Grand Valley State University Institutional Review Board	
G-1: Guidance on Determining If IRB Approval Is Required	
Issued: December 8, 2021	Office of Research Compliance and Integrity

Any activity conducted by GVSU students, faculty, or staff that meets both of the following definitions require prior review and approval by the Institutional Review Board (IRB) before the activity may begin:

a. Research: is a *"systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge*." 45 CFR 46.102(l).

b. Human Subject: *"a living individual about whom an investigator (whether professional or student) conducting research: (i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."* 45 CFR 46.102(e).

Note the intent to publish, present, post to the internet, or otherwise make publicly available the results of research activities is not determinative of whether the activity requires IRB approval. The proper focus for these purposes is whether the activity (i) involves a systematic investigation, (ii) the activity is designed to create or contribute to generalizable knowledge, ***and*** (iii) the activity involves human subjects.

Additional guidance is provided below for common research and/or course activities involving human participants and/or data where the need for IRB approval may be unclear. Additional examples of activities that do not require IRB approval can be found at the end of this document.

If you are ever unsure if an activity requires IRB review and approval, please submit an IRB Research Determination Form in IRBManager and/or contact the Office of Research Compliance and Integrity to discuss further (rci@gvsu.edu; 616-331-3197).

Class Projects and Student Research

Most course activities do not require IRB review. However, simply because an activity is conducted for a course does not automatically mean it lies outside of IRB review—further analysis is needed. Please consult the following table.

Activity	Is IRB Approval Typically Required?
Class projects, either individual or group, that are designed for **pedagogical** purposes only. The goal of such projects is typically to teach students how to conduct research methodology; the activity may seek to answer a research question, but it is not intended to contribute to generalizable knowledge in the field. Examples: Learning how to conduct interviews/surveys, how to analyze data, working directly with a corporate client for class consulting purposes, and/or how to present research results	No. However, note that ethical considerations need to be considered. See the section below this table for more information.
Student research project designed to both answer a research question and contribute to knowledge in the field of research, and that includes any of the following: • Interaction with individuals (in-person or via email, surveys, mail, videoconferencing, phone, etc.) • Intervention with individuals (manipulation of the participants or either environment • Access to private identifiable information and/or identifiable biospecimens Examples: Independent research project, Honors project, McNair Scholars	Yes
Class projects, either individual or group, that are designed for both pedagogical purposes and research. The research component may be individual or group.	Yes
Class projects that the instructor may use in their own research.	Yes, if the instructor anticipates the data gathered by the students could be used in their own research. This applies even if the data are initially being gathered by the students for pedagogical purposes.

This table has been adapted from Duke University (https://campusirb.duke.edu/irb-policies/irb-review-student-research-and-class-projects).

Additional Ethical Obligations of Class Projects Not Requiring IRB Approval

Many courses and degree programs require students to complete a research study that requires IRB review. Simply stating that a survey or interview is being conducted for a course does not mean that IRB review is not required.

Students sometimes collect data from or about other persons by using professional research methods as part of academic course activities, even though the student's work is not expected to contribute to generalizable knowledge. Such projects may not require IRB review. Even if a class project does not require IRB review and approval, it is important to remember that ethical obligations still exist when conducting the activity and interacting with the participants. Please abide by the following guidance when conducting such activities:

Recruitment of Participants

- When the initial contact is made with potential participants, it needs to be explained that the survey, interview, or other interaction is being completed to satisfy a class assignment and that it is not being done for other research purposes.

- If the activity will utilize social media to recruit people to complete the interaction, it must be clear that this is for a class assignment and is not being done for other research purposes.

- Ensure that any permission forms being reviewed by the individuals providing the data do not refer to the activity as research. Similarly, these forms should not be referred to as "research consent forms."

- If any data obtained for class projects is intended to be shared beyond the class itself (instructor and students in the class), the participant should be made aware of this prior to data collection.

Be aware that soliciting responses from a wide variety of people increases the likelihood that the results will be generalizable, and this may cross the line into research that requires IRB review. For this reason, instructors should consider capping the number people who may provide data for analysis in the class project. If at all possible, only de-identified data should be collected.

