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Conflict of Interest ▾

CONFLICT OF INTEREST (COI) DISCLOSURE:

<p>*</p> <p><input type="radio"/> Yes</p> <p><input type="radio"/> 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:

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Reviewer Description ▾

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.

<input type="radio"/> Yes <input type="radio"/> No Clear	<p>Does the IRB have the appropriate expertise to review this research? If no, please contact your IRB coordinator immediately to arrange appropriate consultation (i.e. ad-hoc consultant reviewer).</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.

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.

This study is moderate risk (greater than minimal risk).

Clear

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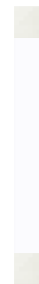
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Amendment Checklist ▾

RISK/BENEFIT DETERMINATION OF AMENDMENT:

<input type="radio"/> Yes <input type="radio"/> No Clear	Risk/Benefit ratio remains appropriate
<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> 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.
<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A Clear	Protections to ensure the privacy of the participants are in place.
<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A Clear	Protections to ensure the confidentiality of data are in place.

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.

<input type="radio"/> Yes	
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<input type="radio"/> No <input type="radio"/> N/A Clear	Revised consent submitted
<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A Clear	Consent document(s), Parental Permission Document(s), Assent Document(s) appropriate.
<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A Clear	Revised protocol summary submitted
<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> 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

Approved with changes/clarifications reviewed by IRB reviewer(s)

Tabled

Disapproved

Clear

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Comments and Attachments ▾

Final Comments:

Attachments:

Add

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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Comments and Attachments ▾



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- Expedited Checklist -

Finish

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:

<p>* <input type="radio"/> True <input type="radio"/> False Clear</p>	<p>The proposed modification(s) is minor, presenting no more than minimal risk to participants.</p>
<p>* <input type="radio"/> True <input type="radio"/> False Clear</p>	<p>The proposed modification(s) is minor because the change in risk level is less than minimal.</p>
<p>* <input type="radio"/> True <input type="radio"/> False Clear</p>	<p>The research study or proposed modification(s) does not involve prisoners.</p>
<p>* <input type="radio"/> True <input type="radio"/> False Clear</p>	<p>The research is not classified.</p>
<p>* <input type="radio"/> True <input type="radio"/> False Clear</p>	<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"> • Change of PI, co-investigators, and/or study personnel. • Advertisements, newsletters, patient education materials, etc. • Minimal consent form changes (i.e. typos, grammar corrections, formatting, etc). • Updated/revised package inserts (approved drugs only). • Minimal Procedural and Administrative changes to the protocol. • Minor increase/decrease in the number of subjects.

*** Determination:**

- The application IS eligible for expedited review.
- The application is NOT eligible for expedited review.
- [Clear](#)

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Finish