INFORMED CONSENT FORM
COVER PAGE

STUDY TITLE:
The Sleep and Teamwork in EMS Study (SaFTiE)

ClinicalTrials.gov Identifier: NCT04456764

University of Pittsburgh Institutional Review Board Identifier: STUDY19040354

Effective Date: 06/27/2022

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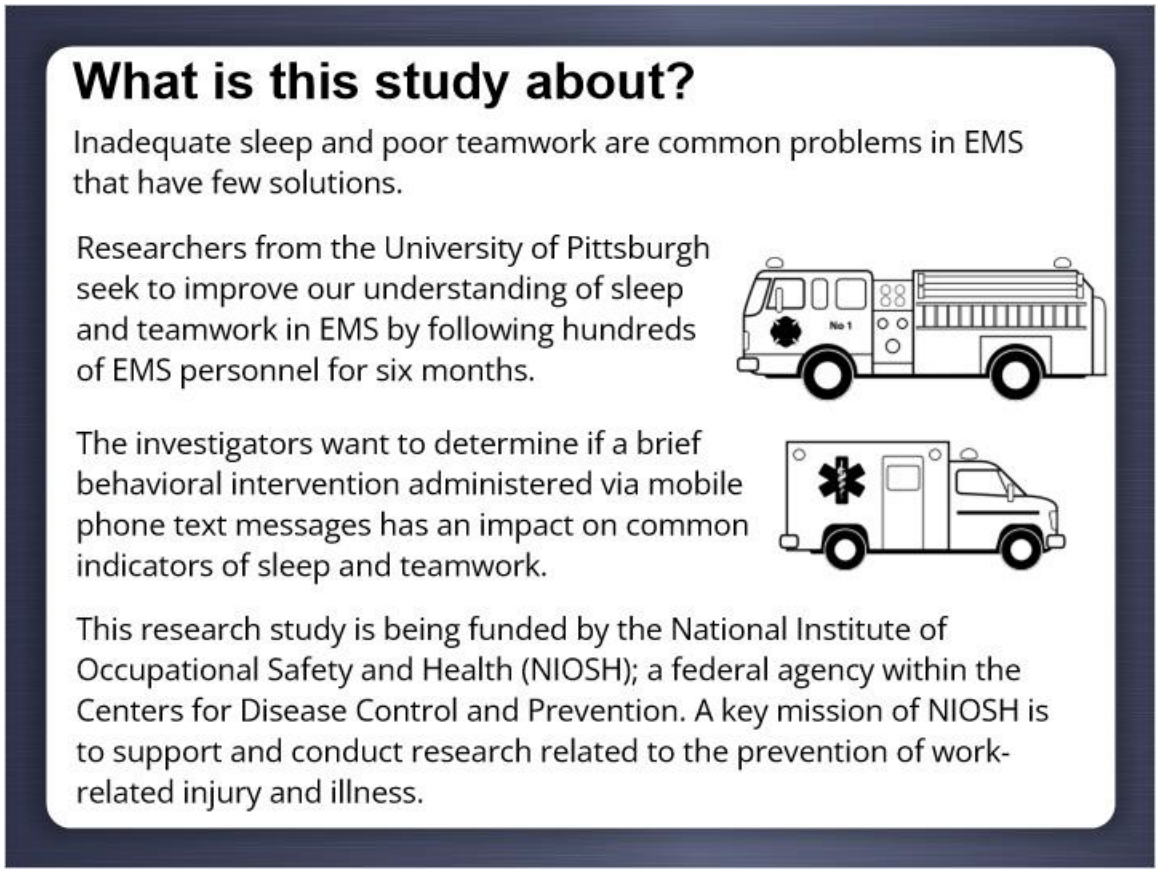
1.1 University of Pittsburgh

Notes:

Welcome to the video based consent for the Sleep and Teamwork in EMS Study led by Drs. Patterson and Guyette of the University of Pittsburgh Department of Emergency Medicine.

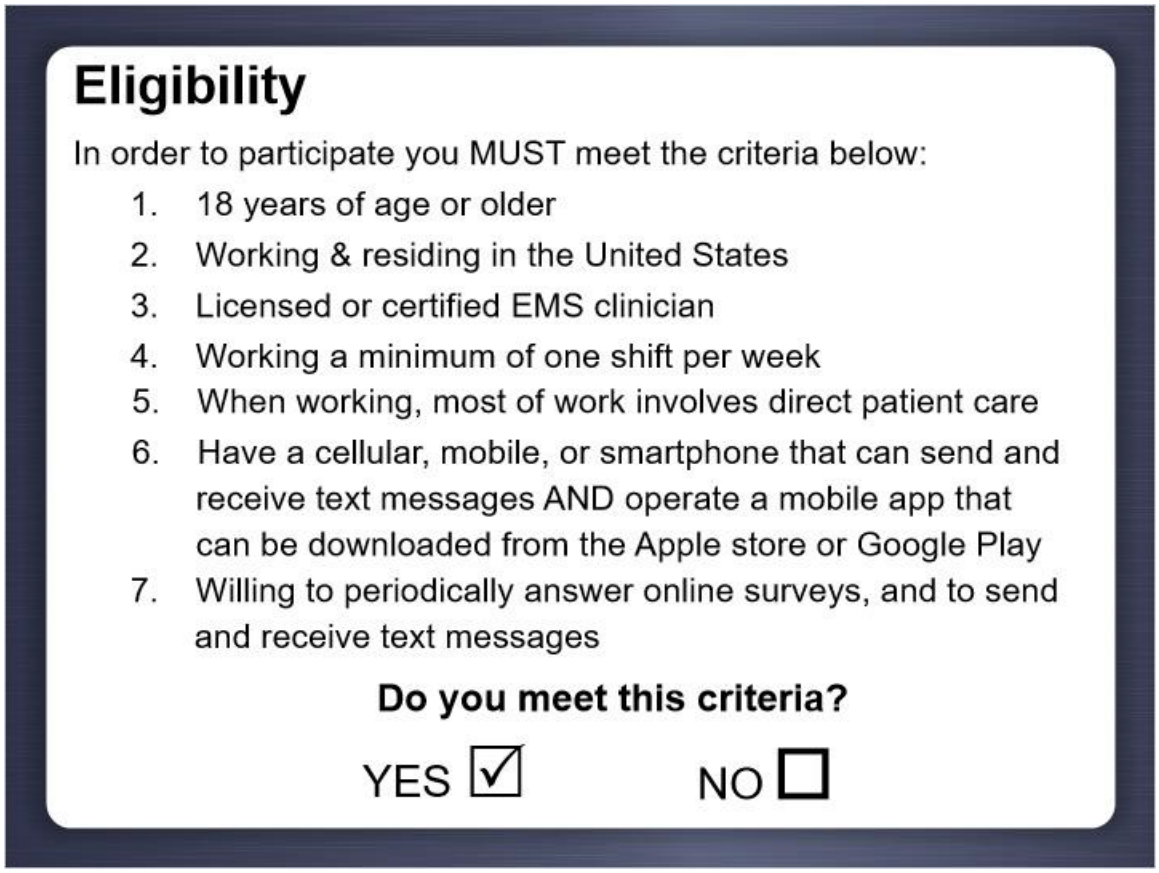
1.2 What is this study about?



Notes:

Inadequate sleep and poor teamwork are common problems in EMS that have few solutions. Researchers from the University of Pittsburgh seek to improve our understanding of sleep and teamwork in EMS by following hundreds of EMS personnel for over nine-months. The investigators want to determine if a brief behavioral intervention administered via mobile phone text messages has an impact on common indicators of sleep and teamwork. This research study is being funded by the National Institute of Occupational Safety and Health (NIOSH); a federal agency within the Centers for Disease Control and Prevention. A key mission of NIOSH is to support and conduct research related to the prevention of work-related injury and illness.

