CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Couple-Based Motivational Interviewing with Technology to Reduce Alcohol Consumption in HIV+ South African Couples

South Africa Principal Investigator	Alastair Van Heerden, Research Director, Health Sciences Research Council

US Principal Investigator	Amy Conroy, Assistant Professor, University of California San Francisco

This is a research study about couples living with HIV and who drink alcohol. The study researchers are Dr. Alastair van Heerden at the Human Sciences Research Council, Centre for Community Based Research in South Africa, and Dr. Amy Conroy at the University of California San Francisco (UCSF) in the United States.

STUDY INFORMATION

We are asking you to consider taking part in a research study taking place at the Human Sciences Research Council and UCSF.

The first part of this consent form gives you a summary of this study. We will give you more details about the study later in the form. The study team will also explain the study to you and answer any questions you have.

Purpose of the study: The purpose of this study is to test how to help couples living with HIV decrease the amount of alcohol they drink. We will be testing a specific counseling method and a technology to measure the alcohol on a person's breath.

You are being asked to participate because you or your partner are living with HIV and consume alcohol.

Study procedures: If you choose to be in this study, you will complete a questionnaire. At the end of the questionnaire, you will be randomly placed into one of three groups. You will have an equal chance of being assigned to:

- Receive brief counseling about alcohol use;
- Receive counseling that may help you decrease your drinking (there will be three counseling sessions over two months);
- Receive counseling that may help you decrease your drinking (there will be three counseling sessions over two months), plus you will be asked to complete breathalyzer tests to measure the amount of alcohol in your system (two times each day for two months).

Additionally, you will complete two more questionnaires at follow-up visits we will arrange with you. When you come for the two-month visit, we will draw blood to measure your HIV viral load and alcohol use. We will use a lancet to prick your finger. To do both tests, we will need 10 drops of blood (approximately 1/5 of a teaspoon).

You will be in the study for approximately six months.

Possible risks: There are risks to taking part in a research study. Some of the most likely risks of participation in this study include:

- Loss of privacy
- Feelings of discomfort
- Conflict in your relationship

We will tell you more about these risks and other risks of taking part in the study later in this consent form. There may also be risks that we don't know about.

Possible benefits: You may or may not benefit from participating in this study.

Your other options: You do not have to participate in this study. Your other choices include:

- Getting your usual care.

We will now give you a more complete description of the study. Please read the description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a copy of this form to keep for future reference.

DETAILED STUDY INFORMATION

Research studies include only people who choose to take part. Please take your time to make your decision about participating and discuss your decision with family or friends if you wish. If you have any questions, you may ask the researchers.

You are being asked to take part in this study because you or your partner is living with HIV and drinks alcohol.

Why is this study being done?

The purpose of this study is to learn more about how to help couples who are living with HIV. We want to help people reduce the amount of alcohol they consume to better manage their HIV.

Who pays for this study?

This study is funded by the National Institutes of Health in the United States, which pays for the partial salary of Dr. Van Heerden and Dr. Conroy, and other study investigators.

What is the usual care for my condition?

The usual care for alcohol use is education and recommendations from healthcare providers to reduce alcohol use.

How many people will take part in this study?

About 90 couples (180 people) will take place in this study.

What will happen if I take part in this research study?

If you take part in this study, you will:

