Conflict of Interest (COI) Disclosure

Yes
No Clear

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?

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

Introduction

1. What is your role for reviewing this report?
Convened Board Reviewer

2. What type of report is being reviewed?

Select all that apply

- [ ] Potential Unanticipated Problem
- [ ] Potential Non-Compliance

Unanticipated Problem

Assessment

◯ True ◯ False Clear	The problem, event or information described in this report **is not expected** (by the researcher or the research participant) given the research procedures and the subject population being studied.
◯ True ◯ False Clear	The problem, event or information described in this report **is related or probably related** to participation in the research or the problem probably or definitely affects the safety, rights and welfare of current participants.
◯ True ◯ False Clear	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:

Non-Compliance

Non-Compliance is a failure to abide by the policies, requirements, and determinations of one or more of the following:

- *An approved research protocol*
- *IRB policies or determinations*
- *Institutional policies and procedures governing human subjects*
- *Federal rules and regulations governing human subjects*
- *VHA Handbook 1200.05*

Evidence for non-compliance may be provided to the IRB in one of the following ways:

- *Self-reported by the PI via the Report Form*
- *Via a complaint from a research participant or others involved in the research*
- *Via an audit conducted by an entity independent of the research team*

It some cases, it may be necessary for the IRB to confirm the evidence for non-compliance via an audit conducted by IRB staff.

ASSESSMENT:

Based upon the preliminary, informal checking of facts to determine 1) 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 information in this report form does not represent non-compliance.**
  The inquiry stops and no further action is taken. A determination of "Not Non-Compliance" will be issued.
- ○ 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:

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:

Corrective and Preventive Actions

Corrective actions should remedy the problem/event or the effects of the problem/event on the research participants, research data, research processes, etc. Corrective actions may include, but are not limited to, the following:

- *Re-consenting participants or notifying them by other means of new information*
- *Correcting research data*
- *Retroactively performing a procedure*
- *Evaluating the status or safety of participants in regard to the problem/event and performing appropriate actions to ensure the rights and welfare of the participants*

A preventive action plan should describe an active process addressing the causal elements so the IRB would conclude that the investigator has a serious and viable plan in place for assuring the safety of research participants and the oversight of data integrity. Preventive actions may include, but are not limited to, the following:

- *Amending the IRB application, protocol, or consent document to correct discrepancies or add new information*
- *Improved data and/or safety monitoring plans*
- *Receipt of additional training in specific topic areas*

Please indicate the corrective and/or preventive actions that are required:

- ○ The submitted corrective and/or preventive action plan is appropriate.
- ○ The following additional corrective and/or preventive actions are necessary (describe additional actions in the Comments box below):

Clear

Comments:

Information for Acknowledgement

Information to be acknowledged does not require a determination for an unanticipated problem (UP) or non-compliance (NC). Generally, but not in all cases, the following types of reports may be acknowledged:

- *Audit reports with no findings or minor findings that do not require prompt reporting according to the UP or NC policies*
- *Closure to accrual/enrollment for expected, non-problematic reasons that would require UP or NC review*
- *Notification of an audit or site visit*
- *Annual reports that do not disclose new problems or events that were not previously reported according to the UP or NC policies*

This list is not all-inclusive. Each report form must be reviewed according to individual circumstances

Does the information provided in this report form indicate any increased risk of harm to participants or others?
If yes, you must complete the UP or NC checklists.

◯ Yes ◯ No Clear

Comments:

Final Assessment

Determinations Selected:

Does this report form require prompt reporting?
Promptly means within 10 business days from the day the investigator was notified of one of the following:

- *Problems/events that are possible Unanticipated Problems*
- *Deviations/Non-compliance that are intended to eliminate apparent immediate hazard to a research participant*
- *Deviations/Non-compliance that are harmful to participants*
- *Deviations/Non-compliance that are possible Serious or Continuing Non-Compliance*

◯ Yes ◯ No Clear

If yes, was this report form submitted promptly, within 10 business days?
◯ Yes ◯ No Clear

Please state any additional comments or recommendations you may have regarding this report in the Comment box below.

Comments: