CONSENT FORM TO BE PART OF A RESEARCH STUDY: AIM 2

Title of Research:	Tailored Response to Psychiatric Comorbidity to Improve HIV Care Engagement in the United States (TRACE)
UAB IRB Protocol #:	IRB-300004217
Principal Investigator:	Michael Mugavero, M.D.
Sponsor:	National Institutes of Health (NIH)

General Information	You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form.
Purpose	The purpose of the study is to test the effectiveness of a counseling intervention for HIV care engagement plus depression, anxiety, PTSD, and/or substance use.
Duration & Visits	You will be in this study for nine months, which includes the baseline, 4 month and 9 month visits.
Overview of Procedures	This study will include completing a series of questionnaires at baseline, 4 and 9 month post-baseline, and the potential to participate in 4 months of weekly therapy sessions, depending on if you are randomized to the therapy intervention or enhanced usual care arm. Information from your medical record will also be collected as part of this study.
Risks	The most common risks include loss of confidentiality and feelings of emotional distress discussing mental health. Study staff will make every effort to keep your information confidential, and trained counselors will follow clinic protocols to respond to participant distress.
Benefits	You may or may not benefit from taking part in the study. Your participation may help future individuals living with HIV stay engaged in care.
Alternatives	If you do not want to take part in the study you can choose not to participate. This will not affect your medical care or opportunities for care coordination.

Purpose of the Research Study

We are asking you to take part in a research study. The purpose of this study is to adapt an effective cognitive-behavioral therapy that helps people living with HIV with things like depression, anxiety, substance use or post-traumatic stress. A cognitive-behavioral therapy is a type of talk therapy where a person discusses their thoughts with a trained counselor. Specifically, we are adapting this therapy to help People Living with HIV (PLWH) with HIV-related stigma and HIV treatment engagement. The ultimate goal of this research is to create a behavioral intervention for HIV care engagement and multiple mental health issues. The University of Alabama at Birmingham will enroll 60 patient participants as part of Aim 2 of the study."

Study Participation & Procedures

If you choose to take part in the study, you will be randomly picked (like the flip of a coin) to take part in either the therapy intervention group or the enhanced usual care group. Depending on how you are randomized, you will either receive the usual care given to patients at the clinic, or you will placed in the therapy group, which will include 7-15 virtual weekly one hour sessions with one of the trained study counselors at the 1917 clinic.

Therapy group: Some of your therapy sessions may be audio and visual recorded for clinical supervision and to ensure that the therapist is following the intervention correctly. You can choose to not give permission for them to be recorded.

Control and therapy groups: During the first study visit you will complete a baseline assessment of questionnaires that will ask about your mental health, substance use and social demographics. Follow-up assessments will occur at 4 months post-baseline visit and 9 months post-baseline visit. All questionnaires will be administered over the phone by a trained research staff member and should take about an hour to complete. The information you share with us will **not** be kept in your medical record. If you do not have a regularly scheduled lab draw at your clinic visit around the time of the 4 and 9 month post-baseline time points, we will ask you to get labs drawn so we can obtain your HIV viral load. Your total involvement in the study will last 9 months.

In addition, information from your medical record will also be collected as part of this study. This information includes demographic characteristics (e.g. age, gender, and race), medication and visit adherence, laboratory results (e.g. CD4 and T-cell counts and HIV viral load).

Risks and Discomforts

As with all research, there is a risk for breach of confidentiality. We try to minimize this risk by keeping your information private and secured, available to those involved with this study trained to keep information confidential, assigning a unique code to your study records instead of using your name or other identifiers on the research data we collect, and password-protecting any electronic research data. Any recorded therapy sessions will be kept on a secure shared drive and will be destroyed following the completion of the study.

Some people feel that giving information for research is an invasion of privacy. Talking about HIV, HIV health care, and/or mental health issues may cause you to feel sad, upset, or angry. You may choose not to answer any question and to end the interview at any time for any reason. If you become distressed during the interview, you will be offered the opportunity to speak with a mental health provider at the clinic.

Risk from blood draw: We will ask you for a viral load blood draw at your 4 and 9-month visit, if you do not already have a viral load scheduled for those time points. Drawing blood can cause pain, bleeding, bruising, or swelling, and, rarely, infection at the site of the needle sticks. Headaches and lightheadedness may be associated with excessive blood collection. Only experienced certified clinical staff will perform the procedure using standard sterile techniques. Laboratory values will be identified by study code.

Benefits

There will be no direct benefit to you from participating in this study. However, the information that you provide may help health professionals learn more about HIV care and treatment.

Alternatives

The alternative to participating in the study is to not participate.

Confidentiality and Authorization to Use and Disclose Information for Research Purposes

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you.

What protected health information may be used and/or given to others?
All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of any kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills; any other information related to or collected for use in the research study, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes; records about any study drug you received or about study devices used; and consent forms from past studies that might be in your medical record.

A description of this clinical trial will be available on 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.

Who may use and give out this information?
Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study.

Who might get this information?
All individuals/entities listed in the informed consent document(s), including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere). Your information may also be given to the sponsor of this research. “Sponsor” includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor, or are providing support to the sponsor (e.g., contract research organization).
Information about you and your health which might identify you may be given to:

- the Office for Human Research Protections (OHRP)
- the U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Governmental agencies in other countries

- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- the University of Alabama at Birmingham - the physicians, nurses and staff working on the research study (whether at UAB or elsewhere); other operating units of UAB, UAB Hospital, UAB Highlands Hospital as necessary for their operations; the UAB IRB and its staff
- the billing offices of UAB and UAB Health Systems affiliates and its billing agents

Why will this information be used and/or given to others?
Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

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 is 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 National Institutes of Health which is funding this project 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 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.

Information obtained during the course of the study which, in the opinion of the investigator(s), suggests that you may be at significant risk of harm to yourself or others will be reportable to a third party in the interest of protecting the rights and welfare of those at potential risk.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of harm to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

What if I decide not to give permission to use and give out my health information?
By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

May I review or copy the information obtained from me or created about me?
You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

May I withdraw or revoke (cancel) my permission?
Yes, but this permission will not stop automatically. The use of your personal health information will continue until you cancel your permission.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Is my health information protected after it has been given to others?
If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others. Including others outside of UAB, without your permission.

Voluntary Participation and Withdrawal

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in it. If you decide not to be in the study, you will not lose any benefits you are otherwise owed.

You are free to withdraw from this study at any time. Your choice to leave the study will not affect your relationship with this institution. Contact the study doctor if you want to withdraw from the study.

If you are a UAB student or employee, taking part in this research is not a part of your UAB class work or duties. You can refuse to enroll, or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation

There will be no cost to you for taking part in this study.

Payment for Participation

You will be paid $50 for the baseline, 4 month and 9 month study visits, for a total of $150. Ask the study staff about the method of payment that will be used for this study (e.g., check, cash, gift card, direct deposit).

New Findings

You will be told by the study doctor or the study staff if new information becomes available that might affect your choice to stay in the study.

Questions

If you have any questions, concerns, or complaints about the research please contact the study doctor. You may contact Dr. Michael Mugavero at 205-996-5822.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Legal Rights

You are not waiving any of your legal rights by signing this consent form.

Signatures

Your signature below indicates that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of an unsigned consent form.

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Signature of Participant Date

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Signature of Person Obtaining Consent Date