Please print legibly: Last name, First name M.I.

Subject Name: Full SSN:

Study Title: **INTEGRATED STEPPED CARE for UNHEALTHY ALCOHOL USE in HIV**

Principal Investigator: **Investigator Name: Michael S. Simberkoff, MD**

Facility Name: **VA NY Harbor Healthcare System** **Version Date:** **November 16, 2015**

INTRODUCTION:

You are being asked to volunteer to participate in a VA-approved research study at the VA New York Harbor Healthcare System (VA NYHHS). It is important that you read and understand the information on this form and discuss it with family and friends if you wish. Ask one of the study staff if there is anything that is not clear or if you would like more details. Take your time to decide.

BACKGROUND AND PURPOSE:

The main goal of this study is to compare the effectiveness of an Integrated Stepped Care (ISC) intervention with that of treatment as usual (TAU) on alcohol consumption in patients who are HIV positive. With this research we hope to learn more about treatment of patients with HIV/AIDS infection complicated by unhealthy alcohol use and improvement of their outcomes. You are qualified for participation in this study, because you are:

- HIV/AIDS positive
- Free of major complications from medical or psychiatric illness as determined by routine laboratory tests and a review of your medical record
- You are age 18 years or older, and are found to meet criteria for unhealthy alcohol use

We expect to enroll 129 patients from the VA New York Harbor at both the Brooklyn and Manhattan campuses. There will be 642 patients enrolled in total from all VA sites. These sites are: Atlanta, GA., Washington DC., and Houston, TX. Dallas, TX, and New York Harbor Healthcare System, NYC.

DURATION OF THE RESEARCH:

Your participation in this research study is expected to take approximately 12 months; this is an 8-year project.

STUDY PROCEDURES:

If you decide to take part in this study, this is what will happen:
You will be treated at your Veterans Administration hospital and will be randomly assigned, by luck of the draw or chance, to one of two groups of patients. Depending on the group to which you are assigned, you will receive one of the following two types of treatments: **Group A)** Integrated stepped care (**ISC**); or **Group B)** Treatment as usual (**TAU**), which is standard care as provided by your treating physician as well as a handout with alcohol information and general health-related information. Both Group A and Group B will have access to an informational website and online counseling to help address your alcohol use.

All patients assigned to the study will be interviewed at the start of the study and then one month, 3 months and 6 months with a 12 month follow-up. You will be asked questions about how you take your HIV medication

and how much you have been drinking (20-minute interview). In addition, you will be interviewed at each visit about other things such as any risky behaviors you might be engaging in (20-minute interview) and you may have blood drawn at these times to monitor your HIV laboratory values and your liver function. Your blood (a finger stick for 5 drops of blood) will also be tested for the presence of alcohol (PETH TEST) or whether there is evidence that you have been drinking in the past 3 months. A breathalyzer test for alcohol will be done at each interview. As part of this study we will also be collecting information from your medical chart regarding services you have received at the VA, medical diagnoses, the medications you are taking and blood work that has been done. We are collecting this information so we can better assess how you have been taking the medications that have been prescribed for your HIV and the care that you receive in the VA.
If you are assigned to Group A:
Integrated Stepped Care, depending on the level of your drinking, you will receive either individual counseling or counseling and medication to reduce your use of alcohol. Integrated Stepped Care means that a beginning level of treatment will be tried first and continued if successful. If this is not successful, then treatment will be "stepped up" or advanced to the next level, which includes Brief Negotiated Interview (BNI), Motivational Enhancement Therapy (MET) and Addiction Physician Management (APM).

Brief Intervention – The Brief Negotiated Interview (BNI)
The purpose of the BNI is to assist you in recognizing and changing levels of alcohol use that pose health risks. This is a counseling session with a Social Worker and is accompanied by a second session (by phone) at two weeks where you will have the opportunity to discuss and explore your accomplishments and setbacks. Sessions will last approximately 15-20 minutes.

