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

OMB No.: 0920-New

Supporting Statement A

October 13, 2016

Contact Information:

Program Official/Project Officer: Eileen F. Dunne MD, MPH

Medical Officer, Division of HIV/AIDS Prevention, NCHHSTP, CDC

Phone Number: +66 081-848-0834, +66 2 580-0669 ext 454

Email address: dde9@cdc.gov

Fax number: +66 2 580-0712

Table of Contents

Att. 15 IRB Approval Letter CDC
Att. 16 EC Approval Letter Thai MOPH
Att. 17 Mahidol University Approval Letter

The goal of the Young MSM Study Thailand is to evaluate risk factors for HIV and sexually transmitted infections (STI), and describe incidence and prevalence in young men who have sex with men (MSM) and transgender women (TGW) in Thailand.

The intended use of the resulting data are to inform evaluation and implementation of biomedical HIV prevention interventions, and support development of HIV prevention strategies and policies in Thailand and globally.

The methods are a prospective cohort design, key informant interviews, and focus groups.

The population to be evaluated are MSM and transgender women (TGW) ages 15-29 years residing in Thailand, and key leaders of adolescents.

The data will be analyzed with survival analysis and appropriate statistical methods to assess HIV and STI incidence, risk factors associated with incidence, and factors important for prevention interventions.

A. Justification

1. Circumstances making the collection of information necessary

The Centers for Disease Control and Prevention requests a 3-year OMB approval for a new information collection request (ICR) entitled "Cohort Study of HIV, STIs and Preventive Interventions among Young MSM in Thailand". The data collection is authorized under the Section 301 of the Public Health Service Act (42 U.S.C. 241) (**Attachment 1).**

Background

The Joint United Nations Programme on HIV/AIDS (UNAIDS) has estimated that 35 million people were living with HIV worldwide in 2013, an increase of 2.1 million people from 2012. In Southeast

Asia, there were an estimated 350,000 people newly infected with HIV in 2012.[1] Although the Thailand Bureau of Epidemiology, Department of Disease Control reported overall HIV incidence in Thailand to be less than 1 per 100 person-years,[2] there is still high HIV incidence in key affected populations (female sex workers, men who have sex with men (MSM), people who inject drug, migrants and youth).[3] In Thailand, most new HIV infections are occurring in MSM and transgender women (TGW), with estimates of over 50% of all new infections occurring in these populations.[4] Silom Community Clinic @Tropical Medicine (SCC @TropMed) has provided HIV and sexually transmitted infection (STI) services, and research on prevention for this community, since 2005; data from MSM attending SCC @TropMed over the last 5 years for HIV testing found an average HIV prevalence of 28% [5]. STIs are also a considerable burden; a survey among gay entertainment venue staff and community-based organization participants in Bangkok and Chiang Mai reported one-fifth (20.0%) of MSM and transgender women had an STI diagnosed in the past year.[7] Although Thailand has developed strategies over more than 25 years that have demonstrated success in reducing new HIV infections, the incidence and prevalence of HIV infection in MSM and TGW remains high.[3, 4] An AIDS Epidemic Model estimated that as many as 43,040 new infections would occur in key affected populations in Thailand from 2012 -2016.[4]

In 2005, the Bangkok MSM Cohort Study (BMCS) was established at Silom Community Clinic, which was critical for describing HIV incidence and risk factors among MSM and TGW in Bangkok, Thailand. This cohort was supported by the Division of HIV/AIDS Prevention, CDC. The BMCS demonstrated risk factors associated with HIV acquisition including young age, living alone or with a roommate (vs. with a partner or family), drug use for sexual pleasure, inconsistent condom use, receptive anal intercourse, group sex, and prevalent herpes and syphilis.[8, 9] This cohort identified that STI were common, including *T. pallidum*, gonorrhea and chlamydia[10, 11]. The study also described risk

factors such as “high parties” in which two or more men have group sex while under the influence of recreational drugs.[12] These data have been used to support prevention efforts in Thailand, including the development of HIV prevention guidelines and recommendations. Data from BMCS has also been instrumental in supporting the need for clinical trials of biomedical HIV prevention products. The clinical research site (CRS), SCC @TropMed, has successfully participated in two HIV prevention network clinical trials supported by NIH (HPTN 067 and MTN 017) and is expected to participate in additional network studies soon including MTN 026 and HPTN 083.

