



Ethical Review Committee, Inc.
 14400 E. 42nd St., Suite 240
 Independence, MO 64055
 Phone: 816.421.0008 ♦ Fax: 816.356.2227

INITIAL PROTOCOL SUBMISSION

Thank you for selecting Ethical Review Committee (ERC) as the Institutional Review Board (IRB) of choice for your new study. Complete each question. Any incomplete or blank questions or those without the proper documentation will delay your review by the ERC. Please FAX or MAIL this form along with the required documentation to the ERC upon completion.

Additional Information: Each question marked with a ♦ indicates that the investigators will be required to know and understand their state regulations regarding human subject research. ERC offers the regulations from all 50 of the United States, as well as Puerto Rico and the District of Columbia, at the ERC web page www.ethicalreview.com

Section A: Sponsor Information <i>(Additional contact information will be addressed in Section H)</i>			
Institution Name:			
Street Address:		City, State, Zip:	
Contact:	Phone: () -	Ext:	Fax: () -
E-Mail:			
Alternate Contact:	Phone: () -	Ext:	Fax: () -
E-Mail:			

Section B: Protocol Information			
1	Protocol Title:		
2	Protocol Number:	Version Date:	Version Number:
3	Has this protocol been reviewed <u>and/or</u> disapproved by another IRB? <input type="checkbox"/> No <input type="checkbox"/> Yes: <i>If Yes, you must include all documentation explaining the reason for disapproval.</i>		
4	Phase of Study: <input type="checkbox"/> Phase I <i>(Please note: Phase I research may require more frequent board review than other phases.)</i> <input type="checkbox"/> Phase II <input type="checkbox"/> Phase III <input type="checkbox"/> Phase IIIB <input type="checkbox"/> Phase IV <input type="checkbox"/> Other:		
5	What is/are the research question(s)? (Hypothesis):		
6	What is the study design? (Check all that apply) <input type="checkbox"/> Single Blind <input type="checkbox"/> Double Blind <input type="checkbox"/> Dose Ranging <input type="checkbox"/> Two-Arm <input type="checkbox"/> Multi-Arm <input type="checkbox"/> Crossover <input type="checkbox"/> Open-Label <input type="checkbox"/> Supportive Care <input type="checkbox"/> Placebo-Controlled <input type="checkbox"/> Parallel <input type="checkbox"/> Randomized; if so describe the arms and the randomization ratio: <input type="checkbox"/> Other:		
7	What are you testing? (Check all that apply and identify each) <input type="checkbox"/> Drug(s): <input type="checkbox"/> Device(s): <input type="checkbox"/> Biologics: <input type="checkbox"/> Behavior(s): <input type="checkbox"/> Other: <i>You will be asked to explain in greater detail throughout the application.</i>		

8	☛ Is this a cancer related study? <input type="checkbox"/> No <input type="checkbox"/> Yes: <i>Indicate type of study:</i> <input type="checkbox"/> Correlative <input type="checkbox"/> Prevention <input type="checkbox"/> Intervention <input type="checkbox"/> Screening/Early Detection <input type="checkbox"/> Therapeutic <input type="checkbox"/> Observational <input type="checkbox"/> Treatment <input type="checkbox"/> Ancillary/Companion; <i>Main study:</i>
9	☛ Will children/minors be participating in this study? <input type="checkbox"/> No <input type="checkbox"/> Yes <i>Note: In the states of Alabama and Nebraska, children under the age of <u>19</u> are considered minors.</i>
10	Total number of anticipated ERC sites? What is the total number of sites nationwide?
11	What is the estimated length of study? Years: Months: Weeks: Days:
12	What is the total number of sub investigators allowed per site? <input type="checkbox"/> <u>No</u> subs allowed; subs allowed

