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 5

**Key Informant Interview (KII) 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: Key Informant Interviews: Assent for study participation

(Participants ages 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 interview is voluntary. You can choose not to answer any questions or stop the discussion at any time. Your decision will not affect the healthcare 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 we want to understand the knowledge, beliefs and HIV prevention practices of teen boys. 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 have a short interview. We will ask you questions about your knowledge and beliefs, health issues and prevention practice for HIV and other sexually transmitted infections. The in-depth interview will take 1-2 hours.

We will record the 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.

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 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 at any time.

You may be worried to disclose your personal information. Whether you join the interview 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?

Your personal information such as your name, surname, address, telephone number will be kept private. We will not use any of this information for the interview. We will use a code number or a nickname, or a name you want us to use. We will have the interview 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.

#### 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, 4<sup>th</sup> 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, 4<sup>th</sup> Floor, The 60<sup>th</sup> 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: <a href="mailto:tmectropmed@mahidol.ac.th">tmectropmed@mahidol.ac.th</a>. 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: Key Informant Interviews: 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.

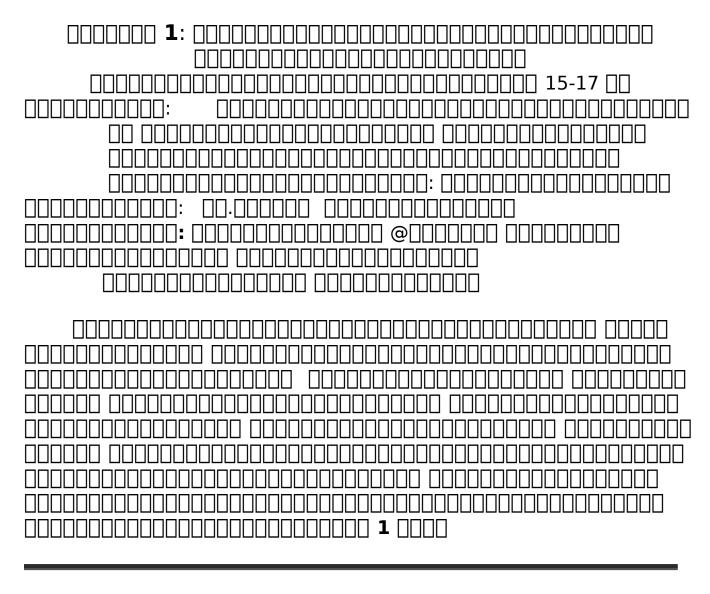
Thai Principle investigator: Dr. Monthinee Vasantiuppapokakorn

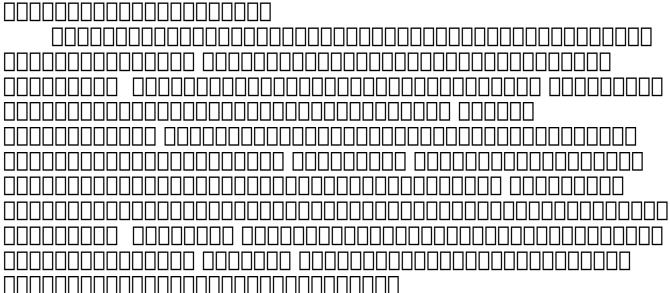
**Study site:** 1) Silom Community Clinic @TropMed

I have read this information about the key informant interview 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 interview 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 key informant interview. 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
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<u>Remark</u>: 1. Witness part will <u>only be filled</u> when the participant is illiterate and the assent form has been read to the participant.





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# Part1: Key Informant Interviews: 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:** Silom Community Clinic @TropMed

#### **Introduction:**

Before giving information about the study to you, we would like to tell you that joining the interview is voluntary. You can choose not to answer any questions or stop the discussion at any time. Your decision will not affect the healthcare 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 have a short interview. 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 would like you to share your opinions regarding best ways to work with young men and support prevention in the community. The in-depth interview will be conducted with a few community members and will take 1-2 hours.

We will record the 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.

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 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 at any time.

You may be worried to disclose your personal information. Whether you join the interview 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**

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. 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.

#### How will my information be protected?

Your personal information such as your name, surname, address, telephone number will be kept private. We will not use any of this information during the interview. We will use a code number or a nickname, or a name you want us to use. We will have the interview in a room that is private. Your private information will not be on articles, reports or presentation about 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: Key Informant Interviews: 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

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Participant's signature
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<b>Remark:</b> 1. Witness part will <u>only be filled</u> when the participant is illiterate and the assent form
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