Informed Consent for Participation in Research
Understanding and intervening with heavy drinking among patients with HIV and HCV

OVERVIEW

You are being asked to participate in a study whose purpose is to help patients who have HIV and Hepatitis C drink less alcohol. This outline is meant to be a guide for you to use while considering the study and reading the consent form. It is not meant to replace the consent form, which you will have to sign if you decide to participate in the study. The consent form contains detailed information about the study and about the risks which you will need to consider before making your decision. Read the consent form carefully and discuss it with others before deciding to take part. And remember that, even if you agree to participate, you can change your mind at any time.

VOLUNTARY

This is a voluntary study, and you do not have to participate if you do not want to. If you do decide to take part in this study, you may stop participating at any time.

ALTERNATIVE TREATMENTS

If you decide to participate in this study, you may still receive other treatments for your alcohol use. A referral guide with information on where to find help will be provided if you would like to find alcohol treatment services in your community.

PROCEDURES

You will be asked to attend a baseline session and follow-up sessions at 30, 60, and 90 days (a total of four appointments). At each session you will complete assessments about your drinking and provide urine and breathalyzer samples if you want to. You have a 50-50 chance of being assigned to one of the groups below:

Group 1: Clinician's Guide & HealthCall Intervention	Group 2: Education Only
▪ At your *baseline appointment* you will meet with a counselor for 20 minutes to discuss your drinking, liver health, and medications and create a plan to reduce your drinking. You will also be given a smartphone and asked to use an app called HealthCall daily to track your drinking and answer questions about your health. ▪ At your *30-day appointment* you will meet with a counselor for 10 minutes to discuss your drinking in the past 30 days and asked to continue using HealthCall ▪ At your *60-day appointment* you will meet with a counselor for 10 minutes to discuss your drinking in the past 30 days. ▪ At your *90-day appointment* you will only complete assessments.	▪ At your *baseline appointment* you will meet with a counselor for 20 minutes to review a pamphlet on how alcohol affects people who have HIV and Hepatitis C. You will also be given advice to decrease your drinking. ▪ At your *30-day appointment* you will meet with a counselor briefly to discuss your drinking. ▪ At your *60-day appointment* you will meet with a counselor briefly to discuss your drinking. ▪ At your *90-day appointment* you will only complete assessments.

RISKS AND INCONVENIENCES

If you decide to participate, the main risk to you is that your name could become known, however we will explain how we protect your information and your confidentiality. You will also be asked sensitive questions about personal habits or health behaviors that might make you feel uncomfortable. You can skip over any questions if you do not want to answer them.

BENEFITS

You may not benefit from participating in this study. This research may also help scientists learn more about how to better treat alcohol use among patients who have HIV and HCV.

QUESTIONS

You may contact the principal investigator of this study, Dr. Jennifer C. Elliott at (646) 774-7953 with any questions.

Informed Consent for Participation in Research

Understanding and intervening with heavy drinking among patients with HIV and HCV

PURPOSE AND OVERVIEW

You are being asked to take part in a research study called ***"Understanding and intervening with heavy drinking among patients with HIV and HCV."*** We are inviting you to take part in this research because your drinking appears to be at a level that is unsafe for your health. The goal of this study is to compare the effects of two different approaches to helping patients drink less. One approach includes brief counseling with use of HealthCall (daily use of a smartphone application to track drinking, with discussion of reported drinking at later follow-up appointments). The second approach will involve providing pamphlets about HIV and HCV with brief advice to decrease drinking. This study is being conducted by researchers from the New York State Psychiatric Institute and is sponsored by the National Institute on Alcohol Abuse and Alcoholism.

VOLUNTARY

Participation in this research study is voluntary. If you decide not to participate, or if you later decide to stop participating, you will not lose any benefits to which you are otherwise entitled. A decision to not participate or to withdraw your participation will not affect your current or future treatment at the New York State Psychiatric Institute, Columbia University, or your HIV clinic.

ALTERNATIVE TREATMENTS

You do not have to participate in this research to receive treatment for your alcohol use. There are a number of different interventions that you can receive instead of participating in this research study, such as support groups like Alcoholics Anonymous, psychotherapy, and medications that have been shown to be effective in helping people reduce their alcohol use. If you do not wish to participate in this study, or if you start out in the study and then want to leave later on, staff at your HIV clinic will help you find alcohol treatment services in your community.

PROCEDURES

Overview

The study begins with a screening session that includes a brief interview to see if you are eligible to participate. If you are eligible and agree to participate, the study involves computerized assessments, meetings with the study counselor, and possible brief (2-3 minutes) daily use of the HealthCall smartphone application to answer simple questions about your daily alcohol use, mood and health. Not including the screening session, there are four

sessions in total, including a first meeting, visits at 30 days and 60 days, and a follow up at 90 days after the start of the study to see how you are doing. The total length of the study including the follow-up is 90 days. The total time of your participation in the study procedures is approximately four to five hours, including the screening session.