Instructor Responsibility

It is the instructor's purview to allow the student classroom activities involving research methodologies to occur as part of the coursework. However, instructors have an obligation to ensure that their students understand their ethical responsibilities in carrying out their assignments. Instructors should provide guidance to students collecting information in order to minimize potential harm to individuals, especially if students will collect personally identifiable private information.

Training

The IRB strongly encourages, but currently does not require, specific training for students in research protections, confidentiality, privacy protections, data security, or other research

areas in order to engage in research methodologies as part of classroom activities. However, instructors should be aware of any requirements their governing department may have concerning the proper conduct of such activities.

FERPA Authorization

Student education records are covered by the FERPA regulations and the researcher will need to consider if FERPA authorization needs to be obtained. Note that FERPA authorization is separate from research consent. For additional specific information on how FERPA intersects with research, refer to IRB guidance document G-17: *Guidance on FERPA in Human Subjects Research Studies*.

Post-facto Research Conducted on Data Previously Collected from Class Activities

If a student or instructor wishes to conduct research on data previously collected as part of a class activity in order to validate, expand or otherwise enhance generalizable knowledge, a research protocol must be approved by the IRB *before* the data may be used for that purpose. The protocol application should include a description of how the data were initially collected and why IRB approval for research was not sought or required at that time.

In most cases this type of research will be exempt under category #4 (existing data, records or specimens), or if not exempt, then expedited category #5 (data previously collected for non-research purposes). Failure to acquire IRB approval before utilizing data outside of the classroom for which the research activities were assigned is considered conduct of unapproved research and is a form of research noncompliance.

Quality Improvement and Program Evaluation Activities

Quality improvement and program evaluation activities typically do not fall within the jurisdiction of the IRB because they are not designed to contribute to generalizable knowledge. Instead, these activities are usually conducted to improve a process at a single location (for example, a clinic) or to evaluate the effectiveness of an individual program. For example, a clinic seeking to improve the quality of patient care at the facility would not meet the definition of "research". Similarly, assessing the effectiveness of a training course by surveying course attendees would not be considered generalizable if the results are only going to be used to improve future offerings of the course.

Note, however, that such activities could potentially include a research component that is designed to contribute to knowledge in the field of research. In these cases, IRB approval would be required. For example, if a study were undertaken to test a clinical intervention for purposes of improving the quality of care for patients at a specific clinic, but also for the purpose of establishing scientific evidence to determine how well the intervention works for any patient (including those outside of the clinic), the activity would require IRB oversight. Similarly, if the instructor of a training course were to survey course attendees to measure the effectiveness of the course, but was also seeking to collect information to generalize a particular training method used in the course, the activity would require IRB oversight.

The following table summarizes the differences between projects that fall under the definition of "research" and those that are considered quality improvement or program evaluation. Note that not all items below need to be identified as research to be considered human subjects research as defined above.

	Research	Quality Improvement/Program Evaluation
Intent	Designed to answer a research question and contribute to generalizable knowledge	Improve a practice or process within an institution or ensure it conforms with expected norms; not designed to contribute to generalizable knowledge
Design	Systematic; follows a rigid protocol; may involve randomization	Adaptive design; may or may not be systematic; usually does not involve randomization
Mandate	Activities not mandated by institution or program	Activity mandated by institution or clinic as part of its operations
Effect on Program or Practice Evaluated	Findings are not expected to directly affect institutional or programmatic practice	Findings are expected to directly affect institutional or programmatic practice
Population	Usually involves a subset of individuals; no requirement to participate; may involve statistical justification of sample size	Most or all involved in the practice/process are expected to participate; may exist a requirement to participate as a component of the program/process or employment; exclusion of some individuals may significantly affect conclusions
Benefits	Participants may or may not benefit directly; there may be a benefit to future knowledge or individuals	Participants may or may not benefit; may directly benefit a process or program
Risks	Participants may incur risk	Typically does not place participants at risk, with the possible exception of privacy and confidentiality risks
Analysis	Conducted to statistically prove or disprove hypothesis	Conducted to compare program or process to established standards
Dissemination of Results	Generally intended at outset of project as part of professional expectations or obligations; results expected to develop or contribute to scientific knowledge in field of research by supporting, refining, or refuting results from other research studies	Often does not occur beyond the institution evaluated; if presented beyond evaluated institution, results expected to identify potentially effective programs, tools, strategies, or benchmarks, instead of developing or contributing to generalizable knowledge

This table has been adapted from Northwestern University (https://cpb-us-e1.wpmucdn.com/sites.northwestern.edu/dist/2/2819/files/2020/01/HRP-1906-GUIDANCE-QI-PE-and-Research_01092020.pdf).

