**INSTRUCTIONS:**

* *Use this “TEMPLATE PROTOCOL (HRP-503)” to prepare a study protocol outlining your research plan.*
* *Depending on the nature of your study, some major sections might not be applicable to your research. If so, simply mark as “N/A.” For example, a simple survey might have many sections with “N/A.” For subsections (e.g., 1.x or 8.x) you can mark as “N/A”if you are certain that the subsection is not applicable.*
* *Once the IRB/HRPP approves your submission, your latest approved version of the protocol will be stored in the IRB Protocol Management online system.*
* *If your research plan changes and you need to modify the protocol, please submit an amendment to Protocol Management with the requested modifications. Download your current protocol from Protocol Management and indicate the changes/revisions using the track changes feature in order to make review of the modifications easier to follow. If you are unable to use track changes, please create a new paragraph wherever you need to make a change, and indicate “Amendment: Date” before making a change to any section. Protocol management will store the older versions of your protocol if the IRB or HRPP staff need to compare them during the review.*

**PROTOCOL TITLE:**

*Include the full protocol title*.

Context-Aware Sit-Stand Intervention for Promoting Healthy Behaviors of Knowledge Workers

**PROTOCOL NUMBER:**

*Include the number assigned in Protocol Management (verify this has been added before submitting protocol to HRPP)*.

IRB#

**PRINCIPAL INVESTIGATOR:**

*Full Name and Degrees*: Sol Lim, Ph.D.

*Department*: Industrial and Systems Engineering

*Telephone Number*: 540-231-0083

*Email Address*: sol@vt.edu

**FUNDING:**

*Sponsor(s)*: Office Ergonomics Research Committee RFP

*Funded already or in the proposal phase?*: Click here to provide a response.

*Is Virginia Tech the primary awardee or the coordinating center of this grant or contract? If not, list the primary institution*: Click here to provide a response.

**VERSION NUMBER/DATE:**

*Include the version number and date of this protocol. Versions should start at 1.0.*

Version 1.0 01/25/2023

**REVISION HISTORY:**

*Use this table to keep track of changes.**Add more rows as needed.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Revision #** | **Version Date** | **Brief Summary of Changes  (i.e., the different sections)** | **Consent Change?** |
| 1.0 | 01/25/2023 | The initial submission |  |
|  |  |  |  |
|  |  |  |  |
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# Study Summary

|  |  |
| --- | --- |
| **Study Title** | Context-Aware Sit-Stand Intervention for Promoting  Healthy Behaviors in Knowledge Workers |
| **Study Design** | In this study, knowledge workers will be recruited for a one-week observational study about their sit and stand behaviors. Each participant’s sit-stand desk will be equipped with our custom hardware to track the desk's height over the study period. Participants will also be provided with a software to tracks workers’ on-screen activities and to pop up window every 10 minutes to collect self-reported standing scores, a measure of workers’ willingness to stand for each time interval. Collected data will be analyzed to investigate the relationship between their working context and their postural statues. Later, a semi-structured interview will be hold to obtain feedback from paricipants. |
| **Primary Objective** | We hope to identify moments and contexts in which workers are willing to transition from sitting to standing and vice versa. |
| **Secondary Objective(s)** | And we want to study specific time points in time when workers would be willing to switch postures during  their working hours to prevent sedentary behaviors with minimal disruption to their work. |
| **Study Population** | Modern knowledge workers who have sit-stand desks. |
| **Sample Size** | 10 participants |
| **Research Intervention(s)/ Investigational Agent(s)** | Surveys, interviews, observations, collecting data |
| **Study Duration for Individual Participants** | One week (5 week days) |
| **Acronyms and Definitions** |  |

# Objectives

* 1. *Describe the purpose, specific aims, or objectives of this study*:

Prolonged siting is associated with increased risks of cardiovascular diseases, low back pain, and premature death. Sit-stand desks are promoted as an effective intervention to promote healthy behaviors among knowledge workers by encouraging them to alternate postures between sitting and standing. The state-of-the-art approach uses a software-based alert that notifies workers to change their posture at fixed intervals. However, the lack of contextual consideration in suggesting a posture switch may be detrimental to productivity, as it can be disruptive to workers, and having an intervention system force the switch between sitting and standing may adversely affect workers’ willingness to switch postures. Hence, in this study, we want to understand the relationship between a worker’s working context and personal preferences to encourage healthy and productive behaviors through collecting data about their sit and stand postures and their working context in real time.

* 1. *State the hypotheses to be tested*:

We hypothesize that knowledge workers are facing challenges in switching sit and stand postures manually or automatically to avoid unnecessary interruptions while working.

We hypothesize that knowledge workers' postural statue switching is related to their ongoing working context.

