**TRILLIUM HEALTH PARTNERS RESEARCH ETHICS BOARD (REB) PROTOCOL DEVIATION/VIOLATION REPORTING FORM**

*Please complete this form if any activities have occurred outside the REB approved study protocol*

| **REB ID#:** | Date form completed: |
| --- | --- |

1. **STUDY DETAILS**
2. Full Study Title:
3. Principal Investigator:
4. Local Principal Investigator:
5. Study Sponsor:        Investigator Initiated Study
6. Tri-agency Funded Study:  Yes  No
7. **PROTOCOL DEVIATION/VIOLATION ASSESSMENT**
8. Type of Deviation/Violation:

| Enrollment of participants or patient chart access during lapse in REB approval |
| --- |
| Enrollment of participant(s) outside of the approved inclusion/exclusion criteria |
| Deviation from approved consent process |
| Study drug/intervention errors |
| Breach of confidentiality |
| Failure to perform a required study procedure |
| Failure to perform a procedure within the required time frame |
| Enrollment of more participants than previously approved |
| Other (please specify): |

1. Date of protocol deviation/violation:
2. Describe in detail the deviation/violation identified above:
3. Was the participant(s) placed at greater risk because of the protocol deviation (e.g. breach in privacy, confidentiality, unapproved exposure to drug)?

Yes  No

1. If yes, please describe the increased risk and how the increased risk has been managed:
2. Does the protocol deviation/violation compromise the integrity of the study data?

Yes  No

1. If yes, please describe:
2. The actions of which party led to the protocol deviation/violation (select all that apply)?

|  |  |  |
| --- | --- | --- |
| Sponsor | Investigator | Research Staff |
| Study Participant | Other (please specify): |  |

1. Please provide details explaining how the deviation/violation occurred:
2. Please indicate what measures have been/will be taken to ensure this does not happen again (*future preventable measures*):
3. Does the protocol deviation/violation require change(s) to the study protocol or consent form?  Yes  No
4. If yes, please submit the changes using the amendment submission form
5. Has the study participant(s) been informed of the protocol deviation/violation?

Yes  No

1. If no, please explain the reason for not informing study participant(s):
2. **DECLARATION BY PRINCIPAL INVESTIGATOR:**

I attest that I as the Principal Investigator have reviewed the above-listed protocol deviations/violations and its safety implications, assessed the relationship of the protocol deviations/violations to the research study and attest to the accuracy of this report.

**I have read the information contained in this form. By signing below I agree that:**

I have assessed the safety implications of this submission and its impact on the study procedures. I assume full responsibility for the scientific and ethical conduct of this study and agree to conduct this study in compliance with the current edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS), Personal Health Information Protection Act (PHIPA) and any other relevant regulations or guidelines.

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| --- | --- | --- | --- | --- |
| Name of Principal Investigator |  | Signature |  | Date |