Study Title: COAPS: Co-Use of Opioid Medications and Alcohol Prevention Study

NCT: 05599672

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THE UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER

Consent and Authorization Document

CONCISE SUMMARY

We have summarized the key information about this research study at the beginning of this consent document. More complete details are included following this summary.

Purpose of the Study:	• We invite you to take part in this research study because you are currently taking an opioid medication and may be using it in a way that might not follow safety instructions on the labeling. • This study will compare the use of pharmacist counseling focusing on alcohol use to standard pharmacy medication counseling to aid people better follow their opioid medication prescription instructions. What group you will be in is decided by chance, like flipping a coin. • Research is voluntary. You do not have to be in this study.
Length of the Study:	• Study participation will last 3 months and may involve having 2 meetings with a pharmacist. Each session/call will last 45 minutes to an hour. • You will be asked to complete surveys on 3 occasions. Surveys will take 30-60 minutes. • If you sign up now, you can still take yourself out of the study later on.
Risks:	• One risk of being in this study is a break in privacy. • There may also be risks of emotional distress. • There may be a risk of inconvenience and possible loss of privacy and confidentiality. • Please be sure all your questions are answered before you decide to be in the study.
Benefits of the Study:	• You may not get any direct benefit from being in this study.

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Alternative procedures:	• If you choose not to take part in or to stop participating in this study, you will receive your regular care and/or treatment. • These treatments include regular care outside of this study. You may also choose no treatment.

BACKGROUND
You are being invited to take part in a research study to test an intervention that may help you better manage how you take your opioid pain medications (opioid medications are medicines prescribed by your doctor such as Vicodin, Percocet, hydrocodone, and oxycodone) and possible alcohol use. We plan to include 40 individuals from 3 community pharmacies in the Greater Nashville area for about 3 months.

You are being asked to participate in this study because you: are filling an opioid medication, have indicated you have recent alcohol use, are 18 years and older, are not receiving cancer treatment, have a positive screen for opioid misuse, are English speaking, and have a reliable telephone or mobile phone.

You are also being asked to participate in this study because you: are not pregnant, have not experienced major mental health (psychotic and/or manic) problems in the last 30 days (see screening section below for details about the specific mental health issues), are not planning to leave the area for an extended period of time in the next 3 months, and are not solely filling buprenorphine (a medication that is used for treatment of opioid addiction). After signing the consent form, you will get a signed copy of it to keep.

This study will compare the use of pharmacist counseling focused on alcohol use to standard pharmacy medication counseling. If you are assigned to the pharmacist condition focused on alcohol use, you will meet with a pharmacist to talk about how you use your pain medication(s) and how you might do better at taking it according to your doctor's prescription and how to avoid risky alcohol use. This study or the pharmacist do not replace your regular medical care or the need to follow your doctor or pharmacist's instructions for your health care. This study is designed to help you become more engaged and stay involved with your health care. If you are assigned to standard medication counseling, you will receive usual treatment at the pharmacy.

STUDY PROCEDURES
If you agree to take part in this study, several things will happen for research purposes only. You may have 2 meetings with the pharmacist and 3 meetings with a researcher to fill out surveys. Your first visit will be in-person or over the telephone at the community pharmacy. The remainder of visits will take place at that pharmacy, in our designated research office, at clinics, virtually, or other locations in the community.

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RANDOMIZATION

Part of this research trial involves comparing different treatments. One group will get one treatment, and another group will get a different treatment. In this study, you will be put in one group or the other by random chance. This means that a computer will decide by chance which group a person is in, not the doctors running the trial. After you do the interview, you will be assigned to a study group. You will be randomly assigned to either the standard medication counseling or pharmacist counseling focusing on alcohol, called: Alcohol-targeted Brief Intervention Medication Therapy Management condition.

Screening

In addition to the questions, you already answered on the iPad, you will receive a screening to make sure you are eligible to participate in this study. This screening will include verifying: you have not had a psychotic (for example, hallucinations and seeing things that others cannot) or manic (for example, have had out of control energy that has led to problems in your life) mental health episode in the last 30 days. The screening will also verify that to your knowledge you are not pregnant, you have a reliable telephone or mobile phone, have at least 2 reliable contacts ("Locators," see below), and you are not leaving the area for an extended period in the next 3 months.

Baseline Visit:

During the first study visit, you will be asked to fill out a contact information form and sign a HIPAA Release of Protected Health Information Form. You will also complete an assessment with a study team member and your answers will be entered into a research database. This first visit may last up to 2 hours.