# Background

* 1. *Summarize the relevant prior research on this topic and gaps in current knowledge within the field of study*:

Prolonged sitting is associated with increased risks of multiple types of diseases [1-3]. The state-of-the-art approach to suggest modern knowledge workers to switching between sitting and standing postures are using a software-based alert that notifies workers to change their posture at fixed intervals (e.g., alternating between 30–50 minutes of sitting time and 10–20 minutes of standing time [4-6]). However, there appears to be relatively little research focused on intelligently suggesting users to switch postures based on their ongoing working contexts to avoid distractions and disruptions.

[1] Taylor, W. C. Prolonged Sitting and the Risk of Cardiovascular Disease and Mortality. Curr. Cardiovasc. Risk Rep. 5, 350–357 (2011).

[2] Corlett, E. N. Background to sitting at work: research-based requirements for the design of work seats. Ergonomics 49, 1538–1546 (2006).

[3] Ekelund, U. et al. Does physical activity attenuate, or even eliminate, the detrimental association of sitting time with mortality? A harmonised meta-analysis of data from more than 1 million men and women. The Lancet 388, 1302–1310 (2016).

[4] Sharma, P. P., Mehta, R. K., Pickens, A., Han, G. & Benden, M. Sit-Stand Desk Software Can Now Monitor and Prompt Office Workers to Change Health Behaviors. Hum. Factors 61, 816–824 (2019).

[5] Barbieri, D. F. et al. Sit–Stand Tables With Semi-Automated Position Changes: A New Interactive Approach for Reducing Sitting in Office Work. IISE Trans. Occup. Ergon. Hum. Factors 5, 39–46 (2017).

[6] Chau, J. Y. et al. Desk-based workers’ perspectives on using sit-stand workstations: a qualitative analysis of the Stand@Work study. BMC Public Health 14, 752 (2014).

* 1. *Describe any relevant preliminary data*:

No preliminary data.

* 1. *Based on the existing literature, provide the scientific or scholarly rationale for and significance of your research and how will it add to existing knowledge*:

Frequently switching postures for modern knowledge workers are necessary to stay in health, especially for long-time required work. Sit-stand desk is a helpful intervention to promote healthy behaviors by allowing users to release physical stresses. Meanwhile, using software-based approaches could notify users to switch postures effectively. The proposed research aims to investigate the problems of finding appropriate time points to suggest users to switch postures according to their working contexts. And the result should be applicable to modern knowledge workers in general.

# Study Endpoints

* 1. *Describe the primary and secondary* ***study*** *endpoints. See links below for discussion of study endpoints and how they may differ from study objectives. These are most common in clinical trials but are sometimes applicable to other types of biomedical research, as well as social, behavioral, or educational research. See link below for a discussion.*

[*https://docs.google.com/document/d/1Wocz7K7a0hCQJPPO\_khh5l1SQQjhGDDGHzcOPRHR5Tw/edit?usp=sharing*](https://docs.google.com/document/d/1Wocz7K7a0hCQJPPO_khh5l1SQQjhGDDGHzcOPRHR5Tw/edit?usp=sharing)

We will finish the study until we have recruited enough number of participants to collect data. As for current design, we plan to recruit 10 modern knowledge workers.

Not applicable.

* 1. *Describe any primary or secondary* ***safety*** *endpoints. These should be included for all studies that are greater than minimal risk. (Minimal risk: The probability and magnitude of harm or discomfort anticipated in the research that are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.)*:

We will finish the study if we notify any safety issues during the user study. In addition, if we find any safety vulnerable points in the task or participant's working environment, we will end the study.

# Study Design and Statistical Analysis Plan

* 1. *Describe the basic study design/approach (e.g., qualitative study using five focus groups of first year students to describe assimilation into the university community; randomized controlled trial of a behavioral change intervention to increase dietary intake of whole grains; pre- post-test evaluation of new pedagogical techniques to improve adult literacy)*:

Each participant’s sit-stand desk will be equipped with our custom hardware to track the desk's height over the study period. Participants will also be provided with a software to tracks workers’ on-screen activities and to pop up window every 10 minutes to collect self-reported standing scores, a measure of workers’ willingness to stand for each time interval. During the whole user study, participants will be asked to use their computers and sit-stand desks with our devices installed to do their normal daily work as usual. After the study, we will gather data collection, such as desk height and font-most application. Additionally, a semi-structured interview will be used to understand daily work routines and work contexts, and to determine how to adapt this information to an engaging, personalized sit-stand intervention system. The process of interview will be recorded by devices.

* 1. *Describe corresponding data analysis plan/approach (e.g., content analysis of focus group transcripts; descriptive analysis followed by linear regression modeling; nonparametric analysis of pre- and post-test measures)*:

Collected data will be analyzed with exploratory data analysis. Next, the data will be analyzed to understand when modern knowledge workers would like to switch their postures during working. For the interview result, we will conduct thematic analysis to analyze participants' answers.

