Informed Consent for Participants in Research Projects Involving Human Participants

Title of Project: North American Fatigue Management Program

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I. Purpose of this Research/Project

The purpose of this study is to evaluate the potential benefits of the North American Fatigue Management Program (NAFMP). This will help us develop better ways at: (1) improving driver sleep quantity and quality, psychomotor performance, eating habits and exercise habits; (2) improving carrier best practices in scheduling and safety climate; and (3) reducing near-crashes or crashes, missed work days, and health care claims. Data from this study will be used in a confidential way to understand commercial vehicle driving. This Informed Consent Form is to explain your role in this study. You will be given a Smartphone (which will be used to complete various questionnaires) and watch (that measures your sleep quality and quantity).

II. Procedures

If you agree to participate in this study, you will be asked to do the following:

1. Read and sign this Informed Consent Form.
2. Fill out a W9 form.
3. Complete several questionnaires up to four times over the course of the 8-month study (months 1, 2, 5, and 8), including: demographic questionnaire, diet and exercise, wellbeing, family interactions, and job satisfaction.
4. Drive your vehicle equipped with study instrumentation for up to 8 months on your normal route(s). The vehicle instrumentation includes a camera that records your face and upper body in the driver's seat and a second camera facing out the front of the truck at the forward road. Video and audio are recorded in 30-second snippets (15 seconds before, 15 seconds after) surrounding an event of interest such as hard braking or acceleration, hard lateral swerves, speeding (10 mph over the posted speed limit). The corresponding vehicle data is also collected at the same time (how hard you brake, your speed, GPS location, etc.).
5. Wear an actigraph watch for up to 8 months. This watch is always to be worn (unless swimming) and will monitor your sleeping patterns. You will be required to charge the watch battery once per week in order to keep it running.
6. Complete the following assessments three times a day, on both working days and non-working days. On working days, you will complete each assessment prior to the start of your first driving period, approximately halfway through the total driving period for your day, and at the end of your driving period. On non-working days, you will complete each assessment within two hours of waking, approximately halfway through you day, and within two hours of going to bed. During each of the described time periods, you will complete:
    a. A psychomotor vigilance test (PVT) that requires you to look at the Smartphone screen and tap the screen when you see a counter appear at random (chance) intervals during the 3-minute test. This test measures your reaction time.

Virginia Tech Institutional Review Board Protocol No. 17-1087
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b. A drowsiness assessment, caffeine diary, perceived stress diary, and a sleep/wake/duty diary on the provided Smartphone.

These assessments will take approximately 30 minutes each day. You will also be required to charge the Smartphone approximately once per day in order to keep it running.

7. Participate in a brief (approximately 5 – 10 minute) phone call with a researcher, once a week, to review your assessments.
8. Attend a 30-minute debriefing meeting at the end of your participation to return the actigraph watch and Smartphone. You will also be asked to provide your feedback from the study to a member of the research team at this time.
9. Complete various portions of the NAFMP, including the following modules (dependent on your carrier): Driver Education, Family, and Sleep Disorders.
10. Study participants should understand the research team will obtain carrier records, including existing crash data, electronic log data, carrier crash reports, missed work days, turnover rates, and costs associated with the NAFMP (training, recruiting new drivers, crash costs, compensation claims, etc.).

For this study we will be collecting data from up to 180 commercial-vehicle drivers like you. The starting day of data collection is determined by the date when your truck is instrumented and you obtain your watch and Smartphone.

III. Risks and Discomforts

There are some risks and discomforts to which you may be exposed to in volunteering for this research. These risks include:

1. The risk of filling out the questionnaires is minimal and similar to completing office paperwork.
2. The risk that if the provided phone is lost or stolen, or confiscated by law enforcement or an employer, that these other persons will be able to view the research data and learn a driver's participant number.
3. The risk of a crash associated with driving a truck as they usually do.
4. If you drive into an area where cameras are not allowed, including international border crossings, certain military and intelligence locations, and certain manufacturing facilities, there is a risk that you may be detained or arrested or that your vehicle may be impounded.

