



*François-Xavier Bagnoud Center*  
University of Medicine & Dentistry of New Jersey

# **Trainer Manual**

*for Community Advisory Boards*

## **Module 3**

**Informed Consent  
and Counselling**

Version 1.0 – May 2007



## MODULE 3: INFORMED CONSENT AND COUNSELLING

### Proposed Agenda\*

**Opening Activity: Family Panel Interactive** (30-60 minutes)

**Part I Slides and Discussion** (45 minutes)

**Confidentiality Role Play** (45 minutes)

**Part II Slides and Discussion** (30 minutes)

**Informed Consent Role Play** (45 minutes)

**Participant Evaluation** (15 minutes)

*\*Modules may be divided and adapted to fit the available time frame, to meet the specific needs of individual CABs, and to provide adequate break time for participants and trainer(s). Please adapt the participant evaluation forms as needed so that they are appropriate for the training plan.*



## OPENING ACTIVITY

### Module 3

### Family Panel

Time frame **(30-60 minutes)**

#### Purpose

- To allow participants to hear first-hand experiences of families who have participated in clinical trials, with a particular focus on their experience with the consent process
- To allow participants a chance to ask panel members about their primary concerns regarding research and about how they think the informed consent process might be improved (including potential peer counselling from CAB members)

#### Materials needed

- Chairs for panel
- Table for panel (optional)
- Flipchart and marker or chalkboard and chalk for note-taking (optional)
- List of suggested questions: adapt the questions to your panel.

#### Instructions

- To prepare for the family panel, the trainer will want to work with the research team to identify at least 3 but no more than 5 clinical trial participants (past or present) willing to take part in a panel discussion with the CAB. Explain to panel volunteers:
  - The purpose of the panel
  - Who will be in the audience
  - Purpose of a CAB
  - The questions you will ask them
- The panel members should be seated where they can be seen by all participants. If possible, it is better to avoid seating the panel on a stage or dais above the audience. It is best if the panel is close to the audience so as to encourage conversation and interaction.
- Begin by explaining the purpose of the panel discussion to participants. Tell participants that they are encouraged to interact with the panel by commenting on the discussion and by asking questions of the panel members. The discussion is meant to be informal, and you do not have to follow a “script”.
- Thank the panel for coming, and then ask each panel member to introduce him/herself.
- Begin the conversation by asking the panel (or one particular panelist) a question (See suggested questions list). You may create your own questions, or add or subtract from these questions as needed.
- Try to allow 5 minutes or more for a wrap-up where the trainer reviews the important points made during the panel discussion.
- Thank the panel for their time and their input, and end the session with applause.

## Family Panel: Suggested Questions

- When you were first approached about participating in a clinical trial, how did you feel about it?
- What were your thoughts about research before you participated in this trial?
- With whom did you feel most comfortable talking about the research? To whom did you usually address questions?
- Describe for us the consent process leading to your participation (or your child's participation) in the trial?
- Did you feel you had a clear understanding of the trial?
- Since joining the trial, has anything happened that you (1) hadn't been prepared for or (2) didn't understand in advance?
- Have you felt frustrated at any time while participating in the trial?
- Have you felt the health care you received as a participant is better or worse than the health care you received before joining the clinical trial?
- How do you think the CAB members here with us today might help improve the process of research for community members?
- Do you feel the community in general needs more information about research?
- Are there concerns or questions you would like the researchers at your site to hear?



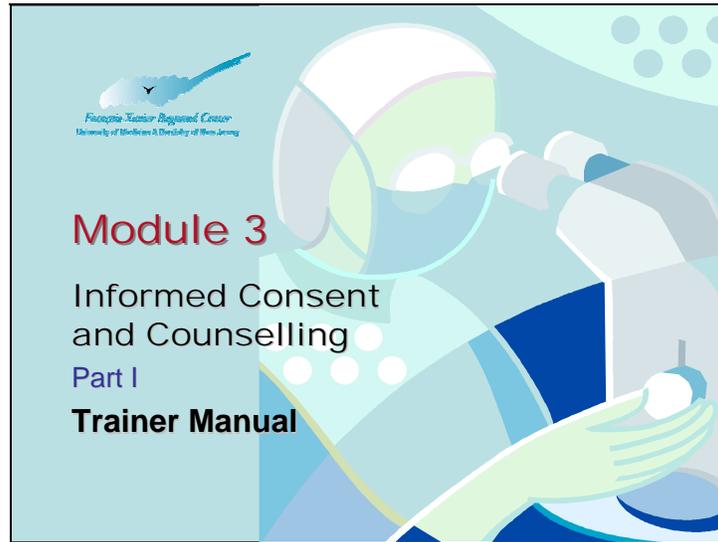
## **Module 3**

### **Part I Slides – Insert Here**





Slide 1



## Slide 2

This teaching tool was developed by the François-Xavier Bagnoud Center at the University of Medicine and Dentistry of New Jersey, with the support of the International Maternal Pediatric and Adolescent Clinical Trials (IMPAACT) network.

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Claire Schuster, BS, MPH  
Network Community Coordinator  
Social & Scientific Systems, Inc.  
Email: [cschuster@ss3.com](mailto:cschuster@ss3.com)  
(301) 628-3319



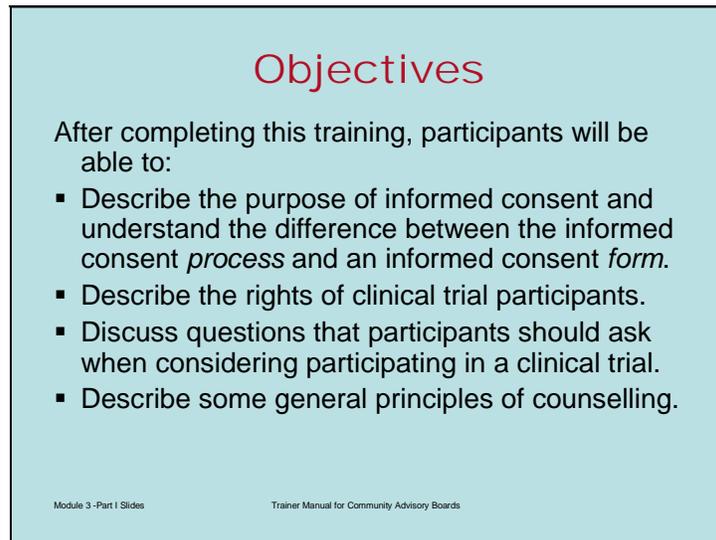
*François-Xavier Bagnoud Center*  
University of Medicine & Dentistry of New Jersey

Mary Jo Hoyt, RN, MSN  
IMPAACT Global Training Director  
François-Xavier Bagnoud Center  
Email: [info@fbcenter.org](mailto:info@fbcenter.org)  
(973) 972-9230

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Module 3 -Part I Slides Trainer Manual for Community Advisory Boards

## Slide 3



The slide is a light blue rectangle with a black border. At the top center, the word "Objectives" is written in a red, serif font. Below it, the text "After completing this training, participants will be able to:" is in a black, sans-serif font. This is followed by a bulleted list of five items, each starting with a black square bullet. At the bottom left, there is small text: "Module 3 -Part 1 Slides". At the bottom center, there is small text: "Trainer Manual for Community Advisory Boards".

## Objectives

After completing this training, participants will be able to:

- Describe the purpose of informed consent and understand the difference between the informed consent *process* and an informed consent *form*.
- Describe the rights of clinical trial participants.
- Discuss questions that participants should ask when considering participating in a clinical trial.
- Describe some general principles of counselling.

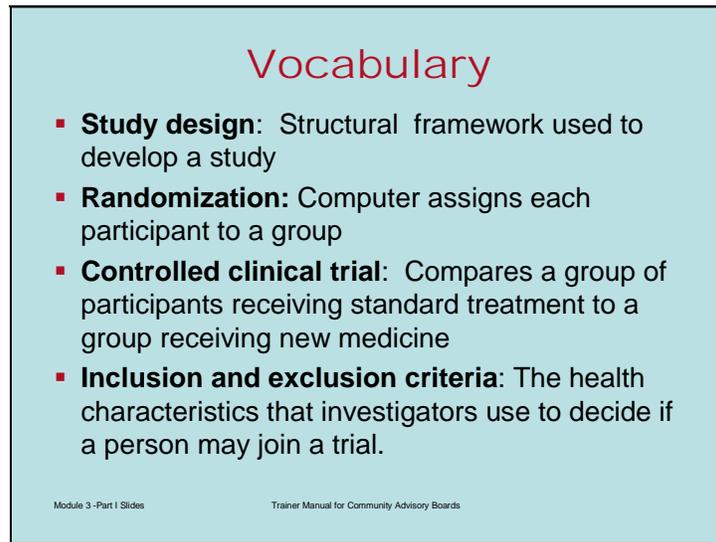
Module 3 -Part 1 Slides

Trainer Manual for Community Advisory Boards

This slide lists the learning goals for this training. The slides we will show and the activities should help you to learn the answer to these questions.

- What is informed consent?
- How do you help a person decide whether to join a clinical trial?
- How do we counsel people who are considering a clinical trial?
- What are some of the rights of a research subject?
- What is the difference between an informed consent form vs. the informed consent process?

## Slide 4

A light blue rectangular box with a black border containing the title 'Vocabulary' in red and four bullet points in black. At the bottom left of the box is the text 'Module 3 -Part 1 Slides' and at the bottom right is 'Trainer Manual for Community Advisory Boards'.

