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Modification

1. Summarize your proposed changes.

The proposed changes to our protocol include: 1) recruitment of additional participants, 2) expanding the number of rotations which residents can be recruited, 3) adding additional COVID-19 cleaning protocols for the Fitbits, and 4) adding an additional investigator to the protocol (Dr. Preya Jhita). We have enrolled twelve participants in the study to date, and we are hoping to enroll an additional 40 more participants to adequately power our study. Previously, we were only recruiting anesthesia residents who were rotating on the general OR rotation, but we would also like to follow them when they are on their OB anesthesia rotation as they also do night float shifts during that rotation. The consent form has been updated to include the additional rotations that will be recruited, but no changes need to be made for the previously enrolled participants

2. Indicate Level of Risk

No Change

3. Update the Conflict of Interest (COI) section if any changes in COI have been made since the last protocol submission.

N Is there a change in the conflicting interest status for any existing personnel on this protocol?

Protocol Director

Name		**Degree (Program/year if student)**		**Position, e.g. Assistant Professor, Resident, etc.**
Alexandra Ruan		MD		Clinical Instructor
Department	5640	**Phone**	(650) 725-8544	**E-mail**
Anesthesia		5103664937		aruan@stanford.edu
CITI Training current				Y

Admin Contact

Name		**Degree (Program/year if student)**		**Position, e.g. Assistant Professor, Resident, etc.**
Alexandra Ruan				Clinical Instructor
Department	5640	**Phone**		**E-mail**
Anesthesia		5103664937		aruan@stanford.edu
CITI Training current				Y

Investigator

Name		**Degree (Program/year if student)**		**Position, e.g. Assistant Professor, Resident, etc.**
Dr. Natalya Sarah Hasan		MD		Clinical Assistant Professor
Department	5640	**Phone**	(650) 725-8544	**E-mail**
Anesthesia		(650) 497-8057		nhasan@stanford.edu
CITI Training current				Y

Other Contact

Name		**Degree (Program/year if student)**		**Position, e.g. Assistant Professor, Resident, etc.**
Department		**Phone**		**E-mail**

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CITI Training current	

Academic Sponsor

Name		**Degree (Program/year if student)**		**Position, e.g. Assistant Professor, Resident, etc.**
Dr. Pamela Flood		M.D.		Professor-Med Ctr Line
Department	5640	**Phone**	(650) 725-8544	**E-mail**
Anesthesia - OB (Endowments)		(650) 723-7377		pflood@stanford.edu
CITI Training current				Y

Other Personnel

Name		**Degree (Program/year if student)**		**Position, e.g. Assistant Professor, Resident, etc.**
Preya Jhita		MD		Resident
Department	5640	**Phone**		**E-mail**
Dean's Office Operations - Dean Other		504-220-6138		pjhita@stanford.edu
CITI Training current				Y

Participant Population(s) Checklist	**Yes/No**
• Children (under 18)	N
• Pregnant Women and Fetuses	N
• Neonates (0 - 28 days)	N
• Abortuses	N
• Impaired Decision Making Capacity	N
• Cancer Subjects	N
• Laboratory Personnel	N
• Healthy Volunteers	N
• Students	N
• Employees	Y
• Prisoners	N
• Other (i.e., any population that is not specified above)	N
• International Participants	N
Please enter the countries separated by comma	

Study Location(s) Checklist	**Yes/No**
• Stanford University	Y
• Clinical & Translational Research Unit (CTRU)	

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• Stanford Hospital and Clinics	Y
• Lucile Packard Children's Hospital (LPCH)	Y
• VAPAHCS (Specify PI at VA)	
• Other (Click ADD to specify details)	

General Checklist

Multi-site	**Yes/No**
• Is this a multi-site study? A multi-site study is generally a study that involves one or more medical or research institutions in which one site takes a lead role.(e.g., multi-site clinical trial)	N

Collaborating Institution(s)	**Yes/No**
• Are there any collaborating institution(s)? A collaborating institution is generally an institution that collaborates equally on a research endeavor with one or more institutions.	N

Cancer Institute	**Yes/No**
• Cancer-Related Studies (studies with cancer endpoints), Cancer Subjects (e.g., clinical trials, behavior/prevention) or Cancer Specimens (e.g., blood, tissue, cells, body fluids with a scientific hypothesis stated in the protocol).	N