1.3 Eligibility



Notes:

In order to participate you MUST meet the criteria below:

1.18 years of age or older

2.Working & residing in the United States

3.Licensed or certified EMS clinician

4.Working a minimum of one shift per week

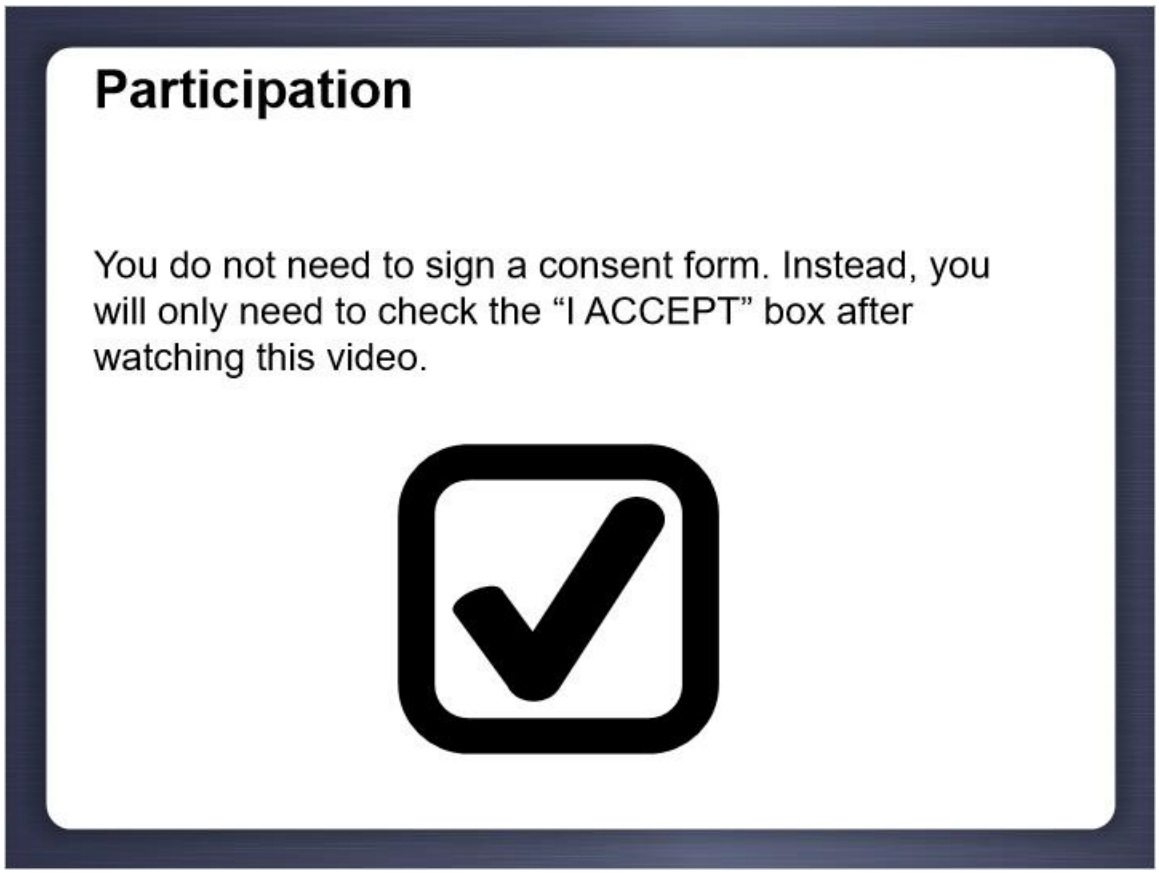
5.When working, most of work involves direct patient care

6.Have a cellular, mobile, or smartphone that can send and receive text messages AND operate a mobile app that can be downloaded from the Apple store or Google Play

7.Willing to periodically answer online surveys, and to send and receive text

messages

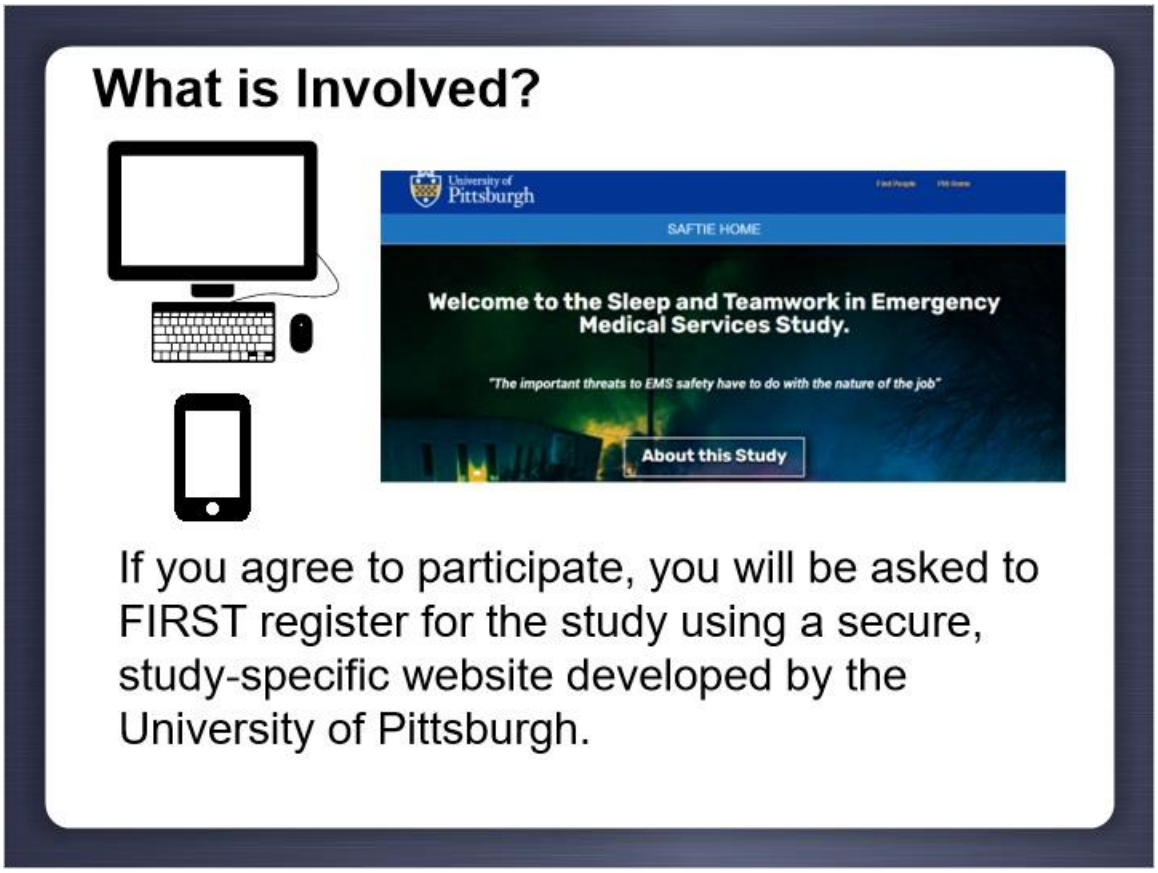
1.4 Participation



Notes:

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

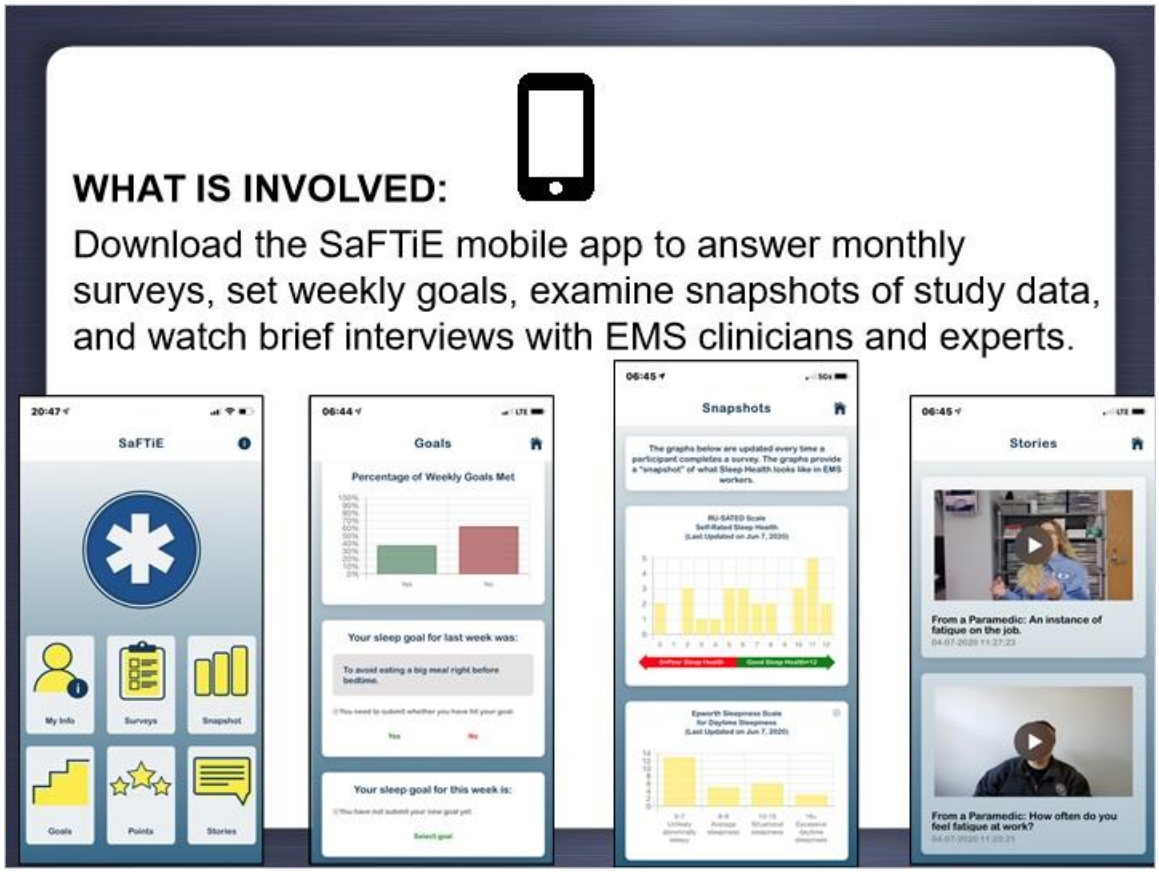
1.5 What is Involved?



