



Ethical Review Committee, Inc.

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INVESTIGATOR DRUG BROCHURE APPLICATION FOR AMENDMENT

Completely answer each question. Any incomplete or blank questions or those without the proper documentation will delay your review by the Ethical Review Committee (ERC). Please FAX or MAIL this form to the ERC upon completion. Your prompt response will allow for timely review and approval.

Section A: Sponsor Information			
Institution Name:			
Address:			
Contact:	Phone:	Ext:	Fax:
E-Mail:			
Alternate Contact:	Phone:	Ext:	Fax:
E-Mail:			

Section B: Drug Information
Name of Drug:
Please indicate all studies related to this drug.

Section C: Amendment Information	
1	Are there added risks to the subjects? <input type="checkbox"/> No <input type="checkbox"/> Yes <hr/> <i>If yes, please answer the following:</i> A. Please indicate all of the added risks to the subjects. B. Who will the risks affect? <input type="checkbox"/> Previous Subjects* <input type="checkbox"/> Current Subjects <input type="checkbox"/> Both* <i>*Please describe how will you be contacting the previous subjects.</i> C. Will the informed consent form (ICF) need to be revised due to the added risks? <input type="checkbox"/> No <input type="checkbox"/> Yes <i>If no, please indicate why the changes are not necessary.</i>
2	Has the dosing level <input type="checkbox"/> increased, <input type="checkbox"/> decreased, or <input type="checkbox"/> stayed the same? <i>If applicable, please indicate the dosing changes.</i> <i>Previous level(s):</i> <i>Amended level(s):</i>

3	Will the location of administration of the drug be altered?	<input type="checkbox"/> No <input type="checkbox"/> Yes
<i>If yes, indicate new location:</i> <input type="checkbox"/> Subject will take home to self-administer <input type="checkbox"/> Inpatient Hospital <input type="checkbox"/> PI place of practice <input type="checkbox"/> Other:		
4	Has the person administering the drug changed? <i>If yes, indicate who will be administering the drug:</i>	<input type="checkbox"/> No <input type="checkbox"/> Yes

Signature and title of person completing form

_____/_____/_____
Date