Clinical Trials	**Yes/No**
• Investigational drugs, biologics, reagents, or chemicals?	N
• Commercially available drugs, reagents, or other chemicals administered to subjects (even if they are not being studied)?	N
• Investigational Device / Commercial Device used off-label?	N
• IDE Exempt Device (Commercial Device used according to label, Investigational In Vitro Device or Assay, or Consumer Preference/Modifications/Combinations of Approved Devices)	N
• Will this study be registered on# clinicaltrials.gov? (See Stanford decision tree)	N
• Is Stanford responsible for ClinicalTrials.gov registration? (See Stanford decision tree) NCT#	N

Tissues and Specimens	**Yes/No**
• Human blood, cells, tissues, or body fluids (tissues)?	N
• Tissues to be stored for future research projects?	N
• Tissues to be sent out of this institution as part of a research agreement? For guidelines,	N

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please see https://sites.stanford.edu/ico/mtas

Biosafety (APB)	**Yes/No**
• Are you submitting a Human Gene Transfer investigation using a biological agent or recombinant DNA vector? Please review the Administrative Panel on BioSafety website form more information.	N
• Are you submitting a Human study using biohazardous/infectious agents? If yes, refer to the Administrative Panel on BioSafety website prior to performing studies.	N
• Are you submitting a Human study using samples from subjects that are known or likely to contain biohazardous/infectious agents? If yes, refer to the Administrative Panel on BioSafety website prior to performing studies.	N

Human Embryos or Stem Cells	**Yes/No**
• Human Embryos or Gametes?	N
• Human Stem Cells (including hESC, iPSC, cancer stem cells, progenitor cells)	N

Veterans Affairs (VA)	**Yes/No**
• The research recruits participants at the Veterans Affairs Palo Alto Health Care System(VAPAHCS).	N
• The research involves the use of VAPAHCS non-public information to identify or contact human research participants or prospective subjects or to use such data for research purposes.	N
• The research is sponsored (i.e., funded) by VAPAHCS.	N
• The research is conducted by or under the direction of any employee or agent of VAPAHCS (full-time, part-time, intermittent, consultant, without compensation (WOC), on-station fee-basis, on-station contract, or on-station sharing agreement basis) in connection with her/his VAPAHCS responsibilities.	N
• The research is conducted using any property or facility of VAPAHCS.	N

Equipment	**Yes/No**
• Use of Patient related equipment? If Yes, equipment must meet the standards established by Hospital Instrumentation and Electrical Safety Committee (650-725-5000)	N
• Medical equipment used for human patients/subjects also used on animals?	N
• Radioisotopes/radiation-producing machines, even if standard of care? http://www.stanford.edu/dept/EHS/prod/researchlab/radlaser/Human_use_guide.pdf More Info	N

Payment	**Yes/No**

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- Subjects will be paid/reimbursed for participation? See payment considerations. Y

Funding	**Yes/No**
• Training Grant?	N
• Program Project Grant?	N
• Federally Sponsored Project?	N
• https://doresearch.stanford.edu/policies/research-policy-handbook/definitions-and-types-agreements/specialized-categories-sponsored-p Industry Sponsored Clinical Trial?	N

Funding

Funding - Grants/Contracts

Funding - Fellowships

Gift Funding

Dept. Funding

Department Name : Anesthesiology

Other Funding

Resources :

a) Qualified staff.

Please state and justify the number and qualifications of your study staff.

Preya Jhita, MD - resident physician in anesthesia
Alexandra Ruan, MD. Natalya Hasan, MD and Pamela Flood, MD - attending anesthesiologists who will provide organizational and data analysis support, and access to activity trackers for this study.

b) Training.

Describe the training you will provide to ensure that all persons assisting with the research are informed about the protocol and their research-related duties and functions.

All members of study staff listed above have completed CITI training

c) Facilities.

Please describe and justify.

All studies will take place in the Stanford Hospital and Lucille Packard anesthetizing locations during the participants normal activities. There will be no change to the participants normal activities.

d) Sufficient time.

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Explain whether you will have sufficient time to conduct and complete the research. Include how much time is required.

The planned time course of this project is 2 years. We will aim to collect between responses from 40-60 participants (each night float lasts 1 week and there will be one week run in before and one week of post call activities to evaluate effects). We will continually de-identify, process and analyze data to assure that analysis programs are intact.

e) Access to target population.