Results from quality improvement and program evaluation activities may be disseminated without IRB approval, but care should be taken to ensure the activity is not referred to as "research" in publications and presentations. It is recommended that a statement such as the following be included in the dissemination: "This quality improvement project was not designed to be generalizable beyond the study population and therefore does not meet the criteria for human subjects research."

If a researcher wishes to conduct research on data previously collected as part of a quality improvement project, recognizing the enhancement generalizable knowledge or other reasons, a research protocol must be approved by the IRB *before* the data may be used for that purpose. The protocol application should include a description of how the data were initially collected and why IRB approval for research was not sought or required at that time.

In some cases, an outlet/journal may require you to provide documentation of IRB approval or a determination from the IRB that the activity did not require IRB approval prior to dissemination. To obtain an official determination letter, please submit an IRB Research Determination Form in IRBManager. If you plan to publish the results in a journal that you know requires such documentation, you are encouraged to request the determination letter prior to conducting the activity.

Upon receiving a formal determination that the project does not require IRB approval, it is recommended that a statement such as the following be included in the dissemination: "This quality improvement project was reviewed by the Grand Valley State University Institutional Review Board and was determined to not meet the criteria for human subjects research." Investigators should inform the Office of Research Compliance and Integrity if a journal does not accept the formal determination letter.

Journalism and Oral History Projects

Research activities including journalistic interviews, oral histories, biographical profiles, and similar activities normally do not fall within the jurisdiction of the IRB. In these cases, the individuals being interviewed understand that they are being quoted, and have every expectation that their views will be made known for educational purposes. The interviewees should be advised of their right to remain anonymous, to have their remarks printed without attribution, or kept 'off the record'. If direct quotes will be used, interviewees should be allowed to read or hear the quotations attributed to them. The interviewee also should be advised of any publication plans for the project. Individuals conducting these activities must adhere to their discipline-specific code of conduct, principles and best practices to ensure the ethical conduct of this work.

Biography or oral history research involving a living individual is not generalizable beyond that individual. Therefore, it does not meet the definition of research in the federal regulations at 45 CFR 46.102(l) and does not require IRB review and approval.

Medical Case Reports

For IRB purposes, a "single case report" is the retrospective analysis of one, two, or three clinical cases and generally does not require review by the IRB. The results obtained from analyzing

such a small series of patients does not typically allow for the formation of a research hypothesis that could subsequently be prospectively and systematically investigated. Thus, single case reports are typically not generalizable and do not meet the definition of "research".

When a larger cohort of patients is being studied, investigators are more likely to be able to formulate specific research questions and use formal, systematic methods to collect the data. As such, these activities are more likely to meet the definition of human subjects research and therefore require IRB review.

If an investigator wishes to have their project assessed by the IRB to see if their planned case study meets the definition of human subjects research, the investigator should submit the IRB Research Determination Form in IRBManager.

In some cases, a journal may require you to provide documentation of IRB approval or a determination from the IRB that the activity did not require IRB approval upon dissemination. To obtain an official determination letter, please submit an IRB Research Determination Form in IRBManager. Investigators should inform the Office of Research Compliance and Integrity if a journal does not accept the formal determination letter.

NOTE: Case reports for publication must be prepared in accord with the requirements of the HIPAA privacy regulations. Any use or disclosure of protected health information (PHI) must be done with authorization of the patient, or, if the patient is deceased, authorization of the patient's family. Publication of a case report is a disclosure of PHI. The HIPAA Privacy Office of the institution responsible for the security of the medical record (hospital, clinic, physician practice group, etc.) should be consulted prior to submission of the case report to ensure proper authorization was obtained. See *Guidance G-2: HIPAA Compliance, Coded Private Information, and De-Identified Data* for further information related to HIPAA compliance.