



COMMONWEALTH UNIVERSITY OF PENNSYLVANIA

QI DETERMINATION FLOWCHART

Is the intention of the project to improve a program or process within a specific setting?

If the primary aim of the project is to improve a program or process within a specific setting, it is QI. However, if the project seeks to improve operations or efficiency outside of a specific setting (e.g., applied at another institution or theorized within the field of study) it is human subjects research.

YES → Next Question

NO → Likely human subjects research. Contact CU IRB.

Are the proposed methods flexible and customizable, and do they incorporate rapid evaluation, feedback cycles, and incremental changes?

Flexible and customizable methods that incorporate rapid evaluation, feedback cycles, and incremental changes are likely not human subjects research and are consistent with projects designed for QI.

YES → Next Question

NO → Likely human subjects research. Contact CU IRB.

Do the methods include any of the following: a control group, randomization, and/or fixed protocol?

Projects with control groups, randomization, or a fixed protocol are human subjects research.

NO → Next Question

YES → Likely human subjects research. Contact CU IRB.

Will the project increase the risk to participants more than the existing program or process?

Projects that increase the risk of participation beyond what is already associated with the existing program or process are considered human subjects research, requiring informed consent.

NO → Next Question

YES → Likely human subjects research. Contact CU IRB.

Does the project involve recruitment of outside participants?

Projects that include most or all the population directly involved in the existing program or practice are likely QI. Projects that seek to recruit outside participants are considered human subjects research.

NO → Next Question

YES → Likely human subjects research. Contact CU IRB.

Will the project test a drug, device, biologic, assay, or medical software?

Projects testing a drug, device, biologic, assay, or software are considered human subjects research.

NO → Next Question

YES → Likely human subjects research. Contact CU IRB.

Has the project received funding that requires it to be conducted as a human subjects research study?

Funding does not automatically classify a project as human subjects research. However, if funding is contingent on the project being conducted as human subjects research, it cannot be a quality improvement project.

NO → Next Question

YES → Likely human subjects research. Contact CU IRB.

Is this project designed with the intent to contribute to generalizable knowledge?

Intent from the outset is the determining factor for dissemination. If you intend not to produce generalizable knowledge, or if you have designed the study to preclude the findings from becoming generalizable, the answer to this question is “No”. The design of the project plays a key role in determining intent. If you intend the project to be a program evaluation or process improvement, designed to evaluate local outcomes, with the goal to report internally only on what happened at the institution/program following the implementation, it is likely not generalizable knowledge. However, if the project uses systematic research methodologies that ensure external validity and reproducibility of results, the project is human subjects research.

NO → Next Question

YES → Likely human subjects research. Contact CU IRB.

Will the results of the project be published, presented, or disseminated outside of the institution conducting it?

Intent from the outset is the determining factor for dissemination. If you do not intend to disseminate your results outside of the institution or program where you conduct the project, the answer to this question is “No”. If there is any potential or intent for results to be disseminated outside of the institution or program where you conduct the project, then the answer is “Yes,” and the project is considered human subjects research. Note that quality improvement projects can be published or presented but cannot be described as research in any form of dissemination. Instead, you must include the statement: “This project was undertaken as a Quality Improvement Initiative and as such does not constitute human subjects research.”

NO → Next Question

YES → Likely human subjects research. Contact CU IRB.

Will the project occur regardless of whether individuals conducting it may benefit professionally from it?

Projects that are undertaken regardless of professional benefit are likely quality improvement. However, if the investigator is largely motivated by professional goals (e.g., obtaining grant funds, seeking a promotion), the project is human subjects research.

YES → Next Question.

NO → Likely human subjects research. Contact CU IRB.

Based on these answers, your project is likely QI. Please reach out to CU IRB if you have any questions. If the project changes in any way that affects the intent or design, complete the questionnaire again.