- **Locator Information Form**
  We will use this form to help us keep in touch with you and remind you of study follow-up visits. The locator form will collect information about how to contact you for your follow-up visits. We will also ask for contact information for at least 2 other persons who may know how to find you should your contact information change, and we cannot find you. For the people that you give the contact information, you will also need to let them know you are in this study (so that it is not unexpected if we need to call them). However, what you tell them about the study is entirely up to you. If we reach any of these people, we will not tell them you are in the study, and we will not tell them the purpose of the study. We will ask them if they know how we can reach you. If we are unable to reach you with the information you have provided on the locator form, we may use publicly available data on the Internet to find updated contact information for you. All reminders will be made in a private manner. We will ask you to update this contact information at the follow-up visits and at other times during the study, as needed. In the event you are no longer in this study, your Locator Information Form will stay with your other identifiable study documents and will be treated as protected information and will be kept in a locked file cabinet and secured computer database. Patients must be able to provide at least 2 collateral contacts to participate in the study.

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- **HIPAA Release of Protected Health Information Form**
  You will complete a HIPAA Authorization and/or pharmacy prescription record release form throughout the study, as needed. Signing this consent form will allow us to review your pharmacy prescription records. We are requesting to look at your pharmacy prescription records in order to review your eligibility to participate in this study (opioid medication prescription or fill). After the project is done, we will use the information to understand how your health care went while you were in this study, this is to say, we will review information about your health care visits. If you receive health care or services, we will also ask you to sign a release form that will allow us to get your records from those other health care services, so we can see how your health care was while you were in this study. This information will only be put into your research records; your research information will not be placed in your medical records. This identifiable medical record information will be made available to members of the research team for an indefinite period. Your authorization is also valid for an indefinite period. You will be offered copies of all forms to keep for your records.

- **Interview**
  After filling out the study forms, you will complete an assessment with a study staff member. The interview will ask questions about you, your health (such as your pain and mental health), drug and alcohol use, and use of health care services. If requested, a staff member may read questions to you from a computer and type your answers into the research database. The interview will take about one hour to complete. You may skip any questions you don't want to answer. You can also stop the interview at any time. Information shared in these interviews may be used for future research studies.

- **Standard Medication Counseling**
  The standard care condition will involve the usual service you receive at the pharmacy for picking up your opioid medication. This requires pharmacists to: (1) offer counseling, (2) document counseling has been offered, (3) offer a counseling process for those not present (i.e., a call-in number for mailed medications; not applicable in the current study), (4) discuss generic prescription substitution, and (5) distribute written medication safety material. This material will mailed/emailed to you. The duration of the face-to-face portion of standard care in the current study is a single 5-10-minute session delivered by a pharmacist.

- **Alcohol-targeted Brief Intervention Medication Therapy Management**
  The other condition you could be assigned to will have two parts. The first part will be to meet with a pharmacist to talk about your medication and alcohol use. In a private room, or over the phone, you and the pharmacist will meet to talk about your medications, when you take it, and make goals to make sure you take it according to your doctor's prescription. This session will last 30-45 minutes. The second part will be to meet with the pharmacist again 7 days after the first session to follow-up. These sessions may also help connect you to participate in other community services (such as housing, food access, transportation).

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FOLLOW-UP VISITS

We will ask you to complete follow up visits at 2 months and then again at 3 months after you enroll in the study. These visits will last for about 30 minutes to 1 hour. During these follow-up visits you will:

1. Update your locator form.
2. Complete an interview like you did for the baseline visit. Assessments will ask about your behavioral health, mental health, physical health, quality of life, opioid medication use, and substance/alcohol use.
3. Complete urine drug screening test. You will urinate (pee) in a cup. The urine will be tested to find out if you have recently used illicit or illegal drugs.

Results of tests to determine recent drug and/or alcohol use will *NOT* affect your study participation.

AUDIO RECORDINGS:

We would like to audio record your sessions with the pharmacist. The purpose of this is to confirm that the study pharmacist is running the session correctly and for the study team to understand the content of the sessions.

- Recordings will be reviewed by members of the research team who are trained to review recordings.
- Recordings will be identified by number only. Your name will not be noted by the study staff or reviewer on any recordings.
- You may choose to stop being recorded at any time and can still be in the study. This decision will not change your care in any way.
- All study recordings will be kept in locked file cabinets and/or password protected computers. Only study staff will have access to them. Study records (including audio recordings) will be stored for at least 7 years.
- Information from the recordings may be published or shared in study reports in aggregate to help describe the sessions and how they were conducted, but your name or other data that might reveal who you are will not be revealed in any reports or writings that may result from this study. Information shared in these interviews may be used for future research studies.

