

## **IRBNet** 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](mailto: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](http://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](mailto:IRB@mtu.edu) for human subject studies, [IACUC@mtu.edu](mailto:IACUC@mtu.edu) for animal use studies, or [IBC@mtu.edu](mailto:IBC@mtu.edu) for institutional biosafety.