ADVERSE EVENT (AE) and OTHER UNANTICIPATED PROBLEM REPORT

OKLAHOMA STATE DEPARTMENT OF HEALTH

INSTITUTIONAL REVIEW BOARD

*Submit within four working days of the event or your notification of the event to the OSDH.*

1. STUDY INFORMATION

OSDH IRB Number

Study Title

Sponsor

Principal Investigator

Address

Phone

E-mail

Is IRB approval required at other outside sites?  Yes  No

If yes, specify IRB

If so, has a report been made to the other IRB?  Yes  No

If yes, please attach copy of report.

If no, please submit when obtained.

What is being reported?  Unanticipated Problem  Non-compliance/Protocol Deviation

1. NATURE OF EVENT

In the judgment of the principal investigator, was the event/problem: (1) unexpected, (2) related or possibly related to the study, and (3) serious.

1. UNEXPECTED - Unanticipated, unforeseen, or unexpected?

Explain

1. RELATED OR POSSIBLY RELATED - Reasonable possibility that the problem may have been caused by research participation?

Explain

1. SERIOUS - Participants or others are at increased risk of harm?

Explain

If all three boxes are checked, continue with Section III. If the unanticipated problem does not meet all three criteria, review Section III and report any applicable information.

1. **EVENT INFORMATION**

Please complete all information. (Attach extra sheets as necessary.)

* 1. **Subject identifier**. *Identify the subject using their initials and patient ID number.*

* 1. **Date and time of the event**. *State the date and time of the event.*

* 1. **Date that the investigator was made aware of the event**

* 1. **Location of the event**. *State the study site that experienced the problem.*

* 1. **Description***. Describe the event and the subject outcome from event.*

* 1. **Risk-benefit analysis update**. *Explain the overall risk-benefit relationship of the research in light of the event.*

* 1. **Subjects informed.** *Is it necessary to inform subjects (or their legally authorized representatives) who have already consented to participate in the study of the adverse event with either an amendment to or a revision of the consent form? If YES, attach a copy of the amendment and/or revised consent form with the changes highlighted. If NO, provide a brief rationale*.

Yes  No

* 1. **Change in procedures.** *Will new procedures be implemented to prevent recurrence of event of minimization of risk to other participants? If YES, describe the new procedures. If NO, provide a brief rationale of why no new procedures*.

Yes  No

* 1. **Changes in protocol.** *In your judgment, is a change in protocol necessary to reduce or eliminate risk? If NO, provide a brief rationale. If YES, attach a copy of the changes and provide a description of the rationale for each change.*

Yes  No

* 1. **Informed consent/document**. *Will the informed consent process or documentation be revised to better inform and protect the rights of subjects? Provide rationale. If YES, attach a copy of the revised consent form with the changes highlighted*. *If NO, describe why not.*

Yes  No

* 1. **Reporting requirements.** *Have you complied with all applicable reporting requirements of the sponsor, NCI, or FDA?*

Yes  No

1. **NON-COMPLIANCE/PROTOCOL DEVIATION**

Non-compliance is defined as any action or activity associated with the conduct or oversight of human subjects research that fails to comply with regulations or policies. Examples include: failure to obtain IRB approval, inadequate supervision, failure to follow recommendations made by IRB, failure to report unanticipated problems, etc. Protocol deviation is defined as alteration or modification to the IRB approved protocol that is not approved by the IRB prior to its initiation. Examples include: contacting a participant who has been incarcerated when protocol has not been approved for inclusion of prisoners or using data collected within a clinic setting without authorization.

* 1. **Number of individuals involved.** *How many participants or others were involved with the event?*

* 1. **Explanation of facts.** *Provide a description of the noncompliance or deviation, including timeline, date of discovery, individuals involved, and other details.*

* 1. **Risk assessment.** *Provide an assessment of any increased risk to participants or others.*

* 1. **Data validity.** *Was the validity of the data compromised? Explain.*

Yes  No

* 1. **Subjects informed.** *Is it necessary to inform subjects (or their legally authorized representatives) who have already consented to participate in the study of the adverse event with either an amendment to or a revision of the consent form? If YES, attach a copy of the amendment and/or revised consent form with the changes highlighted. If NO, provide a brief rationale*.

Yes  No

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Yes  No

* 1. **Changes in protocol.** *In your judgment, is a change in protocol necessary to reduce or eliminate risk? If NO, provide a brief rationale. If YES, attach a copy of the changes and provide a description of the rationale for each change.*

Yes  No

* 1. **Informed consent/document**. *Will the informed consent process or documentation be revised to better inform and protect the rights of subjects? Provide rationale. If YES, attach a copy of the revised consent form with the changes highlighted*. *If NO, describe why not.*

Yes  No

1. **CERTIFICATION OF PRINCIPAL INVESTIGATOR**

As the principal investigator, I have personally reviewed and assessed this report and assure that all information provided is accurate. My signature certifies the following:

All necessary information has been assessed and the form completed in sufficient detail to facilitate IRB Review.

The risks of the research are minimized to the greatest extent possible.

The risk-benefit relationship of the research continues to be acceptable.

The consent form does not require revision. A copy of the current consent form is attached.

The consent form requires revision. A copy of the revised consent form with changes underlined is attached.

**Signature of Principal Investigator Date**