R·I·T

Rochester Institute of Technology

INSTITUTIONAL REVIEW BOARD

585-475-2167 ~ www.research.rit.edu/hsro ~ hsro@rit.edu

Office Use Only
Signed original received: _____
Received by: _____
Electronic copies received: _____

FORM A: Request for IRB Review of Research Involving Human Subjects

- **To be completed by the investigator** after reading the RIT Policy for the Protection of Human Subjects in Research, found in the *Institute Policies and Procedures Manual*, Section C5.0, and on the Office of Human Subjects Research website, http://www.rit.edu/research/hsro/process_geninfo.php.
- Submit **BOTH,** an **electronic version to** hsro@rit.edu **AND the signed original of the completed Form A AND ALL attachments (consents, instruments, tasks, etc.)** to **HSRO**, University Services Center, Suite #2400

Project Title: Personal Data Acquisition for Tremor		
Investigator's Name: Frank Howard	Investigator's Phone:	Investigator's Email: fch3809@g.rit.edu
Investigator's College and Department: Kate Gleason College of Engineering, Biomedical Engineering		
Project Start Date: 8/24/18	Date of IRB Request: 11/12/18	
If Student, Name of Faculty Supervisor: Elizabeth DeBartolo	Faculty's Phone: 585-475-2152	Faculty's Email: eademe@rit.edu
If Not Employed or a Student at RIT, List Name, College & Dept. of RIT Collaborator: N/A	RIT Collaborator's Phone: N/A	RIT Collaborator's Email: N/A
Will this project be funded externally? ☐ Yes ☒ No	Is the Investigator a student? ☒ Yes ☐ No	
If yes, name of funding agency:		
Status of project: ☐ Submitted on	☐ Funding pending	☒ Funding confirmed
Do you have a personal financial relationship with the sponsor? ☐ Yes ☒ No If yes, please read RIT policy C4.0 – Conflict of Interest Policy Pertaining to Externally Funded Projects. Complete the **Investigator's Financial Disclosure Form** and attach it to this Form A. *All information will be kept confidential.*		

BY MY SIGNATURE BELOW, I ATTEST TO AN UNDERSTANDING OF AND AGREE TO FOLLOW ALL APPLICABLE RIT, SPONSOR, NEW YORK STATE, AND FEDERAL POLICIES AND LAWS RELATED TO CONDUCTING RESEARCH WITH HUMAN SUBJECTS. If significant changes in investigative procedures are needed during the course of this project, I agree to seek approval from the IRB prior to their implementation. I further agree to immediately report to the IRB any adverse incidents with respect to human subjects that occur in connection with this project.

Signature of Investigator _____ Date _____

Signature of Faculty Advisor (for Student) or RIT Collaborator (for External Investigator) _____ Date _____

Signature of Department Chair or Supervisor _____ Date _____

Complete the attached Research Protocol Outline and attach to this cover form with other required attachments.

Attachments required for all projects:

- ☒ Project Abstract
- ☒ Investigator Responsibilities and Informed Consent Training Certificate(s) from OHRP (see http://ohrp-ed.od.nih.gov/)

Attachments required where applicable:

- ☒ Informed Consent Materials
- ☒ Questionnaire or survey
- ☐ Relevant Grant Application(s)
- ☐ Letter of Support from School Principal
- ☐ Cover letter to subjects and/or parents or guardians
- ☐ External site IRB approval
- ☐ Other

Form A (continued): Research Protocol Outline

- The RIT Institutional Review Board (IRB) categorizes Human Subjects Research into three Risk Types (Exempt, No Greater than Minimal Risk, and Greater than Minimal Risk, defined at the end of this form). The IRB makes the final determination of risk type.
- **Please complete this entire form (1 through 10 below). ENTER A RESPONSE FOR EVERY QUESTION.** If a question does not apply to your project, please enter "N/A". Leaving questions blank may result in the form being returned to you for completion before it is reviewed by the IRB.
- Underlined terms are defined at the end of this form.

FOR ALL PROJECTS, please complete 1-10 below.

1) If you believe your project qualifies for Exemption, which exemption number(s) apply?
N/A - We do not believe the project qualifies for exemption.
(Note: The IRB makes the final determination of Exemption)

2) Describe the research problem(s) your project addresses.
Validation of a personal data acquisition device for tremor designed and built at RIT.

3) Describe expected benefits to subjects and/or knowledge to be gained from your project.
Benefits: We can't guarantee that participants will personally experience benefits from participating in this study; however, others may benefits in the future from the information we find in this study.

Knowledge: This study gains knowledge that will determine if the device is easy to use and delivers upon the promises effectively acquriing EMG and motion data of a essential tremor.

