SPI Program

University of Michigan Medical School

Valid Consent and Refusal to Participate in Research

An educational exercise emphasizing communication skills with feedback from a Standardized Research Participant Instructor (SRPI)

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PLEASE REVIEW THIS MATERIAL CAREFULLY PRIOR TO YOUR INTERVIEW

VALID CONSENT AND REFUSAL TO PARTICIPATE IN RESEARCH

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INTRODUCTION

In order to protect human participants in research, the need to obtain valid informed consent is a moral imperative. Valid informed consent is more than obtaining a signature on a document – it is achieved only through appropriate, two-way communication.

Discussing research participation with potential volunteers can be challenging. Learning how to obtain valid consent (or refusal) requires more than theoretical knowledge - it requires practice. To "do" consent well, one needs:

- to know the elements of consent and the criteria for competence to make decisions,
- skills to evaluate competence, assess understanding, and relay information in an understandable way,
- skills to determine the right amount and kind of information required for a particular individual for a particular study,
- respect for the values of others including their cultural heritage and religious beliefs, as well as sensitivity to social power structures,
- to be able to recognize and disclose conflicts of interest.

Potential volunteers come to such discussions with their own needs and perceptions, and can be worried about their current health and intimidated by medical personnel. Common difficulties that researchers may face include mistrust, false hopes that an investigational intervention will provide personal health benefits, a lack of understanding of research and scientific terminology, and even language barriers.

Many researchers have not had formal training in communicating with laypersons about research. This exercise will allow you to practice discussing research participation with a potential volunteer, assess your own performance, and receive constructive feedback from a trained instructor.

GUIDELINES FOR THE SPI INTERVIEW

You will participate in an educational exercise intended to help you develop the skills needed to discuss research participation appropriately with potential volunteers.

This is a Standardized Research Participant Instructor (SRPI) exercise that provides you the opportunity to practice techniques and to receive constructive feedback in a non-threatening environment. The person with whom you will interact is simulating the history and presentation of a potential research participant who meets the inclusion criteria for a research protocol.

Your task in this exercise is to communicate with the SRPI about participating in the research, evaluate his/her competence to consent, and obtain valid consent (or refusal) from him/her.

You will be assessed on your ability to effectively perform *informed* consent and communicate appropriately with the potential volunteer.

You will assume the role of a researcher who is not involved in the care of this particular patient. You have never met this potential volunteer. During this exercise you should review the research protocol, options, risks, and benefits for the potential volunteer, including all required elements of consent per current guidelines. If applicable, according to the described research scenario, you should also disclose any potential conflict of interest for you or the institution.

Information about the study, its risks, benefits and alternatives is included in this booklet, as is relevant background material about ethical guidelines. Please become familiar with all of the information provided in this booklet.

The interview with the potential research participant will last no longer than 30 minutes. By the end of the session, you should have completed your discussion of the study with the potential volunteer, and either obtained consent, obtained refusal, or mutually agreed to defer the decision until some specific day and time. At no time should you break from your role as a researcher. Likewise, the potential volunteer will maintain his/her role throughout the interview.

At the end of the session, an additional 20 minutes will be used for you and the patient to discuss the overall interview. The standardized research participant instructor will review with you the strengths and weaknesses of your performance during the session.

When you enter the room, shake the potential research participant's hand and say, "Good afternoon, Mrs. or Mr. Bensen. I am _____." The SRPI will respond with a similar greeting.

Beyond this introduction, you should conduct the interview as you feel is most appropriate. A description of the exact situation is on page 7 of this booklet. Various approaches to discussing research participation with a potential volunteer are included in the "Resources" section of this booklet. If needed, you can ask questions of the potential volunteer, either for additional medical background, or to clarify what they do and/or do not understand. When ending the interview, close appropriately, shake the potential volunteer's hand, and leave the room. At that time, the interview portion of the exercise will be over. For the next 5 minutes you will use the same checklist as the SRPI to assess your own performance during the exercise (see page 6), then the SRPI will invite you to sit down and the two of you will review the entire interview. Feedback from the standardized research participant instructor will be based on the goals and intended learning outcomes outlined in this booklet.

To prepare for this exercise you should review all of the information in this booklet. You will be provided with of a copy of the Informed Consent Document (pages 8-12) to take into the exam room with you.

