| **Form Approved**  **OMB No. 0920-xxxx**  **Exp. Date xx/xx/xxxx** |
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| **Consent to be in a Research Study**  ***Taxi/Rideshare Drivers and Fatigue Study***  CDC estimates the average public reporting burden for this collection of information as 30 minutes per response, including the time for reviewing instructions, searching existing data/information sources, gathering and maintaining the data/information needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Information Collection Review Office, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-XXXX). | | |
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|  | **Key Information** | * **We’re doing a study about sleep and alertness in taxi/rideshare drivers** * **If you’re a licensed taxi or rideshare driver in San Francisco, and plan to be for 5 months, you are eligible to take part** * **There are 5 study periods. Each study period is 10 days** * **The 5 study periods will be spread across 5-6 months** * **We will provide a device to wear on your wrist, all day, for the 10 days of each study period** * **We will provide a tablet or smartphone for use during the study.** * **In the last 7 of the 10 days of each study period, you will be asked to complete a 2-minute electronic diary and attention test, 5 times/day** * **We may ask you to complete a 3-hour online training** * **Being in our study is 100% optional. There are no penalties (like fines, costs or bad feelings) for not signing up** * **If you sign up, you can change your mind any time with no penalty** * **We will check on you via text or email to see if you have any questions or issues while you complete the study activities** * **We won’t interrupt during a shift or tell you to stop working** * **We will protect any information you provide as much as possible** * **No names or other personal information will be stored with the study data** * **Your data will be identified with a study code only** * **There is always a small chance, however, that data security could be compromised** * **In order to provide you with gift cards, the government requires that we get your address and social security number – information that we will store separately** * **We will not provide the company a list of who participated, although it is possible that you will be identified when you wear the wrist device, for example** |
|  | **Who is conducting the study?** | The National Institute for Occupational Safety and Health (NIOSH) is a federal agency that studies worker safety and health. We are part of the Centers for Disease Control and Prevention (CDC). NIOSH is partnering with the Washington State University Sleep and Performance Research Center, West Virginia University, Flywheel, Inc, and the San Francisco Municipal Transportation Agency. |
|  | **What is the purpose?** | The purpose of this study is to find ways that help drivers who transport passengers learn about sleep and how it impacts their health and work. Specifically, we will be looking at the impact of a training in sleep health and driving and wearing an electronic device on your wrist (like a Fitbit) and completing an app that measures alertness. To do this involves research on 180 drivers. |
|  | **What will I do?** | There will be a total of 5 study periods, each will be 10 days. Within the 10 days are 7-day periods where we will ask you to provide information about yourself and your driving to us.  At the beginning of each 7-day period you will be asked to complete 2 electronic surveys:  • Questions about your work, health and habits  • Questions about your knowledge of sleep health  These two surveys should take 60 minutes total to complete. These surveys can be completed at your convenience, but you need to do them at the beginning of each 7-day period.  You will be asked to wear a device on your wrist to measure movement nearly all day (except when showering or swimming, for example) for 10 days straight for a total of 5 times;  Also during this time, we will ask you to complete an attention test (a simple reaction time test) while holding or using one of our electronic devices, five times a day.  During this same time we will also ask you to fill out a sleep and activities diary when you wake up and when you go to sleep. Examples of diary entries include:  • the time you woke up/fell asleep  • nap time and length  • medications taken  • sleepiness and fatigue ratings during the day  In total, these daily tasks should take you about 60 minutes each day. We will talk to you beforehand to see when the best times would be in your day-to-day schedule to complete these tasks.  You may be asked to take an online training that could take up to 3 hours to finish. This training does not need to be taken all at once, you can do as many modules as you want at one time if you are asked to take the training. If so, you will be asked to complete a survey asking you about the training that will take about 15 minutes. You will only be asked to take the training one time. You do not have to take the training if you do not want to.  We will also ask you to submit a photo of yourself performing study activities (but not while driving) such as wearing or using the electronic devices or setting up your work or doing any of the activities recommended by the training if you are asked to take the training. Any photos require you to provide a signed photo release form that we will give you and will be used for scientific presentations, NIOSH research blogs, infographics promoting the study findings. These photos will be publicly available if they are included in study materials, like findings and sleep health promotion materials, tailored to reach the public. Submitting a photo is completely voluntary.  You may choose to complete the study tasks at your convenience as close to the decided upon times as possible, and you may choose to participate in all or only in some parts of the study. You have the right to refuse to answer specific questions or participate in specific aspects of the study. |