Section C: Subject Selection & Recruitment

1	What is the maximum number of subjects to be enrolled? Total in study: Total per site:
2	What is the subject age range? Ethnicity? <input type="checkbox"/> Any/All Ethnic Groups <input type="checkbox"/> Specific: Target population: <i>(Please check all that apply)</i> <input type="checkbox"/> Healthy Volunteers <input type="checkbox"/> Patients <input type="checkbox"/> Adults 65 Years and Older <input type="checkbox"/> Terminally Ill <input type="checkbox"/> Female Only <input type="checkbox"/> Male Only <input type="checkbox"/> ☛ Children/Minors 7-17* <input type="checkbox"/> ☛ Children/Minors Under 7* <input type="checkbox"/> ☛ Comatose/Traumatized* <input type="checkbox"/> ☛ Cognitively Impaired* <input type="checkbox"/> ☛ Persons w/ Psychiatric Disease* <i>*Vulnerable populations: If you plan on enrolling any vulnerable populations, please discuss the special protections being implemented to minimize risk of coercion or undue influence.</i>
3	Will the subjects be paid to participate? <input type="checkbox"/> No <input type="checkbox"/> Yes**: \$ at study completion <i>(If paying by the visit):</i> \$ per visit **Note: Payments <i>must</i> be described in the consent form.
4	What are the primary <u>inclusion(s)</u> criteria(s)?
5	What are the primary <u>exclusion(s)</u> criteria(s)? <i>As applicable, please note which exclusions are relevant to subject safety.</i>
6	Please describe the standard of care (SOC) for the subject population. Will the subjects be withdrawn from the SOC for the purpose of the study? <input type="checkbox"/> No <input type="checkbox"/> Yes: <i>Explain:</i>
7	What is the estimated length of subject participation? Years: Months: Weeks: Days:
8	Where will research subjects be seen? <input type="checkbox"/> Inpatient ONLY <input type="checkbox"/> Outpatient ONLY <input type="checkbox"/> Both In & Outpatient
9	How many study visits will occur during the course of the study? How often will the visits occur?
10	Will recruitment materials such as ads, flyers, or others be used? <input type="checkbox"/> No <input type="checkbox"/> Yes

11 What is the record retention policy?

Section D: Drug & Biologics

1 Please check all that apply:

A. This study does **NOT** involve drugs or biologics. *(Please proceed to Section E)*

B. The Food and Drug Administration (FDA) does **NOT** regulate the vitamins, herbs, and/or supplements involved with this study.

C. This study is using an FDA approved drug(s), drug combination(s), or biologics for the indication at the route of administration or dosage level, and within the patients' population in which it was intended.

D. This study is using an FDA approved drug(s), drug combination(s), or biologics for the indication at the route of administration or dosage level, and within the patients' population in which it was **NOT** intended.

E. This study uses **Non-FDA approved** (*investigational new drug*) drug(s), drug combination(s), or biologics. Please provide an explanation of your determination for the exemption status as defined by the FDA in [§312.2\(b\)](#).

List FDA-Approved Drug(s)/Biologics Below:

Drug Name	Dose	Route of Administration

List Non-FDA Approved and Investigational New Drug (IND)/Biologics Below:

Drug Name	IND	Sponsor of the IND

2 **Pharmacy Information:**

A. Will the site(s) be using an Investigational Pharmacy? No Yes: *Proceed to Section E*

B. Will sterile admixing be required to prepare the drug(s)/biologic? No Yes: *Location*

C. Which study location will the drug(s)/biologics be administered? PI place of practice
 Inpatient Hospital Subject will take home to self-administer*** Other:

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

E. 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.

F. 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;

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

Section E: Devices

Please check all that apply:

- A. This study does **NOT** involve the use of a device. *(Proceed to Section F)*
- B. This study involves an **FDA-approved** device.
- C. This study involves a **humanitarian use device (HUD)** and/or an **investigational device exemption (IDE)**.

List FDA-Approved Devices Below:

1	Device Name	Manufacturer

List Investigational or Humanitarian Use Devices Below:

1	Device Name	IDE#/HUD#	Sponsor of the IDE/HUD

- 2 A. Is this a **significant risk device** or a **non-significant risk device** ? Please provide an explanation of your determination that this device meets the classification of “non significant risk” as defined in [21 CFR 812.2\(b\)\(1\)\(ii\)](#).
- B. Describe the storage location of the device:
- C. Describe the plan for controlling and handling the study device:

Section F: Study Procedures

Please indicate below if any of the following procedures will be taking place during the duration of the study.

1	Testing for illegal drug use?	<input type="checkbox"/> No <input type="checkbox"/> Yes
2	Pregnancy testing?	<input type="checkbox"/> No <input type="checkbox"/> Yes
3	Blood draws?	<input type="checkbox"/> No <input type="checkbox"/> Yes
4	★ HIV/AIDS testing?	<input type="checkbox"/> No <input type="checkbox"/> Yes
5	Use of placebo?	<input type="checkbox"/> No <input type="checkbox"/> Yes
6	Storage of blood/tissue for purposes not related to this project?	<input type="checkbox"/> No <input type="checkbox"/> Yes
7	Investigational surgical procedure(s)?	<input type="checkbox"/> No <input type="checkbox"/> Yes
8	★ Recombinant DNA testing?	<input type="checkbox"/> No <input type="checkbox"/> Yes
9	★ Genetic testing?	<input type="checkbox"/> No <input type="checkbox"/> Yes

