

NONCOMPLIANCE FORM

Abbreviated title or Acronym:	
Protocol number:	
Principal Investigator:	
Date form completed	
Date of noncompliance:	

Deviation pertains to participant(s):	No		Yes	
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If yes

Participant ID(s):				
Is the deviation indicated on the CRF(s) or equivalent?	No		Yes	
Did the deviation result in an adverse event?	No		Yes	
Was this a major noncompliance	No		Yes	
If yes was it / will it be reported to Ethics Committee	No		Yes	

Noncompliance pertains to	Protocol <input type="checkbox"/> GCP <input type="checkbox"/> Unit policy, process, SOP <input type="checkbox"/> Regulatory requirements <input type="checkbox"/> Other <input type="checkbox"/>
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Description of noncompliance:

Reason for noncompliance:

Steps taken to correct this noncompliance and to prevent from reoccurrence:

Due date of correction	
Responsible Person	
Date reported to sponsor	
Date reported to EC (if applicable)	

Completed by (*Name*)

Signature

Date

Reviewed by PI

Signature

Date