

Control Driver Verbal Consent

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Sponsor / Study Title: **National Highway Traffic Safety Administration / “Crash Risk Associated with Drug and Alcohol Use by Drivers in Fatal and Serious Injury Crashes”**

Protocol Number: **1**

Principal Investigator: **Dennis Thomas, Ph.D.**

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Driver verbal consent script

“We are conducting a voluntary and anonymous driver survey. You are being asked to participate in a research study to better understand how medications and other drugs may impact motor vehicle crashes. The survey and breath test take just a few minutes and you will be paid \$5.00 upon completion of both. There is no cost to you. You may skip any question or stop participation at any time. The survey is completely anonymous as none of your responses will be directly linked to you in any way. You will complete the survey on a tablet computer, and I can assist you if needed. This part should take about 5 minutes. If you agree to continue now, you will read more information on this tablet about the study and then you can decide if you want to take the survey. May we continue?”

Tablet consent language

By proceeding with this survey, you are consenting to allow your responses to be included in the research effort that is examining how medications and other drugs impact motor vehicle crashes. Survey questions ask about your background, where you are driving to and from, and opinions about driver safety. You will then be asked to give a breath sample, and you may be asked to give a small blood sample.

You must be 18 years or older to take part in this study. All results of the study will only be reported at the group level and your responses to this survey cannot be linked to you in any way. We do not expect any direct benefit to you, but you may help improve traffic safety in the future. We will give you a copy of information about this study with contact information for study staff. Do you have any questions right now that I can answer?

Driver consent on tablet

By pressing “Continue” below, you agree to participate.

Driver Breath Sample Verbal Consent:

“Now I’d like to get a sample of your breath. The results are put into the study database. There is no link to your identity. Our device does not display any readings that I can see, so there is no risk to you. [Show Preliminary Breath Test device to subject]. This will take just a few seconds. Do you have any questions right now for me? Are you willing to participate in this part of the study?”

“I will indicate on my survey that you said”: YES NO

Blood Draw Verbal Consent (Initial consent):

“We are also asking individuals to give a blood sample for this study. If you provide the sample, I will pay you \$50. The purpose is to measure some blood components that may be related to driving safety. This is completely anonymous and the results are sent directly to the lab and analyzed. There is no way the results can be matched with you. Leftover blood will be destroyed, and no genetic testing will be done. I am a licensed phlebotomist (nurse or EMT) and it should take about five minutes. To participate in the blood in this part of the study, you must not be taking any blood thinners (like Coumadin), or receiving injections such as Calciparine or Liquaemin, and not have a blood disorder such as hemophilia. Do you have any questions right now that I can answer? Are you willing to participate in this part of the study?”

“I will indicate on my survey that you said”: YES NO

Consent Information

Purpose:

The purpose of this study is to identify factors contributing to safe and unsafe driving. Volunteers are being asked to take part as “control” participants. These are individuals who were driving on the road, and were not involved in a traffic incident or in a crash.

Procedures: This study has three parts:

1. Taking a short survey
2. Giving a breath sample
3. Giving a blood sample (about 10 mL, or 2 teaspoons)

Risks and Benefits:

There is no direct benefit to those who take part in this study. It is hoped that others will benefit from knowledge gained about traffic safety issues. Because data are anonymous and there is no way to connect information back to you as individual, there is no expected risk to participants. For those providing a blood sample, risks are considered minimal. This may include dizziness, nausea, fainting (with or without injury from falling), and soreness or bruising at the site of the blood draw. We will minimize these to the extent possible.

Personal Information: As this is an anonymous study about drivers, we are not collecting any information that can identify you individually. We are not collecting information about your name, address, driver’s license, and there is no way we can link your personal information to this study. No genetic testing will be done.

Confidentiality:

All results of the study will be reported at the group level and survey responses will not be linked to participants in any way. Leftover blood may be stored for up to 2 years, then destroyed. No genetic testing will be done.

Costs/Compensation:

There is no cost to you for taking part. Participants are paid \$5 for a breath sample and \$50 for a blood sample.

Voluntary Participation:

Your participation in this study is completely voluntary and you may withdraw at any time. If you withdraw before the sample collections, however, you will not receive payment.

Contact Information:

If you have any questions about the study, you may call the study’s Principal Investigator, Dennis Thomas, Ph.D. at (203) 323-8464. This study has been reviewed by Advarra IRB, which is a committee to help ensure that your rights and welfare are protected. If you would like to contact them about your rights as a research participant, their email address is

adviser@chesapeakeirb.com and the toll-free number is 877-992-4724. The study number is Pro00022129. The University of Florida's Institutional Review Board also reviewed this study, IRB201800117. Their number is 904-244-3155.

Participant Statement for Blood Draw

If you qualify and agree to provide the blood sample, please check below.

I certify that I am at least 18 years old. I am not taking any blood thinners and have not been diagnosed with any blood conditions such as hemophilia.

I acknowledge that the procedure has been explained to me and that I have had the opportunity to discuss the blood draw procedure with the Certified Phlebotomist (or nurse or EMT). I understand that all blood results are anonymous. I further understand that my participation is completely voluntary and that I may withdraw from this part of the study at any time.

I have read the foregoing Paper Consent Information Sheet and agree to the terms set out for being a volunteer participant, and I give my consent to have the Certified Phlebotomist (or nurse or EMT) draw my blood today.

- I agree to provide blood samples
- I DO NOT agree to provide blood samples

Witness _____

Month: _____ **Year:** _____

Thank you for Your Time!
[for those who do not participate in breath or blood sample]

You were asked to **VOLUNTARILY PARTICIPATE** in a voluntary and anonymous research study funded by the Department of Transportation's National Highway Traffic Safety Administration to better understand the drug crash risk patterns on our nation's streets. This type of study is a valuable way to learn how we can improve traffic safety. We respect your right to decline taking part in the breath or blood sample request.

In keeping with our mission of protecting our nation's drivers, I collect general observational data on all drivers who enter the study area. If you have concerns about making it to your next location safely, please inform me before leaving the site so I can help you. As part of our effort, we are prepared to provide assistance to drivers to safely make it to their next location.

If you have additional questions related to this study, you may contact the Principal Investigator, Dennis Thomas, Ph.D. at (203) 323-8464.