The BMCS identified that young MSM ages 18-21 years were at greatest risk for HIV, at an incidence rate of 8 per 100 person-years.[13] This is consistent with other surveillance data in Thailand and globally demonstrating young MSM are a key population. An area with gaps of understanding regarding the HIV epidemic in Thailand, as well as globally, is the epidemiology, risk factors, and HIV beliefs and knowledge of gay identified and transgender youth. In 2013, the Joint United Nations Programme on HIV and AIDS (UNAIDS) reported that 95 percent of new HIV infections were in low- and middle-income countries, where more than one third were in young people (<18 years) who were unaware of their HIV status.[20] Adolescents living with HIV are more likely to die from AIDS, and there is little tracking of the HIV epidemic and outcomes in adolescents.[21] The WHO 2013 Adolescent HIV Guidelines call for a better understanding of the needs and behavior of adolescents in order to strengthen services for them. Inclusion of adolescent boys and transgender youth at risk for HIV infection in our cohort is critical to strengthen prevention activities in Thailand and to provide key information to inform prevention strategies globally. In addition to the need for more information on HIV and STI incidence and risk factors in adolescent boys, more data are needed on acceptance and willingness to test for HIV and to adopt prevention strategies such as HIV pre-exposure prophylaxis (PrEP). Qualitative data including key informant interviews (KII, **Attachment 6**) and focus group discussions (FGD,

Attachment 4) from adolescent boys and key adolescent leaders in the community will also support prevention efforts directed to this vulnerable population.

A study of young MSM in Thailand is urgently needed to support HIV prevention efforts. The Thailand Ministry of Public Health's Strategic Plan for prevention and management of the national AIDS situation (2014–2016) aims to eliminate new HIV infections in Thailand to zero with 3 targets, i.e., zero new HIV infections, zero AIDS-related deaths and zero stigma and discrimination.[3] This strategy will be achieved through activities that promote a clear understanding of HIV and STI risk factors in young men in Thailand, and research to evaluate prevention strategies, such as novel biomedical approaches. The Bureau of Epidemiology, Department of Disease Control, Thailand recognizes the need to develop an HIV prevention package that encourages young men to access the health care system for HIV testing, as well as HIV and STI education and other prevention approaches, to support the goals of HIV prevention in Thailand. The data from this study in Thailand will inform the direction of prevention approaches and policies for Thailand, as well as globally.

2. Purpose and use of information collection

The purpose of this study is to collect critical information on HIV and STI incidence in a key affected population, men who have sex with men (MSM) and transgender women (TGW).

The study will collect qualitative data in the form of focus groups and key informant interviews with a focus on HIV prevention and risk. The study will also enroll and collect data from 500 Thai MSM and TGW at Silom Community Clinic @ Tropical Medicine (SCC @Trop Med) who are HIV-uninfected and ages 15-29 years, with follow-up every 3 months for 3 years (Cohort study). The cohort study will be conducted in 3 sites in Thailand, Silom Community Clinic in Bangkok, Thailand, Bangrak Hospital in Bangkok Thailand, and Rainbow Clinic, in Nakon Sawon, Thailand; the clinical site sponsored by CDC is SCC @ Trop Med in Bangkok, Thailand and at this site, 500 participants will be followed (study

total is 740 participants). The data collected will include behavioral, clinical and laboratory data. The data will be collected at the clinical site, and will be stored electronically, using encryption and password protection. All paper-based collection, including consents, will be stored in a locked cabinet with access only by study staff, at each location. HIV and STD information will be disclosed to the participant in a timely fashion, and according to Standard Operating Protocols and Thai and CDC Guidelines. This study is a 3 year study in total, with enrollment over a 2 year period (5 year study).

