**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.

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