

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 11

Enrollment 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 Enrollment: 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 may have information that you have read, but do not yet understand. You can ask our study staff to explain to you until you fully understand it. You then will receive a copy of this document. You can take it home to talk with your parents, relatives, doctors, nurses, friends, or others that you want to consult with to help you decide if you want to be a part of this study. We also have a teen advocate that you can talk to about the study. Whether you join this study is completely up to you. It is voluntary and will not affect schooling or services that you receive. It is ok if you do not want to be a part of it. You can also change your mind after joining the study and not be a part of it. 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 in this study because you are:

- 15-29 years old
- Male at birth
- HIV- uninfected at enrollment
- Live in Bangkok and vicinity or Nakhon Sawan province
- Have a same sex interest or history of oral or anal intercourse with a man
- Willing to join the study and can come for follow-up every 3 months for 3 years (Total 12 visits)

What are we doing in the study?

We are following a total of 740 young men and adolescent boys for 3 years; 500 boys/men will be from Silom Community Clinic @ Trop Med and 120 boys/men each will be from Nakhon Sawan and Bangrak Hospital. In this study, we have a total of 12 visits with follow-up every 3 months.

At the first visit (enrollment visit) we will collect your blood (about 18 cc, not over 1 1/2 tablespoons) and test for Hepatitis A, B, C, Human Papillomavirus (HPV), HIV NAAT, and syphilis and we will collect an anal swab for Human Papillomavirus (HPV). Hepatitis infection can affect your liver and health, and there are prevention methods for many of these infections. The results of the hepatitis tests will be given to you at the first follow-up visit. HPV is a STI that is frequently detected in those who have sex, especially men who have sex with men. This infection does not need treatment as it usually clears on its own. The results of the HPV tests will not be provided as it will not change your clinical care. If the results of the HIV NAAT (a test for early HIV) are positive we will contact you for counseling and referral.

At the enrollment visit at Silom Community Clinic @ Trop Med, the nurse will teach you how to collect your own urine and an anal swab. At Silom Community Clinic @ Trop Med, you will collect samples for us at each visit, and at Bangrak Hospital and Nakhon Sawan, a provider will collect the samples. The urine and rectal swab will be tested for gonorrhea (NG) and chlamydia (CT). If you test positive for NG, CT or syphilis you will be asked to come back for treatment, for free. At the enrollment

visit, we will also do a review of your medical record and a brief physical examination. Finally, we will provide condoms and lubricants, free of charge.

At the end of the enrollment visit we will schedule follow-up visits with you.

The activities at *each* follow-up visit (every 3 months) will be:

- Self-response questions by computer
- Review of medical issues/changes
- Pre and post HIV-test counseling and risk reduction counseling (for HIV and STIs). This would include information on the meaning of the test results and how to prevent infection.
- Blood draw (about 12cc, not over a 1 tablespoon) for HIV and syphilis testing
- Urine and rectal swab for NG and CT
- Provision of condoms and lubricants, free of charge

The additional activities every 12 months will be:

- Blood draw (about 6 cc, not over ½ tablespoon) for HPV testing.

The questions, pre-test counseling, blood draw and collection of urine and anal swabs will take about 30 minutes.

You will receive the HIV results and post-test counseling. If your HIV rapid test is negative we will also test you for early infection using a Nucleic Acid Amplification Test or NAAT. The NAAT test will be back in 2-4 weeks. If you are positive to either of these tests 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. We will also tell you the results of Syphilis, NG (gonorrhea), and CT (chlamydia) tests. If your test result is positive, we will ask you to come to clinic to get treatment. You do not have to pay for this.

Special HIV testing that can look out how recent the infection is will be done at the end of the study. This test is called an HIV 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. The anal swab might make you feel some discomfort. This will not harm you. 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 each 3 monthly visit, you will receive health counseling. Our nurses will explain about HIV and STIs, how they are transmitted and how to prevent these infections. The HIV and STIs testing we offer intensively as a part of this study is more frequent so you can know test results early. This may help you get treatment early, which can benefit your health. If you have HIV, we will provide a referral for treatment and care. If you have STIs you will be offered treatment. 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. But your participation may also help others, if our study could find the best way to reduce HIV infection in young men who have sex with men.

Tokens of Appreciation

You do not have to pay anything to be in the study. You will receive 800 baht (about 25 U.S. dollars) 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.