Explain and justify whether you will have access to a population that will allow recruitment of the required number of participants.

The participants in the study will be residents within the Stanford University Department of Anesthesia who choose to participate in this study of the effect of call on activity and sleep. There are 4 residents on each rotation per month, so between the general OR and OB anesthesia rotations, we could recruit up to 8 participants per month in order to enroll our target number of participants

f) Access to resources if needed as a consequence of the research.

State whether you have medical or psychological resources available that participants might require as a consequence of the research when applicable. Please describe these resources.

A possible consequence of the research is that participants become more aware of different night float systems can affect their sleep and activity which may affect their attitude towards call. We have a strong PRIME (resiliency in medical education) program within the department that can support the residents if they feel any symptoms of burnout. There is always the remote possibility of identifiable data release. We are putting processes into play including secure data storage in Redcap and immediate de-identification at the end of each resident's participation.

g) Lead Investigator or Coordinating Institution in Multi-site Study.

Please explain (i) your role in coordinating the studies, (ii) procedures for routine communication with other sites, (iii) documentation of routine communications with other sites, (iv) planned management of communication of adverse outcomes, unexpected problems involving risk to participants or others, protocol modifications or interim findings.

Expedited Form

A protocol must be no more than minimal risk (i.e., "not greater than those ordinarily encountered in daily life") AND must only involve human subjects in one or more of the following paragraphs.

Select one or more of the following paragraphs:

1. N **Clinical studies of drugs and medical devices only when condition (a) or (b) is met.**
   a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
   b) Research on medical devices for which
      i) an investigational device exemption application (21 CFR Part 812) is not required; or
      ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. N **Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:**

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a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. N **Prospective collection of biological specimens for research purposes by non invasive means.**

4. Y **Collection of data through non invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)**

Examples:

a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
b) weighing or testing sensory acuity;
c) magnetic resonance imaging;
d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. N **Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this paragraph may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)**

6. N **Collection of data from voice, video, digital, or image recordings made for research purposes.**

7. Y **Research on individual or group characteristics or behavior(including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)**

1. Purpose

a) In layperson's language state the purpose of the study in 3-5 sentences.

With increasing awareness about physician fatigue and its effect on patient safety residency programs are transitioning to a night float call system. In other industries, multiple night shifts in a row
can cause a disruption in the circadian rhythm, sleep debt, shift work
disorder, that is related to chronic medical conditions such as

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obesity
and cardiovascular disease. We will evaluate the effect of night float
call on resident activity, sleep and self reported measures of wellness.

b) State what the Investigator(s) hope to learn from the study. Include an assessment of the importance of this new knowledge.

We will learn how different lengths of night float affects a resident's activity level, sleep and self reported wellness. These objective measurements
can be used to assess targets for intervention with an altered call paradigm or increased support to prevent long term disability from changes identified. In the long term, we hope to reduce physician burnout and improve physician wellness.

c) Explain why human subjects must be used for this project. (i.e. purpose of study is to test efficacy of investigational device in individuals with specific condition; purpose of study is to examine specific behavioral traits in humans in classroom or other environment)

The purpose of the study is the examine specific behavioral patterns, specifically sleep pattern and activity level, in humans who are working during a night shift system.

2. Study Procedures

a) Please SUMMARIZE the research procedures, screening through closeout, which the human subject will undergo. Refer to sections in the protocol attached in section 16, BUT do not copy the clinical protocol. Be clear on what is to be done for research and what is part of standard of care.

Participants will be recruited via an email once they are scheduled for a week of night float in the Stanford Main Operating room or Obstetric anesthesia. Potential participants who are taking prescription medications that might affect their alertness during the study period will not be enrolled.

We will quantify the changes in sleep pattern and activity during the week before, during, and after the night float call week. Self reported aspects of well being including fatigue, physical function, and positive affect will be assessed with NIH PROMIS surveys at the end of each week during the study period.
We will the Fitbit Alta HR to quantify the change in total amount of sleep, sleep interruption and sleep phase and steps per day. Data will be analyzed only when it is coincident with heart rate data to correct for periods when the device is not used.

Activity will not alter from the participants normal except that they will wear the Fitbit and respond to the NIH PROMIS surveys over the study period. After completing all surveys and returning the fitbit, the participants will receive a $10 gift certificate as a recognition for their time.
Based on their rotation schedule, they will have the option to wear the Fitbit for an additional 3 weeks for additional data collection.

