**APPENDIX 10**

**OKLAHOMA CHRISTIAN UNIVERSITY**

 **ADVERSE EVENT REPORTING FORM**

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| **Protocol Information** |
| RPI First Name: | RPI Last Name: |
| Date: MM/DD/YY  | Human Subject’s Initials and/or Identifier: |
| Complete Title of Research Project: |
| Research Sponsoring Agency (e.g., NIH, NSF): |
| **Description of Event** |
| Date of Event: \_/ /  | Time of Event: : AM? PM?  |
| Location: | Attending Physician: |
| Hospital or Site of Medical Care: |
| Provide a brief description of the event. Attach any additional documentation that may be helpful (lab or x-ray reports): |
| Medical Treatment Received: |
| Describe the Subject’s Prognosis and Outcome. Attach any follow-up reports if the outcome is indeterminable at the time of this report. |

**Nature of the Event**

Serious? A serious adverse event is any event occurring those results in any of the following outcomes. Check the outcome that applies:

\_\_\_\_\_death

\_\_\_\_\_life-threatening event

\_\_\_\_\_in-patient hospitalization

\_\_\_\_\_prolongation of existing hospitalization

\_\_\_\_\_a persistent or significant disability/incapacity

\_\_\_\_\_a congenital anomaly/ birth defect (pregnant subjects only)

An unexpected adverse event is any adverse event, the specificity or severity of which is not listed in the current informed consent.

Unexpected? Yes\_\_\_\_\_No \_\_\_\_\_

Probable (The adverse event is likely related to the study.) Probable? Yes \_\_\_\_\_ No \_\_\_\_\_

Possible (The adverse event may be related to the study.) Possible? Yes \_\_\_\_\_No \_\_\_\_\_

Unlikely (The adverse event is doubtfully related to the study.) Unlikely? Yes\_\_\_\_\_ No \_\_\_\_\_Unknown? \_\_\_\_\_

Provide a brief rationale for your assessment. State whether the same adverse event has occurred previously and provide incidence data whenever relevant.

 Was the study blind broken as a result of the event? Yes \_\_\_\_\_No \_\_\_\_\_

**Impact on Study**

**Protocol Changes**. In your judgment, is a change in the protocol necessary to reduce or eliminate the risk?

\_\_\_\_\_Yes. Attach a Protocol Amendment.

\_\_\_\_\_No. Provide a brief rationale in the space provided

**Informed Consent Document**. Are any changes required in the informed consent document(s) to better inform and protect the rights of subjects enrolled hereafter?

\_\_\_\_\_Yes. Attach two (2) revised consent forms.

\_\_\_\_\_No. Provide a brief rationale in the space provided.

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| **Impact for Existing Subjects**. Should/will subjects and/or guardians who have already consented to participate in thestudy be informed of this new information?\_\_\_\_\_Yes. Attach an information sheet or consent addendum form.\_\_\_\_\_No. Provide a brief rationale in the space provided. |
| NOTE: This form must be completely filled out.Incomplete forms will be returned to the RPI for the completion of missing information. |
| Signature of Responsible Project Investigator: | Date Signed: \_/ /  |
| Consulting Physician Report(Required for "Serious" Adverse Events whether expected or unexpected) |
| Please describe the severity of the event, the likelihood in your judgment that it was related to the research protocol, and any other information you feel would be important: |
| Signature of Consulting Physician (if required): | Date Signed: /\_ /  |
| \*\*\* FOR IRB USE ONLY \*\*\* FINAL DISPOSITION |
| Review Category:\_\_\_\_\_Expedited\_\_\_\_\_Full | Action:\_\_\_\_\_Approved\_\_\_\_\_Disapproved |

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| Recommendations: |
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| Signed by IRB Chair: | Date Signed: /\_ /  |
|  |
| Continuing Review Deadline: / \_/  |
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