

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 8
Screening 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: Cohort Screening: 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

2) Bangrak Hospital, Bangkok

3) Rainbow Clinic, Nakhon Sawan province



Introduction: This document is to get your permission to be screened for the Cohort Study. You can ask our study staff to explain the procedure until you fully understand it. We have a teen advocate that you can talk to about the study. Whether you join this screening or not, it will not affect healthcare services that you 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 work with the Thailand Ministry of Public Health and the U.S. Centers for Disease Control and Prevention. We are doing a study on HIV/AIDS and sexually transmitted infections (STIs) in young men. HIV is a virus that causes AIDS and can be transmitted by having sex. A person can have HIV or STIs without knowing it. We are doing this study to understand how often HIV and other STIs occur in young men and adolescent boys. We also want to know risk factors for these infections. This study is important so that we can find the best ways to prevent these infections. This is a 3 year study with 740 boys/men included; 500 boys/men will be from Silom Community Clinic @ Trop Med and 120 boys/men each will be from Nakhon Sawan and Bangrak Hospital.

You are invited to be screened for this study because you are:

- 15-29 years old

- Male at birth
- Live in Bangkok and vicinity or Nakhon Sawan province
- Have a same sex interest or history of oral or anal intercourse with a man

What are we doing in the screening process?

You are asked to be screened for possible inclusion into this study. At this visit we will check your eligibility for the study, provide pre-test and post-test HIV counseling, an HIV test, and we will ask you to answer questions by computer.

The questions, pre-test counseling and blood draw will take about 30 minutes. The study nurse will draw approximately 12 cc, not over a tablespoon of your blood.

You will receive the HIV result (HIV rapid test result) and post-test counseling. If you are positive you will be counseled about HIV. We will ask you to answer some questions by computer and you will be referred to a special doctor for teens, off site, who can provide HIV treatment. We will also have a support group for teens that test HIV positive and we will have an HIV case manager you can talk to.

Special HIV testing that can look out how recent the infection is will be done at the end of the study. These tests are called a Nucleic Acid Amplification Test or NAAT, and an incidence assay. We will not provide the results of these tests to you as they will not change your medical care or follow-up.

Is there any risk or discomfort?

It will hurt a small amount to get your blood taken. Your arm may be swollen or bruised. That should go away in 2-3 days. Some questions about risk behavior might make you feel uneasy, worried, shy or uncomfortable. You do not have to answer those questions and you can stop answering questions at any time. We will not discuss any of your results with anyone but you, however if you have HIV infection we will encourage you to go to a doctor to get treatment. In that case, they may need to have a parent or guardian support treatment.

Are there any benefits to me or others?

At this visit, you will receive health counseling. Our nurses will explain about HIV, how it is transmitted and how to prevent it. If you have HIV, we will provide a referral for treatment and care. You will receive PrEP counseling, condoms and lubricants as a part of HIV prevention package services. If you would like to take PrEP we can provide it free to you during the study at Silom Community Clinic @ TropMed. Taking part in this study may not directly benefit you. However, getting HIV test results can help you be informed on your HIV status and also may help you get treatment early, which can benefit your health.

Token of Appreciation

You do not have to pay anything for the screening. You will receive 800 baht (about 25 U.S. dollars) as a token of appreciation.

Can I choose not to be screened?

It is your choice to be screened or not. No one will be mad or disappointed in you. Whether you want to be screened is your choice. Saying 'No' will not affect healthcare services you may receive.

Do I have other choices if I do not want to be screened?

You can have your health check-up, HIV and STIs testing from government and private clinic or hospitals. We can advise you and give you a list of clinics or hospitals. You can also attend our clinic for PrEP, HIV and STI testing without getting screened for the study.

When will I know the result?

You will know the results of the HIV test at this visit.

How will my information be protected?

Your personal information such as your name, surname, address, telephone number, test results and your answers in the questionnaire will be kept private. We will use the code number to refer to you. We will not give your test result to anybody unless you want us to. Only you know the result. Your name and surname will not be shown in the articles, reports or presentation about this study.

