BROWN UNIVERSITY
CONSENT FOR RESEARCH PARTICIPATION

Project ReACH
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KEY INFORMATION:

You are invited to take part in a Brown University research study. Your participation is voluntary. We are conducting this study in collaboration with El Rio Health, Howard Brown Health Center, LA LGBT Center, Whitman-Walker Health, and the Montefiore Medical Center AIDS Center. Only people receiving HIV care at one of these health centers are eligible to participate. This project is sponsored by the National Institute on Alcohol Abuse and Alcoholism.

- **PURPOSE:** The purpose of this study is to compare the effectiveness of two different approaches to counseling people with HIV about their alcohol use.

- **PROCEDURES:** You will be asked to complete a baseline survey about your alcohol use and health. You will also need to give us permission to confirm that you receive HIV care at one of our participating health centers. After these steps are completed, we will ask you to complete a brief conversation by telephone about your alcohol use with one of our counselors. Using a process like flipping a coin, half of participants completing that conversation will be selected to receive up to five additional sessions of counseling on alcohol use. Those counseling sessions will be conducted through Zoom, which is a web-based platform, or can be done on the phone. If you use Zoom, you may need to download this application to your device. At 6 and 12 months after enrolling you in the study, we will send you surveys to complete online or by telephone if you are not able to get internet access. You will also receive reminder emails or texts to complete the surveys. Standard text rates may apply. At 12 months, you will be asked to send us a spot of your blood by mail. Some participants also will be asked to complete an exit interview with a study staff member at the end of their study participation. You do not have to provide the blood spot or complete the interview to participate in the study. The counseling sessions and exit interview will be audio recorded.

- **STUDY DURATION:** Your participation in this study will span approximately 12 months. Surveys take about 30 minutes to complete, and counseling sessions last 10 to 50 minutes. Any texting interaction you have should take two minutes or less to complete.

- **COMPENSATION:** You will receive a $30 Amazon gift card within one week of completing the baseline survey and having your HIV care confirmed, a $20 Amazon gift card within one week of completing your initial conversation with a study counselor, and a $25 Amazon gift card within one week of completing each of the follow-up surveys. For providing a blood spot, you will receive $30 and for completing the exit interview, you will receive $20. If you are unable to use an Amazon gift card, you may arrange with staff to receive a ClinCard, which is a pre-paid Mastercard that works like a debit card.

  RISKS: There are three potential risks to study participation, which are considered minimal include: 1) potential discomfort related to completing questionnaires about sensitive information such as psychological and alcohol/drug problems and engaging in discussions around drinking, HIV, and health during counseling session, 2) potential breach of confidentiality and/or privacy, 3) discomfort from a finger stick.

- **BENEFITS:** Participating in our study may not benefit you directly. We hope that what we will learn from your participation will help us to develop programs to help people with HIV manage their drinking.

- **ALTERNATIVES TO PARTICIPATION:** There are many different options for receiving alcohol counseling, including online resources. If you would like us to, we can provide you information on those programs.

1. Researcher(s):

The Principal Investigator of the study is Dr. Christopher Kahler. For questions about this study or research-related concerns please contact Dr. Kahler at 401-863-6651.

2. What is this study about?

The purpose of the study is to compare the effects of two different counseling approaches on participants' alcohol use and health. The study will involve the completion of a baseline survey, one to six individual sessions of counseling, and surveys at 6 and 12 months after enrolling. The counseling sessions will be completed by telephone or videoconference depending on your preference. The videoconference sessions will be conducted through Zoom, which is a software program.

You are being asked to be in this study because you are receiving care for HIV at one of our participating health centers, and you drink alcohol. You are 18 years of age or older.

3. What will I be asked to do?

If you choose to be in the study, you will be asked to agree to participate at the end of this consent form before you begin the study.

Baseline Online Survey. You will first be asked to complete an online baseline survey. This survey will include questions about your alcohol and drug use, HIV medication adherence, and sexual life. You may skip questions that you don't want to answer. You can also stop the survey at any time. The survey will take about 30 minutes to complete.

Confirm HIV Care. You will need to provide us a release of information so that we can confirm with your health center that you are receiving HIV care there.

Counseling Sessions. After you have completed the baseline survey and your HIV care has been confirmed, you will be asked to have a telephone conversation with one of our study counselors. This session will take about 10 minutes.

When you join the study, you will also be assigned to one of two groups using a process like flipping a coin.