Data from NIH PROMIS surveys, Fitbit and provided demographic

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information including age, sex and BMI, and number of previous night float periods previously completed. After association, data will be completely deidentified.

All data will be normalized to the participant's baseline values during the run-in week. The call week and post call week will be analyzed with a time series mixed effects model using R and/or NONMEM (a program for Nonlinear Mixed Effects Modeling). The effects of the above demographic variables will be assessed as potential covariates.

The intended goal of this project is to improve the current resident call structure within the anesthesia department (QI); however, we are applying for IRB approval because we believe that the data gathered about the impact of night float on sleep patterns and physician well-being can be generalized and we would want to publish this data in the
future. We anticipate that this observational study will be the first of many studies looking at the effects of changing sleep patterns on activity and well-being

b) Explain how the above research procedures are the least risky that can be performed consistent with sound research design.

Our research protocol constitutes very low risk to participants because
it does not require that they deviate from their usual behavior pattern.There is always a remote risk that data confidentiality will be breached. Steps taken to prevent that risk are data storage in Redcap and only using de identified data for analysis. All investigators have or will (Jhita) complete CITI training prior to study initiation.

c) State if deception will be used. If so, provide the rationale and describe debriefing procedures. Since you will not be fully informing the participant in your consent process and form, complete an alteration of consent (in section 13). Submit a debriefing script (in section 16).

N/A

d) State if audio or video recording will occur. Describe what will become of the recording after use, e.g., shown at scientific meetings, erased. Describe the final disposition of the recordings.

N/A

e) Describe alternative procedures or courses of treatment, if any, that might be advantageous to the participant. Describe potential risks and benefits associated with these. Any standard treatment that is being withheld must be disclosed in the consent process and form. (i.e. standard-of-care drug, different interventional procedure, no procedure or treatment, palliative care, other research studies).

N/A

f) Will it be possible to continue the more (most) appropriate therapy for the participant(s) after the conclusion of the study?

This is an observational study.

g) Study Endpoint. What are the guidelines or end points by which you can evaluate the different treatments (i.e. study drug, device, procedure) during the study? If one proves to be clearly more effective than another (or others) during the course of a study, will the study be terminated before the projected total participant population has been enrolled? When will the study end if no important differences are detected?

n/a

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3. Background

a) Describe past experimental and/or clinical findings leading to the formulation of the study.

Studies in other settings have shown that day sleep is 1 to 4 hours shorter than night sleep. Frequent night shifts can lead to chronic sleep loss, increased incidence of shift work disorder. These changes are associated with increased rates of obesity, cardiovascular disease, and cancers such as breast and colorectal.

b) Describe any animal experimentation and findings leading to the formulation of the study.

N/A

4. Radioisotopes or Radiation Machines

a) List all standard of care procedures using ionizing radiation (radiation dose received by a subject that is considered part of their normal medical care). List all research procedures using ionizing radiation (procedures performed due to participation in this study that is not considered part of their normal medical care). List each potential procedure in the sequence that it would normally occur during the entire study. More Info

Identify Week/Month of study	Name of Exam	Identify if SOC or Research

b) For research radioisotope projects, provide the following radiation-related information:

Identify the radionuclide(s) and chemical form(s).

For the typical subject, provide the total number of times the radioisotope and activity will be administered (mCi) and the route of administration.

If not FDA approved provide dosimetry information and reference the source documents (package insert, MIRD calculation, peer reviewed literature).

c) For research radiation machine projects, provide the following diagnostic procedures:

For well-established radiographic procedures describe the exam.

For the typical subject, identify the total number of times each will be performed on a single research subject.

For each radiographic procedure, provide the setup and technique sufficient to permit research subject dose modeling. The chief technologist can usually provide this information.

For radiographic procedures not well-established, provide FDA status of the machine, and information sufficient to permit research subject dose modeling.

d) For research radiation machine projects, provide the following therapeutic procedures:

For a well-established therapeutic procedure, identify the area treated, dose per fraction and number of fractions. State whether the therapeutic procedure is being performed as a normal part of clinical management for the research participants's medical condition or whether it is being performed because the research participant is participating in this project.

For a therapeutic procedure that is not well-established, provide FDA status of the machine, basis for dosimetry, area treated, dose per fraction and number of fractions.

