



NON-COMPLIANCE (Deviation/Violation) REPORT

To the Principal Investigator:

All major non-compliance with the conditions of IEC approval of the Protocol must be submitted not later than 7 days of discovery. Reports of minor/administrative deviations can be submitted with the Continuing Review Application. Failure to report major protocol deviations/violations promptly is in itself an instance of non-compliance.

If changes are made to the IEC-approved Protocol, such changes must be submitted as Protocol Amendment, and not as Protocol Deviation/Violation.

Please obtain an electronic copy of this Form, fill-out the requested information, and make your submission both in electronic version and hard copy. Print in letter-sized paper with printer default set at A4.

I. PROTOCOL INFORMATION	IEC Protocol Tracking No.
Study Protocol No.	Protocol Approval Date: <dd/mm/yy>
Study Initiation Date: <dd/mm/yy>	Expected End Date: <dd/mm/yy>
Title:	Version Number, Date
Name of Principal Investigator	Contact Nos.:
Sponsor/CRO	
Study Site	
Type of Review (<i>To be determined by IEC</i>) <input type="checkbox"/> Full Board <input type="checkbox"/> Expedited	

II. INFORMATION REQUIRED	NON-COMPLIANCE REPORT SUBMISSION DATE <dd/mm/yy>
1. Nature of the Report: <input type="checkbox"/> Minor Protocol Deviation - A non-compliance with defined procedures, as described in the IEC-approved protocol, that poses no conceivable threat to participant safety or data integrity. This includes deviations that are administrative in nature. <input type="checkbox"/> Major Protocol Deviation/ Violation: A non-compliance with defined procedures, as described in the IEC-approved protocol that impacts participant safety or data integrity.	
2. Date of Protocol Deviation/ Violation: <dd/mm/yy>	Date Resolved: <dd/mm/yy>



3. Details of Protocol Deviation/Violation	
4. Details of corrective/preventive action taken by PI/ Sponsor	
5. Risk Assessment (<i>include impact on safety of participants, and on scientific/ ethical acceptability of the protocol</i>)	
<p><i>I declare that the above information/statements are true and correct to the best of my knowledge.</i></p> <p><i>I declare that the study is being conducted in keeping with the conditions of IEC approval of the Protocol.</i></p>	
_____	_____
<i>Signature Over Printed Name of Principal Investigator</i>	<i>Date:</i>

III. IEC RECOMMENDATION	Specifics
<input type="checkbox"/> UPHOLD ORIGINAL APPROVAL WITH NO FURTHER ACTION <input type="checkbox"/> REQUEST INFORMATION <input type="checkbox"/> RECOMMENDED FURTHER ACTION	
Reviewer <input type="checkbox"/> Primary <input type="checkbox"/> Secondary	_____ <i>Reviewer's Signature Over Printed Name</i> _____ <i>Date</i>