4) Describe the population sample for your project.

a) How many subjects will participate in this project?
1 subject will participate in this project.

b) How will these subjects be identified and selected for participation?
Subject will be friend who we will ask and is willing to participate. We will only allow partcipants over the age of 18.

c) Describe the rationale for inclusion or exclusion of any subpopulation.

Exclusion: Participants under the age of 18 will be excluded because they cannot give consent. Additionally anyone who self-reports not having a essential tremor will not be allowed to participate.

Inclusion: All genders and ethnictites can be tested.

d) How will you recruit subjects?

We will have a friend to participate in study.

e) Describe any incentives for participation you plan to use.

N/A

5) Will you include any of the following vulnerable populations in your research? (Check any that apply)

☐ Children	☐ Mentally Ill
☐ Prisoners	☐ Mentally Handicapped/Disabled
☐ Pregnant Women	☐ Fetuses

If any of these populations are to be included, please addresses the following:

a) Rationale for selecting or excluding a specific population:
We will not include children under the age of 18, because they are not able to give consent. Not including anyone with a sleep disorder will ensure personal safety.

b) Description of the expertise of project personnel for dealing with vulnerable populations:
N/A

c) Description of the suitability of the facilities for the special needs of subjects:
N/A

d) Inclusion of sufficient numbers of subjects to generate meaningful data:
N/A

6) Describe the data collection process.

a) Will the data collected from human subjects be anonymous? ☒ Yes ☐ No

b) Will the data collected from human subjects be kept confidential? ☒ Yes ☐ No

c) Describe your procedures for ensuring anonymity and/or confidentiality:
Ensuring Anonymity: In order to keep the collected data anonymous, participants will be asked not to identify themselves on the given survey.
Ensuring Confidentality: No information that could break confidentiality will be collected; however, to ensure that all information is kept confidential, all collected information including text files will be protected via a password protected database

d) How much time is required of each subject? Approximately 1 hour

e) If subjects are students, will their participation involve class time? No

f) What methods, instruments, techniques, and/or other sources of material will you use to gather data from human subjects?

7) Will this research be conducted at another university or site other than RIT? ☐ Yes ☒ No

If yes, describe location: N/A

Note: If you will be conducting human subjects research at another university or college, you will also need to obtain IRB approval from that institution. **Attach a copy of that approval to this application.**

8) Describe potential risks (beyond minimal risk) to subjects:

a) Are the risks physical, psychological, social, legal or other?
Minimal

Physical

Psychological

If the subject experiences any uncomfortable sensations while testing, the subject can leave the study at any time.

There may be additional risks that cannot be predicted.

b) Assess their likelihood and seriousness to subjects:
Minimal

c) Discuss the potential benefits of the research to the population from which your subjects are drawn:
N/A, minimal

d) Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others, or in relation to the importance of the knowledge to be gained as a result of the proposed research:
N/A, minimal

e) Describe the planned procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness:

f) Where appropriate, describe plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects:
N/A, minimal

9) Will you be seeking informed consent? ☒ Yes ☐ No
If yes, describe:

a) What information will be provided to prospective subjects?

Brief overview of study, risks, benefits, confidentiality, incentives, participant rights, and contact information of the study.

b) What (if any) information will be concealed prior to participation, and why?
None

c) How will you ensure consent is obtained without real or implied coercion?
Participants will be allowed to stop participation at any time point in the study.

d) How will you obtain and document consent?
By providing and collecting a signed consent form from each participant.

e) Who will be obtaining consent? Provide names of specific individuals, where available, and detail the nature of their preparation and instructions for obtaining consent.

Frank Howard will obtaining consent from participant and he will be the team lead on this study. Also, he has completed the CITI Social and Behavioral Research Human Subjects Training.

10) Attach a copy of all additional materials (Consents, protocol, scripts, instruments, tasks, etc.- everything a subject does or sees) to this application.

RIT IRB Risk Type Classification

Exempt

Research activities in which the only involvement of human subjects will be in one or more of the following six categories of **exemptions** are not covered by the regulations:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. ***If the subjects are children, this exemption applies only to research involving educational tests or observations of public behavior when the investigator(s) do not participate in the activities being observed.*** [Children are defined as persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law or jurisdiction in which the research will be conducted.]

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not exempt under section (2) above, if the human subjects are elected or appointed public officials or candidates for public office; or federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (a) if wholesome foods without additives are consumed or (b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the US Department of Agriculture.

No Greater than Minimal Risk – The probability and magnitude of harm or discomfort anticipated in the research *is no greater than* those ordinarily encountered in daily life or in the performance of routine physical and psychological examinations or tests.