5. Devices

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a) Please list in the table below all Investigational Devices (including Commercial Devices used off-label) to be used on participants

b) Please list in the table below all IDE Exempt Devices (Commercial Device used according to label, Investigational In Vitro Device or Assay, or Consumer Preference/Modifications/Combinations of Approved Devices) to be used on participants.

6. Drugs, Reagents, or Chemicals and Devices

a) Please list in the table below all investigational drugs, reagents or chemicals to be administered to participants.

b) Please list in the table below all commercial drugs, reagents or chemicals to be administered to participants.

7. Medical Equipment for Human Subjects and Laboratory Animals

If medical equipment used for human patients/participants is also used on animals, describe such equipment and disinfection procedures.

We will use the commercially available Fitbit Alta HR activity tracker according to its intended use to track physical activity and sleep. Between each individual user, the Fitbit will be rinsed with water and wiped with a small amount of rubbing alcohol as per the Fitbit Wear & Care guidelines (https://www.fitbit.com/product-care#:~:text=FOR%20ELASTOMER%20BANDS%3A&text=Do%20NOT%20use%20hand%20soap In light of the current COVID-19 pandemic, we will also allow at least 72 hours between each user. The devices will not be used on animals.

8. Participant Population

a) State the following: (i) the number of participants expected to be enrolled at Stanford-affiliated site(s); (ii)the total number of participants expected to enroll at all sites; (iii) the type of participants (i.e. students, patients with certain cancer, patients with certain cardiac condition) and the reasons for using such participants.

We aim to recruit 40-60 participants. The sample size is a convenience sample based on interest by half of all residents eligible. All participants enrolled will be anesthesia residents currently rotating in the Stanford Main Operating Rooms or on OB anesthesia

b) State the age range, gender, and ethnic background of the participant population being recruited.

We will recruit participants who are PGY2-5, which means they will generally be between 26-36 years of age. We will aim to recruit an equal number of males and females which is reasonable give the demographic distribution of Anesthesia residents. Finally, we aim to have a people with a variety of races and ethnicity involved but this will not be specifically targeted or evaluated due to the limited pool of eligible subjects.

c) State the number and rationale for involvement of potentially vulnerable subjects in the study (including children, pregnant women, economically and educationally disadvantaged, decisionally impaired, homeless people, employees and students). Specify the measures being taken to minimize the risks and the chance of harm to the potentially vulnerable subjects and the additional safeguards that

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have been included in the protocol to protect their rights and welfare.

n/a

d) If women, minorities, or children are not included, a clear compelling rationale must be provided (e.g., disease does not occur in children, drug or device would interfere with normal growth and development, etc.).

n/a

e) State the number, if any, of participants who are laboratory personnel, employees, and/or students. They should render the same written informed consent. If payment is allowed, they should also receive it. Please see Stanford University policy.

All participants in the study will be employees of Stanford Hospital through Graduate Medical Education.

f) State the number, if any, of participants who are healthy volunteers. Provide rationale for the inclusion of healthy volunteers in this study. Specify any risks to which participants may possibly be exposed. Specify the measures being taken to minimize the risks and the chance of harm to the volunteers and the additional safeguards that have been included in the protocol to protect their rights and welfare.

All participants in this study will be healthy volunteers who are able to perform daily functions at work.

g) How will you identify and recruit potential participants about the research study? (E.g., by: chart review; notified by treating physician; response to ad). All final or revised recruitment materials, flyers, etc. must be submitted to the IRB for review and approval before use. You may not contact potential participants prior to IRB approval. See Advertisements: Appropriate Language for Recruitment Material.

Participants will be recruited via email solicitation once they have been scheduled for the above rotations.

h) Inclusion and Exclusion Criteria.

Identify inclusion criteria.

All residents who are scheduled for a night float rotation in the general Stanford Operating room or on OB anesthesia will be included.

Identify exclusion criteria.

Participants who report taking prescription medications that may effect alertness during the study period will not be enrolled.

i) Describe your screening procedures, including how qualifying laboratory values will be obtained. If you are collecting personal health information prior to enrollment (e.g., telephone screening), please request a waiver of authorization for recruitment (in section 15).

Demographic information will be collected via an electronic survey distributed at the beginning of the study period. We will not collect any PHI prior to enrollment.

j) Describe how you will be cognizant of other protocols in which participants might be enrolled. Please explain if participants will be enrolled in more than one study.

