July 2021

UNIVERSITY OF WATERLOO
OFFICE OF RESEARCH ETHICS

Incidental and Secondary Findings Report Form

Incidental Findings is a term that describes "discoveries made in the course of research that are outside the scope of the research" (TCPS 2, Article 3.4) and/or "results that are outside the original purpose for which a test or procedure was conducted" (Presidential Commision for the study of bioethical issues, 2013).These discoveries may be anticipated or unanticipated. Secondary findings are a result that are not the primary target of the test or procedure but is an additional result. Refer to the Waterloo Guidelines for Reporting of Incidental and Secondary Findings.

The Principal Investigator (PI), in the case of Health Canada regulated research, or Faculty Supervisor, in the case of student research, is responsible for reporting any incidental or secondary finding discovered during any stage of their research, including screening for eligibility. Research Ethics must be notified about the discovery of any incidental or secondary findings as soon as possible but no later than 24 hours (1 day) after the discovery of the finding. In addition, researchers must complete and submit this incidental and secondary finding form within 72 hours (3 days) of reporting the discovery. Research Ethics will then work with the PI to identify the best course of action for Research Ethics Board (REB) review of the finding and reporting to a study participant. Participants are not to be contacted about the finding until REB review of the finding is completed.

Information provided in this form needs to contain a full and complete description so that an appropriate path forward may be developed. In all cases, a participant's wish to know or not know about incidental or secondary findings should be respected. Please attach additional pages to describe the findings as needed.

Please do not submit handwritten forms. Typewritten forms must be provided. This form is a fillable PDF

Ethics Application #: _____ **Ethics Clearance Date (D M Y):** _____

Study Title: _____

Name of Principal Investigator or Faculty Supervisor: _____

Name Department/School: _____

A. GENERAL DETAILS ON THE DISCOVERY OF THE INCIDENTAL OR SECONDARY FINDING:

Date of Discovery (D M Y): _____ Time: _____

Location: _____

B. GENERAL DETAILS RELATED TO THE INCIDENTAL OR SECONDARY FINDING:

1.a) Was the finding unexpected?

☐ YES NO ☐

If **no**, was the possibility of uncovering this type of incidental finding along with a disclosure plan outlined in the Risks section of the Research Ethics Application and the Information Letter and Consent Form?

☐ YES NO ☐

b) Was the finding discovered during the course of the research (i.e., primary findings) and could be considered part of the research results?

☐ YES NO ☐

If **yes**, this form is not appropriate and should not be submitted to Research Ethics. Researchers are advised to consult the Director if they require assistance returning research results to the participant.

c) Was the finding a secondary finding such that it was not the primary target of the test or procedure; rather, it is an additional result that was actively sought?

☐ YES NO ☐

2. Did the participant indicate a willingness to be informed about a possible incidental or secondary findings at the time of original consent?

☐ YES ☐ NO ☐ This was not asked of participants during initial consent

3. Is the incidental or secondary finding considered material? Consider the below criteria.

a) Will disclosure of the finding have significant welfare implications for the participant?

☐ YES NO ☐

b) Does the finding meet generally accepted criteria of scientific and clinical validity (criteria widely recognized by the medical community)?

☐ YES NO ☐

c) Does the finding have clinical utility for the participant (e.g., benefits associated with communication of result outweigh risks, prevention or treatment available, individual, familial, and social factors considered)?

☐ YES NO ☐

4. Could disclosure of the finding cause worry/concern for the participant (e.g., a condition that has no cure, chronic health condition, etc.)?

☐ YES NO ☐

If **yes**, how will the finding be communicated to the participant taking into consideration their emotional and psychological health?

5. Will the participant require assistance (e.g., family physician, genetic counsellor) to understand the implications of the finding?

☐ YES ☐ NO ☐ Uncertain

6. Is it possible that the finding will have implications for the participant's biological relatives? Under certain circumstances results may be returned to family members. These circumstances are laid out in the Guidelines for the Reporting of Incidental Finding to Study Participants.

☐ YES ☐ NO

7. Has this type of finding been uncovered previously in this study or a related study?

☐ YES ☐ NO

If **yes**, provide the title of the study, Ethics Application #, under which the previous finding was uncovered. Describe the circumstance under which this occurred.

8. Is this type of finding likely to be uncovered again?

☐ YES ☐ NO ☐ Uncertain

9. Will any changes to the study procedures (e.g., on-going consent process) be implemented because of this finding?

☐ YES ☐ NO

If **yes**, provide an explanation below and submit an Amendment Form for ethics review along with any revised documents.

C. DETAILED DESCRIPTION OF THE FINDING(S) AND OF THE ACTION TAKEN

1. Describe the finding(s) and how it was discovered. Include details of any potential physical or psychological impact on the participant from the finding. (approx. 500 words)

2. Provide details (step-by-step) of the **proposed** action(s) that you advise to be taken immediately following the discovery of the finding(s) including who needs to be contacted (i.e., REB, participant, colleague, physician, etc.), the need for a re-consent process, and any other follow-up. Please note when necessary, the researcher should direct the participant to the appropriate health professional, counselor, or other support person to discuss any implications of the finding. Please include specific detail regarding who will receive information regarding the finding for example, a family physician. **NOTE:** The reporting of these findings must be ethically justified and the process for making the determination and returning the results reviewed and approved by one of Waterloo's two Research Ethics Boards. (approx. 500 words)

3. Provide a copy of the proposed letter to be sent to the participant that informs them of the finding. Please ensure this letter includes:
    - a definition of incidental or secondary findings;
    - what results or findings will be offered to participants;
    - how findings will be reviewed so that a determination can be made if they are appropriate to return;
    - if results will not be provided an explanation as to why;
    - disclosure procedures (e.g., genetic counseling);
    - possible implications of the findings for the participant or their family members; and
    - how participants are to opt in or out of receiving results now or in the future including how participants will be contacted and offered a "result-specific" consent describing implications or ramifications of receiving a result that has been found.

4. Will professional follow-up be encouraged by the researcher?
☐ YES ☐ NO
Please explain.

5. Will the participant be discontinued from the study as a result of the finding?
☐ YES ☐ NO

6. Is there any plan for follow-up contact with the participant (e.g., in one month, 3 months, six months, 1 year)?
☐ YES ☐ NO
If **yes**, please explain.

Principal Investigator/Faculty Supervisor Confirmation

As Principal Investigator/Faculty Supervisor on this project, I confirm the details contained in this report are an accurate account of the incidental or secondary finding(s) that was discovered on the date noted above.

Signature of Principal Investigator/ Signature of Faculty Supervisor: _____ **Date:** _____

Please print and sign the completed form and send an electronic copy to Research Ethics at reb@uwaterloo.ca

For Research Ethics/REB Use Only Incidental and Secondary Findings Report Form:

Action Required: ◯ Yes ◯ No further action is required

Change(s) are required to:

- ☐ Study Procedures
- ☐ Information Consent Document
- ☐ Other

Study Disposition:

- ☐ Continuation of study permitted
- ☐ Continuation of study conditional on change(s) noted
- ☐ above Suspension of study pending further review by REB

_____ _____

Julie Joza, MPH
Director, Research Ethics
University of Waterloo

Date

_____ _____

Heather Root, Ph.D
Senior Manager, Research Ethics
University of Waterloo

Date