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Expiration Date: XX/XX/XXXX

Form 1462
Video Consent Slides

Under the Paperwork Reduction Act, a federal agency may not conduct or sponsor, and a person is not required to respond to 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 XXXX-XXXX (expiration date: MM/DD/YYYY). The average amount of time to complete this survey is 10 minutes. All responses to this collection of information are voluntary. If you have comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden send them to Information Collection Clearance Officer, National Highway Traffic Safety Administration, 1200 New Jersey Ave, S.E., Washington, DC, 20590.

NHTSA Form Number 1462

University of Pittsburgh
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

The EMS Sleep Health and Fatigue Education Study

(Electronic Video Consent)

NHTSA Form Number 1462

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Study

WHAT:

Dr. Patterson and his associates and the University of Pittsburgh are asking you to participate in this research study: The EMS Sleep Health and Fatigue Education Study

This research study is supported with funding from the National Highway Traffic Safety Administration and the National Association of State EMS Officials and the University of Pittsburgh.

WHY:

You are being recruited for this study to help researchers learn more about sleep health and fatigue education of EMS shift workers.

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To evaluate the impact of sleep health and fatigue education and training on indicators of EMS clinician sleep health and fatigue.

We are seeking to enroll approximately 1,000 EMS clinicians affiliated with multiple EMS organizations that operate within the United States.

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ELIGIBILITY:

In order to participate you MUST meet the criteria below:

1. 18 years of age or older
2. Currently working as an EMS clinician
3. Working a minimum of one shift per week
4. Working & residing in the United States
5. Working at one of the EMS organizations that has previously agreed to participate in this study
6. Have a cellular, mobile, or smartphone that can send and receive text messages
7. Willing to answer online surveys and respond to text-message queries for 7 days in a row every third week of the month for a total of 24 weeks/6 months.

Do you meet this criteria?

YES ☑ NO ☐

Participation:

You do not need to sign a consent form. Instead, you will only need to check the "I ACCEPT" box after watching this video.

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WHAT IS INVOLVED?:

If you agree to participate, you will be asked to register for the study using a secure, study-specific website developed by the University of Pittsburgh.

You will be asked to visit this website using the internet to securely login and answer a set of survey questions.

- The survey includes questions about your demographics, your sleep habits and fatigue, and shift work.

