VIRTUA HEALTH
INSTITUTIONAL REVIEW BOARD
(856) 761-3844
Fax: (856) 761-3834

IRB Reportable Event Form

STUDY INFORMATION

IRB Protocol Number: *Click here to enter text.*

Principal Investigator (include degree(s)/certifications): *Click here to enter text.*

Co- Investigators (include degree(s)/certifications): *Click here to enter text.*

Study Title: *Click here to enter text.*

Definitions (to consider before completing the form)

- **Unanticipated**: *Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document, and (b) the characteristics of the subject population being studied.*
- **Possibly Related:** *There is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research. The IRB interprets "reasonable possibility" to mean "more likely than not". Therefore "possibly related" means "more likely related than unrelated"*
- **Serious Adverse Experiences or Events that Require Prompt Reporting:** *A serious adverse experience or event requires prompt reporting when it meets both of the following criteria:*
  - unanticipated (defined above)
  - indicates that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.
- **Non-serious Adverse Experiences or Events that Require Prompt Reporting:** *A non-serious adverse experience or event requires prompt reporting when it meets both of the following criteria:*
  - unanticipated (defined above)
  - indicates that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.
- **Deviation:** *Protocol deviation is defined as any departure in study activity from the currently-approved protocol. Deviations can be major or minor and can be the result of actions by the participant or the investigator or his/her study team.*

REPORTABLE EVENT INFORMATION

Please submit the most recently approved Informed Consent with this form.

Submission Type:

☐ *Data Safety Monitoring Report (please complete Sections 1 and 6)*

☐ *Acknowledgment Request (please complete Sections 2 and 6)*

☐ *Reportable Event (please complete Sections 3 and 6)*

☐ *Unanticipated Problem (please complete Sections 4 and 6)*
Event must be reported
- *Within 24 hours of discovery for death in an interventional study whether or not study related*
- *Within 7 days if determined serious, related and unexpected*
- *Within 10 days for all other unanticipated problems*

☐ *Protocol Deviation/Violation (please complete Sections 5 and 6)*
Event must be reported within 10 business days of awareness if determined to impact subject safety, welfare/rights, or data integrity.

Please ensure that appropriate items are attached and that the report is signed and dated by the principal investigator.

SECTION 1

Please enter the date received by the investigator: Click here to enter text.
Please attach the Data Safety Monitoring Report.

As determined by the investigator, does the report indicate any increased risk to the participant population?

☐ *Yes*
☐ *No*

Are changes to the study/consent form recommended based upon this report?

☐ *Yes*
☐ *No*

SECTION 2

Provide a description of the acknowledgment request: Click here to enter text.

SECTION 3

Select the report type:

☐	*Initial Report*	*AND*	☐	*Medical/Clinical Event*
☐	*Follow-Up Report #: Click here to enter text.*		☐	*Non-Medical Event*

As assessed by the Principal Investigator,

is the event unexpected?	☐ *Yes*	☐ *No*	*Rationale: Click here to enter text.*
is the event related to the research study?	☐ *Yes*	☐ *No*	*Rationale: Click here to enter text.*
does the event put the participant(s) or others at greater risk of harm?	☐ *Yes*	☐ *No*	*Rationale: Click here to enter text.*
does the event change the risk/benefit profile of the study? - *Do risks remain reasonable in relation to anticipated benefits?* - *Are subjects at greater risk than previously known or recognized?*	☐ *Yes*	☐ *No*	*Rationale: Click here to enter text.*

Was there a death in an interventional study for which Virtua is the IRB of Record that occurred within 30 days of the intervention?

☐ *Yes*
☐ *No*

Was the sponsor notified?

☐ *Yes, provide documentation.*
☐ *No, please provide an explanation as to why: Click here to enter text.*

SECTION 4

Please provide a description of the event, relevant medical history, and any immediate or planned follow-up actions to resolve the event. If this is a follow-up report, please summarize what has changed since the last report. Click here to enter text.

