

## Clinical Research Case Study

<b>Case Study 1</b>	<b>Situation</b>
Natalie and her daughter, Sarah	I am 40 years old. I am HIV negative. My daughter's name is Sarah. She has AIDS. She is 12 years old. I have many fights with my daughter to make her take her medications. When she is in the bathroom getting sick, I feel terrible. But I am very thankful that we live in a big city where excellent medical care is available to us. We have a very close family, so we have a lot of help taking Sarah to doctor's appointments and tests. Last month, Sarah told her doctor she would like to take fewer pills. She also asked him to find her something else that will help her. Her doctor found a study that Sarah is eligible for.

### Questions for the Table Group

1. What are some benefits Sarah might find by participating in a study?

2. What are some risks Sarah might have by participating in a study?



## Clinical Research Case Study

<b>Case Study 3</b>	<b>Situation</b>
Niran	<p>My parents are poor. Providing for my eight brothers and sisters is very difficult for them. I am the oldest child. I grew up in Pattaya, a city on the east coast of Thailand. After leaving school, I moved to Chiang Mai. I needed money, so I tried to sell my blood. I was informed I had HIV. I was 16 years old and all alone. I told my sister. She told my parents and grandmother. My family is very embarrassed and will not talk to me. I am 16 years old and facing death with no family support. This is my welcome to adulthood. I realize I can let the disease win, or I can do whatever is needed to try to fight the disease. I was told to contact the Thai Red Cross AIDS Research Centre to get help. They told me to contact the Silom Community Clinic and the Bangkok Christian Hospital to find out about treatment. I was told I can participate in research that might help me.</p>

### Questions for the Table Group

1. What are some benefits Niran might find by participating in a clinical trial?
2. What are some risks Niran might have by participating in a clinical trial?

## Clinical Research Case Study

<b>Case Study 4</b>	<b>Situation</b>
Lina	My husband just found out he is HIV positive. I am HIV negative. I am 6 months pregnant with our first child. I have always wanted a child, and this baby will be the first grandchild in both of our families. No one in our families knows my husband is HIV positive. We live in a small village. The nearest doctor is in the next village. I have to take a 3-hour bus ride each way to get to the nearest doctor.

### Questions for the Table Group

1. What are some benefits Lina might find by participating in a clinical trial?

2. What are some risks Lina might have by participating in a clinical trial?

## Clinical Research Process Case Study

<b>Case Study 1</b>	<b>Situation</b>
Natalie and her daughter, Sarah	<p>Natalie and Sarah want to understand everything they can before signing up for the study that Sarah's doctor found for her.</p> <p>There are some words they do not understand.</p> <p>With your group, find out what the following words mean: <b>microbicide</b> and <b>vaccine</b>.</p> <p>Then select one of the words and practice how Sarah's doctor might explain the word to Natalie and Sarah.</p> <p>After you finish practicing, demonstrate the explanation to the whole class.</p>

## Clinical Research Process Case Study

<b>Case Study 2</b>	<b>Situation</b>
Akia	<p>Akia wants to understand everything he can before signing up for the study he found that might help his partner.</p> <p>There are some words he does not understand.</p> <p>With your group, find out what the following words mean: <b>placebo</b> and <b>randomized trial</b>.</p> <p>Then select one of the words and practice how Akia's doctor might explain the word to him.</p> <p>After you finish practicing, demonstrate the explanation to the whole class.</p>

## Clinical Research Process Case Study

<b>Case Study 3</b>	<b>Situation</b>
Niran	<p>Niran wants to understand everything he can before signing up for the study he found that might help him.</p> <p>There are some words he does not understand.</p> <p>With your group, find out what the following words mean: <b>blinded</b> or <b>blinded study</b> and <b>Phase II vaccine trial</b>.</p> <p>Then select one of the words and practice how someone from the clinic might explain the word to him.</p> <p>After you finish practicing, demonstrate the explanation to the whole class.</p>

## Clinical Research Process Case Study

<b>Case Study 4</b>	<b>Situation</b>
Lina	<p>Lina wants to understand everything she can before signing up for a study her doctor told her about that might help her and her baby remain healthy.</p> <p>There are some words she does not understand.</p> <p>With your group, find out what the following words mean: <b>efficacy</b> and <b>randomized trials</b>.</p> <p>After you finish practicing, demonstrate the explanation to the whole class.</p>