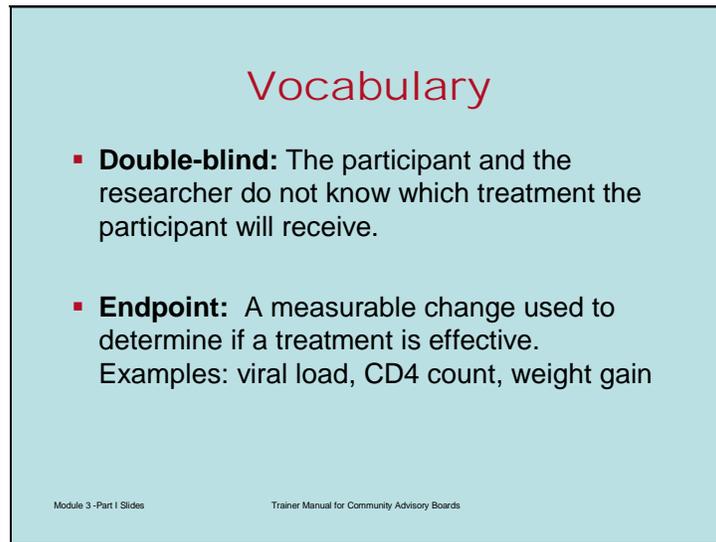
### Vocabulary

- **Study design:** Structural framework used to develop a study
- **Randomization:** Computer assigns each participant to a group
- **Controlled clinical trial:** Compares a group of participants receiving standard treatment to a group receiving new medicine
- **Inclusion and exclusion criteria:** The health characteristics that investigators use to decide if a person may join a trial.

Module 3 -Part 1 Slides Trainer Manual for Community Advisory Boards

- **Trainer:** Skip this slide if your training participants are already comfortable with all of these definitions and concepts.

## Slide 5



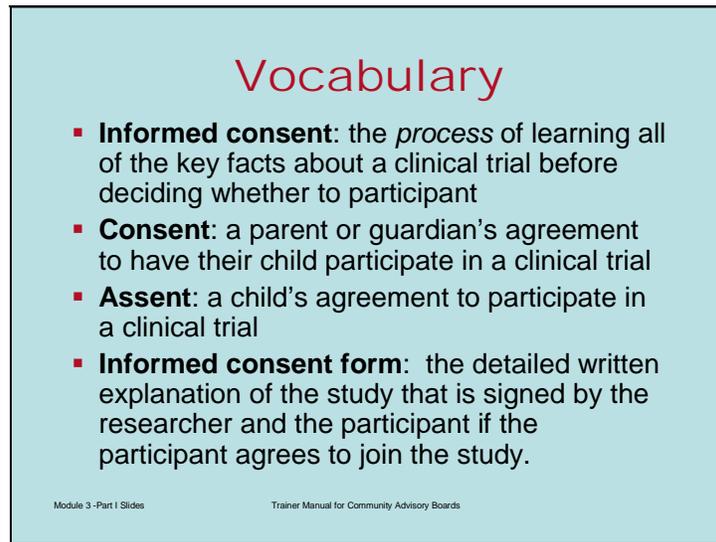
## Vocabulary

- **Double-blind:** The participant and the researcher do not know which treatment the participant will receive.
- **Endpoint:** A measurable change used to determine if a treatment is effective.  
Examples: viral load, CD4 count, weight gain

Module 3 -Part 1 Slides Trainer Manual for Community Advisory Boards

- **Trainer:** Skip this slide if your training participants are already comfortable with all of these definitions and concepts.

## Slide 6



**Vocabulary**

- **Informed consent:** the *process* of learning all of the key facts about a clinical trial before deciding whether to participant
- **Consent:** a parent or guardian's agreement to have their child participate in a clinical trial
- **Assent:** a child's agreement to participate in a clinical trial
- **Informed consent form:** the detailed written explanation of the study that is signed by the researcher and the participant if the participant agrees to join the study.

Module 3 -Part 1 Slides

Trainer Manual for Community Advisory Boards

These words may be new to you. Later in the training, we will use them when talking about clinical trials that involve children.

**Trainer:** Review slide

## Slide 7

**Benefits and risks of joining a clinical study**

Reasons to join a study	Reasons NOT to join a study
▪ Receive medicine	▪ If randomized study, may not receive new medicine
▪ May receive a more effective treatment	▪ Not convenient
▪ Receive high quality care	▪ Risks
▪ Receive more frequent follow up	▪ Too many clinic visits
▪ Feel good about helping others	▪ May require contraception

Module 3 -Part I Slides      Trainer Manual for Community Advisory Boards

This table reviews some of the things a patient would think about when deciding about participating in a clinical trial.

- Some volunteers cannot get treatment unless they participate. They may not have the money to pay for ARV medicines.
- Sometimes the quality of health care is better in a clinical trial—participants may see their clinicians more often.
- Some people like to have more frequent clinic visits and testing; others feel more clinic visits are a burden.
- On the positive side, many people feel good about being in a clinical trial and helping improve the health care of people with the same health problem (like HIV) they have.
- Traveling to the site may take along time or the clinic may be open on days when the volunteer cannot come.
- Volunteers may be worried about having serious side effects.
- Becoming pregnant is usually not allowed during a clinical trial because the effects of experimental medicines on the fetus are not known.

**Discussion question:** What other reasons can you think for either joining or not joining a clinical trial?

## Slide 8

## Informed consent

- To make decisions about participating in a clinical trial, volunteers need to hear and understand specific information about the research.



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- Joining a clinical study is a choice. For the volunteer, **informed consent** is the *process* of learning about the details of a clinical study before deciding whether to participate. Every volunteer has the right to learn about the details of the study and to ask questions. Getting all of this information is part of the informed consent process.
- The goal of the informed consent process is not to convince a potential volunteer to participate. The goal is to give the volunteer all of the information needed to make an informed decision about joining the trial.

## Slide 9

### Informed consent form

- Purpose of study
- Medicine to be studied
- Schedule
- Procedures
- Possible benefits
- Possible risks
- Other ways to receive treatment
- Confidentiality, other rights



Module 3 - Part 1 Slides  
Trainer Manual for Community Advisory Boards

- The research team must also provide the participant with a paper (called the **Informed Consent Form**) that gives all of the detailed information about the study. But informed consent is a process, and the paper form is just one part of the process. This slide gives a list of all of the “parts” of an informed consent form, all of which must be discussed during the informed consent process.
- Informed consent process works well only if volunteers understand the information they receive. This means that a member of the research team should spend a considerable amount of time discussing and explaining the study. It’s not appropriate to just hand someone an informed consent form.
- The informed consent form must be in simple (non-scientific) language, but even then the form is a long and complex document.
- Participants (or volunteers) generally need a lot of help to understand the information on the form.
- Only after the volunteer understands (1) the details of the trial, (2) that joining is voluntary, and (3) that there are other ways to receive treatment, and has had all questions answered, can he or she make a decision about joining the trial. Signing and dating the form indicates that the person is agreeing to participate in the trial.

## Slide 10



### Elements of informed consent

- Why is the study being done?
- What medicines are being studied?
- Why do the researchers think the new medicine will be effective?
- If I do not join the study, what other treatments are available?
- What are the possible benefits? Possible risks?
- How do these risks and benefits compare with other treatments?

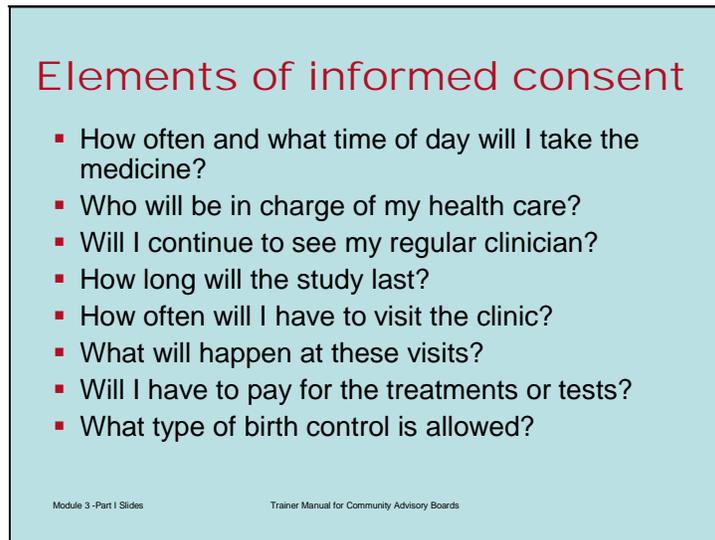
Module 3 -Part 1 Slides

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- When thinking about joining a clinical study, there are many things to consider. It can be difficult for patients to know what to ask and what to expect, and they may be overwhelmed with the volume of information provided in an informed consent form.
- There are rules that must be followed in creating informed consent forms. These rules tell us what information must be included in the consent form. The questions on this slide and the next 2 slides might be helpful for you to understand all of the components of the informed consent process and the informed consent form, and might be helpful for patients to think about when they are considering a clinical trial.
- These questions address everything that must be understood by the patient before giving consent to participate in a trial.
- You do not have to remember all of these questions!

**Trainer:** Please show the informed consent pocket card.

## Slide 11

A light blue rectangular slide with a black border. The title 'Elements of informed consent' is at the top in red. Below it is a bulleted list of seven questions. At the bottom left is the text 'Module 3 -Part 1 Slides' and at the bottom center is 'Trainer Manual for Community Advisory Boards'.

### Elements of informed consent

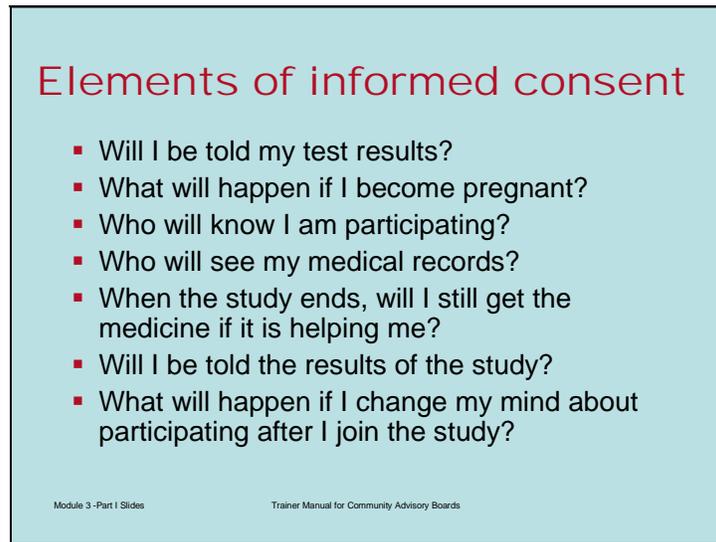
- How often and what time of day will I take the medicine?
- Who will be in charge of my health care?
- Will I continue to see my regular clinician?
- How long will the study last?
- How often will I have to visit the clinic?
- What will happen at these visits?
- Will I have to pay for the treatments or tests?
- What type of birth control is allowed?

