



The National Institute for Occupational Safety and Health

## Consent to be in a Research Study

### Online training for law enforcement to reduce risks associated with shift work and long work hours

<b>1</b>	<b>Who is conducting the study?</b>	NIOSH is a federal agency that studies worker safety and health. We are part of the Centers for Disease Control and Prevention (CDC). NIOSH has partnered with Washington State University (WSU) to carry out this pilot study.
<b>2</b>	<b>What is the purpose?</b>	This pilot study will test a new online training program that NIOSH and Washington State University developed to educate law enforcement officers and their managers about strategies to reduce the health and safety risks that are linked to shift work, long work hours, and not getting enough sleep. The pilot study will examine participants' sleep before and after taking the training and ask their feedback on the training program.
<b>3</b>	<b>Criteria for police officers participating in the pilot study</b>	These are the criteria for police officers to participate in the pilot study. <ul style="list-style-type: none"><li>• Patrol police officer working full time (no alternate assignment because of injury, illness, or other reasons)</li><li>• Working fixed night shift including hours of midnight to 6 AM (no rotating work schedules)</li><li>• Not pregnant or planning to become pregnant during the 12 week study period</li><li>• No travel across three or more time zones in the previous 3 months or plans for travel across three or more time zones during the 12 week study period</li><li>• New patrol police officers in their first field experience after graduating from the police academy who have worked less than 1 year as a police officer</li><li>• Experienced patrol officers who have worked 2 to 10 years as a police officer.</li></ul>

4

**What will I do?**

**When, where, for how long will I be needed?**

- 1) If you are interested in participating, you will send an email to Dr. Claire Caruso (policestudy@cdc.gov). After getting your email, she will schedule a phone call at a convenient time that will take about 30 minutes. During the call, she will ask if you meet the study criteria, explain the study, and answer your questions. Dr. Caruso will be available by phone (513-533-8535) or email to answer your questions during the study.
- 2) You will read and sign this informed consent and send it to Dr. Caruso in a postage paid envelop.
- 3) NIOSH staff will insert your ID number on your survey, diary, and actigraph files before sending these to you. The study number will enable NIOSH study staff to connect all your survey and actigraph data together. This will enable us to compare your responds before and after taking the training. The study ID number will not be visible on the actigraph device, diary, or survey.
- 4) NIOSH study staff will email you links for the surveys and diaries that you will fill out during the study.
- 5) During the study, you will have four conference calls with Dr. Claire Caruso.
- 6) You will have an initial 30-minute conference call with Dr. Caruso. She will mail you a wrist actigraph, which you will wear to record your activity and estimate the times of your sleep. Dr. Caruso will explain the study including the actigraph, online sleep diary, surveys, and answer any questions you have. You will fill out an online survey which asks basic information such as your age, work experience, your sleep, and worktime sleepiness.
- 7) For the next 28 days, you will keep an online sleep activity diary and wear the actigraph. While wearing the actigraph, you will go about your life as usual. You can remove the actigraph to bathe (although you do not have to – they are waterproof). Otherwise please keep it continuously on your wrist during this 28-day period. The online sleep activity diary takes about 1 minute at the beginning of your day and 1 minute at the end to complete. We are using the sleep diary and actigraph together so we can obtain a more accurate timing of your sleep and activity.
- 8) During week 3 of the study, NIOSH study staff will send you a link for the online training. This will take about 2 to 3 hours to complete. You can take the training at any times that are convenient for you. You can take it all at one time or over a series of several short time periods during week 3.
- 9) Immediately after taking the training, you will complete an online survey that will check what you learned and will ask your feedback about the training, for example what you liked or did not like. This survey will take about 10 minutes.
- 10) You will continue to wear the actigraph and keep the online sleep activity diary until the end of week 4 of the study.
- 11) At the end of week 4, you will have a 10-minute conference call with Dr. Caruso to answer any questions. You will mail back to Dr. Caruso the actigraph in a postage paid envelope.
- 12) No data collection occurs during the next 6 weeks which are weeks 5 to 10 of the study.
- 13) At the beginning of week 11 of the study, Dr. Caruso will mail you the actigraph and you will have a 10-minute conference call with her to begin wearing the actigraph and keeping the sleep activity diary for the next 14 consecutive days (during weeks 11 and 12 of the study).
- 14) At the end of week 12, you will have a 15-minute meeting with Dr.

