Guiding good research

Key findings from a review of biomedical research ethics

Abstract

Ethical scrutiny of health research has been integrated into the research process only recently, and is characterised by a multitude of bodies and countries issuing different sets of regulations and recommendations - on what should be universal values. Add to this the personal and cultural factors that guide interpretation of core ethical principles, and varying operating frameworks of ethics committees, and the stage is set for inconsistent outcomes from ethics reviews. The system is viewed by researchers as burdensome and bureaucratic, and in response, efforts have been made in several countries to streamline and standardise processes.

Key Finding 1: Systematic ethical scrutiny of health research is a relatively recent practice. Even though consideration of the ethical aspects of biomedical research is no new phenomenon, its systematic integration into the research process has lagged behind the progress of medical discovery itself. While governments and professional bodies have taken measures to uphold standards and protect the public, cases of malpractice have made clear the need to formulate basic ground rules to be followed by all those involved in research.

Key Finding 2: Ethical guidance is characterised by a multitude of sources of guidance and differing interpretations of key ethical principles. By its nature, ethics guidance seeks universality and authority, yet regulations, recommendations, statements and comments are issued by a wide range of bodies within and across countries. Also, the practical interpretation of universally acknowledged core principles is guided by other personal and cultural values and contextual parameters, which can lead to differing outcomes.

Key Finding 3: Most research locations require ethical review of planned research but operating frameworks for ethics committees vary significantly. Most biomedical research is now required to undergo ethical review, either through national laws or as a condition of funders, host institutions, research partners, or publishers. However, the belief that the ethical dimension of research must be examined furnishes no obvious guidance as to who is best placed to judge such issues, and how. Accordingly, a range of ethics committee models has emerged. Also, the scope and impact of committee authority can vary substantially as committees cover various areas and can have different responsibilities.

Key Finding 4: Ethics reviews aim to support good research but they are often seen as burdensome and questionable, as identical applications do not necessarily produce consistent review outcomes. Many researchers have voiced their frustration on the issue of the bureaucracy of ethics reviews, to the point of suggesting that the system has degenerated into a self-sustaining ‘machinery’ with a vested interest in complications. Also, there is ample, if anecdotal, evidence for variation in ethics committee decisions, both within countries and internationally, most particularly within multicentre studies.

Key Finding 5: Several measures have been designed to facilitate ethics reviews. Depending on local or national context, different steps have been taken to ensure that proposed research is reviewed more reliably, and with as little disruption as possible. In less research-intensive regions, the creation of more ethics committees has been a fundamental step. Efforts have also been made in several countries to standardise application documents and processes, despite reservations about a ‘one-size-fits-all’ approach to ethics review.
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