UNIVERSITY OF WASHINGTON
CONSENT FORM

Cognitive, Behavioral, and Aging Effects of Pain Medication in Alcohol Users

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24-hour emergency telephone number 206-559-7660 to page Dr. Gregory Terman

Researchers' statement

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

The purpose of this study is to see how middle age and older adults who consume alcohol react to a pain medicine (oxycodone). There will be about 250 people in this study.

STUDY PROCEDURES

If you decide to be in the study, we will ask you to come in for two study visits. The study will take place at the University of Washington Clinical Research Center (UW- CRC) or the Seattle VA. You will only be seen for this study at one of these locations.
The first visit will take about 4 hours and the second will take all day. We will also call you the day after the second visit and ask you some questions. This call should last about 15 to 20 minutes. The two visits and phone call will happen over about 2-3 weeks.

Visit 1 (about 4 hours)

Before your first visit, you will need to not drink any alcohol for 24 hours. During the visit, you will take a breath test to determine if there is any alcohol in your body. If the test shows alcohol, you will not be able to be in the study.

During this visit, we will ask you about your health history and give you a brief physical exam and collect a blood and urine sample. We will ask you questions about how much alcohol you usually drink. It is important that you answer these questions honestly. Special tests will also be done during this visit.

Pain Stimulus

We will ask you to put your hand in cold water. You may experience pain from the cold. However, you may remove your hand and put it in warm water at any time. The warm water will reduce and eliminate any pain. We will ask you some questions about the effect of the

cold water, and any effects, other than pain, that you may have felt. You do not have to answer any question that you do not wish to answer.

Information processing and balance tests

We will give you some information processing tests on paper and on the computer, which will take about 2 hours to complete. The purpose of these tests is to see how quickly and how well you can solve problems and remember words. For example, one task you will be asked to do is to move an image of a car to different areas on a computer screen. These tests are for research purposes only. You will not be given the results of these tests and the results will not be placed in your medical record.

At the end of visit 1, if you are eligible for the study, you will be asked to return to the UW CRC for one more visit. The study staff will give you information about how to prepare for your second study visit.

Although it is not known, the study drug may pose a risk to an unborn baby. If you are a woman, you will be asked if you are pregnant or at risk for being pregnant. You will also be given a urine pregnancy test at visit 2 if you have not yet gone through menopause (stopped menses). You cannot be in the study if you are pregnant.

If you are not eligible, your part in the study will be finished at the end of this visit.

Visit 2 (all day / about 10 hours)

Before this visit, you will need to not drink alcohol for one day (24 hours). You will also need to stop any pain medicines two days (48 hours) before the visit. We will provide meals for you during this visit.

During this visit, you will have a breath test to determine if there is any alcohol in your body. We will ask you for a urine sample to determine if there are any drugs or medicines in your blood that are not allowed during this study. If drugs are present, the study visit will be stopped and you will not be allowed to complete the study.

If you are a woman who has not gone through menopause, you will have a pregnancy test. You cannot be in this study if you are pregnant or are trying to become pregnant.

During the day, we will do several tests to see how your body is reacting to the study medicine. Tests include:

Blood samples

We will take blood samples from you several times during the day. In order to do this, we will place a small needle (IV) in a vein in your arm. We may use a small amount of numbing medicine (lidocaine) to decrease the discomfort. The total amount of blood that we will take from you will be about 5 tablespoons (or 70 milliliters). These blood samples will be used to:

Compare the study medicine levels over the day. Identify and examine genes in your body that help process the study medicine and alcohol.

Measuring pupil size

Pupil size changes when people take the study medicine. To measure pupil size, you will look into a device while sitting still. This test takes about one minute and causes no discomfort.

Measuring oxygen in blood

To measure how much oxygen is in your blood, we will place a small plastic clip on one of your fingers. You may remove the clip at any time to go to the bathroom.

Blood Pressure

We will measure your blood pressure using the same kind of machine your doctor uses.

Information processing and balance tests

You will take the same information processing tests that you took on the first visit. This visit, we will add some balance tests that involve sitting and standing. These tests will last about 75 minutes and will be repeated three times during the day.

