For NU IRB use:

Date Received: _____ *NU IRB No.* _____

Review Category: _____ *Approval Date* _____

APPLICATION FOR APPROVAL FOR USE OF HUMAN PARTICIPANTS IN RESEARCH

Before completing this application, please read the Application Instructions and *Policies and Procedures for Human Research Protections* to understand the responsibilities for which you are accountable as an investigator in conducting research with human participants. The document, *Application Instructions*, provides additional assistance in preparing this submission. ***Incomplete applications will be returned to the investigator. You may complete this application online and save it as a Word document.***

If this research is related to a grant, contract proposal or dissertation, a copy of the full grant/contract proposal/dissertation must accompany this application.

Please carefully edit and proof read before submitting the application. Applications that are not filled out completely and/or have any missing or incorrect information will be returned to the Principal Investigator.

REQUIRED TRAINING FOR RESEARCH INVOLVING HUMAN SUBJECTS

Under the direction of the Office of the Vice Provost for Research, Northeastern University is now requiring completion of the NIH Office of Extramural Research training for all human subject research, regardless of whether or not investigators have received funding to support their project.

The online course titled "Protecting Human Research Participants" can be accessed at the following url: http://phrp.nihtraining.com/users/login.php. ***This requirement will be effective as of November 15, 2008 for all new protocols.***

Principal Investigators, student researchers and key personnel (participants who contribute substantively to the scientific development or execution of a project) must include a copy of their certificate of completion for this web-based tutorial with the protocol submission.

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☐ Certificate(s) Attached

☐ Certificate(s) submitted previously – on file with the NU's Office of Human Subject Research Protection

A. Investigator Information

Principal Investigator (**PI cannot be a student)** **Sarah Ostadabbas**

Investigator is: NU Faculty **X** NU Staff _____ Other _____

College: **Northeastern University College of Engineering**

Department/Program **Electrical and Computer Engineering**

Address **805 Columbus Ave, Boston, MA 02120**

Office Phone **(617)373-4992** Email **ostadabbas@ece.neu.edu**

Is this student research? YES __X__ NO _____ If yes, please provide the following information:

Student Name **Eric Alvarez, Nicolo Mega, Dave Pleteau** Anticipated graduation date **May 2022**

Undergrad __X__ MA/MS ___ PhD ___ AuD ___ EdD ___ DLP ___ Other Degree Type ___

College: **Northeastern University College of Engineering**

Department/Program **Electrical and Computer Engineering**

Full Mailing Address **10 Forsyth Street, Mailbox #906**

Telephone **787-365-2909** Primary Email **alvarez.e@northeastern.edu**

Cell phone **787-365-2909** Secondary Email ___
mega.n@northeastern.edu, pleteau.d@northeastern.edu

B. Protocol Information

Title **Fatigue Detection using Electromyography and Electrodermal Activity**

Projected # subjects **3**

Approx. begin date of project **02/25/2022** (month, day, year) Approx. end date **04/15/2022** (month, day, year)

It is the policy of Northeastern University that no activity involving human subjects be undertaken until those activities have been reviewed and approved by the University's Institutional Review Board (IRB).

- **Anticipated funding agency/source for project (or none)** **none**
- **Has/will this proposal been/be submitted through:**
  - NU's Office of Research Administration and Finance (RAF) _____
  - Provost _____
  - Corp & Foundations _____
  - Other_____
- **Grant Title:** _____
- **Grant ID:** _____

C.

Will Participants Be:	Yes	No
Children (<18)		X
Northeastern University Students?	X	
Institutionalized persons?		X
Prisoners?		X
Cognitively Impaired Persons?		X

Does the Project Involve:	Yes	No
Blood Removal?		X
Investigational drug/device?		X
Audiotapes/videotapes?	X	

Non or Limited English Speaking Persons?		X
People Living outside the USA?		X
Pregnant Women/Fetuses?		X
Other? *(Please provide detail)*		X

Please answer each of the following questions using non-technical language. Missing or incomplete answers will delay your review while we request the information.

D. What are the goals of this research? Please state your research question(s) and related hypotheses.

We aim to collect three sets of ECG and EDA data for three subjects and discover a correlation between these biomarkers and early signs of fatigue. This will be determined by looking at discrepancies between these signals when taken in the morning versus at the end of the day while taking a standardized test. We hope to, in the future, implement these findings into a mobile sensor that shines an LED light when fatigue is detected.

