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

INSTITUTIONAL REVIEW BOARD (IRB)
REVIEW PROCESS AND TYPES OF REVIEWS

1. Purpose

The Institutional Review Board (IRB) reviews applications in accordance with the Revised Common Rule, the Belmont Report, and other applicable federal and state laws and regulations.

2. Pre-Review Determinations

The IRB only reviews research projects that meet the federal definition of "research" involving "human subjects." The IRB has developed an online questionnaire to assist Principal Investigators (PI) in determining whether their project meets the federal definition of human subjects research that requires IRB oversight. The PI will be informed if the project does not require IRB oversight. If the project requires IRB review, the PI will be informed of the type of review that is appropriate for the project.

If the PI who completes the questionnaire is a student, faculty mentors must approve the answers before the IRB will make a determination. Once this approval is received, the IRB will contact the faculty mentor and the student investigator to let them know if IRB review is required.

3. Exempt Reviews

Some studies that meet the federal definition of research may be exempt from IRB oversight. However, the IRB must make this determination, not the PI. The application is submitted online. The IRB chair or an experienced IRB member will read these applications and contact investigators to notify them if their project does or does not meet the criteria for exempt review. Data collection may not begin until the IRB has sent a notification that the project meets the criteria for exempt review. Continuing review is not required for exempt research.

4. Limited Reviews

Studies that meet all of the requirements for exemption categories 2 and 3 as defined by the OHRP but include identifiable data are eligible for limited review. Limited review focuses on the privacy and confidentiality of the data. Limited reviews will be conducted using the same

review mechanisms used for expedited review. Continuing review is not required for projects completing Limited reviews.

See regulations §46.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8) here for OHRP definitions of limited reviews.

5. Expedited Reviews

Some studies that meet the federal definition of human subjects research may be eligible for expedited review if they present no more than minimal risk to human subjects and involve only the activities defined in the expedited review categories described by the OHRP. The application for expedited review is identical to the application for full review. The IRB determines if a project meets the criteria for expedited review. If it does not, the study goes through full review. Studies that go through the expedited review process are reviewed by at least one experienced member of the IRB or the IRB chair, but may be reviewed by more than one IRB member or a convened IRB. Continuing review is not required for expedited research.

6. Full Reviews

Studies that meet the federal definition of human subjects research and present more than minimal risk to human subjects or do not fall into one of the expedited categories described by the OHRP require full IRB review. Studies that go through the full review process are initially reviewed by at least two IRB members who will do a preliminary review and seek additional information from the PI as necessary before the application goes to the full IRB committee for review. All studies that require full review are reviewed by a convened IRB. IRB approval is valid for one year, unless circumstances arise to change that. Continuing review is required for research that goes through full IRB review and lasts longer than one year.

7. Continuing Review

Continuing review is required for research requiring full review for which interventions are ongoing for more than one year from the date of IRB approval. Continuing review is ***not*** required for the following research:

- Research that is eligible for exempt, limited or expedited review,
- Research that has completed all interventions and now only includes analyzing data, even if the information or biospecimens are identifiable, and
- Research that has completed all interventions.

8. Changes to Approved Protocols

Once a research protocol has been reviewed and approved by the IRB, the approved protocol should be followed consistently. In the event that circumstances change and the protocol must be changed, the PI must submit the requested change to the IRB for review and approval. The change must not be implemented until IRB approval is received. The magnitude of the change and the nature of the protocol will determine the level of review required.

The exception to this rule is when a change in protocol is needed to prevent immediate harm to research subjects. In this case, the hazardous situation must be reported to the IRB immediately and the change in protocol submitted to the IRB as soon as possible.