MRC Medical Research Council

MRC Ethics Guide

Research involving human participants in developing societies

2004

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Introduction

The MRC expects all researchers that it funds to follow these guidelines when their research involves developing societies. We hope that other researchers and those reviewing or supervising research will also find them helpful. The guidance given here is brief; we encourage readers to consult the key sources of further information listed on page eight. Although there is some difference of opinion in the published sources, there is also a large measure of agreement on important areas of guidance.

General principles

The MRC's key ethical principles, outlined in *Responsibility in Investigations on Human Participants and Material and on Personal Information*, 1992, apply to research conducted in developing societies:

1. The research must be of potential scientific or practical value: it must address an important question, and be feasible and well-designed. The scientific rationale for conducting the research must be sound.

2. The research must use the minimum number of human participants consistent with the objectives of the study, without compromising the integrity and validity of the research.

3. The potential and known risks of the research, as well as its potential benefits to the participants or others, must be considered by both participants and investigators.

4. The research must whenever possible be done only with the full and informed consent of the individual participants. Particular restrictions and safeguards are required when this is not possible (eg, emergency situations, mentally incapacitated individuals, children).

5. There must be neither inducement nor coercion to participate. However, for certain types of research without a therapeutic component participants may be recompensed for their expense, time, and inconvenience.

6. The research should be done only with the approval of an appropriate independent research ethics body, in addition to which the MRC always considers the ethical propriety of the proposals.

7. Information about identifiable individuals derived from the research must be regarded as confidential, and appropriate safeguards must be in place governing access to such information by others.

8. The research must conform to all relevant legal requirements.

In addition, investigators are expected to follow other MRC guidance as appropriate:

- *MRC policy on antiretroviral therapy (ART) for people infected with HIV and involved in research in developing countries: general guidance notes for consideration*, 2002.
- *MRC guidelines for good clinical practice in clinical trials*, 1998, which are based on the principles of the International Conference on Harmonisation harmonised tripartite guideline, *Good Clinical Practice: Consolidated Guideline*, 1997.
- *Personal information in medical research*, 2000.
- *Human tissue and biological samples for use in research*, 2001.
- *Cluster randomised trials: methodological and ethical considerations*, 2002.
- *Health technology assessment in surgery*, 2003.
- *MRC interim guidance on ethics of research involving human material derived from the nervous system*, 2003.

Specific considerations

Over and above these general principles, the conduct of MRC-sponsored research in developing societies should follow the specific guidance listed below.

1. Organisations from developed countries should not normally support research, in pursuit of their own goals, involving people in developing societies if that research could be carried out reasonably well in a developed community.

2. Special care must be taken to ensure that the social and economic characteristics of the developing society, or poor communications, do not diminish the researchers' respect for the rights and interests of the people involved, or the community as a whole.

3. The reason for undertaking the research will usually be its relevance to the health/healthcare needs of the community in which it is carried out, either in the short-term or long-term.

4. Research on topics without a therapeutic component needs especially careful scrutiny, taking account of the balance of risks and benefits to participants in the particular circumstances and setting of the study.

5. When setting the standard of care, the MRC follows the recommendation of the Nuffield Council on Bioethics, 2002:

   "For the control group in a particular research study… wherever appropriate participants in the control group should be offered a universal standard of care for the disease being studied. Where it is not appropriate to offer a universal standard of care, the minimum standard of care

that should be offered to the control group is the best intervention available for that disease as part of the national public health system."

The fact that a treatment tested in a trial may not currently be affordable to the local population should not in itself necessarily be a reason to preclude the study on ethical grounds, but the information given to patients should set out the position unequivocally. In research on public health interventions to benefit a host country, the use of locally practicable standards of care may be required.

6. With respect to placebo-controlled trials, the MRC follows the recommendation of the Council for International Organizations of Medical Sciences, 2002, that placebo may be used:

"…when use of an established effective intervention as comparator would not yield scientifically reliable results and use of placebo would not add any risk of serious or irreversible harm."

7. Ethics review should take place in the UK and in the host country. Local ethics review of research proposals is required to judge the ethical acceptability of the research in accordance with the customs and traditions of the community concerned. As with research conducted in developed societies, the local ethics committee members should include lay people qualified to represent the cultural and moral values of their community as well as professionals. The committee should be chaired by someone entirely independent of the research and have at least one other independent member.

8. Special care should be taken to obtain genuine informed consent from participants, including the use of reliable intermediaries as appropriate to ensure that the implications of participation are fully understood. In particular, all prospective participants must fully understand that their participation is entirely voluntary and that they are free to refuse to participate or withdraw at any time without loss of any entitlement. Although there is no substitute for individual consent, the cultural need for the potential participant to consult a senior family member or community leader should be respected, and in some cases this person may need to be consulted first. A permanent personalised record of consent should be retained, although this need not necessarily be in the form of a signature.

9. There should be discussion in advance with relevant parties in the developing society about the plans for research and about dissemination of results to study participants and local people. In anticipation of any beneficial results of research with a therapeutic component, the discussion should include how the product/intervention being evaluated might be made available locally after the study.

Further reading

1. World Medical Association (WMA). *World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects.* As adopted by the 52nd WMA General Assembly, 2000, with note of clarification on paragraph 29 added 2002.

2. Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO). *International ethical guidelines for biomedical research involving human subjects*. Geneva: CIOMS, 2002.

3. Nuffield Council on Bioethics. *The ethics of research related to healthcare in developing countries*. London: Nuffield Council on Bioethics, 2002.

4. Council of Europe Steering Committee on Bioethics. *Additional protocol to the Convention on Human Rights and Biomedicine, on biomedical research*. Strasbourg: Council of Europe, 2004.

5. European Group on Ethics in Science and New Technologies to the European Commission. *Opinion Nr 17 on ethical aspects of clinical research in developing countries*. Luxembourg: Office for Official Publications of the European Communities, 2003/04.

6. European Council and European Parliament. *Directive 2001/20/EC of the European Parliament and the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use*, April 2001, adopted by Member States 2003, to be applied with effect from May 2004.

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