Valparaiso University
Institutional Review Board (IRB)
Office of Sponsored and Student Research

INSTITUTIONAL REVIEW BOARD (IRB)
UNANTICIPATED PROBLEMS

1. Purpose

Investigators make concerted efforts to conduct research in a way that minimizes risk to the participants. However, despite their best efforts, unanticipated problems occur. Unanticipated problems must be reported to the IRB to assure the safety and well-being of research participants.

2. Definitions

An unanticipated problem is any incident, experience or outcome that is:

- *Unexpected* (in terms of nature, severity or frequency) given the description of the likely harms in the protocol, the consent form or the other materials submitted to the IRB, and the characteristics of the subject population;
- *Related* to a subject's participation in the research; and
- Suggests that the research places subjects or others at *greater risk of harm* - physical, psychological, economic, or social - than was previously known or recognized.

Examples include:

- Serious Adverse Event (SAE);
- Unintentional or intentional change to the IRB-approved protocol (protocol deviation);
- Breach of privacy or confidentiality;
- Complaint from a subject or family member;
- Lab or medication errors that may involve risk to subjects;
- Disqualification or suspension of a study investigator;
- Change in the status of a subject that might affect their eligibility to remain in a study, such as becoming pregnant or becoming incarcerated;

- New information that suggests an unexpected change to the risk-benefit assessment or results in sponsor-imposed suspension of study or enrollment due to newly recognized risk;
- Change in FDA labeling because of adverse consequences;
- Withdrawal of investigational agent due to adverse events; and
- Publication in the literature, study monitoring reports, DSMB reports, or interim study results

3. Required Reporting to the IRB

The Valparaiso University IRB requires that problems and events that meet the criteria for being an unanticipated problem be reported promptly.

Reports that suggest that subjects or others are placed at a greater risk of harm than initially anticipated should be accompanied by an Action Plan that outlines the steps that will be taken to mitigate the newly identified risk(s). The Action Plan may include one or more of the following:

- A modification to the protocol;
- A modification to the consent form;
- A change in the study procedures;
- Changes to the research team's education or oversight procedures; and/or
- A notification of current or former study participants.

The IRB will review the problem/event and the Action Plan. Any corrective action should be considered part of the IRB review/approval of the project and be implemented by the PI accordingly.