**PARKWAY INDEPENDENT ETHICS COMMITTEE**

**NONCOMPLIANCE REPORT FORM**

**Instructions:**

* For reporting of Noncompliance, Protocol Deviations and Complaints.
* Only significant events that, in the judgement of the principal investigator, increase risk or cause harm to the subjects or others and/or undermine the scientific integrity of the study are required to be reported to PIEC.
* All reportable events shall be reported as soon as possible but not later than 7 calendar days after first knowledge by the principal investigator.
* **Other study team member** or **non-study team member** may also report an alleged non-compliance or complaint to PIEC. The identity of the reporter will not be disclosed.
* **Submit one report for ONE event only.**

| **PIEC Reference No.:** | Text Field |
| --- | --- |
| **Protocol Title:** | Text Field |
| **Principal Investigator:** | Text Field |
| **Study Site:** | Text Field |
| **Date of Event:**  | Text Field |
| **Subject ID:** | Text Field |

| 1. **Please provide a thorough description of the event.**

Text Field |
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| 1. **Explain why or how this event occurred.**

Text Field |
| 1. **Describe the outcome of this event.**

Text Field |
| 1. **In your judgment, did this event increase risk/cause harm to the participant or others and/or affect the rights or welfare of the participant?**

Text Field |
| 1. **In your judgment, how might this event compromise the scientific integrity of the study? How will this be mitigated?**

Text Field |
| 1. **Is the subject aware of this event?**

Text Field |
| 1. **Describe any follow-up action or corrective action to prevent this event from recurring in the**

 **future.** Text Field |
| 1. **Do you have any other comments?**

Text Field |
| 1. **Has this event been reported to the study sponsor?**

**[ ]  Not applicable as there is no study sponsor.****[ ]  No.** *If “No”, please provide rationale for not reporting:* Text Field**[ ]  Yes.** *If “Yes”, please describe feedback from the sponsor.* Text Field |
| 1. **Did this event result in UPIRTSO event(s) (Unanticipated Problems Involving Risks to Subjects or Other)?**

**[ ]  Yes.** *If “Yes”, please also complete and submit the PIEC UPIRTSO Report Form to PIEC.***[ ]  No.** *If “No”, please explain why not.* Text Field |

| **Declaration Of Reporter:** |
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| **I confirm that the information submitted above is true and accurate at the date of submission of this report.****\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** **Signature Date**

|  |  |
| --- | --- |
| **Name:** | Text Field |
| **Study Role:** |  **Others:** Text Field |
| **Institution:**  | Text Field |
| **Contact Number:** | Text Field |
| **E-mail:** | Text Field |

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| **FOR PIEC OFFICIAL USE ONLY** |
| **Is noncompliance serious?** [ ]  **Yes** [ ]  **No Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****Is noncompliance continuing?** [ ]  **Yes** [ ]  **No Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** **Action required:** [ ]  Noted. Table summary at next convened meeting. [ ]  Table for discussion at next convened meeting. [ ]  Any other action that PIEC deems appropriate.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Reviewer’s Name Reviewer’s Signature & Date** |