**Unanticipated Problem and/or**

**Noncompliance Reporting Worksheet**

OMB#: 0925 – 0753 Expiry Date: 05/31/2024

**STATEMENT OF CONFIDENTIALITY**

The purpose of the information collection is to conduct reviews of clinical trial studies. NCI guidelines mandate the participation of institutions in the CIRB for Network group studies. You are being requested to complete this instrument so that we can conduct activities involved with the operations of the NCI CIRB Initiative. Although your participation in Network group research and completion of the forms is voluntary, if you wish to participate in the CIRB, you must complete all questions on the form. The information you provide will be combined for all participants and reported as summaries. It will be kept private to the extent provided by law.

**NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN**

Public reporting burden for this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0753). Do not return the completed form to this address.

**Signatory Institution Information**

Submitting User Information

 Name of Signatory Institution:

**General Information**

1. Enter Study ID Number. (Click here if you would like to review a list of studies currently covered by the NCI CIRB.)

If more than one study is affected, enter the additional study ID numbers below.

2. Is this an NCI, Division of Cancer Prevention Phase 0/I/II Cancer Prevention Clinical Trials Program (Consortia) or a Cancer Prevention Clinical Trials Network (CP-CTNet) protocol?

These DCP-sponsored studies use the following Study ID naming convention:

 a. Consortia lead org ABBREVIATION YYYY-Submission cycle-protocol#

 For example:

 MAY2017-09-01

 MDA2013-02-02

 NWU2017-09-01

 UAZ2015-05-01

 UWI2016-08-01

 b. CP-CTNet lead org ABBREVIATION YY-Submission cycle-protocol#

[ ]  Yes

[ ]  No

 3. Enter Principal Investigator email address.

If more than one Principal Investigator is affected, enter the additional names below.

3. Enter each study's Protocol Version Date associated with the incident, experience, or outcome.

4. Enter the Study Participant(s) Registration Number(s), if the incident, experience, or outcome involved a study participant(s).

**Description of Incident, Experience, or Outcome**

1. Enter the date incident, experience, or outcome occurred.

2. Describe the incident, experience, or outcome and/or add an attachment.

Add applicable attachment:

3. Has the Network Group/sponsor, the Study Chair, or a Federal agency been notified of this incident, experience, or outcome?

[ ]  Yes

[ ]  No

If Yes, identify those notified.

Attach a copy of the notification and any response(s) received from those notified. Include the AdEERS report, if applicable.

4. Select the type of report submission.

 Note: Unanticipated Problem should be selected for events that may be a potential serious adverse event

 [ ]  Unanticipated Problem

[ ]  Serious or Continuing Noncompliance

Unanticipated Problem should only be selected for events that occur without any deviation from the protocol.

**Section C: Potential Unanticipated Problem**

1. Is this incident, experience, or outcome unexpected?

[ ]  Yes

[ ]  No

If Yes, describe how the incident, experience, or outcome is unexpected.

Add applicable attachment:

2. Is this incident, experience, or outcome related or possibly related to participation in the research?

[ ]  Yes

[ ]  No

 If Yes, describe how the incident, experience, or outcome is related or possibly related to participation in the research.

 Add applicable attachment:

3. Did the incident, experience, or outcome place the study participant(s) or others at a greater risk of harm?

[ ]  Yes

[ ]  No

 If Yes, describe how the incident, experience, or outcome placed the study participant or others at a greater risk of harm.

 Add applicable attachment:

4. Describe any corrective action and preventative plan the Signatory Institution and/or Principal Investigator has taken, is taking, or is planning to take, to address the incident, experience, or outcome.

 Add an attachment, if applicable.

**Section D: Potential Serious or Continuing Noncompliance Report**

1. The definition of serious noncompliance is noncompliance that adversely affects the rights and welfare of study participants or results in any untoward medical occurrence that meets the criteria of “serious” or significantly impacts the integrity of study data.

Serious is defined as side effects that may require hospitalization or may be irreversible, long-term, life-threatening, or fatal.

Is the incident, experience, or outcome potential serious noncompliance?

[ ]  Yes

[ ]  No

If Yes, describe how the incident, experience, or outcome is potential serious noncompliance and/or add an attachment.

2. The definition of continuing noncompliance is a pattern that, if unaddressed, could jeopardize the rights and welfare of research participants or the integrity of the study data due to noncompliance with the protocol, Federal regulations, and/or the requirements of the CIRB.

Is the incident, experience, or outcome potential continuing noncompliance?

[ ]  Yes

[ ]  No

If Yes, describe how the incident, experience, or outcome is potential continuing noncompliance.

Add applicable attachment:

3. Does the incident, experience, or outcome affect the study participant’s continued participation in the study?

[ ]  Yes

[ ]  No

If Yes, describe how the study participant’s continued participation in the study is affected.

Add applicable attachment:

4. Describe any corrective action and preventative plan the Signatory Institution and/or Principal Investigator has taken, is taking, or is planning to take, now and in the future, to address this incident, experience, or outcome.

Add applicable attachment:

If this is a preliminary report and a management plan is not yet available, indicate when the management plan or corrective action will be submitted.