

Valdosta State University

Policy Guidance

Research Activities under the Jurisdiction of the Institutional Review Board (IRB)

IRB Jurisdiction

The IRB is a federally mandated administrative body established to protect the rights and welfare of human research participants recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated. The IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified by both the federal regulations and local institutional policy. Research that has been reviewed and approved by an IRB may be subject to review and disapproval by officials of the institution. However, those officials may not approve research if it has been disapproved by the IRB (Part 45, Code of Federal Regulations, Chapter 46, Paragraph 112).

An organization is considered to be engaged in research when its employees or agents intervene or interact with living individuals for research purposes or obtain individually identifiable private information for research purposes (45CFR46.102(f)). Agents include all individuals performing institutionally designated activities or exercising institutionally delegated authority or responsibility.

The Valdosta State University Institutional Review Board (IRB) for the Protection of Human Research Participants, is a federally mandated body within the University that is responsible for protecting the rights and welfare of human participants when the university is engaged in research.

All University Institutional Research Board (IRB) research involving minor children under the age of eighteen shall be governed by and comply with all requirements of the Valdosta State University IRB, the University System of Georgia and Valdosta State University's policies for programs serving minors.

Definition of Research

Research is defined by federal regulation as "a systematic investigation, including research development, testing and evaluation, designed to develop **or** contribute to generalizable knowledge" (45CFR46.102(l)). The VSU IRB has adopted this definition of research. Because the federal regulations do not further define systematic investigation or delineate activities that constitute a contribution to generalizable knowledge, the VSU IRB offers the following guidance to assist faculty, staff, and students in determining if proposed activities involving humans are classified as research for the purpose of IRB oversight.

The VSU IRB considers any type of quantitative or qualitative study, including experimental, nonexperimental, and quasi-experimental designs; observational studies; oral history; action research in an educational setting; evaluation of public health, human service, and educational programs; and any other commonly accepted research practices specific to the disciplines (such as ethnographic research) to constitute a systematic investigation. The VSU IRB further interprets the federal definition of research to apply when the initial intent of the activities is to develop new knowledge that will be shared through publication of results or some other form of broad public dissemination.

Only those activities, which are a systematic investigation *or* are intended to contribute to generalizable knowledge are within the IRB's federally-mandated purview. The VSU IRB also includes within its purview qualitative studies that are intended to contribute to a body of disciplinary knowledge. There may be occasions when a systematic investigation is undertaken, but there is no intent to publish or otherwise publicly disseminate findings. An example is a systematic evaluation of a practice, such as drug therapy or a behavioral intervention, to determine efficacy but without an attempt to infer causality or to generalize results. This type of activity does not meet the federal definition of research and is not subject to IRB oversight.

More commonly, particularly in clinical practice and in educational settings, information that is developed without a systematic plan is subsequently shared publicly. For example, a faculty member engaged in providing clinical services may be presented with an interesting case that he/she wishes to share with other clinicians at a professional meeting. Although the meeting attendees may learn something of value from the case study that may later be useful in clinical practice, the information was not obtained through a systematic investigation, nor was the intention of developing a case study the likely intent when the client first received services. Therefore, this activity is not considered research and is not subject to IRB oversight.

Research Subject to IRB Oversight

All research involving human participants conducted by Valdosta State University faculty, staff, and students that meets the federal definition of research, as interpreted by the VSU IRB is subject to IRB oversight. Some types of research projects may be determined to be exempt from IRB review. Authority for determination of exemption from IRB review has been delegated by the IRB to the Office of Sponsored Programs & Research Administration. Research protocols that are not exempt from IRB review may be eligible for an expedited review process in which an expediting team reviews and either approves the research or refers it for a full board review. Non-exempt research that does not qualify for expedited review must be reviewed and acted on during a convened meeting of the IRB.

Class Assignments Intended to Teach Research Methods

Most class assignments that involve interaction with people outside the classroom are intended primarily to teach research methods and most frequently deal with the collection of information that is not considered personal or private. For example, although a survey about satisfaction with a community recycling program involves participants, satisfaction with a public service would not be considered personal information. Often, the methods employed in class assignments are not as robust as would be required for peer reviewed research. For example, students may propose to use a convenience sample for the class project, whereas, in the world of peer-reviewed research, the research question might call for a random sample or a stratified random sample and a much larger sample drawn from the population. Likewise, although the results may be shared at an on-campus poster presentation or at a professional meeting primarily to give students experience presenting, most class assignments are not intended to contribute to generalizable knowledge or a disciplinary body of knowledge.

Although most class assignments are designed to teach research methods and are not the type of activities typically overseen by the IRB, there are instances when the nature of these projects is such that participants could be put at some risk of harm. For example, if the student proposes to ask women visiting a free health clinic about experiences with spousal abuse and the women's responses can be linked to their identities; there is risk of harm if confidentiality is breached. At the least, breach of confidentiality could create emotional stress for the participant; at worst, it could lead to escalated violence against the woman. In addition to its

federally mandated role, the IRB has been given an institutional role of reviewing those classroom projects that have the greatest potential for physical, psychological, social, or financial harm to the participants.

