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|  | Institutional Review Board  **UNANTICIPATED PROBLEM REPORT FORM** |

Unanticipated problem report forms should be submitted to the Office of Research, or via email to irb@mica.edu. Electronic submissions are encouraged.

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| **General Information** |

Project Title:

Principal investigator:

Mailing address:

P. I’s Telephone number:

Email:

Did the problem occur at a local site  or an outside site ?

Date of the unanticipated problem:

Date the research team discovered the problem:

Date and description of latest study-related intervention (relevant to this event):

Did the problem result in injury to the participant?  Yes  No

If yes, please describe:

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| **Description of Unanticipated Problem**  (adverse event, incident, experience, or outcome) |

List key words describing the problem (e.g., a breach of confidentiality):

Briefly describe the problem (Include information such as nature of the unanticipated problem, description of the situation that led to the problem, individuals present, referral for medical/psychological care, etc.):

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| **Determination of Unanticipated Problem** |

Yes  No The problem is unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied.

If yes, explain the basis for determining that the problem is unexpected:

Yes  No The problem is related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research).

If yes, explain the basis for determining that the problem is related or possibly related:

Yes  No The problem places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

If yes, explain the basis for determining that the problem placed participants or others at a greater risk of harm:

If you checked NO to any of the items in Section III above, the problem is not considered an “unanticipated problem” and you are not required to complete and submit this form to the IRB. However, you are required to report the problem in the summary to the IRB at the time of continuing review (annual review).

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| **Corrective Actions** |

Yes  No Should the protocol be revised?

If yes, provide a description of the proposed protocol changes and attach a revised protocol (with changes indicated):

Yes  No Should the research be suspended or terminated?

If yes, describe procedures you will follow for the suspension or termination of the research:

Yes  No Should enrolled participants be notified about this problem/event?

If yes, attach a revised consent form or draft letter of notification with this report.

Yes  No Should other corrective action be taken in response to the unanticipated problem?

If yes, provide a description of the proposed corrective action:

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| **Notification of Entities** |

Yes  No  N/A Sponsor has been notified (either federal or non-federal).

FOR IRB USE ONLY

UW IRB chair/designee review of problem report:

The problem:

Does not represent an unanticipated problem involving risks to participants or others (review by expedited procedures)

Does represent an unanticipated problem involving risks to participants or others (refer to convened IRB for review)

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Signature of IRB chair/designee Date

Investigator’s signature Date