RESEARCH SUBJECT INFORMED CONSENT FORM

Study Title: The effect of Opiate Integrated Treatment including Methadone and Buprenorphine/Naloxone (Suboxone®) Maintenance Treatment for Injecting Drug Users at community in Ho Chi Minh City, Viet Nam

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You are being asked to take part in a research study. Your participation is voluntary which means you can choose whether or not to take part. If you choose not to join the study, your decision will not affect your care at the clinic or your chance of being in other research studies.

Before you make a decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk with you about the study and give you this consent form to read. You do not have to decide now whether you want to join the study. You can take the consent form home and discuss it with your family, friends or doctor.

If you do not understand what you are reading, do not sign this form. Please ask the study doctor or staff to explain anything you do not understand, including any medical language contained in this form. You may ask to have this form read to you. If you decide to participate, you will be asked to sign this form and a copy will be given to you.

What is the purpose of the study?

The purpose of this research study is to evaluate the medication assisted treatment - methadone, buprenorphine/naloxone (Suboxone®) - for opiate addiction integrated within the Go Vap HIV treatment program. The study will

evaluate on how long people will stay in treatment, their drug use and use of injection equipment and their risky sexual behavior. Another purpose of the study is to assess the costs of the treatment and relate these costs to how well it works.

Why are you being asked to join the study?
You are being asked to join the study because you are entering the Go Vap clinic for treatment of your opiate addiction.

How long will you be in the study? How many other people will be in the study?
You will be in the study for one year. In total, up to 500 people treated at the Go Vap Clinic will be in this study.

Where will the study take place?
You will receive treatment at the Go Vap clinic and all study visits will take place at the clinic. The study will be conducted in a room where you can speak freely and that assures your privacy.

What will you be asked to do in the study?
The first thing that will happen is that you will be asked questions to see if you are eligible to join the study. If you are found to be not eligible, you will proceed with treatment as usual consisted of medication assisted treatment and Behavioral and Drug Risk Counseling (BDRC) sessions.

If you are eligible and willing, you will be enrolled into the study and you will receive treatment with either methadone or buprenorphine/naloxone (Suboxone®) and Behavioral and Drug Risk Counseling (BDRC) sessions for 12 months. You will also be asked to complete interviews with a research staff person (not clinician or counselor) and you will be asked to complete some self-questionnaires.

Study visits
You will be asked to come daily at the clinic to receive your methadone or buprenorphine/naloxone (Suboxone®) and you will have to meet with the doctor and/or nurse to monitor your treatment. You will also receive a weekly counseling session (BDRC) from week #1 (first week of treatment) to week # 12 (about three months of treatment). Then, you will receive a monthly BDRC from week#16 (four months of treatment) to week #52 (twelve months of treatment).
You will also complete study assessment visits at the entry in treatment, six months and twelve months later. These study assessments will be completed by a research staff person (not clinician or counselor). During these study visits, you will answer interview questions and complete questionnaires about your drug use, drug use behaviors, sexual behaviors, health status, living situation and use of medical and social services, recent criminal behavior and history of arrest and incarceration, psychiatric symptoms, and risk taking behaviors. You will also be

tested for HIV, hepatitis C, and urine will be collected for rapid testing of opiates (heroin, opium), benzodiazepines, stimulants such as amphetamines and methamphetamines, and marijuana or cannabis. For woman, a pregnancy test will be performed as part of the study procedures. None of this information will be shared with clinic staff other than your assigned BDRC counselor.

We will ask you to complete a locator interview at each study visit so that we can contact you to remind you when your study visits take place. The locator interview collects information such as your address, phone number, e-mail address, contact information of friends or family and places where you hang out. Even if you stop receiving treatment, you will stay in the study and we will ask you to come back to complete the study visits. If we contact people to try to find you, we will only say we are calling from the clinic; we will not say that you are in a research study.

Medication assisted treatment for opiate addiction

You will receive medications (Methadone or buprenorphine/naloxone (Suboxone®)) for your addiction to opiates. Both medications have been shown to be safe and effective for treating opiate addiction. Your doctor will follow a standard protocol in accordance with evidence-based practice and the Vietnamese policy. The type of treatment (methadone or buprenorphine/naloxone (Suboxone®)) and the doses will be clinically determined by your doctor. You will be asked to come daily at the clinic to take your treatment and monitor your treatment with your doctor and/or nurse.

Counseling sessions

The same day of your enrollment visit, you will meet your counselor to schedule your first Behavioral and Drug Risk Counseling (BDRC) session. You will meet with your counselor for about 45 minutes every week for 12 weeks. After the first 12 weeks, you will meet with your counselor once a month for about 45 minutes. During these sessions, you and your counselor, a member of the clinic staff, will discuss how drug addiction is a chronic medical condition. Like other chronic medical conditions successful treatment requires the patient to do certain things to stay healthy. You will discuss the importance of taking your treatment every day. You will also talk about changes you can make that will help you avoid drugs and risky behaviors. You and your counselor will develop a simple plan at each session that you will practice until the next counseling session.