- Everyone will talk with a counselor at least once. However, some people will be assigned to longer more in-depth counseling sessions.
- In one group, you will receive no further counseling after the first counseling session. However, you will be asked to complete surveys at 6 and 12 months after that session. At 12 months, you will again have a brief conversation with a counselor to check in.
- If you are chosen for another group, you will be offered additional counseling sessions. In total, you can choose to receive up to 5 additional sessions over the next 12 months. Each session takes 20-50 minutes to complete. After 12 months, regardless of how many additional sessions you completed, you will have a brief check-in phone conversation with a counselor. You also will be offered to participate in a text messaging program focused on helping people manage drinking. If you choose to participate in that program, you will receive several text messages each day that will ask about your drinking and provide you with feedback about it. You will also receive text messages once a week asking about your HIV medication, and providing tips and encouraging comments. After 30 days of this program, we will only ask you to respond to text messages once a week and will send three additional messages each week that do not require a response. Each interaction with the texting program should take two minutes or less.
- It is important for you to know that we will not be able to respond in real-time to your text messages except for the expected responses that are sent to our phone number. That is, we will not respond to any text message outside the scope of the questions we ask. If you are experiencing an emergency, you should call 911.
- You are not required to use text messaging to participate in this study and can opt out of receiving text messages at any time.

Follow Up Online Survey. At 6 and 12 months after your first counseling session, you will be asked to complete an online follow-up survey. This survey will also include questions about your alcohol use, HIV medication adherence, sexual life, and your input on the counseling. You may skip questions that you don't want to answer. You can also stop the survey at any time. The survey will take about 30 minutes to complete.

Medical Records Request. When you enroll in the study and at 12 months after enrollment, we will contact your health center to request data on your HIV care, including viral load and CD4 count. We will also request the most recent results from other routine lab work including your liver function, kidney function, and complete blood count. If you change where you receive your care during follow-up, we will ask you to sign a HIPAA authorization to allow us to request medical data from that provider.

Exit Interview. After completing the follow up survey, you may be asked to complete an exit interview with a staff member. During the interview, you will be asked what you thought about the counseling and how the study can be improved. Whether you complete this interview is up to you.

Blood spot. At the end of the 12-month survey, you will be asked if you would be willing to provide us a dried spot of your blood in order for us to test how much your body has been exposed to alcohol recently. We would mail you a kit to collect this spot, along with detailed instructions. You can decide at the time whether you are willing to do this. We would ask you to send back the blood spot within 7 days of receiving the collection kit and will provide a prepaid envelope for shipping it at no cost to you.

Reminders. You will receive emails or texts to remind you to complete your next surveys.

Audio Recording. The counseling sessions and exit interviews will be audio recorded. You can ask the counselor not to have the counseling sessions recorded and still participate.

Your participation in this study will last approximately 12 months.

4. Will I be paid?

You will receive a $30 Amazon gift card code by email within one week of completing the baseline survey and our confirming that you are receiving HIV care at one of the following clinics: El Rio Health, Howard Brown Health Center, LA LGBT Center, Whitman-Walker Health, and the Montefiore Medical Center AIDS Center. If you are not receiving care for HIV at one of these clinics, you cannot participate in this project. You will not be compensated for your baseline survey and your data will not be kept for research. After completing your first conversation with a study counselor, you will receive a $20 Amazon gift card code by email. For 6- and 12-month surveys, you will receive a $25 Amazon gift card code by email for each

survey you complete. If you complete the exit interview, you will receive a $20 gift card. For sending in a dried blood spot within 7 days of receiving the collection kit, you would receive a $30 gift card.

If you are unable to use an Amazon gift card, payment for participating in this study will be made using ClinCard, a pre-paid Mastercard that works like a debit card.

We will mail you the card. You will be given one card for the entire time of your participation. You will also get information about how to use this card and whom to call if you have any questions. Be sure to read this information, including the cardholder agreement from Greenphire.

Money will be added to your card based on the study's payment schedule. You may use this card online or at any store that accepts Mastercard. Please read the FAQ information sheet from your study coordinator for details about the ways you can use the card, some of which may involve fees that will reduce the amount of money on the card.

If you earn $600 or more from Brown University in a single calendar year (either in a one study or across multiple studies), Brown will request your social security number to correctly identify you in the payment system and issue you an IRS 1099 Form. You may also be asked to complete a Form W9. This may affect your taxes. Only payments for being in research studies will be used to decide if you should receive the IRS form. Money for study-related parking, food, and other expenses are not included in this IRS disclosure.

This card is administered by an outside company called Greenphire. Greenphire will be given your name, address, and date of birth. They will use this information only as part of the payment system, and it will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study in which you are participating.

If your card is lost or stolen, please call the study coordinator for a free replacement card. If you request a replacement card from Greenphire directly, you may be charged a fee.

5. What are the risks?

There are three potential risks to study participation.

1. *Potential discomfort with survey questions and counseling sessions.* It is possible that some of the survey questions and the counseling session activities may produce embarrassment or discomfort in some participants. You do not have to answer any questions you do not wish to answer. You can stop a survey at any time. If you feel discomfort during the counseling sessions, you can discontinue your participation at any time. You can withdraw from this study at any time for any reason, without penalty. You do not have to give reason. The investigators also have the right to stop your participation at any

time. This could be because you have failed to follow instructions, have undermined the right or privacy of another participant, or because the entire study has been stopped.

