# Document Coversheet

Study Title: A Telemedicine and mHealth Intervention for Reducing Alcohol Consumption Among People Living With HIV/AIDS

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**Department of Veterans Affairs**

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**ATLANTA VA HEALTH CARE SYSTEM**
**Consent to be a Research Subject**

**TITLE:** *TRAC: Tracking and Reducing Alcohol Consumption Randomized Waitlist-Controlled Trial*

**PRINCIPAL INVESTIGATOR:** Vincent Marconi, MD

**SPONSOR'S NAME:** National Institute of Alcohol Abuse and Alcoholism (NIAAA)

**INTRODUCTION/PURPOSE:** We are asking you to volunteer in a research study. The goal of this study is to reduce alcohol consumption among people living with HIV/AIDS. Research has found that drinking alcohol can have negative consequences for those with HIV, because it not only affects their physical health, but can also make them less likely to take their medication. The study will provide free alcohol reduction counseling during an eight-week program, delivered using cell phones and videoconferencing. You are being asked to participate in this study because you are: 1) HIV-positive, 2) 18 years of age or older, 3) An at-risk drinker, as identified by your responses on an earlier questionnaire, 4) currently taking HIV medication and 5) a patient receiving care at one of the study recruitment sites. You always have the option to skip any questions in assessments that make you uncomfortable. You are also free to conclude any intervention without any penalties. We will recruit 60 participants for this study.

If you agree to participate, you will be asked to complete an eight-week alcohol reduction intervention delivered using communication technologies. You will be randomly placed into one of two groups (Group A and Group B). Group A will begin the eight-week intervention right away, and Group B will wait until eight weeks have passed before beginning the intervention. Both groups will receive the same intervention and will participate for the same amount of time. Using two groups simply allows the researchers to better examine the effects of the intervention. You will also complete several questionnaires regarding your health behaviors, mental health, and attitudes. Overall, your participation in this research will span 24 weeks, with up to 28 hours and 5 minutes spent on study activities. This time period includes the 8-week intervention and follow-up questionnaires. You will need to come into the clinic for two appointments as part of your participation.

**PROCEDURES:** Please read this consent form. Before you decide to take part, discuss any questions or concerns with the research team. If you agree to be in this study, you will need to sign this consent form and a HIPAA form before starting in the study.

If you decide to participate, you will be asked to complete the eight-week TRAC alcohol reduction intervention. This intervention is not considered standard of care; it is intended to be an optional, supplemental activity. As mentioned, you will be randomly placed into one of two groups (Group A and Group B). We will use a random number generator to determine which group you will be placed into. Group A will begin the eight-week intervention right away, and Group B will wait until eight weeks have passed before beginning the intervention.

For the first session of this intervention, you will visit the VA clinic and complete a half-hour videoconferencing session with a counselor. During this session, you will receive and be trained to use a cell phone and breathalyzer, which you will use to monitor your alcohol and medication use during the course of the study. The breathalyzer will connect wirelessly to your cell phone and transmit your blood alcohol level to an app. If your own phone is compatible and you would prefer to use it for the study instead of being given a study phone, you will be instructed on how to install the

breathalyzer app. On each day of the eight-week intervention, you will be texted at two random times (morning and night) and asked to complete a breathalyzer reading and short questionnaire about your alcohol, medication use, and mental health. These questionnaires should take you no more than 10 minutes each.

Following this initial session, you will continue to meet weekly with the counselor for 30 minutes each time. The 2nd through 8th sessions will all take place via cell phone, so you **do not** need to be present at the VA. We simply ask that you find a private and quiet location from which to speak with your counselor using your cell phone. After each session with your counselor, you will be asked to complete a short 5-minute questionnaire on your mobile phones providing your feedback on the session.

After you have completed all 8 sessions, you will again return to the VA. You will not meet with your counselor during this time, but you will return your cell phone and breathalyzer to the clinic and complete a follow-up questionnaire.

On the rare occasion when study visits may be unexpectedly delayed, visits will not be delayed more than 1 week.

For participants who elect to use a study-provided phone: If at any time you lose or damage the cell phone, please inform the researchers so that the phone may be remotely wiped of all personal information. Any damage to or loss of the cell phone will result in your immediate dismissal from the study; however, you will be entitled to the incentive payments you had previously earned.

As part of this research, you will complete several electronic questionnaires that ask a variety of questions, including some about your alcohol consumption, drug use, mental health, and your attitudes toward technology. These questionnaires will take approximately 45-60 minutes each and can be done online using a computer, tablet, or mobile phone. You will take this questionnaire at 4 different times so that we can examine long-term behaviors: at the beginning of your enrollment, 8 weeks later, 16 weeks later, and 24 weeks later. Both Groups A and B will complete the questionnaires on this schedule. Additionally, we will conduct chart reviews to examine your viral load as determined through your routine bloodwork. We will examine the most recent viral load collected prior to you beginning the intervention (must have been within the previous 3 months), and the subsequent viral load values collected during the following 24 weeks.