Notes:

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

1.6 Untitled Slide

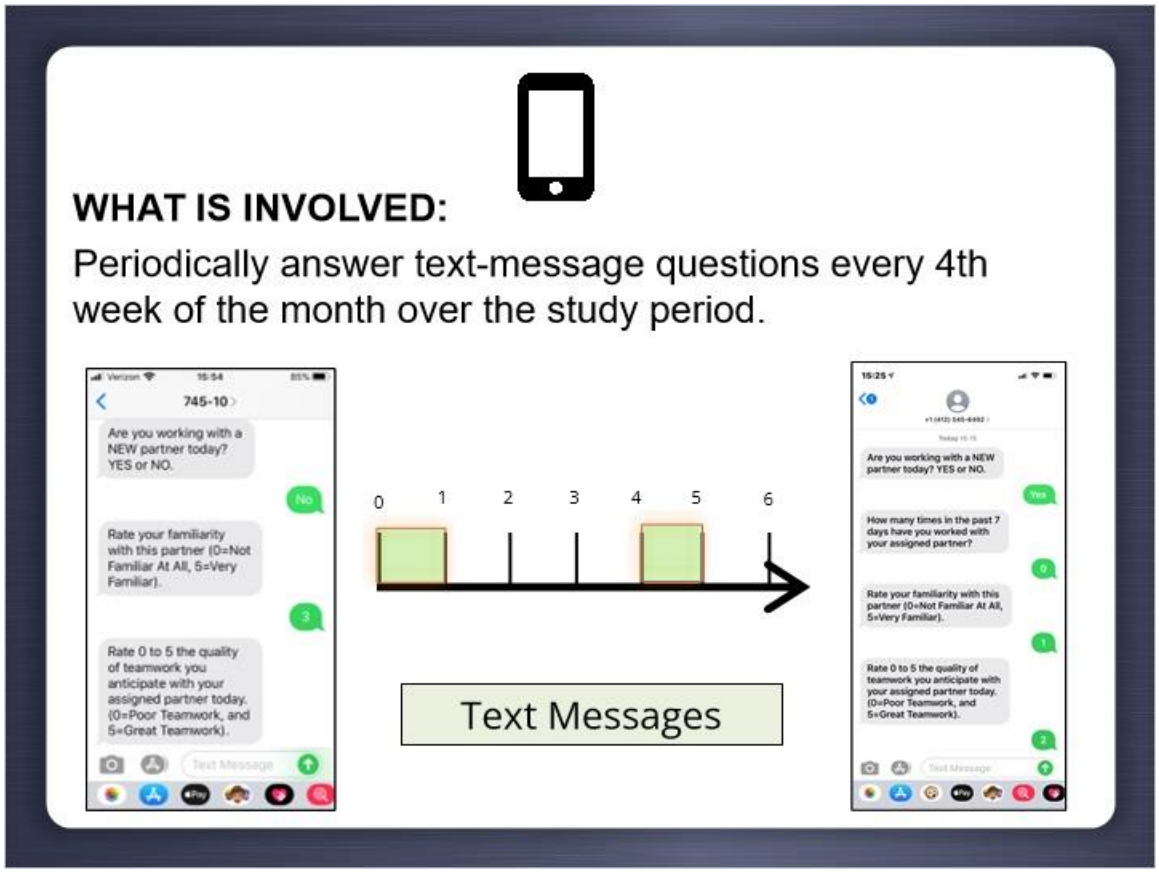


Notes:

WHAT IS INVOLVED:

Download the SaFTiE mobile app to answer monthly surveys, set weekly goals, examine snapshots of study data, and watch brief interviews with EMS clinicians and experts.

1.7 Untitled Slide

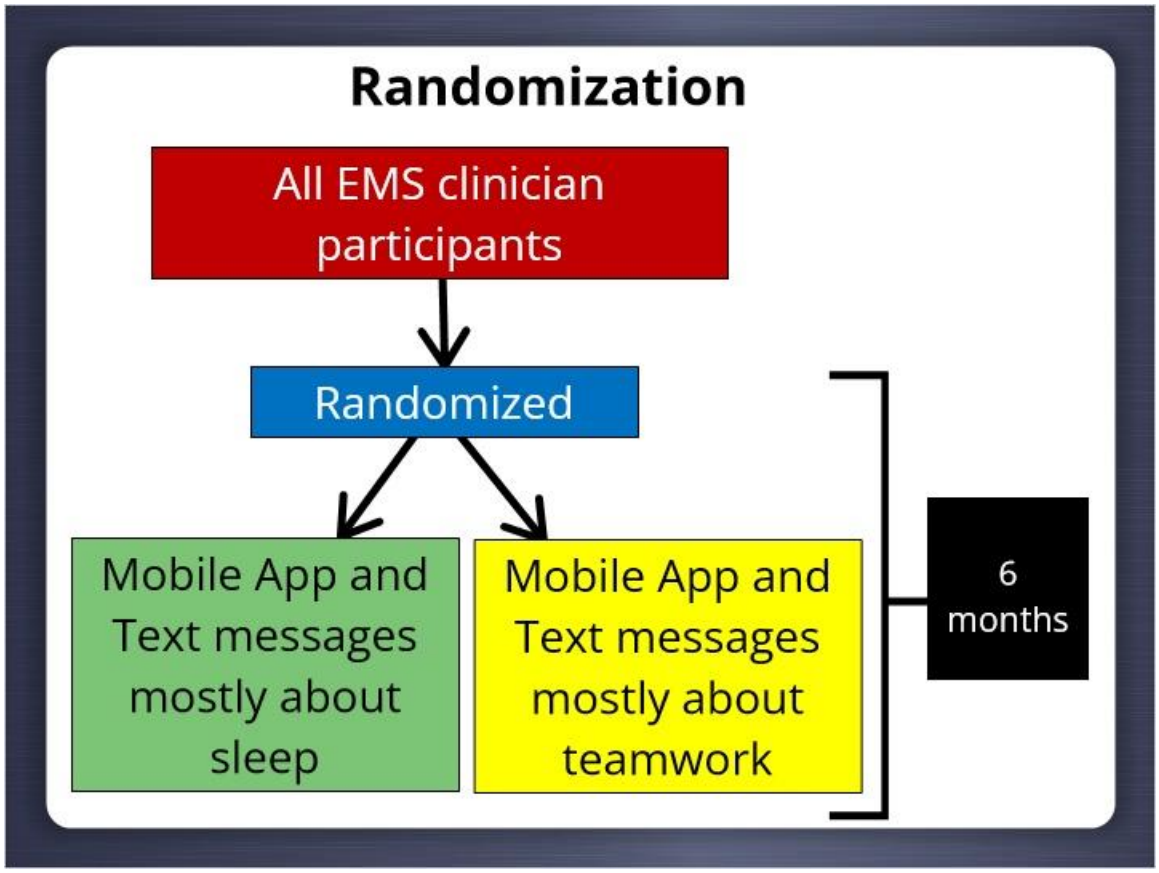


Notes:

WHAT IS INVOLVED:

Periodically answer text-message questions every 4th week of the month over the study period.

