HRH REB Unanticipated Problem Reporting Form

HRH Principal Investigator:	REB Number:
Protocol #:	Primary Contact Name:
Primary Contact E-mail:	Primary Contact Telephone:

SECTION I – SCREENING QUESTIONS

Please consult the accompanying guidance document prior to completing this form.

1. Please indicate the type of study event:

a) ☐ Protocol Deviation

b) ☐ Adverse Event

If you selected **b)**, please indicate whether the adverse event is: ☐ **Internal** or ☐ **External**

c) ☐ Other Unanticipated Event

2. Brief summary of study event (including the date the event[s] being reported occurred). Please make all reasonable attempts not to include any identifiable personal health information.

3. For an event to constitute an Unanticipated Problem it must meet **all three** of the following criteria:

a) The event:

⇒ Is **unexpected** (in terms of nature, severity or frequency); ☐

⇒ Is **related or possibly related** to participation in the research (either by research participants, or by research team members assisting with the research procedures); ☐

⇒ Suggests a **potential increase in risk of harm** to research participants or others (study team members, patients, visitors, etc.) ☐

b) Does the study event constitute an Unanticipated Problem? ☐ Yes ☐ No

Note: only choose yes to **#3 b)** if you have checked **all three** boxes under **#3 a)** above)

NEXT STEPS

⇒ If you answered "Yes" to Screening Question **#3 b)**, please complete the rest of this form and submit it to the HRH REB.

Note: for "external" adverse events, the site should obtain all information required for this form from the sponsor.

⇒ If you answered "No" to Screening Question **#3 b)**, there is no need to complete the rest of this form, nor is there a need to submit documentation about this event to the HRH REB. However, please see the "IMPORTANT NOTES" section below for information about other documentation and reporting requirements that may apply. **The HRH REB requires a periodic (eg. quarterly) safety update report of these external problems that are not being submitted individually on this form**.

SECTION II – IMPACT OF UNANTICIPATED PROBLEM
Please complete this section for all types of Unanticipated Problems:

Did the Unanticipated Problem:

1. Result in any harm to one or more study participants at the HRH site? ☐ Yes ☐ No

If "Yes" complete the ◆ subsection under "**SECTION III – RESPONSE PLAN**" below.

b) If "No", attach documentation from the Sponsor indicating that they have assessed this event and concluded that it constitutes an Unanticipated Problem. ☐ Attached

2. Result in any harm to others at the HRH site (study team members, patients, visitors, etc.)? ☐ Yes ☐ No

If "Yes" complete the ◆ subsection under "**SECTION III – RESPONSE PLAN**" below.

3. Have an impact on the study data?

☐ Yes **a)** Describe: **b)** Is it possible to correct the impact (e.g. - re-obtain data point[s])? ☐ Yes ☐ No If "Yes", describe the actions that will be taken to correct the impact on the study data:	☐ No ☐ Not Yet Known **a)** Explain why:

4. Have an impact on study documents/procedures?

☐ Yes Please complete the 📄 subsection under "**SECTION III – RESPONSE PLAN**" below.	☐ No

SECTION III – RESPONSE PLAN

Please complete this section only as indicated in SECTION II:

Note: only complete this ◆ subsection if you answered "Yes" to #1 and/or #2 under "SECTION II" above.

◆ ***Affected Individual(s) at HRH Site***

1. Select all that apply**:**
☐ **Study Participant** ☐ **Study Team Member** ☐ **Patient (not participating in study)** ☐ **Visitor** ☐ **Other:**

2. Describe the harm that occurred:

3. Is it possible to mitigate or minimize the harm to the affected individual(s)?

☐ Yes **a)** What will be done/was done? **b)** What are/were the anticipated outcomes of these actions?	☐ No **a)** Explain why this is not possible:

Complete #4 and #5 only if you indicated under #1 above that a Study Participant was affected.

4. Can this individual remain enrolled in the study?

☐ Yes **a)** Is an explicit reconfirmation of consent planned? ☐ Yes ☐ No If "Yes": **i)** Please describe plan (process, documentation, timelines): **ii)** Will you use: ☐ an ICF Addendum or ☐ conduct a full re-consent? **b)** If "No" to **a)**, explain why reconfirmation of consent is not necessary:	☐ No Attach a separate document articulating the withdrawal plan for this participant: process, documentation, plans for inclusion or exclusion of individual's data in the final study data analysis, timelines. ☐ Attached

Minimization of Risks to Other HRH Study Participants

5. Is it possible to minimize the risk of this same Unanticipated Problem happening to other HRH research participants?

☐ Yes **a)** Describe plan (process, documentation, timelines):	☐ No **a)** Explain why this is not possible:

Note: only complete this subsection if you answered "Yes" to #4 under "SECTION II" above.

Impacted Documents/Procedures at HRH Site

1. Does this Unanticipated Problem impact the Investigational Product Documentation (IPD), such as Investigator Brochures, Product Monographs, or Device Manuals?

☐ Yes	☐ No
a) Describe your plan to revise this documentation (changes proposed, process, timeline) or attach revised IPD to this form with a summary of changes.	**a)** Explain why this isn't necessary:

2. Does this Unanticipated Problem impact the content of:

☐ the informed consent form(s) [ICFs]?

☐ the research protocol?

☐ other protocol-related documents that guide the conduct of the study (e.g. – standard operating procedures [SOPs])?

☐ Yes	☐ No
a) Please describe your plan to revise this documentation (changes proposed, process, timeline) **or** attach revised documents to this form with a summary of changes and a completed Amendment Form.	**a)** Explain why this isn't necessary:

SECTION IV – COMMUNICATION PLAN
Please complete this section for <u>all types of Unanticipated Problems</u>:

Communication Plan

1. Do you plan to inform local research participants about this Unanticipated Problem?

☐ Yes	☐ No
a) Describe plan (process, documentation, timelines): **b)** Is an explicit reconfirmation of consent planned?	**a)** Explain why it is not necessary to inform local research participants:

☐ Yes	☐ No
i) Describe plan (process, documentation, timelines): **ii)** Will you use: ☐ an ICF Addendum **<u>or</u>** ☐ conduct a full re-consent?	**i)** Explain why reconfirmation of consent is not necessary:

IMPORTANT NOTES

⇒ Study events that do not constitute unanticipated problems and do not require reporting to the REB may still require documentation (e.g. – logging) and reporting.

⇒ Sponsors, funders and regulators (Health Canada, FDA, OHRP) as well as HRH (via institutional policies) may have documentation and reporting requirements that differ from the HRH REB's requirements. See **<u>supplementary guidance</u>** for further information.

⇒ It is the responsibility of the Principal Investigator to be aware of all applicable laws, regulations, guidance and policies to his/her research study. The above guidance is meant to be helpful in this respect, but is not intended to be exhaustive.

Principal Investigator Attestation: "I confirm that I have reviewed this Unanticipated Problem Report and that all information contained herein is complete and accurate."

Principal Investigator Signature: _____

Date of PI Signature (YYYY-MM-DD):