Do I have other choices for getting healthcare if I do not want to join the study?

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 this clinic for PrEP, HIV and STI testing without being in the study.

When will I know the result?

You will know the results of the HIV rapid test at each follow-up visit. You will know the results of the NAAT test if positive in 2-4 weeks. You will know the results of the Hepatitis and STIs within 2 weeks. When the study is over we will know all the results. We will tell the results from the whole study to you and the community through presentations or reports. It is important to know, the research reports are overall data. Your private information will not be published or presented. If what we found in the future is good or bad for you, we will tell you quickly and clearly.

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 study 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 get a token of appreciation 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 specimens 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 while being in study?

If enrolled 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 enrolled 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 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: Cohort Enrollment 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 this study and the assent form. The study staff explained about all study procedures. I had an opportunity to ask questions and had them answered. I understand that whether I agree to be a part of the study 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 about this research and to put my name at the end of this form, it means that I agree to be in the study. 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

..... 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 Enrollment; 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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- 3)

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Part 1: Cohort Enrollment: 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 may have information that you have read, but do not yet understand. You can ask our study staff to explain to you until you fully understand it. You then will receive a copy of this document. You can take it home to talk with your parents, relatives, doctors, nurses, friends, or others that you want to consult with to help you decide if you want to be a part of this study. Whether you join this study is completely up to you. It is voluntary and will not affect schooling or services that you receive. It is ok if you do not want to be a part of it. You can also change your mind after joining the study and not be a part of it. 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 are from Silom community Clinic @ Trop Med and 120 boys/men each are from Nakhon Sawan and Bangrak Hospital.

You are invited to be in this study because you are:

- 15-29 years old
- Male at birth
- HIV- uninfected at enrollment
- Live in Bangkok and vicinity or Nakhon Sawan province
- Have a history of oral or anal intercourse with a man
- Willing to join the study and can come for follow-up every 3 months for 3 years (Total 12 visits)

What are we doing in the study?

We are following a total of 740 young men and adolescent boys for 3 years; 500 boys/men will be from Silom Community Clinic @ Trop Med and 120 boys/men each will be from Nakhon Sawan and Bangrak Hospital. In this study, we have a total of 12 visits with follow-up every 3 months.

At the first visit (enrollment visit) we will collect your blood (about 18 cc, not over 1 ½ tablespoon) and test for Hepatitis A, B, C, Human Papillomavirus (HPV), HIV NAAT and syphilis, and we will collect an anal swab for Human Papillomavirus (HPV). Hepatitis infection can affect your liver and health, and there are prevention methods for many of these infections. The results of the hepatitis tests will be given to you at the first follow-up visit. HPV is a STI that is frequently detected in those who have sex, especially men who have sex with men. This infection does not need treatment as it usually clears on its own. The results of the HPV tests will not be provided as it will not change your clinical care. If the results of the HIV NAAT (a test for early HIV) are positive, we will contact you for counseling and referral.

At the enrollment visit at Silom Community Clinic @ Trop Med, the nurse will teach you how to collect your own urine and an anal swab. At Silom Community Clinic @ Trop Med, you will collect samples for us at each visit, and at Bangrak Hospital and Nakhon Sawan, a provider will collect samples. The urine and rectal swab will be tested for gonorrhea (NG) and chlamydia (CT). If you test positive for NG, CT or syphilis you will be asked to come back for treatment, for free. At the enrollment visit, we will also do a review of your medical record and a brief physical examination. Finally, we will provide condoms and lubricants, free of charge.

At the end of the enrollment visit we will schedule follow-up visits with you.

The activities at *each* follow-up visit (every 3 months) will be:

- Self-response questions by computer
- Review of medical issues/changes
- Pre and post HIV-test counseling and risk reduction counseling (for HIV and STIs). This would include information on the meaning of the test results and how to prevent infection.
- Blood draw (about 12 cc, not over 1tablespoon) for HIV and syphilis testing
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The additional activities every 12 months will be:

- Blood draw (about 6 cc, not over ½ tablespoon) for HPV testing.

The questions, pre-test counseling, blood draw and collection of urine and anal swabs will take about 30 minutes.