If at any point during the study your counselor is concerned about excessive alcohol use that may be endangering yourself or others, they will send a referral to your care team at the VA. This will not automatically disqualify you from continuing the study, but your care team may recommend that you receive supplementary treatment or guidance regarding your alcohol use.

The following tables provide an overview of the primary study activities:

**GROUP A:**

| Week(s) | Tasks | Time Commitment | Total Time |
|---|---|---|---|
| 0 (Baseline appointment) | Questionnaire #1 | 45-60 min | 1 hr, 50min |
| | Videoconferencing session with counselor | 30-45 min | |
| | Post-session questionnaire | 5 min | |
| 1-7 | Phone sessions with counselor | 30 min | |

| | | | |
|---|---|---|---|
| | Post-session questionnaires | 35 min | 2 hrs, 55 min/week (22 hrs, 45 min total) |
| | Daily monitoring | 2 hrs, 20 min | |
| 8 | Questionnaire #2 | 45-60 min | 60 min |
| 9-11 | NO PARTICIPATION REQUIRED | -- | -- |
| 12 | Booster phone session with counselor | 30 min | 30 min |
| 13-15 | NO PARTICIPATION REQUIRED | | |
| 16 | Questionnaire #3 | 45-60 min | 60 min |
| 17-23 | NO PARTICIPATION REQUIRED | -- | -- |
| 24 | Questionnaire #4 | 45-60 min | 60 min |
| **TOTAL TIME** | | | 28 hrs, 5 min |

**GROUP B:**

| **Week(s)** | **Tasks** | **Time Commitment** | **Total Time** |
|---|---|---|---|
| 0 (Baseline appointment) | Questionnaire #1 | 45-60 min | 60 min |
| 1-7 | NO PARTICIPATION REQUIRED | -- | -- |
| 8 | Questionnaire #2 | 45-60 min | 1 hr, 50 min |
| | Videoconferencing session with counselor | 30-45 min | |
| | Post-session questionnaire | 5 min | |
| 9-15 | Phone session with counselor | 30 min | 2 hrs, 55 min/week (22 hrs, 45 min total) |
| | Post-session questionnaires | 35 min | |
| | Daily monitoring | 2 hrs, 20 min | |
| 16 | Questionnaire #3 | 45-60 min | 60 min |
| 17-19 | NO PARTICIPATION REQUIRED | -- | -- |
| 20 | Booster phone session with counselor | 30 min | 30 min |
| 24 | Questionnaire #4 | 45-60 min | 60 min |
| **TOTAL TIME** | | | 28 hrs, 5 min |

**NOTE ABOUT CHANGES TO PROCEDURES DUE TO COVID-19:**

If your provider or the VA determines that attending study visits puts your health at risk due to the spread of COVID-19, then you will be provided the option to complete all study tasks remotely. If this is the case, this consent form and HIPAA release will be sent via mail and the interventionist will call you to review both documents. Once they are signed, you will use a pre-paid envelope to send them back to the VA. If you are in Group A, following receipt of the consent, you will be shipped study equipment, documentation, and a ClinCard, and your initial visit will be scheduled with the interventionist. You will speak to the interventionist for the first visit using videoconferencing on your mobile phone, and if that is not possible, a traditional phone call will be held. The remaining part of the study will continue as originally scheduled, and you will not return to the VA for the Week 8 visit. You will be sent a pre-paid shipping box, which you will use to send your study equipment back to the VA. Once the equipment is received by the study team, you will receive compensation you are owed for the final visit. Group B will follow the same remote procedure, but will not be shipped equipment or meet with the interventionist until the 8-week mark. You will also complete all study questionnaires remotely using your own phone or computer, with the option to complete paper questionnaires as needed. These questionnaires (both daily surveys and Questionnaires #1-4) will contain some questions regarding your attitudes toward COVID-19, COVID-19 related behaviors, mental health, and exposure to/experiences with COVID-19. Your interventionist will work with you throughout the study to address any technology issues or barriers that arise due to the remote nature of the intervention.

**RISKS:**
For all participants, there is the potential risk of discomfort or emotional distress when completing questionnaires or receiving intervention content. To protect against distress, you always have the freedom to skip any questions in assessments that make you uncomfortable. You are also free to conclude any ongoing intervention session without penalty.