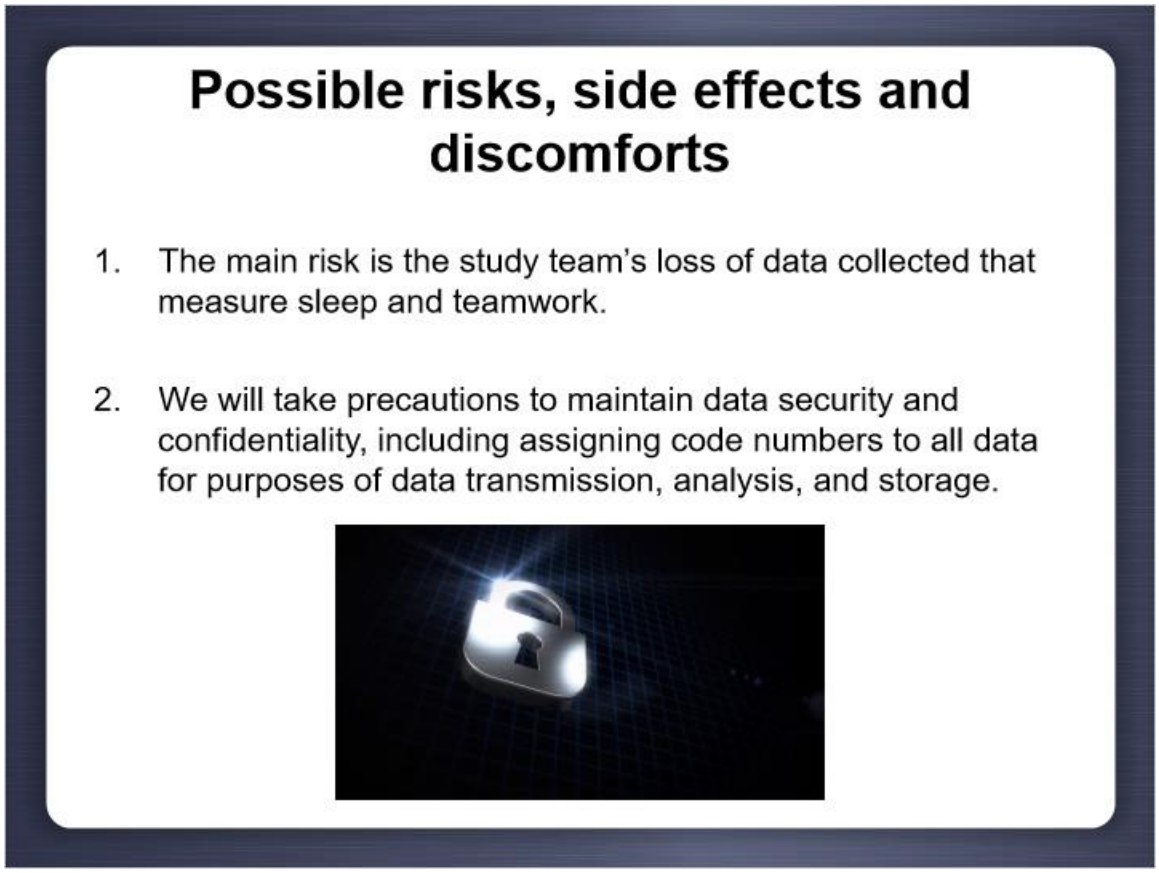
1.8 Randomization



Notes:

The content of the text messages will vary somewhat between individuals who have chosen to enroll in the study. Some will receive text messages that deal mostly with the topic of sleep. Others enrolling in the study will receive messages that deal mostly with the topic of teamwork. Text messages will be sent periodically for a total of 6 months.

1.9 Possible risks, side effects and discomforts

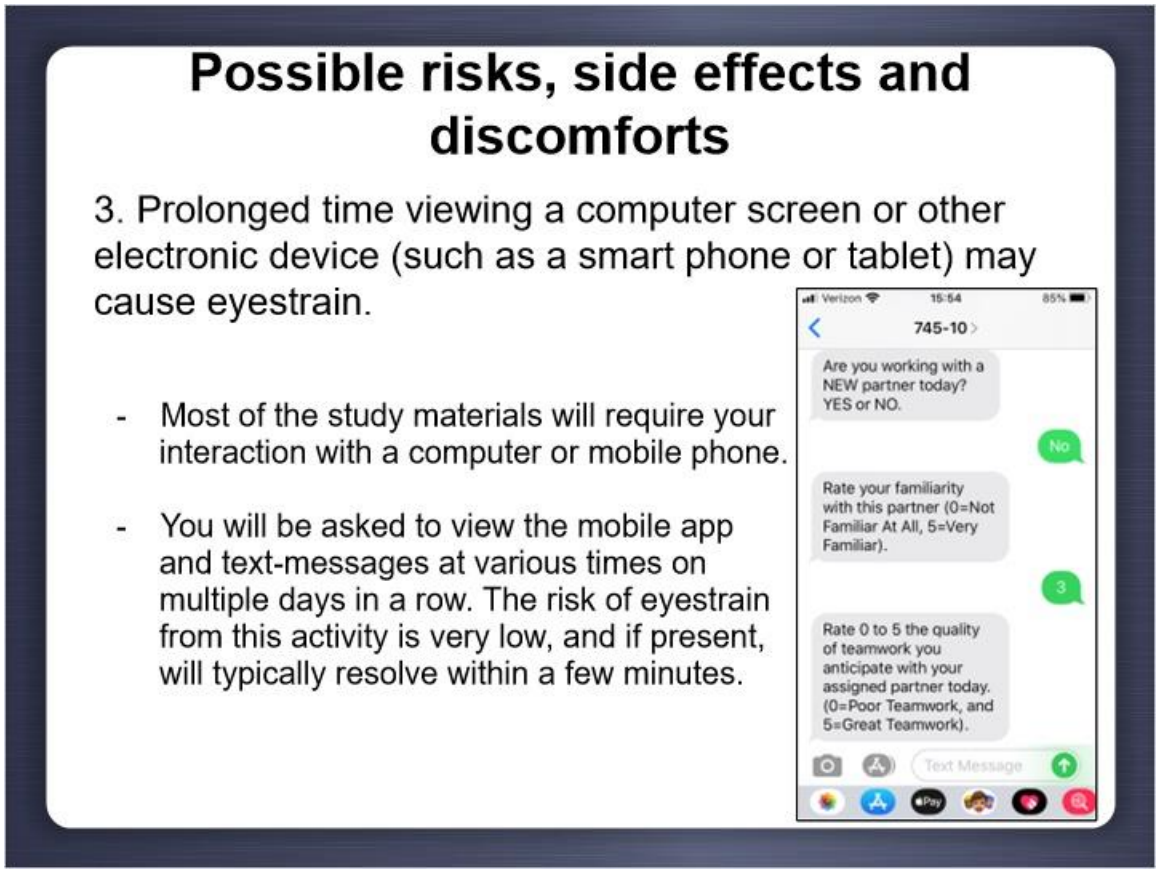


Notes:

1. The main risk is the study team's loss of data collected that measure sleep and teamwork.

2. We will take precautions to maintain data security and confidentiality, including assigning code numbers to all data for purposes of data transmission, analysis, and storage.

1.10 Possible risks, side effects and discomforts



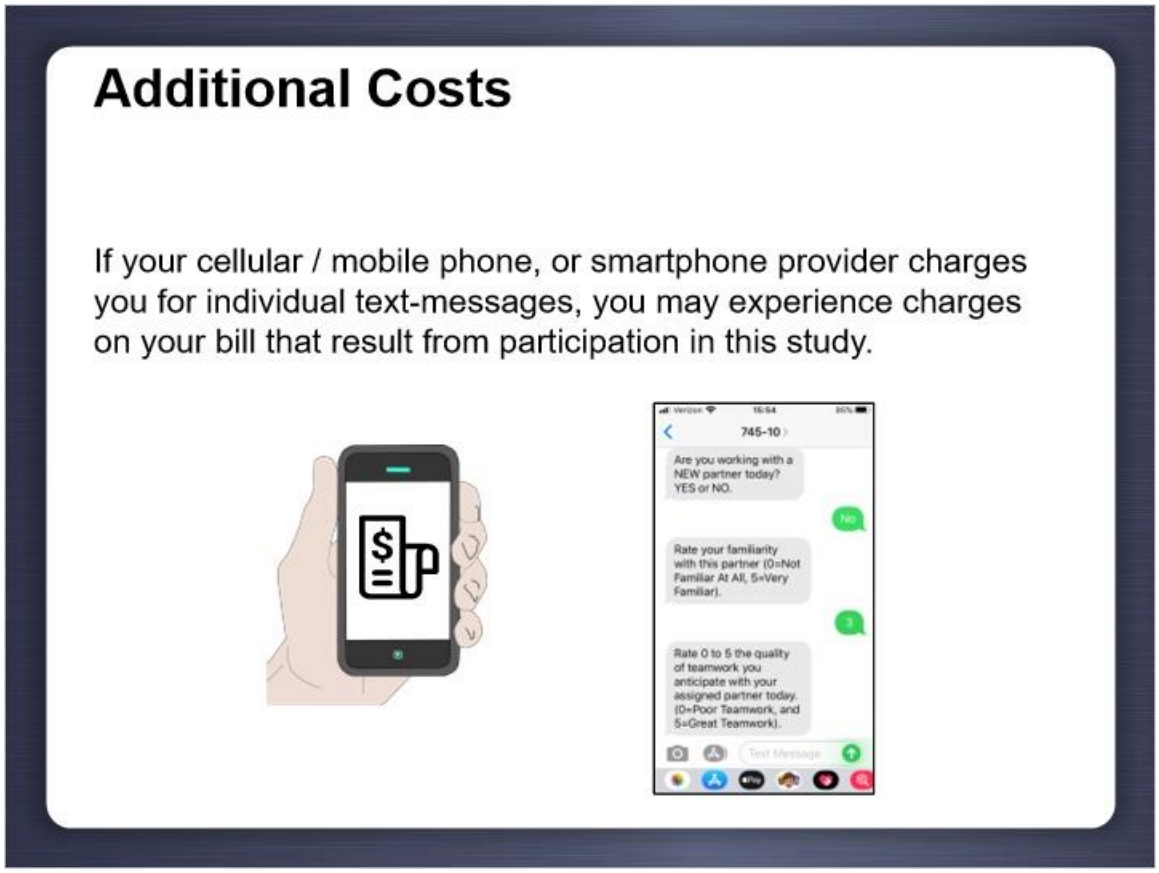
Notes:

