

Determining if a project requires IRB review depends on whether it constitutes **research** involving **human subjects**. The table below is intended to help determine if a project meets the definition of research requiring submission to the IRB. If the project involves some characteristics of a research project, submission to the IRB for review is expected. Contact the UWG IRB if you have questions.

| | Human Subjects Research | Quality Improvement | Program Evaluation | Student Project |
|--------------------------|---|---|---|--|
| Purpose/Intent | Intent of project is to develop or contribute to generalizable knowledge (e.g. testing a hypothesis) | Intent of project is to improve a practice or process within a particular institution or ensure it confirms with expected norms | Intent of project is to improve a specific program | Intent of project is to provide an educational experience about the research process or methods |
| Motivation for Project | Project occurs in large part as a result of individual professional goals and requirements (e.g. seeking tenure, obtaining grants, dissertation, etc.) | Project occurs regardless of whether individual(s) conducting it may benefit professionally from conducting the project | Project not initiated by the evaluator and occurs regardless of whether individual(s) conducting it may benefit professionally from it | Project occurs as part of assigned course work or a requirement of an educational program to learn a new technique or pass a course/fulfill an assignment |
| Intent/who Benefits | Designed to contribute to generalizable knowledge and may not directly benefit subjects | Designed to promptly benefit a process, program, or system and may or may not benefit subjects | No benefit to participants expected; evaluation concentrates on program improvements or whether the program should continue | Participants may or may not benefit directly; benefit is primarily for the investigator conducting project for his/her own knowledge or fulfillment of educational requirements |
| Risks/Burdens | May place subjects at risk and stated as such | By design, does not increase participant risk, with exception of possible privacy/confidentiality concerns | Concentrates on program improvements, does not increase participant risk | Should not increase participant risk, but depending on topic may place subjects at risk and stated as such |
| Population | Usually involves a subset of individuals – universal participation of an entire program, department, clinic is not expected; generally statistical justification for sample size used to ensure endpoints can be met | Information on all or most receiving a particular treatment or undergoing a particular practice or process expected to be included: exclusion of information from some individuals significantly affects conclusions | Information on all or most participants within or affected by receiving a particular treatment or undergoing a particular practice or process expected to be used: exclusion of information from some individuals significantly affects conclusions | Can either include all, most, or a subset of individuals; statistical justification may be used in the context to understand the process of subject selection; however recruitment often utilizes convenience sampling |
| Data collection | Systematic data collection | Systematic data collection | Systematic data collection | Not designed to develop or contribute to generalizable knowledge |
| Testing/Analysis | Complex with inferential statistics to promote generalizability of results | Descriptive statistics or statistical process control charts for trended data | Descriptive statistics or statistical process control charts for trended data | Design is often an example or template provided by a professor or course book |
| Extraneous variables | Controlled and/or measured, tight protocol control | Acknowledged but not measured | Acknowledged but not measured | May or may not be acknowledged |
| End Point | Answer a research question | Promptly improve a program/process/system | Concentrates on program improvements or whether the program should continue | Assigned coursework completed, new skills learned and modeled in exercise. |
| Dissemination of results | Intent to publish or present generally presumed at the outset as part of professional expectations, obligations/ dissemination of information usually occurs in research/scientific publications or other research/scientific for a; results expected to develop or contribute to generalizable knowledge by filling a gap in scientific knowledge or supporting, refining, or refuting results from other research studies | Intent to publish or present generally not presumed at the outset; dissemination of information often does not occur beyond the institution evaluated; dissemination of information may occur in quality improvement publications; when published or presented to a wider audience, the intent is to suggest potentially effective models, strategies, assessment tools or provide benchmarks or base rates rather than to develop or contribute to generalizable knowledge | Intent to publish or present generally presumed at the outset of the project; dissemination of information to program stakeholders and participants; may be publically posted (e.g., website) to ensure transparency of results; when published or presented to a wider audience, the intent is to suggest potentially effective models, strategies, assessment tools or provide benchmarks or base rates rather than to develop or contribute to generalizable knowledge | Any presentations, posters, or publishing is simply to document the educational experience or completion of programmatic requirements. Text for publications/presentations: This project was undertaken as a Teaching-Learning project and was not formally reviewed by the University of West Georgia's Institutional Review Board. |