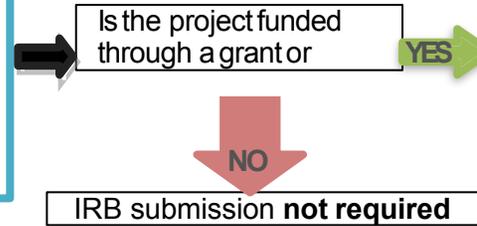


Does my quality improvement project need IRB approval?

Chose one of the following categories for your project:

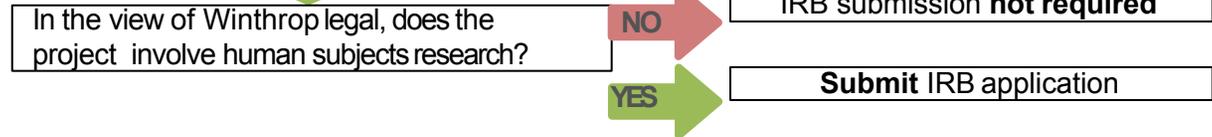
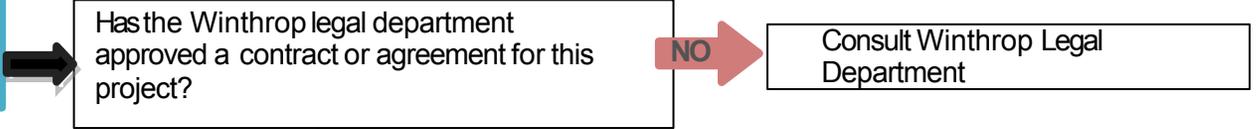
(1) All project activities are intended to answer questions that are initiated by a Winthrop hospital or safety committee and concern that entity's own operations, OR the activities address a question that is within the project leader's job description to answer for a Winthrop entity's safety or quality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



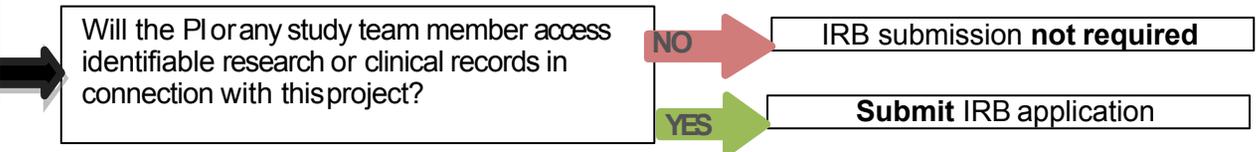
- Are any of the following TRUE:**
- The activity uses a fixed clinical protocol that may not be altered by caregivers and staff;
 - The activity has objectives other than producing an improvement in safety or care that will be sustained over time (e.g., study will compare outcomes without a clear intent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



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



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



(4) The project involves an IND/IDE.



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

