INSTRUCTIONS
FOR COMPLETING THE
ADVERSE EVENTS REPORTING FORM

A. Project Information
Follow instructions and provide complete information requested. If the research is a multi-site collaborative project, you should also follow the reporting procedures of the approving IRB.

B. Adverse Event & Unanticipated Problem—Definitions
According to guidance from the federal Office for Human Research Protections, an ***adverse event*** is defined as any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign, 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.* An ***unanticipated problem*** is an incident, experience, or outcome during participation or apparently resulting from participation in the research that was not foreseen by researchers, including physical, psychological, economic, or social harm. If you are unsure whether an incident during or as an apparent result of the research activity fits these definitions, please contact the IRB Chair.

C. Corrective Actions
This would include any actions taken at the time of the event to attend to the affected participant, or at the time researchers became aware of the event or problem, as well as follow-up actions such as suspension of protocol, communication with others, etc.

D. Signature
In the interest of timely reporting, a digital version of this form may be submitted to the IRB Chair via email with an electronic signature, to be followed by a pdf or hard copy with a written signature. For an electronic signature, type the full name and the UMW user ID of the signer. Submit the form to the IRB Chair through the UMW email system.