# Setting

* 1. *Describe the sites or locations where your research team will conduct the research. Consider each of the items listed below:*
     + *Identify where your research team will identify and recruit potential subjects.*
     + *Identify where the team will perform the research procedures.*
     + *Describe the composition and involvement of any community advisory board(s).*
     + *For research conducted in other locations, describe:*
       - *Site-specific regulations or customs affecting the research at those locations.*
       - *Local scientific and ethical review structure at those locations.*

*Examples include work in other cultures or ethnic groups (within or outside of the U.S.) and work with churches. The HRPP will provide additional guidance for international research.*

The study will be conducted at participants' personal working area, e.g., where their sit-stand desks are.

Semi-structured interview will be conducted online or at Usability Lab 133 (D, E, F) at McBryde Hall

# Study Intervention(s)/Investigational Agent(s)

*7.1 Describe the study interventions (including behavioral interventions) and/or investigational agents (e.g., drugs or devices) to be used in this study. Consider each of the items listed below:*

* + - *Drug/Device Handling: If the research involves drugs or devices, describe your plans to store, handle, and administer the drugs or devices so that they will be used only on subjects, and only by authorized investigators.*
    - *Describe whether any of the following will be used: microwaves, X-rays, DEXA scans, general anesthesia, or sedation*
    - *If control of the drugs or devices used in this protocol will be accomplished by following an established, approved organizational SOP (e.g., Research Pharmacy SOP for the Control of Investigational Drugs, etc.), please reference the SOP in this section.*

N/A

* 1. *List the name of all drugs (including any vitamins, supplements, herbs, or nicotine) to be used in the study. Indicate whether they have FDA approval, and list any limitations for their use*:

N/A

* 1. *List all devices, how they will be used, their purpose in the study, and if they will be used in a manner consistent with their approved uses. If they will be used in ways that are not yet FDA approved, indicate whether they need an IDE or a determination that they are exempt from the IDE Determination. If a determination of significant risk or non-significant risk is needed for any of the devices, include the researcher’s recommendation for each of those devices*:

N/A

* 1. *If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:*
     + *Identify the holder of the IND/IDE/abbreviated IDE.*
     + *Explain procedures followed to comply with sponsor requirements for FDA regulated research for the following:*

|  |  |  |  |
| --- | --- | --- | --- |
|  | ***Applicable to:*** | | |
| ***FDA Regulation*** | ***IND Studies*** | ***IDE studies*** | ***Abbreviated IDE studies*** |
| ***21 CFR 11*** | ***X*** | ***X*** |  |
| ***21 CFR 54*** | ***X*** | ***X*** |  |
| ***21 CFR 210*** | ***X*** |  |  |
| ***21 CFR 211*** | ***X*** |  |  |
| ***21 CFR 312*** | ***X*** |  |  |
| ***21 CFR 812*** |  | ***X*** | ***X*** |
| ***21 CFR 820*** |  | ***X*** |  |

N/A

# Procedures Involved

* 1. *Describe and explain the study design*:

The study is aimed to investigate appropriate time points to suggest modern knowledge workers to switch their postural status according to their working contexts. During the study, each participant’s sit-stand desk will be equipped with a device to track the desk's height over the study period. Participants will also be provided with a software to tracks workers’ on-screen activities. During the whole user study, participants will be asked to use their computers and sit-stand desks with our devices installed to do their normal daily work as usual. After the study, we will gather data collection, such as desk height and font-most application. We will use collected data to test our hypothesizes and answer research questions. At last, we gather data generated during the study and conduct brief interview to collect subjective feedback from participants.

* 1. *Provide a description of:*
     + *All research procedures being performed*
     + *If the study has more than one procedure, session, and/or subject population, describe each procedure, session, and/or study population separately. For complex studies, you are encouraged to include a figure or chart.*

The study will take place at participants' working places where their sit-stand desks are. The whole study will take a week (5 weekdays).

The interview will be conducted online through zoom or at Usability Lab 133 (D, E, F) at McBryde Hall and this will take approximately 30 minutes for each participant.

For the one-week user study, when participants arrive, they will be taught how to install our customized device on their sit-stand desks with instruction in details. Then, we will install our screen tracking applications on participants' computers. Once all set, participants can start the user study with their devices at their working environment as usual. There are no specific requirements or rules about how percipients should do during this study.

After the study, we will retrieve our devices back and uninstall software on participants' computers. Then, participants will be interview about their past experience in person or remotely.

* 1. *Describe:*
     + *Procedures or safeguards intended to reduce the probability and magnitude of risks. (For example: Reducing the risk of injury in a virtual reality study either by having the subjects sit during the study or by providing an obstacle-free space for walking.)*
     + *Be sure to describe all drugs and devices used in the research, when they will be administered or used, and their purpose.*
     + *Methods used to collect data about subjects. Please upload all data collection forms to Protocol Management. Some common examples are:*
     + *Screening questionnaires*
     + *Survey(s), including online surveys*
     + *Demographic questionnaire(s)*
     + *Interview guide(s), e.g., questions or pool of questions for semi-structured interviews*
     + *Focus group guide(s)*
     + *Other documents used to collect data*

The study will take place at participant's working environment where there sit-stand desks are. We encourage participants to finish the study at places where they are comfortable and familiar with.

