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

Yes No <b>Clear</b>	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?
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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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## Introduction

### 1.1 What is your role for reviewing this report?

Convened Board Reviewer

### \* 1.2 What type of report is being reviewed?

Report Type

Potential Unanticipated Problem

Potential Non-Compliance

[Clear](#)

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## Unanticipated Problem

### ASSESSMENT:

True False <span style="color: orange;">Clear</span>	The problem, event or information described in this report <b>is not expected</b> (by the researcher or the research participant) given the research procedures and the subject population being studied.
True False <span style="color: orange;">Clear</span>	The problem, event or information described in this report <b>is related or probably related</b> to participation in the research or the problem probably or definitely affects the safety, rights and welfare of current participants.
True False <span style="color: orange;">Clear</span>	The problem, event or information described in this report suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic or social harm) than was previously known or recognized.

**DETERMINATION:** Does the report possibly represent an unanticipated problem involving risks to participants or others (all of the above assessments are "true")?

\*    Yes    No Clear

If the reported problem, event or information might represent an unanticipated problem involving risks to subjects or others ("yes" to the above determination), the problem must be referred to the convened IRB for review.

If the reported problem, event or information does not represent an unanticipated problem involving risks to participants or others ("no" to the above determination), no further action is required by the IRB. The PI must be instructed to include a description of problem at continuing review.

### Comments:



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## Final Comments

As the convened board reviewer, you will be required to present your recommendations to the board. The board will then determine if the event or information represents either

- an unanticipated problem involving risks to participants or others, or
- serious or continuing non-compliance

Please state any additional comments or recommendations you may have regarding this report:

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