

# **Valid Informed Consent or Refusal Standardized Research Participant Instructor Face-to-Face Interviews**

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## **Introduction**

The third component of the Valid Informed Consent and Refusal curriculum is the face-to-face interview with the Standardized Research Participant Instructor (SRPI). During this one hour session, learners practice new communication techniques and approaches in one-on-one simulated interviews, followed by individualized feedback sessions with the SRPI in a non-threatening environment.

The following is a step by step outline of the SRPI recruitment, SRPI training, and Administration of the SRPI Exercise.

## **Methods**

### **A. SRPI Recruitment**

The SRPI component of the curriculum was developed with the assistance of the Standardized Patient Program at the University of Michigan Medical School. Standardized Patients are individuals trained to portray specific patient roles, assess learner performance (including communication skills) against specific criteria, and provide constructive feedback to learners based on their assessment. Increasingly, standardized patients have been used as an educational tool to assess and evaluate the competencies of students within the health sciences (Medical, Dental, Public Health, etc.). Should you chose to implement this piece of the curriculum, we strongly recommend you contact your institutions Standardized Patient Program. If your institution or place of business does not have a program, please visit [www.aspeducators.com](http://www.aspeducators.com) for further information.

Due to the demographic flexibility of the individual described in the 3 provided SRPI cases, recruitment should not be difficult, though the challenge of recruiting Standardized Research Patient Instructors may very depending on your location. The utility of a Standardized Patient Program cannot be understated as these programs often have databases of competent and previously trained individuals who are familiar with the pedagogy of Standardized Patients. Furthermore, the majority of practicing Standardized Patients have been trained to give verbal feedback to learners.

The most important factors to recruitment are: your programs ability to provide the SRPI with pay and parking, the SRPIs ability to role play a case, accurately complete an evaluative checklist from memory at the conclusion of the scenario, and the ability of the SRPI to provide verbal feedback in a constructive, non-threatening manner.

### **B. SRPI Training**

Training of the SRPI is broken down into 4 two-hour training sessions:

#### **Training 1 – Introduction**

Participants – SRPIs, Trainer, and Program Director/Informed Consent “expert”

Materials – SRPI training binder complete with cases, checklists, guide to completing checklist, guide to providing verbal feedback, and resources for learning more about the process and policies regarding valid informed consent or refusal in research. Training video.

Location – Conference Room

The first hour of Training #1 should be spent distributing case materials. Each case and checklist should be reviewed with the SRPIs along with the handout describing the criteria for rating a learner's performance on the checklist, as well as the guide to providing verbal feedback. If possible, SRPIs should be shown a video of a Study Coordinator walking a potential participant through the process of consent.

The second hour of Training #1 should allow for an introduction to the Valid Informed Consent and Refusal curriculum, complete with handouts to better familiarize SRPIs of national and local policies regarding consent and research participants rights. Should your program have a resident expert on Informed Consent or Bioethics, it is often useful to include this person at this time in training to provide your SRPIs with an informed overview.

The session should conclude with an overview of Training #2 and a reminder to SRPIs to review their materials prior to the next session.

### Training #2 – Review of Materials and Role Plays

Participants – SRPIs and Trainer

Materials – SRPI Training Binders

Location – Conference Room

The first hour of Training #2 should begin with asking the SRPIs if they have any questions about case materials. After answering questions, the Trainer should perform an informal quizzing session to test SRPIs knowledge of case details. Once the quiz session has finished, the Trainer should direct a quick review of the guide to the checklist and the guide to providing verbal feedback.

During the second hour of the training, the Trainer and SRPIs should perform abbreviated role plays of the cases with the Trainer playing the role of the Study Coordinator (all SRPIs should participate in at least one role play with the Trainer). At the conclusion of the role play, each SRPI – whether they took part in the role play or simply observed – should complete the checklist. Once all parties have penciled in their answers, the Trainer should provide the portraying SRPI with feedback on their ability to play the role, followed by a review of the checklist items and the necessary rationale for correct or incorrect answers. The checklist review should be followed by the portraying SRPI providing verbal feedback to the Trainer.

The session should conclude with an overview of Training #3 and a reminder to SRPIs to review their materials prior to the upcoming Practice Interviews.

### Training #3 – Practice Interviews

Participants – SRPIs, Trainer, Practice Interviewees

Materials – Scenario descriptions, Consent Forms, Checklists, Exercise Evaluations, Pencils

Location – Clinical Exam Room or Small Conference Room (recording capability recommended)

Training #3 is designed to provide the SRPIs with a simulated live experience which tests their ability to portray the case, complete the checklist, and provide verbal feedback. Practice Interviewees for the exercise should be recruited from the group of faculty/staff affiliated with the project and/or willing Study

Coordinators within the institution. If possible, the interview should be video/digitally recorded in order to provide the SRPI with feedback (Practice Interviewees should be asked to consent to be recorded).

The training session should be as close to the real experience as possible. Practice Interviewees should be given 30 minutes to complete the exercise, the SRPI and Practice Interviewees should complete their respective checklists at the conclusion of the interview, and the session should finish with the SRPI providing the Practice Interviewees with verbal feedback. If possible, the SRPI should participate in two practice interviews.

If a video feed is available, the Trainer should watch the live broadcast of the interview and take notes for the Training #4 Debriefing Session. When the interviews have finished, the Trainer should ask the Practice Interviewees to fill out a feedback form evaluating the SRPI and exercise.

Once the practice interviews are completed, the session should conclude with a solicitation for questions from the SRPIs and an overview of Training #4.

#### Training #4 – Practice Interview Debriefing

Participants – SRPIs, Trainer, Practice Interviewees

Materials – Scenario descriptions, Consent Forms, Checklists, Exercise Evaluations, Pencils, TV/DVD for projection of recorded interviews (if possible and applicable)

Location – Conference Room

The fourth and final training is intended to provide the SRPIs with feedback based on the observations of the Practice Interviewees and Trainer (if possible). In addition, tweaking of SRPI performance, checklist completion, and verbal feedback should take place at this time. SRPIs should also share their Practice Interview experiences in order to broach confusing situations and enhance the knowledge of the collective group.

The training should conclude with each SRPI ready to “go live”.

### **C. Administration of the SRPI Exercise**

With the completion of Training #4, the SRPIs are now prepared to work one-on-one with Valid Informed Consent or Refusal to Participate in Research curriculum participants. Each curriculum participant should be contacted in order to schedule a one hour time-slot to complete the exercise. In addition, the participant should be mailed a copy of the Valid Informed Consent or Refusal to Participate in Research SRPI booklet to review prior to their scheduled session.

The SRPI exercise should take place in clinical exam rooms or small conference rooms which are in close proximity to one another. The area should be relatively quiet in order to avoid interruptions. The rooms should be outfitted with two comfortable chairs, a desk, and a clock.

Once the SRPIs are in their assigned rooms with doors closed, the exercise can start. Participants should be asked if they have read the SRPI booklet and allowed to ask questions about case materials prior to beginning the exercise. At the completion of the question and answer, the Exercise Coordinator should provide the participants with a copy of the case scenario, the consent form, and blank paper. At this time, the Exercise Coordinator should also inform the participants about the exercise logistics: 30 minutes to interview the

SRPI with a 10 minute warning knock, 10 minutes to complete the checklists in room with SRPI, and 20 minutes for verbal feedback/discussion with SRPI.

At the conclusion of the SRPI exercise, each participant should be asked to complete an evaluation of the exercise. The Exercise Coordinator will collect all checklists/evaluations and provide them to faculty/staff affiliated with the project for processing.