Quantitative data will be automatically generated and saved by our hardware and software devices. And Qualitative feedback will be recorded by the experimenter in digital documents. For the interview, we will only record audio answers.

* 1. *What data will you collect during the study and how you will obtain them? Please include descriptions of electronic data collection, database matching, and app-based data collection*:

Hardware device will record sit-stand desks height automatically. Screen tracking application will log data for timestamps and screen front-most applications.

We will record users' interview during the experiment. And we will ensure only audio will be recorded.

After the study, all data will be exported and stored safely in a password-protected computer in the EchoLab for further data analysis.

* 1. *Who will transcribe or code audio and/or video recordings?*:

PIs

* 1. *Include a description of any deception to be used in the study. Include justification for the use of deception (why the deception is necessary), describe the debriefing process, and describe how the study meets all the following criteria for alteration of consent (deception is considered an alteration of informed consent):*
* *The research involves no more than minimal risk to the subjects*
* *The alteration will not adversely affect the rights and welfare of the subjects*
* *The research could not practicably be carried out without the alteration/deception*
* *(Optional but encouraged in most cases) Subjects will be provided with additional pertinent information after participation (i.e., debriefing for studies involving deception)*

N/A

* 1. *If the study involves long-term follow-up (once all research related procedures are complete), describe what data will be collected during the follow up period and when it will occur*:

N/A

# Data and Specimen Long Term Storage and Use

* 1. *If you will store data or specimens for future use, describe where you will store the data or specimens, how long they will be stored, and how and by whom the data or specimens will be accessed*:

All study data will be stored in a password-protected computer in the EchoLab and will be stored for a year for future possible analysis. Only the protocol investigators will have the permission to access to the data.

The consent form will be stored in EchoLab for 3 years after the study is closed. After 3 years, all consent forms will be deleted permanently.

* 1. *For specimens, list the data to be stored or associated with each specimen*:

N/A

* 1. *Describe the procedures to release data or specimens outside of the research team, including the process to request a release, approvals required for release, who can obtain data or specimens, and what data will be provided with specimens*:

N/A

* 1. *Describe the identifiers to be included with stored data or specimens, as well as any key or code that could be used to make them identifiable. Describe where the code will be stored, who will have access to it, and when it will be destroyed*:

Name will only be collected on consent forms and is not part of the stored data. Participants will only be identified by a study code on all data documents. No key linking study codes to names will be kept.

* 1. *Please select the identifiers you will obtain (whether directly from participants or from another source), including but not limited to:*

|  |  |
| --- | --- |
|  | *Name* |
|  | *Geographical subdivisions smaller than a state, including street address, city, county, precinct, zip code, and equivalent geocodes (note, the initial three digits of a zip code are not considered identifiable)* |
|  | *Elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death, and single year of age over 89 and all elements of dates (including year) indicative of such age (note, such ages and elements may be aggregated into a single category of age 90+)* |
|  | *Phone numbers* |
|  | *Fax numbers* |
|  | *Electronic mail addresses (e-mail)* |
|  | *Social Security numbers* |
|  | *Medical record numbers* |
|  | *Health plan beneficiary numbers* |
|  | *Account numbers* |
|  | *Certificate/license numbers* |
|  | *Vehicle identifiers and serial numbers, including license plate numbers* |
|  | *Device identifiers and serial numbers* |
|  | *Web Universal Resource Locators (URLs)* |
|  | *Internet protocol (IP) address numbers* |
|  | *Biometric identifiers, including finger and voice prints (audio recording)* |
|  | *Full face photographic images and any comparable images (including video recording)* |
|  | *Student record number or identification number* |
|  | *User name for online or computer accounts* |
|  | *Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data)****:*** Click here to explain. |

# Sharing of Results with Subjects

* 1. *Describe whether you will share results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) with subjects or others (e.g., the subject’s primary care physician). If so, describe how you will share the results and include this information as part of the consent document. Upload materials you will use to explain the results to subjects*:

No

# Study Timelines

* 1. *Describe:*
     + *The duration of an individual subject’s participation in the study (for example, 1 hour, 2-4 weeks, 3-5 years).*
     + *The amount of time expected to enroll all study subjects (weeks, months, years, etc.)*
     + *The amount of time expected for the investigators to complete this study including primary data analyses.*

The user study will take a week long (5 weekdays) and the interview session will take approximately 30 minutes. We plan to recruit and finish the study for 4 weeks.

And the following analysis of the study should take four weeks.

# Inclusion and Exclusion Criteria

* 1. *Describe how you will screen individuals for eligibility. When will screening occur and what procedures will you use? Upload any screening scripts or surveys to Protocol Management*:

We will need participants who are 18 or older. Participants should have a sit-stand desk and macOS computer for their working and identified as a knowledge worker. We will ask participants for their age and their equipment upon signing up.

