



## AMENDMENT APPLICATION FORM

IERB no.		Protocol no.		DETR no.	
Study Title:					
Principal Investigator					

<b>AMENDMENT TO RESEARCH STUDY (Choose all that apply)</b> <ul style="list-style-type: none"> <li><input type="checkbox"/> Change(s) to research protocol (<i>attach tracked versions of protocol</i>)</li> <li><input type="checkbox"/> Change(s) to consent form scripts (<i>attach clean and tracked version of document(s)</i>)</li> <li><input type="checkbox"/> Change to study population</li> <li><input type="checkbox"/> Addition of Study Site</li> <li><input type="checkbox"/> Change to sample size</li> <li><input type="checkbox"/> Initiation of new study phase</li> <li><input type="checkbox"/> Changes of recruitment materials, data collection forms, instruments, questionnaires/surveys (<i>attach tracked version of revised documents with new version number</i>)</li> <li><input type="checkbox"/> Change to drug or device information for FDA regulated study</li> <li><input type="checkbox"/> Change in conflict of Interest</li> <li><input type="checkbox"/> Other change (<i>describe below</i>)</li> </ul>
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Describe changes to the approved protocol/IERB application form. Explain in detail in the space below the reasons for requesting these changes and which part(s) of the approved document will be amended. Please highlight changes in the revised document.

Describe changes to the ICF/assent form/recruitment advertisement, etc. Explain which sections of these items are being changed. Please highlight changes in the revised document.

<b>SIGNATURE</b>	
_____ Signature of Principal Investigator <i>(signature of co-investigator or study staff is not acceptable)</i>	_____ Date

To be filled up by IERB

Date received:		Received by:
		Signature over Printed Name

<b>Recommendations</b> <input type="checkbox"/> Uphold Approval <input type="checkbox"/> Request an amendment to the protocol or the consent form. <input type="checkbox"/> Request further information. <input type="checkbox"/> Approved <input type="checkbox"/> Disapproved amendment  _____	<b>Type of review:</b> <input type="checkbox"/> Expedited review <input type="checkbox"/> Full board review  <b>Date of meeting:</b> _____
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<b>IERB Final Decision:</b>	
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<b>Primary Reviewer :</b>
<i>Signature over Printed Name / Date</i>

<b>Approved by : IERB Chair</b>
<i>Signature over Printed Name / Date</i>