Institutional Review Board

IRB REVIEWER CONSENT FORM CHECKLIST

Principal Investigator: _____ IRB # _____

Brief Application Title: _____ Date: _____

	Yes	No	Does Not Apply
General Considerations:			
Is the length of the form appropriate for the complexity of the study?			
Is clear, concise, non-technical language used throughout?			
Are appropriate subheadings and sequence used throughout?			
Is the first page printed on departmental/institutional letterhead?			
Is a blank line for subject initials included in the lower right corner of each page (except the signature page)?			
Is the use of person consistent throughout?			
Are all pages numbered sequentially?			
Title			
Is the general title "Consent to Participate in Research (or Clinical) Study included?			
Is the study title identical to that listed on the protocol? If no, has justification been provided for the use of a different title?			
Investigators			
Is the name, address, and phone number of each investigator listed?			
Source Of Support			
Is the source of financial support for the study listed and consistent with the cover sheet?			
Study Description			
Is there a clear statement of the purpose of the study?			
Is there a clear explanation of the reason a particular subject was invited to participate?			
Is it clearly stated that the subject is participating in a research study?			
If important to the decision to participate, is the approximate number of subjects to be studied noted (including gender and age range)? Is there a statement as to why this information is important?			
Is the duration and length of each subject's participation included?			
Is the description of all experimental treatments and procedures complete?			
Is there a description of all tests or diagnostic procedures being done for research purposes?			
Is the dose, route, and frequency of drug(s) to be given noted?			
Is the FDA approval status of the drugs to be given indicated?			
If the study involves the use of questionnaires, is there a description of the general content and time required to complete them?			
Is the total volume of blood to be drawn (if any) described in tablespoons or teaspoons?			

IRB REVIEWER CHECKLIST

Risks And Benefits Section	Yes	No	Does Not Apply
Is there a complete and clear description of the potential risks (i.e., is quantitative information on the expected frequency of the listed side effects provided)?			
Are reproductive risks adequately described and is appropriate birth control language included?			
Is there a clear description of the precautions taken to minimize risks?			
Are the potential benefits to the subjects (if any) clearly described?			
Alternative Treatments			
If applicable, have all alternative treatments been satisfactorily described?			
New Information			
Has the standard statement been included, if appropriate?			
Costs And Payments			
Is the language included in this section the same as that included in the protocol?			
Confidentiality			
Have adequate measures been taken to protect subjects from breaches of confidentiality and/or invasion of privacy?			
Is the assurance of confidentiality clear and complete?			
Does the section sufficiently state who will have access to subject records (e.g., the FDA, study sponsor, Research Office, and Academic Department, if applicable)?			
Does this section indicate that all research records must be kept for a period of at least five years?			
Right To Withdraw			
Is this section clearly worded and non-coercive?			
Are the risks of subject withdrawal stated (if applicable)?			
Are reasons why a subject might be withdrawn from the study by investigators clearly defined?			
Are procedures for ensuring continued care of the withdrawn subject adequately addressed?			
If the investigator is recruiting from his/her own patient population, is the standard wording included to explain the conflict of interest inherent in the dual role of clinician/investigator?			
Compensation For Injury			
Is the standard statement or other satisfactory wording included?			
Voluntary Consent			
Is there an offer by the investigator(s) to answer questions?			
Is the statement regarding the availability of the IRB Office, to answer questions and the phone number (473-444-4175, Extension 2221) included?			
Are there appropriate lines for the date and signatures of the subject, surrogate/proxy, and witness?			

IRB REVIEWER CHECKLIST

Is there an Investigator's Certification section?			
Is the Verification of Explanation section included if children ages 6-13 are included in the study?			
Are there appropriate signature spaces included if children 14-17 are included in the study?			
If the protocol provides a justification for the use of proxy consent, are there appropriate signature spaces included?			

I have reviewed the proposed consent form in accordance with the University's policies related to the protection of human subjects and the institutional assurance to U.S. federal Department Health and Human Services. My comments and recommendations are furnished for use in arriving at the IRB consensus and writing the minutes. I have no conflict of interest or involvement with this investigation.

I recommend:

- ☐ *Full approval – no comments*
- ☐ *Approved subject to the modifications noted below*
- ☐ *Reconsideration*
- ☐ *Disapproval*

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Reviewer Name: _____ Review signature: _____

Date: _____