If you answered yes to questions 8 and/or 9, please answer the following:

- A. Has the protocol been reviewed by the Recombinant DNA Advisory Committee (RAC)? No Yes

If you answered yes to #9A, please attach the following: **1. NIH Response to Appendix M**

N/A

2. Correspondence from RAC		<input type="checkbox"/> N/A
10	Use of radiation?	<input type="checkbox"/> No <input type="checkbox"/> Yes
<i>If you answered yes to question 10, please answer the following:</i>		
A. Are all radioisotopes and/or radiation exposure being administered as SOC?		<input type="checkbox"/> No <input type="checkbox"/> Yes
B. Is there exposure to radioisotopes?		<input type="checkbox"/> No <input type="checkbox"/> Yes
If yes: Isotope: _____ Dosage and Procedure: _____		
C. Is there exposure to radiation-emitting equipment <u>not</u> including ultrasound and MRI?		<input type="checkbox"/> No <input type="checkbox"/> Yes
D. Is the radiation exposure due to only <u>one</u> screening chest x-ray?		<input type="checkbox"/> No <input type="checkbox"/> Yes
E. Is the radiation exposure due to only <u>one</u> screening dexa scan?		<input type="checkbox"/> No <input type="checkbox"/> Yes

Section G: Consent Form Procedures	
Please describe the consenting process:	
1	<input type="checkbox"/> Written Consent Form: <i>(Please check all that apply)</i> <input type="checkbox"/> Adult Participant <input type="checkbox"/> Surrogate Decision Maker <input type="checkbox"/> Parental Permission/Child Assent <input type="checkbox"/> Genetic Testing <input type="checkbox"/> Withdrawal Follow-Up <input type="checkbox"/> Tissue/Serum Repository <input type="checkbox"/> Notarized Certification <input type="checkbox"/> Back Translation <input type="checkbox"/> Foreign Language:
2	<input type="checkbox"/> Oral Consent Form: <i>(Please provide justification for requesting waiver of documentation of consent):</i> <input type="checkbox"/> The research presents no more than minimal risk of harm and involves no procedures for which written consent is usually required outside the research context. <input type="checkbox"/> Other:
3	<input type="checkbox"/> Request for Waiver of Consent: <i>(If checked, please demonstrate how the protocol meets the following criteria):</i> <ol style="list-style-type: none"> 1. The research involves no more than minimal risks to subjects. 2. The waiver will not adversely affect the rights and welfare of the subjects. 3. The research could not practicably be carried out without the waiver. 4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Section H: Additional Contact Information	
CRO Information	<input type="checkbox"/> N/A <input type="checkbox"/> Same as Section A
Name:	
Street Address:	City, State, Zip:
Contact:	Phone: () - Ext: Fax: () -
E-Mail:	
Alternate Contact:	Phone: () - Ext: Fax: () -

E-Mail:

SMO Information N/A Same as Section A

Name:

Street Address: City, State, Zip:

Contact: Phone: () - Ext: Fax: () -

E-Mail:

Alternate Contact: Phone: () - Ext: Fax: () -

E-Mail:

Investigator Initiated Information N/A Same as Section A

Name:

Street Address: City, State, Zip:

Contact: Phone: () - Ext: Fax: () -

E-Mail:

Alternate Contact: Phone: () - Ext: Fax: () -

E-Mail:

Section I: Billing Information *(This section MUST be complete and the billing representative signature MUST be obtained prior to ERC review.)*

Billing will go to the Sponsor CRO PI Other:

Name: *(Signature required below)*

Street Address: City, State, Zip:

Contact: Phone: () - Ext: Fax: () -

E-Mail:

If there are any special billing instructions please indicate here:

Signature of Responsible Billing Party _____ Date ____/____/____

Name of Person Preparing This Application _____ Title _____

Signature of Person Preparing This Application _____ Date ____/____/____

An acknowledgment of receipt will be faxed to your site. *File a copy of this completed form, and all documents you receive from the ERC, in your study file.*

Internal Checklist			
Application Complete	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Application Audited By: _____
Protocol	<input type="checkbox"/> Included	<input type="checkbox"/> Missing	
Consent Form	<input type="checkbox"/> Included	<input type="checkbox"/> N/A	Study Manager Assigned: _____
Recruitment Materials	<input type="checkbox"/> Included	<input type="checkbox"/> N/A	
Drug Brochure	<input type="checkbox"/> Included	<input type="checkbox"/> N/A	Date: ____/____/____
Signatures Obtained	<input type="checkbox"/> Preparer	<input type="checkbox"/> Billing	