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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:**

Save | Exit | Hide/Show Errors | Print... | Jump To: 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](#)

Save | Exit | Hide/Show Errors | Print... | Jump To: Reviewer Role ▾



## Non-Compliance

### ASSESSMENT:

Based upon the preliminary, informal checking of facts to 1) determine if there is a reasonable basis for the allegation and 2) if the allegation can be supported or proved by the evidence:

\*

The allegation of non-compliance is determined **not to be** a credible confirmed report of non-compliance in fact by definition.

*The inquiry stops and no further action is taken.*

The allegation of non-compliance is determined **to be** a credible, confirmed report of non-compliance in fact by definition.

*The allegation of non-compliance is considered a confirmed report of non-compliance by definition. The inquiry proceeds.*

Clear

### Comments:



Save | Exit | Hide/Show Errors | Print... | Jump To:

## Serious or Continuing Non-Compliance

**Serious Non-Compliance** is an act or omission to act that resulted in increased physical, psychological, safety, or privacy risk that compromised the rights and welfare of research participants.

**Continuing Non-Compliance** is a pattern of repeated actions or omissions to act that suggests a future likelihood of reoccurrence and that indicates a deficiency in the ability or willingness to comply with Federal regulations, VA Handbook 1200.5 or the policy, requirements, and determinations of the IRB governing human subject research.

### DETERMINATION:

\* Does the confirmed report of non-compliance possibly represent **serious** non-compliance?

Yes No [Clear](#)

\* Does the confirmed report of non-compliance possibly represent **continuing** non-compliance?

Yes No [Clear](#)

If the reported problem, event or information might represent serious or continuing non-compliance ("yes" to either of the above determinations), the problem must be referred to the convened IRB for review.

If the reported problem, event or information does not represent serious or continuing non-compliance ("no" to both of the above determinations), no further action is required by the IRB. The PI must be instructed to include a description of problem at continuing review.

### Comments:

Save | Exit | Hide/Show Errors | Print... | Jump To:



## Corrective Actions

**Please indicate the corrective actions that are required (Examples of corrective actions):**

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The submitted corrective action plan is appropriate.

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The following additional corrective actions are necessary:

[Clear](#)

**Comments:**



Save | Exit | Hide/Show Errors | Print... | Jump To: Final Comments ▼

## 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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