Informed Consent

TITLE OF RESEARCH: Alcohol Research Consortium in HIV-Intervention Research Arm (ARCH-IRA)

IRB PROTOCOL: IRB-160706007

PRINCIPAL INVESTIGATOR: Karen L. Cropsey, Psy.D.

SPONSOR: National Institute on Alcohol Abuse and Alcoholism (NIAAA)

Purpose of the Research

You are being asked to participate in a research study to test a method that was designed to reduce risky drinking. We hope to learn if this method helps to reduce drinking.

Research studies include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As a study staff member discusses this consent form with you, please ask him/her to explain any information that you do not clearly understand. We expect that a total of 606 participants will be enrolled at UAB, the University of California at San Diego, and the University of Washington. Approximately 259 of these participants will be enrolled at UAB.

Explanation of Procedures

As part of your routine assessment on the computer for the CNICS study, you are asked questions about alcohol use. Based on your responses to these questions, we are asking you to also participate in a study designed to reduce risky alcohol use. You will watch a brief video about alcohol use and participate in online counseling, if recommended by an algorithm (a set of guidelines or rules for making decisions). This information, along with guidelines about treatment options for hazardous alcohol use, will be given to your HIV doctor. Your doctor may offer you medicine to help with your alcohol use.

The interventions we use in this study will depend on the severity of your alcohol use. After your initial visit, when you return for your next two follow-up clinic visits at about four to six and at about 12 months following your first visit, we will approach you again. At these visits we will ask you to complete a few questionnaires that you usually do at the clinic visit.

Interventions

Group 1: Those with risky drinking who do not meet the diagnosis of alcohol use disorder or have an alcohol disorder classified as mild and do not have depression, or panic disorder

Visit 1: You will see a brief computer-delivered video regarding alcohol use and asked to complete a patient satisfaction survey about how you liked the videos

and using the computer system. The surveys will be used to develop future computer-based interventions.

Visit 2 (at about 4-6 months later; could be earlier or later): If drinking has been reduced, you will watch a video congratulating you on reducing or stopping your drinking. If drinking is still risky, you will watch another video regarding alcohol use and asked to complete a patient satisfaction survey about how you liked the videos and using the computer system. The surveys will be used to develop future computer-based interventions. You will be encouraged to go online and complete the 6 modules of Computer Based Training for Cognitive Behavioral Therapy (CBT4CBT) designed to address risky drinking behavior and a 7th module addressing risky HIV behavior. These modules can be done at your own pace in your home. If study staff cannot meet to follow up on CBT4CBT during Visit 2, we will call you in about a week's time from Visit 2 to follow up on the progress of the CBT4CBT component. Study staff may make up to 6 attempts in about a month's time to reach you.

Group 2: Those with risky drinking who do not meet the diagnosis of alcohol use disorder or meet alcohol use disorder classified as mild, but do have depression, or panic disorder

Visit 1: You will see a brief computer-delivered video regarding alcohol use and asked to complete a patient satisfaction about how you liked the videos and using the computer system. You will be encouraged to go online and complete the 6 modules of Computer Based Training for Cognitive Behavioral Therapy (CBT4CBT) designed to address risky drinking behavior and a 7th module addressing risky HIV behavior. These modules can be done at your own pace in your home. Around a week from enrollment, we will call you to follow-up on the progress of the Computer Based Training for Cognitive Behavioral Therapy (CBT4CBT) computer study component. Study staff may make up to 6 attempts in about a month's time to reach you.

Visit 2 (at about 4-6 months later; could be earlier or later): If drinking has been reduced, you will watch a video congratulating you on reducing or stopping your drinking. If study staff cannot meet to follow up on CBT4CBT during Visit 2, we will call you in about a week's time from Visit 2 to follow up on the progress of the CBT4CBT component. Study staff may make up to 6 attempts in about a month's time to reach you.

If your drinking is still risky, you will watch another video regarding alcohol use, complete another patient satisfaction questionnaire, and an algorithm will be used to determine the best medication to help with your alcohol use. In addition, an addiction-trained physician may make a recommendation to your doctor for medication to help reduce your drinking. The medications recommended in this

study are naltrexone, acamprosate, or disufiram, which are all FDA-approved to treat alcohol disorders.