The following precautions will be taken to ensure minimal risk to you:

1. The participant's participation (or withdrawal) will not have an influence on their status as an employee with their current company.
2. The data collection apps on the provided Smartphone will not operate while the vehicle is in motion.
3. The participant's name will not be stored with their data, only a Participant ID number (e.g., Participant 001) so that it is not possible to identify a participant from their parametric data.
4. If the provided Smartphone is lost or stolen, we will perform a remote data wipe. However, the research data will be viewable up to that point.

5. All vehicle data (video and parametric) will be encrypted at the time it is collected (e.g., when the file is written) and will not be decrypted until it is loaded onto a Seeing Machines server. Once the data arrives at Seeing Machines, it will be stored on a secure server. Seeing Machines will delete their copy of the data at the end of the study.

IV. Benefits

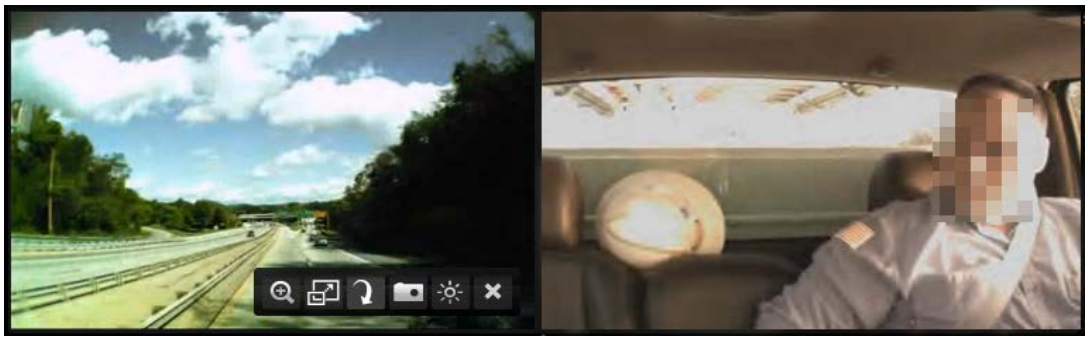
There are no direct benefits to you for the data collection portion of this study, other than you will have the opportunity to be involved in this very important research study.

V. Extent of Confidentiality

The data gathered in this experiment will be treated with confidentiality. Shortly after participating, your name and the company you work for will be separated from the data and replaced with a number. That is, your data will not be attached to your name, but rather to a number (e.g., Participant 001, Location A). It is possible that the Institutional Review Board (IRB) may view this study's collected data for auditing purposes. The IRB is responsible for the oversight of the protection of human subjects involved in research.

While you are driving the vehicle, a camera will record 30-second snippets (15 seconds before, 15 seconds after) if the Seeing Machines is triggered because of an event of interest such as hard braking, hard acceleration, hard lateral swerve, speeding (10 mph over the posted speed limit), or random baselines. Video of your face and out the front of your truck will be recorded during this 30 seconds, as well as audio. An example is shown below. Please note that the driver's face has been blurred in this image, but your face will not be blurred in the collected data.

All Seeing Machines data will be encrypted at the time of data collection and will be decrypted only once it arrives back at Seeing Machines and will be stored on a secure server. Seeing Machines will delete their copy of the data at the end of the study.



This study will collect existing data that may be used to personally identify you, such as GPS and the date and time of driving events/crashes. Authorized employees of the research sponsors, and authorized research team personnel will have access to the data collected in this study. Other qualified researchers may be given limited access to this type of identifiable data (crash date/time), solely for authorized research purposes and with the consent of an IRB. This limited access will be under the terms of a data use license or contract that, at a minimum, provides you with the same level of confidentiality and protection provided by this Consent Form. However,

even these qualified researchers will not be permitted to copy raw study data that identifies you, or that could be used to identify you, or to remove it from the secure facilities in which it is stored without your consent. A de-identified data set (i.e., with no information that could be used to identify you) will be posted online at the end of the study for public use.

