ARCADIA UNIVERSITY
— COMMITTEE ON THE PROTECTION OF RESEARCH SUBJECTS

Institutional Review Board (IRB)
Protocol Deviation Form

1. **Type of report:**

☐ Initial ☐ Follow-up

2. **Date of the occurrence:**

3. **Date the PI became aware of the occurrence:**

4. **Details of Occurrence/ PI Categorization of Occurrence:**

5. **Provide a summary description of the issue:**

6. **Describe the suspected cause:**

7. **Describe corrective actions taken or proposed, including any plans to re-consent subjects:**

8. Request for amendment of protocol (if applicable):

9. Has occurrence resolved?:

☐ Yes ☐ No

10. If applicable, is the funder aware of the occurrence?

☐ Yes ☐ No

11. Should subjects remain in study?:

☐ Yes ☐ No

12. In the judgment of the Principal Investigator:

a. Was this occurrence unexpected in nature, severity and/or frequency?

☐ Yes ☐ No

b. Is it more likely than not that this occurrence was related to the research or will affect a change in research activities?

☐ Yes ☐ No

c. Does this occurrence suggest that subjects or others are placed at an increased risk of harm than was previously recognized (consider physical harm, psychological harm, financial harm, legal risks, risks from breach of confidentiality, etc.)?

☐ Yes ☐ No

d. Does this occurrence adversely affect the rights and/or welfare of the subject(s)?

☐ Yes ☐ No

e. Does this occurrence affect the scientific integrity of the study?

☐ Yes ☐ No

f. Should the consent document be revised because of this occurrence? (If yes, also submit a request for modification with supporting documents)

☐ Yes ☐ No

g. Should the protocol be revised because of this occurrence? (If yes, also submit a request for modification with supporting documents)

☐ Yes ☐ No

h. Should currently enrolled participants be notified about this occurrence? (If yes, also submit a request for modification with supporting documents to be used for notification)

☐ Yes ☐ No

13. If applicable, attach any other relevant documents.