## Elements and Principles of Clinical Research Case Study

<b>Case Study 1</b>	<b>Situation</b>
Natalie and her daughter, Sarah	<p>Natalie and Sarah now feel quite sure they want to take part in the trial Sarah's doctor found for her. Natalie and Sarah will be meeting with the research team soon.</p> <p>However, Sarah is very worried about some of the questions she will be asked with her mother sitting nearby. She knows the research team will ask questions about her experience with AIDS. She is worried that some of the questions she may not be able to answer. And she is worried that some of the questions she may not want to answer because she does not want her mother to hear the answers.</p> <p>Natalie is also worried about some of the questions that will be asked during the meeting with the research team. She is afraid the research team will think she is a bad mother because Sarah has AIDS and she does not.</p> <p>It will be very important for the research team to interview Sarah and Natalie and respect their privacy and confidentiality. However, they know they need to have an informed consent document signed before they can proceed. And they know that Sarah really wants to participate in any research available to her.</p>

### Questions for the Table Group

1. If you were a member of the research team, what kinds of things would you do and say that would help you get accurate information about Sarah from her mother?
2. If you were a member of the research team, what kinds of things would you do and say that would help you get accurate information from Sarah?
3. If you were a member of the research team, what kinds of things would you do and say that would help you get a signature on the informed consent document?
4. How can the research team maintain Sarah's confidentiality?

## Elements and Principles of Clinical Research Case Study

<b>Case Study 2</b>	<b>Situation</b>
Akia	Akia has found a research study that he can participate in that might help people who are HIV positive. Akia is currently HIV negative, but he knows that may change at some time in the future. While Akia is healthy, he wants to participate in any research opportunities available to him. Akia has also found a research study for HIV-positive people. He would like his partner to participate in any research opportunities available to him. However, Akia is not sure his partner will be willing to do that. Akia and his partner do not discuss their health concerns and their personal histories. Akia is uncomfortable about asking his partner anything personal. Akia is going to his first meeting with the research team. They know they will need to ask Akia some questions about his partner's health and history and Akia's health and history.

### Questions for the Table Group

1. If you were a member of the research team, what kinds of things would you do and say that would help you get accurate information about Akia and his relationship to his partner?
2. If you were a member of the research team, what kinds of things would you do and say that would help you get accurate information from Akia's partner if he agreed to help?
3. If you were a member of the research team, what kinds of things would you do and say that would help you get a signature on the informed consent document?
4. How can the research team maintain Akia's confidentiality?

## Elements and Principles of Clinical Research Case Study

<b>Case Study 3</b>	<b>Situation</b>
Niran	Niran is now 17 years old and alone in Bangkok. He does not trust his sister, and his family will not speak to him. They have told him not to come home so the neighbors do not find out he is sick. The Silom Community Clinic has identified two research projects Niran might qualify for. Niran's first priority is to get started on a treatment, so he is very interested in the one where he can get Kaletra. And he qualifies for a patient assistance program that will pay for the medication. Niran is going to his first meeting with the research team. He is desperate to get accepted for the trial. The research team is concerned about some of Niran's answers to their questions. They wonder if he is hiding important information. They also worry because Niran looks very young. When the research team asked Niran how old he is, he said "18." However, Niran had no identification to prove his age.

### Questions for the Table Group

1. If you were a member of the research team, what kinds of things would you do and say that would help you get accurate information about Niran?
2. If you were a member of the research team, what kinds of things would you do and say that would help you get accurate information about other people in Niran's life that will support him if he participates in a trial?
3. If you were a member of the research team, what kinds of things would you do and say that would help you get the informed consent document signed by the right person(s)?
4. How can the research team maintain Niran's confidentiality?