It is expected that the data we capture throughout the course of the entire study will be a valuable source of data on how drivers respond to certain situations (e.g., how safe you drive when well rested) and how the roadway and vehicle might be enhanced to improve driver safety. Researchers who study traffic congestion and traffic patterns may also find the data useful. Therefore, it is expected that there will be follow-on data analyses using all or part of the data with PII indefinitely. These follow-on analyses will be conducted by qualified researchers with IRB approval, as required by law, who may or may not be part of the original study team. In consenting to this study, you are consenting to future research uses of the information and videos we gather from you, consistent with the protections described above and elsewhere in this document.

To protect your privacy and confidentiality we have obtained a Certificate of Confidentiality from the Department of Health and Human Services, U.S. Government. This Certificate protects the researchers and project sponsors from involuntarily disclosing personally identifiable information about you in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level even under a court subpoena. This Certificate does not prevent researchers from voluntary disclosure on such things as child abuse, communicable disease, or threat to self and others. The Certificate does not prevent disclosure in the case of an audit by the U.S. government of federally funded research. While the Certificate will help us keep your participation in the study confidential, you should know that in some rare instances involving alleged improper conduct by you or others, you may be prevented by a court from raising certain claims or defenses unless you agree to waive the confidentiality protection. The researchers will use the Certificate to resist any demands for information that would identify you, except for the special cases explained previously in this section. The Certificate of Confidentiality is not an endorsement of the project by the Department of Health and Human Services, U.S. Government.

If you are involved in a crash while participating in this study, the data collection equipment in your vehicle will likely capture the events leading up to the event. You are under NO LEGAL OBLIGATION to voluntarily mention the data collection equipment or your participation in this study at the time of a crash or traffic offense.

VI. Compensation

You may receive up to $968 if you participate for the full 8 months of this study. Compensation of $121 each month will be delivered in the mail via a check. If you elect to withdraw from the study or if your employment is terminated, you will be compensated for your participation up to that time (each month will be prorated at $30.25 per week). You will be asked to return the actigraph watch and Smartphone if you end your participation early.

VII. Freedom to Withdraw

Participation in this research is voluntary. You are free to withdraw at any time without penalty. If you withdraw, are dismissed from the study, or if your employment is terminated, we will retain data collected before that time, but delete any data collected in the interval between when we become aware of the withdrawal/dismissal. If you withdraw from the study, or if your employment is terminated, you will be compensated for your participation up to that time. Withdrawal from this study will not adversely affect your employment status.

VIII. Approval of Research

This research project has been approved, as required, by the Institutional Review Board for Research Involving Human Participants at Virginia Polytechnic Institute and State University. You should know that this approval has been obtained and is valid for the dates listed at the bottom of this form.

IX. Participant's Responsibilities

I voluntarily agree to participate in this study. I have the following responsibilities:

1. You will be instructed to follow your company's safety policies.
2. You will maintain a valid CDL-A throughout the course of the study.
3. To follow the experimental procedures as well as I can.
4. To inform the experimenters if I incur difficulties of any type.

I understand that by participating in this study I agree to the following:

1. My employer will know that I am participating in this research study.
2. Seeing Machines will collect 30 second snippets containing video and audio data of me while I am driving my normal routes.

X. Participant's Permission

I have read and understand the Informed Consent and conditions of this project. I have had all my questions answered. I hereby acknowledge the above and give my voluntary consent for participation in this project.

If I participate, I understand that I may withdraw at any time without penalty.

_____	_____	_____
Participant's name (print)	*Signature*	Date
_____	_____	_____
Experimenter's name (print)	*Signature*	Date

Should I have any questions about this research or its conduct, I may contact:

Jeffrey Hickman, *Principal Investigator* (540) 231-1542, jhickman@vtti.vt.edu

If I should have any questions about the protection of human research participants regarding this study, I may contact:

Virginia Tech Institutional Review Board for the Protection of Human Subjects
Telephone: (540) 231-3732; Email: irb@vt.edu

Participants must be given a complete signed copy (or duplicate original) of the Informed Consent.