- Complete a questionnaire. A trained interviewer will ask you questions and enter your answers directly into a computer. At the same time, another trained interviewer will interview your partner in a different room. Your partner will not know what you say.
- The questionnaire will last around 90 minutes and will be conducted in a private room in a community-based location. There will be questions about your relationship with your partner, including things like unity, trust, and satisfaction in your relationship, and how you and your partner communicate around alcohol and HIV. There will also be questions about your alcohol use.
- If you are living with HIV, we will access your medical record so that we can obtain information on your health, such as your HIV test results.
- You will be assigned to one of three treatments, which are described below. The assignment will be random, like rolling dice. You will have an equal chance of getting any of the three treatments. To participate in this study, you must be willing to participate in whatever kind of treatment you are assigned to.
- One treatment is for couples to receive one brief counseling session (around 10-15 minutes) to learn about alcohol use. If you are assigned to this treatment, you will also come back in two months and six months to complete other questionnaires. If you are living with HIV or drink alcohol, we will also test your blood at the two-month visit.
- The second treatment is for couples to have three counseling sessions (around 60-90 minutes each) once a month for two months. These counseling sessions will be audio-recorded so that study staff can review the sessions with the counselors. These sessions will be typed word-for-word into a computer so that information from the sessions can be part of the study data. All names and identifying information will be removed from the transcripts. After the study is completed, the tapes will be deleted. If you are assigned to this treatment, you will also complete questionnaires at two months and six months. If you are living with HIV or drink alcohol, we will also test your blood at the two-month visit.
- The third treatment is for couples to have three counseling sessions (60-90 minutes each) once a month for two months and to use small breathalyzer. These counseling sessions will be audio-recorded so that study staff can review the sessions with the counselors. These sessions will be typed word-for-word into a computer so that information from the sessions can be part of the study data. All names and identifying information will be removed from the transcripts. After the study is completed, the tapes will be deleted. In this group, participants who drink will be sent text messages asking them to complete breathalyzer tests (two tests per day for two months). The results of the breathalyzer tests will be sent to their counselor, their partner, and the study staff. If you are assigned to this treatment, you will also complete questionnaires at two months and six months. If you are living with HIV or drink alcohol, we will also test your blood at the two-month visit.
- The drops of blood that we collect to do tests about the amount of HIV in your blood and the nature of your alcohol use will be tested using dried blood spots. The drops of blood will be put on a card and sent to a laboratory where they will be tested. These samples

will only be used for our study. Your name will not be used to identify the blood sample; instead, we will use confidential study numbers.

Storage for future testing

We will store the blood at a laboratory until it is processed and we receive the results. We will use the blood to do tests to find out about the amount of HIV and HIV medications in the blood, and the nature of your alcohol use; these samples will only be used for our study. Your name will not be used to identify the blood sample – instead we will use confidential study numbers. You will not be contacted with any test results.

Optional future studies

At the end of this form, we will ask you if you would like to provide consent for us to keep your contact information so that we may contact you about any future research studies for which you may be eligible.

How long will I be in the study?

The study will last for around six months. During that period, you and your partner will come to our community-based venue to complete questionnaires and blood tests. These three visits will take approximately 90 minutes each. If you are assigned to one of the treatments that receives counseling, you will also come for three counseling sessions lasting 60-90 minutes each. Depending on which treatment you are assigned to, your total participation will be either approximately 5 hours over 6 months or approximately 9 hours over 6 months.

Can I stop being in the study?

Yes. You can decide to stop at any time. Just tell the study researcher or staff person right away if you wish to stop being in the study. Also, the study researcher may stop you from taking part in this study at any time if he or she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What side effects or risks can I expect from being in the study?

1. The finger prick may hurt. Very rarely, the site of the blood draw can become infected.
2. The questionnaire includes personal questions about your health, your alcohol use, and about your relationship. If any question makes you uncomfortable, you can choose not to answer it. You can also end the interview at any time you choose.
3. If you are assigned to the treatment that receives counseling, you may find these sessions uncomfortable.
4. The largest risk could be a breach of confidentiality. Your information such as your HIV status could be shared with someone outside of the study. The study answers are secret and we do all we can to keep what you say private.
5. It is also possible that your partner may ask you about your responses to certain questions that come up in the interview. This may cause you some discomfort or distress when talking about difficult issues with your partner. Should you experience any difficulties resolving disagreements or conflict with your partner, you can consult with one of our counselors at HSRC. In addition, all participants will receive a list of community-based resources, including mental health counseling, general health services, and other services for couples.

6. Please be aware that you will not be told any information that your partner says in his or her interview. This includes any information your partner might say about his or her health, even if we think you do not know this information. Likewise, no information you say in your interview will be told to your partner, even if we think your partner might not know this information.
7. The study involves periodic in-person meetings and therefore poses some risk to infection from Covid-19. We have developed and will follow a Covid-19 Risk Management Plan to minimize the risk to Covid-19. We will also monitor the South Africa Department of Health and the World Health Organization for changes in Covid-19 guidance.
8. For more information about risks and side effects, ask one of the researchers.