HIV testing

Everyone in this study will be tested for HIV (the virus that causes AIDS) at the time of his/her enrollment, 6-month and 12-month study visits. The HIV counseling staff will use a “rapid” HIV test procedure to determine whether or not you are infected with HIV.

This “rapid” test involves:

- Talking with a trained counselor about HIV, the “rapid” test method and the meaning of the HIV test results
- Counseling that includes discussing behaviors that put you at risk for HIV infection and what you can do to avoid becoming infected
- Collecting a drop of blood from your finger
- Waiting 20 minutes for the test result and discussing with the counselor the meaning of your test result

To complete the “rapid HIV test”, the counselor will use a lancet, a piece of plastic with a metal point, to take a drop of blood from your finger. The counselor will hold a paper strip to your finger so a drop of blood can soak onto it. The paper strip is placed in a test kit. After 20 minutes, the test kit will give a test result. The test result will tell us if you have HIV antibodies in your blood. Antibodies are made by the body to fight diseases. When antibodies to a disease are in your blood, it means you have been exposed to the disease.

There are two possible test results:

- **Non-reactive or negative** means the test did not find HIV antibodies in your blood. If you have had no possible exposure to HIV in the last 6 months, you can trust that the negative result is correct. If you had an exposure to HIV in the last 3 to 6 months, it is still possible that you are infected with HIV because it can take a few months for your body to produce HIV antibodies.
- **Reactive or preliminary positive** means that you may be infected with HIV. If one rapid HIV test comes positive, a second rapid test will be conducted to confirm the result.

What if you test positive for HIV?

If it is determined that you are infected with HIV, you will be referred directly to Go Vap HIV clinic for initial assessment and a doctor will determine the appropriate treatment. You will receive treatment for both opiate addiction and HIV at the same place.

Hepatitis C testing

Everyone in this study will be tested for Hepatitis C (HCV) at the time of his/her enrollment, and at 6-month and 12-month study visits.

The counseling staff will use a “rapid” HCV test procedure to determine whether or not you are infected with Hepatitis C.

This “rapid” test involves:

- Talking with a trained counselor about HCV, the “rapid” test method and the meaning of the HCV test results
- Counseling that includes discussing behaviors that put you at risk for HCV infection and what you can do to avoid becoming infected
- Collecting a drop of blood from your finger

- Waiting 20 minutes for the test result and discussing with the counselor the meaning of your test result

The procedure is exactly the same than for the HIV rapid testing.

What if you test positive for Hepatitis C?

If it is determined that you are infected with Hepatitis C, you will be referred directly to initial assessment and a doctor will determine the appropriate treatment.

Urine tests

You will also be asked to give a urine sample approximately two times per month for rapid drug testing. Rapid means that the test results will be known in 5-10 minutes. The urine test will not be scheduled so you won't know when you will be asked to give your sample. The results of the urine test will be used to guide your counseling sessions. Moreover, at each study visit with a research staff person, you will be asked to give a urine sample (at treatment entry, and at 6 months and 12 months after you start the treatment).

What are the risks of being in the study?

You can experienced minor side effects that occurred mainly at the beginning of the medication assisted treatment such as headache, stomach pain, nausea, vomiting, constipation, warmth or tingly feeling, increased sweating, weakness, back pain, increased of anxiety and/or depression symptoms, sleep problems (insomnia) or runny nose. Serious side effects appeared mostly with misuse/ inappropriate use of the medication or when the medication is combined with any other non-prescribed drug (alcohol, benzodiazepine). To avoid any serious side effects, you should strictly follow the prescription established by your doctor. Your doctor has received an extensive training to adequately prescribe the medications and there is a very small risk for you to experience serious side effects.

There are also a few risks associated with HIV and Hepatitis C testing. Your finger may become bruised or sore following the collection of blood for the HIV and Hepatitis C testing. Also, if the tests determine that you are infected with HIV and/or Hepatitis C, you may have an emotional reaction and become depressed or angry. If this happens, the research staff will help you get counseling.

Although the research staff will work very hard to protect your privacy and the confidentiality of your test results, it is possible that someone may discover the results of your testing. Also, you may be embarrassed by some of the personal questions that the research staff will ask. Finally, it is possible that someone could find out about your participation in the study and determine that you are in treatment for drug dependence.

How will you benefit from being in the study?

We cannot promise any direct benefit to you for participating in this study. You will receive medication assisted treatment for your opiate addiction. The discussions with your counselor may help you gain a better understanding of drug addiction. The counseling may also help you become more successful in reducing or stopping drug use and, if you are HIV infected, more successful in observing your HIV treatment. Finally, the counseling sessions may give you some ideas on how to improve relationships with family and friends.

Everyone in this study will be tested for HIV and Hepatitis C. The HIV test and the Hepatitis C test will provide you with important information about your health status. You may benefit from the testing by learning about your status for both HIV and Hepatitis C. If you are positive, you will get appropriate treatment at the Go Vap Clinic. If you are negative these tests may benefit you by learning about ways to continue to avoid infection in the future.

What happens if you do not choose to join the study?

If you choose not to participate in the research, you will not loose any access to services now or in the future. This decision will not affect you in any way and you will receive any care you need.

When is the study over? Can you leave the study before it is over?

