



Online Ethics Center
FOR ENGINEERING AND SCIENCE

Human Subjects (RCR Role Plays)

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Description

One of nine role play scenarios developed by Michael Loui and C. K. Gunsalus. This page, on research with human subjects, includes the summary, human subjects resources, and handouts to be given to various participants. *The full role play instructions with discussion guidelines are included in pdf format.*

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Role-Play Summary

This role-play addresses issues involved with human subject research and working with an Institutional Review Board (IRB). The Belmont Report (1979) identifies three

basic ethical principles that underlie all human subject research. These principles are Respect for persons, Beneficence, and Justice. Respect for persons requires us to treat individuals as autonomous human beings and not to use people as a means to an end. We must allow people to choose for themselves and provide extra protection to those with limited ability to choose, such as children. Rules derived from the principle of respect for persons include the requirements to obtain informed consent and to respect the privacy of research subjects. Beneficence reminds us to minimize harms and maximize benefits. Rules derived from the principle of beneficence include the requirement to use the best possible research design to maximize benefits and minimize harms, the requirement that researchers perform procedures competently and mitigate risks, and the prohibition of research whose risk-benefit ratio is unfavorable. Justice requires us to treat people fairly and to design research so that its burdens and benefits are shared equitably. Rules derived from the principle of justice include the requirement to select subjects equitably and the requirement to avoid exploitation of vulnerable populations or populations of convenience.

IRBs ensure that research with human subjects follows these principles. Research may be reviewed by a convened Institutional Review Board (full review), by one or more IRB members (expedited review), or by an individual designated by the institution who may not be an IRB member (exemption approvals). Criteria for determining who will conduct the review include the level of risk, the type of research activity, vulnerability of subjects, and institution-specific criteria. It is a critical task to make the distinction between activities that meet the definition of research with human subjects and those that do not. If a project doesn't meet the definition, it will not need review by an IRB.

Consent forms are normally required except when the research involves no more than minimal risk or when subjects are anonymous. Informed consent begins with recruiting and screening of subjects and continues throughout the subjects' involvement in the research procedures. Researchers must provide specific information about the study to subjects in a manner comprehensible to them, answer questions to better ensure subjects understand the research and their role in it, give subjects adequate time to consider their decisions, and obtain the voluntary agreement of subjects to participate in the study. The agreement is only to enter the study, because subjects may withdraw at any time, and they may decline to answer specific questions or complete specific tasks.

This role-play also covered issues involving communication and collegiality. In this case, unfortunately, the data collected before IRB approval probably cannot be included in the analysis and publication.

Resources on Responsibilities with Human Subjects

[The Belmont Report](#)

[The Illinois White Paper: Improving the System for Protecting Human Subjects: Counteracting IRB Mission Creep](#)

[Office for Human Research Protections \(OHRP\)](#)

[University of Illinois Institutional Review Board](#)

Faculty Adviser Role

What follows is an outline of your role. You will need to improvise to some extent – be creative but try to stay within the bounds of what seems realistic.

You are a professor at a research institution. Your friend and colleague at another institution has asked you for a favor. She has performed numerous favors for you over the years that have been critical to advancing your career. Your friend wanted a graduate student to conduct a small number of short surveys or interviews. Since the favor was a fairly small task, you immediately agreed to help her.

A first-year graduate student has started working for you. This student was perfect to assign to the task of conducting the surveys. Assigning this student the task not only allows you to do a favor for your friend, it is great training for your graduate student with the process of taking a project through IRB approval, and collecting, recording, and reporting data to collaborators at another institution. You feel it is ideal for helping your graduate student experience an overview of the IRB approval process, and since it is a well-designed protocol, you feel happy about assigning your graduate student to this project.

Your graduate student has filed the IRB application with your friend's protocol and has begun arranging for access to potential interview subjects. You know your student is a little frustrated with the initial responses of the IRB staffer who was assigned to review the IRB application. Unfortunately, the IRB at your institution tends to be very particular about specific details and language in the consent forms. In your upcoming meeting with your graduate student you would like a good

progress report and to talk through any obstacles with the IRB so you can help your graduate student work through them. Exposing your student to this process will be an important learning experience. You may suggest that you and your graduate student set up a meeting with the IRB staffer to discuss the protocol, though you would let the student handle the meeting. Meeting face-to-face may speed up the application process.

