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| IRB No: IRB0001234 | Title: enter study title as in eIRB submission. |
| PI: First and Last Name. | Subject ID: Do not enter initials or identifiers. |

***The following deviations are always reportable to the IRB:***

* *Deviations involving errors during eligibility process that caused the enrollment of an ineligible subject*
* *Missed protocol-required labs or procedures indicated before study intervention, including pregnancy tests (even if harm did not occur)*
* *REMS requirements deviations*
* *Drug dosing errors* ***involving safety concerns*** *(for example, if a subject was dosed incorrectly at a lower or higher dose, or if the drug was not stored per manufacturer indications)*
* *Consent process errors (when subjects did not receive an adequate explanation of study, or there is no correct documentation of consent)*
1. Please give a brief description of the protocol deviation and how/why it occurred: Please explain when you learned about the issue, details about the problem being reported, and other information that would be useful for IRB review.
2. Date of the deviation: Click here to enter a date.
3. Was the deviation a substantive change from the protocol adversely affecting at least one of the following (\*):

The rights, welfare, or safety of the subjects: ☐ Yes ☐ No
The integrity of the research data: ☐ Yes ☐ No
The subjects’ willingness to continue participation: ☐ Yes ☐ No

 ***(\*) You may report this event if the protocol, contract, or sponsor requires it.***

1. Please explain the basis for this decision and how this deviation affects the above areas: Insert text.

1. Please describe the root cause of this issue: Insert text.
2. Please describe: (i) corrective action, if applicable, for the deviation; and (ii) a plan for preventing recurrence (if applicable): Insert text.
3. Does this deviation require a revision of the protocol and/or consent form? ☐ Yes ☐ No
(If yes, attach the proposed changes with clean and highlighted copies)
4. Do subjects need to be notified of this protocol deviation? ☐ Yes ☐ No
5. Indicate if this deviation needs to be reported to:
	* IRB ☐ Yes (\*) ☐ No
	* FDA ☐ Yes ☐ No
	* Sponsor ☐ Yes ☐ No

(\*) If yes, please use e-IRB.

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Person completing this form name Signature Date

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Principal Investigator Name Signature Date