

**Adverse Effect/Event Report Form**

*(To be completed by the Principal Investigator)*

*Please provide all requested information: (please refer to instructions on last page)*

|  |
| --- |
| Principal Investigator: |
| Contact Person: |
| Sponsor: |
| E-mail: | Phone: | Fax: |
| Title of Protocol: |
| Event Date: | Date event reported to PI: |  |

|  |  |  |
| --- | --- | --- |
| Event Report: | Initial | Follow-Up |
| Event Location: | EU campus | External site |

Brief description of the event:

Brief description of actions taken:

|  |  |  |
| --- | --- | --- |
| Causality: *(check one)* |  | Event Severity Classification: *(check one)* |
| Definite | Possible | Serious Unexpected |
| Probable | Unrelated | Moderate Unexpected |

Protocol Modification: Is it your intention to modify the protocol/consent form to address increased monitoring or to provide new information to the research subjects?

Yes  Submit a modification request form w/revised protocol and/or consent documents

No  Explain rationale:

**DECLARATION: I certify that I have reviewed the attached report and conclude that the risk- benefit ratio of the research continues to be acceptable, and that the risks are minimized to the greatest extent possible. By signing below, I certify that the information contained in this report is correct to the best of my knowledge.**

|  |  |  |
| --- | --- | --- |
| Signature  | Print Name  | Date  |
|  Principal Investigator |
| Signature  | Print Name  | Date  |
| Faculty Sponsor (if P.I. is a student) |

**The EU-Institutional Review Board:**

IRB Chair Date

E-mail or send the completed form to:

Dr. Rodney Bassett

IRB (Institutional Review Board) Chair,

2301 Westside Drive

Rochester, NY 14624

BassettR@roberts.edu

**Guidelines for Reporting Adverse Events**

Investigators must report all UNEXPECTED adverse events of MODERATE OR GREATER SEVERITY associated with the study intervention for subjects at Roberts Wesleyan College.

Only UNEXPECTED SERIOUS adverse events associated with the study intervention that occur at an external site (i.e., sponsor-generated reports) are required to be reported.

 An adverse reaction is considered serious if it is fatal or life-threatening; requires or prolongs hospitalization; produces a disability; or results in a congenital anomaly/birth defect.

 An adverse reaction is considered to be of moderate or greater severity if it requires medical evaluation (such as additional laboratory testing) and/or medical treatment; or if it is a serious adverse reaction.

 An adverse reaction is considered to be unexpected if it is not identified in nature, severity, or frequency in the current IRB-approved research protocol or informed consent document.

 An adverse reaction is considered to be associated with the research intervention if there is a reasonable possibility that the reaction may have been caused by the research intervention (i.e., a causal relationship between the reaction and research intervention cannot be ruled out by the investigator(s)).