

Table: Ethical Requirements for the Protection of Human Participants in Quality Improvement (QI) Activities*

Requirement	Explanation
Social or scientific value	The gains from a QI activity should justify the resources spent and the risks imposed on participants.
Scientific validity	A QI activity should be methodologically sound (i.e., properly structured to achieve its goals).
Fair participant selection	Participants should be selected to achieve a fair distribution of the burdens and benefits of QI.
Favorable risk-benefit ratio	A QI activity should be designed to limit risks while maximizing potential benefits and to ensure that risks to an individual human participant are balanced by expected benefits to participant and to society.
Respect for participants	A QI activity should be designed to protect the privacy of participants and the confidentiality of their personal information.
	Participants in a QI activity should receive information about findings from the activity that are clinically relevant for their own care.
	All patients and workers in a care delivery setting should receive basic information about the program of QI activities.
	QI results should be freely shared with others in the health care system, but participant confidentiality should be protected by putting results into non-identifiable form or obtaining specific consent to sharing.
Informed consent	Consent to inclusion in minimal-risk QI activities is part of the patient's consent to receive treatment.
	Patients should be asked for informed consent to inclusion in a specific QI activity if the activity imposes more than minimal risk.
	The risk to patients should be measured relative to the risk associated with receiving standard health care.
	Workers (employees or non-employee professionals who provide care within an organization) should participate in minimal-risk QI activities as part of their job responsibilities.
	Workers should be asked for their informed consent to inclusion in a QI activity that imposes more than minimal risk.
	The risk to workers should be measured relative to the risk associated with the usual work situation. This does not include any risk to economic security (for example, if a QI activity reveals that the worker is incompetent or that the organization can provide quality care without that worker).
Independent review	Accountability for the ethical conduct of QI should be integrated into practices that ensure accountability for clinical care.
	Each QI activity should receive the kind of ethical review and supervision that is appropriate to its level of potential risk and project worth.

Table from Lynn, J., M.A. Baily, M. Bottrell, et al. "The Ethics of Using Quality Improvement Methods in Health Care," *Annals of Internal Medicine* 2007;146 (9):666-673.

* The 7 topics are derived from Emanuel EJ, Wendler D, Grady C. "What makes clinical research ethical?" *JAMA*. 2000;283:2701-11.