



Ethical Review Committee, Inc.

14400 E. 42nd St., Suite 240

Independence, MO 64055

Phone: 816.421.0008 ♦ Fax: 816.356.2227

EXPEDITED REVIEW: INITIAL PROTOCOL SUBMISSION

Thank you for choosing the Ethical Review Committee (ERC) for your new study. Completely answer 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 to the ERC upon completion. Your prompt response will allow for timely review and approval.

The ERC will conclusively determine whether or not your research can be reviewed using an expedited procedure.

Section A: Sponsor Information			
Institution Name:			
Street Address:		City, State, Zip:	
Contact:	Phone: () -	Ext:	Fax: () -
E-Mail:			
Alternate Contact:	Phone: () -	Ext:	Fax: () -
E-Mail:			

Section B: Study Information			
1	Protocol Title:		
2	Protocol Number:	Version Date: / /	
3	Has this protocol been reviewed <u>and/or</u> disapproved by another IRB? <i>If yes, you must include any supporting documentation.</i>		<input type="checkbox"/> No <input type="checkbox"/> Yes
4	What is the total number of sub-investigators allowed per site? <input type="checkbox"/> No subs allowed subs allowed		
5	Estimated length of study: Years: Months: Weeks: Days:		
6	Length of subject participation: Years: Months: Weeks: Days:		
7	Number of total subjects:	Number of total sites:	How many sites will be reviewed by ERC:

Section C: Expedited Category: FDA 21 CFR 56.110, please choose any of the following 7 categories that apply:	
<i>For a complete listing of the classifications please visit http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm</i>	
1	<input type="checkbox"/> Clinical studies of drugs and medical devices only when condition (a) or (b) is met: A. <input type="checkbox"/> Research on drugs for which an investigational new drug application is not required. B. <input type="checkbox"/> Research on medical devices for which an investigational device exemption application is not required; or the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2	<input type="checkbox"/> Collection of blood samples by finger, heel, or ear stick, or venipuncture as follows: A. <input type="checkbox"/> From healthy, non pregnant adults who weigh at least 110lbs. Amount drawn must not exceed 550ml in an 8 week period and collection may not occur more frequently than 2 times per week. B. <input type="checkbox"/> From other adults and children, considering the age, weight, and health of the subjects. Amount drawn may not exceed the lesser of 50ml or 3ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
3	<input type="checkbox"/> Prospective collection of biological specimens for research purposes by noninvasive means. Example of non-invasive: hair and nail clippings, external secretions (sweat and saliva), placenta removed at delivery, etc.
4	<input type="checkbox"/> Collection of data not involving general anesthesia or sedation; also excluding x-rays or microwaves.

5	<input type="checkbox"/> Research involving materials that have been previously collected or will be solely collected for non-research purpose.
6	<input type="checkbox"/> Collection of data from voice, video, digital, or image recordings made for research purposes.
7	<input type="checkbox"/> Research on individual or group characteristics or behavior, or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Section D: Study Design

1	What is the research question(s)? (<i>Hypothesis</i>):
2	Data Source (<i>Where is the data coming from?</i>):
3	Data Retention Period:
4	Intended Use of Data:
5	Will the subjects be paid to participate? <input type="checkbox"/> No <input type="checkbox"/> Yes*: \$ _____ at study completion (If paying by the visit); \$ _____ per visit, for a total of _____ visits. <i>*Note: Payments must be described in the consent form.</i>
6	Special Template Documents: <input type="checkbox"/> Consent form <input type="checkbox"/> Recruitment Materials <input type="checkbox"/> Phone Scripts <input type="checkbox"/> Surveys <input type="checkbox"/> Standardized Form to Gather Chart Data <input type="checkbox"/> Other: _____
7	Translated Consent: <input type="checkbox"/> No <input type="checkbox"/> Yes, what language(s)? Back Translation: <input type="checkbox"/> No <input type="checkbox"/> Yes Notarized: <input type="checkbox"/> No <input type="checkbox"/> Yes

CRO Information N/A

Name:			
Street Address:		City, State, Zip:	
Contact:	Phone: () -	Ext:	Fax: () -
E-Mail:			
Alternate Contact:	Phone: () -	Ext:	Fax: () -
E-Mail:			

Billing Information

Billing will go to the	<input type="checkbox"/> Sponsor	<input type="checkbox"/> CRO	<input type="checkbox"/> Principal Investigator	<input type="checkbox"/> Other:
Name:				
Street Address:		City, State, Zip:		
Contact:	Phone: () -	Ext:	Fax: () -	
E-Mail:				

Signature of Person Completing Form

_____/_____/_____
Date

Print Name and Title