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Approval Date: August 19, 2020
Expiration Date: **(Does Not Expire)**

ACTIVITY TRACKER CONSENT FORM

FOR QUESTIONS ABOUT THE STUDY, CONTACT:
Protocol Directors
Alexandra Ruan, MD (510-366-4937, aruan@stanford.edu)

DESCRIPTION: You are invited to participate in a research study which aims to evaluate the effects of a night float system on sleep and well-being. The purpose of this study is to better understand the impact of acute sleep disruption on sleep patterns and activity.

You will be asked to wear an activity tracking device on your wrist for three to six weeks in order to track sleep patterns – including number of awakenings, REM sleep and light sleep, number of steps taken per day, and heart rate variability. The data from the device is collected via Bluetooth to your phone. The Fitbit phone app has no identifiers and is attached to an anonymous Gmail account without identifiers. Data will be downloaded from the Fitbit website for analysis without any personal data.

You will also be asked to take a series of three surveys throughout the study period as a subjective measure of physical and mental health. You will receive a gift card in the amount of $10 at final survey completion as a thank you for contributing your time to this important project.

Once you agree to participate in the study, you will be asked to provide your name and email address in order to send you the surveys and also to send you the gift card at the end of your participation period. You will not be asked to provide any other personally identifying information. The collected activity tracker data and survey results will be de-identified and stored on a password-protected computer. It will be deleted once the research has been published.

RISKS AND BENEFITS:
We cannot and do not guarantee that you will receive any benefits from this study.

Potential benefits of the study include:
- Contribution to our understanding of the impact of call paradigms on trainee wellness
- Fitness trackers have been shown to increase a user's activity levels
- Increased insight into your sleep patterns and daily activity levels
- Opportunity to learn about healthy sleep habits

Potential risks of the study include:
- Participants may learn information about their sleep habits related to shift patterns that may cause increased dissatisfaction at work

Your decision whether or not to participate in this study will not affect your employment. We will provide activity trackers for you for the study. You may be responsible for damages incurred to activity tracker device during the study.

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TIME INVOLVEMENT: Data collection will take place over 21 days, where you will be asked to continue to follow your typical daily schedule. Your active participation in this experiment will take approximately 30 minutes. This involves surveys as well as study orientation. If your study period is longer than 21 days, there will be no additional surveys to complete and we will only collect Fitbit data.

PAYMENTS/REIMBURSEMENTS: You will receive a $10 gift card at the end of final survey completion as payment for your participation.

PARTICIPANT'S RIGHTS: If you have read this form and have decided to participate in this project, please understand your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. The alternative is not to participate. You have the right to refuse to answer particular questions.

The results of this research study may be presented at scientific or professional meetings or published in scientific journals. Your individual privacy will be maintained in all presented, published and written data resulting from the study. Data collected will be de-identified and, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional consent from you.

CONTACT INFORMATION:
Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Alexandra Ruan, MD (510-366-4937 or aruan@stanford.edu). You should also contact her at any time if you feel you have been hurt by being a part of this study.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 3000 El Camino Real, Five Palo Alto Square, 4th Floor, Palo Alto, CA 94306.

EXPERIMENTAL SUBJECTS BILL OF RIGHTS: As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;

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- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

I understand that after the initial study period of three weeks, I will have the option of continuing to wear the Fitbit for up to an additional three weeks. This is completely voluntary and I have the option of ending the data collection at any time during this period. I give consent to wear the Fitbit for up to an additional three weeks.

Please initial: ___Yes ___No

The extra copy of this signed and dated consent form is for you to keep.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

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Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?

The purpose of this study is to better understand the impact of acute sleep disruption on sleep patterns and activity. You will be asked to wear an activity tracking device on your wrist over the course of three to six weeks which will track sleep patterns – including number of awakenings, REM sleep and light sleep, number of steps taken per day, and heart rate variability. You will also be asked to take a survey at the beginning and the end of the study period as a subjective measure of physical and mental health.

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: Alexandra Ruan, MD (aruan@stanford.edu or 300 Pasteur Drive, H3580 Stanford, CA 94305)

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What Personal Information Will Be Obtained, Used or Disclosed?

Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to, sleep patterns, heart rate, activity level, and sleep aids. Identifiable demographic information collected will include name, BMI, and date of birth as part of identifiable demographic information. You will also be asked to provide your email address in order to receive survey links as well as the participation gift.

Who May Use or Disclose the Information?

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director: Alexandra Ruan, MD
- Research Team Members: Preya Jhita, MD
- Faculty Sponsors: Pamela Flood, MD and Natalya Hasan, MD
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary

Who May Receive or Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?

Your authorization for the use and/or disclosure of your health information will end on December 31, 2025 or when the research project ends, whichever is earlier.

_____ _____

Signature of Adult Participant Date

_____
Print Name of Adult Participant