



# Ethical Review Committee, Inc.

14400 E. 42nd St., Suite 240

Independence, MO 64055

Phone: 816.421.0008 ♦ Fax: 816.356.2227

## SUB INVESTIGATOR SUBMISSION FORM

Completely answer each question. For questions requiring additional explanation or documentation, attach the materials to this form for submission. Any incomplete or blank questions or those without the proper documentation may delay your review. The Institutional Review Board (IRB) cannot review this submission until this submission is complete. Please FAX or MAIL this form to the Ethical Review Committee (ERC) upon completion. Your prompt response will allow for timely review and approval.

**Protocol Title and/or Number:**

**Principal Investigator:**

Section A: Sub Investigator (Sub-I) Information	
<b>Sub-I:</b>	<b>Phone:</b> ( ) -
<b>Primary Research Facility:</b>	<b>Fax:</b> ( ) -
<b>Street Address:</b> <input type="checkbox"/> Also document shipping address	<b>City, State, Zip:</b> <i>If shipping address is different, please indicate:</i>
<b>24 Hour #:</b> ( ) - <i>(After business hours contact number)</i>	<b>Sub-I E-Mail:</b>

Section B: Contact and Site Information	
<b>Primary Contact:</b> <input type="checkbox"/> PI <input type="checkbox"/> Sub-I <input type="checkbox"/> Other: Title:	<b>Telephone:</b> ( ) - <b>Ext:</b>
<b>Contact Address:</b> <input type="checkbox"/> Same address as listed in Section A	<b>E-Mail:</b>
	<b>Fax:</b> ( ) -

Section C: Sub Investigator Professional Information	
<b>1</b>	<b>Have you had previous clinical trial experience?</b> <input type="checkbox"/> No <input type="checkbox"/> Yes
<i>If yes, is it listed on your CV?</i> <input type="checkbox"/> No <input type="checkbox"/> Yes	
<i>If your experience is not listed on your CV, please provide a listing of clinical trials.</i>	
<b>2</b>	<b>Have you had any human subjects research training?</b> <input type="checkbox"/> No <input type="checkbox"/> Yes
<i>If yes, please identify which training courses you have completed.</i>	
<input type="checkbox"/> Collaborative IRB Training Initiative (CITI) <input type="checkbox"/> NCI Human Participant Protections Education for Research <input type="checkbox"/> Institutional (PI place of practice) Human Subjects Protection Training <input type="checkbox"/> NIH online tutorial, <i>Protecting Human Research Participants</i> <input type="checkbox"/> Other Training:	
<i>If no, would you like to receive a copy of the ERC's guidebook, "Investigator Regulatory Information for Clinical Trials"?</i> <input type="checkbox"/> No <input type="checkbox"/> Yes	
<b>3</b>	<b>Do you have hospital privileges?</b> <input type="checkbox"/> No <input type="checkbox"/> Yes
<input type="checkbox"/> I am a Nurse Practitioner / Physician Assistant and am not eligible for hospital privileges.	
<i>If no, please identify how you will follow any hospitalized subjects.</i>	