E. Provide a brief summary of the purpose of the research in non-technical language.

The purpose of this research is to identify early signs of mental fatigue using an individual's vitals and be able to relay this information to the user.

F. Identify study personnel on this project. Include name, credentials, role, and organization affiliation.

This research is conducted by three Northeastern University students: Eric Alvarez, Electrical Engineering; Nicolo Mega, Bioengineering; and Dave Pleteau, Electrical and Computer Engineering.

G. Identify other organizations or institutions that are involved. Attach current Institutional Review Board (IRB) approvals or letters of permission as necessary.

No other organizations or institutions were involved.

H. Recruitment Procedures

Describe the participants you intend to recruit. Provide all inclusion and exclusion criteria. Include age range, number of subjects, gender, ethnicity/race, socio-economic level, literacy level and health (as applicable) and reasons for exempting any groups. Describe how/when/by whom inclusion/exclusion criteria will be determined.

The participants were three students from the Healthcare Technologies class. The research focuses on reading electrocardiography (ECG) and electrodermal activity (EDA) signals under a time constraint and while taking a standardized test. Due to this, the ideal candidates for our research are those between ages 18-22 with no underlying health conditions. Each participant mentioned is 21 years old and has no underlying health conditions.

Describe the procedures that you will use to recruit these participants. Be specific. How will potential subjects be identified? Who will ask for participation? If you intend to recruit using letters, posters, fliers, ads, website, email, PsyLink description, HIT, etc., copies must be included as attachments for stamped approval. Include scripts for intended telephone recruitment.

Given the fact that this research was part of an in-class project, participants were recruited amongst their respective group project members. Recruiting process was minimal as participants involved were the one conducting the research.

What remuneration, if any, is offered?

No renumeration is offered.

I. Consent Process

Describe the process of obtaining informed consent*. Be specific. How will the project and the participants' role be presented to potential participants? By whom? When? Where? Having the participant read and sign a consent statement is done only after the researcher provides a detailed oral explanation and answers all questions. Please attach a copy of informed consent statements that you intend to use, if applicable. **Click here for consent form templates.**

If your study population includes non-English speaking people, translations of consent information are necessary. Describe how information will be translated and by whom. You may wait until the consent is approved in English before having it translated.

Given that the participants of the research will be the same people conducting the research, the consent process was essentially the planning of the procedure, which every member agreed to carrying out.

If your population includes children, prisoners, people with limited mental capacity, language barriers, problems with reading or understanding, or other issues that may make them vulnerable or limit their ability to understand and provide consent, describe special procedures that you will institute to obtain consent appropriately. If participants are potentially decisionally impaired, how will you determine competency?

Our population did not include children, prisoners, people with limited mental capacity, etc. All people involved spoke fluent English and were at the undergraduate level.

*If incomplete disclosure during the initial consent process is essential to carrying out the proposed research, please provide a detailed description of the debriefing process. Be specific. When will full disclosure of the research goals be presented to subjects (e.g., immediately after the subject has completed the research task(s) or held off until the completion of the study's data collection)? By whom? Please attach a copy of the written debriefing statement that will be given to subjects.

J. Study Procedures

Provide a detailed description of all activities the participant will be asked to do and what will be done to the participants. Include the location, number of sessions, time for each session, and total time period anticipated for each participant, including long term follow up.

For data collection, we will follow the 3 test subjects as their days progress for a total of 3 days for each subject. The day would begin by having the test subject collect 2 minutes of ECG and EDA data in the morning, during which the subject is not engaging in any mentally taxing activity. After this, the test subject would continue their day until around 6pm, at which point they were tasked with taking another 1-hour standardized test. This time, however, their ECG and EDA signals will be measured before and as they were taking the test. ECG and EDA measurements will be taken every 10 minutes for 30 seconds throughout the span of the 1 hour the test subject had to complete the test. This will result in a total of 3 minutes and 30 seconds of data for a given subject taking the standardized test.

With this procedure, we aim to induce mental fatigue in each test subject by both controlling the time of day which they take the test and the type of test that is being taken.

Who will conduct the experimental procedures, questionnaires, etc? Where will this be done? *Attach copies of all questionnaires, interview questions, tests, survey instruments, links to online surveys, etc.*

The experimental procedures will be conducted by one of the students whose data is not actively being collected that day. Data will be collected in a private study room to remove any other external factors that may otherwise sway the performance of the test subject.

K. Risks

Identify possible risks to the participant as a result of the research. Consider possible psychological harm, loss of confidentiality, financial, social, or legal damages as well as

physical risks. What is the seriousness of these risks and what is the likelihood that they may occur?