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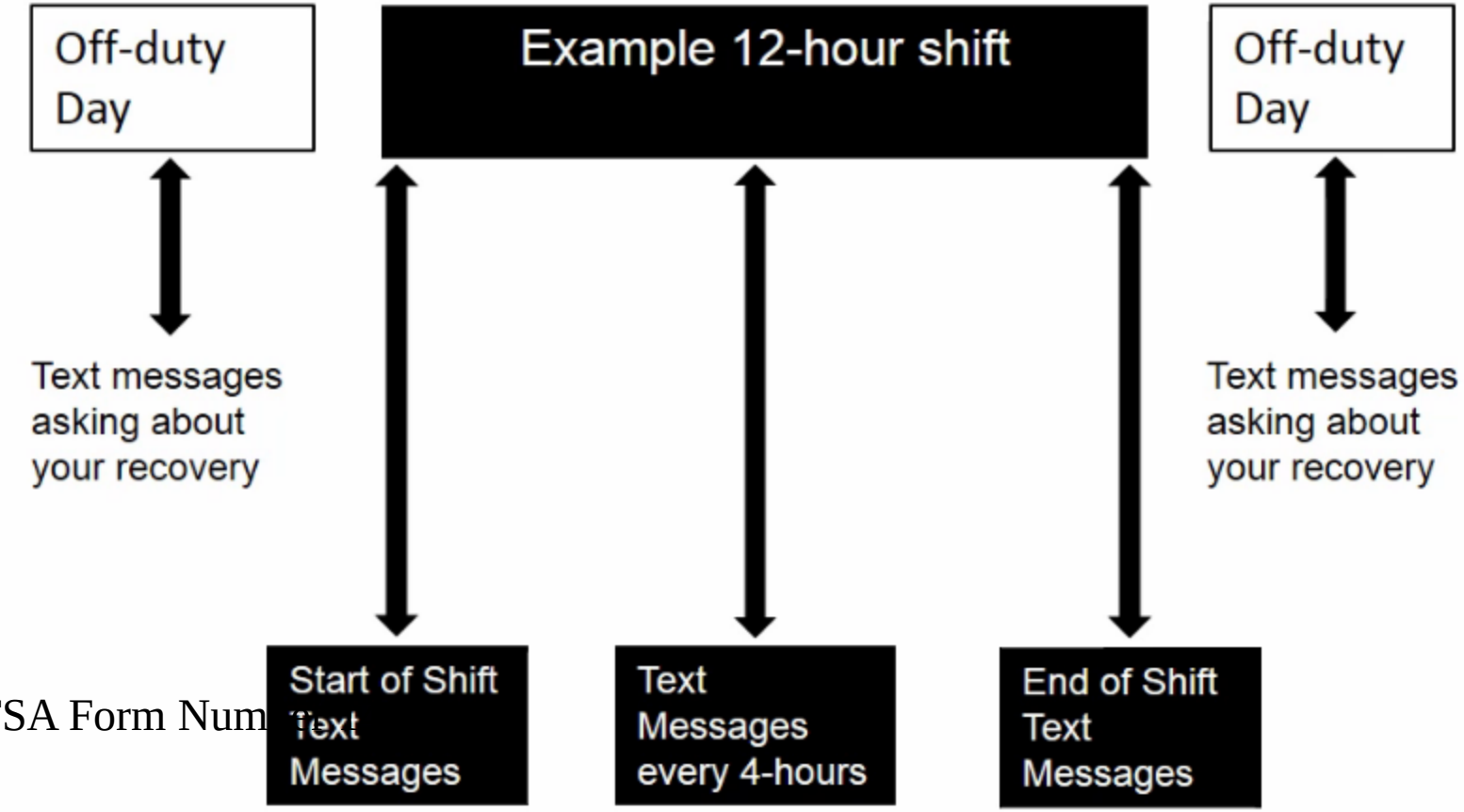
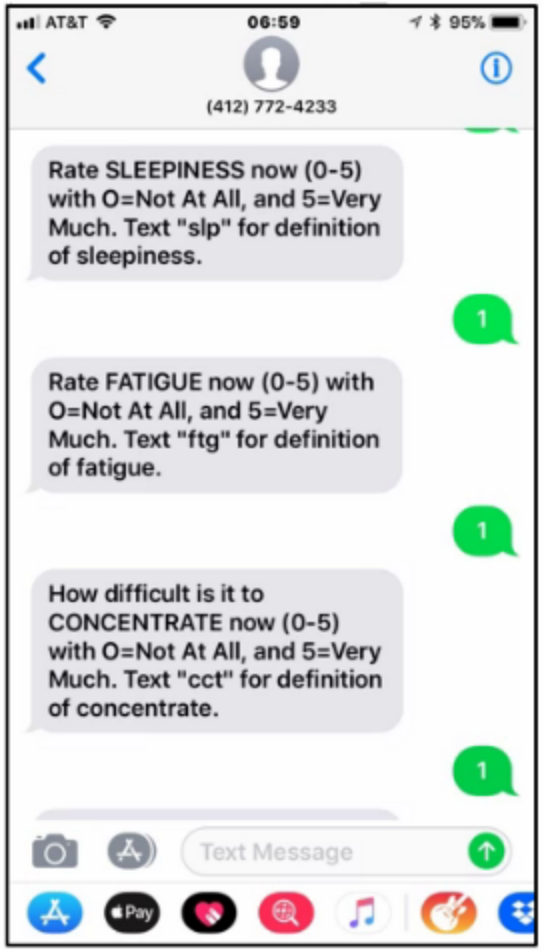
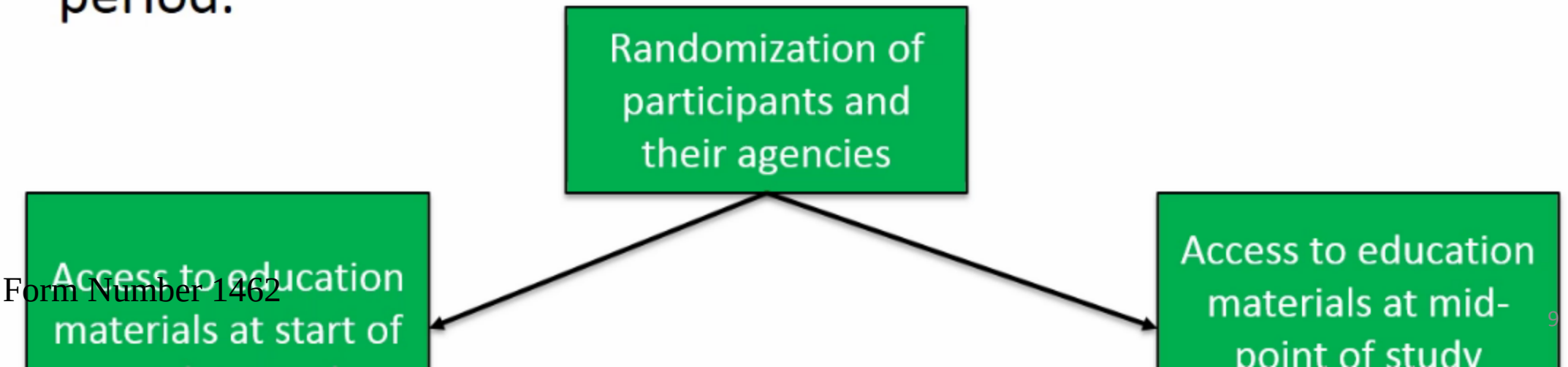
WHAT IS INVOLVED:

You will be asked to periodically use your mobile phone / cellular phone / or smart phone to answer a brief set of questions about your sleep and fatigue during both scheduled shifts and between shifts.