Module 3 -Part 1 Slides

Trainer Manual for Community Advisory Boards

Review the slide.

## Slide 12



**Elements of informed consent**

- Will I be told my test results?
- What will happen if I become pregnant?
- Who will know I am participating?
- Who will see my medical records?
- When the study ends, will I still get the medicine if it is helping me?
- Will I be told the results of the study?
- What will happen if I change my mind about participating after I join the study?

Module 3 -Part 1 Slides Trainer Manual for Community Advisory Boards

Review the slide.

- It may take more than one visit with the research team before the volunteer makes a decision to join or not. Joining a research study is rarely an emergency.
- Many people choose to discuss the information about the study with family members or friends before making the decision about joining the trial.

**Discussion question:** Can someone explain, in your own words, the difference between an informed consent form and an informed consent process?

## Slide 13

## Knowing your rights: confidentiality

- All medical and personal information is private.
- Research reports do *NOT* include any patient names.

\*PID=patient identification

PID: 215894\*  
VL: \_\_\_\_\_  
CD4: \_\_\_\_\_

Module 3 -Part 1 Slides      Trainer Manual for Community Advisory Boards

- A member of the research team should speak with each participant about his or her rights.
- One of the most important rights is the right to privacy (having personal information about you kept secret). This is also called **confidentiality**.
- The steps put in place at each study site to protect confidentiality are checked regularly by monitors. When the results of a clinical trial are published, the names of participants are never included.



## Slide 15

**Knowing your rights:  
Informed consent**

- Participation in clinical trials is **always voluntary**.



Module 3 -Part 1 Slides      Trainer Manual for Community Advisory Boards

- No one should ever feel pressure to join a clinical trial.
- Saying “No” to being in a clinical trial should never affect a person’s ability to receive care from their usual healthcare team.
- If a person chooses not to join a clinical trial, he or she may still volunteer for a different trial in the future.
- Joining a clinical trial is not like a contract. A person who joins a clinical trial can change his/her mind during the trial and stop participation (without any penalty).

## Slide 16



- The volunteer must take the time to read the consent form, even if you have discussed the study in detail.
- The consent form must be available in the volunteer's language. If you know the volunteer cannot read, or are not sure, then ask if it is all right to read the consent form with the volunteer.
- After the volunteer has read the form (or you have read it together) and you have answered all of the questions, the volunteer may ask for more time to think about participating. Or the volunteer may wish to say "yes" or "no" to participating after the reading. The principal investigator or a representative of the investigator must be there to witness the signing and dating of the informed consent form when a volunteer decides to join the study.
- Special rules apply for patients unable to sign their name or write the date, and the research team at your site can explain them to you.

## Slide 17

**Informed consent**

- Informed consent is an ongoing process.
- Participants must be kept informed during the trial.

New Information

Module 3 -Part 1 Slides  
Trainer Manual for Community Advisory Boards

- The informed consent process does not end when the volunteer signs the form. To continue the process, participants must receive all new information about the trial. Any new information, and any questions the participant has, should be discussed at every clinic visit.
- If the researchers discover new benefits or risks during a trial, the law requires them to tell the participant. When the new information is very important, the researchers must prepare a new Informed Consent Form. All participants who decide to continue in the study will sign the form.

**Discussion question:** What kind of new information might make a participant decide to keep participating in a clinical trial? To stop participating?

**Examples:**Continue:

Positive information from early data (like lower viral loads or improved health)

Positive results of a similar trial that has been completed

Stop:

New and serious side effects are reported

Early results not encouraging (no improved health)

## Slide 18

## Right to leave the trial

- It is possible to stop being in the study at any time, even after signing the consent form.
- The form is not a contract.



Module 3 -Part 1 Slides Trainer Manual for Community Advisory Boards

- Again, participants may stop participating in the study at any time, even after signing the consent form. Signing a consent form is *not* like signing a contract.
- A participant and his or her clinician may decide the participant should withdraw from the trial if (1) his or her health is getting worse, (2) the participant is having bad side effects, or (3) the participant cannot meet the study requirements (cannot come to the clinic as often as required).
- When thinking about leaving the trial, it is important for the participant to talk with the clinician and/or researcher. When a participant leaves a study, the clinician and/or researcher should know why. Usually, researchers want to continue to follow the health of the participant after he or she leaves, even though the participant is no longer taking the medicine. With this information and the reason the participant left the study—they can better understand the study results.

## Slide 19

## Assent for Children\*

- U.S. government policy states that children 7 years of age and older must **assent** (agree) to participate in a clinical trial

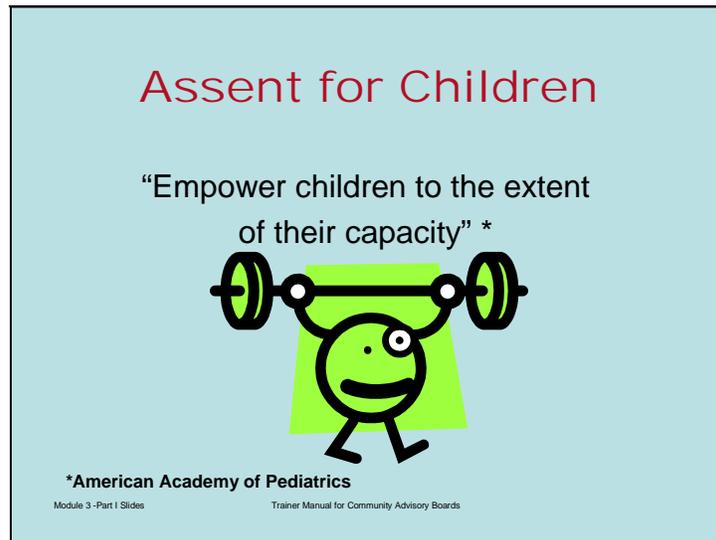


\*See sample assent document in appendix of Trainer Manual.

Module 3 -Part I Slides Trainer Manual for Community Advisory Boards

- There is a U.S. government policy that children age 7 years and older must be given information about the clinical trial they may be participating in. This applies to any clinical trials funded by the U.S. government, anywhere in the world, including all of the clinical trials conducted by IMPAACT. So in children 7 and older, there must be informed consent from the parent or guardian, and assent (agreement) from the child.
- The research team must seek each child's **assent** (agreement) before the child can join a trial.
- This means that a guardian or parent cannot force a child to join a trial unless the child agrees. Assent from a child is not sought until the parent or guardian has given consent for the child to join the study.
- The assent process respects the rights of children, and there are laws about requiring assent that protect those rights. But assent does differ significantly from informed consent, because the information given to a child must be much simpler. The amount of information given to a child depends on the child's age. **Trainer:** It would be helpful to have an assent form for participants to review. One such form is provided in the appendix to this manual.

## Slide 20



- Many people involved in treating young people believe that the child or adolescent should play a role in the decision to enter a research study.
- Most importantly, **the information given must match the knowledge and developmental level of the child.** For this reason, the U.S. government has not made specific rules about how much information should be given to a child, how the information is communicated, etc. This leaves a lot of planning and decision making at the local level. Individual research sites must decide how they will approach and document the assent process.
- A major goal of the assent process is to create an atmosphere where the child feels comfortable enough to ask questions, and where the parent or guardian and the health care professionals find a way to answer the child's questions so the child can understand.

## Slide 21

## Summary

- There are both benefits and risks of joining a clinical trial
- Informed consent is a process by which a person learns all of the information needed to make an informed decision about participation. The process of keeping people informed continues throughout the trial
- Participation is completely voluntary, and consent can be withdrawn at any time
- Assent must be sought from any child over 7 before the child can be enrolled in a study.

Slide 22



# CONFIDENTIALITY ROLE PLAY

## Module 3

Time frame **(30-45 minutes)**

### Purpose

- To review and apply the principles of informed consent

### Advance Preparation

- Review the informed consent role-play script to be sure it reflects local names and local policies. If needed, ask a research team member to help you change the script.
- Move two chairs to the front of the room and arrange them to face each other.
- Have copies of the Case Report Forms available for participants to refer to and use during the role play. (See Appendix 2)
- Copies of the role play script for participants.

### Instructions

- Ask participants to refer to the role-play script.
- Ask for two volunteers to be the “players,” who will practice the script and read it during the role play. Have them choose a role — “Research nurse” or “patient”. (Or if preferred, recruit volunteers in advance of the training).
- Suggest they practice outside the training room.
- Give the players about 10-15 minutes to practice their roles.
- Tell the audience to think about the issues discussed regarding counselling, informed consent, and confidentiality while they listen to the role play.
- Bring the players back into the room, and invite them to sit in the two chairs at the front.
- Read the introduction to the script to the group.
- Have them begin the role play.
- When finished, thank them for their assistance and applaud them.

### Debriefing

- Ask the role-play volunteers to summarize how they felt when playing their roles.
- Write the words “Challenges to Confidentiality” on a flipchart.
- Ask the audience to talk about the greatest challenge to preserving confidentiality in your local clinical and/or research setting.
- Record the challenges to confidentiality on the flip chart.
- Ask the audience for suggestions about how the challenges to confidentiality might be addressed.
- Remind participants that all patients and participants have a right to confidentiality.
- Ask the audience if they have any thoughts about the counselling skills of the research nurse in the role play. How could the research nurse have improved her performance? (Hint: Did she really listen (hear) what Mrs. Jones was most concerned about?)

