ARCADIA UNIVERSITY
— COMMITTEE ON THE PROTECTION OF RESEARCH SUBJECTS

Institutional Review Board (IRB)
Adverse Event Report

PART I: EVENT TYPE

1. **Date report completed:**
2. **Relationship of Event to experimental protocol:** Choose One
3. **Type of Report:** Choose One

DEMOGRAPHICS

4. **Name of Clinical Trial Site/ Organization:**
5. **Reporter Name:**
   a. Reporter Telephone Number:
   b. Reporter E-mail Address:
6. **Research Participant's study identification number:**
   a. Research Participant's gender:
   b. Research Participant's date of birth:
   c. Research Participant's date of death (if applicable):
7. **Which Arm/Cohort/Treatment group was the subject assigned to? (if applicable):**
8. **Were there any protocol deviations/violations/exceptions for this participant?:**

☐ **Yes**
☐ **No**

If yes, please explain:

PART II: DETAILED ADVERSE EVENT INFORMATION

9. **Event Date:**
10. **Seriousness of the AE (choose one):** Choose One
11. **Description of event (What attributed to it?):**

12. **Relevant tests (e.g. x-rays) and results:**

13. **Treatment(s) of Adverse Event (Include medications used to treat this event):**

14. **Pre-existing conditions/ relevant clinical history:**

15. **Date(s) of treatment(s) of the adverse event:**

16. **Outcome of the event:** Choose One

    If other, please describe:

17. **In the event of death, was an autopsy performed?**

    ☐ **Yes**

    ☐ **No**

    If yes, date:

18. **Documentation accompanying the report (e.g., H&P, Progress Notes, Discharge Summary, Lab or Autopsy Reports, Other, etc.) If other, please describe:**