

Form Approved
OMB No. 0920-New
Expiration Date: XX/XX/XXXX

Cohort Study of HIV, STIs and Preventive Interventions
among Young MSM in Thailand

Attachment 3

Focus Group Discussion (FGD) Consent Assent

Public reporting burden of this collection of information is estimated to average 30 minutes, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; Attn: OMB-PRA (0920-New)

Part 1: Focus Group Discussion: Assent for study participation

(Participant age 15-17 years)

Project title: Cohort study of HIV, STI and preventive interventions among young men who have sex with men (YMSM) in Thailand

Thai Principle investigator: Dr. Monthinee Vasantiuppapokakorn

Study site: Silom Community Clinic @TropMed

Introduction:

Before giving information about the study to you, we would like to tell you that joining the focus group discussion is voluntary. You can choose not to answer any questions or stop the discussion at any time. Your decision will not affect the health care services you may receive. If you agree to be in this study and sign the consent form, you will receive a copy of the signed consent form.

Why are we doing this?

We are researchers who want to know more about HIV in teen boys and how to prevent it. We work with the Thailand Ministry of Public Health and the U.S. Centers for Disease Control and Prevention. We are talking with you to understand the knowledge, beliefs and HIV prevention practices of teen boys. We also want to know about interest in being a part of HIV prevention studies. There are many young men infected with HIV each year and we do not understand why this is happening. You may have an idea or know about it and we would like to talk to you as a part of this study.

What are we doing in this study?

If you agree to be part of the study, we will ask you questions about your knowledge and beliefs, health issues and prevention practice for HIV and other sexually transmitted infections. We will also ask you about your lifestyle such as how you find friends, internet use, health knowledge, substance use, alcohol use and risk behaviors.

We will talk in a small group. This is called a focus group discussion. Everyone in the group can share ideas. Each group will have 6-8 members aged between 15-17 years old. Our staff will talk with you using a guide of questions. This will take about 1-2 hours. During the discussion, if you have questions about the topics, you can ask our moderator and we will spend some time on this topic.

We will record the group discussion. This is to make sure that we understand the issues that are being talked about. Afterward, we will take notes from the recording and we will save this to a file on the computer. If you do not want your words to be recorded, you can ask to stop the recording. If audio recording is stopped for a long time (more than 15 minutes) or the note taker cannot take notes of the conversation, the group discussion will be cancelled and a new discussion will be made.

Data that can link to persons will be deleted from the transcript. We will keep the audio files in a locked cabinet. Only the study staff can have access to these files and listen to them. Once the transcripts are finished, the audio file will be destroyed. We will analyze the contents of the discussion using a computer program. The result from data analysis will be used as study findings. There will be no information to identify you or others in this data.

We hope that the information we get from talking with you and others can be used to learn about how to prevent HIV in young men.

Is there any risk or discomfort?

There are a few risks from being a part of the study. Some questions we ask are private and might make you feel worried and uneasy. You do not have to answer all questions or talk about things you do not want to. You can choose to not answer the question and you can stop answering or leave the group at any time.

You may be worried to disclose your personal information to others in the group. To protect your privacy and confidentiality, the moderator will have rules at the start of the discussion to respect the privacy of everyone in the group. The moderator will tell everyone not to disclose or talk about the discussion outside of the session. Whether you join the discussion or not, it will not have a negative effect on you or health benefits and services you may receive.

Are there any benefits to me or others?

As a part of this study, you will learn more about HIV and STIs and prevention. Results from this study will help us learn about the best ways to prevent HIV among young men. You will receive

information about HIV/AIDs, prevention, treatments. You will receive condoms and lubricants as a part of HIV prevention package services.

Tokens of Appreciation

You do not have to pay anything to be in the study. You will receive 500 baht as a token of appreciation.

Can I choose not to be in the study?

You do not have to be in this study if you do not want to. No one will be mad or disappointed in you. Whether you want to be in the study is your choice. If you say ‘Yes’ now and change your mind later, it is still okay. You can stop being in the study at anytime. Saying ‘No’ or withdrawal from this study will not affect your schooling and healthcare services you may receive.

How will my information be protected?

We will ask everyone not to talk about the discussion with others outside of the session. Your personal information such as your name, surname, address, telephone number will be kept private. We will not use any of this information such as your name during the group. We will use a code number or a nickname, or a name you want us to use in the group. We will have the group discussion in a room that is private. Your private information will not be on articles, reports or presentation about this study.

