**RESEARCH ETHICS BOARD - INCIDENTAL FINDINGS REPORT**

**USE OF THIS FORM**

This form is to be used for the **mandatory** reporting of all incidental findings. The ROHCG REB uses this information to ensure that research studies are proceeding according to approved protocol procedures.

Please submit this form within **5 business** days of the finding, or of the PI became aware of it. The form may be emailed to the REB office at: Heidi.vulin@theroyal.ca

**TERMS/DEFINITIONS**

Material incidental finding: An unanticipated discovery made during the course of a research study that is perceived to considerably increase the risk to participants, or affect the welfare of participants. Examples may include the discovery of a physical abnormality, perceived child abuse, or suicidal ideation.

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| --- | --- |
| **REB NUMBER:** Click here to enter text.**PROTOCOL TITLE:** Click here to enter text. | **DATE:** Click here to enter a date.**PRINCIPAL INVESTIGATOR:** Click here to enter text. |

**DESCRIPTION OF THE FINDING AND THE RESPONSE**

1. Date of the finding:

**Click here to enter a date.**

1. Location of the finding:

 **Click here to enter text.**

1. Full description of the finding. Please include the effect on participant if applicable:

**Click here to enter text.**

1. Describe the actions taken, or will be taken, to inform the participant, and/or their primary healthcare provider:

 **Click here to enter text.**

1. If the primary healthcare provider will not be informed, why not?

**Click here to enter text.**

1. Has the participant withdrawn from the study?

**Click here to enter text.**

1. Has this incidental finding resulted in a change to the study procedures, requiring an amendment? (Please note that until an amendment is approved by the REB, amended study procedures may not commence)

**Click here to enter text.**

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*I confirm to the best of my knowledge that the information provided above is accurate and true.*

*I agree to conduct this trial as per the Tri-Council Policy Statement (TCPS-2), the ICH Good Clinical Practice Guidelines (GCP), and all other regulatory guidance that may be applicable to this study including the Health Canada Division 5 Food & Drug regulations, Natural Health Product regulations, Division 3 Radiopharmaceutical regulations and the Health Canada Medical Device regulations, as well as all institution specific policies and procedures.*

**Qualified/Principal Investigator Name (typed):** Click here to enter text.

**Qualified/Principal Investigator Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date of Signature:** Click here to enter a date.

***You must keep a copy of this completed form for your study file***