A summary of the information collection includes: Focus Group Discussion (FGD) Assent and FGDs, Key Informant Interviews (KII) Assent/Consent and KIIs, Screening and Enrollment Assent/Consent, Screening CASI, HIV CASI, Follow-up CASI, YMSM Clinical form, and HIV CASI for the cohort. The estimated total burden is 814 hours/year. The study will collect data from individuals as described, but also will collect laboratory data.

The positive consequences of collecting this data will be the availability of critical information including clinical and behavioral risk factors for prevalent and incident HIV and STDs in order to develop policies for, and implement, HIV prevention interventions for MSM and TGW, a key affected population. In addition, qualitative data will provide needed information on HIV prevention for adolescents including optimal types and settings for HIV prevention, and HIV prevention knowledge, attitudes and practices. The negative consequences to not having the information include not having sufficient data to generate global and local HIV prevention strategies, and as a result, increases in HIV transmission and burden. The SCC @Trop Med, the clinical site of the activity, is a Clinical Research Site (CRS) and has conducted HIV prevention research in network clinical trials supported by the National Institutes of Health (NIH). Participants in the cohort study can also be enrolled in important HIV prevention research studies through the NIH supported network studies if they meet the eligibility inclusion criteria. This study will also generate critical data on HIV and STD incidence and prevalence in young men and adolescent males. This is the first study of its kind in Bangkok to collect data on HIV and STI

incidence, access to HIV prevention, and attitudes about HIV prevention in adolescents ages 15-17 years. In addition to the cohort activities in which young men are followed over 3 years, this study will collect needed qualitative data in the form of focus group discussions (FGD, **Attachment 4**) and key informant interviews (KII, **Attachment 6**) from teens and those that serve these teens in the community on HIV prevention, access to testing, PrEP and other issues relevant to HIV prevention.

The objectives of the study are:

- To characterize the epidemiology of HIV and STI infections (rectal/urethral chlamydia, gonorrhea and syphilis) among young MSM ages 15–29 years over a 3 year period in three settings in Thailand
    - To identify risk factors associated with prevalence and incidence of HIV infection and STIs.
- To conduct qualitative assessments of adolescent boys aged 15–17 years regarding HIV prevention, including HIV testing, sexual behaviors, and prevention interventions.
- To provide data to support inclusion in HIV prevention interventions

Secondary objectives are:

- To identify early and recent HIV infections using novel assays
- To estimate the prevalence of hepatitis A, hepatitis B and hepatitis C and human papillomavirus infection
- To estimate the prevalence and incidence of antimicrobial resistant gonorrhea infection.

3. Use of improved technology and burden reduction

All the data collection instruments will be electronic. The focus groups and key informant interviews will use open ended questions using a guide, and there will be an audio recording so there is no written form. The transcription will be digital and will analyzed by study staff (**attachments 4, 6**). The screening for the cohort (**attachment 7**) will use check lists that can be electronically entered by study

staff, and the questionnaires for the cohort (**attachments 9, 10, 12, 14**) will be computer assisted self-interview (CASI) administered to the participant and entered by the participant in Thai. The clinical form will be electronic form entered by the study nurse/physician in English (**attachment 13**). The only forms that are paper are the consent/assent that are administered in Thai (**Attachments 3, 5, 8, 11**). All data will have incorporated programs for skip patterns and data checks to ensure ease of data entry. Our clinical research site, SCC @Trop Med, has experience in these methods to facilitate ease of study implementation from the participant and study staff perspective. All of the data collection will be using electronic means, only 4 of the 12 forms are collected in paper format (33% of all forms).

4. Efforts to identify duplication and use of similar information

The data collected as a part of the Young MSM Study Thailand are unique and the data will be collected from young MSM and TGW in Bangkok, Thailand, through a clinic that serves MSM and TGW. Although there are other MSM and TGW clinic settings in Bangkok, there is no cohort data providing information on incidence and risk factors for HIV incidence in the young. In order to determine the existence of similar or overlapping data, the project officer conducted an email survey of NGOs, government and other clinics in Thailand to assess if any cohort was being planned or currently occurring. The only on-going cohorts occurring in Thailand are two cohorts that are in support of planned HIV vaccine trials with the Armed Forces Research Institute of Medical Sciences (AFRIMS). A summary of the AFRIMS projects are described below:

