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Responsible Conduct of Research Role-Plays: Human Subjects

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Responsible Conduct of Research

Role Plays

Human Subjects

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Using Role-Plays in Ethics Education
Role-playing can be a powerful learning experienceand stimulate lively discussion and debate. However this active learning technique, which most people are unfamiliar with, can also make participants feel awkward and uncomfortable at first. The key to its use is to introduce and frame the technique to any group before starting.

Note to Moderator:
After the workshop participants should receive as a handout the section labeled "Resources." That section also includes a summary of the role-play.

Introduction (2-3 minutes)
We generally start a session by talking about the technique and why we use it. We often label it as "experiential" or "active" learning as we talk about it. This introduction can be done relatively quickly and will improve the participation and comfort level of the group.

Points we make include:

- Role-playing is a type of active learning technique. As such, it promotes deep learning, long-term retention and can be very memorable and powerful
- Participants might feel awkward at first, but they are encouraged to participate as fully as possible. The more authentically they engage in their role the more they will learn
- There are no "right" answers in role-plays
- Participants are not being graded
- The purpose of the exercise is to provide an active learning experience in a safe setting where ethical issues can be explored without being about a real problem
- Because role-plays (or simulations) are participatory, educators believe that the information learned will be retained longer and will be more easily accessible in the future if it is needed
- This training will help participants be prepared to recognize and address ethical problems. By grappling with the sorts of ethical problems that arise regularly in professional life in this safe, non-threatening role-play setting, participants can think through the problem and gain some skills and tools to use should they ever encounter such a problem. We think of this as an "inoculation model." By practicing these conversations you become "vaccinated" and thus better able to resist confusion and anxiety when questions of ethical research arise
- These scenarios are based on real situations that real people encountered (You cannot make this material up)
- After the role-play we will discuss the experience. We also will discuss the outcome of the real-life situation upon which the role-play is based, where possible
- For anyone who is truly too uncomfortable to try it out, we have an observer role. The observers are expected to take notes as they watch others do the role-play and then to provide comments back to the other participants in their group at the end of the process.

Instructions (3-5 minutes)
After introducing the technique, we give the group instructions and an overview of the procedures.

1) Materials should have been copied in advance on different color paper, so the roles are easy to distinguish. For example, the professor role might be on blue paper, the student on yellow paper, and the observer role on green paper. **Participants know only what is in their own roles, and have no information on what is in the other roles; that comes out as the session proceeds. Decide in advance whether you will be distributing the discussion starters with the roles. If you are, the discussion starters for each role (and only that role) should be on the same color paper as the role.**

2) Ask participants to divide into groups of two (professor/administrator and student) or three (professor, student, and observer). Each group must have one each of the two main roles (professor/administrator and student).

3) Announce that everyone will start together and end together. (This keeps the noise level down while directions are being given.)

4) When partners have been selected, hand out the roles and discussion starters. Participants are not obligated to use the discussion starters, but it does make the exercise less daunting for many.

5) Verify that every group has two or three people and that each one has a different color paper.

6) Ask participants to leaf through their materials: each should have role information and a role-play starter. Using the role-play starters is optional, not required. They are provided to help those who need a little guidance to ease into the role-play.

7) Announce the amount of time available. 10-15 minutes is plenty of time for these short scenarios.

8) Provide a bit of time for individual preparation. Suggest that participants make notes of what you want to find out, and what your first sentence will be.

Optional step:
If time and space permit, it can help focus the role-plays and make sure all aspects of the scenario are covered if you verbally review the key points of the scenario and the participants' role. To do this, take one group — all of whom are playing the same role — out into the hallway and keep the other together in the classroom. If there is only one discussion leader, appoint one member of one of the groups to read the role information aloud to the group while the discussion leader works with the first group. When the leader finishes

briefing the first group, leave that group to discuss the role among themselves and go brief the second group and answer any questions they might have.

9) Start the role-play. Walk around the room, listening to various groups to get a sense of topics discussed and how the activity is proceeding. Stop the process after it appears that most have exposed the main dilemma and have spent a little time talking about how to approach it.

10) Make sure at the end of the session that participants receive the "Resources" sheets as a take-away handout.

Discussion (30-45 minutes)
After the role-play the moderator should lead a discussion. Follow the discussion guidelines provided following the role-play. It's also useful to plan for a few concluding remarks at the close of the session to consolidate the discussion.

Tips for Leading Discussions
Opening questions and guidelines for leading a discussion are provided below.

- After the role-play, discussion usually takes off on its own in light of the experience. However, if no one speaks right away, don't worry.

- After you ask the opening question, let at least 10 seconds go by to give people a little time to volunteer. When you are at the front of the class 10 seconds feels like eternity, but that amount of time allows participants to begin to gather their thoughts and work up the nerve to respond.

- If the discussion is really lagging at any point, a useful technique can be to ask participants to discuss whatever the proposition is with their neighbors. This "buzz groups" approach can build up enough confidence that people will start talking.

Role-Play Discussion Guidelines: Moderator

General questions to ask:
After the role-play is over and the groups come back together, ask the participants what was going on in this interaction.

