

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
<ul style="list-style-type: none"> ▪ At your <i>baseline appointment</i> 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 <i>30-day appointment</i> 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 <i>60-day appointment</i> you will meet with a counselor for 10 minutes to discuss your drinking in the past 30 days. ▪ At your <i>90-day appointment</i> you will only complete assessments. 	<ul style="list-style-type: none"> ▪ At your <i>baseline appointment</i> 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 <i>30-day appointment</i> you will meet with a counselor briefly to discuss your drinking. ▪ At your <i>60-day appointment</i> you will meet with a counselor briefly to discuss your drinking. ▪ At your <i>90-day appointment</i> 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.