25. Document from Research Workshop: "The Ethics of Research"

A. YOUR ROLE AS AN ETHICAL STUDENT RESEARCHER

Over the course of the last several years, we've learned a lot about how to do research studies with people. We've learned that it's important to consider the perspective of our research sample, and that as researchers we must ensure their safety and well-being. We must not take advantage of them in any way. A whole area of study has evolved, so that there are courses you can take or journals you can read about research ethics. As a researcher yourself, you, too, will consider the ethics of the research you will be conducting. This is consistent with the mission of RSL at Duke, which emphasizes ethical inquiry within the context of scholarly research.

There are a series of steps with regard to research ethics you must take to conduct your RSL project. Duke University requires that student research projects must reflect the general standards of ethics in research, particularly if the results of the study will be shared with a public audience. RSL funded projects will be shared through publication and/or presentations, so you must follow the appropriate procedures. As you plan your study, think about your research study from the perspective of the people with whom you interact during the course of the study. That is to say, start to think about the people you interview, or those who complete your questionnaire. Depending on the nature of your project, these may be considered https://doi.org/10.100/journal.com/journal.com/ project. See Student Research with Human Subjects for a helpful explanation.

B. RESEARCH ETHICS AT DUKE: THE OFFICE OF RESEARCH SUPPORT

Duke has a structure to guide you in the ethics of research as you plan your study. <u>The Duke University Office of Research Support</u> (ORS) guides and supports research of all kinds at Duke

University Arts and Sciences. The staff at ORS is very helpful and is available to answer questions and look over your materials as you prepare your research study. One "arm" of this office is the Committee for the Protection of Human Subjects, a collection of Duke faculty and staff and others who work together to ensure that research participants do not have a negative experience in a research study.

You must take two steps before you are ready to start collecting data for your project: first, you and your faculty mentor must be trained in research ethics and "certified" as such you must submit your project idea to the Committee for the Protection of Human Subjects for approval.

1) Certification

To conduct an RSL project with human subjects, you must be certified as an investigator - Duke wants to be sure that you have adequate training in the ethics of research. This is true even if you are working on an independent study with a faculty member as your guide—independent work requires certification of you and of your faculty mentor. You can read the on-line material from the Office of Research Support here:

http://www.ors.duke.edu/irb/fundamentals/certification.html#initial

To become certified, you will need to take the Duke Medical Center tutorial, "Protecting Research Subjects," which is available on-line at http://researchethics.mc.duke.edu/. Your faculty mentor will need to do these, too, unless he or she is already certified. These are the only medical center modules you will complete if you are conducting research through Trinity College of Arts and Sciences. You can take the course through streaming video, which takes

approximately 33 minutes, or slides, which can be studied at your own pace. You must pass the subsequent quiz to receive certification. You will receive a certificate once you have completed the training. You'll need that for you RSL records.

The Office of Research Support directs that you SHOULD NOT complete any Medical Center tutorials other than "Protecting Research Subjects," unless at the request of the IRB.

2) Project Approval

i) Submitting a protocol—Once you have received the training the University offers in research ethics, you must submit a description of your Specific research project for approval. You will not be allowed to proceed with your RSL project without the University's sanction.

You and your mentor will complete a <u>form</u> (attached to this document) that will give you the chance to fully describe your project. This link includes information on the following:

- Investigator and Project Information
- Assurances
- Instructions for Preparing Project Description
- Submission Information and Checklist

You will provide a great deal of information about your project, such as who will serve as the participants, how you will find them, exactly what questions you will ask. Answering these questions is not a simple formality—this is a critical step in the development of a research project—take them seriously! You will probably want to consult with your faculty mentor on some of them. The depth of this information reflects the large commitment you are making in planning a research project—you will need to determine, ahead of time, what you wish to accomplish with your study and how you will get there.

Basically, you will need to know before you begin what you want to find out and the ways you want to find that information. Will you ask people questions in person? Will you develop a questionnaire to give to several people? Will you observe people carefully and take notes about what they do? How will you record information, who will have access to the information, how will you disseminate your results? Be prepared to think hard as you prepare this document.

Completing these forms will take time and careful thought—and every bit of that is an important investment in the validity, relevance, and integrity of your research project.

Once you have completed the form, you'll take copies to the Office of Research Support.

They will give it a preliminary evaluation, contact you and/or your mentor if there are any immediate questions or concerns, and let you know the Committee's decision. You may be asked to revise part of your study—don't be discouraged, and don't take it personally. This is another reason to plan ahead and give yourself time to take care of these critical issues. The RSL Coordinator can assist you at any step of the way.

- ii) Calendar—The Human Subjects Committee meets on a regular schedule, and you must have materials turned in to them by particular dates. Because your faculty mentor needs to "sign off" on the project before the Committee sees it, make sure you give yourself enough time for your mentor to do a careful review before turning it all in. You can check the schedule here: http://www.ors.duke.edu/irb/schedule/index.html.
- **iii) Exempt studies**—Some studies are "exempt." That means that some studies do not need to be fully evaluated by the Committee.

Read about Exemption here: http://www.ors.duke.edu/irb/types/screening.html .

You cannot decide on your own that your study is "exempt" from review—and neither can your faculty mentor. There's a form you must complete, with the guidance of your mentor, and the ORS staff will determine if you need to submit a full proposal to the Committee.

C. DOING ETHICAL RESEARCH TAKES TIME AND THOUGHT

Does this sound like a large project? You're right—these preliminary steps to doing a research study require a great deal of time and thought, but they are critical steps to the success of a project, and they will help you develop a stronger project.

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