Please provide the date(s) the event occurred Click here to enter text.
Please provide the date this event was first reported to the study team: Click here to enter text.
If applicable, please enter the participant ID(s): Click here to enter text.

As assessed by the Principal Investigator,

is the event unexpected?	☐ *Yes*	☐ *No*	*Rationale: Click here to enter text.*
is the event related to the research study?	☐ *Yes*	☐ *No*	*Rationale: Click here to enter text.*
does the event put the participant(s) or others at greater risk of harm?	☐ *Yes*	☐ *No*	*Rationale: Click here to enter text.*
does the event change the risk/benefit profile of the study? - *Do risks remain reasonable in relation to anticipated benefits?* - *Are subjects at greater risk than previously known or recognized?*	☐ *Yes*	☐ *No*	*Rationale: Click here to enter text.*

Is this event required by the sponsor to report?

☐ *Yes, provide documentation.*
☐ *No, please provide an explanation as to why: Click here to enter text.*

Does event require any changes to the currently approved procedures or study documents?

☐ *Yes, please submit a modification form and revisions in both clean/tracked change documents.*

☐ *No, please provide an explanation as to why: Click here to enter text.*

SECTION 5

Please provide the date of the protocol deviation/violation:Click here to enter text.
Please provide the date this event was reported to the Principal Investigator: Click here to enter text.
If applicable, please enter the participant ID(s): Click here to enter text.

Please confirm that study records have been reviewed to determine whether any other subjects were impacted by similar deviation.

☐ *All records have been reviewed on Click here to enter date*

Is this deviation a recurrence of a previously reported deviation/violation on this protocol?

☐ *Yes, please provide date of prior deviation/violation submission and include how CAPA will be revised*
☐ *No*

Please describe the deviation(s)/violation(s), including the date(s)/timeline, explanation of why it occurred/root cause, and the outcome: Click here to enter text.

Please describe how the deviation/violation was identified: Click here to enter text.

As assessed by the Principal Investigator, did the deviation(s)/violation(s):

affect participant safety?	☐ *Yes*	☐ *No*	*Rationale: Click here to enter text.*
increase the risks to subjects?	☐ *Yes*	☐ *No*	*Rationale: Click here to enter text.*
affect the integrity of the data?	☐ *Yes*	☐ *No*	*Rationale: Click here to enter text.*
violate the rights and welfare of the subjects?	☐ *Yes*	☐ *No*	*Rationale: Click here to enter text.*
affect the participant's willingness to participate in research?	☐ *Yes*	☐ *No*	*Rationale: Click here to enter text.*

The following entities were notified:

sponsor	☐ *Yes, provide documentation.*	☐ *No, Please provide explanation as to why*
medical monitor	☐ *Yes, provide documentation.*	☐ *No, Please provide explanation as to why*
oversight entity (FDA/DSMB, etc.)	☐ *Yes, provide documentation.*	☐ *No, Please provide explanation as to why*

SECTION 6

Corrective action plan: Click here to enter text. Describe the corrective actions taken or planned by the site and any plans to communicate the deviation/violation to participants as applicable. Please also include the procedures used to document resolution of the problem and who is responsible for the procedures.

Actions to be taken because of the event. (Check all that apply)

	The protocol or study procedures will be modified. Please complete and submit the modification form.
	Retraining of the study team – date of training and who attended: Click here to enter text.
	Revise consent form
	Not applicable, explanation: Click here to enter text.
	Please provide an explanation as to why: Click here to enter text.

Effective date of resolution: Click here to enter text.

Preventative action plan: Click here to enter text. This may include any preventative actions taken or planned by the site to avoid this being an issue again in the future.

ADDITIONAL INFORMATION

Please attach any documentation from the Sponsor and/or FDA communications.

If applicable, please upload any other documents that have been specified in previous questions and that are needed for IRB review.

If there is any additional information that you wish to include about the study, please include it below. Click here to enter text.

INVESTIGATOR SIGNOFF

Signature of PI: _____ *Date:* _____