|  | **When, where, for how long will I be needed?** | All of your participation will be done virtually through phone/video calls to learn about the study and then in the privacy of your home where we will ship you the study devices you will be using.  We will start contacting drivers for a Summer, 2024 target.  You will be doing the study during your typical work and waking hours. Five (5) times a day, you will be asked to use a smart device to complete a daily diary and take an alertness test: right when you wake up, right before you go to bed, and at least three more times during your waking time—for example, during your first break, during your mid-shift meal and right before your last meal. You will be asked to do all this while also wearing a device on your wrist every day for 10 days. While driving the only study activity you will be doing is wearing the device on your wrist – absolutely no other study activities should be performed while driving. We estimate that this will take you not more than 1 hour per day. Before these 10 days start, our first visit together will take 1 hour to go through your tasks and baseline surveys. During these 10 days, we will also be checking in to see how you are doing, and, if needed, replace a broken device or a device low on battery. We will ask you to do this 5 separate times, spaced about a month apart.  We may also ask you to take a 3-hour training at your convenience between the 2nd and 3rd 10--day periods. At the end of your last data collection period you will repackage and ship the devices using a label we send you and we will answer any questions you might have for us. We will also ask for your feedback regarding your experience participating in this study. Including the enrollment and consenting process, the 50 total study days, and the baseline calls before each period, we estimate that participation in this study will take up to 56 hours of your time spread across 5-6 months. If you are selected to take the 3-hour training, your total participation will be 59 hours. |
|  | **Are there any risks?** | There are only very minor risks involved with this study. There are no known or perceived physical risks or harms associated with drivers doing their jobs while simultaneously wearing the device on your wrist appropriately, which functions and feels like a Fitbit or Apple Watch for activity tracking, or using the personal electronic device designated for completing surveys. The device on your wrist will be worn almost all of the time during data collection, including while driving. It is important no other study activity is conducted while driving so there is no risk for distracted driving.  Wearing the device on your wrist all day for 10 days straight may be uncomfortable. And, while it is not common, wearing it on your wrist for a long period of time could cause a skin rash for people with sensitive skin. If this happens, you will not be asked to keep wearing the device on your wrist. A possible solution is to remove the device, clean the device by wiping it down with water or a small amount of rubbing alcohol and wash your skin with soap and water; if, however, the problem continues, we suggest you remove it from your wrist and contact a member of the study team to discuss the issue and to determine whether you would like to continue participating in the study.  Since we will be collecting data non-stop while you sleep there may also be an over-identification of sleep patterns that may affect your sleep health but do not necessarily need medical attention. There may also be a risk of psychological stress from receiving individual feedback on some sleep health questions where we suggest you ask your healthcare provider about at your next routine medical appointment. The low risk of follow-up medical expenses if you choose to receive study results, the cost of medical appointments made if your healthcare provider suggests you continue medical assessment, and further costs for treatment or continued evaluation may occur. We consider all of these risks to be low.  You may be provided the results of a screening tool for sleep apnea. If you choose to follow up with a healthcare provider there might be a cost that you will be responsible for paying.  We also include pregnant participants if they wish to enroll and meet study criteria. There are no known risks to a fetus that could arise from participation in this study.  In addition, as in any study, there is always the risk of a breach of data security. If such a breach occurs it could cause psychological stress due to a loss of privacy. There is also a low risk that your coworkers may find out that you participated. We take these issues very seriously. All of the information we get from you will be stored on a private server dedicated to the study, to which only the research team and its partners directly involved with the study have access. Your data will be kept private and will only be described in general ways or along with other data.  If NIOSH researchers become aware of something that poses an imminent danger to yourself or others, the researchers will immediately notify you, other workers and the management at your company. |