## CONFIDENTIALITY ROLE PLAY SCRIPT

### Module 3

**Introduction:** A patient [CHOOSE A TYPICAL FIRST NAME IN YOUR COUNTRY.] is coming to the clinic to speak with the research nurse [CHOOSE A TYPICAL FAMILY NAME IN YOUR COUNTRY.] about participating in a clinical trial. The patient is HIV-infected and is very interested in joining the trial, because she may be receiving a new antiretroviral medicine. The clinic is busy and the research nurse has set up a space in the back of the room where she and the patient will sit and talk.

<i>Research nurse</i>	Hello, (patient name). I am (research nurse's name), and I am a member of the research team
<i>Patient</i>	Hello.
<i>Research nurse</i>	Thank you for coming to talk with me today about the clinical trial. Please, sit down.
<i>Research nurse</i>	So, I understand you are interested in joining the trial?
<i>Patient</i>	Yes, but I am very worried about something. And I need to ask you about it before I decide if I am going to join.
<i>Research nurse</i>	<i>Research nurse moves her chair closer to the patient.</i> I can see you are worried. What are you worried about the most? Maybe I can help.
<i>Patient</i>	Well, you know, this is a small village. And everyone knows everyone else's business. If my friends and neighbors hear I am in the trial, I am worried they will know I am HIV-infected.  <i>The patient looks around. She can see the waiting area from her seat, and notices the clinic is crowded. The research nurse observes the patient looking toward the waiting area.</i>
<i>Research nurse</i>	I wish we had a private office to sit in, but space is so limited here. I am certain that no one will hear us talking back here.  I understand that you are worried that people will find out you have HIV infection. I want you to know that when you participate in this trial, you have the right to privacy. That means all of your personal and medical information will not be given to anyone except for research team and your doctor.
<i>Mrs. Jones</i>	I am glad to hear that.  But I still feel like people are wondering why I'm sitting here speaking with you right now.  Will we always have to meet like this? People are so curious sometimes!
<i>Research nurse</i>	I don't think they can hear us, do you?  Here is an example of one of the forms, called a Case Report Form.* We use it to collect information about everyone who joins the study. But instead of using your name on the form, we use a Patient Identification <i>Number</i> . This keeps your name and health information private. <i>* See Appendix 1 of this trainer manual for a sample Case Report Form.</i>
<i>Patient</i>	But, what about the people who take care of me in the clinic?
<i>Research nurse</i>	The <i>only</i> people who will know you are in the trial will be the doctors and nurses who are caring for you.
<i>Patient</i>	That makes sense.
<i>Research nurse</i>	Would you like to come learn more about the study?
<i>Patient</i>	Yes, but can we go somewhere else?



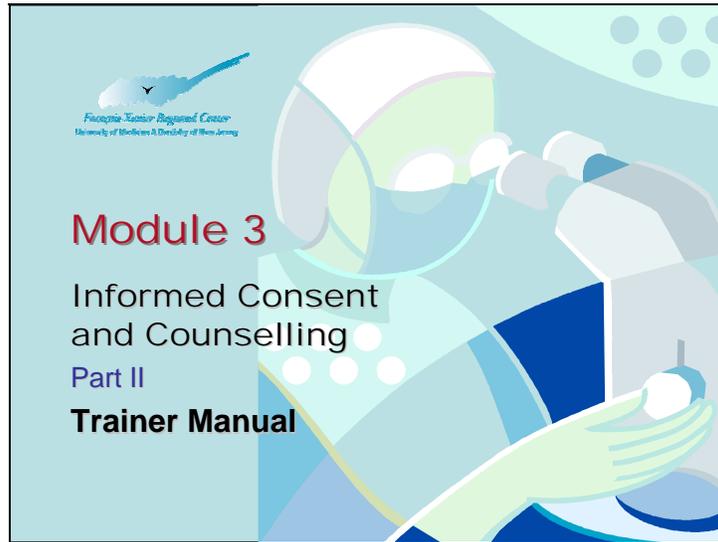
## **Module 3**

### **Part II Slides – Insert Here**





Slide 1



## Slide 2

This teaching tool was developed by the François-Xavier Bagnoud Center at the University of Medicine and Dentistry of New Jersey, with the support of the International Maternal Pediatric and Adolescent Clinical Trials (IMPAACT) network.

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Claire Schuster, BS, MPH  
Network Community Coordinator  
Social & Scientific Systems, Inc.  
Email: [cschuster@ss3.com](mailto:cschuster@ss3.com)  
(301) 628-3319



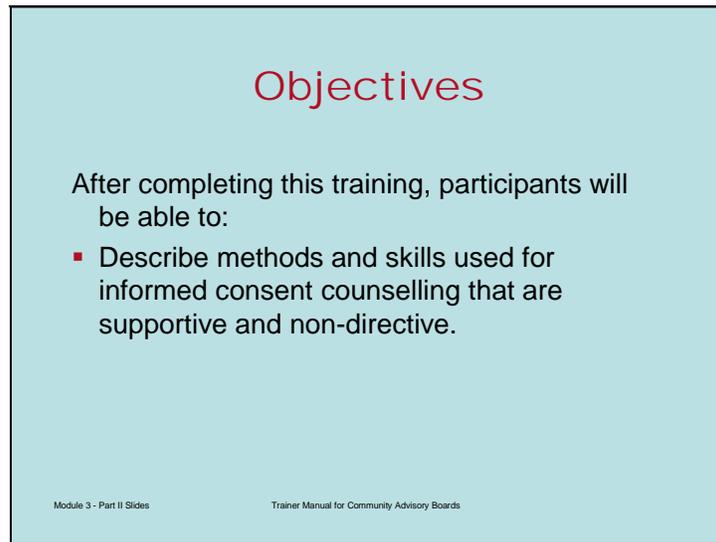
*François-Xavier Bagnoud Center*  
University of Medicine & Dentistry of New Jersey

Mary Jo Hoyt, RN, MSN  
IMPAACT Global Training Director  
François-Xavier Bagnoud Center  
Email: [info@fbcenter.org](mailto:info@fbcenter.org)  
(973) 972-9230

**Version 1.0 – May 2007**

Module 3 - Part II Slides      Trainer Manual for Community Advisory Boards

## Slide 3



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## Objectives

After completing this training, participants will be able to:

- Describe methods and skills used for informed consent counselling that are supportive and non-directive.

Module 3 - Part II Slides

Trainer Manual for Community Advisory Boards

- In this section of our training, we're going to talk about and demonstrate more of the basic skills used in counselling. The goal is to make sure that the counselling will always be
  - Supportive
  - Non-directive (not telling people what they should do)
  - Truthful
- Even if it is never your role to counsel people about informed consent, these tips for counselling are very general and you can apply them in other situations.

## Slide 4

**Tips for counselling**

"I would like to help you understand what this study is about."

*Research team member*

Counselling should be supportive, non-directive, and truthful.

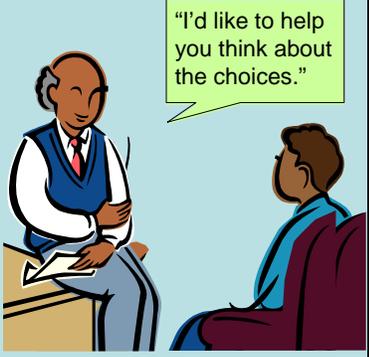
Module 3 - Part II Slides      Trainer Manual for Community Advisory Boards

- CAB members at some sites may be asked to participate in the informed consent process by counselling a volunteer. Sometimes people feel more comfortable with a peer than with a health care professional, and will ask more questions or better understand explanations. However, CAB members cannot be the only source of information for a participant, and cannot be the sole witness when a person signs an informed consent form.
- Before you help to counsel anyone about a study, a member of the research team should teach you about the trial and demonstrate informed consent counselling. You should feel confident you have accurate information about a study before speaking to anyone about it. For complex questions or health care questions unrelated to the trial, be sure to ask for help rather than risk giving incomplete or inaccurate information.
- It is very helpful to prepare in advance how to explain difficult concepts, such as "randomization," "control group," or "side effects." This is a good topic for the CAB and the research team to discuss together. (The CAB glossary may be helpful in helping to find ways to explain these concepts, but you and the people at your site are the best judge of how to explain these things with your patients).
- The members of the research team have the final responsibility for discussing the study and the treatment choices. CAB members are *not* responsible for talking about other treatment options or recommending treatment options.
- **Trainer:** Review this slide. "Non directive counselling" means counselling to give the person information. It is not counselling to tell the person what to do, or push a person to join the study. It is neutral.

## Slide 5

### Tips for counselling

- Counsel in a quiet and private area.
- Emphasize your job is to help the person understand treatment choices.



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It helps volunteers to relax and feel comfortable if you:

- Sit in a quiet and private area to set a calm mood.
- Say your job is to help the volunteer to understand the treatment choices, not to make the person join the trial.
- Promise the volunteer the conversation is private.
- Tell the volunteer the decision is completely his or hers to make.
- Assure the volunteer he/she will have time to think about the choices and discuss them with family and/or friends.

## Slide 6

**Tips for counselling  
about a clinical trial**

**Ask open-ended questions such as:**

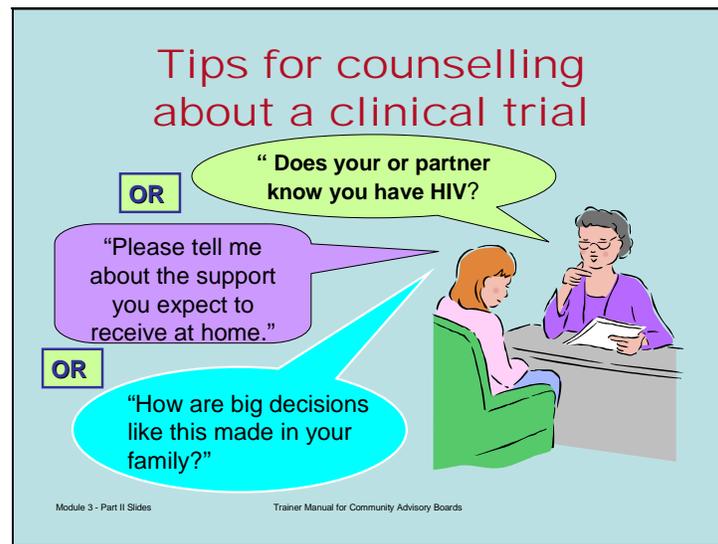
- “What have you heard from others about this research?”
- “How do you feel about participating in research?”
- “What are your thoughts about what you have heard?”

