



**CONFLICT OF INTEREST (COI) DISCLOSURE:**

<p>Yes</p> <p>No</p> <p>Clear</p>	<p>Do you have a conflict of interest (personal, financial, academic or other interest) in reviewing this protocol that would prevent you from conducting a fair and objective review?</p>
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If No, please continue with your review by completing all areas of the checklist.

If Yes, please contact your IRB Coordinator immediately. You will be provided with specific instructions should your conflict of interest be valid. Please complete this COI section only and save this checklist in the appropriate study within the ERICA system.

- *Example of personal COI – your spouse, an immediate family member, your advisor*
- *Example of academic COI – your student, my research partner/colleague*
- *Example of financial COI – income from stock in etc. the Sponsor or company whose business is substantially related to the subject matter of the research.*

**Reviewer Description of Conflict of Interest:**



**Reviewer Description of Study/Study Progress/Amendment:**

*Please provide, in your own words, a description of the study here. You can read this at the meeting in order to summarize the study.*

Yes No <span style="color: orange;">Clear</span>	<p><b>Does the IRB have the appropriate expertise to review this research?</b>  <i>If no, please contact your IRB coordinator immediately to arrange appropriate consultation (i.e. ad-hoc consultant reviewer).</i></p>
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**For new studies:** A risk category (e.g. minimal, moderate) has preliminarily been assigned to this study by the IRB staff. Document the risk category for the study.

**For continuing reviews and amendments:** The risk assessment has been assigned. Continue to the next page. Consideration of changes in the risk assessment will be addressed in a separate portion of the checklist for continuing reviews and amendments.

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The study is minimal risk.

- *Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.*

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The study is greater than minimal risk.

Clear



**RISK/BENEFIT DETERMINATION OF AMENDMENT:**

Yes No Clear	Risk/Benefit ratio remains appropriate
Yes No N/A Clear	If information relating to changes in the study appear that they may affect the willingness of the participant to continue his/her participation, a plan has been provided to relay this information to them.
Yes No N/A Clear	Protections to ensure the privacy of the participants are in place.
Yes No N/A Clear	Protections to ensure the confidentiality of data are in place.
Yes No N/A Clear	Based on the information provided, may the study proceed without an audit or observation of the consent process? <ul style="list-style-type: none"> <li><i>If the IRB is concerned about the conduct of a study, the IRB may consider whether, as part of providing adequate oversight of the study, an active audit is warranted. The IRB also has the authority to observe the consent process. Please see the Board Member Guidance Series: IRB Authority-Observation of Consent and Conduct of Research.</i></li> </ul>

**REQUESTED REVISIONS/CLARIFICATIONS OF AMENDMENT:**

**DOCUMENT REVIEW:** Please compare the currently approved protocol summary and consent/parental permission/assent documents that have been provided by the IRB office.

Yes No	
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N/A Clear	<b>Revised consent submitted</b>
Yes No N/A Clear	Consent document(s), Parental Permission Document(s), Assent Document(s) appropriate.
Yes No N/A Clear	<b>Revised protocol summary submitted</b>
Yes No N/A Clear	Protocol summary appropriate

**Requested Revisions/Clarifications:** Provide more information if you answered "No" to any questions above.



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**FINAL DECISION:** Please mark your recommendation below.

- **Refer to guidance "Categories of Action" section in the IRB Member Handbook.**

 Approved as submitted

 Approved with changes/clarifications reviewed by IRB chairman or designee

 Tabled

 Disapproved

[Clear](#)
**Continuing Review:**

***If you are reviewing an amendment, proceed to "Final Comments" below.***

Continuing Review of research should be conducted by the IRB at intervals appropriate to the degree of risk and not less than once per year. Please select how often this study should be reviewed:

 1 Year

 6 Months

 Other

[Clear](#)

If Other: Please explain ( *example: after first 5 participants enrolled, for a period of 4 months*):

*Criteria for protocols that will generally be reviewed more often than annually include but are not limited to the following:*

- novel high-risk studies involving new therapeutic modalities, drugs, biologics or significant risk medical devices;*
- other high-risk studies as IRB members deem appropriate (this includes research for which the IRB determines that reports to the IRB of monitoring data should be more frequent than annually).*

**Final Comments:****Attachments:**

Name	Version	Date Created	Date Modified
There are no items to display			

**Please Note:** All studies also undergo administrative review by at least two IRB staff members. The revision letter sent to the investigator will contain reviewer comments, comments from the board discussion, as well as the staff members' comments.

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Amendment ▼

**AMENDMENT APPLICATION - EXPEDITED REVIEW**

Directions: Please determine whether this new study qualifies for an expedited review by the following questions and guidelines.

All of the following must be true:

True	False	Clear	The proposed modification(s) is minor, presenting no more than minimal risk to participants.
True	False	Clear	The proposed modification(s) is minor because the change in risk level is less than minimal.
True	False	Clear	The research study or proposed modification(s) does not involve prisoners.
True	False	Clear	The research is not classified.
True	False	Clear	<p>The proposed modification(s) is minor because the modification requests one of the following minor changes, or is similar in context:</p> <ul style="list-style-type: none"> <li>• Change of PI, co-investigators, and/or study personnel.</li> <li>• Advertisements, newsletters, patient education materials, etc.</li> <li>• Minimal consent form changes (i.e. typos, grammar corrections, formatting, etc).</li> <li>• Updated/revised package inserts (approved drugs only).</li> <li>• Minimal Procedural and Administrative changes to the protocol.</li> <li>• Minor increase/decrease in the number of subjects.</li> </ul>

**Determination:**

The application IS eligible for expedited review.

The application is NOT eligible for expedited review.

Clear

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