

Ethical Requirements for the Protection of Human Participants in QI Activities

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—properly structured to achieve its goals.

Fair subject 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 minimize risks and maximize potential benefits, and to ensure that risks to an individual human participant are proportionate to benefits to the participant and to society.

Respect for participants

A QI activity should be designed to protect the privacy of participants through confidentiality.

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, with participant confidentiality protected by putting results into non-identifiable form or obtaining specific consent to sharing.

Informed consent

Patients should give background consent to inclusion in minimal risk QI activities as part of consent to receive treatment.

Patients should be asked for informed consent to be included in a specific QI activity if the activity imposes more than minimal risk.

The risk-harm ratio for patients is measured relative to the risk associated with receiving standard health care.

Workers (employees or nonemployee professionals who provide care within an organization) are expected to 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 is measured relative to the risk associated with the usual work situation and does not include any risk to economic security that might result if a QI activity reveals that the worker is incompetent or that the organization can provide quality care with fewer workers.

Independent review

Accountability for the ethical conduct of QI should be integrated into the system of 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.

Excerpted from:

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