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- It may be helpful to start the counselling process by asking what (if anything) the volunteer knows about research in general and about the specific clinical trial you are discussing. The answers to these questions will give you an idea about how to go forward with the counselling.
- Ask open-ended questions to encourage conversation, not closed-ended questions that can be answered with a simple “yes” or “no.” There are some examples of open-ended questions on the slide.

**Trainer:** Review this slide with participants.

## Slide 7



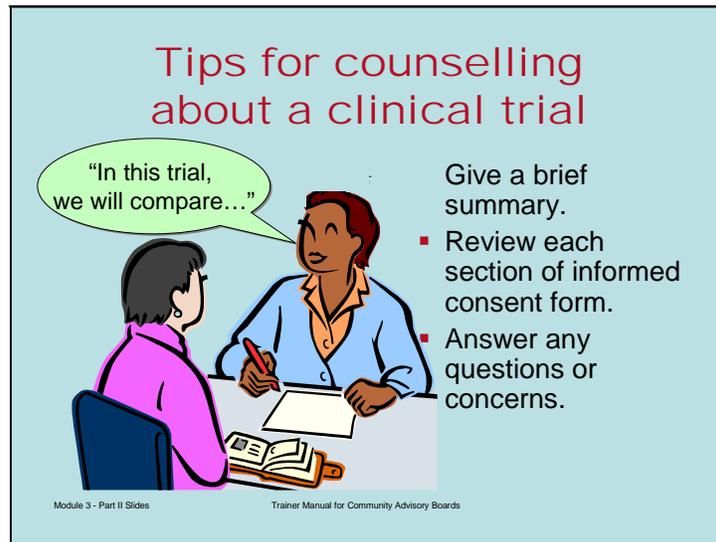
- As you continue the counselling process, encourage *discussion* by asking open-ended questions. (Trainer: Review examples on slide). Closed-ended questions are useful in situations where you need very specific information, such as “*Does your husband (or partner) know that you tested positive for HIV?*”

**Discussion question:** What are some open-ended questions the counsellor might ask?

Examples:

- *Would you tell me a little bit about your family, and what kind of support you expect at home if your start HIV treatment (in a clinical trial or not)?*
- *How are big decisions like this usually made in your family?*
- *Can you tell me what your experience with getting treatment at the clinic has been?*
- *What experiences have you had taking medicine in the past? (or giving medicine to a child)?*

## Slide 8



### Tips for counselling about a clinical trial

“In this trial, we will compare...”

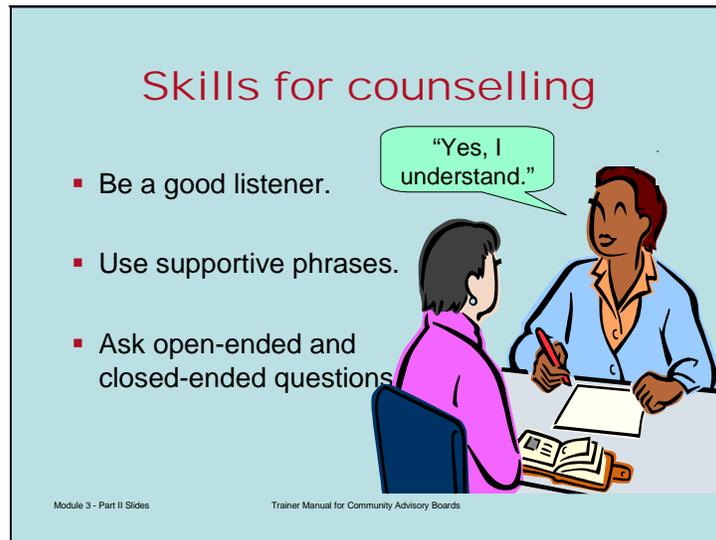
- Give a brief summary.
- Review each section of informed consent form.
- Answer any questions or concerns.

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Think of your role of counsellor as four-step process. You will shape the counselling differently for each volunteer, based on his or her knowledge of and experience with being in a clinical trial.

- Give a brief, simple summary of the trial. Then ask the volunteer to tell you what he/she understands about the trial and correct any information that is not correct. Then ask the person if he/she is interested in hearing more about the trial.
- Talk about each section of the informed consent form briefly. Include the most important concepts, but do not give too many details. After each section, ask the person to tell you what he/she understood, and discuss any information that is not correct.
- If the person remains interested, have the him/her read the consent form (or read it with him/her if needed). Answer any questions or concerns. After reviewing all of the sections, ask if he/she is still interested in participating.
- In most circumstances, the person can be allowed (or encouraged) to take the consent home for further study and to discuss it with family or friends before making a commitment.

## Slide 9



**Skills for counselling**

- Be a good listener.
- Use supportive phrases.
- Ask open-ended and closed-ended questions.

The illustration shows a male counsellor in a blue shirt sitting at a desk with a female client in a pink shirt. The counsellor is holding a pen and looking at the client. A speech bubble above the counsellor says "Yes, I understand." There are some papers and a pen on the desk.

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There are some simple skills that can help to improve the counselling for informed consent. As we mentioned earlier, these are good communication skills that are useful in almost any interaction with other people.

To be a good counsellor one must be a good listener.

- Good listening is *active*. Be an active listener by showing interest and using phrases such as “*I understand*,” “*Go on*,” or “*Tell me more about that*.”

As we said earlier, ask open- and close-ended questions, depending on the kind of information you are seeking:

- Open-ended questions when you want a lot of information (“What kind of support can you expect from your partner or husband?”)
- Close-ended questions when you need specific information (“How many children do you have?”)

## Slide 10

**Skills for counselling**

- Reflect on feelings of the volunteer.
- Summarize what the volunteer says.

"It sounds like you feel happy about your decision."

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Another easy to learn skill to use to show active listening is summarizing what the volunteer says. For example:

- *"From our discussion, I understand you are interested in joining this clinical trial, but you have some concerns: You are worried about what your husband will think about the study, and you are worried about being able to come to the clinic for all of the visits. Is this correct?"*

By summarizing, you show you are paying attention and care about what the volunteer is saying. You are also checking that your understanding of what the volunteer said is correct.

Another good skill is to describe the emotions the volunteer is expressing, as the CAB member in the slide is doing. Other examples: "Your questions tell me you feel pretty anxious about participating." or "It sounds like you feel upset that you have to start treatment for your HIV infection."

## Slide 11

## Summary

- CAB members may discuss research studies with people once they have a good understanding of the study. But CAB members should not obtain informed consent alone.
- The research team should help CAB members understand the study in order to be fully prepared for counselling.
- Counselling about a study is non-directive and neutral. A few simple skills can be used to make counselling more effective.

Module 3 - Part II Slides

Trainer Manual for Community Advisory Boards

Slide 12



# INFORMED CONSENT ROLE PLAY

## Module 3

### Trainer Instructions

Time frame **(30-45 minutes)**

#### Purpose

- To help participants identify and discuss important parts of informed consent.
- To observe an experienced research team member demonstrate informed consent counselling
- To observe the interaction and the skills utilized during a communication between the mother and the research team member.
- To discuss important questions a participant should ask about the research protocol.
- To emphasize that the research team must make sure all aspects of the trial are discussed and understood.

#### Materials Needed

- Chairs for role players
- Role-play script and Schema for PACTG P1041.
- Checklist for observing the informed consent process\* (copy for participants).

#### **Trainer please note:**

- Please encourage the role-players to modify the role play script to make it better fit your site. For example, it would be best if explanations for concepts such as “randomization”, “double-blind” and “placebo” are given in a way that is consistent with what the research team does in “real” consent situations. The script given here is only a framework, and should be adapted to make it complete and appropriate for your site, and to fit the time frame available for training. (This role play is quite long! It is OK if you need to do it two or more parts)
- Trainers may choose to select a different clinical trial for this exercise, or to develop a role play for an assent in addition to a consent discussion. A clinical trial that is open at the site is probably best. The Schema and Informed Consent form should be included in the Participant Manual, along with the Checklist for Informed Consent

#### Instructions

Prior to the training session:

- Select a CAB member and a research team member to play the roles.
- Make sure each one has a copy of the role-play instructions, the schema, and the informed consent form you want to use.

- Review the role-play instructions with the role players. If you are using the sample role play provided with this manual, make sure the role players understand that they can adapt the role play to fit the language and culture of the site.
- Discuss with the role players the purpose and background of the exercise, and the questions you will ask participants at the conclusion of the exercise.
- If time allows, do a practice session with the role players.

*During* the training session:

- Instruct the participants to use the checklist as a guide while watching and listening for the important aspects of informed consent.

## Roles

*Study nurse/research coordinator/other researcher*

- Played by a research nurse, study coordinator, or other researcher
- He/she will explain informed consent and answer the mother's questions.

*Sandra, mother of a 3½ month old baby girl Dalila (Please change names to names used in your country.)*

- Sandra should be played by the training facilitator or a CAB member who has participated in a research study.
- She will listen as the study nurse/coordinator explains informed consent, ask questions as needed, and respond to the study nurse/coordinator's questions.

## Background

Sandra and Dalila are both HIV-infected but are not sick at this time. Prior to giving birth to Dalila, Sandra was given *brief* information about this clinical trial, and at that time she expressed some interest in participating. She has had family members with tuberculosis in the past, and she understands that TB is especially dangerous for people with HIV. This is Sandra's first *detailed* discussion about the study. For your review, a suggested discussion format and questions are provided with these instructions.

