*Deviations are every research study departure from the procedures set forth in the IRB-approved protocol. Various terms are used to describe these departures, including “protocol deviations,” “protocol violations,” and “non-compliance.” If these departures placed subjects at increased risk of harm or has the potential to occur again, they fall under the definition of unanticipated problems involving risks to subjects and others and must be reported. They are commonly referred to as serious/continuous noncompliance or major deviation/violation.*

*All reportable protocol deviations must be reported by the PI to the IRB* ***within ten (10) days*** *of learning of the incident. If it is necessary to make a permanent change to the study procedures in order to avoid harm to other subjects, then a protocol amendment should be submitted, by the PI, as soon as possible. If appropriate to maintain safety of the subjects, new subject enrollment should be temporarily stopped by the PI until the amendment is approved.*

*For any questions, please contact IRB office at* [*researchsection@phcc.gov.qa*](mailto:researchsection@phcc.gov.qa)

|  |  |
| --- | --- |
| Study Title: |  |
| IRB Reference No.: |  |
| Principal Investigator: |  |
| Subject ID: |  |
| Date of the Report: | (dd/mmm/yyyy) |

**BACKGROUND INFORMATION:**

1. **Is this a multi-site study where PHCC IRB is serving as the reviewing IRB for external sites?**

YES NO

If Yes, please identify the site where the incident occurred in the text box below and provide the names, email addresses & phone numbers for the site Investigator and Study Contact that the IRB can contact with questions related to the incident

1. **Please note the study Enrollment Status:**

Study has not begun (no subjects consented)

Open to subject enrollment

Closed to subject enrollment

1. **Please note the current enrollment at the site where the incident occurred:**

Total number of subjects consented:

Number of active subjects:

Number of subjects in follow up:

**SUMMARY: Please provide the following details for the incident being reported. If there was a significant delay in reporting from the time of identification, please describe the reason for this delay.**

1. Date when the incident occurred: Click or tap to enter a date.
2. Date when the incident was identified**:** Click or tap to enter a date.
3. **Provide a brief description of the incident and how it was identified:**
4. **Why did the incident occur? What were the circumstances? (root-cause analysis)**
5. **Was there any effect of this incident on the risk(s) associated with the study?**

Yes No

If yes, please explain:

1. **Please discuss the corrective action plan taken or planned by the PI to correct this incident. Please also discuss any preventative actions taken or planned to prevent this incident from occurring in the future:**

**Please Note: If a protocol amendment is planned to address this incident, please note when the amendment will be submitted.**

**CLASSFICATION:**

|  |  |  |  |
| --- | --- | --- | --- |
| Enrolment/Randomization of ineligible subjects |  | Recruiting more than the IRB approved sample size |  |
| Study procedures are not done as required by Protocol |  | Incorrect handling of samples/data |  |
| Failure to obtain informed consent |  | Failure to keep IRB approvals up to date |  |
| Consent Form:   * All required signatures not present * Missing Informed Consent * Wrong version/version not approved by IRB used for consent |  | Other: |  |

1. **Did this incident adversely affect the welfare or safety of participant(s)?**

Yes No

If yes, please explain:

1. **Did this incident adversely affect the scientific integrity of the study?**

Yes No

If yes, please explain:

1. **Did this incident adversely affect the rights\* of participant(s)?**

* These rights include:

1. To have enough time to decide whether to be in the research study and to make that decision without any pressure.
2. To refuse to be in the study at all, and to stop participating at any time.
3. To be informed of all the applicable required elements of consent.
4. To receive a copy of the consent form
5. To ask questions

Yes No

If yes, please explain:

1. **Did this incident affect the subject’s willingness to participate in the research?**

Yes No

If yes, please explain:

By signing this form, the principal investigator certify that he/she has disclosed to the IRB all relevant information that might affect the risk to benefit analysis of this study.

**Signature of principal investigator:                 Date:**