**PARKWAY INDEPENDENT ETHICS COMMITTEE**

**UNANTICIPATED PROBLEMS INVOLVING RISKS TO SUBJECTS OR OTHERS (UPIRTSO) REPORT FORM**

(For Reporting of External Events – local/overseas sites that are not under the purview of PIEC)

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| --- | --- | --- | --- |
| **(1) PIEC Reference No.:** | Text Field | **(2) Protocol Title:** | Text Field |
| **(3) Name of Principal Investigator (PI):** | Text Field | **(4) Is the Investigational Product (IP) registered in S’pore? (Yes / No / NA):** | Text Field | **(5) IP Name:** | Text Field |

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| 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 |
| S/N | MFR Control Number of CIOMS / MEDWATCH/ IND Safety Report | Date of Report(DD/MMM/YY) | Onset Date of Event (DD/MMM/YY) | Date of first knowledge by PIEC’s approved site(DD/MMM/YY) | Type of Report (I – Initial, F – Follow Up) | Study Site / Country | Participant Identifier(U – Unknown, NA – if no Research Participant involved) | Participant’s Age  | Participant’s Gender (M / F / U) | Is Participant still in study? (Y / N / U) | Was study blind broken? (Y / N / NA)  | Which study arm is Participant in?(1 – Study Drug, 2 – Comparator, 3 – Placebo, 4 – Not applicable, U – Unknown) | Status of Investigational Product (1 – Continued, 2 – Discontinued, 3 – Temporarily stopped, 4 – Not applicable, U - Unknown) | Local PI’s Opinion(Y / N) | Sponsor’s Opinion(Y / N) | Event Name(s)(Indicate all if more than one) | Is problem already described in any study documents e.g. Consent Document, IB, Protocol? (Y/ N) | Has the study’s Risk-Benefit ratio changed? (Y / N) | Has problem been resolved? (Y N) | Does PI recommend changes to Protocol / Consent Document? (Y /N) If ‘Yes’ to field #24 and ‘No’ to this field, please complete Appendix I of this form. |
| Is it serious? | Is it Related? | Is it Unexpected? | Is it serious? | Is it Related? | Is it Unexpected? |
| 1 |       |       |       |       |   |       |       |    |   |   |    |    |   |   |   |   |   |   |   |       |   |   |   |   |
| 2 |       |       |       |       |   |       |       |    |   |   |    |    |   |   |   |   |   |   |   |       |   |   |   |   |
| 3 |       |       |       |       |   |       |       |    |   |   |    |    |   |   |   |   |   |   |   |       |   |   |   |   |
| 4 |       |       |       |       |   |       |       |    |   |   |    |    |   |   |   |   |   |   |   |       |   |   |   |   |
| 5 |       |       |       |       |   |       |       |    |   |   |    |    |   |   |   |   |   |   |   |       |   |   |   |   |

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| 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 |
| S/N | MFR Control Number of CIOMS / MEDWATCH/ IND Safety Report | Date of Report(DD/MMM/YY) | Onset Date of Event (DD/MMM/YY) | Date of first knowledge by PIEC’s approved site(DD/MMM/YY) | Type of Report (I – Initial, F – Follow Up) | Study Site / Country | Participant Identifier(U – Unknown, NA – if no Research Participant involved) | Participant’s Age  | Participant’s Gender (M / F / U) | Is Participant still in study? (Y / N / U) | Was study blind broken? (Y / N / NA)  | Which study arm is Participant in?(1 – Study Drug, 2 – Comparator, 3 – Placebo, 4 – Not applicable, U – Unknown) | Status of Investigational Product (1 – Continued, 2 – Discontinued, 3 – Temporarily stopped, 4 – Not applicable, U - Unknown) | Local PI’s Opinion(Y / N) | Sponsor’s Opinion(Y / N) | Event Name(s)(Indicate all if more than one) | Is problem already described in any study documents e.g. Consent Document, IB, Protocol? (Y/ N) | Has the study’s Risk-Benefit ratio changed? (Y / N) | Has problem been resolved? (Y N) | Does PI recommend changes to Protocol / Consent Document? (Y /N) If ‘Yes’ to field #24 and ‘No’ to this field, please complete Section 27. |
| Is it serious? | Is it Related? | Is it Unexpected? | Is it serious? | Is it Related? | Is it Unexpected? |
| 6 |       |       |       |       |   |       |       |    |   |   |    |    |   |   |   |   |   |   |   |       |   |   |   |   |
| 7 |       |       |       |       |   |       |       |    |   |   |    |    |   |   |   |   |   |   |   |       |   |   |   |   |
| 8 |       |       |       |       |   |       |       |    |   |   |    |    |   |   |   |   |   |   |   |       |   |   |   |   |
| 9 |       |       |       |       |   |       |       |    |   |   |    |    |   |   |   |   |   |   |   |       |   |   |   |   |
| 10 |       |       |       |       |   |       |       |    |   |   |    |    |   |   |   |   |   |   |   |       |   |   |   |   |