|  | **Are there other benefits?** | There is one direct benefit to being in the study: the free online training for sleep health and measures to reduce fatigue. There are no additional benefits or costs for being in this study. Your participation in this research will help us design effective trainings and tools to promote sleep health and further safety habits among drivers who drive for a living.  In addition, you may receive very detailed information about your wake and sleep patterns, and about how your sleep quantity and quality may affect your alertness and attention throughout the day. You may receive a training about sleep health and how to become a better sleeper. This information is for your records only and will not serve as a diagnosis of any kind in any capacity.  You may decline to receive these results if you so choose. Upon request after your last “study day,” we will schedule a virtual debriefing with you where we will mail you a physical report printed out on paper which will detail the data that we collected on your during your participation. This data can include day-to-day summaries of scores, data, numbers, and trends related to sleep quality and quantity, and sleep health survey scales. |
|  | **Is my participation voluntary?** | Your participation in the study is voluntary. You may choose to answer any or all questions. You may decline to participate or drop out any time, for any reason, with no penalty or loss of benefits to which you are otherwise entitled.  Your participation in the study may be ended without your consent if you are unable or unwilling to follow the required study protocols or if we believe there is a risk to your safety or health.  If you decide to no longer participate in the study at any point, we will still use and analyze your data to answer our research questions to the extent possible and contact you with the contact information you provided to see if you would like a report of your sleep patterns and sleep health questions you were asked. |
|  | **What if I am injured or harmed at a NIOSH research facility or at another location where the NIOSH research project is being conducted?** | NIOSH will summon emergency medical aid by calling 911. If NIOSH finds your injury was a direct result of participation in the study and if appropriate documentation is provided, NIOSH may provide short-term medical treatment that it deems necessary to treat the immediate medical needs arising from the injury. In general, no long-term medical care or financial compensation of research-related injuries will be provided by NIOSH, the CDC, or the Federal Government. However, if you believe NIOSH has been negligent in conducting the research study and you believe you have suffered a harm as a result, you have the right to pursue a legal remedy under the Federal Tort Claims Act (28 U.S.C. §§ 2671-2680 and 28 U.S.C. § 1346(b)). To learn more about how to file a Federal Tort claim, call the General Law Division of the HHS Office of the General Counsel at (202) 619-2155 or go to [https://‌www.hhs.gov/‌about/‌agencies/‌ogc/‌key-personnel/‌general-law-division/‌index.html](https://www.hhs.gov/about/agencies/ogc/key-personnel/general-law-division/index.html). |
|  | **Will I be reimbursed or paid?** | You will receive $40 for each data collection period as a token of appreciation for your time and inconvenience. You will be asked to complete 5 data collection periods. If you complete these data collection periods, you will receive $200. You may also be asked to take a 3-hour online training where you will receive a total of $53.40 at a rate of $17.80 per hour for your time and inconvenience. You will need to complete an IRS W-9 form and the amount of payment that you receive will be sent to the IRS. |
|  | **What alternative procedures might benefit me?** | No alternative procedures are available for this study. |
|  | **Will my personal information be kept confidential?** | NIOSH is authorized to collect your personal information and will protect it to the extent allowed by law. Monitors, auditors, the IRB, and/or the regulatory authorities will be granted direct access to your study records for verification of study procedures and/or data, without violating the confidentiality of your data, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, you are authorizing such access.  Any personal information we collect from you will be kept confidential and secure to the extent allowed by law. During the fatigue data collection periods, for the purposes of collecting research data and answering our research questions, we will not ask you to give us information that could expose your identity. That being said, we will ask you for private confidential information that is kept completely separate from the research study data and used for non-research purposes in three specific cases:   * First, to get in touch with you during this study for checking in and for follow-up data collection periods, we will ask you for your contact information (phone number and email). * Second, in order to reimburse you for your effort, we will need to ask you to provide your name, social security number and contact information for the purposes of shipping the data collection devices to you and providing you with your reimbursement at the end of each data collection period. This information allows us to pay you and will not be used for any other purpose and will not be connected to the research data. However, we will not ask for this information if it is not required by law. * Third, if you are interested in a general list of our findings once we have completed our study and reviewed all the data, you can leave your contact information with us so we can send you this report once this part of the study has finished.   