RISKS

One risk of being in this study is a break in privacy. You will be asked questions about private and personal matters. Assessments will ask about your demographics, how often you take your medication, substance use, and other health conditions you may have, such as pain, depression, etc.

Some answers you give in the research visits (like whether you use illegal drugs) might put you at risk if other people find out. To keep what you say private, your study records will use a code number instead of your name. We will protect your records by keeping all your materials in locked file cabinets or secure password-protected computer files, away from clinic records. Only research staff will have access to your private information. Any information on computers is only available to research staff. Despite taking all of the safety measures mentioned above, there is a risk that your privacy will be broken.

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There are no known psychological risks associated with the interview questionnaires, procedures, or counseling in this study. It is possible discussing sensitive topics, such as substance use, may cause emotional discomfort in some participants. There may also be risks of emotional distress, inconvenience, and possible loss of privacy and confidentiality associated with taking part in a research study. The study may include risks that are unknown at this time. If you decide to take part in this study, there is no guarantee that your health will improve.

UNFORESEEABLE RISKS
In addition to the risks listed above, you may experience a previously unknown risk or side effect.

BENEFITS
You may not get any direct benefit from being in this study. However, information gained from this study may help to improve health care for other individuals in the future. Further, if it is determined that you need more help because of this study, you will be referred to other treatments, doctors, clinics and/or therapists who may be able to help you.

PERSON TO CONTACT
If you have questions, complaints, concerns about this study or think you may have been injured from being in this study, you can contact Kenneth Hohmeier (615) 532-0228. Dr. Hohmeier can be reached at this number during regular business hours, 9-5pm. If you are having suicidal thoughts or a mental health crisis, you may contact the statewide crisis line to discuss any issues (855) CRISIS-1 or (855) 274-7471. If you are having a medical or psychiatric emergency, please call 911.

Institutional Review Board:
Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints, or concerns which you do not feel you can discuss with the investigator. The University Tennessee Health Science Center IRB may be reached by phone at (901) 448-4824.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

RESEARCH-RELATED INJURY
You are not waiving any legal rights or releasing the University of Tennessee or its agents from liability for negligence. In the event of physical injury resulting from research procedures, the University of Tennessee does not have funds budgeted for compensation for medical treatment. Therefore, the University of Tennessee does not provide for treatment or reimbursement for such injuries.

If you are injured or get sick as a result of being in this study, call the study team immediately. The study doctor will provide acute medical treatment and will provide you with a subsequent referral to appropriate health care facilities.

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No compensation will be available to you for any extra expenses that you may have as the result of research-related physical injuries, such as additional hospital bills, lost wages, travel expenses, etc.

No compensation will be available to you for any non-physical injuries that you may have as a result of research participation, such as legal problems, problems with your finances or job, or damage to your reputation.

The hospital has not set aside any money to pay the costs for such care. The hospital will work with you to address costs from injuries. Costs would be charged to you or your insurance company (if you have insurance), to the study sponsor or other third party (if applicable), to the extent those parties are responsible for paying for medical care you receive. Since this is a research study, some health insurance plans may not pay for the costs. By signing this consent form you are not giving up your right to pursue legal action against any parties involved with this research.

VOLUNTARY PARTICIPATION
Your participation in this research study is completely voluntary. You may refuse to take part in it, or you may stop participating at any time, even after signing this form. Your decision will have no effect on your relationship with or the medical care you receive.

Your doctor or your pharmacist may be an investigator in this research study, and as an investigator, is interested both in your medical care and in the conduct of this research. Before entering this study or at any time during the research, you may discuss your care with another doctor or pharmacist who is in no way associated with this research project. You are not obligated to participate in any research study offered by your doctor.

We may contact you in the future for participation in one or more additional studies. If we do so, you will have the option to participate or not, and a new informed consent document will be reviewed with you regarding the study for your consideration.

RIGHT OF INVESTIGATOR TO WITHDRAW PARTICIPANTS
The researchers may withdraw you from participation if you act in a way that is harmful or disruptive, for failure to follow study procedures, the sponsor's withdrawal of the study, or if otherwise deemed appropriate.

COSTS AND COMPENSATION TO PARTICIPANTS
The parts of your care that would normally be done as standard treatment such as filling your opioid pain medication or other medications will be billed to you or your insurance company.

