**PARKWAY INDEPENDENT ETHICS COMMITTEE**

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

**(For Reporting of Internal Events – All study sites under PIEC’s purview)**

| **Section A: Basic Information** |
| --- |
| **1) PIEC Reference No:** | Text Field |
| **2) Protocol Title:** | Text Field |
| **3) Principal Investigator:** | Text Field |
| **4) Onset Date:** *(DD/MMM/YYYY)* | Text Field | **5) Date of First Knowledge by Site:** *(DD/MMM/YYYY)* | Text Field |
| **6) Study Site:** | Text Field |
| **7) Type of Report:** |

|  |  |
| --- | --- |
| [ ]  Initial Report | [ ]  Follow Up report |
| If ‘Follow Up Report’, state the Initial report date: Text Field *(DD/MMM/YYYY)* |

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| **Section B: Does this problem involve a research participant in particular?** |
| [ ]  **No** [ ]  **Yes.** *If ‘Yes’, please answer the following:-*

|  |  |  |  |
| --- | --- | --- | --- |
| **1) Participant Identifier:** | Text Field | **2) Age:** | Text Field |
| **3) Gender :**  | [ ]  Male [ ]  Female | **4) Is the participant still in study? :** | [ ]  Yes [ ]  No |
| **5) Which study arm is the participant in?** | [ ]  Study Drug [ ]  Comparator [ ]  Placebo [ ]  Unknown [ ]  Not applicable |

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| **Section C: Does this problem involve an Investigational Product** *(drug/ device/ biologic/ other agent)***?**  |
| [ ]  **No** [ ]  **Yes.** *If ‘Yes’, please answer the following:-*

|  |  |
| --- | --- |
| **1) Investigational Product Name** | Text Field |
| **2) Was the study blind broken?** | [ ]  Yes [ ]  No [ ]  Not Applicable |
| **3) Is the Investigational Product registered in Singapore?** | [ ]  Yes [ ]  No [ ]  Not Applicable |
| **4) The Investigational Product was** | [ ]  Continued [ ]  Discontinued [ ]  Temporarily StoppedIf ‘Discontinued’ or ‘Temporarily Stopped’, state the stop date: *(DD/MMM/YYYY)* Text Field |

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| **Section D:** **Unanticipated Problem Assessment** *(Tick all applicable)* |
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| **1) Did the unanticipated problem result in death?** [ ]  Yes [ ]  No [ ]  Not applicable**2) Opinion of the PI:** ***Please submit to PIEC only if the answer to all four following questions is ‘Yes’ or the problem resulted in death.***

|  |  |
| --- | --- |
| **a) Is this problem unexpected?** | [ ]  Yes [ ]  No |
| **b) Is this problem related or possibly related to the study?** | [ ]  Yes [ ]  No  |
| **c) Is this problem serious?** | [ ]  Yes [ ]  No |
| **d) Does this problem place subjects or others at greater risk of harm?** **Note: If adverse event is serious, answer is always ‘Yes’.** | [ ]  Yes [ ]  No |

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| **Section E:** **Problem Summary** *(Please attach additional pages as needed.)* |
| 1. **Please use keywords, e.g. Liver Failure, Loss of Data, Dispensing Error, etc, to concisely describe the problem.**

|  |  |
| --- | --- |
| Event Keywords: | Text Field |

1. **Describe the problem**.

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| --- |
| Text Field |

1. **Describe the outcome of the problem, including details of what action was taken to resolve the problem, and if there was any resulting impact on the participant or others.**

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| Text Field |

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| **Section F:** **Additional comments by Principal Investigator** |
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| --- | --- |
| 1. **Is this problem already listed/described in the consent document?**
 | [ ]  Yes [ ]  No |
| 1. **Has the study’s risk-benefit ratio changed?**
 | [ ]  Yes [ ]  No |
| 1. **Has this problem been resolved?**
 | [ ]  Yes [ ]  No |
| 1. **Do you recommend changes to protocol and/or informed consent document?**

*If ‘Yes’,* *please submit the amendments with the PIEC Study Amendment Cover note.*  | [ ]  Yes [ ]  No |
| **4a) If the answer to question 4 is ‘No’, please provide the justification including details on the corrective actions that are proposed or have been taken in response to the unanticipated problem.** Text Field |
| 1. **Any other Comments** *(Please attach additional pages if needed.)*
 |  |
| Text Field |

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| **Section G: Declaration of the Principal Investigator** |
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| **I confirm that the information submitted in the above report is true and accurate at the submission of the report.**

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| *Investigator’s Signature* | *Date* |
|  |  |
| Full Name: | Text Field | Study Role: |  |
| Institution: | Text Field | Department: | Text Field |
| ***Only for multi-centre study with a Coordinating PI appointed:*** If you are not the Coordinating PI of the study, please kindly notify the Coordinating PI of this UPIRTSO. Please also provide the contact details of Coordinating PI for our information in the following:

|  |  |
| --- | --- |
| Name of Coordinating PI: | Text Field |
| Institution: | Text Field |
| Telephone no.:  | Text Field |
| Fax no.: | Text Field |
| Email address: | Text Field |

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| **FOR OFFICIAL USE ONLY** |
| **Action by PIEC Coordinator:-**[ ]  Not an Unanticipated Problem Involving Risks to Subjects and Others[ ]  Unanticipated Problem Involving Risks to Subjects and Others  | **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.
1. **Related or possibly related to participation in the 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

1. **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 recognised.

**Reporting Timeline and Requirements for Internal Events**

1. **Urgent Reporting:** All problems involving deaths, whether related or not, should be reported immediately – within 24 hours after first knowledge by the study investigator. For multi-centre study, this reporting is not limited to Coordinating PI. Site PI of the site where the reported problem occurred can report to PIEC but is responsible to keep the Coordinating PI informed.
2. **Expedited Reporting:** All other problems must be reported as soon as possible but not later than 7 calendar days after first knowledge by the study investigator. For multi-centre study, this reporting is not limited to Coordinating PI. Site PI of the site where the reported problem occurred can report to PIEC but is responsible to keep the Coordinating PI informed.
3. For locally registered products, please submit ALL internal and external UPIRTSO events that arise from the same **clinical trial protocol that is approved by PIEC**.
4. For locally unregistered products (including different use from locally 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.
5. For active comparator, please submit internal UPIRTSO events that arise from the **clinical trial protocol that is studied in Singapore.**

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

1. If you are reporting a single internal event that is applicable for multiple studies, please submit the following items:-
	1. One UPIRTSO Report Form with the PIEC reference numbers and protocol titles of all the applicable studies written in Section A of the form
	2. One associated CIOMS I/MedWatch 3500 form