**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