In cases of extreme distress, adverse events, or threats of self-harm, the researchers will contact your local provider at the VA who will follow-up with you. The counselor will be required to refer you if you show signs that you may hurt yourself or others. If the counselor believes it is necessary and immediate harm to yourself or others is possible, they will contact emergency services to provide transportation to your local emergency department for assessment and intake. You and/or your insurance plans will be responsible for all costs incurred related to emergency transportation.

There is a risk of loss of confidentiality, as identifying information will be collected in order to monitor your data throughout the course of the planned research. There are also risks associated with using mobile phones for health, as they are less secure methods of communication. By agreeing to participate in this intervention, you are stating that you understand the risks associated with discussing health information over mobile connections and wish to participate in spite of these risks. In the event that identifying information is released to an unauthorized party, your HIV-positive status or other health information could be revealed to unwanted individuals. This could potentially cause harm, but is unlikely considering the careful plans in place regarding data management and protection (see Confidentiality section below for further information).

Unknown Risks. Though the procedures used in this study have been used before, there may be risks, discomforts or side effects that are not yet known.

**BENEFITS:**
If you participate in this research, you will benefit primarily by receiving free alcohol reduction counseling, which has potential to not only reduce your alcohol use, but improve your HIV medication adherence and, in turn, your overall health. The self-monitoring aspect will also increase your own awareness of your behaviors and potentially improve your ability to recognize things that encourage alcohol use or a lack of medication adherence. By demonstrating feasibility of the intervention through this pilot research, the study will set the stage for a large-scale randomized controlled trial and the opportunity to extend this intervention to a much wider population.

**ALTERNATIVES:**
You do not have to be in this study to receive treatment for your condition. Your study doctor can discuss with you the alternative treatments.

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 efficacious in the treatment of unhealthy alcohol use. If you are not eligible to participate or decline to participate you may still receive treatment and other services to which you are otherwise entitled. Additionally, you can call the SAMSHA's National Helpline at 1-800-662-HELP (4357). This Helpline is a confidential, free, 24-hours-a-day service that can help you to find community resources and treatment for reducing your alcohol use.

**CONFIDENTIALITY:**
During the course of this intervention, we will collect your contact information to use for scheduling, delivering intervention materials, and monitoring your data. This identifying information will be kept

separately from any and all data you provide us—linked only by an ID number. Only the researchers will have access to a code key, which will link your ID number to your contact information. Once data collection is complete, this key will be permanently deleted and all identifying information will be removed from records.

To secure data on mobile phones, you will be taught how to delete messages or photos if you are worried about your information being compromised. Both you and your counselor will be trained and required to secure your phones using a password. A web-based service that allows complete control over data will be chosen to deliver your self-monitoring reminders, and any data collected during this process will be downloaded to a secure computer and deleted from the website following the completion of data collection.

If you choose to use a study phone instead of your own smartphone: These phones will be capable of being remotely wiped in the case of loss or theft to protect your information. If at any point you lose your phone or have it stolen, notify the researchers IMMEDIATELY at 404-386-5648. After you conclude the intervention, the phone you used will undergo a factory reset to remove any traces of data or identifying information.

We will keep information about you, including any research records we create, strictly confidential to the extent required by law. We may be required to release your record if we receive a subpoena or a court order. The study staff will keep your study files locked in a file cabinet in a private office. We will use a study number rather than your name on study records when we can. Your name and other facts that might point to you will not appear when we present this study or publish its results." People other than those doing this research study may have access to your medical and study records including:

- University of Georgia
- University of Kentucky
- The National Institute of Alcohol Abuse and Alcoholism
- The Office for Human Research Protections
- The Government Accountability Office (GAO)
- The Office of Research Oversight (ORO)
- The Inspector General
- The Emory University Institutional Review Board and other offices in Emory University that help run and/or oversee studies
- The Atlanta Research and Education Foundation (AREF)
- The Atlanta VA Research Compliance Officer
- VA research staff within the VA Hospital or at Emory University (when data is stored at Emory)
- Any appropriate state or federal government agencies that make rules and policy about how research is done that are not listed above

If you are participating in a study where a test and/or procedure may be performed at Emory and you are not and have never been an Emory patient, you do not have an electronic medical record. Please note that an Emory medical record will be created if you have any services or procedures done by an Emory provider or facility for this study.

All research records and/or identifiers will be destroyed in accordance with the VA record retention schedule.The survey data will be collected using Qualtrics survey software operating under the University of Georgia's license. Only that data necessary for analyzing the effectiveness of the study intervention will be shared with Dr. Carolyn Lauckner (the NIH study awardee) at the University of

Kentucky. Your name and Social Security number will not be shared. No attempt by Dr. Lauckner will be made to identify or contact you from the data shared with her.