You will receive the HIV result (HIV rapid test result) and post-test counseling. If your HIV rapid test is negative we will also test you for early infection using a Nucleic Acid Amplification Test or NAAT. The NAAT test will be back in 2-4 weeks. If you are positive to either of these tests you will be counseled about HIV. We will ask you to answer some questions by computer and you will be referred for HIV treatment. We will also tell you the results of Syphilis, NG (gonorrhea), and CT (chlamydia) tests. If your test result is positive, we will ask you to come to clinic to get treatment. You do not have to pay for this.

Special HIV testing that can look out how recent the infection is will be done at the end of the study. This test is called an HIV 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. The anal swab might make you feel some discomfort. This will not harm you. 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 each 3 monthly visit, you will receive health counseling. Our nurses will explain about HIV and STIs, how they are transmitted and how to prevent these infections. The HIV and STIs testing we offer intensively as a part of this study is more frequent so you can know test result early. This may help you get treatment early, which can benefit your health. If you have HIV, we will provide a referral for treatment and care. If you have STIs you will be treated. 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. But your participation may also help others, if our study could find the best way to reduce HIV infection in young men who have sex with men.

Token of Appreciation

You do not have to pay anything to be in the study. You will receive 800 baht (about 25 U.S. dollars) 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.

Do I have other choices if I do not want to join the study?

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 this clinic for PrEP, HIV and STI testing without being in the study.

When will I know the result?

You will know the results of the HIV test at each follow-up visit. You will know the results of the NAAT test if positive in 2-4 weeks. You will know the results of the Hepatitis and STIs within 2 weeks. When the study is over we will know all the results. We will tell the results from the whole study to you and the community through presentations or reports. It is important to know, the research reports are overall data. Your private information will not be published or presented. If what we found in the future is good or bad for you, we will tell you quickly and clearly.

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 study 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 given a token of appreciation 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 specimens 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 while being in study?

If enrolled 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 enrolled 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 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: Cohort Enrollment 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 this study and the consent form. The study staff explained about all study procedures. I had an opportunity to ask questions and had them answered. I understand that whether I agree to be a part of the study 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 about this research and to put my name at the end of this form, it means that I agree to be in the study. 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 Enrollment; 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

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附錄三：個人資料保護及資料管理政策
（修訂日期：**18-29**）

本政策旨在保護個人資料的準確性、完整性及可存取性，並確保資料以適當、安全及符合法律的方式處理。資料管理政策應包括以下各項：

- 個人資料保護政策
- 1) 資料的收集、處理及儲存
 - 2) 資料的準確性、完整性及可存取性
 - 3) 資料的安全性

本政策應包括以下各項：
個人資料的收集、處理及儲存
資料的準確性、完整性及可存取性
資料的安全性
資料的保留及銷毀
資料的轉移及國際傳輸
資料的訪問及查詢
資料的更正及刪除
資料的保護及加密
資料的備份及恢復
資料的保護及加密
資料的備份及恢復

本政策應包括以下各項：
資料的收集、處理及儲存
資料的準確性、完整性及可存取性
資料的安全性
資料的保留及銷毀
資料的轉移及國際傳輸
資料的訪問及查詢
資料的更正及刪除
資料的保護及加密
資料的備份及恢復

本政策的實施日期為：2018年2月9日。如有任何查詢，請聯絡：(084-874-2164)

ສາທາລະນະລາຍການສົ່ງຂໍ້ມູນ @ ສາທາລະນະລາຍການສົ່ງຂໍ້ມູນ ສາທາລະນະລາຍການສົ່ງຂໍ້ມູນ ສາທາລະນະລາຍການສົ່ງຂໍ້ມູນ
ສາທາລະນະລາຍການສົ່ງຂໍ້ມູນ (ສາທາລະນະລາຍການສົ່ງຂໍ້ມູນ 083-058-7438) ສາທາລະນະລາຍການສົ່ງຂໍ້ມູນ
ສາທາລະນະລາຍການສົ່ງຂໍ້ມູນສາທາລະນະລາຍການສົ່ງຂໍ້ມູນສາທາລະນະລາຍການສົ່ງຂໍ້ມູນ ສາທາລະນະລາຍການສົ່ງຂໍ້ມູນ ສາທາລະນະລາຍການສົ່ງຂໍ້ມູນ
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ສາທາລະນະລາຍການສົ່ງຂໍ້ມູນສາທາລະນະລາຍການສົ່ງຂໍ້ມູນສາທາລະນະລາຍການສົ່ງຂໍ້ມູນສາທາລະນະລາຍການສົ່ງຂໍ້ມູນ