2. *Potential risks of data collection and loss of confidentiality.* We will use several strategies to protect your confidentiality. All information that you provide to us will be stored on secure servers with restricted access. Your name or any other identifying information will not appear on any stored files. Instead, we will assign you an identification number that will replace your name on the data files. Only members of the study team will have access to your files. If you provide a blood spot sample, we will mail that to an independent laboratory for testing identified only by your study identification number. The laboratory will not have access to your personally identifying information. We will make every effort to protect your confidentiality, but there is a small possibility that information you provide could become known to others.

   The counseling sessions and exit interviews will be audio recorded. They can be stopped at any time. These recordings will be destroyed within five years of our completing the study.

3. *Discomfort from finger stick*. If you choose to provide a dried blood spot, you will experience brief bleeding and mild discomfort associated with a finger stick. You can choose not to provide this blood spot at any time and do not have to agree to this procedure to participate in this study.

6. What are the benefits?

You may not directly benefit from being in this research study. You will have an opportunity to discuss your alcohol use and make decisions about changes to drinking you may choose to make.

7. How will my information be protected?

We have your email address and phone number for administrative purposes. Email addresses are necessary for sending an appointment reminder and connecting you to the Zoom program to do the online sessions. Your email and phone number will be kept for five years after the study ends, given your consent. Personal information will not be linked to any of the information that you provide in the survey or interview. Your personal information will not be used for any additional correspondences after the completion of the study.

Your participation in this study will be kept confidential and private as permitted by law. This includes the information you provide to us in the baseline and follow-up surveys, as well as the counseling sessions. A secure videoconference protocol through Zoom will be used for videoconference counseling sessions. Every effort will be taken to protect your identity as a participant in this study. You will not be identified by name in any report or publication of

this study or its results. Instead, you will be known only through a study ID number. Any data linking your name to your study ID number will be on a secure server separate from your research data.

Your answers are confidential. The findings of the study may be published, but individual participants will not be identified. There is a possibility that the FDA may inspect study records. Any reports related to child abuse/neglect or elder abuse will be reported by us to the appropriate authorities.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the agency which is funding this project or for information that must be disclosed in order to meet the requirements for the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law if we think you intend to seriously harm yourself or someone else, or if there is reason to believe that you have committed child or elder abuse or neglect.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, Brown University will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives at Brown University, research sponsors, or government agencies for purposes such as quality control or safety. At

the end of the study, all of your de-identified data collected from the study will be coded and stored in our servers in Providence, Rhode Island.

Every effort will be made to keep your participation in the study and any personal information about you private and confidential. However, absolute confidentiality cannot be guaranteed. For example, if a study staff member learns something that would immediately put you or others in danger, the study staff member is required by law to take steps to keep you and others safe. This means that study staff members have to report to the authorities (hospital, police, or social services) any information you say that suggests that you might be in danger, such as telling staff that you plan to hurt or kill yourself, hurt or kill someone else, or if someone is abusing or neglecting you.

In addition, your records may be reviewed by certain agencies or people who make sure that the study staff are doing what they are supposed to and everyone in the study is being protected. Under the guidelines of the Federal Privacy Act, the sponsoring agency at the National Institutes of Health (NIH) and the Brown University IRB may look at your records. If your study records are reviewed, your identity could become known to them. However, these persons are expected to maintain your individual confidentiality. This means that they will not tell others information about you or that you are in the study.

Most people outside the research team will not see your name on your research information. This includes people who try to get your information using a court order in the United States. One exception is if you agree that we can give out research information with your name on it or for research projects that have been approved under applicable rules. Other exceptions are for information that is required to be reported under law, such as information about child or disabled abuse or neglect or certain harmful diseases that can be spread from one person to another. Personnel of a government agency sponsoring the study may also be provided information about your involvement in the research study.

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

8. Are there any alternatives to this study?

There are a number of options available for people who want help reducing drinking or quitting drinking. These involve local addictions treatment program and mutual help programs and websites providing information about alcohol problems. We can provide you with these referrals at any time if you would like them.

9. What if I want to stop?

You do not have to be in this study if you do not want to be. Even if you decide to be in this study, you can change your mind and stop at any time.

If you refuse to participate in or leave the study, your current or future relationship with Brown University or with your local health center will not be affected.

10. Who can I talk to if I have questions about this study?

If you have any questions about your participation in this study, you can call Dr. Christopher Kahler at (401) 863-6651 or email Christopher_Kahler@brown.edu

11. Who can I talk to if I have questions about my rights as a participant?

If you have questions about your rights as a research participant, you can contact Brown University's Human Research Protection Program at 401-863-3050 or email them at IRB@Brown.edu.

12. Consent to Participate

If you agree to voluntary participate in this study, please enter your initials:

____ I agree to participate in this research study

IF VERBALLY CONSENTING: Study staff will be redirected to a version of the consent form that hides participant-facing signature and instead displays the following:

Do you agree to voluntarily participate in this study?

____ No, participant did not agree to participate (check box)

____ Yes, participant agreed to participate

If Yes, type participant's name here _____

Type name of staff member administering consent: _____