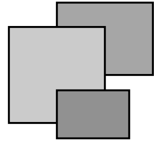

Ethical Review Committee, Inc.
14400 E. 42nd St., Suite 240
Independence, MO 64055
Phone: 816.421.0008 ♦ Fax: 816.356.2227

PRINCIPAL INVESTIGATOR EXPEDITED SUBMISSION FORM

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) will not review this application until the 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:

Section A: Principal Investigator (PI) Information	
PI:	**Site Phone:** ( ) -
Primary Research Facility:	**Site Fax:** ( ) -
Site Street Address: ☐ Also document shipping address *If different from study site, please indicate*:	**24 Hour #:** ( ) - *(After business hours contact number)*
City, State, Zip:	**PI E-Mail:**

Section B: Contact and Site Information	
Primary Contact: ☐ PI ☐ Other: Title: **Contact Address:** ☐Same address as listed in Section A	**Telephone:** ( ) - **Ext:** **E-Mail:** **Fax:** ( ) -
Secondary Contact: ☐ PI ☐ Other: Title: **Contact Address**: ☐Same address as listed in Section A	**Telephone:** ( ) - **Ext:** **E-Mail:** **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 the site?** ☐ Dialysis Center ☐ Hospital ☐ Medical Office ☐ 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 contact information for the additional site(s):*	

Section C: Principal Investigator Professional Information		
1	**Have you had previous clinical trial experience?**	☐ No ☐ Yes
	*If **no**, please provide a listing of clinical trials.* *If **yes**, is it listed on your CV?* ☐ Yes ☐ No	
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
	If issued, attach all copies of EIR Forms (Established Inspection Reports). *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 any 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 any 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 any supporting documentation)*	
8	**Have you had any board actions filed with any medical licensing agency?**	☐ No ☐ Yes
	*If **yes**, please explain: (Attach any supporting documentation)*	
9	**Have you had any legal actions against you within the past 5 years?**	☐ No ☐ Yes
	*If **yes**, attach documentation of the allegations brought forth, current status of the case(s), and resolution or outcome.*	
10	**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**?	☐ No ☐ 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**?	☐ No ☐ 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?	☐ No ☐ 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**?		☐ No ☐ Yes
E. Have an ownership or royalty interest in any intellectual property utilized in this protocol?		☐ No ☐ Yes

If you answered <u>yes</u> to any of questions A-E, please describe on a separate sheet.

Section D: Community Information

1	**Will you need a translated consent form for your patient population?**	☐ No ☐ Yes
	If yes, what language(s)?	
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	

Section E: 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 Issued: ________ Expiration Date: ________

All Board Certifications: ________ States Approved to Practice: ________

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 (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 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 Signature ____ Date ______/______/_______

Must be original signature. Stamps will not be accepted.

Type or Print Name ________