know what is required of them? Do they know how long it will take? Is the participant legally able to provide consent (e.g., are they a minor)? How will informed consent be obtained, and by whom? If someone other than you is obtaining consent, have they been trained and given explicit instructions on how to do so? How will you know if another trained data collector understands and is following the directions for obtaining consent?	Use an IRB template Write and speak using lay language at an 8th grade level Use active consent strategies Develop a written script and oral presentation explaining the study and what is involved Use the script exactly the same way with everyone If there are multiple data collectors, collect the first sets of data together as a group Keep a journal of any deviations that might occur Establish rapport, trust, and respect
Voluntary participation	Are participants told their participation is voluntary? Are participants told they can stop participating at any time and without penalty? Was any coercion involved? Are any rewards involved, like extra credit for class?	Include this information in the consent form and in the script for the oral explanation of the study Do not pressure anyone or ask people you know to participate If rewards are involved, they should be minimal and consistent with what is asked of them during participation (e.g., do not promise an A in a class for someone completing a 5-minute survey)

Confidentiality and anonymity	What personal information will participants provide (name, city in which they live, university they attend)? Will multiple people participate at the same time and in the same space? How will collected data be transported from the collection site and stored? If participants have to participate multiple times, how will their data be connected? Can any collected data be used to trace responses back to a particular person or small group (e.g., those who live in a particular dorm or are taking a particular class)?	Keep responses and signed consent forms double-locked Use password protected files Do not ask a friend to help input data unless they are listed as an investigator on the same study and have been through training Use numbers to identify participants rather than names If multiple participants are participating together, provide directions on maintaining confidentiality
Risk of harm	What are the benefits of the study for the people participating, for society, and for knowledge and theory? What are the potential reactions of participants before, during, and after participation?	Ensure the purpose of the study has strong potential benefits Consider any potential psychological, emotional, physical, and social reactions participants MIGHT experience Include information about seeking help in case of a negative reaction and provide this in writing Observe participants as they participate and look for any signs of distress or negativity
Deception	Has any information about the purpose of the study or nature of participation in it been withheld from participants?	If you must, develop a debriefing that occurs after participation where you explain the true purpose of the study Make sure you can demonstrate how the potential benefits of the study outweigh the potential harm that could come from deceiving participants

Accuracy in analysis and reporting	Do you have clear procedures for data entry and analysis? Do you have the right expertise in analyzing and interpreting results? Have you asked for help? Are you being honest with all details of the study and its results?	Double check everything Know that if your results are not significant or as expected that it is okay Maintain confidentiality and anonymity Do not plagiarize Keep the original data and consent forms for the time required by your IRB Use unbiased language Be culturally competent Use pseudonyms for qualitative studies