* 1. *Describe the eligibility criteria that define who will be included and who will be excluded from enrollment for each procedure of your study. Include any geographic criteria (e.g., Virginia Tech undergraduate students, a national sample of adults with engineering degrees, minors aged 8-12 in the New River Valley, university faculty in Virginia and Paris, France)*:

18 or older.

Knowledge workers.

Have a sit-stand desk and macOS computer for daily working.

* 1. *Indicate specifically whether you will include or exclude each of the following special populations: (You may not include members of these populations as subjects in your research unless you indicate them in the description of your subject population.)*
     + *Minors, as defined by state law where the study is performed (infants, children, teenagers)*
     + *Pregnant women (can be included in minimal risk studies by mentioning in section 13.1)*
     + *Prisoners (including all incarcerated individuals)*
     + *Adults not capable to consent on their own behalf*

N/A

# Vulnerable Populations

* 1. *If the research involves individuals who are vulnerable to coercion or undue influence, please describe additional safeguards you will include to protect their rights and welfare. Consider the applicable items listed below:*
     + *If the research involves Virginia Tech students, indicate whether these are students of any of the investigators. If so, describe whether the activities will take place during class time as part of the curriculum and the steps you will take to reduce the possibility that students feel obliged to participate in order to improve their course grade. The HRPP can provide further guidance as needed. Describe whether you will request access to student records (e.g., SAT, GPA, GRE scores).*
     + *If the research involves employees of Virginia Tech or the research sponsor, describe steps you will take to ensure that the employees are freely participating and describe how their data will be protected from inspection by their supervisors.*
     + *If the research involves Virginia Tech NCAA athletes, you must obtain approval from the athletic department.*
     + *For research involving Montgomery County Public Schools, you must obtain county approval (after obtaining contingent Virginia Tech approval). Other locales have different requirements; please check on these and describe here. Approval is typically granted by the superintendent, principal, and classroom teacher (in that order). Approval by an individual teacher is insufficient. School approval, in the form of a letter or a memorandum should be uploaded as a supporting document.*
     + *If the research involves pregnant women, review “CHECKLIST: Pregnant Women (HRP-412)” to ensure that you have provided sufficient information in this protocol.*
     + *If the research involves prisoners, review “CHECKLIST: Prisoners (HRP-415)” to ensure that you have provided sufficient information in this protocol.*
     + *If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research (minors), review the “CHECKLIST: Minors (HRP-416)” to ensure that you have provided sufficient information in this protocol.*
     + *If the research involves cognitively impaired adults, review “CHECKLIST: Cognitively Impaired Adults (HRP-417)” to ensure that you have provided sufficient information in this protocol.*

N/A

# Number of Subjects

* 1. *Indicate the total number of subjects to be enrolled and how this number was determined (e.g., sample size calculation [show], number of available subjects in a finite pool, number of tests funding award would allow)*:

We plan to recruit 10 participants.

* 1. *If this is a multi-site study, indicate the number of subjects to be enrolled at this site and the total to be enrolled from all sites*:

N/A

* 1. *If applicable, indicate the number of potential subjects you expect to screen for enrollment, and the number of subjects you will need to complete the research procedures*:

10 participants to screen and 10 participants to finish the study

* 1. *If the study has more than one procedure, indicate the total number of subjects to undergo each procedure separately*:

N/A

# Recruitment Methods

* 1. *Describe when, where, and how you will recruit potential subjects*:

Participants will be recruited via email advertisement and Slack Channels.

* 1. *Describe the source of subjects (for example, clinic patients with specific conditions, students in the library, community members at a gathering, or members of a local gym)*:

Participants will be recruited from the university and local community.

* 1. *Describe the methods that you will use to identify potential subjects*:

N/A

* 1. *Describe materials that you will be use to recruit subjects. Attach copies of these documents with this protocol in Protocol Management and be sure to include the IRB protocol number on each document.*
* *For flyers, attach the final copy of printed flyers.*
* *For Virginia Tech News, Facebook postings and ads, newspaper ads, websites, MTurk/SONA/online survey systems, etc., attach the final wording and graphics to be used.*
* *For email recruitments, please include the subject line.*
* *For advertisements meant for audio broadcast, please submit the wording of the advertisement prior to taping (to avoid having to re-record with approved language) and submit the final recorded version for IRB review before use.*

*Describe any compensation to subjects. Separate compensation into appropriate categories, such as: reimbursement for expenses, time and effort, and additional incentives for study participation. For each category, specify the amount (including any pro-rated amount), schedule, and method of payment.*

EchoLab and "" are inviting you to participant in a research study with sit-stand desk and working contexts. Our team is investigating the best time points to notify you to switch your postural statues during long-time working. The study wants to enhance your working productivity and help you stay by acknowledging your working contexts and habits.

