Facilitator Guide
Small Group Experience

The small group sessions occur at the completion of the lecture portion of the course. The facilitator role is to assist group members to learn communication skills from each other through role playing, through responses to role playing and to experience the real, difficult and time sensitive ethical situations faced by the person conducting the initial informed consent process. To promote a learning environment, it is essential for the facilitator to make group members feel comfortable and safe with their participation in the role playing experience.

General “Tips”
The size of the group may be a determinate of the number of role-playing scenarios that the group accomplishes, for example, a larger group will generally need more discussion time to integrate the various viewpoints.

It is helpful to know the characteristics of the group taking the course in order to provide the most successful group experience. For example, a group with members known to each other versus a group with people who do not know each other, affect group dynamics.

At times, role-playing a scenario can become a lengthy process. Adequate time is needed to build the scenario, and adequate time is also needed to integrate and synthesize the role-playing experience with group discussion. The facilitator may want to stop the role playing, when enough material for discussion has occurred whether or not a conclusion regarding study participation has been reached.

Lastly, the exercise is meant to be enjoyable and growth producing – not fear producing. A sense of humor while doing the scenarios helps group members to relax and “be themselves” and ground rules that feedback remain constructive are helpful.

Suggestions for role-playing

• Bring the group into a tight circle.

• Ask each group member to briefly introduce themselves, to state their experience with the informed consent process and, briefly state with any issues or concerns they may have about informed consent.

• Ask for role-playing volunteers and distribute roles.

• If the group is large, ask people playing the various roles to move their location so that they are sitting next to each other.

• Prep the group with a brief overall description of the role playing scenario.
• Describe the role playing scenarios and the way they will work

• The roles are real-life situations that present ethical dilemmas. Vignettes help us understand those dilemmas in a real way, experiencing them, rather than reading about them.

• Role playing volunteers have more information about their roles than the group as a whole.

• The group has general information about the scenario. During role-playing, the group sits in observation and in support of the roles the volunteers play. They listen to retain information for later discussion to integrate information about what does, and does not contribute to an effective informed consent process. In particular they should listen for the investigator’s use of the “talk back” method and exploration of a possible subject’s motivations to participate and the subject’s response to the investigator’s communication strategies.

• Role playing volunteers are asked to “throw themselves into the role” and to try to stay in character.

• Role descriptions provide direction, but no specifics. Role-playing volunteers are encouraged to use their imagination when playing roles. They do not need to be concerned with playing themselves or getting the content “right”. There are no right or wrong ways to play a role.

• Role playing volunteers may ask for a “time out” from the scenario if they have questions or comments that would like to briefly discuss. This assists volunteers with varying amounts of informed consent experience with the role playing experience.

• At the conclusion of the role playing, give role playing volunteers the first opportunity to make observations about their role playing experience and then open discussion to the group as a whole.

**Suggested Questions for Group Discussion**
Any of the following questions may be useful to stimulate group discussion concerning the role-playing experience.

**Questions for the role-players**

*For both role-playing participants*

• What was it like to be role-playing this scene? In what way do you think your experiences might be similar to real life?

• How difficult was it to “get into the role”? What might this say about real life experiences?
Investigator

- What was on your mind at various points [select time points] in the role playing?
- Could you tell us what you were experiencing as the role playing character?
- How easy, difficult was it to use the “talk back” method and to ask about motivations?
- What were some of the easiest and some of the hardest ethical decisions you believed needed to be made quickly during the role playing?

Possible subject

- What was on your mind at various points [select time points]?
- What was the experience like for you as a possible subject participant when the investigator used the “talk back” method and when they didn’t?
- How well were the concerns that you had, or the possible motivations to participate, drawn out during the discussion?
- Was your point of view understood?

For the group as a whole

- What is your assessment of the informed consent process as it played out? What did you experience? Group member’s observations may be discussed with the role playing volunteer investigator or subject to help confirm opinions or assessments about the role playing.
- How has this role playing brought up concerns that you may have had about the informed consent process?
- How does this role playing compare to experiences you may have had?
- Are there strategies you have used in the past in similar situations? How well did they work, or not work?
- Are there some suggestions that you might have for how the investigator might have dealt with a particularly difficult situation that arose during the role playing?
- How does the talk-back method and asking about motivations raise the ethical dilemmas associated with informed consent in a way that just giving the elements of informed consent to a subject does not?
- How did verbal and nonverbal behavior affect discussion during the role-playing?
- Do you believe the investigator understood the possible subject’s concerns and motivations? Why or why not?
- How often have you or others focused on educating subjects about each of the elements of informed consent and not used communication methods to understand a possible subject’s concerns or motivations? Does use of these communication methods complicate or facilitate the informed consent process?
- How easy or difficult is it to use these methods?