We will lock documents about you in a cabinet with a lock and a key. Data that can link to persons will be deleted from the transcript. Only study staff can have access to these files. The DSMB board, the authorities and Ethics Committees, which are group of people who inspect our work, can also see them but they promise to keep these private.

Even when we do everything to keep your information private, it is possible that your friends or other persons may know that you joined the group. This could create social harm, such as they may think you have HIV or an STI. We will do our best to prevent this from happening. You can talk to our nurses if you feel uncomfortable, worried or ashamed about being in the study.

Who do I contact if I have questions while being in study?

You can talk to P’ A or Khun Kanokpan Pancharoen (Tel no. 084-874-2164 or Silom Community Clinic @TropMed 12th Floor Ratchanakarin Building Hospital for Tropical Diseases 420/6 Ratchawithi Road Bangkok 10400) about any issues regarding this study.

This study has been reviewed and approved by the Ethics Committee of Department of Disease Control, Ministry of Public Health: Building 1, 4th floor, Tiwanon road, Taladkwan, Muang district, Nonthaburi 11000. Telephone no. 02-590-3149 Fax no. 02-965-9610 and the Ethics Committee of the Faculty of Tropical Medicine, Mahidol University, 4th Floor, The 60th Anniversary of His Majesty the King's Accession to the Throne Building Faculty of Tropical Medicine, Mahidol University, 420/6 Ratchawithi Road, Bangkok 10400, Thailand. Telephone no. 02-354 9100-19 ext. 1349 dial 16 or 66 (0) 2306 9126 Fax no. 02-306 -9126. E-mail: tmectropmed@mahidol.ac.th. It has also been approved by the U.S. Centers for Disease Control and Prevention.

You can contact the chair of the Ethics Committee or their representative according to the address and number above if you have questions or concerns about your rights in this study.



Part 2: Focus Group Discussion: Assent for study participation

(Participant age 15-17 years)

Project title: Cohort study of HIV, STI and preventive interventions among young men who have sex with men (YMSM) in Thailand.

Thai Principle investigator: Dr. Monthinee Vasantiuppapokakorn

Study site: 1) Silom Community Clinic @TropMed

I have read this information about the focus group discussion process. The study staff explained about all procedures. I had an opportunity to ask questions and had them answered. I understand that whether I agree to join the discussion or not, it will not affect my medical care or any healthcare services that I may receive. The researcher will take all steps to keep my information confidential and this information will only be shared with designated study staff or persons who are responsible for supporting or monitoring the study. If I become injured from the study, the researcher will help you get necessary treatment and referral under the Universal health coverage that I am entitled to. I may contact Dr. Montinee Vasantiuppapokakorn at 086 408 0588 for information regarding care and/or referral at any time. I understand that to put my name at the end of this form, it means that I agree to join the focus group discussion. I will then receive a signed copy of this document for my own record.

Participant's signature

..... Date.....

Print name (.....)

Study staff's signature

..... Date.....

Print name (.....)

Witness's signature (if needed)

..... Date.....

Print name (.....)

Remark: 1. Witness part will only be filled when the participant is illiterate and the assent form has been read to the participant.

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Part 1: Focus Group Discussion: Consent for Study Participation

(Participant age ≥ 18 years)

Project title: Cohort study of HIV, STI and preventive interventions among young men who have sex with men (YMSM) in Thailand

Thai Principle investigator: Dr. Monthinee Vasantiuppapokakorn

Study site: Silom Community Clinic @TropMed

Introduction:

Before giving information about the study to you, we would like to tell you that joining the focus group discussion is voluntary. You can choose not to answer any questions or stop the discussion at any time. Your decision will not affect the health care services you may receive. If you agree to be in this study and sign the consent form, you will receive a copy of the signed consent form.

Why are we doing this?

We are researchers who want to know more about HIV in teen boys and how to prevent it. We work with the Thailand Ministry of Public Health and the U.S. Centers for Disease Control and Prevention. We are talking with you because you are in the community and have worked with teen

boys. We want to understand the knowledge, beliefs and HIV prevention practices of teen boys. We also want to know your thoughts on the opportunities to improve teen health services and prevention in the community. There are many young men infected with HIV each year and we do not understand why this is happening. You may have an idea or know about it and we would like to talk to you as a part of this study.