If you are a veteran who is a patient at the Atlanta VA Health Care System, a copy of your signed and dated consent and HIPAA forms may be placed in your medical record(s). If you are a non-veteran receiving clinical services (i.e., use of the laboratory, radiology, audiology, etc.) as part of this study, you will have an electronic medical record created for you. You will also be given a VA Notice of Privacy Practices (NOPP) and we will ask you to sign a form saying that you have received this notice.

If you are in an FDA sponsored clinical trial: 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 website at any time.

We have obtained a Certificate of Confidentiality from the Federal Government. This helps protect your privacy by allowing us to refuse to release your name or other information outside of the research study, even by a court order. By law, information 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. The Certificate does not prevent you or a member of your family from releasing data about yourself or your involvement in this study.

**COMPENSATION:**
There are multiple incentives available in exchange for your participation in this study. They are as follows:

- $20 for attending all intervention sessions via videoconferencing or phone (including booster session)
- $1 for each completed breathalyzer reading (up to 14/week, with $1 bonus for completing all readings)
- $30, $40, $40, and $40 for completing health questionnaires
- TOTAL POSSIBLE: $450

On the rare occurrence that a study visit is delayed, the participant may receive additional compensation equivalent to the tasks completed, but no more than $30.

These incentives will be paid to you with money deposited remotely to a ClinCard debit card or mailed to you by check. ClinCard works like a debit card and is provided by Greenphire. You will receive deposits on a weekly basis while actively participating in sessions, and will receive payment after questionnaires are complete for weeks in which you are not meeting with the counselor. The total amount of these cards will vary depending on if you have completed all the study activities. Payments will be available to use in approximately 1 business day. Greenphire and its Customer Support members will have access to your name, address and date of birth. This information will help them provide customer service in case you have questions or need support while using the ClinCard.

If at any point during the study you lose or damage the breathalyzer or study smartphone (if applicable), you will be dismissed from study participation and unable to earn any further incentive payments. However, you will be entitled to the payments you earned prior to the loss of or damage to the equipment.

You will get emergency medical care if you get injured from being in this study. Under Federal Law, you will qualify for follow-up treatment if the injury was related to the research study. You may or may not get further compensation if you are injured in this study. This rule would not apply if you do not follow study procedures. If you believe you have been injured by this research, you should contact Dr. Vincent Marconi at 404-321-6111 ext 207592.

**CONFLICT OF INTEREST:** None.

**COSTS:**
Some Veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services that are not part of this study.

**CONTACT PERSONS:**
If you have any questions, concerns, or complaints about this study you can call a member of the study staff: Vincent Marconi 404-321-6111 ext 207592.

If you have been harmed from being in this study call Dr. Vincent Marconi at 404-321-6111 ext 207592.

If you want to speak to someone who is not a member of the study to discuss problems, ask questions or voice concerns, you can call:

> The Emory University Institutional Review Board (404) 712-0720 or toll free at 1-877-503-9797
> Or
> The Research Compliance Officer at (404) 321-6111 ext. 206964 or the Clinical Studies Center Director at (404) 321-6111 ext. 206933

If you have any questions about your rights as a participant in this research study, call the Emory University Institutional Review Board at (404) 712-0720 or toll free at 1-877-503-9797.

**ADDITIONAL RESEARCH OPPORTUNITIES:**
There may be additional reseach studies in the future that you may participate in. We would like to keep your contact information after the close of the study in order to contact you about future research.

_____ (initials) YES, you may store my contact information after the close of the study

_____ (initials) NO, you may NOT store my contact information after the close of the study.

**VOLUNTARY PARTICIPATION AND WITHDRAWAL:**
Your participation is voluntary and you have the right to refuse to be in this study. You can stop at any time after giving your consent. This decision will not affect in any way your current or future medical care or any other benefits to which you are otherwise entitled. The study doctor, investigator, or sponsor may stop you from taking part in this study at any time if they decide it is in your best interest or if you do not follow study instructions. If you decide to withdraw from the study, the information that

can be identified as yours will be kept as part of the study and may continue to be analyzed, unless you make a written request to remove, return, or destroy the information.

For participants who elect to use a study-provided phone: If at any time you lose or damage the cell phone, please inform the researchers so that the phone may be remotely wiped of all personal information. Any damage to or loss of the cell phone will result in your immediate dismissal from the study.

We will give you a copy of this consent form to keep. If you are willing to volunteer for this research, please sign below.

**RESEARCH PARTICIPANT'S SIGNATURE AND DATE:**

_____
Research Participant's name

_____ _____ _____
Research Participant's Signature Date Time
(to be entered by participant)