We will lock documents about you in a cabinet with a lock and a key. Only some of the study team can see them. 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 screening because they see you in the clinic. 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.

Can I stop being a part of the study?

Taking part in this study is completely your choice. However, you can leave the study at any time for any reason without penalty or loss of benefits, such as your medical care services. If there is an evidence that being a part of the study will affect your safety or well-being, it is possible that we may take you off the study without your consent.

If you decide to leave the study, you can tell the study staff and we can make the arrangements and discuss your future care as appropriate. We may ask you questions about your health and your experience in the study. You will be paid for the visits and procedures that you completed.

We would like to ask your permission to keep a small amount of blood and other samples for future testing. It might be used to check for other infections, germs, or conditions. It also may be used to find a new method to detect HIV, for a vaccine that prevents HIV infection and or a way to cure HIV. Testing of the stored sample will not harm you. There will be no identifiers on the specimens, only a specimen ID. Your Identifiable information will not be used in the report or any articles of the study result.

We will store samples that you allow us to keep at the TUC laboratory which is located in the Ministry of Public Health, Nonthaburi province. They will be kept there for a maximum period of 5 years. If we would like to keep your samples longer than 5 years or use them in the other studies with different purposes from this study, we will have to ask for an approval from the government authority that is related to good research conduct (for example The Ethics Committee of the Department of Disease Control, Ministry of Public Health and the Ethics Committee of the Faculty of Tropical Medicine, Mahidol University).

The stored samples will not be used for commercial purpose. If you do not allow us to store your leftover samples, you still can be in the study. If you first say yes but change your mind later, you can tell our staff and we will destroy your samples. We will try to contact and tell the result to you, if the future testing shows an important result about your health.

Who do I contact if I have questions about the screening?

If you are screened at Silom Community Clinic @TropMed in Bangkok, 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).

If you are screened at Bangrak Hospital in Bangkok, you can talk to P' Daeng or Khun Naruemon Yenyasun (Tel no. 083-058-7438 or Bangrak Hospital 9 Sathorn Road, Yan Nawa, Sathon, Bangkok 10120), and if you live in Nakhon Sawan province you can talk to P Sairoong or Khun Sairoong Chantraprasart (Tel no. 081-046-0059 or Rainbow clinic, Office of Disease Prevention and Control Region 3, Matulee Road, Mueang, Nakhon Sawan province 60000). They all can answer the questions you may have about this

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. 0-2306-9126 Fax no. 0-2306 -9126. E-mail: tmectropmed@mahidol.ac.th. It has also been approved by the U.S. Centers for Disease Control and Prevention IRB.

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: Cohort Screening: 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

2) Bangrak Hospital, Bangkok

3) Rainbow Clinic, Nakhon Sawan province

I have read this information about the screening 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 be screened 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 be screened. 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.

Part 3: Cohort Screening: Permission for storage of specimens

(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
 - 2) Bangrak Hospital, Bangkok
 - 3) Rainbow Clinic, Nakhon Sawan province

I (name)..... know and understand that whether I allow having my leftover specimen stored or not, it will not affect my medical care or any healthcare services that I may receive. My sample will not be used for commercial purposes. I understand that even if I choose to have my sample stored I can change my mind later. I will then receive a signed copy of this document for my own record.

I make a choice by marking ✓ or ✗ in the gap

_____ **I agree** to store my leftover specimen for future testing

_____ **I do not agree** to store my leftover specimen for future testing

Contact Information: If you have questions about storage please contact P’A or Khun Kanokpan Pancharoen (Tel no. 084-874-2164) if you are screened at Silom Community Clinic @TropMed in Bangkok, P’ Daeng or Khun Naruemon Yenyasun (Tel no. 083-058-7438) if you are screened at Bangrak Hospital and P Sairoong or Khun Sairoong Chantraprasart (Tel no. 081-046-0059) if you are screened at Nakhon Sawan Rainbow clinic.