		<p>Caruso to complete a 5 minute online survey. It will ask about your sleep and any changes you made since taking the training. Dr. Caruso will mail you a gift card for \$20, which will be a small token of our appreciation for your participation in this pilot test. You will mail back the actigraph in a postage paid envelope. After this conference call, your participation in the study ends.</p>
<b>5</b>	<b>Are there any risks?</b>	<p>We do not foresee problems from filling out the survey and sleep diary, wearing an actigraph, and taking the online training program. Researchers have safely used actigraphs for many years in studies. NIOSH study staff will keep the list matching the study identification number and your name and contact information on an encrypted folder on the NIOSH computer network. Only NIOSH staff working on this project will have access to the matched list. When we complete the study, we will destroy the matched list with your study identification number and name. When we publish the study results, we will report grouped data and will not report any individual's data. With these procedures, we think the chances are very low that the confidentiality of your data will be lost.</p>
<b>6</b>	<b>Is my participation voluntary?</b>	<p>The study is voluntary. You may choose to be in the study or not. You may choose to answer any or all questions. You may drop out any time for any reason and without consequences to you. However, please keep in mind that pilot testing the new training program is a critical part of developing effective training. We expect that once we finalize the training and release it to the public, law enforcement officers and their managers nation-wide will benefit from it. By completing the pilot study, you will be helping the law enforcement community across the nation.</p>
<b>7</b>	<b>What if I am injured or harmed at a NIOSH research facility or at another location where the NIOSH research project is being conducted?</b>	<p>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 <a href="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</a>.</p>
<b>8</b>	<b>Will I be reimbursed or paid?</b>	<p>We will give you a gift card worth \$20 after you complete the four conference calls with Dr. Caruso. The gift card is a small token of our appreciation for your participation in this pilot test.</p>

<p><b>9</b></p>	<p><b>Are there other benefits?</b></p>	<p>The new training will give you strategies for coping better with shift work, long work hours, and will give you strategies to improve your ability to sleep well and be alert on the job. After you take the training program and use the strategies in your daily life, you may benefit from improved health, safety, and sense of well-being. Your relationships with family, friends, and people at work may also improve because of improving your sleep and other daily habits. Your long-term health may also improve as you use these strategies since these reduce the chances for injuries due to fatigue and the development of a wide range of chronic diseases like high blood pressure, heart disease, and diabetes.</p>
<p><b>10</b></p>	<p><b>Will my personal information be kept private?</b></p>	<p>NIOSH is authorized to collect your personal information and will protect it to the extent allowed by law. There are conditions under the Privacy Act where your information may be released to collaborators or contractors, health departments or disease registries, to the Departments of Justice or Labor, or to Congressional offices. We will destroy your personal identifiable information after we complete the data analyses.</p>
<p><b>11</b></p>	<p><b>Will I or anyone else receive study results?</b></p>	<p>The online training program includes a sleepiness scale that you will fill out. The website points out that if your score is 10 or greater on the sleepiness scale that raises concern. You may need to get more sleep, improve your sleep practices, or seek medical attention to determine why you are sleepy. A score of 13 indicates you should see your healthcare provider. If your responses on the other sleep questionnaire indicate a high chance for a sleep disorder, we will inform you by mail. We will not inform anyone outside of the NIOSH research team about your responses on the surveys or actigraphs. If you have concerns about your sleep or sleepiness, you can contact Dr. Claire C. Caruso who can give information about finding an accredited sleep disorders clinic.</p>
<p><b>12</b></p>	<p><b>Who can I talk to if I have more questions?</b></p>	<p>For questions about the research study, contact the principal investigator, Claire C. Caruso PhD RN, 1090 Tusculum Avenue MS C-24, Cincinnati, OH 45226; <a href="mailto:policestudy@cdc.gov">policestudy@cdc.gov</a> or 513-533-8535.</p> <p>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.</p> <p>You can also contact the Chair of the Washington State University Institutional Review Board (IRB) in the Human Research Protection Program at (509) 335-3668.</p>

<p><b>13</b></p>	<p><b>Your signature</b></p>	<p>The study was explained to me. My questions were answered. I agree to be in the study.</p> <hr/> <p>Printed name of participant</p> <hr/> <p>Participant signature <span style="float: right;">Date</span></p> <hr/> <p>Address</p> <hr/> <p>Phone number</p> <hr/> <p>Email address</p> <p>I have accurately described this study to the participant. <i>[Optional]</i></p> <hr/> <p>NIOSH representative signature <span style="float: right;">Date</span></p>
------------------	------------------------------	---

Updated March 29, 2016