Faculty Adviser Role-Play Notes:

- Your friend at another institution has performed many favors for you, and you would like to reciprocate
- The project will be a great learning experience for your graduate student
- You want to successfully mentor your graduate student in the IRB approval process
- Think about suggesting a meeting with the IRB staffer to discuss the application

Plan for your meeting:

- Write questions that you will ask your student
- Follow-up questions that you might ask
- Questions that the student might ask you, and your answers

Graduate Student Role

What follows is an outline of your role. You will need to improvise to some extent – be creative but try to stay within the bounds of what seems realistic.

You are a graduate student in your first year of study. You are working on a tedious project assigned to you by your adviser for the “experience.” Even though your own project is more exciting and interesting, your adviser says it cannot be started until you complete this project. You know that the time you are putting into this project is helping out a friend of your adviser’s at another institution, but it is keeping you from your starting your own work.

Your adviser’s friend wants to collect information from multiple locations to fill out a dataset, and you must conduct interviews in your community to assemble this information. You only need another twenty-five interviews to complete the project. You are frustrated because you need IRB approval, and the process is taking an extremely long time. The delay is due to your difficulty in conveying to the IRB that

this project has minimal risk and should probably be exempt. The entire approval process especially annoys you because your adviser's friend has had IRB approval for this exact protocol for many years at her institution. It is obvious that none of the experiments' subjects are in any kind of danger and the interviews do not cover sensitive topics.

You are preparing for a conversation with your adviser in which you want to propose that you "quietly" conduct some of the interviews. Even though you are still communicating with the IRB staffer assigned to review this protocol, and do not yet have approval, you hope to convince your adviser to agree to this. You have actually already conducted about half of the survey/interviews without your adviser's knowledge. You don't really want to tell your adviser that you've done this, so it would be ideal to leave the conversation with permission to start some "pilot" survey/interviews before your approval in order to refine your technique. Keep in mind that the sooner you finish this task, the sooner you can start the project that you are really interested in.

Graduate Student Role-Play Notes:

- You cannot start your own project until you complete the project for your adviser's friend.
- The IRB process is taking an extremely long time.
- You want permission from your adviser to run interviews before receiving IRB approval.
- You don't want to tell your adviser that you've already started running interviews.

Plan for your meeting:

- Write questions that you will ask your adviser.
- Follow-up questions that you might ask
- Questions that your adviser might ask you, and your answers

Starting the Human Subject Role-Play

Professor: Hi... How is the IRB application process going?

Grad Student: Well, I'm having some problems with the IRB staff... They are very slow and the project is still not approved...

Professor: Are there any protocol issues that you're having? Is it something that was previously established that's not working?

Grad Student: No, actually our protocol is exactly the same as your friend's protocol at the other institution... so I don't understand how your friend has the project approved while our IRB seems to find problems with it...

Professor: I've worked with the committee before, and they can be picky... it is very frustrating.

Grad Student: Yes... and I'm thinking since this protocol is already approved by your friend's institution, maybe she can help us with the process in terms of explaining our project to the IRB staff...

Professor: I think that is your best option right now... perhaps looking at her IRB application will help you improve yours...

Grad Student: That's a good idea... I also was actually wondering if it is possible to begin pilot testing some subjects while we wait for approval?

Observer Role

- Read both roles on the following pages.
- Watch the interview and take notes.
- If the conversation appears to be stopping early, encourage discussion on topics that still haven't been addressed.

What is the student trying to convey?

What is the professor trying to achieve in this meeting?

Did the student "read" the signals from the adviser well? What cues did you see?

Did the professor "hear" the student well? What signals of this were there?

What questions do you think could/should have been asked that were not? What do you think could have been said that was not?

Contributor(s)

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Rights

Use of Materials on the OEC

Resource Type

Case Study / Scenario

Parent Collection

Role-Play Scenarios for Teaching Responsible Conduct of Research

Publisher

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