

Reportable Negative Event/s Form

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|--------------------------|---|--------------------|
| ERC Protocol No. | Sponsor Protocol No | Date of submission |
| | | |
| Study Title: | | |
| Investigator | | Contact No.: |
| Sponsor: | | Contact No.: |
| Type of Review | <input type="checkbox"/> Full board <input type="checkbox"/> Expedited | |
| Reported by | | Contact No.: |
| Description of RNE: | | |
| Assessment of RNE: | <input type="checkbox"/> Participants <input type="checkbox"/> Study Team <input type="checkbox"/> Data | |
| Name and Signature of PI | | Date: |
| Noted by (Secretariat) | | Date: |

FOR MMERC

Comment on the risk and harm on the participants:

RECOMMENDATION

| | | |
|-----------------|---|------|
| Decision | <input type="checkbox"/> Recommend suspension of the study until risk is resolved <input type="checkbox"/> Withdrawal of ethical clearance <input type="checkbox"/> Submission of a plan to mitigate risk/harm <input type="checkbox"/> Require an amendment to the protocol <input type="checkbox"/> Uphold original ethical clearance | |
| Reviewer's Name | | Date |
| Signature | | |