**INSTITUTIONAL REVIEW BOARD**

**REPORTABLE EVENT FORM**

**WHEN TO USE THIS FORM**

Use this form to submit a reportable event to the MU IRB in accordance with HR Policy 98.104. The following should be reported within 10 calendar days:

1. Any unanticipated problem or adverse event meeting **all of** the following criteria:
* Unexpected;
* possibly, probably, or definitely related the research study; and
* suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized.
1. Any Data Safety Monitoring Board (DSMB) or similar report which describes new information regarding risks or unanticipated problems involving risks.
2. Any instances of non-compliance, protocol deviations, and serious non-compliance.

**HOW TO SUBMIT THIS FORM**

The completed form and any supporting documents should be submitted to:

1. E-mail to orc@mu.edu;
2. Type “Reportable Event for HR-####” in subject line. HR-#### will be the MU IRB protocol number assigned to your study;
3. The PI must be the sender or must be cc’d in the e-mail.

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| **SECTION A: ADMINISTRATIVE INFORMATION** |
| **INSTRUCTIONS**: If PI is a student, complete #6 and #7. |
| A2. Study Title: |  |
| A2. MU IRB HR#: | HR- |
| A3. Principal Investigator(PI): |  |
| A4. PI e-mail: |  | A5. PI Phone#: |  |
| A6. Name of advisor: |  |
| A7. E-mail of advisor: |  |

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| **SECTION B: EVENT TYPES** |
| **INSTRUCTIONS**: Check all that apply and complete the corresponding section. |
| B1. Type of event: | [ ] Unanticipated Serious Adverse Event -------------------------------------🡪 COMPLETE SECTION C & G[ ] Unanticipated Adverse Event -----------------------------------------------🡪 COMPLETE SECTION C & G[ ] Unanticipated Problem Involving Risks to Participants or Others--🡪 COMPLETE SECTION C & G[ ] Protocol Deviation -------------------------------------------------------------🡪 COMPLETE SECTION D & G[ ] Follow-up to a previously submitted report ----------------------------🡪 COMPLETE SECTION E & G[ ] New information regarding risks or unanticipated problems ------🡪 COMPLETE SECTION E & G[ ] Complaint from participant--------------------------------------------------🡪 COMPLETE SECTION F & G |

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| **SECTION C: UNANTICIPATED AE, SAE, & PROBLEM INOLVING RISKS TO PARTICIPANT OR OTHERS** |
| **INSTRUCTIONS**: Complete the section below if “Unanticipated Serious Adverse Event,” “Unanticipated Adverse Event,” or “Unanticipated Problem Involving Risks to Participants or Others” were selected in #6. |
| C1. Date of event occurrence [mm/dd/yyyy]: |
| C2. Did the event occur internal or external to MU? [ ] INTERNAL [ ]  EXTERNAL |
| C3. Was this event unexpected in regards to the known risks of the study procedure, drug, device, or the subject’s disease or condition or individual health issues? [ ] NO [ ] YES (explain) |
| C4. Was the event more likely to be caused by study participation than circumstances or events outside the study? [ ] NO [ ] YES (explain) |
| C5. Does the event place subjects or others at a greater risk of harm than was previously known or result in (or require medical or surgical intervention to prevent) death, a life-threatening experience, inpatient hospitalization, prolonged hospitalization, persistent or significant disability or incapacity, congenital anomaly or birth defect, OR jeopardy to any subject’s rights, safety, or welfare? [ ] NO [ ] YES (explain) |
| C6. Describe the event by explaining what happened, where it happened, and who was involved. Do not include subjects’ personally identifiable information in the description (i.e., no medical record numbers, no initials, no SSN, etc.). A study subject ID number or other reference number may be used. |
| C7. Does the event impact the integrity of the research study? [ ] NO [ ] YES (explain) |

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| **SECTION D: PROTOCOL DEVIATION** |
| **INSTRUCTIONS**: Complete the section below if “Protocol Deviation” was selected in #6. If you think the deviation may occur again in the future, submitting an amendment to your study should be considered. |
| D1. Date deviation occurred [mm/dd/yyyy]: Date deviation discovered [mm/dd/yyyy]: |
| D2. Describe the deviation by explaining what and why it happened, and who were involved: |
| D3. Did the deviation result in an increased risk to the subject(s)? [ ] NO [ ] YES (explain) |
| D4. Describe any actions you have taken to prevent reoccurrence:  |
| D5. Does the deviation impact the integrity of the research study? [ ] NO [ ] YES (explain) |

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| **SECTION E: NEW INFORMATION AND FOLLOW-UP** |
| **INSTRUCTIONS**: Complete the section below if “Follow-up to a previously submitted report” or “New information regarding risks or unanticipated problems” were selected in #6. |
| E1. Describe the new or follow-up information. If this is a follow-up report, explain what the original report was for. |

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| **SECTION F: COMPLAINT FROM PARTICIPANT** |
| **INSTRUCTIONS**: Complete the section below if “Complaint from participant” was selected in #6. |
| F1. Describe the complaint, and explain what actions you have taken. |

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| **SECTION G: PI ASSESSMENT** |
| **INSTRUCTIONS:** * E-mail to orc@mu.edu;
* Type “Reportable Event for HR-####” in subject line. HR-#### will be the MU IRB protocol number assigned to your study;
* The PI must be the sender or must be cc’d in the e-mail.
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| G1. Do you recommend a change to the protocol? | [ ] YES | [ ] NO | [ ] NA |
| G2. Do you recommend a change to the consent form or consent process? | [ ] YES | [ ] NO | [ ] NA |
| G3. Will additional information and/or follow-up be provided to current and/or past subjects? | [ ] YES | [ ] NO | [ ] NA |
| G4. Will current subjects be asked to re-consent to participation? | [ ] YES | [ ] NO | [ ] NA |
| G5. Will the study be voluntarily placed on hold or stopped? | [ ] YES | [ ] NO | [ ] NA |
| G6. Other (explain): |

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| **\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\* ORC ONLY \*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*** |
|  [ ]  Acknowledged | Date: | Name: |
|  [ ]  Additional Information Needed prior to determination |
|  [ ]  Refer to Full Board |
|  [ ]  Refer to Chair, Vice Chair or Other Member |
|  [ ]  Request Amendment |
|  [ ]  Other |
| Comments: |