Given that the test subject will only be asked to take an hour-long standardized test, the only risk that they would be exposed to would be that of mental fatigue. This would be considered minimal risk given the fact that the test subject is sitting still and is not asked to exert force or be subjected to force in any physical manner.

Describe in detail the safeguards that will be implemented to minimize risks. What follow-up procedures are in place if harm occurs? What special precautions will be instituted for vulnerable populations?

The other student who is not actively partaking in the standardized test taking is responsible for collecting the test subject's data before and during the test and provide support if test subject is unable to complete the task.

L. Confidentiality

Describe *in detail* the procedures that will be used to maintain anonymity or confidentiality during collection and entry of data. Who will have access to data? How will the data be used, now and in the future?

The only people who will have access to the data are the students conducting the research and said data are of the aforementioned students. No other data of these students will be shared, and they will be stored both locally and online in an encrypted folder.

How and where will data be stored? How will electronic data be encrypted? When will data, including audiotapes and videotapes, be destroyed? If data is to be retained, explain why. Will identifiers or links to identification be destroyed? When? Signed consent documents must be retained for 3 years following the end of the study. Where and how will they be maintained?

M. If your research is HIPAA-protected, please complete the following; Individual Access to PHI

Describe the procedure that will be used for allowing individuals to access their PHI or, alternatively, advising them that they must wait until the end of the study to review their PHI.

This research involved the data collection of each individual's ECG and EDA signals by our own BITalino sensor and not by a healthcare organization, which means the data is not considered PHI.

N. Benefits

What benefits can the participant reasonably expect from his/her involvement in the research? If none, state that. What are potential benefits to others?

Fatigue can create a range of different physical, mental, or emotional symptoms, such as nausea, depression, and a general reduction in mental or physical productivity. Given its widespread physiological effects, fatigue can severely hinder one's performance at their job. Some of the causes of fatigue can be overworking, sleep deprivation, or even lack of physical activity. Since its effects are so common, a portable device capable of analysing and detecting fatigue in workplace settings could be incredibly useful. Our project strives to realize this goal by making use of BITalino's electrocardiography (ECG) and electrodermal (EDA) sensors to recognize signs of fatigue for an individual. With these, workers can actively circumvent or plan around potential periods of mental exhaustion.

O. Attachments

Identify attachments that have been included and those that are not applicable (n/a).

_____ Copy of fliers, ads, posters, emails, web pages, letters for recruitment *
_____ Scripts of intended telephone conversations*
_____ Copies of IRB approvals or letters of permission from other sites
_____ Informed Consent Form(s)* (see our templates for examples)
_____ Debriefing Statement*
_____ Copies of all instruments, surveys, focus group or interview questions, tests, etc.
_____ Signed Assurance of Principal Investigator Form ***(required)***
_____ NIH Human Subject Training Certificate(s) ***(required if not already on file at HSRP)***

(Approved forms must be stamped by the IRB before use)

P. Health Care Provision During Study

Please check the applicable line:

___**X**___ I have read the description of HIPAA "health care" within Section 4 of the Policies & Procedures for Human Research Protection. I am not a HIPAA-covered health care provider and no health care will be provided in connection with this study.

_____ I am a HIPAA-covered health care provider or I will provide health care in connection with this study as described in Section 4 of the Policies & Procedures for Human Research Protection. This health care is described above under "Study Procedures," and the Informed Consent and Health Information Use and Disclosure Authorization form will be used with all prospective study participants.

If you have any questions about whether you are a HIPAA-covered health care provider, please contact Nan C. Regina, Director, Human Subject Research Protection at n.regina@neu.edu or (617) 373-4588.

Completed applications should be submitted to Nan C. Regina, Director, Human Subject Research Protection *with the exception of applications from faculty and students of the College of Professional Studies, which should be submitted to Kate Skophammer, IRB Coordinator for CPS.*

Nan C. Regina, Director Northeastern Univ., Human Subject Research Protection 360 Huntington Ave., Mailstop: 560-177 Boston, MA 02115-5000 Phone: 617.373.4588; Fax: 617.373.4595 n.regina@northeastern.edu	**CPS applications only** Kate Skophammer, IRB Coordinator Northeastern Univ., College of Professional Studies Phone: 617.390.3450; k.skophammer@northeastern.edu

The application and accompanying materials may be sent as email attachments or in hard copy. A signed Assurance of Principal Investigator Form may be sent as a scan, via fax or in hard copy.