This study is expected to end after all participants have completed all visits, and all information has been collected.

This study or your involvement may also be stopped at any time by your physician or the study sponsor (National Institute of Health, NIH) without your consent because:

• The Primary Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
• You have not followed study instructions.
• The Sponsor or the study Principal Investigator has decided to stop the study.

You are free to leave the study at anytime. If you decide you want to stop participation, simply inform the research staff of your decision. Withdrawal will not interfere with your future care.

Even if you stop the medication and the counseling session, we will ask you to return to complete the follow-up interviews with a research staff member only. You will not be asked to see any doctor, nurse and counselor.

How will your confidentiality be maintained and how will your privacy be protected?

The investigator and staff involved with the study will keep your personal and health information collected for the study strictly confidential. Aside from your doctor and your counselor, no member of the clinic staff will have access to study

information. The collected data will be kept in locked cabinets in locked rooms. Your name will not appear on any of the data collection forms. All forms containing personal information will be securely stored separate from the forms containing research data. Data forms will be identified by a study number that research staff can use to link the data to you. The data that are collected during the study will be shared outside of the Vietnam with investigator's in the USA and in France. Your name will not appear on any of these shared data and it will be impossible to identify you.

What happens if you are injured from being in the study?

If you have a medical emergency during the study you should go to the nearest emergency room. You may contact the Principal Investigator or Go Vap HIV Clinic. You may also contact your own doctor, or seek treatment outside of the Go Vap HIV Clinic, Ho Chi Minh City.

Be sure to tell the doctor or his/her staff that you are in a research study being conducted at the Go Vap HIV Clinic, Ho Chi Minh City.

Will you have to pay anything to be in the study?

You will not have to pay for anything related to study visits.

Will you be compensated for participating in the study?

You will be paid the equivalent of US$4.80 (100,000 VND) for each data collection visit while you are a participant in this study. These data collection visits will occur at entry into the study, at 6 months, and at 12 months. This money is being given to compensate you for your time and travel. You will not receive money for participating in the counseling sessions.

What information about me may be collected, used or shared with others?

We will ask you to complete a locator interview at each study visit so that we can contact you to remind you when your study visits take place. The locator interview collects information such as your address, phone number, e-mail address, contact information of friends or family and places where you hang out.

You will complete study assessment visits at the time of enrollment, 6 months and 12 months later. During these study visits, you will answer interview questions and complete questionnaires about your drug use, drug use behaviors, sexual behaviors, health status, living situation and use of medical and social services, recent criminal behavior and history of arrest and incarceration, psychiatric symptoms, and risk-taking behaviors. Everyone in this study will be tested for HIV and Hepatitis C at the time of his/her enrollment, at 6-month and 12-month study visits. You will also be asked to give a urine sample for rapid drug testing approximately once per week for the first three months of treatment, and once per month thereafter.

None of this information will be shared with clinic staff other than your doctor and the assigned counselor.

Why is my information being used?

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- do the research
- oversee the research
- to see if the research was done right.

Who may use and share information about me?

The investigator and staff involved with the study will keep your personal and health information collected for the study strictly confidential. Aside from your doctor and your counselor, no member of the clinic staff will have access to study information. The collected data will be kept in locked cabinets in locked rooms. Your name will not appear on any of the data collection forms. All forms containing personal information will be securely stored separate from the forms containing research data. Data forms will be identified by a study number that research staff can use to link the data to you.

How long may the University of Pennsylvania use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the investigator for the study. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

Who can you call with questions, complaints or if you are concerned about your rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator. This phone number

can be found on the front page of this form. If a member of the research team cannot be reached, or you want to talk to someone other than those working on the study, you may contact the Go Vap HIV Clinic, Ho Chi Minh City by calling (+84) 913806466.

Consent Quiz

Please, read all of the sentences below. For each of them, indicate if you think that the statement is True or False.

1. I am free to decide whether or not to be in this study. θ True θ False

2. To participate to this study, I should meet the criteria for opiate addiction. θ True θ False

3. I can choose whether or not I get medication for opiate addiction (methadone, buprenorphine/ naloxone - Suboxone®) in this study. θ True θ False

4. Beside medication for opiate addiction, I will have to complete counseling sessions. θ True θ False

5. I will be tested for HIV as part of the protocol study. θ True θ False

6. If I am HIV positive, I will be referred out of the study. θ True θ False

7. To avoid serious side effects, I should strictly follow the prescription established by my doctor. θ True θ False

8. As part of this study, I will be asked to complete interviews with research staff. θ True θ False

9. Once I start in this study, I have to continue until the end. θ True θ False

10. If I decide not to be in the study, I can try to get into any other drug treatment program I want. θ True θ False

11. The research staff will share my personal information with everyone who asks for. θ True θ False

12. I could contact the Principal Investigator of the study if I have any questions, complaints or concerns about my rights as a participant of this study. θ True θ False

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the Go Vap HIV Clinic to use your personal health information collected about you for research purposes within our institution. However, no one involved with your care will be given any of the research information collected.

A copy of this consent form will be offered to you.

Print name of subject	Signature	Date

Print name of person obtaining consent	Signature	Date