RV 254 – Acute HIV Study Cohort, currently following 300+ participants who were diagnosed with acute HIV infection. This is an observational, open cohort that aims to describe clinical, immunological, and virological characteristics of persons with acute HIV and identifies volunteers who may be candidates for future HIV intervention or treatment protocols due to diagnosis of HIV during acute infection. Many subjects are co-enrolled in treatment protocols but this protocol is for observation only and does not offer any treatment. This protocol is conducted in conjunction with the Thai Red Cross

AIDS Research Center where participants undergo HIV testing and is open to men and women who are 18 years of age and older. This cohort is open and ongoing.

RV 217 (Pattaya Study) – This is a MSM/TG cohort based in Pattaya that follows HIV-seronegative individuals with twice weekly testing to define the incidence and prevalence of HIV in a high risk population. Since the cohort started in 2010, over 650 participants have been enrolled. Incidence for MSM through Oct 2014 was 8.2 infections per 100 person years, and 5.3 infections per 100 person years for TG. Recruitment is ongoing.

The differences with these described cohorts, and the Cohort Study of HIV, STIs and Preventive Interventions among Young MSM in Thailand is these cohorts do not focus on the young MSM and TGW population. Neither of these cohorts include participants < 18 years. In addition, only one of the cohorts is occurring in Bangkok, Thailand and the cohort in Bangkok is enrolling those who recently seroconverted (unlike our study that is enrolling those who are HIV negative).

Based on our review of the existing activities and research in Thailand, we could find no other institution or organization collecting similar data. This new cohort study is critical to describe the HIV and STD incidence in Thailand in young MSM and TGW to support HIV prevention interventions and support biomedical HIV prevention clinical trials.

5. Impact on small businesses or other small entities

The data collection does not impact small businesses or other small entities. This data collection will not involve small businesses.

6. Consequences of collecting the information less frequently

The consequences to the federal program or policy activities if the collection of this data is not collected would be that critical data needed to inform evaluation and implementation of biomedical HIV

prevention interventions, and support development of HIV prevention strategies and policies would not be available. This includes information that is needed to support biomedical HIV prevention trials that the SCC @ Trop Med participants in as a CRS. Inclusion in NIH network clinical trials is critical to fulfill the mission of the Division of HIV and AIDS Prevention (DHAP), CDC, to prevent HIV acquisition. These clinical trials support assessment of biomedical prevention approaches that might be feasible and scalable, and could be implemented in the US and globally. In addition, our key partner, the Thailand Ministry of Public Health, would not have critical data available that leads to steps to address the public health epidemic of HIV in young MSM and TGW and identify approaches for prevention. The length of the study (5 years) is required because incidence data is valid when sufficient data is collected over time; collection over 3 years (with a 1-2 enrollment period) will provide a sufficient sample size to assess incidence. The participants in the study will come back every 3 months for HIV testing, STI testing and treatment if necessary. The frequency of every 3 months is needed for purposes of valid data on HIV and STI incidence, and retention of young men, especially those less than 24 years; this age group is a specific challenge for follow-up in cohort studies. Young MSM and TGW have high HIV incidence, and frequent testing allows for early determination of HIV status, early STI detection and treatment, and early referral to care if HIV positive. Early HIV treatment has been found to reduce morbidity and mortality and so there are distinct advantages to early and frequent HIV and STI testing.

7. Special circumstances relating to the guidelines of 5 CFR 1320.5

This guideline fully complies with the regulation 5 CFR 1320.5

8. Comments in response to the Federal Register Notice and efforts to consult outside the Agency

A 60-day federal register notice to solicit public comments was published on January 14, 2016, Volume 81, Number 9, Page Number 1952-1953. A copy of this publication is attached (**Attachment 2**). Two

comments were received from the public in response to the 60-day Federal Register Notice, and a CDC standard response was sent (**Attachment 2a**).

The project officer consulted with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of the instructions and record keeping, disclosure, or reporting format and this information. The persons consulted included Dr. Chris Beyer and Dr. Patrick Sullivan.