Motivational Enhancement Therapy (MET)
Motivational enhancement therapy will be provided by a staff psychologist that will help you move through stages of change and help build relapse prevention skills. The initial session lasts 30 minutes to 45 minutes. There also are three follow-up sessions that occur 2, 4 weeks and 6 weeks after the initial session, respectively, and that last 20 to 30 minutes each.

Addiction Physician Management (APM)
APM will provide care that is typically provided by physicians in specialty referral programs. After an initial 45-minute evaluation session, the physician will administer APM weekly for 2 weeks, every 2 weeks for 4 weeks and then monthly until week #24. During the Addiction Physician Management, your psychiatrist will assess the impact of unhealthy alcohol use on your medical, psychiatric, social, employment, and legal functioning; educate you about alcohol dependency; and, if necessary, encourage you to take a medication which will help you to decrease your alcohol consumption, such as naltrexone, disulfiram or acamprosate.

If you are assigned to Group B:
You will not receive any targeted psychosocial or pharmacologic treatment directly from participation in the study and have treatment as usual, provided by your treating doctor. You will discuss your diet, exercising, reducing of alcohol and smoking habit and other questions with your doctor.

As part of this study, testing for hepatitis may be done. A positive hepatitis test result must be reported to your state department of public health. If you test positive for hepatitis, this report will be made with your name and other identifying information included. If you do not wish to have test results reported you should refuse to participate in the study.
If you are a woman and become pregnant while taking naltrexone (one of the medications that physicians use to treat unhealthy alcohol use) you will be offered another appropriate medication, and may remain in the study.

We are also requesting your permission to audiotape all of your counseling sessions with the study Social Worker and study Psychologist so that we may be able to monitor your treatment and provide you with the best care possible. The audiotapes may be used for any purpose relevant to research and medical education, within the discretion of the Dr. Michael Simberkoff, and will be erased 12 months after the completion of the study. Please See: **CONSENT FOR USE OF PICTURE AND/OR VOICE.**

Collection of Patient Locator Information:
For better communication with you during your participation in this study, we created a Patient Locator Form, which will give us information on 5 people, including you and your relatives or friends, who will be able to reach you. We will notify you by phone and/or mail before each assessment. If after three attempts we still cannot reach you, contact with the other 4 people will be initiated, and if unsuccessful a registered letter will be sent to you.

POSSIBLE RISKS OR DISCOMFORTS:
Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unforeseeable (unanticipated) risks also may occur.
Survey questions may make you uncomfortable. You are free to skip any questions that you would prefer not to answer.

Risks associated with drawing blood are small. Sometimes a bruise will occur at the puncture site, and, rarely, a blood clot or infection may form in the vein.
If your Step Treatment includes offering you medication to decrease your alcohol consumption, you may be prescribed one of the following by the study Addiction Physician: naltrexone, disulfiram or acamprosate.

While there is a risk of the naltrexone interacting with the HIV medicines you are taking, based on prior research, we believe this is unlikely to happen. Naltrexone may cause a slight increase in your liver enzyme tests but this has been found to be an uncommon occurrence and we will be monitoring your liver tests throughout the time you are receiving treatment in the study. We will also monitor you closely for any signs of bad side effects. It is also important for you to know that narcotic pain medications (for example, oxycodone or hydrocodone) will be less effective if you are taking naltrexone. Therefore, you will not be given naltrexone if you are presently taking narcotic pain medications.

Disulfiram may cause tiredness, dark urine, yellowing of the skin or eyes, large appetite changes, weakness, dizziness or loss of coordination, diarrhea or vomiting. Disulfiram can cause minor side effects that usually happen in the first 2 weeks of treatment. These include acne, headache, rash, impotence, mild drowsiness, metallic aftertaste and fatigue. Disulfiram cannot be taken if you are consuming alcohol due to a known adverse effect. Disulfiram may cause a slight increase in your liver enzyme tests but this has been found to be an uncommon occurrence and we will be monitoring your liver tests throughout the time you are receiving treatment in the study.

The side effects of acamprosate include diarrhea, dizziness, gas, loss of appetite, nausea, trouble sleeping, or weakness. You may experience anxiety; behavior changes; depression; mental or mood changes; nervousness; panic attacks; restlessness.

