

Quality Improvement or Research Worksheet

In general, a QI project does not require IRB review and approval because it is not research that is subject to the federal regulations. The following questions may be helpful in determining whether a proposed activity is a QI project and does not involve human subjects research. If all of the questions below can be answered as a YES, IRB review is not required. If the answer to any of these questions is NO, please consult with the IRB for assistance since IRB review may be required. To obtain an authoritative determination from the IRB, please make a submission via iRIS and include a completed copy of this worksheet signed by the PI and by the Chair of the PI's department.

Project Description		
1	<u>Purpose</u> Is the project intended to improve the process/delivery of care while decreasing inefficiencies?	<input type="checkbox"/> Yes <input type="checkbox"/> No
2	<u>Funding</u> Is the project internally funded/supported or externally supported by agencies for direct benefit to existing patients?	<input type="checkbox"/> Yes <input type="checkbox"/> No
5	<u>Project Staff</u> Is the proposed project conducted by clinicians and staff who provide care or are responsible for the performance quality in the institutions where the activity will take place?	<input type="checkbox"/> Yes <input type="checkbox"/> No
6	<u>Project Design</u> Is the project flexible, including rapid and incremental changes such as in a plan-do-study-act (PDSA) cycle?	<input type="checkbox"/> Yes <input type="checkbox"/> No
7	<u>Population</u> Will the activity involve a sample of the population (patients/staff) ordinarily seen in the institution where the activity will take place?	<input type="checkbox"/> Yes <input type="checkbox"/> No
8	<u>Consent</u> Will the planned activity only require consent that is already obtained in clinical practice, and could the activity be considered part of the usual care?	<input type="checkbox"/> Yes <input type="checkbox"/> No
9	<u>Benefits</u> Is it true that most of the current patients at the institution where the planned activity will be implemented could potentially benefit from the project?	<input type="checkbox"/> Yes <input type="checkbox"/> No
10	<u>Risk</u> a) Is the risk to patients no greater than what is involved in the care they are already receiving? OR b) Can the burden of participating in the activity be considered acceptable or ordinarily expected when reforms are being introduced to the way care is provided?	<input type="checkbox"/> Yes <input type="checkbox"/> No

Adapted with permission from Yale University IRB.