**RESEARCH ETHICS BOARD - PROTOCOL DEVIATION REPORT**

**USE OF THIS FORM**

This form is for the mandatory reporting of any Protocol Deviation defined below. This information is used by the ROHCG REB to ensure the study is proceeding safely, respectfully, and according to its accepted protocol procedures.

**If there is an imminent threat of harm or breach of data security, please contact the ROHCG REB office immediately to discuss:** heidi.vulin@theroyal.ca

Please note that protocol deviations must be reported to the REB office within **5 business days** of the occurrence/event of the event or finding, or of the PI becoming aware of it.

**DEFINITIONS**

**Protocol Deviation:** A change or modification from the approved study protocol, informed consent forms, or other study appendices, whether deliberate (e.g. to avoid potential harm) or unplanned (e.g. in response to unexpected circumstances), or if the deviation jeopardizes participant safety, study efficacy, or data integrity.

 There are several different kinds of deviations that may occur during the life of a research study:

1. **Major Deviation:** A modification or departure from the approved protocol for the protection of life or physical well-being of a participant. These types of deviations can be unanticipated, and there is not enough time to seek REB approval. Other major deviations may include changes to the consent process, participant eligibility (as approved by the sponsor), or any other changes that may affect the efficacy of the research or data integrity.
2. **Minor Administrative Deviation:** A modification or departure from the approved protocol that does not affect participant safety, nor jeopardize the efficacy of the study. For example: a participant attends a study appointment out of the approved study window, or signs an out-of-date consent form.

**WHAT DO I REPORT?**

**Any major deviation that meets the following criteria (in accordance with N2 CAREB SOP 404.003):**

* Deviations that jeopardize participant safety, or
* research efficacy or data integrity;
* Participant eligibility criteria is waived due to sponsor;
* The process for obtaining informed consent is revised;
* An AE or SAE occurs as a result of the deviation (please submit a separate AE/SAE Report to the REB)

**Deviations that fit this criteria** must be reported within **5 business days** of the occurrence, or of the PI becoming aware of it.

While minor administrative deviations are **not** reportable to the REB, it is the responsibility of the study team to report all deviations in a **study deviation log.**

***Please delete this page once you have completed the form. Do not submit this page with the form.***

**PROTOCOL DEVIATION REPORT**

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

1. **DESCRIPTION OF THE DEVIATION**
	1. Date of deviation: Click here to enter a date.
	2. Participant ID# (this is required for all clinical trials): Click here to enter text.
	3. Where did the deviation take place? Click here to enter text.
	4. Describe the deviation and effect on participants:

 Click here to enter text.

1.5 Who was informed of the deviation? (e.g. privacy office, funding agency, sponsor, etc.)

Click here to enter text.

1. **ACTION TAKEN/FOLLOW-UP**

 2.1 Describe the actions taken, or will be taken:

 Click here to enter text.

 2.2 Describe any actions taken, or will be taken, to address the effect on participants:

 Click here to enter text.

 2.3 Did any participants withdraw, or were withdrawn, as a result of the deviation?

 [ ]  Yes [ ]  No

 If yes, please describe: Click here to enter text.

 2.4 As a result of the deviation, are changes required to the Protocol, consent form(s), or other

 study appendices?

 ☐ Yes ☐ No

 If yes, please list the documents that require revision: Click here to enter text.

  *\*Please note that all amendments must be approved by the REB prior to study changes being*

 *implemented.*

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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.

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 **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***