

Does my quality improvement project need IRB approval?

Chose one of the following categories for your project:

(1) All project activities are intended to answer questions that are initiated by a JHHSC hospital or safety committee and concern that entity's own operations, OR the activities address a question that is within the project leader's job description to answer for a JHHS entity's safety or quality purposes.

Is the project funded through a grant or

YES

NO

IRB submission **not required**

NO

Are any of the following TRUE:

- The activity uses a fixed clinical protocol that may not be altered by caregivers and staff;
- The activity has objectives other than producing an improvement in safety or care that will be sustained over time (e.g., study will compare outcomes without a clear intent to implement the superior intervention);
- The activity involves non-JHHSC sites;
- The activity involves a randomized intervention, or
- The activity involves an intervention that poses risks greater than those presented by routine clinical care.

YES

Submit IRB application

(2) The project was initiated by (or will be undertaken in cooperation with) a product manufacturer or other outside entity.

Has the JHHS legal department approved a contract or agreement for this project?

NO

Consult JHHS Legal Department

YES

In the view of JHHS legal, does the project involve human subjects research?

NO

IRB submission **not required**

YES

Submit IRB application

(3) The project is limited to analyzing existing data from a QA/QI project previously conducted at a JHHSC entity (data must exist when the project begins).

Will the PI or any study team member access identifiable research or clinical records in connection with this project?

NO

IRB submission **not required**

YES

Submit IRB application

(4) The project involves an IND/IDE.

YES

Submit IRB application

(5) None of these categories fully describes the project.

Consult OHSR for further assistance.