## Instructions

When the role play is complete:

- Ask each player about the experience of playing the role.
- Ask participants to identify the aspects of informed consent they observed.
- Ask participants for their impressions of the interaction between the researcher and mother.
  - Did the researcher help the mother to be comfortable with asking questions?
  - Did he/she provide understandable answers to the mother's questions?
  - Did the mother appear to understand the research protocol?
  - What is the value of asking open-ended questions vs. closed (yes/no) questions?

# INFORMED CONSENT ROLE PLAY SCRIPT\*

## Module 3

This is a *suggested* approach for discussing the study with a prospective participant. Please modify for your site.

### **PACTG P1041: A Randomized, Double Blind, Placebo Controlled Trial to Determine the Efficacy of Isoniazid (INH) in Preventing Tuberculosis Disease and Latent Tuberculosis Infection among South African Infants with Perinatal Exposure to HIV**

#### **Short Title: Efficacy of Isoniazid to Prevent Tuberculosis in South African Infants Perinatally Exposed to HIV**

#### Introduction

Hello, Sandra. My name is \_\_\_\_\_. I am here to talk to you about the 1041 study, which is about prevention of tuberculosis in babies who have been exposed to HIV or who are infected with HIV. I understand that you are interested and would like to discuss it further.

Before we read the consent form together, I'm going to summarize parts of it and give you a chance to tell me what you understand and to ask me questions about anything you don't understand. Then you can tell me if you are still interested. If you are still interested, we'll read the informed consent form together.

But before we start, I want you to know that participating in the study is a choice, and that your baby will continue to be cared for here whether you decide to participate in the study or not.

#### Purpose

This study is being done to find out if children who are born to HIV-infected mothers may benefit from treatment with an antibiotic called isoniazid (INH). INH may prevent these children from becoming infected with TB or ill with TB disease. The study will also show whether INH is safe for children if it is used for two years.

*Could you tell me what you know about tuberculosis and your child's risk of tuberculosis?*

*Has anyone explained the difference between becoming infected with TB versus becoming ill with TB? Can you tell me what you know about this?*

#### Treatment

It's important for you to understand that not all of the infants on the study will receive the antibiotic (INH). Giving INH to HIV-exposed infants is not a standard treatment right now, because it hasn't been studied. This study will help to determine if it should be a standard treatment in places like this where the risk of tuberculosis is very high. But in order to know if INH is safe and effective for the infants, a group of infants who will take INH will be compared with a group of infants who will not be receiving INH. Instead, these infants will receive a "look-alike" pill that contains no medicine. The "look-alike" pill is called a placebo.

To summarize this: One group will receive INH and babies in the other group will not receive INH. Instead, babies in the second group will receive pill that does not contain any medicine. It's important to know that no one (researcher or parent) chooses a group assignment. There is a computer program that makes the assignments randomly, so that about ½ of the participants are assigned to one group, and ½ of the participants are assigned to the other group. It's a lot like flipping a coin; you can't predict a group assignment and you can't influence what the computer will tell you to do. It's important because it reduces the risk of any bias. This means that assignments are made fairly and that the groups will be relatively equal in terms of their health, gender, age, etc.

- *How do you feel about the randomization aspect of study participation?*

All the infants will be examined and tested exactly the same way throughout the study. Your doctor will discuss the results of the test with you. But neither you nor the researchers will know if your baby is receiving INH until the study ends.

Even though your doctor will not know if your baby is getting INH or placebo, there are other scientists who will be checking the information we collect on all the babies in the study to see if there are any problems in the groups. If problems were occurring in one group and not the other, the study would be stopped so that all the babies could be put in the group that was doing better. These scientists will know which study participants are in each group.

- *I'd like to stop here and have you tell me what you understand about the purpose of this study? Can you tell me in your own words what you understand about why this study is being done?*

## Study Visits and Study Tests/Examinations

Let's talk a bit about your baby's care on the study, and what will be expected of you if you choose to participate.

Participants will be on the study for four years. Before your child is enrolled in the study, some tests will be done to make sure that your baby can enter the study, and that there are no unexpected problems with the baby's health.

During the four years of the study, your child's study visits will be done here in the clinic about every 3 months. At every visit, your baby will be examined and a small amount of blood will be drawn from a vein. A special examination will be done to make sure the baby doesn't have numbness in the hands or feet (peripheral neuropathy), which is a rare side effect of the INH. This takes a few minutes, and consists of checking the baby's reflexes and playing a few games with the baby. The study nurse or doctor will ask you about how well the baby takes the medicine, and if any medicine doses have been missed. You'll also be asked if the baby has any health problems you want to discuss with the doctor.

Every baby in the study will be receiving a TB skin test 3 times during the four years of the study.

- *Are you familiar with the TB skin test?*

A positive skin test indicates that the baby has been exposed to TB and is infected with the TB germ. A positive skin test does not tell you if the baby has TB disease. The baby can be infected with TB without being sick with TB.

- *It's important to understand that your baby will feel a small amount of pain when her blood is drawn, and when the TB skin test is given. We try to minimize discomfort, and to help you comfort the baby, but nevertheless, the baby will be briefly uncomfortable when these things are done. The blood tests would not normally be part of your baby's care if she were not enrolled in the study.*

The participants in the study are watched very closely for signs or symptoms of TB disease. If there are any signs of TB illness in the baby, or if the TB skin test is positive, more tests will be done to find out whether or not the baby actually has TB disease.

It's very important that you bring the baby to every study appointment, so she can be examined and checked. These examinations look not only for tuberculosis, but also to learn about the baby's general health and possible side effects of the medicine. If you anticipate any problems coming to an appointment, we will ask you to call the clinic to discuss the issue with one of the staff, who can help you reschedule or help you to come to the scheduled appointment if possible.

- *Tell me what you think about the study visits, and the examinations that will be done on the study.*
- *Do you have any questions or comments about the blood tests or the TB skin test or the tests that would be done if your baby has symptoms that could indicate TB disease?*
- *Do you anticipate any problems with being able to come to the study visits? What kind of problems might come up for you in terms of being able to attend clinic visits regularly?*

## Risks

Although the side effects of INH treatment are rare, it's important to know what they are and to watch for them. Also, a large study of HIV-exposed or infected infants receiving INH for 2 years has never been done before, so it's possible that there are risks or side effects that we don't know about. INH has been used in babies with TB disease and is approved for this use.

Most known side effects are temporary, and they might include feeling sick to the stomach and/or vomiting, stomach pain, rash, feeling tired, or having a fever. INH can cause peripheral neuropathy, which means numbness in the hands and/or feet. The doctors do a special exam every study visit to check for peripheral neuropathy. Also, INH can cause liver damage. This is rare, but can cause light colored stools, yellowing of the eyes or skin, and stomach upset. The blood test done at every visit checks to make sure there is no evidence of damage to the liver. The study plan is very specific about what to do if side effects occur. Serious side effects will be attended to quickly, and in some cases this will mean that the study medicine will be stopped.

The other antibiotic, co-trimoxazole, has been given to HIV exposed and infected infants for many years, so more is known about this medicine. It may cause a skin rash or stomach sickness, or changes in the number of white blood cells (which help fight infection) or red blood cells (a decrease can cause anemia) loose stools, weakness, or difficulty sleeping. Generally, this medicine is well tolerated and the side effects are temporary. But again, if you feel your baby is experiencing any problems or potential side effects, you should speak to a member of

the study team to discuss the problem. You will be given directions and a telephone number to let you know what to do if you need to contact the doctor or a member of the study team.

- *Many parents worry about side effects of medicines on their child. Tell me what you understand about the side effects that your child may have with the medicines used in this study.*

## Benefits

Now that we've spoken about the potential risks involved in participating in this study, I'd also like to mention the potential benefits of being in the study. We hope that INH proves to help prevent TB infection and/or disease, but we don't know if your child will receive INH or a placebo. We also hope that careful examinations and follow up help to keep your child healthy. Nevertheless, it's important to know that we cannot guarantee that your child will receive any direct benefit from participation in the study. We do know, however, that the information gained from this study is important for the future treatment of other infants with HIV infection, or who are exposed to HIV infection.

## Other Choices

Again, you do not have to give permission for your child to participate in this study. It's also important to know that if you do give permission for the baby to join the study, you can change your mind at any time and decide to stop participating. The study team will continue to communicate with you about the study, and will let you know if any new information is learned that might influence your decision to allow your baby to participate. No one will be upset with you if you choose not to participate or change your mind about study participation. If you do not want your baby to be in this study, you will still have a choice for the baby to participate in other studies if there are studies available that are appropriate for your child.

If you choose not to participate, your child will still be treated here. Your child's doctor will discuss the care for the baby, but overall your child will be offered the same care as any other child in these circumstances. For example, your child will still receive co-trimoxazole; this is part of regular (non-study) care for all HIV exposed or infected children.

If you join the study, you should not give your baby any other medicine (or herbs or home remedies) without first discussing it with the research team.

## Confidentiality

We do not tell anyone that your child is involved in the research study. The forms that we use to collect your child's information during the study do not have your child's name on them. The forms and the information about your child that is entered into the computer are identified by number rather than by your child's name. No one outside the study team knows the number assigned to your child. This information is kept private, in a locked cabinet so anyone who is not part of the research staff will not be able to see it.

Information about your child's physical examination and tests are part of your child's medical record. The medical record is the same as usual, and is identified with your child's name. For the purpose of monitoring (checking) on the performance of the study at this site, some officials from this institution or from the study sponsors may review these records. They do not remove any personal information that includes your child's name.

Results from the study may eventually be published in a medical journal, so that other health care professionals can learn about them. Publications never contain the names of any participants in the study.

