

Protocol Deviation

Submission of protocol deviation / violation

Protocol Deviation / Violation

PD1. Please briefly describe in lay language the details of the deviation and / or violation, including what site it occurred at and when it occurred.

Dependents: 1

PD.2 Did the problem/event cause harm or place the participant or a non-participant at increased risk of harm?

- Yes
- No

[Depends on PD.2 Participant harm](#)

PD.2.1 Please explain your answer:

PD3. Have the appropriate people been informed?

- Yes
- No

Dependents: 1

PD3.1. Have the affected participants been informed?

- Yes
- No

[Depends on PD3.1. Have the affected participants been informed?](#)

Please justify the decision not to inform participants when answering PD4 below.

PD4. Please explain your answer including who has been informed

PD5. Have any corrective actions been taken by the study team to date? Explain the measures taken to avoid reoccurrence.

Dependents: 1

PD6. Should the research plan (and/or Sponsor's protocol) be revised, and should other participants be informed of this deviation or violation?

Yes

No

[Depends on PD6. Research plan revision.](#)

PD6.1 Please explain your answer. Note if changes to the study are required you will have to submit an amendment with a revised research plan/protocol with track changes or a summary of changes.

PD.7. Please upload details of the protocol deviation / violation

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