## Elements and Principles of Clinical Research Case Study

<b>Case Study 4</b>	<b>Situation</b>
Lina	<p>Lina has agreed to sign up for the study her doctor told her about that might help her and her baby remain healthy. Lina has also been told about a research study for HIV-positive people that her husband could participate in. Lina is afraid her husband will not sign up for any research projects. In fact, she is concerned he will not want her to sign up for any research projects. Lina's husband will not talk to her about how and when he might have become HIV positive. He says it is none of her business as long as she remains HIV negative. As far as he is concerned, he plans to live their lives just as they did before he found out he is HIV positive. Lina has made an appointment to meet with the research team. Her doctor feels it is very important for her to participate in any research projects that might help her and her baby stay healthy. The doctor knows Lina's husband is not supporting her, so she has offered to attend the appointment with Lina as support. The research team can see that Lina is frightened and worried about what her husband will do. Having her doctor at the appointment might be helpful, but they need to be careful about confidentiality.</p>

### Questions for the Table Group

1. If you were a member of the research team, what kinds of things would you do and say that would help you get accurate information about Lina's likelihood for participation?
2. If you were a member of the research team, what kinds of things would you do and say that would help you get accurate information about other people in Lina's life that may affect her if she participates in a trial?
3. If you were a member of the research team, what kinds of things would you do and say that would help you get a signature on the informed consent document?
4. How can the research team maintain Lina's confidentiality?

## Community Advisory Boards and the Research Process Case Study

<b>Case Study 1</b>	<b>Situation</b>
Natalie and her daughter, Sarah	Sarah has been accepted to participate in the first clinical trial she applied for. All of the information Sarah and Natalie have received encourages them to work with people around them who will be available to answer questions, provide support, and encourage them if things sometimes get difficult. Think about the people in Natalie's and Sarah's community in Australia. Then brainstorm answers to the questions.

### Questions for the Table Group

1. What community members will be likely to provide support to Sarah?
2. What community members will be likely to provide support to Natalie?
3. What community members will be likely to provide support to Sarah and Natalie together?
4. In what ways will community and CAB support help Sarah be more likely to successfully complete the research she is part of?

## Community Advisory Boards and the Research Process Case Study

<b>Case Study 2</b>	<b>Situation</b>
Akia	Akia has been accepted to participate in the first clinical trial he applied for. However, Akia's partner is not happy that Akia will be participating in any research, because he feels Akia will share too much personal information about them. All of the information Akia received encourages him to work with people around him who will be available to answer questions, provide support, and encourage him if things sometimes get difficult. Think about the people in Akia's community in South Africa. Then brainstorm answers to the questions.

### Questions for the Table Group

1. What community members will be likely to provide support to Akia?
2. What community members will be able to provide support to Akia's partner, if he will accept it?
3. What community members will be able to provide support to Akia and his partner together?
4. In what ways will community and CAB support help Akia be more likely to successfully complete the research he is part of?

## Community Advisory Boards and the Research Process Case Study

<b>Case Study 3</b>	<b>Situation</b>
Niran	Niran has not been accepted to participate in the first clinical trial he applied for. The research team could not confirm Niran's age, so Niran could not sign the necessary consent document. Niran is very concerned about his ability to participate in any kind of research until he can get proof of his age. And Niran is afraid to contact his parents for the necessary proof or their consent. However, Niran is not alone. The clinic he first visited in Bangkok is trying to help him. The clinic staff and volunteers have promised to answer questions, provide support, and encourage him when things sometimes get difficult. Think about the people in Niran's community in Thailand. Then brainstorm answers to the questions.

### Questions for the Table Group

1. What community members will be likely to provide support to Niran?
2. What community members will be able to provide support to Niran's family, if they will accept it?
3. What community members will be able to provide support to Niran and his family together?
4. In what ways will community and CAB support help Niran to successfully enroll in future research trials?

## Community Advisory Boards and the Research Process Case Study

<b>Case Study 4</b>	<b>Situation</b>
Lina	Lina has been accepted to participate in the first clinical trial she applied for. However, Lina's husband refuses to sign up for any research projects, and he is not happy that Lina will be participating in any research. He is very worried people in their village will find out he is sick. After their baby is born, he thinks the people in his village will wonder why Lina still has to go to the doctor so much. All of the information Lina received encourages her to work with people around her who will be available to answer questions, provide support, and encourage her if things sometimes get difficult. Think about the people in Lina's community in the Philippines. Then brainstorm answers to the questions.

### Questions for the Table Group

1. What community members will be likely to provide support to Lina?
2. What community members will be able to provide support to Lina's husband, if he will accept it?
3. What community members will be likely to provide support to the baby after the baby is born?
4. What community members will be able to provide support to Lina and her husband and child together?
5. In what ways will community and CAB support help Lina be more likely to successfully complete the research she is part of?