

Protocol Deviation Log [Ongoing Logs]

⚠ Missed Visits are not captured on the Protocol Deviation Log; Please complete the PRN Missed Visit CRF linked with the visit which was missed.

01	REDCap entry Date:	⚠ <i>You do not need to enter a date on this paper CRF, but you will be prompted to click the "Today" button when entering this Protocol Deviation in REDCap.</i>
02	Deviation Date:	___ / ___ / _____ (dd/mm/yyyy)
03	Site Awareness Date: ⚠ <i>Deviations should be recorded in REDCap within 3 days of site awareness.</i>	___ / ___ / _____ (dd/mm/yyyy)
04	Description of Deviation: <div style="border: 1px solid black; border-radius: 15px; height: 150px; margin-top: 10px;"></div>	
05	Type of Deviation:	<input type="checkbox"/> Inappropriate enrollment <input type="checkbox"/> Failure to follow randomization or blinding procedures <input type="checkbox"/> Study product management deviation <input type="checkbox"/> Study product dispensing error <input type="checkbox"/> Study product use/non-use deviation <input type="checkbox"/> Conduct of non-protocol procedure <input type="checkbox"/> Missed required procedure at visit <input type="checkbox"/> Visit completed outside of window <input type="checkbox"/> Counseling deviation <input type="checkbox"/> Unreported AE <input type="checkbox"/> Breach of confidentiality <input type="checkbox"/> Physical assessment deviation <input type="checkbox"/> Lab assessment deviation <input type="checkbox"/> Mishandled lab specimen <input type="checkbox"/> Staff performing duties that they are not qualified or delegated to perform <input type="checkbox"/> Questionnaire administration deviation <input type="checkbox"/> Use of non-IRB/EC-approved materials <input type="checkbox"/> Use of excluded concomitant medications, devices, or non-study products <input type="checkbox"/> Informed consent process deviation <input type="checkbox"/> Participant non-compliance <input type="checkbox"/> Other (answer 05a)

⚠ *05a. Complete only if other type of deviation:*

"Other" type of deviation, specify: _____

Protocol Deviation Log (Continued)

06	Additional Details of Deviation (if applicable): <div style="border: 1px solid black; border-radius: 15px; height: 150px; margin-top: 5px;"></div>
07	Plans and/or action taken to address the deviation: <div style="border: 1px solid black; border-radius: 15px; height: 150px; margin-top: 5px;"></div>
08	Plans and/or action taken to prevent future occurrences of the deviation: <div style="border: 1px solid black; border-radius: 15px; height: 150px; margin-top: 5px;"></div>
09	Additional details, if needed: <div style="border: 1px solid black; border-radius: 15px; height: 150px; margin-top: 5px;"></div>

CRF Completed By: _____ (initials)

CRF Completion Date: ___ / ___ / _____ (dd/mm/yyyy)