Pain Stimulus

There will be cold water to put your hand in, the same way as your first visit. There will be warm water to place your hand in that will eliminate any pain. We will ask you the same questions that we asked in your first visit. You do not have to answer any question that you do not wish to answer.

Study Pill (medication)

After you have taken all the tests once, you will be given the study medication, oxycodone. This pill is like other pain medication, such as Percocet or Vicodin. About 1 hour after taking the pill, you will repeat the tests.

After all the tests have been done twice, you will relax for about 3 hours and then repeat the tests.

About 7 hours after taking the study medication, you will take the final set tests. The purpose of waiting this long is to make sure the effects of the medicine are gone or nearly gone from your body before you leave for home. However, urine tests may detect oxycodone up to three days.

Below is an outline of Visit 2:

Visit 2 Study Procedures	**Approximate Time**
Breath and urine test	5 minutes
Insert IV for blood samples	10 minutes
Attach finger clip, measure blood pressure, pupil size, and draw blood sample from IV	10 minutes
Information processing and balance tests	75 minutes
Pain stimulus and other effects questions	10 minutes
Take study medication (oxycodone)	10 minutes
Take blood pressure, measure pupil size, draw blood from IV – 0, 30, 60, 90 and 120 minutes following medicine then every 60 minutes	10 minutes
RELAX	1 hour
Information processing and balance tests	1¼ hour
Pain stimulus and other effects questions	10 minutes
LUNCH	30 minutes
RELAX	2¾ hours
Information processing and balance tests	1¼ hour
Pain stimulus and other effects questions	10 minutes

RELAX	2 hours
Information processing and balance tests	1¼ hour
Pain tolerance test and other effects questions	10 minutes
LEAVE FOR HOME	**Total time: 9-10 hours**

RISKS, STRESS, OR DISCOMFORT

Description of any procedures that may result in discomfort or inconvenience

Pain stimulus. You may experience pain, but you will be in control of stopping the pain when you wish by removing your hand from the cold water. The pain will not continue after you place your hand in the warm water.

Questions. We will ask questions about your health and alcohol drinking habits. You may consider some of these questions to be personal. We do not expect these questions to make you uncomfortable; however, you do not have to answer any question you do not wish to answer.

Information processing tests. The results of these tests show how quickly and how well you can solve problems and remember words. The results of these tests are for research only and will not be shared with you. This may make you feel anxious or worried.

Balance tests. You may feel unsteady from the repeated motions. A staff member will be near you to make sure you do not fall.

Steering test on computer. You may experience some mild motion sickness from this task. You do not have to continue the task if you develop this feeling.

Blood sample. The needle to collect blood samples may cause discomfort when it is first placed in the vein. The pain should be brief and there should be no pain when blood samples are taken. Sometimes when the needle is taken out, there can be bruising or a small amount of bleeding.

Potential risks of the study:

Although the study medicine (oxycodone) is a well-studied drug, there may be risks that are currently not known. We may need to contact you if we learn of a new study risk, even if you have completed the study. You may be asked to sign a new (updated) Consent Form to document that the new information has been explained to you. Below are study-related risks that are known at this time:

Oxycodone. You may experience side effects of oxycodone, which include: mild drowsiness, nausea and vomiting, dizziness, holding urine (urinary retention), itching, a feeling of uneasiness, decreased breathing.

You will be given a low dose of oxycodone, making these side effects less likely. However, we will ask you several times during visit 2 if you are having any side effects. If the side effects get worse, we will treat you. If the study drug causes severe effects, we will give you a medicine that reverses its effects. As with any drug, there may be side effects that we don't currently know about.

Lidocaine. We may use a small amount of lidocaine when putting the needle in your vein (IV). This can cause some local stinging for a few seconds. Rarely, there may be an allergic reaction to lidocaine or the chemicals in it. This could cause itching and, if severe, wheezing or low

blood pressure (signs of anaphylactic shock), which can be life-threatening. Severe reactions will be treated. Please tell us if you have ever had a reaction to local anesthetic before (such as when you were visiting the dentist).

