

GRAIL 3 - NOTE TO FILE Protocol Deviation

SITE AWARENESS DATE: _____

DEVIATION DATE: _____

SUBJECT ID: _____

SITE NUMBER: _____

Has or will this deviation be reported to local IRB/EC?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Type of deviation (Select one)	<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"/> Improper AE; <input type="checkbox"/> Unreported AE; <input type="checkbox"/> Unreported SAE; <input type="checkbox"/> Breach of confidentiality; <input type="checkbox"/> Lab assessment deviation; <input type="checkbox"/> Mishandled lab specimen; <input type="checkbox"/> Staff performing duties that they are not qualified 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"/> Visit completed outside of window; <input type="checkbox"/> Other
Description of deviation	

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Plans and/or action taken to address the deviation	
Plans and/or action taken to prevent future occurrences of the deviation	
Deviation reported by	

SITE PI MADE AWARE OF THE DEVIATION ON THIS DATE: _____

PRINT NAME: _____

SIGN NAME: _____

DATE: _____