**PROTOCOL VIOLATION/ DEVIATION REPORT - CFREB**

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

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

[ ]  Follow-Up report

**Ethics ID#** Click here to enter text.

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

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

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

1. **Describe the violation and how/why the violation occurred:**

Click here to enter text.

1. **Has the violation been resolved by the PI and study team?** Yes [ ]  No [ ]

**If yes, describe how the violation was resolved by the PI and study team**:

Click here to enter text.

1. **In the opinion of the PI, does this protocol violation 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, does this protocol violation increase the risk to participants or others affected by the research?**

Yes [ ]  No [ ]

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

1. **Was the protocol violation the result of an error or incorrect action by the PI and/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 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 show a concerning trend for which the CFREB 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 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