Dr. Chris Beyrer MD, MPH, Professor of Epidemiology, International Health, and Health Behavior and Society, Department of Epidemiology, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, 21205. Tel: 410 614 5247, email: cbeyrer@jhu.edu.

Dr. Patrick Sullivan DVM, PhD, Professor, Rollins School of Public Health, Emory University, Atlanta, GA.

9. Explanation of any payment or gift to respondents

MSM and TGW are considered difficult to reach populations for research activities and essential for this activity. Tokens of appreciation are required for engagement of this population in research. The amount of the token for participants has been vetted by the local ethics review committee, and the MSM community advisory board, and has been agreed upon and used a recent study in MSM and TGW (e.g. MTN 017 a study of Tenofovir rectal gel, CDC IRB Protocol 6379).

This is a standard practice and requirement of the local ethics committee, the Ministry of Public Health, Thailand. The tokens of appreciation for this study are as follows: 500 baht (about 15 US Dollars) for the Focus Group and Key Informant Group participation, 800 baht (about 24 US Dollars) for the cohort screening visit, 800 baht for the cohort enrollment visit, 800 baht for each cohort follow-up visit and 200 baht (about 6 US dollars) if there is a follow-up urgently needed for HIV or STD testing. These small cash tokens of appreciation will be used to increase the response rate.

10. Protection of the privacy and confidentiality of information provided by respondents

This study has been reviewed by NCHHSTP PRA Coordinator, which determined that the Privacy Act does not apply because the survey does not collect names, social security numbers or other information in identifiable form but with a study ID and no personal identifiers. The study activity will take place at the SCC @TropMed and at this clinical research site (CRS) there are a number of in place controls to minimize the possibility of unauthorized access or use, or dissemination of the information collected. The control steps includes the technical controls of: Required user identification, passwords, firewall, and virtual private network. The physical controls include locked access of the study space, and key cards for entry. The administrative controls include electronic back-up daily to a central server, supported by CDC, user manuals (SOP) for information collection, trainings for engaged study staff, and methods in place to ensure only a study role based access to study information. There are policies in place with regard to the retention and destruction of IIF, and this occurs upon study closure. Personnel will be trained about the importance of protecting private information, and all staff receive human subjects and Good Clinical Practice (GCP) training.

In addition, this research activity has obtained IRB approval through local and CDC human subjects review processes. This includes the Thailand MOPH Department of Disease Control (Department of Disease Control, DDC), and CDC. Silom Community Clinic @ Tropical Medicine has a longstanding history of conducting research and is a clinical research site (CRS) with Emory-CDC (EMC^2) Clinical Trials Unit. The protection of human subjects are described in the protocol in detail but in brief, we protect privacy by storing any information with personal identifiers in a locked cabinet with access only by specified study staff, or storage in an electronic file that is password protected. When we collect data, it is only using a study ID and no personal identifiers.

Monitoring and Responding to Privacy and/or Security Incidents: The systems security plan defines the process for handling security incidents. The systems team and the Office of the Chief Information Security Officer (OCISO) share the responsibilities for event monitoring and incident response. Direct reports of suspicious security or adverse privacy related events to the component's Information Systems Security Officer, CDC helpdesk, or to the CDC incident Response Team. The CDC OCISO reports to the HHS Secure One Communications Center, which reports incidents to US-CERT as appropriate.

CDC will retain and destroy de-identified records in accordance with the applicable CDC Records Control Schedule.

11. Institutional review board (IRB) and justification for sensitive questions

The protocol has been reviewed by CDC IRB and the Mahidol University and Thailand Ministry of Public Health Human Subjects Review Boards. The ethical approval letters are provided in (**Attachement 15 IRB Approval Letter CDC, Attachment 16 EC Approval Letter Thai MOPH, and Attachement 17 Mahidol University Approval Letter)**.

We are asking sensitive questions on sexual behaviors, sexual orientation, and methods for prevention including condom use and Pre-Exposure Prophylaxis as this is needed to define risk factors and optimize prevention of HIV and STIs. The instrument for sensitive questions will be administered using Computer Assisted Self-Interview (CASI) in a private room. CASI is a method to administer sensitive questions in a private setting without an interviewer or observer, and this method improves acceptability and validity of reports on sensitive information.