- *Can you tell me how you feel about other people seeing any information about your child?*
- *Do you feel confident that your child's information will be kept private enough for you to feel comfortable with the study?*

### Other Issues

- Costs
- Payment
- Injury
- Whom to call with questions or problems

### Conclusion

*Please remember, you can ask questions of any of the research team about this study and about your child's treatment choices at any time.*

- *I want to make sure that I answer any other questions you have.*
- *If you think you are still interested in having your baby join the study, then it's important that you read the entire consent form. If you have not done so, we have time to read it now. Would you like for me to read it with you?*
- *You are welcome to take the consent form home to study, or to discuss with someone you trust. You do not have to decide right now. However, your child may join the study only between 91 and 120 days after birth (3-4 months), so if you would like to baby to join, she must be enrolled by (give date).*

## CHECKLIST FOR OBSERVING INFORMED CONSENT

### Module 3

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#### **What is the purpose of this study?**

- Why is the study being done?
- What medicines are being studied?

#### **What are the potential risks of participating?**

- If my child doesn't receive the study medicine, what treatment will he/she receive?
- What is known about the potential side effects or risks associated with the study medicine?
- What is known about the side effects and risks of standard treatment?
- What happens if my child experiences side effects from the medicine he/she receives during the trial?
- Will I know which treatment my child is receiving?
- What happens if my child's condition worsens during the trial?
- How will this study affect my child's future treatment options?

#### **What are the potential benefits of participating?**

- What are the chances my child will receive the study medicine?
- Why do the researchers believe that the treatment being studied may be better than the one being used now? Why may it not be any better?
- What are the potential benefits of the study medicine vs. other treatment?

#### **What are the alternatives for my treatment?**

- Would I be advised to start (or change) this treatment for my child now, even if this trial weren't taking place?
- If my child does not join the study, what other choices does he/she have for receiving treatment?
- How does the treatment my child would receive in this trial compare with the other treatments available?

#### **What will be required of me?**

- How often will my child take the medicine and at what time of day?
- Will my child's usual doctor/nurse continue to take care of him/her?
- If not, who will be in charge of my child's health care during the study?

- How often will I have to bring my child to the clinic?
- How long will these visits generally take?
- What tests and exams will my child be having during these visits?
- Is there a way to contact someone after clinic hours if I have any urgent questions or important concerns about my child's treatment, side effects, or symptoms?
- How long will the study last?
- Will I have to pay for any of the treatments, tests, or visits?
- Are there medications or treatments my child cannot take during the trial?

**What are my rights?**

- Who will know my child is participating?
- Who will see my child's medical records during the study?
- Will my child's doctor/nurse still take care of my child if I decide not to allow my child to participate in this study?
- What will happen if I change my mind about my child's participation after the study begins?
- What happens if new information about the medicine is discovered during the trial?
- Will I be told the results of my child's tests and examinations during the trial?
- If I have questions or concerns about my child's rights during the study, with whom can I speak?
- When the study ends, will I be told the results?
- After the study ends, will my child still receive the medicine if it is helping him/her?

## 1041 SCHEMA\*

### Module 3

**A RANDOMIZED, DOUBLE BLIND, PLACEBO CONTROLLED TRIAL TO DETERMINE THE EFFICACY OF ISONIAZID (INH) IN PREVENTING TUBERCULOSIS DISEASE AND LATENT TUBERCULOSIS INFECTION AMONG SOUTH AFRICAN INFANTS WITH PERINATAL EXPOSURE TO HIV**

<b>DESIGN</b>	Phase II/III, multi-center randomized, placebo-controlled, double blind
<b>SAMPLE SIZE</b>	Total: 1300 study participants 500 HIV-infected study participants 800 HIV-exposed uninfected study participants
<b>POPULATION</b>	Infants born to HIV-infected women will be enrolled between 91 and 120 days of age.
<b>RANDOMIZATION, STRATIFICATION AND BALANCING</b>	Randomization to INH or INH placebo will be in a 1:1 ratio and will be stratified by the study participant's HIV infection status: Stratum I: HIV-infected study participants Stratum II: HIV -exposed uninfected study participants
<b>REGIMEN</b>	Stratum I: HIV-infected study participants randomized to: <ul style="list-style-type: none"> <li>▪ INH (10–20 mg/kg/dose orally, once a day) or placebo beginning any time between 91-120 days of age</li> </ul> Stratum II: HIV-exposed uninfected study participants randomized to: <ul style="list-style-type: none"> <li>▪ INH (10–20 mg/kg/dose orally, once a day) or placebo beginning any time between the 91st and 120th day of life</li> </ul>
<b>TMP/SMX Prophylaxis</b>	All study participants will receive TMP/SMX (5mg/kg dose of the trimethoprim component orally once a day) at the time of study enrollment, if not already started at 6-8 weeks of life.  For HIV-infected study participants, TMP/SMX will be given until 12 months of age and will continue after 12 months of age if the study participant meets the WHO guidelines for continuing PCP prophylaxis.  For HIV-exposed but uninfected study participants, TMP/SMX will continue until a repeat HIV DNA PCR test is performed at 6 months (24 weeks) of age, at which time prophylaxis will be continued if HIV-infected or if HIV-uninfected but still breastfeeding.
<b>TREATMENT DURATION</b>	Study participants will receive INH or placebo for 96 weeks and will be followed on study for an additional 96 weeks (a total of 192 weeks from enrollment).

\*Edited for use with the CAB curriculum

# 1041 OBJECTIVES

## Module 3

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### **Primary:**

1. To determine whether INH prophylaxis decreases the incidence of TB disease while receiving study drug, among HIV-infected study participants
2. To determine whether INH prophylaxis decreases the incidence of TB infection while receiving study drug, among perinatally-exposed, HIV-uninfected study participants

### **Secondary:**

Among both perinatally-exposed HIV-infected and HIV-uninfected study participants:

1. To assess the toxicity and safety of INH prophylaxis
2. To determine whether INH prophylaxis is associated with a lower incidence of TB infection and a lower incidence of TB disease during the post-prophylaxis period
3. To determine whether INH prophylaxis is associated with lower mortality while receiving study drug and during the post-prophylaxis period

*Among HIV-infected study participants only:*

4. To determine whether INH prophylaxis is associated with a lower incidence of TB infection while receiving study drug
5. To determine whether INH prophylaxis is associated with slower HIV disease progression while receiving study drug and during the post-prophylaxis period

*Among perinatally-exposed HIV-uninfected study participants only:*

6. To determine whether INH prophylaxis is associated with a lower incidence of TB disease while receiving study drug

## PARTICIPANT EVALUATION FORM

### Module 3 Part I

#### Informed Consent and Counselling

#### INSTRUCTIONS:

- Your opinion is important to us.
- There are no RIGHT or WRONG answers.
- Your answers are private. You do not need to put your name on this form.
- Please answer ALL the questions to help us improve this training.
- For questions 1 - 4, please rate the *effect* the training has had on your understanding of the following:

0= No effect, 1= Some effect, 2= Much effect	No Effect	Some Effect	Much Effect
1. The participant's point of view about clinical trials ( <b>The Family Panel Exercise</b> )	0	1	2
2. The definition and principles of informed consent for research	0	1	2
3. For giving you useful skills to counsel others about research, this module had...	0	1	2
4. Counselling skills and informed consent ( <b>The Confidentiality Role Play</b> )	0	1	2
For the last 2 questions, 0= Not useful, 1= Useful, 2= Very useful			
5. The materials in the training manual	0	1	2
6. This training as a whole	0	1	2

## PARTICIPANT EVALUATION FORM

### Module 3 Part II

#### Informed Consent and Counselling

#### INSTRUCTIONS:

- Your opinion is important to us.
- There are no RIGHT or WRONG answers.
- Your answers are private. You do not need to put your name on this form.
- Please answer ALL the questions to help us improve this training.
- For questions 1 - 4, please rate the *effect* the training has had on your understanding of the following:

0= No effect, 1= Some effect, 2= Much effect	No Effect	Some Effect	Much Effect
1. Skills related to counselling	0	1	2
2. How to apply counselling skills to the process of informed consent	0	1	2
3. Skills that will be useful when informing others about research	0	1	2
4. For increasing your understanding of informed consent, the Role Play had...	0	1	2
For the last 2 questions, 0= not useful, 1= useful, 2= very useful			
5. The materials in the training manual were...	0	1	2
6. This training as a whole was...	0	1	2

*Please continue on the next page.*

*Please answer the following questions to the best of your ability:*

After this training, what help might you need to apply this information?

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What changes would you suggest to make the training more useful?

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What part of this training did you find the **most useful**?

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What other training programs do you feel are important for CAB members?

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Other comments:

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***Thank you for your comments!***

## TRAINERS' ASSESSMENT: POST-TRAINING

### Module 3

#### Informed Consent and Counselling

*Please help us evaluate the training for this module by telling us about the level of improvement you observed in the participants' knowledge of Informed Consent.*

	NO IMPROVEMENT	SOME IMPROVEMENT	MAJOR IMPROVEMENT
1. Definition and principles of informed consent	0	1	2
2. Applying informed consent counselling skills	0	1	2
3. Understanding the components of the consent process	0	1	2

What changes would you suggest to make the training more useful?

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What part of this training did you find the **most useful**?

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Trainer Name:	Signature:	Date:
---------------	------------	-------

**Please use the back of this form for additional comments and suggestions.**





# **Module 3**

## **Appendices**





## APPENDIX 1

### SAMPLE ASSENT FORM

VERBAL GUIDE FOR OBTAINING ASSENT FOR CHILDREN AGES 7-12 YEARS  
FOR PARTICIPATION IN A RESEARCH STUDY

**PHASE II SAFETY AND IMMUNOGENICITY STUDY OF QUADRIVALENT HUMAN  
PAPILLOMAVIRUS [TYPES 6, 11, 16, 18] L1 VIRUS-LIKE PARTICLE [VLP] VACCINE  
(GARDASIL®) IN HIV-INFECTED CHILDREN ≥ 7 TO < 12 YEARS OF AGE**

**SHORT TITLE FOR THE STUDY:** Safety and Immunogenicity of Human Papillomavirus Vaccine in HIV Infected Children

**Child is informed of the following:**

You have been asked to be in a study to learn more about your health. This is a study about a vaccination (shot) that might help your body fight a certain germ that can make you sick.

