Instructions for Submitting an Unanticipated Problem or Serious Adverse Event (UP/SAE) Report

This form should be used to report any unanticipated problem or serious adverse event which occurs while conducting the research.

If the adverse event includes a **fatality or hospitalization**, **immediately** notify the Office of Compliance, Integrity, and Safety Director, Joanne Polzien, 906-487-2902 or email jpolzien@mtu.edu.

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, study coordinating centers, and 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 applications for Renewal or Continuing Review or the Closed Protocol Reporting Form].

**Step 1** - Log in to IRBNet (**www.IRBNet.org**). This will take you to the My Projects page.

**Step 2** – Click the title of the study containing the problem or event, then click Project History (left side of the screen).

**Step 3** – Click Create New Package in the center of the Project History page, then click New Document Package (should say Status: Work in Progress).

**Step 4** – This brings you to the Designer page.
   a. **Step 1: Select a Document:** Select document type “Unanticipated Problem / Serious Adverse Event Reporting Form” (from the drop-down menu), complete, and save to your computer.
   b. **Step 2: Documents in this Package:** Click Add New Document, select Document Type Unanticipated Problem or Adverse Event Report and upload the completed form saved to your computer under Step 1.

**Step 5** – Click Sign this Package (left side of screen). Select your title from the drop-down menu, click Sign.

**Step 6** – Click Submit this Package (left side of screen). In the Submission Type drop-down box, choose Unanticipated Problem or Adverse Event. Click Submit.
If you have any questions, please contact our office at 487-2902 or email IRB@mtu.edu for human subject studies, IACUC@mtu.edu for animal use studies, or IBC@mtu.edu for institutional biosafety.