Are there benefits to taking part in the study?

If you choose to be in this study, you can receive free information about how alcohol affects HIV and how to reduce your alcohol use. You and your partner may benefit from the counseling if you are assigned to that treatment. There is also a benefit to your community because the information you give us will help us improve programs in your community. There is also a possibility that you will not receive any benefit from being in the study.

What other choices do I have if I do not take part in this study?

You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you. Your decision will not change the medical care you receive or access to services and support.

How will my specimens and information be used?

Researchers will use your specimens and information to conduct this study. Once the study is done using your specimens and information, we may share the information with other researchers so they can use it for other studies in the future. We will not share your name or any other personal information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

Will information about me be kept private?

We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Health Sciences Research Council (HSRC)
- HSRC Research Ethics Committee
- University of California, San Francisco
- City University of New York
- National Institutes of Health

Are there any costs to me for taking part in this study?

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

Will I be paid for taking part in this study?

In return for your time, each person will each be reimbursed R100 for participation in each of the questionnaires. If both of you complete all three interviews, you will be reimbursed a total of R300. You will also receive R50 for each counseling session you attend, depending on the treatment arm you are assigned to. Couples who are assigned to use the breathalyzer will also receive a small bonus of R5 for each test that is completed (twice per day) with the potential to earn up to R300 per month. All participants will be eligible to win a second-hand iPhone (used in this study) in a lottery drawing at the end of the study.

What happens if I am injured because I took part in this study?

If you have any complaints about ethical aspects of the research or feel that you have been harmed in any way by participating in this study, please call the HSRC's toll-free ethics hotline 0800 212 123 (when phoned from a landline from within South Africa) or the research ethics committee (REC) Administrator, Khutso Sithole at the Human Sciences Research Council on 012 302 2009. You may also contact the administrator on the following email address: research.ethics@hsrc.ac.za.

If you have concerns or questions about the research you may call the project leader Dr. Alastair van Heerden on his office number: 0333245000.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. Your decision will not change the medical care you receive or access to services and support.

Who can answer my questions about the study?

You can talk to the researcher(s) about any questions, concerns, or complaints you have about this study. Contact the researcher Dr. Alastair Van Heerden at 0333245000**.** If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please contact the Research Ethics Committee at the Health Sciences Research Council at 0800 212 123.

Interviewer: Answer the participant's questions about the study before proceeding to the informed consent authorization. Make sure that the participant is participating freely and was not pressured or coerced to join the study.

CONSENT

I have read this form or have had it read to me. I have discussed the information with study staff. My questions have been answered. I understand that I am participating freely and I am not being forced to do so in any way. I also understand that I can withdraw at any point should I not want to continue and that this decision will not in any way affect me negatively.

I have received the telephone number of a person to contact should I need to speak about any issues which may arise in this interview.

I understand that this consent form and my answers will remain confidential.

I understand that I will not be told any information that my partner says in his or her interview.

I understand that the information that I provide will be stored electronically and will be used for research purposes now or at a later stage.

I am aware that the results of the study, including personal details regarding my sex, age, date of birth, and diagnosis will be anonymously processed into a study report.

In view of the requirements by research, I agree that the data collected during this study can be processed in a computerized system by the sponsor or on their behalf.

I understand that I may be audio-recorded if assigned to counseling arm.

CONSENT

You have been given a copy of this consent form to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

Please circle the appropriate answer:

Do you agree to be contacted by study staff about future research projects?	**YES**	**NO**
Do you agree to be visited at home if you miss an appointment?	**YES**	**NO**

If you wish to participate in this study, you should sign below.

Study Staff Name _____

Staff Signature _____ Date ___/___/_____

Participant Name _____

Participant Signature _____ Date ___/___/_____

Witness Name _____

Witness Signature _____ Date ___/___/_____