If you are interested in participating in this study, we will ask you to sign this consent form after you have read it, asked us any questions that you may have, and have understood the study procedures.

Screening Session

The first part of the screening session involved a conversation with a recruiter, who identified you as potentially eligible due to your medical records, explained the study, and referred you to our research team to finalize screening. You appeared to meet study eligibility criteria (those ineligible were given brief advice on reducing alcohol use and, if requested, referral for help with drinking).

As you drink alcohol and meet the other eligibility criteria for the study, you are invited to continue in the study. This will involve completing the screening session, which includes questions from the research team and a questionnaire on your own, on your substance use, mood, and other health behaviors. Then you will be randomly assigned (by chance) to one of two groups. You will have a 50% chance of being assigned to each of the following groups:

Group #1: The Clinician's Guide + HealthCall. If you are assigned to participate in this group, you will be asked to participate in a brief meeting (about 20 minutes) with a study counselor to discuss your drinking, your liver, and your HIV medication adherence (taking your HIV medications when and how you are supposed to). The counselor will give you feedback on your drinking and liver, help you set a drinking goal, and make suggestions to help you reduce your drinking. You will also receive educational materials on HIV, Hepatitis C, and alcohol. You will then be introduced to HealthCall, a smartphone application designed to help you keep track of your alcohol use and other issues relevant to health (reasons for drinking/abstaining, medication adherence, drug use, condom use during sex, and mood) through short daily use. You will be given a study smartphone that has a calling plan and access to HealthCall during the time of the study. You will be shown how to use HealthCall, and you will have the chance to practice using it. You will also set the phone alarm to remind you to use HealthCall each day at a time of your choosing. Over the next 30 days you will be asked to use HealthCall daily. Each use lasts 2-3 minutes. The purpose of daily use is to help you keep track of your alcohol use. Each day, HealthCall will ask about what you drank, how much you drank, and what you thought about drinking (e.g., reasons for drinking or abstaining, commitment to change, desire to drink). It will also ask about other aspects of your health that may relate to drinking (drug use, whether you took medication and why, condom

use, and how you felt that day). You will also receive tips that may help you cut down on drinking. At the end of the 30 days, you will meet with a counselor for a 10- minute interview. At the interview, you will be given a graph showing the results of your use of HealthCall. The counselor will explain the graph and discuss it with you. The counselor will also ask about any changes in your alcohol use and give you feedback on your drinking. You will then be asked to continue using HealthCall for the next 30 days. At the end of those 30 days, the counselor will meet with you for another 10- minute interview to go over your updated graph, and to discuss and summarize your experience with HealthCall. At all meetings, you will also complete a survey that asks about your substance use and other health experiences.

Group #2: Education only. You will receive brief advice to decrease drinking and a request to spend 20 minutes at the clinic, observed by the counselor, reviewing easy-to-read pamphlets on HIV and HCV. At 30 and 60 days, you will talk with your counselor briefly about your drinking. At all meetings, you will also complete a survey that asks about your substance use and other health experiences.

Urine and breath samples, and other medical information

You will also be asked to provide a urine sample for a urine drug screen and breath sample for an alcohol breathalyzer test at each study visit, for a total of four urine and alcohol breath samples. You have the right to refuse to provide these samples. If you refuse, your participation in this research program and in treatment will not be affected.

We will also collect medical information from your clinical record or ask you to provide this information. This includes results of bloodwork related to your HIV and HCV health.

Audio-Recording

You will also be asked to allow audio-recording of your counseling sessions. We would like to record counseling sessions so that a supervisor can review them. If you agree, during the recording, your voice and the counselor's voice will be recorded via a digital recorder. You can request that the recording be stopped or that the digital data file be erased at any time either during or after the counseling session. If you do not agree to audio-recording during your counseling sessions, your participation in this research program and in treatment will not be affected. The digital audio files will be kept for five years after the study completion and then be destroyed. If you agree and then change your mind, the recordings will be erased.

RISKS AND INCONVENIENCES

Risks mainly involve loss of confidentiality (the risk that your name would become known). However, we make

great effort to minimize this possibility. We explain this more below.

During the interviews you will be asked about personal habits and health behaviors. There is a possibility that you will feel upset, tired, or anxious. If this happens, you can choose not to answer specific questions or to have the interview stopped at any time.

It is possible that you may not benefit from participating in the study. If your alcohol use worsens, you will be referred back to your provider for further assistance. You should report any increase in alcohol use (more days of alcohol use or using more alcohol) to your HIV care team right away.

BENEFITS

You may not receive personal benefit from participating in this study. However, if you receive the intervention, it could help you reduce your alcohol use. This research may also help scientists learn more about what treatments work best for reducing alcohol use among patients with HIV and HCV.

CONFIDENTIALITY

All completed study forms will be stored and protected in locked files. Records will only be available to a small number of carefully selected research staff, and state and institutional regulatory personnel (who may review records as part of routine audits). The research staff members who will work with your records for this study have been trained in the importance of confidentiality and methods to protect the study information. Information from using the HealthCall application, the digital audio-recordings and the computerized assessments completed at each of your visits will be stored on a password protected computer. All of the computerized files are identifiable only by a unique code number assigned to you at the beginning of the study (your study ID #). The Principal Investigator will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission. We may publish the results of this research. However, you will not be identified in any publications or presentations.