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 phone.

- You will be asked to view the mobile app and text-messages at various times on multiple days in a row. The risk of eyestrain from this activity is very low, and if present, will typically resolves within a few minutes.

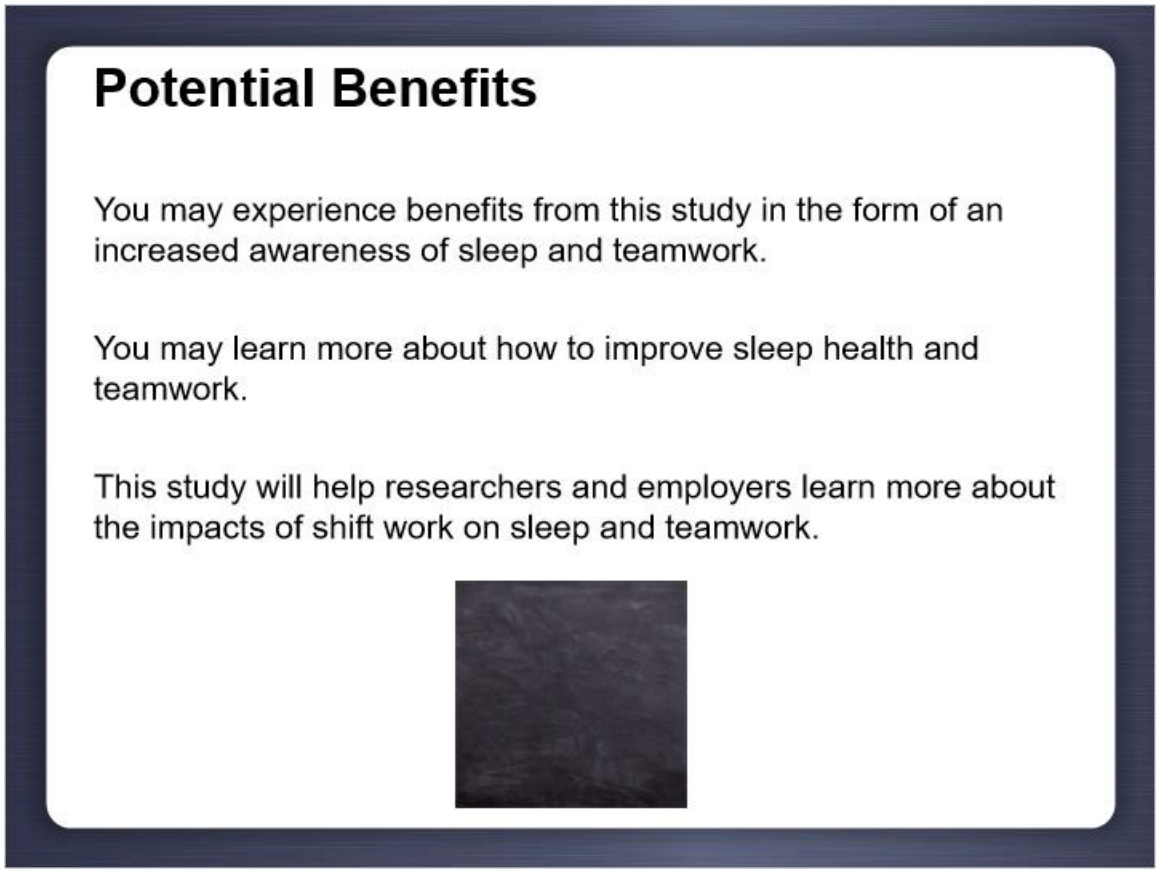
1.11 Additional Costs



Notes:

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

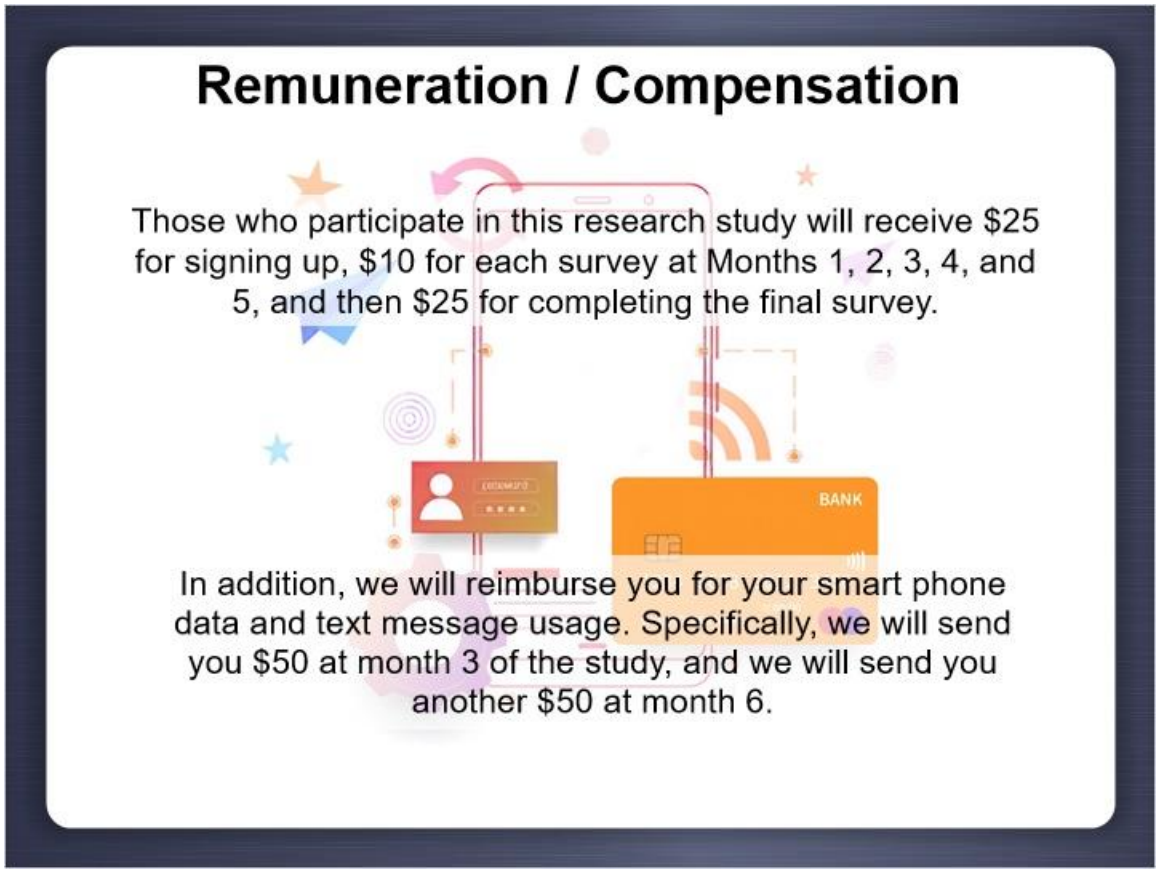
1.12 Potential Benefits



Notes:

You may experience benefits from this study in the form of an increased awareness of sleep and teamwork.
You may learn more about how to improve sleep health and teamwork.
This study will help researchers and employers learn more about the impacts of shift work on sleep and teamwork.

1.13 Remuneration / Compensation



Notes:

Those who participate in this research study will receive $25 for signing up, $10 for each survey at Months 1, 2, 3, 4, and 5, and then $25 for completing the final survey.