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Part 1 :Cohort Screening: Consent for study participation

(Participant age 18-29 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

2) Bangrak Hospital, Bangkok

3) Rainbow Clinic, Nakhon Sawan province



Introduction: This document is to get your permission to be screened for the Cohort Study. You can ask our study staff to explain the procedure until you fully understand it. Whether you join this screening or not, it will not affect healthcare services that you 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 work with the Thailand Ministry of Public Health and the U.S. Centers for Disease Control and Prevention. We are doing a study on HIV/AIDS and sexually transmitted infections (STIs) in young men. HIV is a virus that causes AIDS and can be transmitted by having sex. A person can have HIV or STIs without knowing it. We are doing this study to understand how often HIV and other STIs occur in young men and adolescent boys. We also want to know risk factors for these infections. This study is important so that we can find the best ways to prevent these infections. This is a 3 year study with 740 boys/men included; 500 boys/men will be from Silom Community Clinic @ Trop Med and 120 boys/men each will be from Nakhon Sawan and Bangrak Hospital.

You are invited to be screened for this study because you are:

- 15-29 years old
- Male at birth

- Live in Bangkok and vicinity or Nakhon Sawan province
- Have a history of oral or anal intercourse with a man

What are we doing in the screening process?

You are asked to be screened for possible inclusion into this study. At this visit we will check your eligibility for the study, provide pre-test and post-test HIV counseling, an HIV test, and we will ask you to answer questions by computer.

The questions, pre-test counseling, and blood draw will take about 30 minutes. The study nurse will draw approximately 12 cc, not over a tablespoon of your blood.

You will receive the HIV result and post-test counseling. If you are positive you will be counseled about HIV. We will ask you to answer some questions by computer and you will be referred for HIV treatment.

Special HIV testing that can look at how recent the infection is will be done at the end of the study. These tests are called a Nucleic Acid Amplification Test or NAAT, and an Incidence Assay. We will not provide the results of these tests to you as they will not change your medical care or follow-up.

Is there any risk or discomfort?

It will hurt a small amount to get your blood taken. Your arm may be swollen or bruised. That should go away in 2-3 days. Some questions about risk behavior might make you feel uneasy, worried, shy or uncomfortable. You do not have to answer those questions and you can stop answering questions at any time. We will not discuss any of your results with anyone but you, however if you have HIV infection we will encourage you to go to a doctor to get treatment.

Are there any benefits to me or others?

At this visit, you will receive health counseling. Our nurses will explain about HIV, how it is transmitted and how to prevent it. If you have HIV, we will provide a referral for treatment and care. You will receive PrEP counseling, condoms and lubricants as a part of HIV prevention package services. If you would like to take PrEP we can provide it free to you during the study at Silom Community Clinic @ Trop Med. Taking part in this study may not directly benefit you. However,

getting HIV test results can help you be informed on your HIV status and also may help you get treatment early, which can benefit your health.

Tokens of Appreciation

You do not have to pay anything for the screening. You will receive 800 baht (about 25 U.S. dollars) as a token of appreciation.

Can I choose not to be screened?

It is your choice to be screened or not. No one will be mad or disappointed in you. Whether you want to be screened is your choice. Saying 'No' will not affect healthcare services you may receive.

Do I have other choices if I do not want to be screened?

You can have your health check-up, HIV and STIs testing from government and private clinic or hospitals. We can advise you and give you a list of clinics or hospitals. You can also come to this clinic for PrEP, HIV and STI testing without getting screened for the study.

When will I know the result?

You will know the results of the HIV test at this visit.

How will my information be protected?

Your personal information such as your name, surname, address, telephone number, test results and your answers in the questionnaire will be kept private. We will use the code number to refer to you. We will not give your test result to anybody unless you want us to. Only you know the result. Your name and surname will not be shown in the articles, reports or presentation about this study.

