Unit 9

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| Overview  In this unit, trainees will learn how to read and review a HIV vaccine clinical trial protocol from a community perspective. They will learn the basic elements of a scientific study, how the studies are designed and how community members play an integral role in the development of study protocols.  Objectives  By the end of the unit trainees will be able to:   * Review an HIV vaccine protocol from a community perspective * Explain the difference between the informed consent document and the informed consent process * Describe the kinds of issues that might arise when implementing a study in different communities * Provide community-oriented comments and feedback to an informed consent document   Materials   * Training\_Protocol\_ HVTN\_999.doc – 1 copy per small group * Protocol development.ppt – 1 copy per trainee * How to review a protocol.doc – 1 copy per trainee * Generic Outline of a Protocol.doc – 1 copy per trainee   Approximate time 2 hours |

How to Review a Protocol

# Warm-up/Introduction (20 minutes)

## Trainer Notes

The purpose of this opening exercise is to show how complex a protocol is and that it is OK to not understand all parts the first time you see it.

## Preparation

Look over the protocol and pre-select 2 sentences or paragraphs that contain very complicated words or sentences. Try to use sentences or paragraphs from different sections of the protocol. Note: Section 6, Statistical Considerations, typically has some complicated concepts, as does Section 4, Background, which has a lot of the details of previous studies done in animals.

* Training\_Protocol\_ HVTN\_999.doc

## Procedure

**Step 1:** Explain that a protocol is like a master document, in that it describes exactly how the trial will be conducted. It talks about everything from statistical information to preparing the vaccine injection. It is a long and complex document.

**Step 2:** Ask for a volunteer to read aloud. If there are no volunteers, assign someone to read. Direct the trainees to the first pre-selected passage. Tell the participants the page number and paragraph and ask the volunteer to read it out loud.

The idea is that the person will struggle reading the text because it contains big, unfamiliar terms. However, when he/she finishes reading, you must pretend that everyone understands what was read. Next move on to the next pre-selected passage as though everything is just fine.

**Step 3:** Ask for another volunteer to read the second pre-selected passage. Do not take questions at this point. Make it seem like this is an easily understandable document.

**Step 4:** Once the second person has completed reading, pretend that these sections were very straightforward, easy-to-comprehend paragraphs. Ask someone to quickly explain what they understood from either the first or second reading. Usually no one will volunteer.

**Step 5:** Relieve the tension by pointing out that indeed this is a very complicated scientific document, and what was just read didn’t quite make sense to you either. Most laypersons will not understand this very scientific language. Tell the trainees not to worry, and point out that in this unit they will learn to break down this complex document and review it from a layperson’s community perspective.

# Presentation of Information (40 minutes)

## Preparation

* Protocol Development.ppt

## Procedure

**Step 1:** Use the notes on the slides to guide you through the presentation.

**Step 2:** At the end of the presentation, emphasize the importance of the informed consent document. It is the only part of the protocol that a trial participant will read to understand the trial (although it may be supplemented with other informational tools). The informed consent document is written to describe the protocol, or study, and is intended to be understood by someone with an 8th grade level of education (approximately age 14).

**Step 3:** Refer to the *Protocol Development.ppt* presentation and talk about the role that CAB and staff play in ensuring that the informed consent document is clear and culturally appropriate. It is the role of the local CAB to review the protocols that will be conducted at their site for language, readability, and understanding before the protocols are sent to the local Ethics Committees for regulatory approval.

**Step 4:** Explain that informed consent is not just the document, but rather a process of understanding that includes reading or talking through the informed consent document and discussing issues/questions with a site staff member throughout the trial. Site clinicians have the responsibility of ensuring that the volunteer truly understands the risks and benefits of trial participation. This is done through questions and answers, general conversation and a test of understanding. The process of informed consent is ongoing throughout the conduct of a trial.

**Step 5:** While CAB members play an essential role in the protocol development and consent review process, they are not ultimately responsible for the well-being of the study participants. The legal responsibility falls to the site’s principal investigator and the local Ethics Committee.

# Group work (30 minutes)

## Preparation

* How to review a protocol.doc
* Generic outline of a protocol

## Procedure

**Step 1:** Have the trainees get into pairs. Depending on the number of groups, assign 2 or 3 questions per group from the “*How To Review A Protocol*” handout. For example, Group 1 will answer questions 1 and 2; Group 2 answers questions 3, 4, and 5, etc.

**Step 2:** Tell the trainees to take 25 to 30 minutes to read through *Training Protocol HVTN 999.doc*, focusing on the Schema (page 9), Overview (pages 9, 10), and Sample Informed Consent (Appendix A). The questions they receive may pertain only to certain parts of these sections, but they should look through all areas when searching for their answers. Encourage them to refer to other parts of the protocol as necessary. Let them know that they may write on or highlight the document as they please.

# Wrap-up Activities (30 minutes)

## Procedure

**Step 1:** Once each small group has finished answering its questions, it will present its findings in front of the entire group. Have each small group select a spokesperson to present its findings.

**Step 2:** Direct the spokesperson to read the small group’s question(s) aloud, state on which page and in which section they found their answer, and then proceed to answer the question. Encourage the audience to add any additional information that the presenters may have missed.

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| M Important note:  The protocol used in this exercise has been modified for training purposes and all proprietary information and names have been changed. The vaccine described is fictional. However, if using a real protocol to train a CAB, be sure to collect all protocols and have them either shredded or burned. No one should leave the training with any part of a real protocol, because they include proprietary information that is confidential. |

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