- All participants will be granted access to education and training materials that focus on sleep health and fatigue.
- Access will be provided with a secure link to a study specific website.
- All participants will be asked to watch these materials to learn more about sleep health and fatigue.
- A participant's access to these materials will be either at the start or mid-point of the study period. We will use a randomization procedure to determine when you are granted access; either at the start or mid-point of the study period.



What is involved:

You may also be asked to be a part of a subset of participants that periodically wear an Actigraph wristwatch for 7 consecutive days and complete a paper-based sleep diary.

- These Actigraph watches are used to objectively monitor sleep and wake cycles.
- If you wear an Actigraph watch, you may also be asked to complete a set of computerized measures at different time points during the study that measure your reaction time.
  - These reaction time measures are often used to objectively measure performance.

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Possible risks, side effects and discomforts:

1. The main risk is the study team's loss of data collected that measure sleep, fatigue, and reaction time. This is a small risk (less than 1%, less than 1 out of 100 people).
    - All precautions will be taken to maintain data security and confidentiality, including assigning code numbers to all data for purposes of data transmission, analysis, and storage.

2. You may find some of the study materials to be tedious, stressful and/or boring. You may decide to discontinue participation at any point during the study.

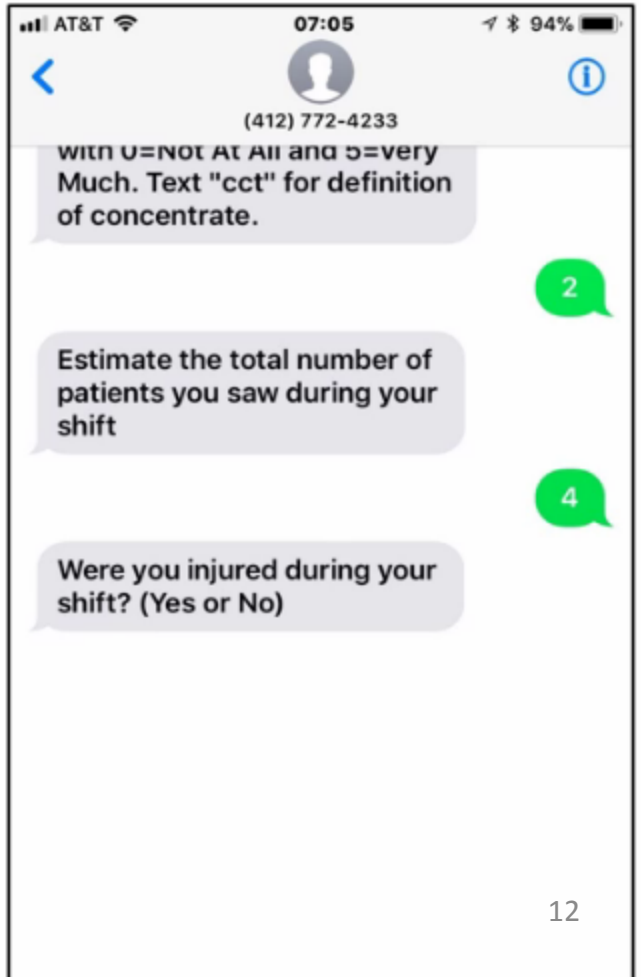
Possible risks, side effects and discomforts:

3. Prolonged time viewing a computer screen or other electronic device (such as a smart phone or tablet) may cause eyestrain.

- Most of the study materials will require your interaction with a computer or mobile smartphone or cellular device.
- You will be asked to view some of these materials on multiple days in a row (e.g. 7-days in a row). These materials include:
- Viewing and responding to text-messages

Other materials require less of your time.

- Eyestrain typically resolves within a few minutes by looking away from the computer.



Possible risks, side effects and discomforts:

4. The subset of participants that will be asked to wear a wrist-worn Actigraph device may experience some discomfort or irritation at the site where the Actigraph is worn.