If you agree to be in the study:

- You will receive a shot at some clinic visits.
- Some blood will be drawn at each visit to see how you are doing. Before having your shot or blood test you will have the numbing cream like you usually do.
- We will also wet a swab on the inside of your mouth. It looks like a Q-Tip. This will not hurt. You must remain still for the time the swab is in your mouth.
- You must tell your mother or father if you don't feel good in any way after the vaccine. You will have your temperature taken for a few days at home after each shot.
- If you are a girl and have had your first period, you will have a pregnancy test done. If you are pregnant you cannot be in the study.
- You will have extra visits to the clinic for the study

You do not have to be in the study if you don't want to. No one will be mad at you and your doctor will still take care of you if you don't want to be in the study or if you decide to quit later.

I have explained the purpose of this study to the volunteer. To the best of my knowledge, s/he understands this assent and agrees to participate in the study:

\_\_\_\_\_  
Name of Person Obtaining Assent

\_\_\_\_\_  
Signature of Person Obtaining Assent

\_\_\_\_\_  
Date

## APPENDIX 2

### SAMPLE CASE REPORT FORMS

PE4821(P1026S)/09-13-04  
**Page 2 of 2**

**COMPREHENSIVE SIGNS AND SYMPTOMS**

Pt. No.  \* Seq. No.  \*\* Step No.  Date   
mmm dd yyyy

1. Has the subject experienced any new, ongoing or resolved signs and/or symptoms since the last evaluation? ..... (1-Yes, 2-No, 3-Not evaluated)
- If No or Not evaluated, STOP.**  
**If Yes, continue. Use the Tab Key after the last entry. All references and codes are on page 1.**

Symptom Code <sup>1</sup>	Site If Required <sup>2</sup>	Grade <sup>3</sup>	Status <sup>4</sup>	Date of Onset/Date of Resolution This Grade <sup>5</sup> (mmm/dd/yyyy)	Diagnosis Related? <sup>6</sup> (1-Yes, 2-No)	If Yes, Diagnosis Code <sup>7</sup>	Eval. Form? <sup>8</sup> (codes 1-5)
a.	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>
Specify Symptom [30]:				<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
b.	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>
Specify Symptom [30]:				<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
c.	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>
Specify Symptom [30]:				<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
d.	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>
Specify Symptom [30]:				<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
e.	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>
Specify Symptom [30]:				<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
f.	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>
Specify Symptom [30]:				<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
g.	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>
Specify Symptom [30]:				<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
h.	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>
Specify Symptom [30]:				<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

PE4811(P1026S)/06-06-05

**COMPREHENSIVE HEMATOLOGY/CHEMISTRY - II**

Page 2 of 4

Pt. No.  \*Seq. No.  \*\*Step No.  Date   
mmm dd yyyy

**I. HEMATOLOGY**

1. Have hematology tests been done at this visit or since the last visit? .....(1-Yes, 2-No)

**At Entry:** Have hematology tests been done as per protocol direction?

**If No,** go to question 2.

**If Yes,** continue.

a. Date specimen obtained (mmm/dd/yyyy):.....

	Value (Use "-1" if not done)	Grade <sup>1</sup>	Evaluation Form Completed? <sup>2</sup> (codes 1-5)
Hemoglobin (g/dl): .....	<input type="text"/> <input type="text"/> . <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hematocrit (%): .....	<input type="text"/> <input type="text"/> . <input type="text"/>		
RBC (million/cu): .....	<input type="text"/> <input type="text"/> . <input type="text"/>		
Mean Corpuscular Volume (MCV) (microns): .....	<input type="text"/> <input type="text"/> <input type="text"/>		
WBC (10 <sup>3</sup> /cu mm): .....	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/>		
Neutrophils (including Bands) (%): .....	<input type="text"/> <input type="text"/>		
Lymphocytes (%): .....	<input type="text"/> <input type="text"/>		
Atypical Lymphocytes (%): .....	<input type="text"/> <input type="text"/>		
Monocytes (%): .....	<input type="text"/> <input type="text"/>		
Eosinophils (%): .....	<input type="text"/> <input type="text"/>		
Basophils (%): .....	<input type="text"/> <input type="text"/>		
Absolute Neutrophil Count (cu mm) (WBC x % Neutrophils including Bands):	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
Platelets (10 <sup>3</sup> cu mm): .....	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
Reticulocyte count (%): .....	<input type="text"/> <input type="text"/> . <input type="text"/>		
Erythrocyte Sedimentation Rate (mm/hr): .....	<input type="text"/> <input type="text"/> <input type="text"/>		

COMPREHENSIVE HEMATOLOGY/CHEMISTRY - II

Pt. No.       \*Seq. No.   \*\*Step No.   Date        
 mmm dd yyyy

II. CHEMISTRY

2. Have chemistry tests been done at this visit or since the last visit? ..... (1-Yes, 2-No)

**At Entry:** Have chemistry tests been done as per protocol direction?

If No, go to question 3.

If Yes, continue.

a. Date specimen obtained (mmm/dd/yyyy):.....

*\* If Amylase is abnormal, obtain sample for lipase and report on the same form (even if different dates) to get combined grade.*

	Value (Use "-1" if not done)	Upper Limit of Normal <sup>2</sup>	Grade <sup>1</sup>	Evaluation Form Completed? <sup>2</sup> (codes 1-5)
Sodium (mEq/L).....	<input type="text"/> <input type="text"/> <input type="text"/>	.....	<input type="checkbox"/>	<input type="checkbox"/>
Potassium mEq/L).....	<input type="text"/> <input type="text"/> . <input type="text"/>	.....	<input type="checkbox"/>	<input type="checkbox"/>
Chloride (mEq/L).....	<input type="text"/> <input type="text"/> <input type="text"/>			
CO <sub>2</sub> (Bicarbonate) (mEq/L).....	<input type="text"/> <input type="text"/>			
Calcium (mg/dl).....	<input type="text"/> <input type="text"/> . <input type="text"/>	.....	<input type="checkbox"/>	<input type="checkbox"/>
Magnesium (mEq/L).....	<input type="text"/> <input type="text"/> . <input type="text"/>	.....	<input type="checkbox"/>	<input type="checkbox"/>
Phosphorus (mg/dl).....	<input type="text"/> <input type="text"/> . <input type="text"/>			
Alkaline Phosphatase (mU/ml).....	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		
SGOT (AST) (mU/ml).....	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
SGPT (ALT) (mU/ml).....	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
LDH (Lactic Acid Dehydrogenase) (mU/ml)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>			
Urea Nitrogen (BUN) (mg/dl).....	<input type="text"/> <input type="text"/> <input type="text"/>			
Creatinine (mg/dl).....	<input type="text"/> <input type="text"/> . <input type="text"/>	.....	<input type="checkbox"/>	<input type="checkbox"/>
Uric Acid (mg/dl).....	<input type="text"/> <input type="text"/> . <input type="text"/>	.....	<input type="checkbox"/>	<input type="checkbox"/>
GGT.....	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
Glucose (mg/dl).....	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	.....	<input type="checkbox"/>	<input type="checkbox"/>
Triglycerides (mg/dl).....	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	.....	<input type="checkbox"/>	<input type="checkbox"/>
Total Bilirubin (mg/dl).....	<input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> . <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
Total Protein (g/dl).....	<input type="text"/> <input type="text"/> . <input type="text"/>			
Albumin (g/dl).....	<input type="text"/> <input type="text"/> . <input type="text"/>			
Globulin (g/dl).....	<input type="text"/> <input type="text"/> . <input type="text"/>			
*Total Amylase(U/L).....	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		
*Lipase (U/L).....	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		
*Reported grade of total Amylase and Lipase .....			<input type="checkbox"/>	<input type="checkbox"/>
Pancreatic Serum Amylase (U/L).....	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
CPK (Creatine Phosphokinase (U/L).....	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	.....	<input type="checkbox"/>	<input type="checkbox"/>
Cholesterol (mg/dL).....	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	.....	<input type="checkbox"/>	<input type="checkbox"/>

12-11-03/05-24-04/07-12-04

**COMPREHENSIVE HEMATOLOGY/CHEMISTRY - II**

Pt. No.       \*Seq. No.   \*\*Step No.   Date        
 mmm dd yyyy

**III. OTHER HEMATOLOGY/CHEMISTRY**

**NOTE: Fasting values must be recorded in question 3.**

3. Have any other protocol directed hematology or chemistry tests been done at this visit or since the last visit?..... (1-Yes, 2-No)

**At Entry:** Have any other hematology or chemistry tests been done as per protocol direction?

**If No, STOP.**  
**If Yes, continue.**

*Use the Tab Key after the last entry.*

Test Code <sup>4</sup>	Value	Limit of Normal <sup>3</sup> If Required (Use "-1" if not applicable)	Grade <sup>1</sup>	Evaluation Form Completed? <sup>2</sup> (codes 1-5)
a. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/>	<input type="text"/>
Date specimen obtained (mmm/dd/yyyy):	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Specify [30]:	_____	
b. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/>	<input type="text"/>
Date specimen obtained (mmm/dd/yyyy):	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Specify [30]:	_____	
c. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/>	<input type="text"/>
Date specimen obtained (mmm/dd/yyyy):	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Specify [30]:	_____	
d. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/>	<input type="text"/>
Date specimen obtained (mmm/dd/yyyy):	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Specify [30]:	_____	
e. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/>	<input type="text"/>
Date specimen obtained (mmm/dd/yyyy):	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Specify [30]:	_____	
f. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/>	<input type="text"/>
Date specimen obtained (mmm/dd/yyyy):	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Specify [30]:	_____	

**NOTE:** Some events listed on this form may **ALSO** require reporting on an SAE Form. SAE reporting is **NOT A SUBSTITUTE** for this form.