Group 3: Those with risky drinking who meet the diagnosis of alcohol use disorder classified as moderate or severe with or without depression, or panic disorder

Visit 1: You will see a brief computer-delivered video regarding alcohol use, complete another patient satisfaction questionnaire, you will be encouraged to go online and complete the 6 modules of Computer Based Training for Cognitive Behavioral Therapy (CBT4CBT) designed to address risky drinking behavior and a 7th module addressing risky HIV behavior. These modules can be done at your own pace in your home. Around a week from enrollment, we will call you to follow-up on the progress of the CBT4CBT computer study component. Study staff may make up to 6 attempts in about a month's time to reach you.

A recommendation will be made to your doctor for medication to help reduce your alcohol consumption. The medications recommended in this study are naltrexone, acamprosate, or disufiram, which are all FDA-approved medications to treat alcohol disorders.

Visit 2 (at about 4-6 months later; could be earlier or later): If drinking has been reduced, you will watch a video congratulating you on reducing or stopping your drinking and will continue the medication prescribed by your doctor.

If your drinking is still risky, you will watch another video regarding alcohol use, complete another patient satisfaction questionnaire, and will continue the medication prescribed by your doctor.

If study staff cannot meet to follow up on CBT4CBT during Visit 2, we will call you in about a week's time from Visit 2 to follow up on the progress of the CBT4CBT component. Study staff may make up to 6 attempts in about a month's time to reach you.

All groups have the option of scheduling another visit to view the video and do the surveys. If you wish, the study staff can call you to remind you about your scheduled visit.

If you choose to give us your cell phone number, all groups will receive approximately three texts per week with inspirational/educational messages regarding how to handle risky drinking behaviors for 4 weeks. You will be asked if you wish to receive 2, 3, or 4 texts per week and you may opt out of texts if you wish by responding with STOP to any text message you receive. These texts be generated by the "PEEDY" software program and will be one-way, meaning that you will receive them but will not be able to reply.

Any medications to treat alcohol dependence that may be prescribed or other medical services that may be provided as part of a treatment plan for your alcohol use will be part of your usual clinical care. Your clinical information regarding any alcohol

pharmacotherapy your provider prescribes will be gathered during the time of the study, coded, and included in the database. You will be asked to allow study staff to look at your medical records. These records will be reviewed for information related to your health care visits such as treatment history and laboratory tests. We will also review your records to obtain contact information, in case the study staff needs to contact you for any reason. If you receive alcohol pharmacotherapy (treatment with medication) and request your medications be mailed to you, study staff will verify your address per standard clinic protocols. Study staff or your patient care coordinator will call you periodically to ask you about side effects of your medication and about your progress on the CBT4CBT modules. We are also requesting your permission to use your data from your electronic medical record and the CNICS study, including the questions you answer via touch screen computer at the start of your visit. The study will use the information captured in the CNICS questionnaires during the timeframe of 9-18 months from enrollment as well.

Risks and Discomforts

It is possible that over the course of watching the brief computer intervention and answering questions in the video, some questions or topics might cause you distress. Although we believe this unlikely to occur, study staff will escort you to the Psychiatry Clinic or Emergency Room for evaluation if needed. You can ask that the video be stopped at any time.

You should know that text messages, including ones from our study, are not 100% secure and may be accessed by someone outside the research project during transmission. While this is unlikely, it is still a risk.

If you stop using alcohol suddenly, you may experience alcohol withdrawal symptoms which include sweating or increased heart rate (over 100 beats per minute), increased hand tremor, insomnia, nausea or vomiting, transient visual, auditory or tactile hallucinations, psychomotor agitation, anxiety, and generalized tonic-clonic seizures. Participants who have been drinking heavily for an extended period of time will be evaluated for the need of medical detoxification and will be referred to inpatient services. Any participants who need alcohol treatment beyond the scope of this project will be referred for appropriate outside treatment.

Should your doctor choose to provide you medication to treat alcohol dependence, you should discuss the risks and benefits of your alcohol treatment plan with your doctor. As medications to treat alcohol dependence may have side effects or interact with other drugs you are taking, make sure you tell your doctor about all the prescription drugs, herbal products, over-the-counter (OTC) drugs, vitamins and natural remedies that you are taking. These risks and benefits are **not specific to this research study** but may be part of the treatment that you and your doctor will decide on for your alcohol use.

