**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

**DEVIATION REPORT FORM**

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

A deviation is any major or minor divergence or departure from approved research procedures, which is under the investigator's control and which takes place without prospective IRB or ERC approval. It can include divergence with approved methods and/or documents.

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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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| **DEVIATION DATE & TYPE** |
| 1. **Date Deviation Occurred**
 | Click here to enter date. | 1. **Date Deviation Identified**
 | Click here to enter date. |
| 1. **Deviation Intent**
 | ☐ Intentional (e.g. in best interest of a subject or subjects) ☐ Unintentional |
| 1. **Deviation Type**
 | ☐ Recruitment Process☐ Consent Process☐ Data Collection Process☐ Drug/Device Administration☐ Data Analysis Process | ☐ Reporting Process☐ Result of Audit Finding - Corrective Action ☐ Result of Subject or 3rd Party Complaint☐ Other  |

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| **DEVIATION SUMMARY** |
| **Describe the deviation. Include (1) the reason why it occurred, and (2) the number or subjects affected.** Click here to enter a description. |

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| **ADDITIONAL INFORMATION** |  |  |
|  | **YES** | **NO** |
| 1. **Does it affect the risk to benefit ratio, or subjects’ welfare or safety?**If yes, describe how. Click here to enter details.
 | ☐ | ☐ |
| 1. **Does it adversely affect subjects’ rights (e.g. to be fully informed, have time to consider, ask questions, refuse, agree and then withdraw, receive a consent form copy, etc.)?**If yes, describe how. Click here to enter details.
 | ☐ | ☐ |
| 1. **Does it affect the integrity of the research data?** If yes, describe how. Click here to enter details.
 | ☐ | ☐ |
| 1. **Does it affect subjects’ willingness to continue participation?** If yes, describe how. Click here to enter details.
 | ☐ | ☐ |
| 1. **Have you notified the funding sponsor about this deviation?**
 | ☐ | ☐ |
| ☐ N/A |
| 1. **Have you notified any other oversight entities (Food & Drug Administration, Data Safety Monitoring Board, etc.) about this deviation?**
 | ☐ | ☐ |
| ☐ N/A |
| 1. **Please describe the corrective action taken or planned. Include any plan to prevent this deviation from occurring in the future, if applicable.**

Click here to enter a description. |
| 1. **What documents are you revising, if any?** Attach any new documents or revised documents (with only new tracking shown) in IRBNet. Click here to enter a description.
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**By electronically signing in IRBNet, the principal investigator declares that the above is an accurate and complete description of the deviation, and that upon receipt of the IRB or ERC’s review, s/he will fully and immediately implement any corrective actions required.**