**(Annexure 11)**

## PASSIVE MONITORING FORM

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* The purpose of this form is for researchers to report to the MPHREC annually on the progress of their research
* The completed form to be submitted by the researcher to MPHREC secretariat on each anniversary of the granting of ethical clearance

|  |  |
| --- | --- |
| 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:**

* Please complete all sections 1-5 below and provide explanations or clarifications where required.

|  |
| --- |
| **1. Stage of Ongoing Research (***Mark with an X inside the box***)** |
|

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |
| * 1. Data Collection Ongoing
 |  | * 1. Data Collection Complete
 |  |

|  |  |  |  |
| --- | --- | --- | --- |
| * 1. Data Analysis Ongoing
 |  | * 1. Data Analysis Complete
 |  |

|  |  |  |  |
| --- | --- | --- | --- |
| * 1. Research Report/Dissertation/ Thesis Writing Ongoing
 |  | * 1. Research Report/Dissertation/ Thesis Writing Complete
 |  |
|  |  |  |  |

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| --- |
| **2. Research Progress:** (Please provide an overall summary of the research progress from the last clearance approval or renewal date to date whichever is applicable) |

*Please click here to comment*

|  |
| --- |
| 1. **Informed consent of participants 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 explain details below, and indicate how they were handled:*Please click here to comment* |
| 1. **Changes in data collection or storage methods**
 |
| 4.1 Has there been any changes in data collection methods or storage in the period covered by this report? |
|

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |
| Yes |  | No |  |

If yes, please explain details below, and indicate how they were dealt with:*Please click here to comment* |
| 1. **Ethical Issues and Adverse Events**
 |
| 5.1 Have any ethical concerns occurred during this period?

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Yes |  |  | No |  |

If yes, give details:*Please click here to comment*5.2 Have any adverse events/ SAE’s been noted since the last review?

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Yes |  |  | No |  |

If yes, give details:*Please click here to comment* |
| 1. **Withdrawal of participants**
 |
| Has there been any withdrawal of participants in the period covered by this report? |
|

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |
| * 1. Yes
 |  | * 1. No
 |  |

If yes, please provide the total number withdrawn and reasons:*Please click here to comment* |
| 1. **Publication/Feedback**
 |
| 6.1 Are there any publications or presentations during this period?

|  |  |  |  |
| --- | --- | --- | --- |
| * 1. Yes
 |  | * 1. No
 |  |

6.1.1 If yes, please provide details:*Please click here to comment*6.2 Have you provided feedback to the institution where the study is being conducted? 6.2.1 If yes, please provide details and the date when feedback was provided:*Please click here to comment*6.2.2 If no, please provide reasons and the date when feedback will be provided:*Please click here to comment* |

|  |  |  |  |
| --- | --- | --- | --- |
| Primary Investigator/ Researcher Signature |  | Secretariat Signature  |  |
| Date completed (DD/MM/YYYY) |  | Date received (DD/MM/YYYY) |  |