In addition, we will reimburse you for your smart phone data and text message usage. Specifically, we will send you $50 at month 3 of the study, and we will send you another $50 at month 6.

1.14 Remuneration / Compensation

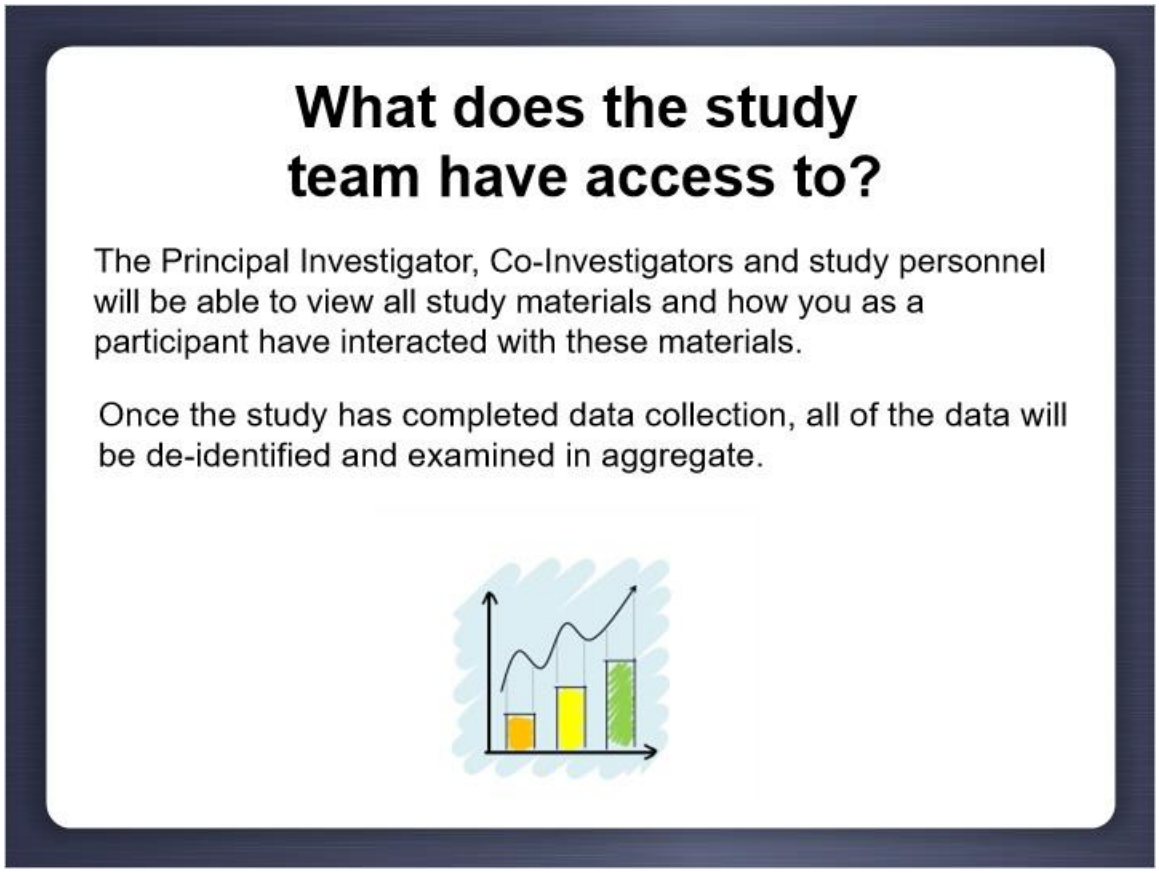
Notes:

You will also receive gifts for each month of participation in the study, including a coffee mug, glove pouch, shoulder patch, challenge coin, wallet card, and pen.

Total remuneration / compensation for completing all aspects of the study with th e mobile app and text messaging will reach a total of $100.

Please don't forget that we will also reimburse you $50 at month 3 and $50 at month 6 for smartphone data and text message related expenses

1.15 What does the study team have access to?

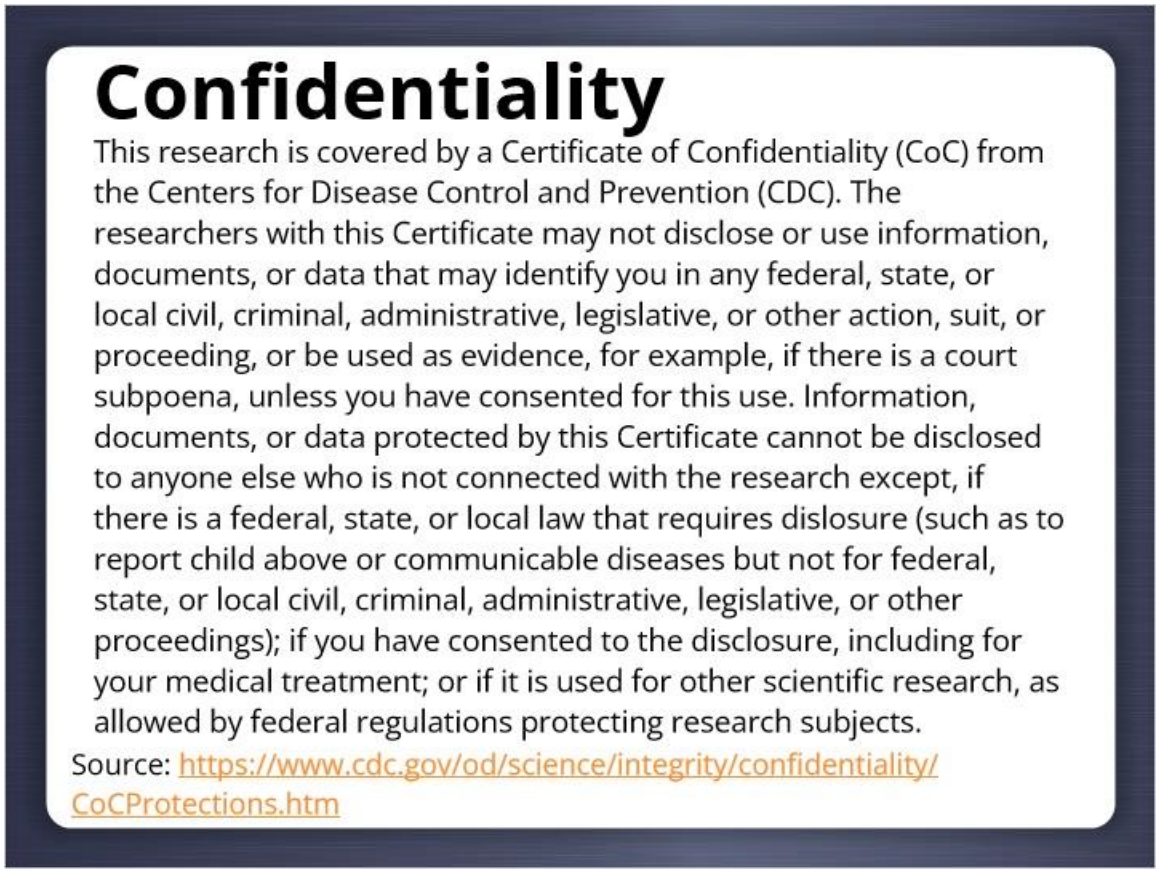


Notes:

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.