The information you provide us through the computerized assessments, HealthCall application, and any urine or breath sample tests will not be used for future research studies or distributed to another investigator for future studies, with or without identifiers. Further any urine or breath samples you provide will be discarded after being tested and will not be used for commercial profit under any circumstances.

A description of this clinical trial, including a copy of the final informed consent will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This Web site does not include information that can identify you. At most, the Web site will include a summary of the results. You can search this web site at any time.

This research falls under protection of a Certificate of Confidentiality, issued by the National Institutes of Health. With this Certificate, the researchers cannot be forced to release any research data in which you are identified, unless (a) required by federal, state, or local laws, (b) for the purpose of other scientific research that complies with federal regulations protecting the rights of participants, or (c) if you consent to release the information. This Certificate will prevent your data from being released, even under a court order or subpoena, without your written consent. The Certificate does not prevent the researchers from reporting suspected or known neglect or sexual or physical abuse of a child, or threatened violence to self or others. Such information will be reported to the appropriate authorities.

Our research staff is separate from your HIV clinic staff. We will alert your provider or crisis services if you indicate intent to harm yourself or others, if you show signs of psychosis, or if we otherwise believe that you are in immediate danger, so that you can receive needed treatment and services. Although we may encourage you to discuss substance use, unsafe sex, and treatment adherence with your providers, as this information is relevant to care, we will not disclose this information without your permission unless we believe that you are in immediate danger.

COMPENSATION

Whether or not you are found eligible for the study after completing the initial screening session, you will receive a $10 gift card. If you are found eligible to participate in the study, you will receive the following:

- $25 gift card immediately after your first visit
- $25 gift card immediately after your 30-day visit
- $35 gift card and a study smartphone or $135 gift card immediately after your 60-day visit
- $35 gift card immediately after your 90-day visit

Altogether, you can earn up to a total of either $230 in gift cards **or** $130 in gift cards and a smartphone for participating in this study.

Transportation: You will also receive a round-trip MetroCard for all study visits including the screening session.

IN CASE OF INJURY

Federal regulations require that we inform participants about our institution's policy with regard to compensation and payment for treatment of research-related injuries. Please be aware that:

1. The New York State Psychiatric Institute, Columbia University and New York Presbyterian Hospital will furnish that emergency medical care determined to be necessary by the medical staff of this hospital

2. You will be responsible for the cost of such care, either personally or through your medical insurance or other form of medical coverage.

3. No monetary compensation for wages lost as a result of injury will be paid to you by Research Foundation for Mental Hygiene, the New York State Psychiatric Institute, Columbia University or by New York Presbyterian Hospital.

4. By signing this consent form, you are not waiving any of your legal rights to seek compensation through the courts.

FUTURE STUDIES

After completing participation in this study, you may be contacted again by a member of the research team to ask if you wish to participate in additional research projects. If this happens, your participation would be entirely voluntary and you can refuse if you wish.

QUESTIONS

You have discussed this research consent form with the research staff and he/she has answered all of your questions about the study to the best of his/her ability.

If you have questions now or in the future about the research procedures, or about your response to the procedures, Dr. Elliott, the Principal Investigator of the study, will answer your questions to the best of her ability. You may contact her during regular office hours at (646) 774-7953.

If you have any questions about your rights as a research participant, want to provide feedback, or have a complaint, you may call the NYSPI Institutional Review Board (IRB). (An IRB is a committee that protects the rights of participants in research studies). You may call the IRB Main Office at (646)774-7155 during regular office hours.

DOCUMENTATION OF CONSENT

A signed and dated copy of this consent will be given to you.

☐ **I agree** ☐ **I do not agree** for my sessions during this study to be digitally recorded.

I voluntarily agree to participate in the research study described above.

SIGNED: _____

PRINT NAME: _____

DATE: _____

I have discussed the proposed research with this participant including the risks, benefits, and alternatives to participation (including the alternative of not participating in the research). The participant has had an opportunity to ask questions and in my opinion is capable of freely consenting to participate in this research.

PRINT NAME: _____

Person Designated to Obtain Consent

SIGNED: _____

DATE: _____

Quiz:

1. After my initial meeting with the study counselor, I will:
   a. Be assigned to complete “The Clinician’s Guide + HealthCall” intervention.
   b. Be given educational materials and brief advice.
   c. Both A and B.
   d. Either A or B, which will be determined by chance.

2. Once I join this research project,
   a. I can stop participating at any time.
   b. I must complete all parts of the study.

3. The focus of this study is to
   a. Help me to decrease my drinking.
   b. Help me stop using drugs.
   c. Help cure my Hepatitis C.

4. This study will last
   a. One appointment.
   b. Four appointments over 90 days.
   c. Ten appointments over one year.