

# Executive Summary

Many people in the developing world suffer from poor health and reduced life expectancy. The role of research that contributes to the development of appropriate treatments and disease prevention measures is vital. However, lack of resources and weak infrastructure mean that many researchers in developing countries have very limited capacity to conduct their own clinical research. They therefore often undertake research in partnership with groups from developed countries. A sound ethical framework is a crucial safeguard to avoid possible exploitation of research participants in these circumstances.

Much attention has been given to providing guidance which addresses ethical issues raised by externally sponsored healthcare-related research in developing countries. A number of international organisations have recently revised existing guidelines or prepared new ones (see paragraphs 1.9–1.15 and Appendix A). The Council held a Workshop, co-hosted with the Medical Research Council (MRC) of South Africa, in February 2004 to explore the practical implications of new and recently revised guidelines since the publication of the Council's 2002 Report.<sup>1</sup> This Paper reports the discussions of four topics at the Workshop: consent, standards of care, what happens after the research is over, and ethical review.

Delegates emphasised that applying guidance in practice is often fraught with difficulty. When the different guidelines are compared, they are markedly inconsistent in some areas. The guidelines vary with regard to the scope and level of detail of information to be provided in the consent process (paragraphs 2.9–2.16), the obligation to provide a universal standard of care to control groups (paragraphs 3.6–3.10), the use of placebos (paragraphs 3.11–3.15), and the extent to which research participants are owed access to successful therapeutics after research is complete (paragraphs 4.4–4.17). There is also variation with relation to the degree of involvement of the host country in the review process (paragraphs 5.8–5.15).

Furthermore, some of the guidelines establish standards that are inappropriate for the developing country setting. A number of case studies provided by delegates illustrate difficulties which have arisen. These include obtaining consent in emergency settings (paragraph 2.7), providing the universal standard of care for control groups in vaccine trials (Box 3.2), and securing guarantees from sponsors or physicians that access to successful therapeutics will be provided to participants once a trial is over (paragraph 4.12). Faithful adherence to some of the provisions within the guidelines is often unachievable. Moreover, despite attempts at clarification, the status of pre-eminent guidelines such as the Declaration of Helsinki, is viewed by some as merely aspirational and by others as akin to regulation. The possibility that researchers may forgo conducting valuable research in developing countries because sponsors in developed countries or review committees in sponsor countries may judge it incompatible with specific provisions of guidance continues to be a cause for concern (paragraphs 6.26–6.34).

Researchers, sponsors and members of ethical review committees must judge for themselves how to approach some of these complex issues. In some countries they will be assisted by national guidance that takes account of local needs and the cultural context. Aligning externally sponsored research with national research priorities (paragraphs 6.22–6.25), and initiating early discussion of the issues with national authorities as well as the local communities concerned, will provide researchers with a crucial counterbalance to the generalised and sometimes unsatisfactory framework of international guidance. The existence of independent research ethics committees is crucial in achieving this aim (paragraphs 5.1–5.24).

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<sup>1</sup> Nuffield Council on Bioethics (2002) *The ethics of research related to healthcare in developing countries* (London: NCOB).

The Paper draws together some of the general themes that were discussed during the meeting, including community participation, the development of expertise, sustainability, partnership and ensuring feedback from research (paragraphs 6.2–6.12). Issues requiring further discussion are also identified, including those raised by chronic diseases, research on public health, and intellectual property (paragraphs 6.13–6.21).