We will not enroll participants who are currently enrolled in other studies.

k) Payment/reimbursement. Explain the amount and schedule of payment or reimbursement, if any, that will be paid for participation in the study. Substantiate that proposed payments are reasonable and commensurate with the expected contributions of participants and that they do not constitute undue pressure on participants to volunteer for the research study. Include provisions for prorating payment. See payment considerations

Participants who complete the study will be compensated with $10 gift card at completion of final survey. We consider this to be an appreciation gift at a token level.

l) Costs. Please explain any costs that will be charged to the participant.

The participant will not be expected to incur any costs while participating in the study. The Fitbits will be

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provided by Dr. Flood that have been used in a previous study.

m) Estimate the probable duration of the entire study. Also estimate the total time per participant for: (i) screening of participant; (ii) active participation in study; (iii) analysis of participant data.

We anticipate that this study will take two years. Screening of each participant will take approximately 30 minutes, we will track their sleep and activity for 3-6 weeks, and 3 surveys will take no more than 5 minutes each and will be delivered with a web link sent by Redcap. We anticipate we will spend 20 hours analyzing all of the collective data per participant.

9. Risks

a) For the following categories include a scientific estimate of the frequency, severity, and reversibility of potential risks. Wherever possible, include statistical incidence of complications and the mortality rate of proposed procedures. Where there has been insufficient time to accumulate significant data on risk, a statement to this effect should be included. (In describing these risks in the consent form to the participant it is helpful to use comparisons which are meaningful to persons unfamiliar with medical terminology.)

The risks of the Investigational devices.

N/A. This is not an investigational device.

The risks of the Investigational drugs. Information about risks can often be found in the Investigator's brochure.

N/A

The risks of the Commercially available drugs, reagents or chemicals. Information about risks can often be found in the package insert.

N/A

The risks of the Procedures to be performed. Include all investigational, non-investigational and non-invasive procedures (e.g., surgery, blood draws, treadmill tests).

N/A

The risks of the Radioisotopes/radiation-producing machines (e.g., X-rays, CT scans, fluoroscopy) and associated risks.

N/A

The risks of the Physical well-being.

There are theoretical risks of wearing Fitbit devices, such as increased exposure to increased wireless radiation. However, this exposure is low and adverse effects have not been quantified.

The risks of the Psychological well-being.

There are theoretical risks that participating in this study may increase self-awareness of the amount of sleep deprivation and fatigue that the resident is currently experiencing, and it may lead to increased work dissatisfaction.

The risks of the Economic well-being.

N/A

The risks of the Social well-being.

N/A.

Overall evaluation of Risk.

Low - innocuous procedures such as phlebotomy, urine or stool collection, no therapeutic agent, or safe therapeutic agent such as the use of an FDA approved drug or device.

b) If you are conducting international research, describe the qualifications/preparations that enable you to both estimate and minimize risks to participants. Provide an explanation as to why the research

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must be completed at this location and complete the [LINKFORINTERNATIONALREASEARCHFORM] International Research Form. If not applicable, enter N/A.

N/A

c) Describe the planned procedures for protecting against and minimizing all potential risks. Include the means for monitoring to detect hazards to the participant (and/or to a potential fetus if applicable). Include steps to minimize risks to the confidentiality of identifiable information.

All of the data collected will be coded after collection. Identifiable data will be stored in Redcap, once coded, data will only be accessible by investigators and analyzed on a secure, Stanford-encrypted, password protected computer.

d) Explain the point at which the experiment will terminate. If appropriate, include the standards for the termination of the participation of the individual participant Also discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the participants.

Because this project is observational only, we do not anticipate the need for termination of the participation of the individual participant. However, if any unforeseen complications occur, such as personal illness or emergency, that they were not able to complete the study period, we would exclude them from the analysis. The participant can take the device off at any time.

10. Benefits

a) Describe the potential benefit(s) to be gained by the participants or by the acquisition of important knowledge which may benefit future participants, etc.

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

11. Privacy and Confidentiality

Privacy Protections

a) Describe how the conditions under which interactions will occur are adequate to protect the privacy interests of participants (e.g., privacy of physical setting for interviews or data collection, protections for follow-up interactions such as telephone, email and mail communications).

All demographic information and PROMIS surveys will be administered, collected and stored in Redcap as this method is approved by Stanford for data security. The data will be coded and only be accessed via secure Stanford University-approved computer that is up to date with the necessary school of medicine privacy software. We will communicate via secure messaging if any PHI is involved.