**(27) Please complete the following table for those events with ‘Yes’ as answer to field #24 and ‘No’ as answer to field #26 of the above UPIRTSO reporting table.**

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| --- | --- | --- |
| **S/N****(according to the above UPIRTSO reporting table)** | **Event Name(s)****(Indicate all if more than one)** | **Please explain why changes to the Protocol/Consent Document are not required and please state the corrective actions that are proposed or have been taken in response to the unanticipated problem (event) in the space below.** |
|  | Text Field | Text Field |
|  | Text Field | Text Field |
|  | Text Field | Text Field |
|  | Text Field | Text Field |
|  | Text Field | Text Field |

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| **Declaration of the Principal Investigator** |
| I confirm that the information submitted in the above report is true and accurate at the time of submission of the report. |
| Signature:  |  | Date: |  |
| Full Name:  | Text Field | Study Role: |  |

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| **FOR OFFICIAL USE ONLY** |
| Action by PIEC Secretariat:  | Are all the above events unanticipated problems involving risks to Subjects and Others? | [ ]  Yes[ ]  No (S/N: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) | Initial & Date: |  |
| Action by PIEC Chairperson:  | [ ]  Not an Unanticipated Problem Involving Risks to Subjects and Others[ ]  Table summary at next convened meeting | [ ]  Table for discussion at next convened meeting[ ]  Any other action, please specify | Initial & Date: |  |

**IMPORTANT NOTES:-**

**Definition**

UPIRTSO refers to problems, in general, to include any incident, experience, or outcome that meets ALL of the following criteria:

 **1. Unexpected**

In terms of nature, severity or frequency, given:-

* + The research procedures that are described in the protocol-related documents, such as the PIEC approved research protocol and informed consent document; and
	+ The characteristics of the subject population being studied.

 **2. Related or possibly related to participation in research**

Possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research; and

 **3. Suggests that the research places participants or others at a greater risk of harm** (including physical, psychological, economic, or social harm) than was previously known or recognized.

**Reporting Timeline and Requirement for External Events**

1. For all external events, including **overseas deaths** and events from other protocols of the same investigational product(s), you are only required to report RELATED and UNEXPECTED events. If there is an overseas event that is unrelated or expected, there is no need to report to PIEC. Reporting timelines for external events are 7 calendar days from investigator’s knowledge of event.
2. For locally registered products, please only submit internal and external UPIRTSO events that arise from the same **clinical trial protocol that is approved by PIEC**.
3. For locally unregistered products (including different use from local approved label), both internal and external UPIRTSO events, including events from other clinical trial protocols using the same investigational products have to be submitted to PIEC.
4. External UPIRTSO events associated with active comparator need not be submitted to PIEC.
5. For multi-centre study, the local Coordinating PI holds the responsibility of reporting external UPIRTSO events.

**Reporting of CIOMS I Form or MedWatch 3500 Form**

1. For reporting of **external events** that are applicable for multiple studies, in a single submission to PIEC, please submit the following items:-
	1. One PIEC UPIRTSO Reporting Table Form with the PIEC reference numbers and protocol titles of all applicable studies written in Field no. 1 and 2 of the form respectively.
	2. All associated CIOMS I/MedWatch 3500 forms for the overseas events.