

PROTOCOL VIOLATION / DEVIATION REPORT - HREB

Date of this report:

Ethics ID:

Study Title:

Study PI:

If applicable:

Participant ID:

Age:

Sex: M F

Date of Violation/Deviation:

Date PI was notified of violation/deviation:

1. Explain any time lapse in reporting to the HREB from the date the PI was notified of the violation/deviation. (>7 days for protocol violations arising from changes to eliminate immediate safety risks to the study participants; >15 days for all other violations)



2. Describe the violation/deviation and why it occurred.

3. Describe how the violation/deviation was resolved by the PI and study team.

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

In pre/screening phase

Comments, if required:

Actively on study

On follow-up

Off study

N/A

5. In the opinion of the PI, does this protocol violation/deviation compromise the scientific integrity of the study?

Yes No

If yes, please comment:

6. 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:

7. 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:

8. 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:

9. Does this protocol violation/deviation show a concerning trend for which the HREB should be made aware?

Yes No

If yes, please comment:

10. In the opinion of the PI, does the protocol violation/deviation warrant:

a) Closure of the study? Yes No

b) Changes to the study procedures? Yes No

c) Revisions to the informed consent form? * Yes No

d) Advising the study participant(s) verbally? Yes No *If yes, upload suggested script.*

* **NOTE:** *If ICF changes are required, please submit any changes as an amendment. In the amendment summary, indicate that a corresponding protocol violation/deviation report was submitted (quote submission Pro000#####_EVT#).*

Supporting documentation for this report should be retained by the PI and made available upon request.