****Risks of the usual care you receive are not risks of the research and are not included in this consent form. You should talk with your health care providers about risks of usual care.**

POTENTIAL BENEFITS:

We can't promise that you will get any benefits from taking part in this research study. However, possible benefits may include helping you to reduce your alcohol use. It will also help us to develop better treatment strategies to be used for treating unhealthy alcohol use in patients with HIV.

ALTERNATIVE PROCEDURES:

As an alternative to participating in this study there are other options available to you: medications and counseling such as cognitive behavioral therapy, twelve-step facilitation, and motivational interviewing have been found to be effective in the treatment of alcohol problems. If you are not eligible to participate or you choose not to be part of this study, you may still receive treatment and other services to which you are otherwise entitled. Counseling and alcohol treatments are available at the Veteran's Affairs Medical Centers in Manhattan and Brooklyn. You may discuss these options with your doctor.

During your participation in this study, you will not be able to participate in any other study that addresses alcohol use or HIV medication adherence.

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Principal Investigator: **Investigator Name: Michael S. Simberkoff, MD**

Facility Name: **VA NY Harbor Healthcare System Version Date: November 16, 2015**

CONFIDENTIALITY OF INFORMATION:
Taking part in this study will involve collecting private data about you. This data will be protected in the following ways:
In all records of the study you will be identified by a number. Your name and address will be known only to the researchers and kept in a locked file cabinet, in the Research Coordinator's locked office. The National Institute on Alcohol Abuse and Alcoholism (NIAAA) may review your records, but your name will not be used in these reviews. Your name will not be used in any scientific publications. Your data information will be disclosed to Yale University School of Medicine, Research Coordinating Center in accordance with HIPAA authorization, under your permission and signed consent form. We still retain a complete record of disclosed information under VA Information security requirements.

PRIVACY AND CONFIDENTIALITY:
To help us protect your privacy, a Certificate of Confidentiality (COC) has been obtained from the National Institute on Alcohol Abuse and Alcoholism. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).
You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. Therefore, this Certificate is not protective if you voluntarily disclose your participation in this study.

Information that will be used: During the course of this study, we will collect private information such as your name, Social Security Number, smart phone number, laboratory values, physical exams, and other medical information. Your name, address, date of birth, and Social Security Number will be used only as necessary. Because this research is sponsored by NIAAA, staff from that and other DHHS agencies may review records that identify you only for audit or program evaluation. They cannot report anything that would harm research subjects, such as personal identifiers: your name, Social Security Number, address, or date of birth.

If you have an adverse experience during the course of the study, your entire medical record may be used and disclosed as clinically necessary pursuant to federal laws and regulations.

The People/Organizations who will receive the information: Every effort will be made to make sure that the information about you obtained from this study will be kept strictly confidential. As stated above, your identity will be known only to the staff of the clinic where you currently get your care; the investigators listed in this consent form, the study coordinator at this site, and authorized personnel at the Coordinating Center at Yale University School of Medicine. The data will be stored at Yale, through TrialDB created through the Yale Center for Medical Informatics (YCMI) (http://ycmi.med.yale.edu). Analyses, however, will occur both at Yale (Yale Center for Analytic Sciences) and the West Haven VA, which is Yale-affiliated.
The Yale Center for Medical Informatics where data will be entered, verified, cleaned, stored and analyzed using a web based clinical trial management system (CTMS) under the direct supervision of lead investigator, Dr. David Fiellin, the overall study Principal Investigator. Data Security is achieved via the following methods; 1) CTMS staff will receive HIPAA and Human Subjects Protection training, 2) Users will act in full compliance with HIPAA regulations, and 3) Sensitive data is encrypted. The CTMS also maintains an electronic audit trail of all modifications to study data. Yale houses and maintains the security and backup of all servers and workstations. Passwords and personal health information will be encrypted in the database server.