You will receive up to $240 for participation in this study over 6 months. You will be paid in the form of a pre-paid or reloadable gift card. Payment will be made after completion of the following activities:

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Payment Schedule

Study Visit	Length of Visit	Payment
Baseline assessment	1-2 hours	$40
2-months assessment	½ - 1 hour	$50
3-month assessment	½ - 1 hour	$75
Completion of all 3-assessment bonus	---	$75
TOTAL (For all visits attended)		**$240**

Since you will be paid for participating in this study, it is necessary for us to collect your Social Security Number. You will provide this information for a Federal W-9 Form that is filed with our Accounts Payable department. Accounts Payable will have limited access to the study information (e.g., the name of the study) for payment purposes. The amount you receive for taking part in this study will be turned into the Internal Revenue Service (IRS) as taxable income. You can choose not to provide us with your Social Security Number for this form and still participate in this study; however, we will not be able to pay you as outlined in this consent form.

NEW INFORMATION

Sometimes during a research project, new information becomes available about the pharmacist services that are being studied. If this happens, your research doctor or pharmacist will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw at that time, your research doctor or pharmacist will make arrangements for your medical care to continue. If you decide to continue in the study, you may be asked to sign an updated consent form. Also, on receiving new information your research doctor might consider it to be in your best interests to withdraw you from the study. He/she will explain the reasons and arrange for your medical care to continue.

NUMBER OF PARTICIPANTS

We expect to enroll 40 participants at 3 community pharmacy locations in the greater Nashville area.

DATA SHARE WEBSITE

Data from this study will be available to researchers on the website, https://nda.nih.gov/niaaa after the study is complete and the data has been analyzed. The primary outcome(s) publication for the full study will also be included along with study underlying primary data in the data share repository. This website will NOT include information that can identify you and it is only available to NIH investigators. This data-share is mandatory, if you do not want your de-identified data to be saved for future research, you should not participate in this study. Future research will not directly affect your health care and we will not share the results from future research with you or your doctors.

AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION

Signing this document means you allow us, the researchers in this study, and others working with us to use some information about your health for this research study. This is the information we will use and include in our research records:

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- Demographic and identifying information like name, address telephone number, and email address
- Social Security Number (you can decide to not tell us your Social Security Number, but we would not be able to compensate you if you decided to do so)
- Related medical information about you such as current and past medications or therapies, how often you attended health care appointments, behavioral health conditions, and outcomes related to your pain medication therapy
- All assessments that will be done in the study

How we will protect and share your information:

- We will do everything we can to keep your information private and confidential, but we cannot guarantee this. Study information will be kept in a secured manner and electronic records will be password protected. Study information may be stored with other information in your medical record. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital. We may also need to disclose information if required by law.

- To further help us protect your privacy, the study is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). This means the study doctors may not disclose study information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, or be used as evidence, for example, if there is a court subpoena.

  However, this Certificate cannot protect your information in all circumstances. Some laws require disclosure; for example, laws to report child abuse or communicable diseases. Additionally, the Certificate cannot protect your information if you have consented to its disclosure for your medical treatment, or if the study information is used for other scientific research. The study information may still be protected by other federal regulations, but this Certificate will not be able to provide additional protection in situations such as these. If audit or program evaluation from the funding agency or the Food and Drug Administration (FDA) is requested, disclosure of your information is required. Furthermore, protected health information collected for research purposes that is added to the medical record may not be protected under this Certificate of Confidentiality.

  You should also understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this study. If you want your study information released to an insurance provider, medical care provider, or any other person not connected with the study, you must provide consent to allow the study doctors to release it. This means that you and your family must also actively protect your own privacy.

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Finally, you should understand that the study doctor is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

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.

- To conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with us on this research:
  - Dr. Kenneth Hohmeier, the site PI and her research team at the University of Tennessee Health Science Center
  - The University of Utah Institutional Review Board (IRB), which reviews research involving people to make sure the study protects your rights
  - The University of Tennessee Health Science Center IRB and any other committees responsible for overseeing the research
  - The study sponsor: National Institute on Drug Abuse
  - The data coordinating center: The University of Utah

- If we share your identifying information with groups outside of the groups, they may not be required to follow the same federal privacy laws that we follow. They may also share your information again with others not described in this form.

- If you do not want us to use information about your health, you should not be part of this research. If you choose not to participate, you can still receive health care services.

What if I decide to Not Participate after I sign the Consent and Authorization Form?

You can tell us anytime that you do not want to be in this study and do not want us to use your health information. You can also tell us in writing. If you change your mind, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

This authorization does not have an expiration date.

You have a right to information used to make decisions about your health care. However, your information from this study will not be available during the study; it will be available after the study is finished.

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