In these three cases, at no point will any of this personal information (phone number, email, social security number, name, etc.) be associated with, stored along with, or in any way connected to the research data we collect (for example, the results of your reaction times, or the surveys you have filled out). When the data collection is done, you have been reimbursed and a report of any results of interest have been provided to you, we will destroy your personal data no later than 1 year after the end of your last data collection period. Any publications using the data collected as part of the research study will preserve the confidentiality of your data and the privacy of your identity. We may work with research partners for specialized analyses through data use agreements designed to preserve the confidentiality of the data. |
|  | **Certificate of Confidentiality** | This research project has a Certificate of Confidentiality from the Centers for Disease Control and Prevention (CDC). Unless you say it is okay, researchers cannot release information that may identify you for a legal action, a lawsuit, or as evidence. This protection applies to requests from federal, state, or local civil, criminal, administrative, legislative, or other proceedings. As an example, the Certificate would protect your information from a court subpoena.  There are some important things that you need to know. The Certificate DOES NOT protect your information if a federal, state, or local law says it must be reported. For instance, some laws require reporting of abuse, communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop reporting required by the U.S. Food and Drug Administration (FDA). The Certificate also DOES NOT stop your information from being used for other research if allowed by federal regulations.  Researchers may release your information when you say it is okay. For example, you may give them permission to release information to insurers, your doctors, or any other person not connected with the research. The Certificate of Confidentiality does not stop you from releasing your own information. It also does not stop you from getting copies of your own information. |
|  | **Will I or anyone else receive study results?** | If requested by you, as part of the study activities, you will be given your individual results personally in the form of an individualized final data report. Also, if you are interested, we can provide a general list of our findings once we have completed and reviewed all of the data. If you wish to do so, please leave your contact information with us so we can send you this report once this part of the study has finished.  At your request, we will send a letter through certified mail or email directly to you with your individualized final data and the overall study findings, within approximately 6 months after the completion of the study. We will not send any individual information to your employer, any company, or union.  Significant new findings developed during the course of this research project that may relate to your willingness to continue participation will be provided to you. |
|  | **Will my personal information or samples collected from me be used in other research?** | We may remove your name and other identifiers from the information that we collect during the study and then use the information for future research studies without asking you for additional consent. We also may remove identifiers from the information that we collect and then share it with other researchers without asking you for additional consent. |
|  | **Is this a Clinical Trial?** | Yes. A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>. 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. |
|  | **Did I receive all necessary information?** | Is there anything about this research study that is unclear to you or you would like to discuss? |
|  | **Who can I talk to if I have more questions?** | For questions about this research study, contact the principal investigator, Cammie Chaumont Menendez, at cmenendez@cdc.gov or 304-285-6233.  For questions about your rights, your privacy, or harm to you, contact the Chair of the NIOSH Institutional Review Board (IRB) in the Human Research Protection Program at 513-533-8591. |
|  | **Your signature** | The study was explained to me. My questions were answered. I agree to be in the study.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Printed name of participant  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Participant signature Date  I have accurately described this study to the participant.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  NIOSH representative signature Date |
|  | **Additional consent** | □ No, do not send me my individual exposure results.  □ Yes, please send me my individual study results.    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Printed name of participant  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Participant signature Date  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Participant mailing address (street address) (apt.#)  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  (city, state & zip code) |