

# Informed Consent

## **Paperwork Reduction Act Statement**

*A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2127-XXXX. The information collected is necessary to help NHTSA to learn more about alcohol and drug-involved driving. We estimate that it will take approximately 10 minutes to complete. The information collected is voluntary. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Information Collection Clearance Officer, National Highway Traffic Safety Administration, 1200 New Jersey Ave SE, Room W45-205, Washington, DC, 20590.*

## **Data Collector Greeting Script and Screening Items**

### **(Read aloud by data collector)**

“Hi, my name is \_\_\_\_\_. You are being asked to VOLUNTARILY PARTICIPATE in an anonymous research study by the National Highway Traffic Safety Administration about traffic safety that deals with medications, alcohol, other drugs, and roadway use. You will be asked to provide a breath sample, a saliva sample, and answer a short questionnaire. If you complete the full survey, you will receive a \$20 cash payment. The entire study takes less than 10 minutes, and you may stop participating at any time without penalty, but you must complete the full survey to receive payment. Again, this study is completely anonymous, which means none of the information or samples provided can or will be directly linked to you in any way. If you would like to continue, there are a couple questions I need to ask to make sure you qualify. May we continue?”

“I will indicate on my tablet you said”:

YES

NO

### **1: Are you at least 16/18 years old (depending on the State’s age at which an individual may legally consent to participate in a research survey)?**

- ☐ Did not ask (person is obviously over the age limit)
- ☐ Yes
- ☐ No (not eligible)

### **2: Did you hear about this survey before we alerted you to it?**

- ☐ Yes
- ☐ No

### **3: If yes, how did you hear about this survey? (Data Collector determines if they sought out the survey)**

- ☐ Sought out survey (not eligible)

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☐ Did not hear about the survey

If ineligible: “I’m sorry but you do not qualify to participate in the study. This sheet contains information about who we are and what the study is about. It also contains contact information if you have any questions or concerns. Thank you very much for your time. Give me a moment to let my team know you are leaving so you can leave safely. Have a great day (daytime) / night (nighttime)!”

If eligible: “Congratulations! You qualify to participate in the study. You will read more information about the study on this tablet and officially decide if you want to complete all or some of the study activities.”

**(Hand tablet to participant to read Consent Form)**

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## Consent Form

Thank you for your interest in this study. Feel free to ask the researcher questions at any time. The purpose of this study is to collect information related to the use of medications, alcohol, and other drugs by drivers and other roadway users. Your participation is voluntary. You may decline to participate in the study without penalty to you. As part of this study, you will provide a breath sample, a saliva sample, and answer a short questionnaire about traffic safety. The entire study will take less than 10 minutes. Your participation will be anonymous. You do not need to provide your name or any other information that will identify you. The breath, saliva, and questionnaire information will be stored by a study-assigned identification number that cannot be linked to you in any way.

By pressing “**Yes**” below, you are volunteering to participate, and data collection will begin.

## Voluntary Participation

- Your participation in this study is completely voluntary.
- You are free to leave at any time without penalty.

## Benefits

- There are no benefits to you for participating in the study other than the \$20 cash payment for your participation when you complete the study.
- The results obtained from this study will benefit traffic safety by providing a better understanding of the use of potentially impairing medications, alcohol, and other drugs by drivers on the roadway.
- If you or the research staff think you may be unsafe to drive for any reason, the study will offer you assistance to make sure you reach your destination safely.

## Confidentiality

- This study is completely anonymous.
- You were selected completely by chance.
- All information and samples collected from you will be maintained anonymously and cannot be linked to you.
- This study is not for law enforcement purposes and will not determine whether you have committed a violation of law.

## Procedure

This study has three parts:

1. Giving a breath sample
2. Giving an oral fluid (saliva) sample
3. Taking a short questionnaire. You are free to skip questions.

## Breath Sample

- Your breath sample will be taken by blowing into a preliminary breath test device. There is no physical discomfort associated with the submission of a breath sample.
- Results of the alcohol breath test are not visible, and results will not be provided to you.
- You are not suspected of being impaired—this information is requested from all

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participants.

## Oral Fluid Sample

- For the oral fluid sample, you will be asked to place a cotton collection pad under your tongue to absorb saliva. The pad may cause a brief sensation of dryness that will go away after the sample is collected.
- Collection takes about 3 minutes, and you will be asked to complete a questionnaire on this tablet.
- The oral fluid sample will be sent to a laboratory to test for the presence of medications and other drugs at a later date.
- Results of the oral fluid test are not immediately available and will not be provided to you.
- No DNA or other testing will be undertaken on the sample you provide.
- All samples will be destroyed upon conclusion of the study.

## Costs/Compensation

- There is no cost to you for taking part in this study.
- You will be paid \$20 cash if you provide **both** a breath and oral fluid sample.

## Contact Information

This study is being conducted by Dunlap and Associates, Inc. and its partners under contract from the National Highway Traffic Safety Administration.

If you have any questions about the study or this informed consent, you may call the study's Principal Investigator, Dr. Dennis Thomas, at (XXX) XXX-XXXX. This study has been reviewed by the Pacific Institute for Research and Evaluation Institutional Review Board (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 IRB@PIRE.org and the toll-free number is 866-PIRE-ORG (866-747-3674) ext. 1.

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The Office of Management and Budget control number is XXXXX. A paper copy of this information is available upon request.

- ☐ **YES, I consent to participate.**
- ☐ **NO, I do not consent to participate.**