We will lock documents about you in a cabinet with a lock and a key. Only some of the study team can see them. 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 screening because they see you in the clinic. 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.

Can I stop being a part of the study?

Taking part in this study is completely your choice. However, you can leave the study at any time for any reason without penalty or loss of benefits, such as your medical care services. If there is an evidence that being a part of the study will affect your safety or well-being, it is possible that we may take you off the study without your consent.

If you decide to leave the study, you can tell the study staff and we can make the arrangements and discuss your future care as appropriate. We may ask you questions about your health and your experience in the study. You will be paid for the visits and procedures that you completed.

Future study and storage of the leftover sample

We would like to ask your permission to keep your specimen for future testing. It might be used to check for other infections, germs, or conditions. It also may be used to find a new method to detect HIV, for a vaccine that prevents HIV infection and or a way to cure HIV. Testing of the stored sample will not harm you. There will be no identifiers on the specimens, only a specimen ID. Your Identifiable information will not be used in the report or any articles of the study result.

We will store samples that you allow us to keep at the TUC laboratory which is located in the Ministry of Public Health, Nonthaburi province. They will be kept there for a maximum period of 5 years. If we would like to keep your samples longer than 5 years or use them in the other studies with different purposes from this study, we will have to ask for an approval from the government authority that is related to good research conduct (for example The Ethics Committee of the Department of Disease Control, Ministry of Public Health and the Ethics Committee of the Faculty of Tropical Medicine, Mahidol University).

The stored samples will not be used for commercial purpose. If you do not allow us to store your leftover samples, you still can be in the study. If you first say yes but change your mind later, you can tell our staff and we will destroy your samples. We will try to contact and tell the result to you, if the future testing shows an important result about your health.

Who do I contact if I have questions about the screening?

If you are screened at Silom Community Clinic @TropMed in Bangkok, 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).

If you are screened at Bangrak Hospital in Bangkok, you can talk to P'Daeng or Khun Naruemon Yenyasun (Tel no. 083-058-7438 or Bangrak Hospital 9 Sathorn Road, Yan Nawa, Sathon, Bangkok 10120). and if you live in Nakhon Sawan province you can talk to P' sairoong or Khun Sairoong Chantraprasart (Tel no. 081-046-0059 or Rainbow clinic Office of Disease Prevention and Control Region 3, Matulee Road, Mueang, Nakhon Sawan province 60000). They can answer the questions you may have about this.

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 IRB.

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: Cohort Screening: Consent for study participation

(Participant age 18-29 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

2) Bangrak Hospital, Bangkok

3) Rainbow Clinic, Nakhon Sawan province

I have read this information about the screening 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 be screened 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 be screened. 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 consent form has been read to the participant.

Part 3:Cohort Screening: Permission for storage of specimens

(Participant age 18-29 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

2) Bangrak Hospital, Bangkok

3) Rainbow Clinic, Nakhon Sawan province

I (name)..... know and understand that whether I allow having my leftover specimen stored or not, it will not affect my medical care or any healthcare services that I may receive. My sample will not be used for commercial purposes. I understand that even if I choose to have my sample stored I can change my mind later. I will then receive a signed copy of this document for my own record.

I make a choice by marking ✓ or ✗ in the gap

_____ **I agree** to store my leftover specimen for future testing

_____ **I do not agree** to store my leftover specimen for future testing

Contact Information: If you have questions about storage please contact P'A or Khun Kanokpan Pancharoen (Tel no. 084-874-2164) if you are screened at Silom Community Clinic @TropMed in Bangkok, P' Daeng or Khun Naruemon Yenyasun (Tel no. 083-058-7438) if you are screened at Bangrak Hospital and P Sairoong or Khun Sairoong Chantraprasart (Tel no. 081-046-0059) if you are screened at Nakhon Sawan Rainbow clinic.

Place Thai Version Here

1: (18-29)

1) @

2)

3)



3: (18-29)

18-29

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084-874-2164