Participants in the study will come to the Usability Lab 133 (D, E, F) McBryde Hall. Participants will be asked to install a hardware on sit-stand desks to detect height and a screen tracking application on computer to track screen activities. During the study, participants will be asked to work on their computers and sit-stand desk as usual. The user study will take a week long (5 weekdays). Later, a interview will be conducted and the entire session will be audio recoded. The interview will take 30 minutes.

We are seeking participants that are:

(1): 10 years or older

(2): Have a sit-stand desk for working

(3): Have a macOS computer

After the user study, each participant will be compensated with $100.

Participation will be on first come first serve basis. For more information, please Donghan Huat hudh0287@vt.edu. The project is supervised by Dr. Sang Won Lee in Computer Science and Dr. Sol Lim in Industrial and Systems Engineering.

This experiment has been approved, as required, by the Virginia Tech Institutional Review Board

# Withdrawal of Subjects

* 1. *Describe circumstances under which you anticipate subjects could be withdrawn from the research without their consent*:

Whenever the participants wish to withdraw from the study

* 1. *If applicable, describe any procedures for orderly termination (e.g., discontinuation of a study drug or debriefing after a behavioral intervention)*:

N/A

* 1. *Describe procedures that you will follow when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection (e.g., participant declines to continue with regular blood draws, but continues with periodic behavioral questionnaires)*:

Data collected from participants during the study will be destroyed permanently.

# Risks to Subjects

* 1. *List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects’ participation in the research. Include for the IRB’s consideration a description of the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, privacy, and economic risks. Do not indicate “No risk” or “N/A.” Instead, for studies with very low risk (e.g., anonymous online questionnaire on a mundane topic) indicate “The investigators are not aware of any risks from participation in this study.” or “No more than risks than are found in everyday life.” The example consent form presents a tabular method for risk information, which you can also use here. Common risk types include:*
* *Physical (e.g., potential for pain, discomfort, infection)*
* *Psychological (e.g., potential for stress, discomfort, and/or embarrassment)*
* *Social (e.g., potential for discrimination or stigmatization and disruption of personal and family relationships)*
* *Legal (e.g., potential for disclosure of illegal activity, negligence)*
* *Privacy (e.g., potential for personal information being accessed, used, or disclosed without the subjects’ knowledge or consent, breach of confidentiality/security)*
* *Economic (e.g., potential for individuals to lose access to economic services, employment, insurability)*

During the task, potential physical movement will be involved. There is some risk that participants will collide with obstacles in the physical environment or contact the physical items.

* 1. *Indicate the measures you will use to minimize risks and monitor subjects for safety. (e.g., asking a subject at regular intervals to rate how they are feeling from 1 to 10, or to slowly crouch in order to check their balance.)*

Click here to provide a response.

* 1. *If applicable, indicate which procedures might have risks to the subjects that are currently unforeseeable. This will be rare, and usually applicable when testing a new drug or device or a new use of an existing drug or device*:

Participants will be informed about the potential risks and will be given the option to quit the study at any time.

* 1. *If applicable, indicate which procedures might have risks to an embryo or fetus should the subject be or become pregnant*:

N/A

* 1. *If applicable, describe risks to others who are not subjects (e.g., collection of sensitive health data that might affect sexual partners if disclosed, mandatory reporting of abuse, DNA testing that might affect family members or relationships)*:

N/A

# Potential Benefits to Subjects

* 1. *Describe the potential benefits that individual subjects might experience from participating in the research. Include the probability, magnitude, and duration of the potential benefits, as this will be useful to the IRB’s risk:benefit analysis. Do not include benefits to society or others. Do not list monetary or non-monetary compensation for participation, as this is not a benefit These should be included in section 2 or 3 of this document*:

This research study will improve our understanding about relationship between knowledge worker's postural status switching and working context. The result can be utilized for future notification design. Study participants will benefit from understanding their working habits and acknowledging the importance of switching postures while working or studying for a quite long time.

* 1. *If applicable, specify that there are no anticipated direct benefits for participants*:

N/A

# Data Management and Confidentiality

* 1. *Describe procedures that you will use for quality control to ensure validity of collected data*:

Investigators will follow pre-defined procedure carefully to ensure the study going smoothly.

* 1. *Describe any existing data or biospecimens you will obtain as part of this study. Include:* 
     + *Variables or samples to be obtained*
     + *Source of the data or specimens*
     + *Your authorization to access or receive the data or biospecimens*
     + *Whether the data or biospecimens are publicly available*
     + *Whether the data or specimens you receive will contain identifiers*

N/A

* 1. *Describe the steps that you will take to handle and secure study data during data collection, storage, use, and transmission. Include information about training of study staff, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, separation of identifiers and data, etc.*:

All data will be saved digitally on a password-protected computer in the EchoLab.