ALTERNATIVES TO TAKING PART IN THIS STUDY

You do not have to be in this study. If you do not want to be in this study, talk with your doctor about what treatments may help you**.**

BENEFITS OF THE STUDY

There is no direct benefit to you for being in this study. The results of this study may help doctors treat people who have pain better in the future

SOURCE OF FUNDING

The study team and/or the University of Washington is receiving financial support, from National Institute on Aging.

CONFIDENTIALITY OF RESEARCH INFORMATION

Your study information will be kept confidential and only the research team will have access to your information. We will use a randomly generated study code number to identify all of your data and the link between the code and your name will be kept separate from the other information collected. All paper study information will be kept in a locked file cabinet in the research office. Electronic information will be kept on a secure UW network with only the study team having access. An electronic copy of the data, identified only by the random study code number, will be kept at secure University of Washington computer servers, with no access to the link between the study code and identifying information. All of the information you provide will be confidential. However, if we learn that you intend to harm yourself or others, we must report that to the authorities.

Your blood samples will be collected and frozen in a secure place. The blood samples will be coded and like your electronic data are de-identified. They will be kept in a secure and locked laboratory at UW, processed as part of this study, and then destroyed at the end of the study. These samples will not be used for future research

We will use the information that we collect for this study only for research purposes, not for profit. However, researchers may use this research information in the future for the development of new ways to treat pain. Neither you nor your family will gain financially from discoveries made using the information and/or blood samples that you provide.

In the future, researchers may write articles using the information collected from this research study. Any future publications will not include any identifying information about you without your approval in writing.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

The U.S. Food and Drug Administration (FDA) reserves the right to review study data that may contain identifying information. A description of this clinical trial will be 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. Your participation in this study will be noted in your UW medical record. If you do not have a UW medical record, one will be created.

We have a Certificate of Confidentiality from the National Institute of Health. This helps us protect your privacy. The Certificate means that we do not have to give out identifying information about you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at the University of Washington, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA;
- Local authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

OTHER INFORMATION

You may refuse to participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled.

All study tests will be done at no cost to you. We will pay you as described below:

- Visit 1…… $40
- Visit 2 . . . . . $240
- Follow-up questions over the phone. . $20

If you complete both visits and the phone call, you will receive $300. If you complete only part of the study, you will receive payment for the time that you completed.

Payment will be sent by mail about 4 weeks after your phone call. You may receive an Internal Revenue Service Form 1099. If so, your social security number will be used for this purpose.

RESEARCH-RELATED INJURY

For a life-threatening problem, call 911 right away or seek help immediately. Contact ontact Dr. Gregory Terman 206.616.2668 (office) or call his pager 206.559.7660) when the medical emergency is over or as soon as you can. For all other non-urgent medical problems during business hours please contact Dr. Gregory Terman at 206.616.2668 or call his pager 206.559.7660. He will treat you or refer you for treatment. For non-urgent, non-medical problems related to this research, contact study staff at 206.616.3075.

If you are injured as a result of being in this study, necessary medical treatment will be offered at a UW Medicine facility. The costs of the treatment may be billed to you or your health insurance just like other medical costs, or it may be covered by the UW's discretionary Human Subjects Assistance Program (HSAP), depending on a number of factors. The researcher may request HSAP coverage by following established procedures. If you wish to request HSAP coverage

yourself, contact the researcher or the UW Human Subjects Division at hsdinfo@uw.edu or 206-543-0098. Ask the researcher if you would like information about the limits and conditions of the HSAP. The UW does not normally provide any other form of compensation for injury. However, the law may allow you to seek payment for injury-related expenses if they are caused by malpractice or the fault of the researchers. You do not waive any right to seek payment by signing this consent form.

Printed name of study staff obtaining consent	Signature	Date

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098. I give permission to the researchers to use my medical records as described in this consent form. I will receive a copy of this consent form.

Printed name of subject	Signature of subject	Date

Copies to: Researcher
Subject
Subject's Medical Record (if applicable)