Work to elicit the whole story, by alternately asking those who played each role what their concerns were:

- For those playing the student, what were their concerns and how they understood the situation?
- Ask those playing the faculty member, what were their concerns and how did they understand the situation?

Then summarize for the group the essential facts of the two main roles. It can be helpful to make a two-part list on an overhead or chalkboard while you are eliciting information, noting the concerns of the faculty member and the concerns of the student.

If there were recurring themes in the groups you picked up while the role-play was under way, work those into your discussion. Ask the group how closely the two versions that emerged in discussions match. If they do align, what was the most helpful in eliciting information and establishing trust, leading to a useful and constructive discussion? If they do not match (you may have some groups in each category), what kept the two versions from aligning? Was information missing? What kept it from coming out?

Other general questions to ask:

- What were the most helpful things that were said?
- What do people on each side wish the person on the other side had asked or said?
- Who should take the next step here? Why?
- Is there a good outcome to this situation?
- What elements might make it more or less likely to come out well?
- What could the student or the adviser have done earlier to change or prevent the current outcome?

If you had any observers, ask them what they saw going on; see if anyone picked up signals the participants missed. What were they? What difference might it have made if the missed signal had been caught? Ask the group to identify the issues that are presented in this role-play.

Specific questions to ask:

Ask the group to identify the issues that are presented in this role-play. (e.g. compliance with IRB regulations, communication between role-players, trust of participants, consequences for failure to abide by regulations or starting the interviews without full approval)

Give a brief overview of your department/university's IRB regulations. Turn the discussion to options for handling the conflict from this point.

- Did all the facts come out in the role-play? If not, the moderator should continue asking questions until all the facts do come out.
- How well did the faculty member frame the assignment to the student so the student can appreciate the value of the assignment? Did that ever come across?
- Did the faculty member find out that the student had already done some interviews?
- What should the faculty member do next?
- What's likely to happen if the faculty member takes those steps?
- What should the student do? What options does the student have if the faculty member categorically refuses to start early on interviews?
- What elements might make this conflict more or less likely to come out well? For example, did the fact that the adviser made the student put the student's own research on hold influence the student's decision? Was there another way for the adviser to have handled the assignment?

Principles that apply in human subjects research:

Human subject research must follow IRB regulations and principles:

- Respect for persons: treat all individuals as autonomous humans beings and not to use people as a means to an end
- Beneficence: reminds us to minimize harms and maximize benefits. This requires researchers to use the best possible research design to this end
- Justice: treat people fairly and design research so that its burdens and benefits are shared equitably
- Subjects are able to leave study at any time

Clear communication and collegiality:

- Helping and collaborating with colleagues at other institutions is an important aspect of university life
- Student and mentor should have open lines of communication. The student should feel comfortable discussing concerns with mentor. The mentor should be able to address those concerns.
- The mentor should explain clearly why it is in the student's interest to do this project: "I want you to do this because then you can learn/I can help you learn how to make an IRB application, which is an important set of skills to have."

Alternative Formats

A. After the discussion, ask for two volunteers, and do the role-play again, in a "fishbowl" format where the audience will observe one pair proceed through the scenario. Stop the action every now and then and ask for suggestions from the audience on what might be done differently to improve the outcome. Ask the role-players to back up a bit in the interaction and try to incorporate that advice as they move forward again. See if there are differences in how the interaction goes. What lessons can be learned?

B. Pass out the roles and have each person prepare individually.
Ask for two volunteers to come forward to do the role-play in a "fishbowl" format, and then follow with the discussion portion.

This role-play comes out of incidents that happen frequently. Make sure the group understands that, if out of frustration, the graduate student begins the interviews before IRB approval has been received, the IRB has the power to rule that none of the data derived from those interviews can be published.

RESOURCES

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
http://ohsr.od.nih.gov/guidelines/belmont.html

The Illinois White Paper: Improving the System for Protecting Human Subjects: Counteracting IRB Mission Creep
http://www.law.uiuc.edu/conferences/whitepaper/

Office for Human Research Protections (OHRP)
http://www.hhs.gov/ohrp/

University of Illinois Institutional Review Board
http://www.irb.uiuc.edu/

Responsible Conduct of Research Resources

Columbia University
http://ccnmtl.columbia.edu/projects/rcr/

Committee on Science, Engineering, and Public Policy, National Academy of Sciences, National Academy of Engineering, and Institute of Medicine, *On Being a Scientist: Responsible Conduct in Research*, National Academy Press, Washington, D.C., 2nd ed., 1995.
http://www.nap.edu/readingroom/books/obas/

ORI Introduction to the Responsible Conduct of Research,
http://ori.dhhs.gov/publications/ori_intro_text.shtml

Online Ethics Center, National Academy of Engineering
http://onlineethics.org

Research Ethics Modules, North Carolina State University,
http://www.fis.ncsu.edu/Grad/ethics/modules/index.htm

Macrina, F. L. (2005). *Scientific Integrity: An Introductory Text with Cases* (3rd ed.). Washington, D.C.: American Society for Microbiology Press.

North Carolina State University Open Seminar
http://openseminar.org/ethics/screen.do

Shamoo, A. E., & Resnik, D. B. (2003). *Responsible Conduct of Research*. New York: Oxford University Press.

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

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?*

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?*

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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?