**GUIDE IN ACCOMPLISHING THE REPORTABLE NEGATIVE EVENT/S FORM (RNEF)**

Purpose: This form is created for the researchers to report adverse events in human subjects during the conduct of their study.

**NOTE: If there are no negative events to report, then please write N/A in appropriate boxes.**

Events are considered adverse when they meet the following criteria:

1. Unexpected (in terms of nature, severity or frequency) given the research procedures that are

described in the protocol-related documents (including consent form) and the characteristics of

the subject population being studied;

1. Definitely or probably related to participation in the research; and
2. Suggests that the research places subjects or others at greater risk of harm than was previously

known or recognized.

Common examples of events that should be reported are:

1. A complaint from a research subject that cannot be resolved by the research team;
2. A breach of confidentiality;
3. A manufacturing or equipment error that was not caused by the study team but posed potential

risk to subjects;

1. Research staff exposure to unexpected risks.

The CNU ERC requires researchers to submit reports that meet the above criteria within 10 days of the

time the event becomes known to the study team with one exception:

1. If the adverse event involved the unforeseen death of a subject and indicated participants or

others are at increased risk of harm, a report must be made within three days;

*Please note that a single Reportable event form can be completed for multiple subjects if the subjects were affected by the same event. If you need to report multiple separate Reportable Events, please contact the CNU ERC in advance to determine the best way to draft your report(s).*

**REPORTABLE NEGATIVE EVENT FORM (RNEF)**

| Title of the study: |  |
| --- | --- |
| Lead Researcher: |  |
| ERC Code: |  |
| Date of reportable event: |  |

1. STUDY SITE INFORMATION:
   1. Is this a multi-site study? \_\_\_\_\_\_\_
   2. Where did the adverse event occur? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. REPORT STATUS: Please indicate whether this is the first time this event has been reported to the CNU ERC or if it is a follow up report.

\_\_\_\_\_\_\_ Not applicable \_\_\_\_\_\_Initial Report \_\_\_\_\_\_Follow-up report

Date of initial report: \_\_\_\_\_\_\_\_\_\_\_\_\_

1. EVENT SUMMARY: Please provide a narrative summary of the event that occurred. The

summary should include the following elements:

* 1. How the event is related to the research (An event is considered related to the research if the cause of the event is deemed related or possibly related to research participation);
  2. The date the event occurred;
  3. The research team member who handled the event;
  4. The date the team became aware of the event;
  5. A description of the event and the subjects that were affected;
  6. Immediate and follow up actions taken in response to the event to date; and
  7. What is the status of the follow-up of this event: Resolved or Unresolved

1. SUPPORTING REPORTS: Please identify any other entities that have been informed of this

event (e.g. Public Safety, Funding agency, etc.), if applicable. Please provide copies of any event-related correspondence (including email) with the mentioned entities as attachments.



1. RESPONSE TO THE EVENT:
2. Does the event(s) require any changes to the currently approved study conduct or documents? \_\_\_\_\_\_\_ Not applicable \_\_\_\_\_\_Yes \_\_\_\_\_\_No

If Yes, Please submit an amendment to the CNU ERC

If No, please explain why these events do not warrant revision of the current study procedures and/or documents.

1. RISK/BENEFIT ASSESSMENT: In light of this event, please re-assess the study overall and provide your rationale for whether or not the protocol exposes subjects to more risk than initially anticipated and whether risks to subjects remain reasonable in relation to the anticipated benefits (if any):



PI Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_