

INSTITUTIONAL REVIEW OF SCHOLARLY PATHWAY PROJECTS & SCHOLARLY PROJECTS

All student projects must undergo an institutional review before data collection.

- A. **If the project has IRB approval, or the proposal indicates that IRB or IACUC approval is pending**, then no additional institutional review is necessary. IRB or IACUC approval must be obtained *before data collection is performed*.
1. The student's mentor is responsible for knowing whether IRB or IACUC review is necessary. In general, projects that utilize human subjects or data from human subjects to create generalizable knowledge must have IRB approval.
 2. The student's mentor or another faculty member must serve as the PI for the IRB application.
 3. The student is considered part of the study team and must follow all institutional rules, including the completion of CITI training (www.citiprogram.org).
- B. **If the mentor does not believe that IRB approval is necessary** because the project is not human subjects research (e.g. quality improvement, within strict guidelines, no goal to create generalizable knowledge – see Special Circumstances), the **scholarly project proposal will be reviewed by a Student-Run Project Ethics Review** panel.
1. The scholarly project (SP) proposal should be submitted on Brightspace as soon as possible, and *before data collection begins*, as per SP guidelines.
 2. The proposal must contain sufficient information re: the purpose, intervention, data collection methods and dissemination plans to enable informed review.
 3. The Project Coordinator (Pathways staff) will send the project proposal to the student panel for review.
 4. All subsequent communication with the proposal author (student) will come from the Project Review committee.
 - Projects that need IRB review will be returned for submission to MCW's or CHW's IRB. For those that do not require further approval, the panel will make recommendations regarding any ethical concerns.

SPECIAL CIRCUMSTANCES

QUALITY IMPROVEMENT: For a project to be considered “primarily/originally QI or QA,” and thus outside the scope of human subjects research, **ALL** of the following criteria must be met:

1. Project is primarily focused on improving patient care within a given patient care environment.
2. Those doing the study have the clear authority to impose changes on care delivery in that environment, based on the results of the QA or QI project.
3. There is a commitment, in advance of data collection, to a corrective plan given any one of a number of outcomes.
4. If the project is funded by any external agency, the IRB office must review the grant or contract to be sure the project is not defined as “research” or “human subjects research,” and to be sure that that the funding agency does not require IRB review.

Signs that a project is “research” rather than QI or QA:

1. Design involves prospective assignment of patients to different procedures or therapies according to a pre---determined plan (e.g., randomization).
2. Design involves a control group, wherein the therapeutic or study intervention is intentionally withheld.
3. Design involves delivering study intervention in a blinded fashion.
4. Assessment of outcome is blinded to the study intervention.
5. Study involves prospective evaluation of a drug, biologic, or device not currently approved by the FDA.
6. Design exposes patients to additional risks or burdens (beyond routine care).

EDUCATIONAL EVALUATION: Educational projects will generally be considered “human research projects,” so you will always have to deal with the IRB if the project is intended for publication/ presentation.

Educational evaluation projects that take place in a recognized/accredited school program and involve normal educational practices may qualify for “exempt status.” To qualify, the investigator must make a regular IRB application in e---Bridge, and indicate that he/she thinks the study might be eligible for “exempt” status. If the study fell into one of these two categories, the chances are good:

1. Studies on regular and/or novel educational strategies
2. Studies evaluating the effectiveness of different instructional techniques or curricula.

If the IRB determines that a study qualifies for “exempt status,” no further IRB oversight is required (no continuing reviews). Other educational evaluation projects are likely to qualify for expedited review, and must maintain IRB oversight until the study is finished.

STUDENT EXERCISE with NO INTENTION OF DISSEMINATION: If the project is clearly devised as a student exercise, with no intent and little possibility of “generalizability” (i.e., it WILL NOT be presented at scientific meetings or written up for publication), that the IRB does not consider it to be “research,” and so no IRB submission is necessary. **Such projects must still be reviewed by the student panel.**