What are we doing in this study?

If you agree to be part of the study, we will ask you questions about your experience working with teen boys, their knowledge and beliefs, health issues and prevention practice for HIV and other sexually transmitted infections.

We will talk in a small group. This is called a focus group discussion. Everyone in the group can share ideas. Each group will have 6-8 members. Our staff will talk with you using a guide of questions. This will take about 1-2 hours. During the discussion, if you have questions about the topics, you can ask our moderator and we will spend some time on this topic.

We will record the group discussion. This is to make sure that we understand the issues that are being talked about. Afterward, we will take notes from the recording and we will save this to a file on the computer. If you do not want your words to be recorded, you can ask to stop the recording. If audio recording is stopped for a long time (more than 15 minutes) or the note taker cannot take notes of the conversation, the group discussion will be cancelled and a new discussion will be made.

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Is there any risk or discomfort?

There are a few risks from being a part of the study. Some questions we ask are private and might make you feel worried and uneasy. You do not have to answer all questions or talk about things you do not want to. You can choose to not answer the question and you can stop answering or leave the group at any time.

You may be worried to disclose your personal information to others in the group. To protect your privacy and confidentiality, the moderator will have rules at the start of the discussion to respect the privacy of everyone in the group. The moderator will tell everyone not to disclose or talk about the discussion outside of the session. Whether you join the discussion or not, it will not have a negative effect on you or health benefits and services you may receive.

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Tokens of Appreciation

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Can I choose not to be in the study?

You do not have to be in this study if you do not want to. Whether you want to be in the study is your choice. If you say 'Yes' now and change your mind later, it is still okay. You can stop being in the study at anytime. Saying 'No' or withdrawal from this study will not affect healthcare services you may receive.

How will my information be protected?

We will ask everyone not to talk about the discussion with other outside of the session. Your personal information such as your name, surname, address, telephone number will be kept private. We will not use any of this information such as your name during the group. We will use a code number or a nickname, or a name you want us to use in the group. We will have the group discussion in a room that is private. Your private information will not be on articles, reports or presentation about this study.

We will lock documents about you in a cabinet with a lock and a key. Data that can link to persons will be deleted from the transcript. Only study staff can have access to these files. The DSMB board, the authorities and Ethics Committees, which are group of people who inspect our work, can also see them but they promise to keep these private.

Even when we do everything to keep your information private, it is possible that your friends or other persons may know that you joined the group. This could create social harm, such as they may think you have HIV or an STI. We will do our best to prevent this from happening. You can talk to our nurses if you feel uncomfortable, worried or ashamed about being in the study.

Who do I contact if I have questions while being in study?

You can talk to Khun A or Khun Kanokpan Pancharoen (Tel no. 084-874-2164 or Silom Community Clinic @TropMed 12th Floor Ratchanakarin Building Hospital for Tropical Diseases 420/6 Ratchawithi Road Bangkok 10400) about any issues regarding this study.

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You can contact the chair of the Ethics Committee or their representative according to the address and number above if you have questions or concerns about your rights in this study.



Part 2 : Focus Group Discussion: Consent for Study Participation

(Participant age \geq 18 years)

Project title: Cohort study of HIV, STI and preventive interventions among young men who have sex with men (YMSM) in Thailand.

Thai Principle investigator: Dr. Monthinee Vasantiuppapokakorn

Study site: 1) Silom Community Clinic @TropMed

I have read this information about the focus group discussion process. The study staff explained about all procedures. I had an opportunity to ask questions and had them answered. I understand that whether I agree to join the discussion or not, it will not affect my medical care or any healthcare services that I may receive. The researcher will take all steps to keep my information confidential and this information will only be shared with designated study staff or persons who are responsible for supporting or monitoring the study. If I become injured from the study, the researcher will help me get the necessary treatment and referral under the Universal health coverage that I am entitled to. I may contact Dr. Montinee Vasantiuppapokakorn at 086 408 0588 for information regarding care and/or referral at any time. I understand that to put my name at the end of this form, it means that I agree to join the focus group discussion. I will then receive a signed copy of this document for my own record.

Participant's signature

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Date.....

2: (≥ 18)

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1) @

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