INTENDED LEARNING OUTCOMES

The goal of the "Valid Consent and Refusal" exercise is:

> To help you develop the appropriate attitudes, knowledge, and skills that will enable you to communicate with potential research participants in appropriate ways that show respect, enhance trust, and meet ethical guidelines for informed consent to research by human volunteers.

At the completion of this exercise you should be able to:

1. Communicate respectfully, knowledgeably, and skillfully with potential research volunteers, in accessible language, in order to obtain valid consent or refusal.
2. Communicate conflicts of interest clearly and in accessible language.
3. Effectively evaluate competence in potential research participants.
4. Evaluate potential volunteers' comprehension of the information you are explaining.

APPROACHES/TECHNIQUES

Suggested approaches to discussing research participation with a volunteer:

Preparation:

1. Know the potential volunteer's medical and personal details, provided in the enclosed scenario (page 7).
2. Know all relevant, available information (e.g., about the research protocol).
3. Review the consent document, be familiar with its contents, and prepare to answer questions about the study.
4. Prepare yourself in advance for what you will say – make a short checklist of points to cover if needed.

Introduction:

1. Introduce yourself.
2. Spend a few minutes establishing rapport.
3. Ask for information from the volunteer to assess his/her knowledge of their current clinical situation.

Achieving understanding:

1. Speak clearly and use non-medical terminology.
2. Be organized in your presentation of information.
3. If necessary, write down any technical terms and show the patient or draw pictures.
4. Find out what the potential volunteer's views are about research.
5. Assess the potential volunteer's understanding of the risks/benefits/alternatives of participation; use the "talk back" method by asking them to tell you in their own words what they understand about the research.
6. Whether s/he consents or refuses, ask for an explanation for that decision.

General Communication:

1. Let the potential volunteer take some of the lead; involve him/her in the decision.
2. Give the potential volunteer appropriate time to ask questions.
3. Maintain eye contact. Be aware of non-verbal cues/communication.
4. Listen to the potential volunteer. Allow him/her time to express concerns, and respond clearly to them.

Honesty:

1. Do not be afraid to say "I don't know."
2. Do not try to "whitewash" any potential conflict of interest you disclose.
3. Be aware of the possibility for the potential volunteer to overemphasize the personal benefits of participation.

Non-Verbal Framework (Structure):

1. Sit close to the patient, facing him/her.
2. Make eye contact with the patient.
3. Use effective body language (posture and proximity).

Closure:

1. Summarize the discussion and outcome.
2. Close the discussion by inviting questions and pointing out resources for future questions.

At the completion of the interview, the Standardized Patient Instructor will complete the following checklist assessing your performance:

SRPI CHECKLIST FOR CONSENT TO RESEARCH

Score the following items as A = Done, B = Needs Improvement, C = Not Done

The learner EXPLAINED*:*

1. The study IS research
2. The purpose of the research.*(to study such-and-such, and list/explain potential benefits to individuals and society)*
3. The study design to the patient.*(including randomization, use of controls, blinding)*
4. The institution's conflict(s) of interest OR explicitly stated that none existed
5. Procedures the patient would undergo
6. Which procedures are experimental
7. Any potential discomfort, risks, or harms which may result from participation *(including that there may be unforeseen discomforts, risks or harms)*
8. Study policies regarding treatments or compensation in the case of harm
9. The timeframe during which the patient would be involved in the study
10. Study policies regarding compensation for study participation (specific amount, including time and effort)
11. Participation is voluntary, thus allowing the patient to stop participation any time without penalty
12. Any costs that could be incurred by the patient if he/she participated
13. Study policies regarding confidentiality of patient's medical and personal history *(including how records would be maintained)*

The learner assessed the patient's UNDERSTANDING of:

14. The purpose of the research
15. The procedures the patient would undergo
16. Any potential discomfort, risk, or harms which may result from participation
17. Voluntary participation (the patient can stop any time without penalty)

The learner:

18. Addressed the patient by formal name
19. Introduced him/herself at the beginning of the interview
20. Spoke to the patient in a respectful manner.*(was friendly and considerate, did not speak down to me)*
21. Maintained eye contact with the patient throughout the interview
22. Used the patient could understand throughout the interview
23. Gave the patient time to consider whether or not to participate *(did not make me feel pressured or coerced, asked me if I needed more time or if I understood everything that had been explained)*
24. Gave the patient a contact information card to use if they have questions or concerns
25. After explaining everything, asked patient to consent to participate by reading/reviewing and signing the consent form