12. Estimates of annualized burden hours and costs

A. <u>Estimated Annualized Burden Hours</u>

The respondents are MSM and TGW attending HIV Voluntary Counseling and Testing Services at SCC @ TropMed, the study is a 3 year study with up to 2 years for enrollment. The qualitative study will enroll 10 in FGD and 4 in KII annualized (30 in FGD and 12 in KII in total over 3 years). The cohort study will enroll a total of 740 participants in the 3 year study, 500 of which are enrolled from SCC @TropMed (167 annualized). The respondent data collection and calculation of burden is summarized below.

For the qualitative data, there will be Focus Group Discussions (FGD, **Attachment 4**) and Key Informant Interviews (KII, **Attachment 6**). FGD and KII are established methods for collecting qualitative data and both use a consent process, and include a guide. These will be conducted in Thai. We have included all elements of the FGD and KII in the forms including the **Attachment 3 FGD Consent/Assent, Attachment 4 FGD, Attachment 5 KII Consent/Assent and Attachment 6 KII**. To calculate the total burden hours for the qualitative activity we calculated the number of participants in the FGD in total (30) and divided by 3 years, so the annualized respondents are 10. For the KII (**Attachment 6**), we calculated the total number of participants in the KII (12) and divided by 3 years, so the annualized respondents are 4. The number of responses/respondent is 1 for these forms/activities.

For the cohort activity, where young men are followed over time with every 3 month visits, the forms will be **Attachment 7 screening checklist, Attachment 8 screening consent/assent, Attachment 9 screening CASI, Attachment 10 HIV CASI, Attachment 11 enrollment consent/assent, Attachment 12 follow-up CASI, Attachment 13 Young Men who have sex with Men (YMSM) Clinical Form, and the Attachment 14 HIV CASI Cohort**. For the screening at SCC @ Trop Med (**Attachment 9**), approximately 900 persons would be screened over 3 years (300 persons annualized). Men who are screened and HIV-negative will be enrolled in the study, a total of 500 MSM or TGW (167 persons annualized). Approximately 20% of the 900 men at baseline will be HIV positive (60 persons annualized) and these men will answer the HIV CASI (**Attachment 10**); these men will be referred for

HIV treatment and will not be enrolled in the cohort study. An enrollment consent/assent (**Attachment 11**) will be administered to 167 persons annualized who meet screening and eligibility criteria. These persons will also complete an YMSM Clinical form (**Attachment 13**) which is a review of medical issues and physical examination if needed. Participants will be followed up in the study for counseling, testing and questions by Follow-up CASI (**Attachment 12**) every 3 months (total of 4 visits/respondent, 167 respondents). Men identified to have HIV during the study will stay in the cohort but will receive a specific follow-up CASI for HIV-infected MSM and TGW (**Attachment 14)** which is 46 men annualized.

The burden in time for each instrument was calculated based on a pilot with 2 Thai study staff reading the instrument in Thai. The estimates were then averaged and a median number of minutes or hours is presented in the table. From previous experience with network and non-network clinical trials, we know that CASI often requires less time than paper based collection, but we used the estimates of the paper version review as a conservative estimate.

Table 12A. Estimated Annualized Burden Hours

Type of respondent	**Form Name**	**No. of Respondents**	**No. Responses/Respondent**	**Average Burden per Response (in hours)**	**Total Burden Hours**
Community members	FGD Consent Assent (Att 3)	10	1	30/60	5
	FGD (Att 4)	10	1	2	20
	KII Consent Assent (Att 5)	4	1	30/60	2
	KII (Att 6)	4	1	2	8
Potential Participant	Screening checklist (att 7)	300	1	15/60	75
	Screening consent Assent (Att 8)	300	1	30/60	150
Potential	Screening CASI (Att	300	1	15/60	75