* 1. *For multi-site studies, describe how data or specimens will be handled and secured for each site (e.g., central or disseminated data storage, data coordinating center)*:

N/A

* 1. *Describe the plan for data disposition following the conclusion of the study (e.g., long term maintenance of data, data destruction methods).* 
     + *What information will be included in the long term storage of data or specimens?*
     + *How long will the data or specimens be stored?*
     + *Where and how data or specimens will be stored?*
     + *Who will have access to the data or specimens during long term storage?*
     + *Who is responsible for receipt or transmission of the data or specimens?*
     + *How will data or specimens be shared or transported?*
     + *When and how will personal identifiers be destroyed?*

The consent forms will be stored in EchoLab for 3 years after the study is closed. After 3 years, all consent forms will be deleted permanently.

All collected data will be saved carefully for a year. And all digital data will be stored on a password-protected computer in EchoLab. Only investigators have permissions to access to saved data. Besides, all data will not be shared. Personal identifier is not stored.

# Provisions to Protect the Privacy Interests of Subjects

* 1. *Describe the steps that you will take to protect subjects’ privacy interests. “Privacy interest” refers to a person’s desire to place limits on with whom they interact or to whom they provide personal information (e.g., collecting the minimal amount of private information required to complete the study, protecting the data once it is obtained)*:

Click here to provide a response.

* 1. *Describe steps that you will take to make subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. “At ease” does not refer to physical discomfort, but the sense of intrusiveness a subject might experience in response to questions, examinations, and procedures (e.g., use of a same gender investigator to place sensors on the torso, a private changing area if clothing must be changed, sensitivity when discussing pregnancy testing with subjects, making it clear on surveys that participants can discontinue at any time, not asking questions about private or sensitive issues unless necessary for the research)*:

We will only ask for a minimal amount of private information from participants and will store such data in a password-protected computer in EchoLab.

* 1. *Describe how you plan to access existing sources of information about the subjects (e.g., medical records, grades) and how you will protect participant privacy through the data security plan*:

Participants will be communicated through email to ask about their feeling to know whether they would like to quit the study at any point.

* 1. *Describe any required reporting that might occur as a result of your research questions, study populations, and data collection methods. Examples for Virginia and Virginia Tech include:*
  + ***Any*** *suspicions (e.g., circumstantial, disclosed) of child abuse (physical, emotional, sexual) and neglect*
  + *Sexual discrimination and/or sexual violence that involves a student*
  + *Disclosure or signs of intention to harm oneself (i.e., suicidal ideation and/or plan)*
  + *Disclosure or signs of desire to harm others (i.e., homicidal ideation and/or plan)*
  + *Suspected abuse, neglect or exploitation of vulnerable adults (e.g., individuals with a disability, elderly persons)*

N/A

# Provisions to Monitor the Data to Ensure the Safety of Subjects

*Safety monitoring is required* *when research involves greater than minimal risk and is sometimes appropriate for other studies.*

* 1. *Describe:*
     + *The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe (e.g., periodic reporting to the IRB, establishing a data monitoring committee, reporting data monitoring committee findings to the IRB and the sponsor).*
     + *What data you will review, including safety data, unexpected events, and data that show the ability to produce the intended results.*
     + *How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with subjects).*
     + *The frequency of data collection, including when safety data collection starts.*
     + *Who will review the safety data and with what frequency.*
     + *The statistical tests for analyzing the safety data to determine whether harm is occurring.*
     + *Any conditions that will trigger an immediate suspension of the research (e.g., a serious adverse event).*

N/A

# Compensation for Research Related Injury

* 1. *If the research involves more than minimal risk to subjects, describe the available compensation in the event of research-related injury, if any*:

N/A

* 1. *Provide a copy of contract language, if any, relevant to compensation for research-related injury. At Virginia Tech, this is most common for sponsored research*:

N/A

# Economic Burden to Subjects

* 1. *Describe any costs that subjects might be responsible for because of participation in the research, including any uncompensated costs for items such as transportation, missed work, and childcare*:

N/A

# Consent Process

* 1. *Indicate the process by which you will obtain consent for study participation. Please upload all consent, parental permission, and assent forms, documents, and scripts referenced in this section to Protocol Management.*

*Describe the following:*

* + - *Where the consent process will take place (e.g., clinic waiting area, classroom, online)*
    - *The time interval between sharing the consent information with the prospective subject and obtaining consent. For lab, interview, and focus group studies, the Virginia Tech IRB prefers that subjects have at least 24 hours to review the consent form and study information before the appointment where consent will be obtained. For simple online survey studies, you can typically present the consent information immediately before subjects begin participation.*
    - *If applicable, processes to ensure ongoing consent or assent (e.g., for multiple sessions; for research in which a minor will turn 18 during the study; for longitudinal research with minors who will later be asked to provide or affirm their assent).*
    - *Please review “SOP: Informed Consent Process for Research (HRP-090)” for recommended procedure. Describe your process, being sure to include:*
      * *The name and role of all study personnel who will be trained and certified by the PI to conduct the consent process*
      * *The time that will be devoted to the consent discussion*
      * *Steps that you will take to minimize the possibility of coercion or undue influence*
      * *Steps that you will take to gauge or ensure the subjects’ understanding*

A consent form will be presented to participants upon arriving at the Usability room. Participants will be asked to read and sign the consent form prior to any study procedure. Donghan Hu will be trained and certified by the PI to conduct the consent process.

