University of Waterloo

**Department of \_\_\_\_\_\_\_\_\_\_\_\_**

**(SAMPLE) Standard Operating Procedure**

A Standard Operating Procedure (SOP) is to be created to direct and guide researchers when performing study protocols, especially those that have the potential to cause harm (or increase risk) to a study participant such as those outlined as a controlled act in the [Regulated Health Professions Act](http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_91r18_e.htm)of Ontario(rhpa).

SOPs are to follow the Deming Cycle, a cycle that identifies "Plan-Do-Check-Act." A SOP is created to:

* outline the procedures that must be executed to effectively follow the study protocol and outline the resources/equipment needed (i.e., PLAN),
* provide detailed instructions for research staff of the steps that must be implemented and the training that must be completed (i.e., DO),
* clearly document the study protocol (i.e., CHECK), and
* aid with continuous improvement (i.e., ACT)

All SOPs are to be maintained and controlled by the Principal Investigator/Faculty Supervisor. The Principal Investigator/Faculty Supervisor is responsible for the current and approved versions.

SOPs are reviewed by the Office of Research Ethics reviewers and/or Research Ethics Committee members in conjunction with their review of the procedures section in the Form 101 or Form 104 (modification request).

Submit only new SOP’s or those which have not been previously approved in conjunction with a prior application. In the procedures section of the 101 form or 104 form state the SOP name, date, and the previously approved ORE number, if applicable.

Title of SOP:

**SOP created on**: [month/day/year] and **Ethics Clearance Received on:** [month/day/year or pending]

**Revised on**: [month/day/year] and **Ethics Clearance Received on**: [month/day/year or pending]

* Add additional “revised on” dates, as needed.
* Use tracking changes as needed to identify changes from a previous version.

**SOP created by:** [insert name of principal investigator/faculty supervisor, title, department]

**Signature:**

**Date:**

□ I acknowledge that as the principal investigator/faculty supervisor I am responsible for updating this SOP and notifying the ORE through a modification form (Form 104) if any of the procedures as outlined above change or require revision.

1. **PURPOSE AND BACKGROUND**
2. Describe in detail the purpose and/or background of the study protocol and procedures to be used.
3. **PROCEDURES/STUDY PROTOCOL**

**Are there any controlled act(s) to be performed: □** Yes □ No

If you checked yes, list the controlled act(s) below:

1. Outline all of the procedures to be conducted, including any that are controlled acts, to perform the study protocol along with diagrams and/or flowcharts, as appropriate.
2. Use subheadings and lay language wherever possible.
3. **EQUIPMENT**
4. List and describe the equipment that will be used in performing the study protocol.
5. Insert diagrams or photos to describe/demonstrate the equipment.
6. If special safety equipment is needed or required, for participants or the researchers, before the procedure(s) can be done, outline these procedures in detail.
7. Outline any safety training courses or other certifications (e.g., operator courses) which are required.
8. Identify the steps taken for a [Health and Safety Hazard Report](http://www.safetyoffice.uwaterloo.ca/) by the Safety Office, if applicable.
9. Outline the equipment certification and maintenance schedule, if applicable
10. **DESCRIPTION TO STUDY PARTCIPANTS**
11. List sequentially (i.e., in a step by step format) how a study participant would experience the procedures/controlled act(s) and equipment (if applicable).
12. Include a photo(s) of how the equipment will be used on or by a study participant.
13. **RISKS**
14. PARTICIPANTS
    1. Describe all possible risks, real or perceived, that a participant may experience by taking part in the study.
    2. Describe all possible risks, real or perceived, that a participant may experience by the use of the equipment.
15. RESEARCHERS
    1. Describe all possible risks, if any, that a researcher could experience by implementing the study protocol.
    2. Describe all possible risks, if any, that a researcher may experience by the use of the equipment.
16. **SAFEGUARDS/SAFETY PROCEDURES**
17. PARTICIPANTS
    1. Describe the safeguards and safety procedures that will be put in place to mitigate risks to participants, if applicable (e.g., including any First Aid or other relevant training).
18. RESEARCHERS
    1. Describe the safeguards that will be put in place to mitigate risks to researchers, if applicable.
19. **REFERENCES (if applicable)**