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

INSTITUTIONAL REVIEW BOARD (IRB)
NONCOMPLIANCE

1. Purpose

Noncompliance occurs when an investigator or research team fails to comply with the requirements of an applicable law, regulation, or institutional policy pertaining to the protection of human subjects, and/or with the requirements or determinations of an IRB. While some instances of noncompliance have little effect on the research study or its participants, other types of noncompliance can put research participants at risk for harm or disrespect participants' autonomy. Serious or continuing noncompliance must be reported to the IRB.

2. Definitions

Serious noncompliance is noncompliance that has a significant adverse impact on the rights or welfare of the participants or on the integrity of the data.

Continuing noncompliance is a pattern of behavior that indicates an inability or unwillingness to comply with applicable laws, regulations or institutional policies pertaining to the protection of human subjects and/or with the requirements or determinations of the IRB. Examples include:

- Failure to obtain prospective IRB approval for an additional research-related activity not previously approved as part of the research protocol (unapproved protocol deviation);
- Failure to obtain required signed informed consent or HIPAA forms from subjects; or
- Enrolling a participant who does not meet the selection criteria.

3. Reporting Noncompliance

Instances of noncompliance must be reported to the IRB Chair within 5 days of the incident occurring or of the investigator's knowledge of the incident. Reports must be in writing (i.e., email) and contain sufficient detail and accompanying documentation to enable the IRB to understand and review the noncompliance and its potential impact on the project and its participants.

4. IRB Review of Noncompliance

The IRB will review the noncompliance report in a timely manner. Possible outcomes of the IRB review include:

- Suspension or termination of the research project;
- Notification of current participants and "re-consenting" them;
- Requiring modifications to the protocol and/or consent documents;
- Re-educating participants about possible impacts;
- Increasing frequency of continuing reviews or requiring additional monitoring requirements; and/or
- Requiring additional training of the investigator and the research team members.

The IRB has the authority to suspend or terminate approval of research that has been associated with unexpected serious harm to participants. The IRB will provide a statement explaining the reason for the action and will promptly report this action to the Provost's Office, the funding agency/sponsor (if applicable), the Office for Human Research Protections (OHRP), and other applicable regulatory authorities.