To further insure your confidentiality, your name will not be associated with any information you give us during signing the consent, nor your name be used in any publications. Data can still be released if we find or suspect child abuse, elder abuse, an intent to harm yourself or others, or if you have an infectious disease that State or Federal law requires us to report.
Your information may also be disclosed to the VA Healthcare System Institutional Review Board (the committee that oversee human research), Yale University IRB, staff of VAHS Education and Compliance office in order to perform audit and compliance duties, and federal agencies, such as Office of Human Research Protections (OHRP) and Government Accounting Office (GAO), the Office of the Inspector General, the VA Office of Research Oversight in order to meet VA and other local regulations. Once your individually identifiable health information is released to outside entities, it may no longer be protected by Federal laws or regulations and may be subject to additional disclosures by those individuals or organizations that receive it.
Use of web-based treatment services will be tracked by the COMpAAAS coordinating center.

COSTS TO PARTICIPANTS AND PAYMENT:

There will be no costs to you for any of the treatment or testing done as part of this research. However, medical care and services provided by the VA that are not part of this study (e.g. normal hospital and prescription expenses which are not part of the research study) may still require you to pay your standard co-payments. The drugs would be **'free' of charge**. Payment offered to participants is to compensate the time of completing the surveys as well as to cover travel expenses. You will be compensated for completion of the baseline ($25) assessment, during treatment assessments at 1 and 3 months ($50), the end of treatment assessment at 6 months ($50), and a follow-up assessment at 12-months ($50). The total possible compensation for the study per patient is $225.

MEDICAL TREATMENT AND COMPENSATION FOR INJURY:

Every reasonable safety measure will be used to protect your well-being. If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you. You or your insurance carrier will not be expected to pay the costs of such treatment. No financial compensation is available. However, you do not give up any of your legal rights by signing this consent form.

VOLUNTARY PARTICIPATION:

You are free to choose not to be part of this study; however, if you choose to be part of this study, you are free to quit this study at any time. If you choose not to participate or if you quit, it will not affect your relationship with the doctors of this clinic or the Veteran's Administration. Your decision will in no way affect your eligibility for future treatment.

NEW FINDINGS:

Sometimes during the course of a research study, new information becomes available about the treatment/drug that is being studied that could change your willingness to continue in the study. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw at that time, your research doctor will make arrangements for your medical care to continue. If you decide to continue in the study, you may be asked to sign an updated consent form. Your research doctor could also decide it to be in your best interests to withdraw you from the study. He or she will explain the reasons and arrange for your usual medical care to continue.

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RIGHT OF INVESTIGATOR TO TERMINATE PARTICIPATION:

Doctor Michael S. Simberkoff and his research investigators may stop your participation in this study without your consent for reasons such as: it will be in your best interest, you do not follow the study plan, such as refusing to complete study surveys, decline to take your medications or social counseling, or you experience a study - related injury. However, even after your study participation ends, you may still continue your regular treatment.

STUDY CONTACT INFORMATION:

If you have a general question about the research study, or if you have any concerns or complaints related to this study, you may call the local **Patient Advocate, Charles Sanky at # 718-836-6600 x 3316**. If you experience any illness, injury, or any other medical problem that you feel may be related to this study, please **call Dr. Michael S. Simberkoff, M.D, PI, at # 212-951-3417 during the day, and the ID Fellow at 212-686-7500 (ask Operator to page after hours). You may also contact, Joseph Leung, M.D., Co-PI at 212-951-6331.**

In case of a medical emergency contact your local emergency medical service or go to your local emergency room.

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the **VA NYHHS IRB Office at 212-686-7500 Ext. 4455**. This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the VA Research Administrative Officer if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input. At the **NY campus call # 212-686-7500 x 7474.** At the **BK campus call # 718-836-6600 x 3838.** Or you may contact the **Research Compliance Officer at # 212-686-7500 x 7443.**

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AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY:

Dr./Mr./Ms._____ _____has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

You voluntarily consent to participate in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it. A copy of this signed consent will also be put in your medical record if applicable.

I agree to participate in this research study as has been explained in this document.

SIGNATURE	PRINTED NAME	DATE SIGNED
Subject:		
Person Obtaining Consent:		