Resource Material

Valid Consent and Refusal to Participate in Research

Reprinted Readings:

Code of Federal Regulations: Title 45, Part 46, Protection of Human Subjects. (*excerpts related to informed consent and assent)*. Entire document available through the Office Of Human Research Protection at http://ohrp.osophs.dhhs.gov/

Belmont Report: Ethical Principles And Guidelines For The Protection Of Human Subjects Of Research. 1979. Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Available through the Office Of Human Research Protection at http://ohrp.osophs.dhhs.gov/

Kass NE, Sugarman J, Faden R, Schoch-Spana M. 1996. Trust: The Fragile Foundation of Contemporary Biomedical Research. Hastings Center Report. 26(5):25-29.

> This article discusses the results of the Subject Interview Study, undertaken by the Advisory Committee on Human Radiation Experiments. Patients often decide to enter clinical trials with hope for personal health benefits as well as from a sense of social altruism. Patient-participants' trust in physicians and medical institutions often also plays a role in their decision to become research participants.

Morin K, Rakatansky H, Riddick FA Jr, Morse LJ, O'Bannon JM 3rd, Goldrich MS, Ray P, Weiss M, Sade RM, Spillman MA. 2002. Managing conflicts of interest in the conduct of clinical trials. Journal of the American Medical Association. 287(1):78-84.

> This article outlines various types of conflicts of interest that arise for clinical investigators in an era of increased interaction between medical research and for-profit corporations. Conflicts discussed include conflicting roles, financial conflicts, and other material incentives. Ways to deal with these conflicts are suggested.

O'Neill O. 2003. Some limits of informed consent. Journal of Medical Ethics. 29(1): 4-7.

> This article locates the duty to obtain valid informed consent in both therapeutic and research contexts in a broader understanding of informed consent as part of everyday moral interactions. It is argued that the requirement of informed consent should not hinge on any particular view of autonomy, but on the moral obligation that research participants and/or patients are not deceived or coerced.

Further Readings:

Appelbaum PS. Grisso T. Assessing patients' capacities to consent to treatment. New England Journal of Medicine. 319(25):1635-8, 1988 Dec 22

Berg JW, Appelbaum PS, Lidz CW, Parker LS. 2001. Informed Consent: Legal Theory and Clinical Practice, Second Edition. New York: Oxford University Press.

Bok S. 1995. Shading the truth in seeking informed consent for research purposes. Kennedy Institute of Ethics Journal. 5(1):1-17.

Buchanan A. 1996. Judging the past. The case of the human radiation experiments. Hastings Center Report. 26(3):25-30.

Caplan AL. 1992. Twenty years after. The legacy of the Tuskegee Syphilis Study. Hastings Center Report. 22(6):29-32

Emanuel EJ, Wendler D, Grady C. 2000. What Makes Clinical Research Ethical? JAMA 283:2701-2711

Faden R, Beauchamp T. 1986. A History and Theory of Informed Consent. New York: Oxford University Press.

Ferguson P.R. 2003. Information Giving in Clinical Trials: The Views of Medical Researchers. Bioethics.17(1):101-111.

Johns MM, Barnes M, Florencio PS. 2003. Restoring balance to industry-academia relationships in an era of institutional financial conflicts of interest: promoting research while maintaining trust. JAMA. 289(6):741-6.

King NM. 1995. Experimental treatment. Oxymoron or aspiration? Hastings Cent Report. 25(4):6-15

Lidz CW, Appelbaum PS. 2002. The therapeutic misconception: problems and solutions. Medical Care. 40(9 Suppl):V55-63.

Lo B, Wolf LE, Berkeley A. 2000. Conflict-of-interest policies for investigators in clinical trials. New England Journal of Medicine. 343(22):1616-20.

McCrary SV, Anderson CB, Jakovljevic J, Khan T, McCullough LB, Wray NP, Brody BA. 2000. A national survey of policies on disclosure of conflicts of interest in biomedical research. New England Journal of Medicine. 343(22):1621-1626.

The Nuremburg Code. *In:* Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law. 10(2):181-182. Washington, D.C.: U.S. Government Printing Office, 1949.

World Medical Association Declaration of Helsinki.

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