The types of class projects involving outside participants that fall within the purview of the IRB are those that:

- Are undertaken with the intent to produce results that will be submitted for peer-reviewed publication or presentation;
- Include minors (e.g., persons under the age of 18);
- Collecting identifiable information (e.g., signatures);
- Targets potentially vulnerable individuals (e.g., those whose capacity to freely give consent may be compromised because of socio-economic, educational, or linguistic disadvantage; cognitive impairment; advanced age; or terminal illness);
- May place pregnant women and/or fetuses at risk of physical harm;
- Deal with a topic of a sensitive or personal nature in a way in which anonymity cannot be sustained and the examination or reporting of participant responses or behavior may be potentially stigmatizing or place the participant at more than minimal risk physically, psychologically, socially, or economically or for civil or criminal liability.
- Involves any other type of activity that places the participants at more than minimal risk, considering both the probability and the magnitude of harm.

Other student-conducted class assignments that are not subject to IRB oversight include those that:

- Are conducted solely within the confines of the classroom or within a departmental research participant pool if they:
 - are a general requirement of a course,
 - have the sole purpose of developing the student's research skills, and
 - will be overseen by a faculty member; or
- Are conducted outside the classroom and outside departmental research participant pools, provided they do not involve minors, do not target vulnerable adult populations, do not pose a risk of physical harm to pregnant women and fetuses, do not deal with a topic of sensitive or personal nature, or do not involve any type of activity that places the participants at more than minimal risk considering both the probability and magnitude of harm.

Additional student-conducted research activities that are not subject to IRB overview as independent research protocols include those that:

- Are part of a larger research project that has current Valdosta State University IRB approval, and the approved protocol includes student engagement in the specific activities; or
- Are part of a larger research project that has current approval of a federally assured IRB at another institution.

Research Using Existing Data

The IRB is responsible for reviewing research that involves the use of private data previously collected about individuals even if there is no additional interaction or intervention with those individuals planned. Depending on the nature of the data and the reason for their initial collection, such studies are often either determined exempt from IRB review or may be reviewed via the expedited process.

On occasion, activities conducted by employees or students of VSU that did not initially require IRB oversight may provide the impetus for research that will require IRB consideration. For instance, a professor teaching research methods classes may have collected results of student projects related to a particular human behavior over a period of years. When the professor begins to see some interesting trends, he/she decides to use the results of the student projects as research data with the hopes of producing a scholarly publication. Because the professor now intends to use data about the human participants the students observed and will analyze the data in a systematic manner with the intention of publishing, he/she must receive clearance from the IRB to use the existing data before beginning the research.

Responsibilities of VSU Researchers, Faculty Advisors, and Faculty Teaching Research Methods

The researcher is primarily responsible for knowing and understanding the ethical principles governing human participant research and for applying those principles in research activities. The researcher should also be knowledgeable of codes of conduct applicable to his/her discipline. In the event that the researcher proposes a research design that is commonly recognized and applied in his/her discipline but does not conform with general IRB requirements, it is the researcher's responsibility to justify application of the disciplinary practices in lieu of IRB requirements and to explain how the disciplinary code of conduct will be observed during the interaction with the participants.

Faculty advisors are responsible for imparting to students an understanding of the ethical principles of human research to which the University adheres. If a student is conducting research or a class activity that falls within the IRB's purview, the faculty advisor must ensure that the student completes appropriate training and secures either an exemption or IRB approval before beginning the study or activity. The faculty advisor also has primary responsibility for overseeing the conduct of the research in its entirety and for ensuring that the student adheres to the approved protocol. The duty of the faculty member is to assess, and, if prudent, veto, activities proposed by a student to fulfill a class assignment should more than minimal risk for harm to either the participants or the student exist. For example, approving a student's proposal to interview gang members in an inner-city neighborhood solely for the purpose of satisfying a requirement of a course intended to teach research methods is not prudent. In this case, the situation creates risk for both the gang member for associating with an "outsider" and the student who may be distrusted enough to also become a target of violence.

Valdosta State University provides resources through the Office of Sponsored Programs & Research Administration regarding the ethical involvement of humans in research. Questions may be directed to that office. Additionally, the CITI training program, which must be completed by the researcher before a protocol can be exempted or reviewed, is available to all faculty, staff, and students. This on-line tutorial can be incorporated into class requirements if desired without any additional cost to the University. Office of Sponsored Programs & Research Administration staff and IRB members are also available for guest presentations in the classroom. Faculty and students are encouraged to contact the Office of Sponsored Programs & Research Administration to seek advice regarding whether a proposed project is subject to IRB oversight.