Confidentiality Protections

b) Specify PHI (Protected Health Information). PHI is health information linked to HIPAA identifiers

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(see above). List BOTH health information AND HIPAA identifiers. If you are using STARR, use the Data Privacy Attestation to ensure that your request will match your IRB-approved protocol. Be consistent with information entered in section 15a.

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.

c) You are required to comply with University Policy that states that ALL electronic devices: computers (laptops and desktops; OFFICE or HOME); smart phones; tablets; external hard disks, USB drives, etc. that may hold identifiable participant data will be password protected, backed up, and encrypted. See http://med.stanford.edu/datasecurity/ for more information on the Data Security Policy and links to encrypt your devices.

Provide any additional information on ALL data security measures you are taking. You must use secure databases such as https://researchcompliance.stanford.edu/panels/hs/redcap RedCap. If you are unsure of the security of the system, check with your Department IT representative. Please see http://med.stanford.edu/irt/security/ for more information on IRT Information Security Services and http://www.stanford.edu/group/security/securecomputing/mobile_devices.html for more information for securing mobile computing devices. Additionally, any PHI data on paper must be secured in an locked environment.

By checking this box, You affirm the aforementioned. Y

We will be using RedCap. Additionally, data will only be handled on a Stanford issued and appropriately encrypted laptop

d) Describe how data or specimens will be labeled (e.g. name, medical record number, study number, linked coding system) or de-identified. If you are de-identifying data or specimens, who will be responsible for the de-identification? If x-rays or other digital images are used, explain how and by whom the images will be de-identified.

Each participant will be issued an unique identifier at the beginning of the trial period by Dr. Ruan. We will not have any specimens, x rays or digital images

e) Indicate who will have access to the data or specimens (e.g., research team, sponsors, consultants) and describe levels of access control (e.g., restricted access for certain persons or groups, access to linked data or specimens).

The members listed on the IRB protocol will be the only individuals who have access to the data. Drs. Ruan and Flood will be the only member to have access to the code which links the participants to their data.

f) If data or specimens will be coded, describe the method in which they will be coded so that study participants' identities cannot be readily ascertained from the code.

Each participant will randomly be assigned a code which contains a letter and number, generated by a random number generator. These data will be kept in Redcap and will otherwise not be accessible.

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g) If data or specimens will be coded, indicate who will maintain the key to the code and describe how it will be protected against unauthorized access.

Our data collected will be immediately coded for analysis. Drs. Ruan and Flood will be the only member to have access to the code which links the participants to their data. These data will be kept in Redcap and will otherwise not be accessible.

h) If you will be sharing data with others, describe how data will be transferred (e.g., courier, mail) or transmitted (e.g., file transfer software, file sharing, email). If transmitted via electronic networks, describe how you will secure the data while in transit.See http://www.stanford.edu/group/security/securecomputing/. http://www.stanford.edu/group/security/securecomputing/. Additionally, if you will be using or sharing PHI see https://uit.stanford.edu/security/hipaa https://uit.stanford.edu/security/hipaa.

Data will be transferred via secure Stanford webmail and Stanford Box

i) How will you educate research staff to ensure they take appropriate measures to protect the privacy of participants and the confidentiality of data or specimens collected (e.g. conscious of oral and written communications, conducting insurance billing, and maintaining paper and electronic data)?

All of our research team are or will be up to date on CITI training before initiation of the study.

12. Potential Conflict of Interest

Investigators are required to disclose any financial interests that reasonably appear to be related to this protocol.

Financial Interest Tasks

Investigators	Role	Email	Has Financial Interest?	Date Financial Interest Answered	Date OPACS Disclosure Submitted	Date OPACS Review Completed
Alexandra Ruan	PD	aruan@stanford.edu	N	05/21/2019		
Dr. Natalya Sarah Hasan	COPD	nhasan@stanford.edu	N	05/21/2019		
Dr. Pamela Flood	FS	pflood@stanford.edu	N	05/19/2019		

13. Consent Background

13. 1 Consent — Sleep Study Consent Form 08/2020

Sponsor's Consent Version Number: (if any) : 3

a) Describe the informed consent process. Include the following.

i) Who is obtaining consent? (The person obtaining consent must be knowledgeable about the study.)