Although this study is not about the efficacy or safety of the following FDA approved medications recommended in this study, the following is a list of the possible side effects of the medications:

The most common side effects associated with the use of naltrexone include nausea or vomiting, diarrhea, constipation, stomach pain or cramping, loss of appetite, dizziness, anxiety, insomnia, drowsiness, headache, mild discomfort at the injection site (injectable form), rash, tearfulness, change in energy, or muscle/joint pain. Less common and more serious side effects naltrexone include signs of an allergic reaction (rash, hives, itching, breathing difficulties, chest tightness, swelling of the mouth, face, lips, or tongue), hallucinations, confusion, blurred vision or eye problems, cough, wheezing, or breathing troubles, severe vomiting or diarrhea. Naltrexone can cause liver damage which would manifest in the following symptoms: pain in the upper right part of the stomach that last more than a few days, yellowing of the skin or eyes, excessive fatigue, unusual bleeding or bruising, loss of appetite, dark urine, and light colored bowel movements. If you are using opioids (e.g., prescription pain medications or heroin) you should tell your doctor as naltrexone will cause immediate withdrawal symptoms from opioids.

The most common side effects associated with acamprosate include nausea, vomiting, stomach pain, loss of appetite; constipation, diarrhea; headache, dizziness, drowsiness; vision problems; problems with memory or thinking; weakness, cold or flu-like symptoms; back pain, joint or muscle pain; dry mouth, decreased or distorted sense of taste; sleep problems (insomnia); impotence, loss of interest in sex; sweating, mild skin rash; or numbness or tingly feeling. Less common but more serious side effects include mood or behavior changes; suicidal thoughts; severe anxiety or depression; feeling like you might pass out; fast or pounding heartbeats; swelling, weight gain, feeling short of breath; confusion, increased thirst; or urinating less than usual or not at all; or signs of an allergic reaction (rash, hives, itching, breathing difficulties, chest tightness, swelling of the mouth, face, lips, or tongue).

The most common side effect associated with disulfiram include skin rash or acne; mild headaches; mild drowsiness or tiredness; impotence; metallic taste in the mouth; or swollen or sore tongue. Less common but more severe side effects include an allergic reaction (swelling of your lips, tongue, or face; shortness of breath; closing of your throat; or hives); seizures; extreme tiredness; dark urine; yellowing of the skin or eyes (jaundice); large appetite changes; weakness, dizziness or loss of coordination; or severe diarrhea or vomiting.

There is the risk of loss of confidentiality, but we will take every precaution to protect your confidentiality.

Information for Women of Childbearing Potential or
Men Capable of Fathering a Child

Some alcohol medications may have additional risks when taken during pregnancy or breastfeeding, and may also influence sperm production. These risks are not specific to this research study but may be part of the treatment that you and your doctor will decide on for your alcohol use. Women who desire to become pregnant or men who may father

a child should discuss with their doctor the risks of any medicines before starting the medicine. If you become pregnant, Dr. Cropsey, one of her colleagues on the study or your clinic doctor may decide it is in your best interest to take you out of the study. This will not affect your routine clinic visits.

Benefits

You may or may not benefit by being in the study; however, the results of this study may help us to learn how to improve patient services at this clinic.

Alternatives

One alternative is always possible: you can choose not to participate in the study and, instead, receive routine treatment. Participating or not participating in the study will not prevent your treatment here or at any other agency where you seek treatment.

Confidentiality

Information obtained about you for this study will be kept confidential to the extent allowed by law. However, research information that identifies you may be shared with the UAB Institutional Review Board (IRB) and others who are responsible for ensuring compliance with laws and regulations related to research, including people on behalf of the National Institutes on Alcohol Abuse and Alcoholism (NIAAA), our collaborators at the University of Washington and Johns Hopkins; and the Office for Human Research Protections (OHRP). The information from the research may be published for scientific purposes; however, your identity will not be given out.

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.

Only a code number, not your name, will be used to identify your information on study materials, including lab specimens. This will be maintained in a password-protected computer database on a secure server within the UAB 1917 Clinic, the Bevill Biomedical Research Building (BBRB), and study staff offices. Any paper materials linking your name and code number will be kept in locked filing cabinets in locked offices of study personnel on a need-to-have basis. Your study materials will be maintained for a period of three years after the conclusion of the study. At that time the research information not already in your medical record will be destroyed. Your lab samples will be sent to a lab outside of UAB (USDTL Lab) and results will be received using a web portal.

