

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

**INSTITUTIONAL REVIEW BOARD (IRB)**  
**COMPOSITION AND FUNCTIONING**

**1. Purpose**

The Institutional Review Board (IRB) is Valparaiso University's authorized body to review research involving human subjects to: 1) Assure compliance with federal and state laws and regulations; 2) Safeguard the welfare, rights and privacy of all persons who participate as subjects in research projects conducted under the University's auspices; and 3) Ensure that research subjects are aware of the rights and protections available to them.

The IRB's review and decision-making process are founded on the principles laid out in the [Belmont Report](#), the [Revised Common Rule](#), and related laws and regulations. The IRB reviews all protocols conducted under the University's auspices whether led by faculty, staff or students as well as research conducted by outside investigators who are using University students, personnel, facilities, or data collected at the University.

**2. Composition**

The IRB is comprised of at least five members representing various departments/colleges and areas of expertise. Membership will include both scientists and non-scientists as well as one member who is not affiliated with the University. Membership will also include both male and female members, with representation of minority populations (when possible). The IRB will be led by the IRB Chair with additional support provided by the IRB Administrator. IRB members are appointed by the President with appointments and renewals facilitated by the Associate Provost for Faculty Affairs. The IRB Administrator will maintain a roster of IRB members.

**3. Terms**

IRB members, including the Chair, will serve up to 4-year terms. Terms are renewable at the discretion of the Associate Provost for Faculty Affairs. As feasible, terms will be staggered so as to assure a mix of more/less experienced IRB members.

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**4. Meeting Schedule and Quorum**

The IRB will meet monthly to review Full applications and conduct other IRB business. At meetings where Full applications are reviewed, a quorum must exist in order to vote on the application. A quorum is defined as a simple majority of the full IRB membership, including the IRB Chair. In months where the review of a Full application is not required, meetings will focus on training.

**5. Training**

New members will participate in orientation with the IRB Chair and IRB Administrator.

Service on the IRB requires familiarity with federal rules and regulations, the principles of the Belmont Report, terms of the Revised Common Rule, and ethical standards in research with human subjects. IRB members are required to complete training as determined by the University.

Currently, the University uses the CITI Program for online training. IRB members are required to complete the "IRB Members" class and several additional individual modules. The IRB Chair is required to complete the "IRB Members" class, the "IRB Chairs and Vice Chairs" class, the "Institutional/Signatory Official: Human Subject Research" class, and additional individual modules. Training certification is valid for 4 years after which it must be renewed. In addition, all IRB members are required to read the Belmont Report and the IRB Chair is required to read the Revised Common Rule. IRB members are encouraged to refresh their knowledge periodically and explore other CITI classes as needed to effectively function as an IRB member.

For Expedited reviews, IRB members will observe at least two discussions among committee members regarding Expedited applications. These discussions usually take place over email and the new member will be copied on all conversations. After observing discussions regarding the two applications, new members will serve as an "extra" reviewer on at least two Expedited applications where they offer input but they do not vote. After serving as an "extra" reviewer on at least two Expedited applications, the new IRB member will serve as a voting member for Expedited reviews. These reviews may be applications that the IRB is considering or they may be case studies that the IRB is completing for training.

For Full reviews, new IRB members will observe at least one convened Full review meeting before being allowed to vote on Full reviews. This Full review may be of an application submitted for review or it may be a case study that the IRB is completing for training. After observing one meeting, the IRB member may participate as a voting member on Full applications.

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**6. Application Review Responsibilities**

The IRB Chair assigns applications to reviewers as needed. Some reviews are done individually with the reviewer's comments and recommendations returned to the Chair. Full reviews are done in a group setting. IRB members are expected to respond promptly to requests and to fully participate in IRB discussions. IRB members will use a checklist to assist in the evaluation of the application. This checklist will also be used during convened Full review meetings to guide the discussion, assure consistency among reviews, and provide documentation of the discussion.

**7. Additional IRB Member Responsibilities**

From time to time, IRB members may be asked to perform responsibilities beyond reviewing applications. These activities may include meeting with faculty and students to explain the IRB process and conducting formal training sessions on campus.

**8. IRB Chair Responsibilities**

The IRB Chair coordinates the activities related to reviewing applications. The Chair works with IRB staff to respond to Questionnaire submissions, and Exempt and Limited applications. The Chair assigns Expedited reviews, Limited reviews, and pre-reviews for Full applications to IRB members. The Chair facilitates the group discussion for Full reviews. The Chair is a voting member of the IRB. The Chair is also involved with process improvement, development of policies and procedures, training, and other IRB-related activities as needed. The Chair serves a 4-year, renewable term.

**9. IRB Administrator Responsibilities**

The IRB Administrator provides administrative oversight and support for the IRB. The Administrator leads efforts to develop/update policies and procedures, prepare and conduct training, assure member compliance with required training, identify future IRB members, and other related activities. The IRB Administrator assures that procedures are reviewed at least annually and are updated in accordance with changes in laws, regulations, and University policies with input and advice from the IRB Chair, IRB members, and other University personnel as appropriate.

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The Administrator is not an IRB member but attends meetings to take minutes and assist the Chair, as needed. The IRB Administrator is a University staff member and serves as IRB Administrator as part of his/her role as Director of Sponsored and Student Research.

**10. Use of Consultants**

Depending on the application being reviewed, it may be advisable to invite an expert to join the IRB review discussions to help assure that the IRB takes special considerations into account. The consultant may provide a written report and/or join the convened IRB meeting. The consultant's role is to share specific expertise; they do not vote on applications. Special topics may include juvenile offenders, the elderly, non-English-speakers, and immigrant populations.

**11. Conflict of Interest**

When an IRB member has a conflict of interest regarding an application, the IRB member must inform the IRB Chair and recuse him/herself from discussions and voting. Consultants are also required to disclose any conflicts of interest.