

PHKL REC PROTOCOL DEVIATION REPORTING FORM

| A. Details of Principal Investigator | |
|--|---|
| Name | |
| Address | |
| Telephone | |
| Email | |
| Fax | |
| B. Details of Study | |
| PHKL REC Reference No. | |
| Full Study Title | |
| Protocol Number (if applicable) | |
| Date of PHKL REC Initial Approval | |
| Sponsor (if applicable) | |
| C. Subject's Information | |
| Subject ID (if applicable) | |
| Subject Recruitment Date (if applicable) (dd-mm-yyyy) | |
| D. Description of Protocol Deviation | |
| Type of Report | <input type="checkbox"/> Initial <input type="checkbox"/> Follow-Up <input type="checkbox"/> Final |
| Type of Protocol Deviation | <input type="checkbox"/> Minor Protocol Deviation <i>(non-systematic protocol noncompliance with minor consequences, in terms of its effect on the participant's/subject's rights, safety or welfare, or the integrity of study data; includes deviations that are administrative in nature)</i> <input type="checkbox"/> Major Protocol Deviation or Protocol Violation <i>(persistent protocol noncompliance with potentially serious consequences that could critically affect data analysis or put patients' safety at risk)</i> |
| Description of Protocol Deviation | <input type="checkbox"/> Performance of a study procedure without PHKL REC approval <input type="checkbox"/> Continuation of study activities during lapse of PHKL REC approval <input type="checkbox"/> Enrolment of research subject who did not meet the protocol inclusion/ exclusion criteria <input type="checkbox"/> Deviation in the consent process (e.g., failure to obtain informed consent prior to initiation of study procedures, use of an invalid consent form, missing date of consent, missing signature) <input type="checkbox"/> Study procedure were not performed as described in the currently approved protocol <input type="checkbox"/> Study drug/ intervention errors (e.g., incorrect study drug/ intervention, incorrect dosage of the study drug given) <input type="checkbox"/> Administrative non-compliance <input type="checkbox"/> Others _____ |
| Date of Protocol Deviation (dd-mmm-yyyy) | |

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| Date of Awareness (dd-mmm-yyyy) | |
| Protocol Deviation Narratives: | |
| Has this type of protocol deviation (or similar deviations) previously occurred in this study or this study site? | <input type="checkbox"/> No <input type="checkbox"/> Yes, if yes has it been reported to PHKL REC? <input type="checkbox"/> Yes <input type="checkbox"/> No |
| How was the protocol deviation made aware? | |
| Does this protocol deviation affect the safety of the subject? | <input type="checkbox"/> No <input type="checkbox"/> Yes, please explain: |
| Does this protocol deviation affect the scientific integrity of the study data? | <input type="checkbox"/> No <input type="checkbox"/> Yes, please explain: |
| Was this protocol deviation unanticipated? | <input type="checkbox"/> No <input type="checkbox"/> Yes |
| Does modification require to the data safety monitoring plan? | <input type="checkbox"/> No <input type="checkbox"/> Yes, please explain: |
| Corrective action done for this event? (if any training is done, please submit supporting document) | <input type="checkbox"/> Not applicable <input type="checkbox"/> No <input type="checkbox"/> Yes, please explain: |
| Preventive action for this event? | <input type="checkbox"/> Not applicable <input type="checkbox"/> No <input type="checkbox"/> Yes, please explain: |
| Has the event been resolved? | <input type="checkbox"/> No <input type="checkbox"/> Yes, please explain: |
| If this report was submitted more than 30 days after awareness of the event, please explain why and how late submission will be avoided in the future | <input type="checkbox"/> No <input type="checkbox"/> Yes, please explain: |
| H. Declaration | |
| I declare that the information in this form is accurate to the best of my knowledge and belief, and I take full responsibility for it. | |
| Principal Investigator: | |
| <hr/> Name: Date: | |
| I. For Office Use Only | |
| Date of Received | |
| Received By | |
| Signature | |

| | |
|---|--|
| PD ID | |
| J. Review by PHKL REC Chairman | |
| Additional actions or information required? If Yes, please specify | <input type="checkbox"/> Yes <input type="checkbox"/> No <hr/> <hr/> |
| Decision | <input type="checkbox"/> Approved. No action required <input type="checkbox"/> Decision deferred until further information is received <input type="checkbox"/> Table for full board meeting |
| Reviewed by: <hr/> Name: Date: | |
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