

**Unanticipated Problem or Adverse Event Form for Research Involving Human Subjects**

**NMU Institutional Review Board (IRB)**

If a subject suffers an injury during research, or if there is an incident of non-compliance with IRB policies and procedures, the investigator must take immediate action to assist the subject and notify the IRB chair and NMU’s IRB administrator within 48 hours.

* ONLY for use by PIs with protocols approved prior to Fall 2023 using paper forms AND for instructional purposes

Human Subjects Project Number:

Principal Investigator:       Department:       E-mail:

Co-Investigator:       Department:       E-mail:

Co-Investigator:       Department:       E-mail:

Project Title:

Funding Agency (if applicable):

**YOU ARE REQUIRED TO PROVIDE THE FOLLOWING INFORMATION AT THIS TIME:**

1. Describe the unanticipated problem or adverse event in detail along with action taken.

1. Indicate the number subjects that participated in the study since the last reporting period.

1. Identify numbers and reasons for withdrawal of subjects from research, if applicable.

1. List any complaints about the research, if applicable.

1. Summarize any recent literature, findings, or other relevant information about risks associated with the research, if applicable