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DOCUMENTED
BRIEFING

Guiding Good Research

Biomedical Research Ethics and
Ethics Review

Observatory on Health Research
Systems

Miriam Shergold

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Summary

Summary: Key Points

- The codification of universal principles for ethics in health research is a 20th century achievement that has not, however, eliminated malpractice or dispute.
- Ethics guidance emanates from a range of different sources, resulting in a 'normative polyphony'.
- Agreement on basic principles does not guarantee identical or even similar decisions on the ethical acceptability of a specific practical research endeavour.
- There are multiple models for the review process to safeguard ethical research, including choice and authority of the reviewers.
- Reviewing the ethical aspects of a research proposal is a demanding task, which researchers find burdensome and which has led to a range of streamlining efforts.

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.

By its nature, ethics guidance seeks universality and authority, yet the world has no single body that can claim to have the last word on ethics. Rather, regulations, recommendations, statements, and comments are issued by a wide range of fora within and across countries around the world. For researchers, guidance translated into national legislation has the greatest immediate relevance. Public debate on ethics is an important influence on such legislation, including the opinion of 'ordinary' citizens who some countries consult on a regular basis.

Although there is universal consensus regarding core principles, such as patient autonomy, the task of determining whether a given piece of proposed research is acceptable requires the practical interpretation of such principles. This interpretation is guided by other personal and cultural values and other contextual parameters that can lead to different outcomes. Some researchers have been disconcerted at the discovery that whereas ethical approval is key to the realisation of research projects, opinions on what is ethical may vary.

Ethics review is conducted according to a set process, and by a group of suitably qualified individuals. Given that the consideration of the ethics of a research project requires both

expert and lay views, most countries and institutions opt for a combination of scientists and non-scientists. However, there is no obvious method for mixing or appointing members, and as a result, no two models appear the same. Main differences exist in the ratio of non-specialists participating, as well as in the choice of experts, such as lawyers, psychologists, or statisticians.

Ethics review committees have to give careful and unbiased attention to each research proposal before them, but researchers are frustrated by what seem to be unduly bureaucratic and burdensome processes. In particular, the time-consuming multiple approval routes of national and international multicentre projects have been highlighted. As well as trying the patience of investigators, delays in approvals diminish the attractiveness of a given research institution to investors. Driven by the desire to combine sound ethical scrutiny with facilitated processes, different countries have devised new approval routes, such as the use of standardised forms and single review points. However, the debate on the optimum path to facilitation continues.