IRB #_____

Unanticipated Problems Involving Risks to Participants or Others

Worksheet: University & Medical Center Institutional Review Board

Principal Investigator Name: [Please specify]

Study Title: [Please specify]

The phrase "unanticipated problems involving risks to participants or others" encompasses those events in human research that are unanticipated (including unexpected either in severity or frequency), related or possibly related to the administration of a research intervention, and involves the risk of harm to the participant or others. Based on guidance from the Office for Human Research Protections (OHRP) and the Food & Drug Administration (FDA), ECU UMCIRB considers *unanticipated problems*, in general, to include any incident, experience, or outcome that meets **all** of the following criteria:

☐ Yes ☐ No 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;

☐ Yes ☐ No related or possibly related to participation in the research (in this guidance document, *possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures or interventions involved in the research); and

☐ Yes ☐ No suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

An unanticipated problem can also be a breach of confidentiality, an incidence of noncompliance by someone on the research team (whether intentional or by accident) and these should be reported as expeditiously as other types of serious events.

If all of the criteria above are not checked "Yes", this event is **not** reportable. This signed page should, instead, be filed with your research records, along with any accompanying documentation regarding the event. If all of the criteria above are checked "Yes", complete the appropriate Reportable Event application within ePirate.

I attest that I have evaluated the circumstances of this event and determined that it does not meet the criteria for reporting to the University & Medical Center Institutional Review Board.

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Signature of Principal Investigator Date