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ii) When and where will consent be obtained?
iii) How much time will be devoted to consent discussion?
iv) Will these periods provide sufficient opportunity for the participant to consider whether or not to participate and sign the written consent?
v) What steps are you taking to minimize the possibility of coercion and undue influence?
vi) If consent relates to children and if you have a reason for only one parent signing, provide that rationale for IRB consideration.

i) Either Dr. Preya Jhita or Dr. Alexandra Ruan ii) consent will be obtained in person at the beginning of the study iii) at least 10 minutes, longer if participant has additional questions. The consent form will also be provided for the participant to read ahead of time iv) yes V) participation is completely voluntary. they are only receiving a nominal participation gift card, and initial recruitment is via email so we hope there is no pressure to respond to them email if unwilling to participate vi) no children will participate in this study

b) What is the Procedure to assess understanding of the information contained in the consent? How will the information be provided to participants if they do not understand English or if they have a hearing impairment? See HRPP Chapter12.2 for guidance.

We do not anticipate any non-english speakers to participate in this study. All participants will be residents with medical degrees

c) What steps are you taking to determine that potential participants are competent to participate in the decision-making process? If your study may enroll adults who are unable to consent, describe (i) how you will assess the capacity to consent, (ii) what provisions will be taken if the participant regains the capacity to consent,(iii) who will be used as a legally authorized representative, and (iv) what provisions will be made for the assent of the participant.

We do not anticipate enrolling any participants who are unable to consent for themselves

14. Assent Background (less than 18 years of age)

15. HIPAA Background

16. Attachments

Attachment Name	Attached Date	Attached By	Submitted Date
PROMIS Fatigue	07/07/2019	aruan	
PROMIS Positive Affect	07/07/2019	aruan	
PROMIS Sleep Disturbance	07/07/2019	aruan	
51495 Ruan Academic Sponsor Review	07/08/2019	ahorwege	
Participant Demographic Survey	07/19/2019	aruan	
Recruitment email v 3.0	08/08/2020	aruan	

Obligations

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The Protocol Director agrees to:

- Adhere to principles of sound scientific research designed to yield valid results
- Conduct the study according to the protocol approved by the IRB
- Be appropriately qualified to conduct the research and be trained in Human Research protection, ethical principles, regulations, policies and procedures
- Ensure all Stanford research personnel are adequately trained and supervised
- Ensure that the rights and welfare of participants are protected including privacy and confidentiality of data
- Ensure that, when de-identified materials are obtained for research purposes, no attempt will be made to re-identify them.
- Disclose to the appropriate entities any potential conflict of interest
- Report promptly any new information, modification, or unanticipated problems that raise risks to participants or others
- Apply relevant professional standards.

Any change in the research protocol must be submitted to the IRB for review prior to the implementation of such change. Any complications in participants or evidence of increase in the original estimate of risk should be reported at once to the IRB before continuing with the project. Inasmuch as the Institutional Review Board (IRB) includes faculty, staff, legal counsel, public members, and students, protocols should be written in language that can be understood by all Panel members. The investigators must inform the participants of any significant new knowledge obtained during the course of the research.

IRB approval of any project is for a maximum period of one year. For continuing projects and activities, it is the responsibility of the investigator(s) to resubmit the project to the IRB for review and re-approval prior to the end of the approval period. A Notice to Renew Protocol is sent to the Protocol Director 7 weeks prior to the expiration date of the protocol.

https://stanfordmedicine.box.com/shared/static/qbsi8u8h47qsotxhdpuzz50xlrqa0sgo.pdf Report promptly any new information, complaints, possibly serious and/or continuing noncompliance, or unanticipated problems involving risks to participants or others.

All data including signed consent form documents must be retained for a minimum of three years past the completion of the research. Additional requirements may be imposed by your funding agency, your department, or other entities. (Policy on Retention of and Access to Research Data, Research Policy Handbook, http://doresearch.stanford.edu/policies/research-policy-handbook/conduct-research/retention-and-access-research-data)

APPROVAL LETTER/NOTICE NOTE: List all items (verbatim) that you want to be included in your approval letter (e.g., Amendment date, Investigator's Brochure version, consent form(s) version(s), advertisement name, etc.) in the box below.

Y By checking this box, I verify that I, as the Protocol Director (PD) responsible for this research protocol, have read and agree to abide by the above obligations, or that I have been delegated authority by the PD to certify that the PD has read and agrees to abide by the above obligations.