**Marywood University - Institutional Review Board and Exempt Review Committee**

Immaculata Hall, 2300 Adams Avenue, Scranton, PA 18509

Phone: (570) 348-6211, x.2418 or Email: [irbhelp@marywood.edu](mailto:irbhelp@marywood.edu)

**ADVERSE EVENT OR UNANTICIPATED PROBLEM REPORT**

**INSTRUCTIONS: Complete this form and submit at** [**www.irbnet.org**](http://www.irbnet.org) as a follow-up package within your existing project. The PI must e-sign in IRBNet before submitting.

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| **Select One** | **☐** | **Adverse Event** | An **untoward or unfavorable occurrence** in a human subject, including any abnormal sign (e.g., abnormal physical exam or lab finding), symptom, or disease, temporally associated with the subject’s participation in the research, whether or not considered related to the subject’s participation in the research. |
| **☐** | **Unanticipated Problem** | Any incident, experience, or outcome that is (1) **unexpected**, (2) **related** or possibly related to participation in the research, and (3) suggests that the research places subjects or others at a **greater risk of harm** (including physical, psychological, economic, or social harm) than was previously known or recognized. |

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| **Today’s Date** | Click here to enter date. | **Principal Investigator** | | Click here to enter PI’s name |
| **Study Title** | *Click or tap here to enter title.* | | | |
| **IRBNet Number** | *Click here to enter project #.* | | While viewing a project at IRBNet, the number appears at the top of each page, in brackets, directly under the photo header and next to the title. Enter only the number before the dash, which is the project number (not package number after the dash). | |

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| **REPORT INFORMATION** | | | | | |
| 1. **Report Type** | ☐ Initial report ☐ Follow up report | | 1. **Event Was** | | ☐ Expected ☐ Unexpected |
| 1. **Event Oversight** | | ☐ Internal Occurred either at MU or with an agent of MU (student, faculty, staff) | | | |
| ☐ External Occurred with unaffiliated agents and under another institution’s IRB oversight (outside researchers or an alternate clinical trial site as part of a multi-site trial) | | | |
| 1. **Event Severity** | | ☐ Severe ☐ Moderate ☐ Mild | | | |
| 1. **Relationship to Study** | | ☐ Definitely related to the research ☐ Probably related to the research  ☐ Possibly related to the research | | ☐ Doubtfully related to the research  ☐ Definitely not related to the research | |
| 1. **Action Taken with  Subject** | | ☐ None  ☐ Discontinued subject(s) permanently  ☐ Discontinued subject(s) temporarily | | ☐ Drug – reduced dose  ☐ Drug – increased dose  ☐ Drug – delayed dose | |
| 1. **Outcome of Event** | | ☐ Resolved – no follow up ☐ Event still present – being treated  ☐ Event still present – not treated ☐ Residual effects – being treated | | ☐ Residual effects – not treated  ☐ Death  ☐ Unknown | |
| 1. **Event Expected to Occur Again** | | ☐ Yes ☐ No ☐ Unknown | | | |

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|  | **YES** | **NO** |
| 1. **Did your approved application form describe the potential event?** | ☐ | ☐ |
| 1. **Did your approved informed consent form describe the potential event?** | ☐ | ☐ |
| 1. **Will you revise your informed consent form for any future subjects?** In IRBNet, attach revised consent form with only new tracking shown.  If yes, explain what you will revise: Click here to enter text.. | ☐ | ☐ |
| 1. **Will you re-consent those who have already provided consent to participate?** | ☐ | ☐ |
| 1. **Are you revising any other parts of your protocol (e.g. procedures, participants, advertisements, etc.) in order to minimize any risk?** In IRBNet, attach revised documents with only new tracking shown.   If yes, explain what you will revise: Click here to enter text.. | ☐ | ☐ |

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| **DETAILED DESCRIPTION** |
| **Provide details about the event and any plans of action.**  Click here to enter details. |

**By electronically signing in IRBNet, the principal investigator declares that the above is an accurate and complete description of the adverse event or unanticipated problem, and that upon receipt of the IRB or ERC’s review, s/he will fully and immediately implement any corrective actions required.**