



## *PROTOCOL AMENDMENT SUBMISSION*

*To the Principal Investigator:*

*An IEC approval must be secured before any protocol amendment can be implemented. It is important to complete and submit this form to fully evaluate its effect on the ethical and/or scientific acceptability of the study.*

*All amended documents must have the changes tabbed and highlighted, and must contain the revised version numbers and dates. A summary or tabulated detail of the changes, together with the page number or section where the changes can be found is further required.*

*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.*

<b>I. PROTOCOL INFORMATION</b>	<b>IEC Protocol Tracking No.</b>
Study Protocol No.	Protocol Approval Date:
Study Initiation Date:	Expected End Date:
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	

<b>NUMBER OF AMENDMENTS</b> <number>	<b>AMENDMENT SUBMISSION DATE</b> <dd/mm/yy>	
<b>Amendment Summary</b>		
Original Version	Amendment	Rationale for Amendment



*I declare that the above information/statements are true and correct to the best of my knowledge.*

\_\_\_\_\_  
*Signature Over Printed Name of Principal Investigator*

\_\_\_\_\_  
*Date*

IEC RECOMMENDATION:	Justification for the Recommendation:
<input type="checkbox"/> APPROVAL <input type="checkbox"/> MINOR MODIFICATIONS <input type="checkbox"/> MAJOR MODIFICATIONS <input type="checkbox"/> DISAPPROVAL	

Reviewer: <input type="checkbox"/> Primary <input type="checkbox"/> Secondary	_____ <i>Reviewer's Signature Over Printed Name</i> _____ <i>Date</i>
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