Participant	9)				
HIV-positive at screening	HIV CASI (Att 10)	60	1	2/60	2
Participants	Enrollment Consent Assent (Att 11)	167	1	30/60	84
Participants	Follow-up CASI (Att 12)	167	4	15/60	167
Participants	YMSM Clinical Form (Att 13)	167	4	20/60	223
HIV-positive Participants	HIV CASI Cohort (Att 14)	46	4	1/60	3
TOTAL					814

B. <u>Estimated Annualized Burden Costs</u>

We calculated annualized costs using the reference for Thai wages using the GDP (9,900 USD per person) and the 2080 hour work year, which calculates to $4.76 US dollars/hour (https://www.cia.gov/library/publications/the-world-factbook/geos/print/country/countrypdf_th.pdf

Table 12B. Estimated Annualized Burden Costs

Type of respondent	**Form Name**	**Total Burden Hours**	**Hourly Wage Rate**	**Total Respondent Costs**
Community members	FGD Consent Assent (att 3)	5	4.76	24
Community members	FGD (att 4)	20	4.76	95
Community members	KII Consent Assent (att 5)	2	4.76	10
Community members	KII (att 6)	8	4.76	38
Community members	Screening checklist (att 7)	75	4.76	357
Potential Participant	Screening Consent Assent (att 8)	150	4.76	714
Potential Participant	Screening CASI (att 9)	75	4.76	357
HIV-positive at screening	HIV CASI (att 10)	2	4.76	10
Participants	Enrollment Consent Assent (att 11)	84	4.76	400
Participants	Follow-up CASI (att 12)	167	4.76	795

Participants	YMSM Clinical Form (att 13)	223	4.76	1062
HIV-positive Participants	HIV CASI Cohort (att 14)	3	4.76	14
Total				$3,876

13. Estimates of other total annual cost burden to the respondents or record keepers

There are no additional cost burden to the respondents or record keepers.

14. Annualized cost to the government

The estimate of all annualized cost to the government include the costs for staffing, overhead, equipment, printing, and support staff. The cost for the clinic staff at Silom Community Clinic @ Tropical Medicine is included in the following table and this information has been used for budgetary support from CDC. The budgetary support from CDC is in the form of the Thailand MOPH-US CDC Cooperative Agreement.

These costs are over a 5 year period and annualized. We do not plan for any contract costs for data/information collection. We will provide funds to the Thailand Ministry of Public Health for activities for data/information collection, noted in the table.

Table 14A. Annualized Cost to the Government

Category	**Annual Budget**	**Total Cost (5 years)**
Personnel – Federal Employees located in Thailand (Locally Employed Staff + US Direct Hire benefits)	$1,000,000	$5,000,000
Operational Costs in Thailand (Travel, Transp., Communications / Supplies / Equipment, and Contractual Costs Other than Contracted Data / Information Collection)	$600,000	$3,000,000
Cooperative Agreement (Thailand Ministry of Public Health)	200,000	$1,000,000

Personnel (contracted)		
Cooperative Agreement (Thailand Ministry of Public Health) Operational Costs; clinical infrastructure; training of staff Participant Compensation; Admin Fee to Thailand Ministry of Public Health	550,000	2,750,000
TOTAL	**2,350,000**	**11,750,000**

15. Explanation for program changes or adjustments

There are no program changes or adjustments. This is new data/information collection.

16. Plans for tabulation and publication and project time schedule

The plans for tabulation and publication are subject to the availability of the data and will be outlined by an investigator group to inform planned data analysis. The analytic techniques will include incidence density calculations, logistic regression, generalized estimating equations and other statistical methods.

The study activity timelines are included here:

Activity	**Time Schedule**
Concentrated outreach activities	After OMB approval
Data Collection	½ month-3 years after initial OMB approval
Begin renewal of OMB approval	2 years after initial OMB approval
Analysis	13 months after initial OMB approval first analysis
Publication	15 months after initial OMB approval, and thereafter
* Overall project is 5 years, renewal for OMB after 3 years necessary	

The goals are to have OMB and all ethics approvals for a study start in late 2016.

17. Reason(s) display of OMB Expiration is inappropriate

Not seeking to not display the expiration date for OMB approval.

18. Exceptions to certification for paperwork reduction act submissions

There are no exceptions to the certification.