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

|  |
| --- |
| **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** |