***Non-English Speaking Subjects***

* + - *Indicate what language(s) other than English are understood by prospective subjects or representatives.*
    - *If non-English speakers will be recruited, describe the process you will use to ensure that the oral and/or written consent information provided will be in a language that they understand.*
    - *If you translate consent forms and study materials, please provide a certified translation of the form as well as the certification document.*
    - *Indicate the spoken language that study personnel obtaining consent will use. Describe how you will assess fluency of personnel obtaining consent to ensure that the translation is accurate.*

N/A

***Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)***

* + - *Review the “CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)” to ensure you have provided sufficient information for the IRB to make these determinations (i.e., that it meets the criteria for a waiver or alteration of the consent process).*

N/A

***Subjects who are not yet adults (minors: infants, children, teenagers)***

* + - *Describe the criteria that you will use to determine legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted (e.g., in Virginia, individuals under the age of 18 years).*
      * *For research conducted in Virginia, review “SOP: Legally Authorized Representatives, Minors, and Guardians (HRP-013)” to determine which individuals in the state meet the definition of “minor.”*
      * *For research conducted outside of the state, please describe the legal requirements for the definition of “minor.”*
    - *Describe the process for obtaining parental permission.* 
      * *Permission from one parent is acceptable for studies that involve no greater than minimal risk OR involve greater than minimal risk but present the prospect of direct benefit to the minor subject.*
      * *Permission from both parents is required in all other cases (unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the minor).*
    - *Describe whether you will obtain permission from individuals other than parents or Legally Authorized Representatives, and if so, who will be allowed to provide permission. Describe the process you will use to determine these individuals’ authority to consent to the minor’s general medical care.*
    - *Indicate whether you will obtain assent from all, some, or none of the minors. If you will obtain assent from some minors, indicate which minors will be required to assent. Consider chronological age and intellectual capacity when determining who will be required to provide assent (e.g., infants are unable to assent. However, teenagers are likely able to read and sign an assent form).*
    - *When assent of minors is obtained, describe whether and how you will document it. Will minors sign an assent form or give verbal assent?*
    - *Attach parental permission and minor assent forms or scripts in Protocol Management.*

N/A

***Adults Unable to Consent***

* + - *Describe the process you will use to determine whether an individual adult is capable of consent.*
    - *List the individuals from whom you will obtain permission in order of priority (e.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and non-minor child).*
      * *For research conducted in the Virginia, review “SOP: Legally Authorized Representatives, Minors, and Guardians (HRP-013)” to determine which individuals in the state meet the definition of “legally authorized representative.”*
      * *For research conducted outside of Virginia, please describe the legal requirements for obtaining permission from a legally authorized representative in the state where the research will occur.*
    - *Describe the process for assent of the subjects.*
      * *Indicate whether you will require assent from all, some, or none of the subjects. If some, indicate which subjects will be required to assent and which will not.*
      * *If you will not obtain assent from some or all subjects, please provide justification for not obtaining assent.*
      * *Describe whether and how you will document assent.*

N/A

# Process to Document Consent in Writing

* 1. *Consult “SOP: Written Documentation of Consent (HRP-091)” for recommended procedures, and describe whether and how consent of the subject will be documented in writing*:

Upon arrival at the Usability room, participants will be asked to read and sign a consent form prior to any study procedure.

* 1. *If the research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, you can request that the IRB waive the requirement to obtain written documentation of consent (e.g., consent to participate is indicated by pressing a button for an online questionnaire – after the consent information is presented and before the questionnaire begins)*:

N/A

* 1. *If you will document consent in writing, attach a consent document with places for signatures. If you will obtain consent, but not document consent in writing, please attach the consent script or text. Review “CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)” to ensure that you have provided sufficient information. You should use “TEMPLATE CONSENT DOCUMENT (HRP-502)”to create the consent document or script*:

N/A

# Resources Available

* 1. *Describe the resources available to conduct the research. For example, as appropriate:*
     + *Describe the PI’s availability to supervise the research.*
     + *Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?*
     + *Describe the time that you will devote to conducting and completing the research.*
     + *Describe your facilities.*
     + *Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated or unanticipated consequence of participation in the research.*
     + *Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions (e.g., training plans, detailed study notebooks).*

PIs are working in human computer interaction area who are familiar with how to design and conduct user studies.

We can recruit 10 participants in two weeks. The study will take place once we find suitable participants.

# Multi-Site Research

*Contact the HRPP for multi-site research (involving multiple institutions) and the details required for this section will be provided. Otherwise, indicate N/A.*

N/A