Greater than Minimal Risk – The probability and magnitude of harm or discomfort anticipated in the research *is greater than* those ordinarily encountered in daily life or in the performance of routine physical and psychological examinations or tests.

Human Subjects Research - Definitions

Anonymity – Anonymity offers the best insurance that disclosure of subjects' responses will not occur. Research data that is anonymous contains no information that would link the data to the individual who provided the information.

Confidentiality – Confidentiality refers to (a) identifiable data (some information about a person that would permit others to identify the specific person, such as a non-anonymous survey, notes or a videotape of the person) and (b) agreements about how those data are to be handled in keeping with respondents' interest in controlling the access of others to information about themselves. The two critical elements of this definition of confidentiality indicate the critical role of informed consent, which states how the researcher will control access to the data and secures the respondent's agreement to participate under these conditions.

Child (Definition of) **and Use of Children in Research -** Children are defined as persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law or jurisdiction in which the research will be conducted. In New York State, a person age 18 is considered an adult and can provide consent without parental permission. However, some students at RIT are under age 18. To use children (individuals under the age of 18 years) in research, you must first obtain the permission of the parent(s) and then obtain **assent** from the child.

Human Subjects - The regulations define human subject as "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information." *(1) If an activity involves obtaining information about a living person by manipulating that person or that person's environment, as might occur when a new instructional technique is tested, or by communicating or interacting with the individual, as occurs with surveys and interviews, the definition of human subject is met. (2) If an activity involves obtaining private information about a living person in such a way that the information can be linked to that individual (the identity of the subject is or may be readily determined by the investigator or associated with the information), the definition of human subject is met.* [Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a school health record).]

Informed Consent – Informed consent is a process by which individuals learn about a study – the substantive issue investigated, participation demands (including time expenditure, types of activities), participant rights (voluntariness, confidentiality), risks, benefits, costs/compensation, contacts if further questions arise, etc. There are multiple **ways to convey these elements of consent**: by written document, oral presentation with script, oral presentation without script. In addition, there are various **ways to document consent**: written signature of the participant, written indication of participant's study identification number, oral recording of consent, oral consent documented by the investigator. In addition, sometimes it is important to obtain separate consent for the use of photographs or videotaped images. The different ways to obtain consent include:

(1) Written consent with written documentation by participant.
   (a) formal style (for study involving mothers and children)
   (b) informal style
   (c) formal style for at-risk population
(2) Written consent with written indication of participant's study identification number.
(3) Written consent without documentation (for no/minimal risk survey studies).
(4) Oral presentation with script with oral consent documented by the investigator.
(5) Oral presentation with script without documentation (includes contact card).
(6) Oral presentation without script without documentation (provides rationale for request for waiver of written documentation and indicates what will be said).
(7) Written consent with written documentation by participant for use of photos.

Population Sample

- Describe the proposed involvement of human subjects in your project.
- Describe the characteristics of the subject population, including their anticipated number, age range, and health status.
- Identify the criteria for inclusion or exclusion of any subpopulation.
- Explain the rationale for the involvement of special classes of subjects.

Research Activity - The ED Regulations for the Projection of Human Subjects, Title 34, Code of Federal Regulations, Part 97, define research as "a systematic investigation, including research, development, testing and evaluation, designed to develop or contribute to generalizable knowledge." *If an activity follows a deliberate plan whose purpose is to develop or contribute to generalizable knowledge, such as an exploratory study of the collection of data to test a hypothesis, it is research.* Activities which meet this definition constitute research whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Risks in Research – As with any activity, there is potential for harm in the social and behavioral sciences – from inconvenience or embarrassment to stigma or legal or economic consequences. Typically, however, in these sciences both the potential harms and the risks of them are minimal and not of the type routinely being assessed in biomedical research. Much of the risk relates to disclosure of the identity of human subjects or the information they provide; thus, considerable effort in these sciences is devoted to safeguarding subjects' privacy and the confidentiality of the data they provide even when the information has no or minimal potential for harm.

Minimal risk means that the probability and magnitude of *harm* or discomfort anticipated in the research 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. "Risk" refers to a probability that some harm will occur. "Harm" refers to a specific outcome(s) or event(s) – and can be inconvenience, physical, psychological, social, economic, or legal in nature. If human subjects are exposed to a degree of harm roughly equivalent to what one would expect in the course of daily life or in the course of routine tests and examinations, then "minimal risk" applies.

Sources of Materials

- Identify the sources of research material to be obtained from individually identifiable living human subjects in the form of specimens, records, or data.
- Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.