Unanticipated Problem/Serious Adverse Event Reporting Form (UP/SAE)

Federal regulations and Michigan Tech policy require investigators to promptly report to the Office of Compliance, Integrity, and Safety (CIS) all unanticipated problems and serious adverse events (UP/SAE) involving harm or risk of harm to human research participants.

If the adverse event includes a **fatality or hospitalization, immediately** notify the CIS Director, Joanne Polzien, 906-487-2902.

This form should be submitted on IRBNet as an additional package to the existing project within 7 calendar days of the UP/SAE. This information should also be provided to sponsors, and any partnering agencies.

An ***unanticipated problem*** is an occurrence that negatively affects one or more research participants that is related or possibly related to the research but was not expected based upon available data or experience. This ***includes any anticipated adverse event that has greater severity of harm or frequency among participants than originally anticipated.***

Adverse events that are anticipated and fully described in the consent form do not need to be reported after each occurrence unless they meet the standard described above. [Note: All anticipated adverse events must be reported in full on the **Update / Modification / Completion Form**].

Researcher Name:

Department: Phone Number:

Protocol Title:

Sponsor(s) / funding source for the research if any:

This ADVERSE EVENT is (check one):

- ☐ Judged to be related to the research or possibly related to the research activity
- ☐ Of unknown relationship to the research activity
- ☐ Not related to the research activity

Please explain your response:

Has the same adverse event occurred previously? If so, how many individuals have experienced this same or similar adverse event?

SUBJECT INFORMATION: Identify the subject by participant ID (name or number) and state date, time, and location of the unexpected problem or serious adverse event.

NATURE OF ADVERSE EVENT: Describe the behavioral nature of the adverse event.

INFORMED CONSENT / ASSENT DOCUMENT: Are any changes required in the consent/assent document(s) to:

a. Better inform and protect future participants?

☐ Yes – Submit a revised consent/assent form and clearly indicate the changes

Or

☐ No – Provide a brief rationale why no alternation is indicated:

b. Re-consent active participants?

☐ Yes – Submit a revised consent/assent form and clearly indicate the changes

Or

☐ No – Provide a brief rationale why no alternation is indicated:

ELECTRONIC SIGNATURES REQUIRED ON IRBNet FOR SUBMISSION

The following person(s) must sign the IRBNet Adverse Event or Unexpected Problem submission:

- Principal investigator
- All co-investigators whom have been granted full access to the project