**PROTOCOL VIOLATION/ DEVIATION REPORT - CHREB**

**Date of this report:** Click here to enter a date.

**Is this a(n):** [ ]  Initial report, OR

[ ]  Follow-Up report

**Ethics ID#**

**Study Title:** Click here to enter text.

**Participant ID**: Click here to enter text.

**Participant initials**: Click here to enter text.

**Age**: Click here to enter text.

**Sex:** M [ ]  F [ ]

**Date of Violation/Deviation:** Click here to enter a date.

**Date Principal Investigator (PI) was notified of violation/deviation:** Click here to enter a date.

1. **Explain any time lapse in reporting to the CHREB from the date the PI was notified of the violation**

(>7 days for protocol violations arising from changes to eliminate immediate safety risks to the study participants; >15 days for all other violations)

Click here to enter text.

1. **Briefly describe the violation/deviation and why it occurred:**

Click here to enter text.

1. **Briefly describe how the violation/deviation was resolved by the PI and study team**:

Click here to enter text.

1. **At the time of the protocol violation/deviation, the participant was**:

[ ]  In pre/screening phase

[ ]  Actively on study

[ ]  On follow-up

[ ]  Off study

[ ]  Comments, if required: Click here to enter text.

1. **In the opinion of the PI, does this protocol violation/deviation compromise the scientific integrity of the study?** Yes [ ]  No [ ]

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

1. **In the opinion of the PI, did this protocol violation/deviation increase the risk to the participant or others affected by the research?**

Yes [ ]  No [ ]

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

1. **Was the protocol violation/deviation the result of an error or incorrect action by the sponsor, PI or study team?**

Yes [ ]  No [ ]

If yes, please comment on what measures will ensure this will not occur in the future: Click here to enter text.

1. **Was the protocol violation/deviation due partially or wholly to actions of the participant?**

Yes [ ]  No [ ]

If yes, please comment on what measures will ensure this will not occur in the future: Click here to enter text.

1. **Does this protocol violation/deviation show a concerning trend for which the CHREB should be made aware?**

Yes [ ]  No [ ]

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

1. **In the opinion of the PI, does the protocol violation/deviation warrant:**
	1. **Closure of the study?** Yes [ ]  No [ ]
	2. **Changes to the study procedures?** Yes [ ]  No [ ]
	3. **Revisions to the informed consent form?\*** Yes [ ]  No [ ]
	4. **Advising the study participant(s) verbally?** Yes [ ]  No [ ]

If yes, upload suggested script

***\*NOTE:*** *If ICF changes are required, please submit any changes as a modification. In the modification summary, please indicate that a corresponding protocol violation/deviation report was submitted.*

*Supporting documentation should be retained by the PI and made available upon request.*