Information from this study may be given to the treating physicians and other medical staff at UAB. In turn, the treating physicians and other medical staff at UAB may provide information about your treatment and care to the study staff. Information relating to this study, including your name, medical record number, date of birth and social security number, may be shared with the billing offices of UAB and UAB Health System affiliated entities so that claims may be appropriately submitted to the study sponsor or

to your insurance company for clinical services and procedures provided to you during the course of the study.

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

Voluntary Participation and Withdrawal

Taking part in this study is your choice. There will be no penalty if you decide not to be in the study and you will not lose any benefits you are otherwise owed. You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with this institution.

You may be removed from the study without your consent if the sponsor ends the study, if the study doctor decides it is not in the best interest of your health, or if you are not following the study rules.

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. The costs of your standard medical care will be billed to you and/or your insurance company in the usual manner.

Payment for Participation in Research

You will not be compensated for this study.

Payment for Research-Related Injuries

UAB and NIH have not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge. The cost for that medical care will be billed to you or your insurance company, just as for other medical care.

Significant New Findings

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

Optional Research

Participants may have two blood samples taken (from which blood spots will be created), one at baseline, and one at Visit 2 (approximately the 6 month visit), to measure blood levels which indicate chronic alcohol use and consumption. We will take an extra 2 mL of blood (about 1/2 teaspoon) and this extra blood will only occur when you are already having blood drawn as part of another study in which you are participating.

Taking 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 doctors and clinical staff will perform the procedure using standard sterile techniques.

Please initial one of the following options:

_____Participant agreed for blood spot

_____Participant DID NOT agree for blood spot

Questions

If you have any questions, concerns, or complaints about the research or a research-related injury including available treatments, please contact Drs. Karen Cropsey or Mugavero. They will be glad to answer any of your questions. Dr. Cropsey's number is 205-975-4204. Dr. Mugavero's number is 205-934-1917. He may also be reached after hours by paging him at 205-934-3411.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the Office of the IRB (OIRB) at (205) 934-3789 or toll free 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday. You may also call this number in the event the research staff cannot be reached or you wish to talk to someone else.

Legal Rights

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

Signatures

Your signature below indicates that you agree to participate in this study. You will be offered a signed or unsigned copy of this document.

_____	_____	_____
Printed name of Participant	Signature of Participant	Date
_____	_____	_____
Printed name of Person Obtaining Informed Consent	Signature of Person Obtaining Informed Consent	Date

University of Alabama at Birmingham
AUTHORIZATION FOR USE/DISCLOSURE OF PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH

Participant Name: _____ **UAB IRB Protocol Number:** IRB-160706007

Research Protocol: Alcohol Research Consortium in HIV- Intervention Research Arm (ARCH-IRA)

Principal Investigator: Karen L. Cropsey, PsyD
Sponsor: National Institute on Alcohol Abuse and Alcoholism

What is the purpose of this form? You are being asked to sign this form so that UAB may use and release your protected health information for research. Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your protected health information may be used for the research.

Why do the researchers want my protected health information? The researchers want to use your protected health information as part of the research protocol listed above and as described to you in the informed consent.

What protected health information do the researchers want to use? 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 whatever 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, and any other information related to or collected for use in the research protocol, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes.

Who will disclose, use and/or receive my protected health information? All Individuals/entities listed in the informed consent documents, including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere); other operating units of UAB, HSF, UAB Highlands, Children's of Alabama, Eye Foundation Hospital, and the Jefferson County Department of Health, as necessary for their operations; the IRB and its staff; the sponsor of the research and its employees and agents, including any CRO; and any outside regulatory agencies, such as the Food and Drug Administration, providing oversight or performing other legal and/or regulatory functions for which access to participant information is required.

How will my protected health information be protected once it is given to others? Your protected health information that is given to the study sponsor will remain private to the extent possible, even though the study sponsor is not required to follow the federal privacy laws. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

How long will this Authorization last? Your authorization for the uses and disclosures described in this Authorization does not have an expiration date.

Can I cancel this Authorization? You may cancel this Authorization at any time by notifying the Principal Investigator, in writing, referencing the research protocol and IRB Protocol Number. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the protected health information that was provided before you cancelled your authorization. **Can I see my protected health information?** You have a right to request to see your protected health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.

Signature of participant: _____Date: _____

or participant's legally authorized representative: _____Date: _____

Printed Name of participant's representative: _____

Relationship to the participant: _____