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

### INSTITUTIONAL REVIEW BOARD (IRB) FACULTY SUPERVISOR REQUIREMENTS

#### Introduction

Valparaiso University encourages students – undergraduate and graduate – to engage in appropriate research to further their education and training. Research can be a powerful way to help students engage with pressing concerns in their fields and provides skill-building that may not come from classroom experiences. The Valparaiso University Institutional Review Board (IRB) oversees human subjects research in accordance with the Belmont Report, the Revised Common Rule (45 CFR 46), other laws and regulations, and Valparaiso University policies.

All students acting as Principal Investigators (PIs) or who are members of a research team must be supervised by a faculty member. The faculty supervisor must be a member of the Valparaiso University faculty. The faculty member is considered the responsible party for assisting the student PI in making ethical decisions throughout the life cycle of the research project. The IRB holds the faculty supervisor responsible for the overall management of the research project in conjunction with the student PI. Management of the research project encompasses the ethical, administrative, fiscal, and applied elements of a project.

### Faculty Supervisor Responsibilities within the Valparaiso University Context

The IRB oversees human subjects research that meets a specific federal government definition. Valparaiso University uses an online questionnaire to determine whether this definition is met. If a proposed project meets the federal definition and requires IRB oversight, an IRB application must be completed and submitted to the IRB for its review. Online applications are provided for each of the four levels of IRB review as defined by the Revised Common Rule. The questionnaire and applications can be found here <a href="https://www.valpo.edu/sponsored-and-undergraduate-research/sponsored-research/institutional-review-board-2/">https://www.valpo.edu/sponsored-and-undergraduate-research/sponsored-research/institutional-review-board-2/</a>.

Student PIs completing a questionnaire must identity their faculty supervisor. The faculty supervisor must review the student's application and attest to its accuracy and completeness. Many class projects do not meet the federal definition of research requiring IRB oversight; the questionnaire will alert the student PI to the need for an IRB application. If IRB oversight is required, the student PI must complete the appropriate IRB application. As with the questionnaire, the faculty supervisor must be identified in the IRB application and that faculty supervisor must attest to the accuracy and completeness of the student's IRB application.

Regardless of whether a research project requires IRB oversight, all research must be conducted ethically and with regard to the safety and autonomy of the human subjects. Faculty supervisors are responsible for teaching and guiding student PIs as they conduct their projects, from the development of the initial concept to IRB review to the conduct of the research to data analysis to the dissemination of the results.

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#### **General Faculty Supervisor Responsibilities**

In general, the faculty supervisor is required to:

- Accept responsibility for protecting the rights and welfare of human research subjects;
- Fulfill the University's training requirement (<u>www.citiprogram.org</u>) and understand the ethical standards and regulatory requirements governing research activities with human subjects;
- Ensure the student PI and faculty supervisor have sufficient training and experience to conduct the research according to the protocol, including but not limited to any cultural sensitivities/norms and/or language/dialect spoken;
- Collaborate with student PIs during the preparation of an IRB application and ensure the proposed research complies with the ethical principles outlined in the Belmont Report, human subject research laws and regulations, and Valparaiso University policies;
- Report any real or potential conflicts of interests in compliance with Valparaiso University's conflict of interest policy;
- Ensure all research activities have IRB approval and any other approvals required by Valparaiso University before human subjects are involved, and implement the research activity as it was approved by the IRB;
- Ensure all research activities are conducted in compliance with applicable policies;
- Consult with the student PI on a regular basis to monitor progress;
- Assist and supervise the student PI in problem-solving if a problem or concern arises;
- Ensure the confidentiality and security of all information obtained from and about human subjects, and that the privacy of subjects is maintained;
- Ensure the student PI promptly reports any adverse events, protocol deviations, or other unanticipated problems or reportable events to the IRB in a timely manner; and
- Ensure a Project Closure Form is submitted to the IRB upon completion of the research. In the event that the student PI is unable or unwilling to do so, the faculty supervisor must do so before the student PI graduates or otherwise leaves Valparaiso University.

In addition to the responsibilities mentioned above, based on past experience with student PI research projects, faculty supervisors should pay special attention to the following:

### **Prior to the Project**

Faculty supervisors must discuss the general principles of ethical conduct in research with student PIs prior to the initiation of the project, including but not limited to:

- Protection of vulnerable/protected participants (children, prisoners, cognitively impaired, etc.) and ways to manage/minimize the use of sensitive topics (sexual activity, illegal behavior, victimization, etc.);
- Review projects for, and suggest ways to maximize privacy and confidentiality and maintain data security. This includes collecting data anonymously, how and where data is stored, and the destruction of data; and
- Whenever participants are asked to provide data (e.g., interview, survey), explain to them who is conducting the project, what it is about, what it is for, and any other relevant information.

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#### **During the Project**

As research projects are undertaken, faculty supervisors must ensure that all surveys/ questionnaires/ interviews are preceded by a disclosure of the following to the respondent. If an information sheet or recruitment materials are used, these points must be in those documents:

- The student PI identifies themselves as a student who is performing the activity to fulfill a course requirement, and the course is specifically identified;
- The name and contact information of the faculty supervisor to contact for questions;
- The persons who have access to the individual data and/or summarized results (e.g., instructor only, company/organization/agency); and
- Respondents are informed that their participation is completely voluntary and confidential.

At every stage of the project, intentional care should be taken to protect the rights and welfare of the individuals who act as participants. Standard research practices should be employed, such as obtaining consent, ensuring confidentiality, responsibly conducting fieldwork, and giving participants a contact name for the study. It is the faculty supervisor's responsibility to make sure that the student PI is educated and guided throughout the process.

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