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

1.16 Confidentiality

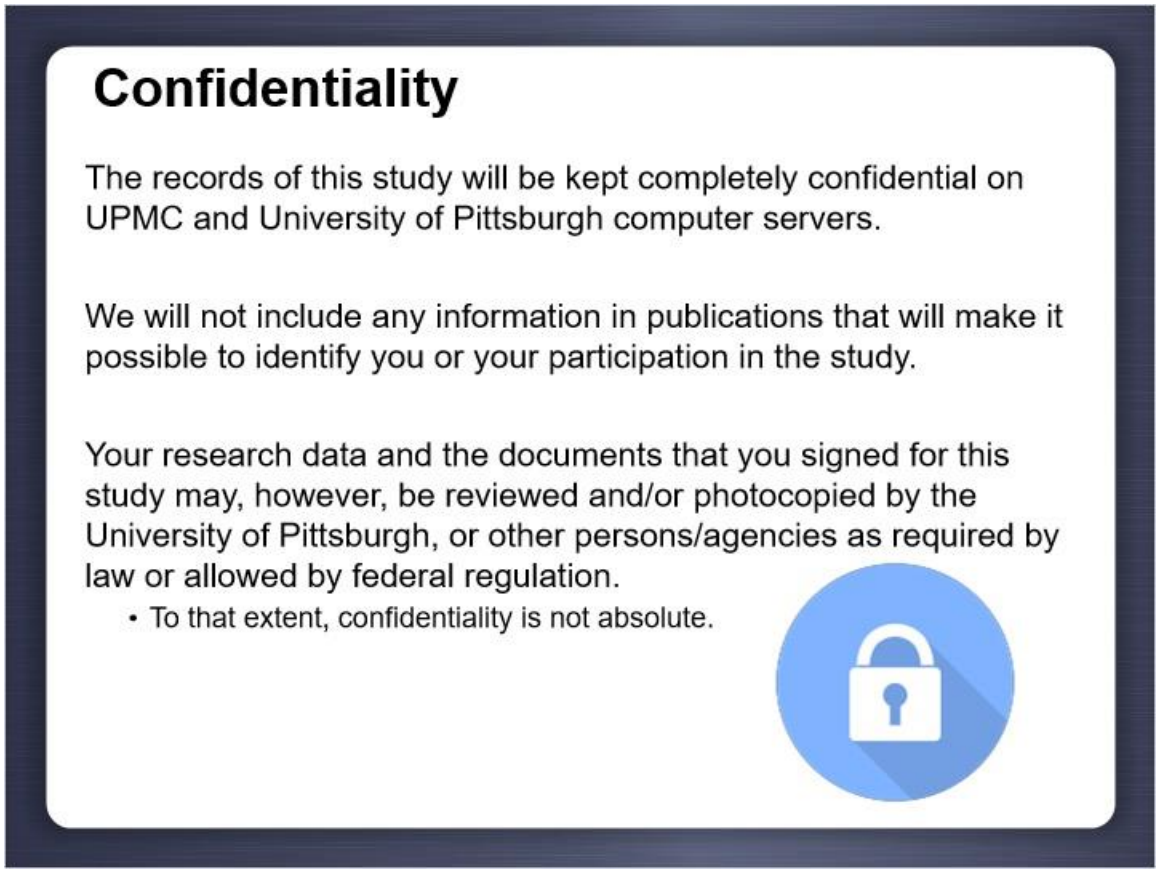


Notes:

This research is covered by a Certificate of Confidentiality (CoC) from the Centers for Disease Control and Prevention (CDC). The researchers with this Certificate may not disclose or use information, documents, or data that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or data protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires dislosure (such as to report child above or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research

subjects.

1.17 Confidentiality

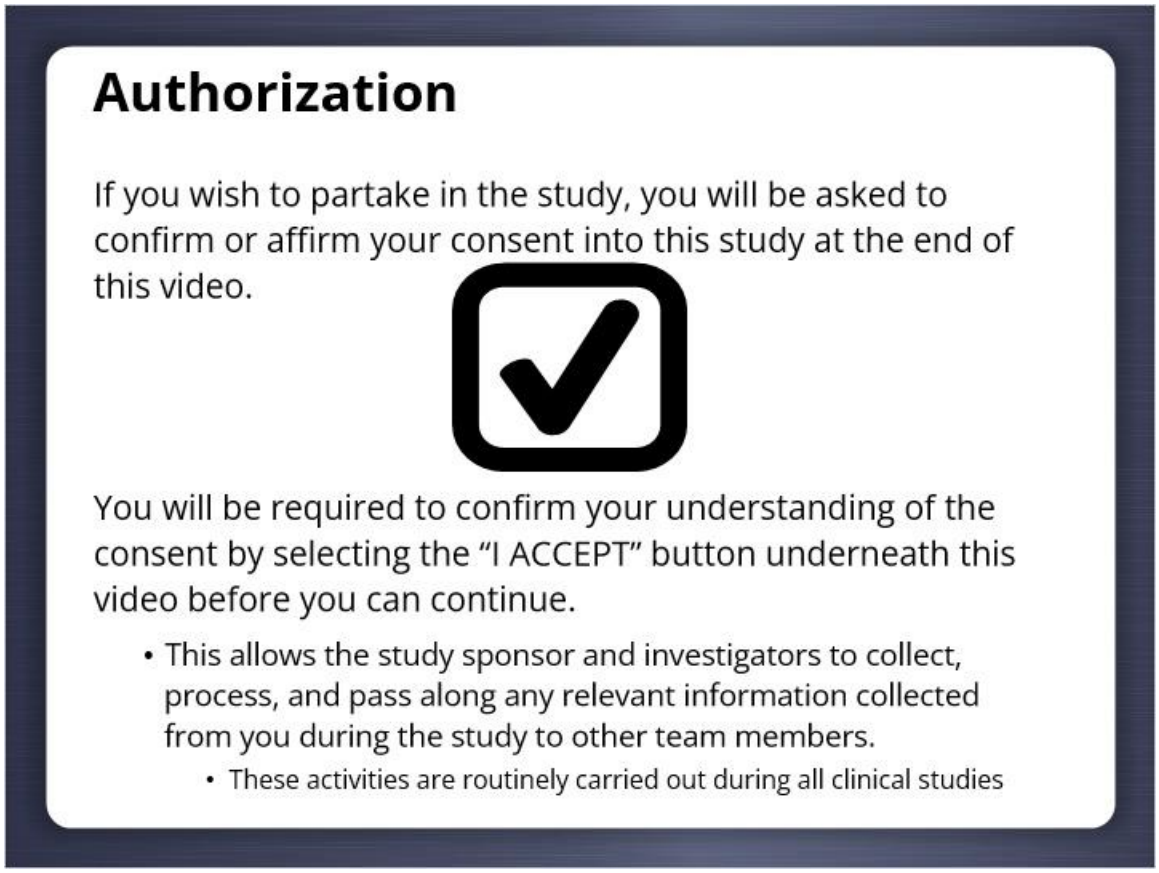


Notes:

The records of this study will be kept completely confidential on UPMC and University of Pittsburgh computer servers.
We will not include any information in publications that will make it possible to identify you or your participation in the study.
Your research data and the documents that you signed for this 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.

- To that extent, confidentiality is not absolute.

1.18 Authorization



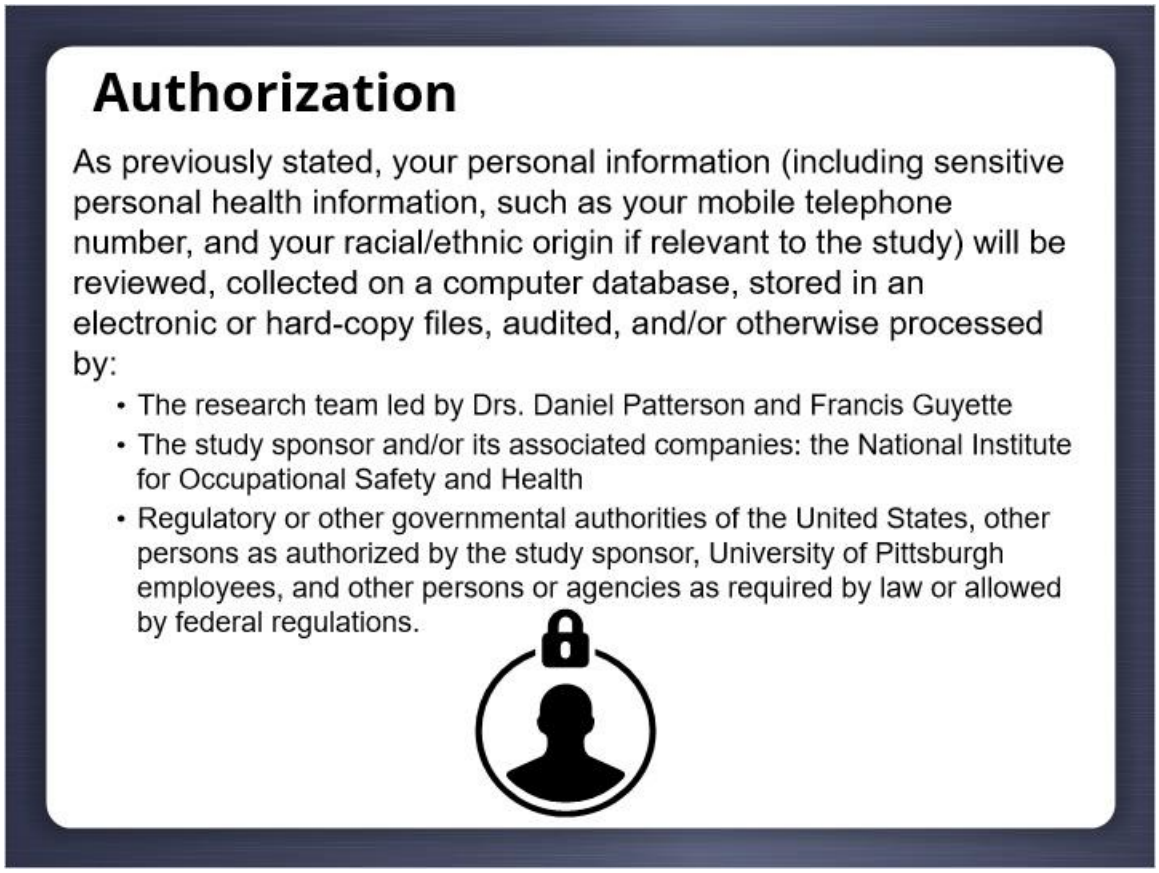
Notes:

If you wish to partake in the study, you will be asked to confirm or affirm your consent into this study at the end of this video.