- This device is commonly used to measure sleep and wake cycles and is a standard tool for research studies that aim to evaluate sleep and fatigue in shift workers.
- The device is most commonly worn on the left or right wrist. It can be removed during showers or baths, or other times when the wrist may be submerged in water for prolonged periods of time.
- If you are asked to wear one of these devices and volunteer to do so, we will provide instructions on how to wear it and remove it for brief periods to avoid irritation.
- You may at any time choose to remove the device and discontinue participation in this aspect of the research study.

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Possible risks, side effects and discomforts:

5. Some participants will be asked to complete a reaction time test at the start and end of scheduled shifts with an iPad/mobile device. The Psychomotor Vigilance Test (PVT) is a standard test that evaluates a person's reaction time by having the participant tap on the screen of the mobile device repeatedly over a period of 3-5 minutes.

- This tapping action may cause some discomfort to the finger. This discomfort typically resolves within a few minutes after completing the test.

- If you participate in this aspect of the study, you may decide at any point to not participate or to stop participation during the tests.

Additional costs:

If your cellular / mobile phone, or smartphone provider charges you for individual text-messages, you may experience charges on your bill that result from participation in this study.

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What does the study team have access to?:

The Principal Investigator, Co-Investigators and study personnel will be able to view all study materials and how you as a participant have interacted with these materials.

The study team will also have access to the data collected with the wrist Actigraph and PVT reaction time test as it is being collected.

Once the study has completed data collection, all of the data will be de-identified and examined in aggregate.

Potential Benefits:

You may experience benefits from this study in the form of an increased awareness of the dangers of fatigue and benefits of good sleep health.

You may learn more about how to improve sleep health and lessen your fatigue.

This study will help researchers and employers learn more about the impacts of shift work on health and safety, and may lead to improvements in the general health, sleep health, and safety of EMS clinicians.

Compensation

Remuneration in the form of a $20 Visa/Mastercard gift card will be provided to each individual EMS clinician at the end of the study period.

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What if I decide to NOT take part in this research study?:

Your participation in this study is completely voluntary. You should feel no pressure to participate. If you decide not to participate in the research study, you will not in any way harm your relationship with Dr. Patterson, his associates, or with the University of Pittsburgh.

You are free to stop participating in the study at any time. This too, will not harm your relations with Dr. Patterson, his associates, or the University of Pittsburgh.

Confidentiality

- The records of this research study will be kept completely confidential.
- In any publication, we will not include any information that will make it possible to identify you or your participation in the research study.
- Your de-identified research data and the documents that you signed for this research study may, however, be reviewed and/or photocopied by the University of Pittsburgh, or other persons / agencies as required by law or allowed by federal regulation.

Confidentiality

- Since you are being compensated for your participation in this study, your name, address, and social security number will be released to the Accounting Office. If the total reimbursement for your participation in research is greater than $600 in a year, this will be reported to the Internal Revenue Service (IRS) as income.
- Your Personally Identifiable Information (PII) will be kept secure and separate from your research study data. Your identity will not be linked to your research study data.
- Because we will de-identify your data, use a Participant ID to track your research study data, and keep your data secure, there is a strong defense against breach of confidentiality.

Authorization

- If you wish to take part in this research study, you will be asked to confirm your willingness to be involved at the end of this video.
- You will then be required to confirm your understanding of the consent by selecting the “I ACCEPT” button underneath this video before you can continue.
- This allows the research study sponsor and investigators to collect, process, and pass along de-identified research study data collected from you during the study to other team members.
- Note that the file containing your name, telephone number, and email will be kept separate from the research study data. No Personally Identifiable Information (PII) will be shared. There is a strong defense against breach of confidentiality.
- Also, of special note, your data will never be shared with your supervisor or employer, and therefore not used for disciplinary action.

Authorization

- As previously stated, your Personally Identifiable Information (PII) will be kept in a secure file separate from your research study data. The research study team will use your PII for purposes of maintaining contact and communication with you during the study. Your PII will not be shared with anyone not on the research study team. We will store your research study data on secure computer servers maintained by the University of Pittsburgh and the University of Pittsburgh Medical Center. These databases may be audited or accessed by the following:
  - [a] the study investigator and research staff of Dr. Daniel Patterson;
  - [b] the study sponsor and/or its associated companies (i.e., the National Highway Traffic Safety Administration in collaboration with the National Association of State EMS Officials); and
  - [c] regulatory or other governmental authorities of the United States, other persons authorized by he study sponsor, the University of Pittsburgh, and other persons or agencies as required or allowed by federal regulations.

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Final Notice:

You have been informed that your name, sleep health, and other relevant personal data will be collected and processed for the purpose of characterizing the impact of sleep health and fatigue education and training on key indicators of sleep and fatigue among EMS clinicians.

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Please select an option below this video:

Thank you for your time!