



Ethical Review Committee, Inc.

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PRINCIPAL INVESTIGATOR SUBMISSION FORM

This application is to be completed by the Principal Investigator (PI). Completely answer each question. For questions requiring additional explanation or documentation, attach the materials to this form. Any incomplete or blank questions or those without the proper documentation will delay your review. The Institutional Review Board (IRB) cannot review this submission until it 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 number and/or title of the study of which you are applying to participate:

Section A: Principal Investigator Information
PI:
Site Phone: () -
Primary Research Facility:
Site Fax: () -
Site Street Address:
24 Hour #: () -
(After business hours contact number)
City, State, Zip:
PI E-Mail:
Sub Investigators under the PI's supervision: [] N/A; no subs allowed ___ subs allowed; Please identify each by name and credentials:

Section B: Contact and Site Information
Primary Contact: [] PI [] Other: Title: Telephone: () - Ext:
Contact Address: [] Same address as listed in Section A E-Mail:
Different address: Fax: () -
Secondary Contact: [] PI [] Other: Title: Telephone: () - Ext:
Contact Address: [] Same address as listed in Section A E-Mail:
Different address: Fax: () -
1 Will the study be conducted in a facility that has its own IRB? [] No [] Yes
If yes, a waiver of jurisdiction must be submitted from the local IRB showing ERC as the IRB of record. Approval for this site cannot be granted by the ERC until the waiver is received.
2 What type of facility is your primary site?
[] Medical Office [] Hospital [] Dialysis Center [] Nursing Home [] Psychiatric Clinic
[] Research Clinic [] University [] Other:
If your site is NOT a hospital, please indicate the name and distance of the nearest hospital:
3 Will you be conducting the study at more than one site? [] No [] Yes
If yes, please identify the site and contact information for the additional site(s):
4 Does your site have equipment and/or personnel to treat life-threatening adverse reactions, should they occur? [] No [] Yes

If yes, please identify which are available: RN MD/DO Oxygen Emergency Meds
 Suction Defibrillator Other:

If no, please describe your policies and procedures for medical emergencies.

5 Are you aware of any research specific laws and/or regulations in your state/province? No Yes

If no, please see the following link www.ethicalreview.com for more information pertaining to your state.

Throughout this application, questions marked with a , indicate state specific questions that may have an affect on your participation.

Section C: Principal Investigator Professional Information

1 Have you had previous clinical trial experience? No Yes

If yes, is it listed on your CV? No Yes

If no, please provide a listing of clinical trials.

2 Have you had any human subjects research training? No Yes

If yes, please identify which training courses you have completed.

- Collaborative IRB Training Initiative (CITI)
- Institutional (PI place of practice) Human Subjects Protection Training
- NCI Human Participant Protections Education for Research
- NIH online tutorial, *Protecting Human Research Participants*
- Other Training:

If no, would you like to receive a copy of the ERC's guidebook, "Investigator Regulatory Information for Clinical Trials" No Yes

3 Have you or your site had any research suspended or terminated by an IRB? No Yes

If yes, please identify which IRB and the reasoning for the suspension or termination.

4 Have you been audited by the FDA at any point during your lifetime of medical practice? No Yes

A. If yes, date of audit: (Attach supporting documentation.)

B. If yes, was an FDA Form 483 issued? No Yes

Attach all copies of Established Inspection Reports (EIR) Forms if you have been audited and the FDA Form 483s if issued.

Also, attach copies of ALL communications you have received from / forwarded to the FDA.

5 Have you had a "For Cause" inspection? ("For Cause" is due to a specific reason.) No Yes

If yes, date of inspection: (Attach supporting documentation.)

6 Have you had your hospital privileges suspended, revoked, restricted, placed on probation, or subject to disciplinary action? No Yes

If yes, please explain: (Attach supporting documentation.)

7 Have you had your medical license subject to suspension, revocation, denial, or interruption in any state? No Yes

If yes, please explain: (Attach supporting documentation.)

8 Have you had any board actions filed with any medical licensing agency? No Yes

If yes, please explain: (Attach supporting documentation.)

