**(Annexure 10)**

## ACTIVE MONITORING REPORT FORM

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* The purpose of this form is for MPHRECTC members (as reviewers) to monitor the progress of selected research projects onsite and report to the MPHREC.
* Reviewers should submit completed active monitoring reports to the MPHREC secretariat for consolidation.

|  |  |  |  |
| --- | --- | --- | --- |
| Researcher’s Name |  | | |
| Supervisor Name (If applicable) |  | | |
| Department/Centre |  | | |
| Research Proposal Title |  | | |
| Original Ethics Clearance Number |  | First Clearance Date |  |
| Last Renewal Date  (if applicable) |  | Number of Renewals |  |

**Instructions to MPHRECTC member carrying out the active monitoring:**

* Please complete all sections 1-11 below and comment on your observations.

|  |
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| **1. Stage of Ongoing Research** |
| |  |  |  |  | | --- | --- | --- | --- | |  |  |  |  | | * 1. Data Collection Ongoing |  | * 1. Data Collection Complete |  |  |  |  |  |  | | --- | --- | --- | --- | | * 1. Data Analysis Ongoing |  | * 1. Data Analysis Complete |  |  |  |  |  |  | | --- | --- | --- | --- | | * 1. Research Report/Dissertation/ Thesis Writing |  | * 1. Research Report/ Dissertation/ Thesis Writing Complete |  | |  |  |  |  | |
| **2. Research progress observed and/or reported by the researcher:** (Please provide an overall summary of the research progress as reported by the researcher from the last clearance approval or renewal.)  *Please click here to comment* |
| 1. **Evidence of informed consent of participants, parents or guardians and assent of minors where applicable** |
| Have there been any challenges in obtaining consent of participants to provide data in the period covered by this report? |
| |  |  |  |  | | --- | --- | --- | --- | |  |  |  |  | | * 1. Yes |  | * 1. No |  |   If yes, please provide details below, and indicate how the consent/assent was documented:  *Please click here to comment* |
| 1. **Evidence of consistency or changes in research methods, data collection instruments, and storage methods** |
| Has there been any changes in research methods, data collection instruments and/or storage in the period covered by this report? |
| |  |  |  |  | | --- | --- | --- | --- | |  |  |  |  | | * 1. Yes |  | * 1. No |  |   If yes, please provide details below, and indicate how they were dealt with:  *Please click here to comment* |
| **5.** **Documentary evidence of Reportable Events/Deviations, etc.** |
| Ascertain if any of the following occurred during the period covered by this report. **Please indicate all associated supporting Adverse Events Reporting forms provided by the researcher, where applicable.** |
| |  |  |  |  | | --- | --- | --- | --- | |  |  |  |  | | * 1. Serious Adverse Event(s) (SAEs) |  | * 1. Non-serious Adverse Event(s) |  |  |  |  |  |  | | --- | --- | --- | --- | | * 1. Related AE(s) |  | * 1. Unrelated AE(s) |  |  |  |  |  |  | | --- | --- | --- | --- | | * 1. Anticipated AE(s) |  | * 1. Unanticipated AE(s) |  |  |  |  |  |  | | --- | --- | --- | --- | | * 1. Proposal Deviation |  | * 1. Proposal Non-compliance |  | |  |  |  |  | |
| **NB 1:** Check whether the researcher reported any SAEs and related AEs within 48 hours of discovery during the research period. ……………………………………………………………………………………………………………………….. |
| **NB 2:** Check whether any non-serious AEs, related AEs, all deviations from the proposal and non-compliances were reported within 5 working days of discovery during the research period. ……………… |
|  |
| 6. **Evidence of voluntary withdrawal of participants where applicable?** |
| Check whether there has been any withdrawal of participants in the period covered by this report. |
| |  |  |  |  | | --- | --- | --- | --- | |  |  |  |  | | * 1. Yes |  | * 1. No |  |   If yes, please explain details below, and indicate how they were handled:  *Please click here to comment* |
| 1. **Evidence of informed consent of participants, parents or guardians and assent of minors where applicable** |
| Have there been any challenges in obtaining consent of participants and assent of minors (where applicable) to provide data in the period covered by this report? |
| |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  | | | * 1. Yes |  | * 1. No |  | |   If yes, please provide details below, and indicate how the consent/assent was documented:  *Please click here to comment* |
| **8. Evidence of consistency and/or changes in data collection and/or storage methods** |
| Has there been any changes in research methods, data collection instruments and/or storage in the period covered by this report? |
| |  |  |  |  | | --- | --- | --- | --- | |  |  |  |  | | * 1. Yes |  | * 1. No |  |   If yes, please provide details below, and indicate how they were dealt with:  *Please click here to comment* |
| **9.** **Documentary evidence of Reportable Events/Deviations, etc.** |
| Ascertain if any of the following occurred during the period covered by this report. **Please indicate all associated supporting Adverse Events Reporting forms provided by the researcher, where applicable.** |
| |  |  |  |  | | --- | --- | --- | --- | |  |  |  |  | | * 1. Serious Adverse Event(s) (SAEs) |  | * 1. Non-serious Adverse Event(s) |  |  |  |  |  |  | | --- | --- | --- | --- | | * 1. Related AE(s) |  | * 1. Unrelated AE(s) |  |  |  |  |  |  | | --- | --- | --- | --- | | * 1. Anticipated AE(s) |  | * 1. Unanticipated AE(s) |  |  |  |  |  |  | | --- | --- | --- | --- | | * 1. Proposal Deviation |  | * 1. Proposal Non-compliance |  | |  |  |  |  | |
| **NB 1:** Indicate whether the researcher report SAEs and related AEs within 48 hours of discovery during the research period. …………………………………………………………………………………………………………………………………….. |
| **NB 2:** Indicate whether any non-serious AEs, related AEs, all deviations from the proposal and non-compliances were reported within 5 working days of discovery during the research period. ……………………………….…….. |
| |  |  |  |  | | --- | --- | --- | --- | |  |  |  |  | | * 1. Yes |  | * 1. No |  |   If yes, please explain the nature of conflict(s) below, and indicate how they were addressed by the researcher:  *Please click here to comment* |

|  |  |  |  |
| --- | --- | --- | --- |
| MPHRECTC Member’s Signature |  | Researcher’s Signature |  |
| Date (DD/MM/YYYY) |  | Date (DD/MM/YYYY) |  |