



**Office of the Commissioner Institutional Review Board  
Research Proposal Review Form**

Date: \_\_\_\_\_

IRB Member Name: \_\_\_\_\_ Application #: \_\_\_\_\_

		YES	NO
<b>1. <u>Risk/Benefit Analysis:</u></b>			
a.	Are both risks and benefits identified, evaluated, and described?	<input type="checkbox"/>	<input type="checkbox"/>
b.	Are risks greater than <i>minimal</i> risk?	<input type="checkbox"/>	<input type="checkbox"/>
c.	Has due care been used to minimize risks?	<input type="checkbox"/>	<input type="checkbox"/>
d.	Are there any undue burdens on potential subjects and/or their guardians?	<input type="checkbox"/>	<input type="checkbox"/>
<b><u>Comments:</u></b>			
<hr/>			
<b>2. <u>Informed Consent:</u></b>			
a.	Is the language and presentation of the information clear and appropriate to the subject population?	<input type="checkbox"/>	<input type="checkbox"/>
b.	Who will be explaining the research to potential subjects?		
c.	Do the explanations of the research provide adequate description of <i>risks and anticipated benefits</i> ?	<input type="checkbox"/>	<input type="checkbox"/>
	• of <i>free choice</i> not to participate or to withdraw?	<input type="checkbox"/>	<input type="checkbox"/>
	• of <i>procedures</i> of the research?	<input type="checkbox"/>	<input type="checkbox"/>
<b><u>Comments:</u></b>			
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<b>3. <u>Selection/Recruitment of Subjects:</u></b>			
a.	Does the nature of the research require or justify using the proposed subjects?	<input type="checkbox"/>	<input type="checkbox"/>
b.	Are there groups who might be more susceptible to the risks presented by the study and who therefore ought to be excluded from the research?	<input type="checkbox"/>	<input type="checkbox"/>
c.	If especially vulnerable subjects are being recruited (e.g., persons who are hospitalized or institutionalized),		
	• are there sufficient measures to ensure that risks are minimized?	<input type="checkbox"/>	<input type="checkbox"/>
	• <i>and that subjects have clear opportunity <u>not</u> to participate?</i>	<input type="checkbox"/>	<input type="checkbox"/>

	YES	NO
d. Does the universe of potential subjects give a fair chance for each person to be selected, (e.g., to receive the potential benefits of the research)?	<input type="checkbox"/>	<input type="checkbox"/>
e. Are there aspects of the recruitment (e.g., financial inducements) that are questionable?	<input type="checkbox"/>	<input type="checkbox"/>
<b><u>Comments:</u></b>		

<b>4. <u>Privacy and Confidentiality:</u></b>		
a. Does the research involve observation or intrusion in situations where subjects would normally have a reasonable expectation of privacy?	<input type="checkbox"/>	<input type="checkbox"/>
b. If investigators want to review existing records to select subjects for further study, whose permission should be sought for access to those records?		
c. Will the investigator(s) be collecting sensitive information about individuals?	<input type="checkbox"/>	<input type="checkbox"/>
d. If so, have they made adequate provisions for protecting the confidentiality of the data through coding, destruction of identifying information, limiting access to the data, or whatever other methods would be appropriate to the study?	<input type="checkbox"/>	<input type="checkbox"/>
e. In substance abuse research, has a certificate of confidentiality been obtained from the federal government?	<input type="checkbox"/>	<input type="checkbox"/>
f. Are the investigator's disclosures to subjects about confidentiality adequate?	<input type="checkbox"/>	<input type="checkbox"/>
g. Should documentation of the consent be waived to protect confidentiality?	<input type="checkbox"/>	<input type="checkbox"/>
<b><u>Comments:</u></b>		

<b>5. <u>Research Design:</u></b>		
a. Is there a sound conceptual model and citation of relevant literature as a basis for the research questions or hypotheses?	<input type="checkbox"/>	<input type="checkbox"/>
b. Does the applicant have the training and experience to conduct this type of research?	<input type="checkbox"/>	<input type="checkbox"/>
c. Are there less invasive ways to address the research questions?	<input type="checkbox"/>	<input type="checkbox"/>

	YES	NO
d. Has risk been minimized as much as possible?	<input type="checkbox"/>	<input type="checkbox"/>
e. Is the potential subject population appropriate given the research questions?	<input type="checkbox"/>	<input type="checkbox"/>
f. Is the proposed sample size adequate for use of inferential statistics (i.e., significance tests) given the number of variables?	<input type="checkbox"/>	<input type="checkbox"/>
g. Is there identification of potential confounding variables?	<input type="checkbox"/>	<input type="checkbox"/>
h. What potential confounding variables were not recognized?		
i. Is there random assignment?	<input type="checkbox"/>	<input type="checkbox"/>
j. If it is a “sample of convenience”, has the applicant conveyed that he/she understands the limitations of the study?	<input type="checkbox"/>	<input type="checkbox"/>
k. Are the persons collecting the data qualified to do so?	<input type="checkbox"/>	<input type="checkbox"/>
l. Are there adequate precautions taken to prevent adverse reactions?	<input type="checkbox"/>	<input type="checkbox"/>
m. Are there qualified professionals available if there are adverse reactions?	<input type="checkbox"/>	<input type="checkbox"/>
n. Are qualified professionals available to review the data (e.g., pediatric cardiologist if EKGs are to be read in a medical procedures study)?	<input type="checkbox"/>	<input type="checkbox"/>
o. Are subjects and their guardians given sufficient information about how to follow procedures and what to do if there is an adverse occurrence?	<input type="checkbox"/>	<input type="checkbox"/>
<b><u>Comments:</u></b>		

**Recommendation(s):**

- The application should **not** be approved.
  
- The application should be approved “as is”.
  
- The application should be approved if the following revisions are made.
  
- The application should be approved under the following conditions.

**Additional Comments:**