9	Have you had any legal actions against you within the past 5 years?	<input type="checkbox"/> No <input type="checkbox"/> Yes
<i>If yes, please describe the allegations brought forth, current status of the case(s), and resolution or outcome”:</i>		
10	Do you have hospital privileges?	<input type="checkbox"/> No <input type="checkbox"/> Yes
<i>If no, please answer the following:</i>		
A. How will you follow hospitalized subjects?		
B. What is the name, address, and phone number of attending physician who has agreed to follow the hospitalized subjects?		
C. How will you assure communication with the attending physician?		
11	Do you or a member of your immediate family (defined as spouse, children, siblings, parents, equivalents by marriage [in-laws], or household members)	
A. 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 equaled 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 may be affected by the outcome of the research?		<input type="checkbox"/> No <input type="checkbox"/> Yes
B. Have consulting agreements, management responsibilities, ownership, interests, equity holdings or options in the sponsoring company, the provider(s) of goods, or subcontractors that may be affected by the outcome of the research?		<input type="checkbox"/> No <input type="checkbox"/> Yes
C. Have a paid or unpaid membership of an advisory or executive board or have a paid or unpaid executive relationship with the company or the providers of the products or services being evaluated?		<input type="checkbox"/> No <input type="checkbox"/> Yes
D. Receive gift funds, educational grants, subsidies, or other remuneration from the sponsoring company that may be affected by the outcome of the research?		<input type="checkbox"/> No <input type="checkbox"/> Yes
E. Have an ownership or royalty interest in any intellectual property utilized in this protocol?		<input type="checkbox"/> No <input type="checkbox"/> Yes
<i>If you answered <u>yes</u> to any of the above questions, please describe on a separate sheet.</i>		

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?	<input type="checkbox"/> No <input type="checkbox"/> Yes
<i>If no, please proceed to question number 2.</i>		
<i>If yes, please answer the following pharmacy-related questions:</i>		
⊛ Massachusetts Investigators Only: <i>If this study is involving an investigational drug, please submit a copy of the Massachusetts Research Registration under which the research will be conducted.</i>		
Registration #:		
A. ⊛ Do you have controlled substance prescribing privileges? <input type="checkbox"/> N/A to this study <input type="checkbox"/> No <input type="checkbox"/> Yes		
B. Will you be using an Investigational Pharmacy? <input type="checkbox"/> No <input type="checkbox"/> Yes; <i>Proceed to question number 2.</i>		
C. Will sterile admixing be required to prepare the drug(s)/biologic? <input type="checkbox"/> No <input type="checkbox"/> Yes; <i>Location</i>		
D. Which study location will the drug(s)/biologics be administered? <input type="checkbox"/> PI place of practice <input type="checkbox"/> Inpatient Hospital <input type="checkbox"/> ⊛ Subject will take home to self-administer* <input type="checkbox"/> Other:		

***NOTE:** Most states require that the following **MUST** be included on the investigational drug label; PI name, contact number, address, subject name, date, statement “For Investigational Use Only” and directions for use. Please see www.ethicalreview.com for specific state regulations.

E. Who will dispense the drug(s)/biologics? Coordinator Investigator Other:

F. Will the drug(s)/biologics require any exclusive handling precautions? No Yes; *Choose category:*
 Cytotoxic: requires cytotoxic precautions **Gene therapy:** requires viral precautions
 The drug is a controlled substance, which requires the Investigator to obtain their DEA license. *If checked, do you currently hold your DEA License?* No Yes; License number:

G. In addition to the requirement that the drug(s)/biologics be kept in a secured location, will the drug(s)/biologics have any special storage requirements? No Yes; *Choose additional requirement:*
Continual documentation of temperature is needed while in:
 Refrigerated Storage (2-8°C) Frozen Storage (-20°C) Deep Frozen Storage (-70°C)
 Room Temperature Other:

H. What location will the drug(s)/biologics be delivered? Investigational pharmacy PI location
 Other:

2 Does this study involve a device? No Yes

If no, please proceed to section E.
If yes, please answer the following storage and handling related questions:

A. Describe the storage location of the device:

B. Describe the plan for controlling and handling the study device:

Section E: Community Information

1 Will you need a translated consent form for your patient population? No Yes

If yes, what language(s)?
Will there be a member of the study team available to translate in the language(s) of the consent form?
 Yes No; Please explain your process for translation:

2 Please identify how you will recruit subjects for this study? (Check all that apply)
 Existing Patients Referrals Subject Database Medical Records
 Advertisements (*Need prior IRB approval*) Newsletters Other:

3 Will you be recruiting subjects who would qualify as a member of a vulnerable population? No Yes

If yes, indicate which vulnerable populations:
 Pregnant Women Children Adults with Diminished Decision-Making Capacity
 Economically Disadvantaged/Unemployed Educationally Disadvantaged/Illiterate
 People with Limited English Skills Employees/Colleagues/Students of the PI and/or Study Staff

4 Who will be conducting the consenting procedures?
 PI Sub-I Research Coordinator Other:

F. Subject Compensation

Subjects will not receive any payment for taking part in this research study.

For their participation, subjects will be paid \$ _____ for each completed visit for a possible total of up to \$ _____

Payment for participation will vary per visit. (*Attach a separate sheet with legible site-specific compensation*)

Medical License(s) #: _____ State: _____ Expiration Date: _____

DEA License (*If applicable*): _____ All Board Certifications: _____

Please provide a copy of your medical license(s).

By signing this form, I hereby state that my medical license(s) where the research site is located, is current, and in good standing and I will notify the Ethical Review Committee 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 Ethical Review Committee 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.

Principal Investigator's Original Signature _____ Date ____/____/____
Stamped signature will not be accepted

Type or Print Name _____