<b>4</b>	<b>Have you or your site had any research suspended or terminated by an IRB?</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes
<i>If yes, please identify which IRB and the reasoning for the suspension or termination.</i>		
<b>5</b>	<b>Have you been audited by the FDA at any point during your lifetime of medical practice?</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes
<p><b>A.</b> <i>If yes, date of audit:</i> (Attach supporting documentation)</p> <p><b>B.</b> <i>If yes, was an FDA Form 483 issued?</i> <span style="float: right;"><input type="checkbox"/> No <input type="checkbox"/> Yes</span></p> <p><i>Attach all copies of EIR Forms (Established Inspection Reports) if you have been audited and the FDA Form 483s if issued.</i></p> <p><i>Also, attach copies of ALL communications you have received from / forwarded to the FDA.</i></p>		
<b>6</b>	<b>Have you had a “For Cause” inspection? (“For Cause” is due to a specific reason.)</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes
<i>If yes, date of inspection:</i> (Attach supporting documentation)		
<b>7</b>	<b>Have you had your hospital privileges suspended, revoked, restricted, placed on probation, or subject to disciplinary action?</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes
<i>If yes, please explain:</i> (Attach supporting documentation)		
<b>8</b>	<b>Have you had your medical license subject to suspension, revocation, denial, or interruption in any state?</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes
<i>If yes, please explain:</i> (Attach supporting documentation)		
<b>9</b>	<b>Have you had any board actions filed with any medical licensing agency?</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes
<i>If yes, please explain:</i> (Attach supporting documentation)		
<b>10</b>	<b>Have you had any legal actions against you within the past 5 years?</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes
<i>If yes, provide allegations brought forth, current status of the case(s), and resolution or outcome.</i>		
<b>11</b>	<b>Do you or a member of your immediate family (defined as spouse, children, siblings, parents, equivalents by marriage [in-laws], or household members)</b>	
<p><b>A.</b> Have financial arrangements with the sponsoring company or the products or services being evaluated, including receipt of honoraria, income, or stock/stock options as payments that equal or exceeded \$10,000, or 5% of the company value, in the past year or will equal or exceed the amount during the course of the project, that are not publicly traded, or whose value <b>may be affected by the outcome of the research?</b></p>		<input type="checkbox"/> No <input type="checkbox"/> Yes
<p><b>B.</b> Have consulting agreements, management responsibilities, ownership, interests, equity holdings or options in the sponsoring company, the provider(s) of goods, or subcontractors that <b>may be affected by the outcome of the research?</b></p>		<input type="checkbox"/> No <input type="checkbox"/> Yes
<p><b>C.</b> Have a paid or unpaid membership of an <b>advisory or executive board</b> or have a paid or unpaid <b>executive relationship</b> with the company or the providers of the products or services being evaluated?</p>		<input type="checkbox"/> No <input type="checkbox"/> Yes
<p><b>D.</b> Receive gift funds, educational grants, subsidies or other remuneration from the sponsoring company that <b>may be affected by the outcome of the research?</b></p>		<input type="checkbox"/> No <input type="checkbox"/> Yes
<p><b>E.</b> Have an ownership or royalty interest in any intellectual property utilized in this protocol?</p>		<input type="checkbox"/> No <input type="checkbox"/> Yes
<b><i>If you answered <u>yes</u> to any of questions A-E, please describe on a separate sheet.</i></b>		

**Section D: Protocol Information** *The questions within this section are pertaining to the protocol of which you are applying.*

**1 Does this study involve drugs and/or biologics?**  No  Yes

*If no, please proceed to question number 2.*

*If yes, please answer the following pharmacy-related questions:*

**⊗ Massachusetts Investigators Only:** *If this study is involving an investigational drug, please submit a copy of the Massachusetts Research Registration under which the research will be conducted.*

**Registration #:**  Registration is under the PI

**A. ⊗ Do you have controlled substance prescribing privileges?**  N/A to this study  No  Yes

**B. Who will dispense the drug(s)/biologics?**  Coordinator  Sub-I  PI  Other:

**2 Does this study involve a device?**  No  Yes

*If no, please proceed to question 3.*

*If yes, please answer the following storage and handling related questions:*

**A. Describe the storage location of the device:**

**B. Describe your role, as the Sub-I, in regards to the controlling and handling the study device:**

**3 Please indicate your roles as the Sub-I while participating in this protocol. (Please check all that apply)**

Consenting  Complete physical examination  Obtain medical history  Complete data forms

Complete source documents  Assess unanticipated problems  Take vitals

Review / Sign laboratory reports  Draw / Collect laboratory specimens

Perform tests, procedures, interventions, questionnaires  Dispense / Collect study medication

Other:

**Section E: Sub Investigator's Statement**

**I, the Sub Investigator, hereby certify that all the information in this document is accurate, complete, and that I am fully aware of my responsibilities with regard to the conduct of this study under this protocol. I further agree that:**

- I will comply with the requirements and requests of the Ethical Review Committee.
- By signing this form, I hereby state that my medical license in the state in which the research site is located is current and active.
- I am in good standing with the Medical Board governing my licensure, except as noted above (if applicable).
- I will notify the ERC if such situation(s) changes.
- I also agree that when my license is renewed I will FAX or MAIL a copy of the renewed license to the ERC and will continue to do so as long as the study I am conducting is ongoing and until the Final Report is submitted to the ERC.
- I agree to protect the rights, safety and welfare of the research subjects according to Good Clinical Practices by adhering to applicable federal, state, and local regulations governing clinical research.
- I will only use the ERC approved consent form and ERC approved recruitment materials for the above mentioned protocol.

\_\_\_\_\_  
Sub Investigator Original Signature

\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
Date