You will 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 study sponsor and investigators to collect, process, and pass along any relevant information collected from you during the study to other team members.
    - These activities are routinely carried out during all clinical studies.

1.19 Authorization

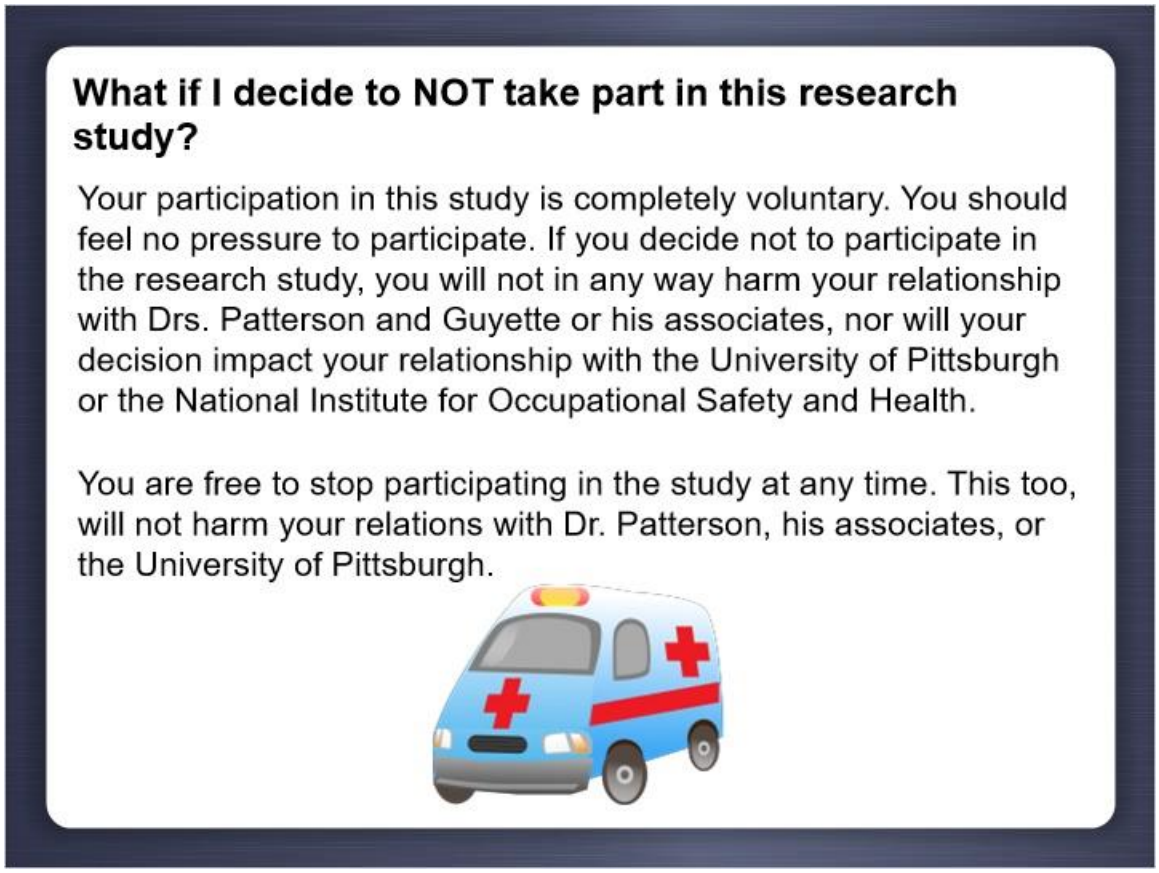


Notes:

As previously stated, your personal information (including sensitive personal health information, such as your mobile telephone number, and your racial/ethnic origin if relevant to the study) will be reviewed, collected on a computer database, stored in an electronic or hard-copy files, audited, and/or otherwise processed by:

- The research team led by Drs. Daniel Patterson and Francis Guyette
- The study sponsor and/or its associated companies: the National Institute for Occupational Safety and Health
- Regulatory or other governmental authorities of the United States, other persons as authorized by the study sponsor, University of Pittsburgh employees, and other persons or agencies as required by law or allowed by federal regulations.

1.20 Untitled Slide



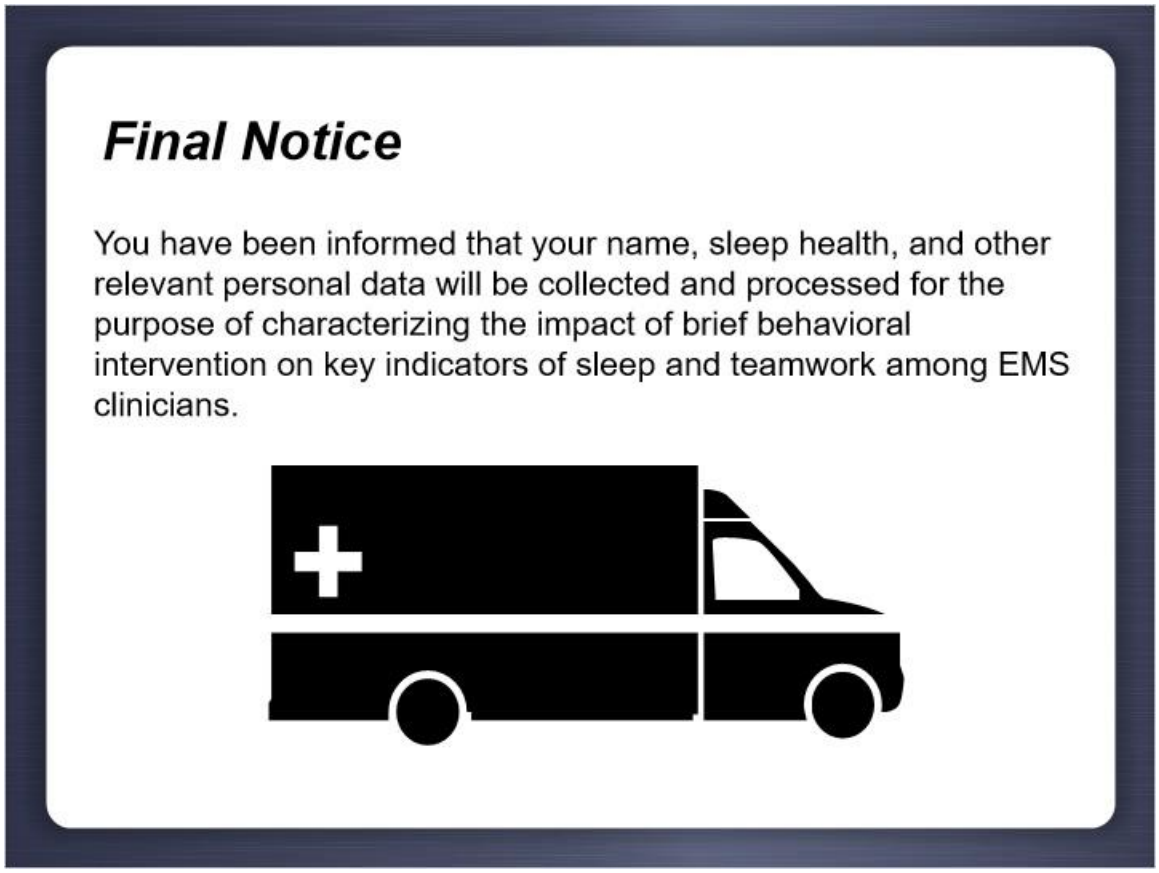
Notes:

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 Drs. Patterson and Guyette or his associates, nor will your decision impact your relationship with the University of Pittsburgh or the National Institute for Occupational Safety and Health.

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.

1.21 Final Notice



Notes:

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 brief behavioral intervention on key indicators of sleep and teamwork among EMS clinicians.

1.22 Please select an option below this video:

☐ I have watched the above informed consent video and agree to participate (I ACCEPT).

☐ I DO NOT ACCEPT and do NOT want to participate in this research study.

Next