For Office Use Only Project#:

EQUIPMENT OR DEVICE SAFETY RISK ASSESSMENT REVIEW FORM

Purpose: The purpose of this risk assessment form is to ensure that a risk assessment has been conducted when a device or piece of equipment which will be used on or tested with humans **(a)** has not been commercially obtained by the University **(b)** has been modified prior to being used.

Process: whenever the activity is occurring **under the auspices of UWaterloo** and will be tested or used on humans, and where the device or piece of equipment has been manufactured or modified, the equipment or device must first be assessed to ensure it is safe to be used on humans. In cases where this is **research requiring REC review**, the risk assessment must be provided with the **ethics application**. The risk assessment process will be proportionate, i.e. devices or equipment which present low risks should receive less scrutiny than those presenting high risks.

This form should be completed and submitted to the Safety Office (**safety@uwaterloo.ca**). The Safety Office will review the information contained on the form and assess the degree of risk involved with the device or equipment and recommend additional scrutiny or expertise if required. If the device or equipment presents above minimal risks, the Safety Office may request that the Laboratory Safety Committee (LSC) or external expert review and approve the device or equipment before it can be tested or used on humans.

DIRECTIONS:

1) Complete this form ensuring that all required supplementary information is provided as outlined in 5) below.
2) Approval **and** inspection may be required before testing or use may occur. Allow 3-5 days after submission for contact from the Safety Office regarding questions and scheduling of the inspection if one is required.
3) In the case of students, the faculty advisor **must** submit this completed Equipment or Device Safety Review Form along with any additional supporting materials to the Safety Office.
4) The "Submitter" , i.e. the student, should be cc'd if the form is submitted by a faculty supervisor;
5) The following applicable attachments accompany this form:
    a. ☐Project Definition Document (for undergraduate and graduate students)
    b. ☐Detailed device information including photographs or drawings
    c. ☐Manufacturer's device electrical/mechanical safety documentation (for devices being modified)
    d. ☐Electrical Safety Testing documentation
    e. ☐Standard Operating Procedure which will be used with the device or piece of equipment
    f. ☐Any other documentation that would assist the committee in determining the level of risk posed by the device
6) Subject line **must** read "Equipment or Device Safety Review From for [submitter's name]".

I. GENERAL INFORMATION	
Project Title: (Max: 142 Characters) Foot-based sensor fusion for ambulatory gait analysis for occupational health & safety: Field studies	
Submitter/ Lead Contact: James Tung	**Submitter Phone:** x43445
Submitter E-mail: james.tung@uwaterloo.ca	**Faculty Advisor:** n/a **Department:** MME
Students involved with project: Shovon Saha (MASc student)	

II. DESCRIPTION

A. This project is:

- ☐ Student thesis/dissertation
- ☐ Student class project
- ☐ Faculty or staff research proposal
- ☑ Product development
- ☐ OTHER (specify):

B. This project is:

- ☐ Not funded or self-funded
- ☑ Funded Name of sponsor: MegaIntech
- ☐ Non-federally funded
- ☑ OTHER (specify): NSERC

C. Check all that apply:

- ☑ Testing or use will occur with **uWaterloo employees or students** involving:
  - a) a new device that was manufactured by the submitter; or
  - b) a commercially bought device that was modified in some way.
- ☑ Testing or use will occur with persons who are **external** to the University Involving:
  - a) a new device that was manufactured by the submitter; or
  - b) a commercially bought device that was modified in some way.
- ☐ I intend to commercially market the device
- ☐ NONE OF THE ABOVE

D. Date you plan to test or use the device:

ASAP

E. Date and location of where the device or equipment will be available for inspection. Approval/inspection must occur prior to any testing or use on humans:

anytime 9-5, location E7 and E5

F. Provide a brief description of **(a) the device**, **(b) its intended purpose**, and **(c) why it is needed**:
(Note: If more space is required, please provide an attachment to this form)

(a) The industrial partner, MEGAInTech, has developed a wearable smart device (ImpactSense™) for use in an insole or footwear utilizing a 6DOF IMU (i.e., 3D accelerometer, gyroscope). In Year 1 of the partnership (conducted in 2021-22), sensor fusion approaches were applied to deliver a set of activity recognition (e.g., walking, stair climbing, sedentary) and gait parameter metrics (e.g., step time, step asymmetry, foot clearance).

(b) Due to technical variances in 1st gen prototypes, only bench and in-laboratory validation testing were conducted in Year 1. Field evaluation of ImpactSense is planned to examine the usability of the developed algorithm(s) under simulated and actual conditions, a field test over 3-5 days will be conducted in a small sample of young, healthy adults.

(c) The primary objective of the study is to develop and validate new wearable sensing tools to acquire biomechanical metrics related to gait and balance, motivated by the need for field studies examining injury risks.

G.	Provide a description of the demographics of who the device is being tested on or those who will use it. Include information such as age, mental or physical status, and any other relevant physical or social factors (e.g., specific medical conditions, prisoners, pregnant women, homeless, family or other factors which may create risks). Currently, the device will be tested with healthy, young adults (i.e., undergraduate and graduate students). This device will not be tested with target populations (e.g., older adults with mobility impairments) at this time. Future iterations (i.e., following control system development) will be need to be re-assessed for safety.
H.	Describe the setting in which the device will be used. For instance, possible locations, and any special considerations related to the environmental setting (flat surface, large room, another person to assist, quiet area, etc.): occupational health and safety (OHS) While the target is to acquire OHS data under actual use conditions, this application is focused on a simulated protocol at University of Waterloo (E5 and E7). Following successful testing conducted at Waterloo, an amendment will be filed to extend collection to target industrial users (e.g., automotive assembly, food processing).
I.	Describe any **(a) mechanical safety**, **(b) electric safety**, and **(c) other risks** associated with the device. Include how these **risks will be minimized**. (Note: If more space is required, please provide an attachment to this form) The following risks and prevention techniques can be identified as the following: (A).1.There is a risk of experiencing fatigue as a result of performing the tasks. i.To minimize fatigue, you will be offered breaks at regular intervals during the study, and may take a break at any time. Water and snacks are available upon request.

II. DETERMINATION ***(For office use only)***

A.	**Reviewed by: _____Date:_____**	
	☐ Testing or use may proceed within proposed use, standard operating procedures and conditions.	☐ Other conditions:
B.	☐ Testing or use may NOT proceed	☐ External review required. Resubmit upon completion. ☐ Insufficient information. Resubmit as per comments below. ☐ Risk is not acceptable.
C.	**Comments/Recommendations:**	