

Chapter 8

Ethical review of research

Introduction

8.1 The requirement that the ethics of proposed research be reviewed (hereafter called ethical review) is designed to protect participants in research. The need for such review is now widely recognised and set out in national and international guidance (Table 8.1 and Appendix 1 Table 4). The research ethics committees which typically undertake such reviews are a relatively recent

Table 8.1

Primary sources of international guidance on reviewing the ethics of research

Guidance	Text
Council for International Organizations of Medical Sciences (CIOMS) 'International Guidelines for Ethical Review of Epidemiological Studies' (1991)	'The requirement that proposals for epidemiological studies be submitted to independent ethical review applies irrespective of the source of the proposals ... Sponsors should recognize the necessity of ethical review and facilitate the establishment of ethical review committees. Sponsors and investigators are expected to submit their proposals to ethical review, and this should not be overlooked even when sponsors have legal power to permit investigators access to data. An exception is justified when epidemiologists must investigate outbreaks of acute communicable diseases ... Nevertheless, in such circumstances the investigator will ... respect the rights of individuals'. Principle 33
CIOMS 'International Ethical Guidelines for Biomedical Research involving Human Subjects' (1993)	'All proposals to conduct research involving human subjects must be submitted for review and approval to one or more independent ethical and scientific review committees. The investigator must obtain such approval of the proposal to conduct research before the research is begun'. The function of ethical review to protect participants whilst ensuring the quality of research is also elaborated: 'Scientific review and ethical review cannot be clearly separated: scientifically unsound research on human subjects is ipso facto unethical in that it may expose subjects to risk or inconvenience to no purpose'. Guideline 14
World Health Organization (WHO) 'Guidelines for Good Clinical Practice (GCP) for trials on pharmaceutical products' (1995)	'The protocol, appendices and other relevant documentation should be reviewed from a scientific and ethical standpoint by one or more (if required by local laws and regulations), review bodies ... constituted appropriately for this purpose and independent of the investigator(s) and sponsor'. Paragraph 2 'The investigator, or the investigator and the sponsor, must consult the relevant ethics committee(s) regarding the suitability of a proposed clinical trial protocol ... and of the methods and materials to be used in obtaining and documenting the informed consent of the subjects ... Subjects must not be entered into the trial until the relevant ethics committee(s) has issued its favourable opinion on the procedures'. Paragraph 3.2 'Prior to its commencement, the investigator must ensure that the proposed clinical trial has been reviewed and accepted in writing by the relevant independent ethics committee(s)'. Paragraph 4.9
International Conference on Harmonization (ICH) 'Harmonised Tripartite Guideline. Guideline for Good Clinical Practice' (1996)	'A trial should be conducted in compliance with the protocol that has received prior institutional review board (IRB)/independent ethics committee (IEC) approval/favourable opinion'. Paragraph 2.6
World Medical Association 'Declaration of Helsinki' (2000)	'The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol. This protocol should be submitted for consideration, comment, guidance, and where appropriate, approval, to a specially appointed ethical review committee ...' Paragraph 13
UNAIDS 'Ethical Considerations in HIV Preventive Vaccine Research' (2000)	'HIV preventive vaccine trials should only be carried out in countries and communities that have the capacity to conduct appropriate independent and competent scientific and ethical review'. Guidance Point 6
WHO 'Operational Guidelines for Ethics Committees that Review Biomedical Research' (2000)	'Countries, institutions, and communities should strive to develop Ethics Committees and ethical review systems that ensure the broadest possible coverage of protection for potential research participants and contribute to the highest attainable quality in the science and ethics of biomedical research. States should promote, as appropriate, the establishment of research ethics committees that are independent, multidisciplinary, multi-sectoral, and pluralistic in nature. Research ethics committees require administrative and financial support'. Paragraph 3

innovation (for example, the first committee in the UK was established in 1966).¹ Committees with responsibility for reviewing the ethics of research now exist in most countries.

Levels of assessment

8.2 The Working Party considers that each proposal for externally-sponsored research in developing countries should receive three levels of assessment:

- relevance to priorities in healthcare within the country(ies)
- scientific validity
- ethical acceptability.

In this chapter, we briefly discuss assessment of the relevance of the research to priorities in healthcare and the scientific review of research, and then focus on ethical review of research. A list of questions that may be relevant during these three forms of review is set out in Appendix 3.

Relevance to priorities in healthcare

8.3 Research ethics committees are not constituted to take policy decisions on, for example, whether the findings of a research project could be implemented in the country. We consider that they should, however, determine if the implications of the possible research results have been considered, including the possibility of introducing and maintaining the availability to the wider community of treatment shown to be successful (see paragraphs 9.32–36). In addition they should request justification for research that does not include provisions for the development of expertise in research within the developing country (see paragraphs 9.50–52).

Scientific review

8.4 Rigorous scientific evaluation of each research protocol is essential. Research which is not appropriately designed will fail to provide answers to the question posed by the research, and thus have limited benefit or no benefit either to the participants, or to the wider community. Some sponsors of research conduct their own scientific review of proposed research. However, these internal reviews cannot always be relied upon. Sponsors are often presented with proposals in outline from applicants that exclude many of the details essential to scientific review, such as the size of the sample of population and the specific definition of the study groups. Internal scientific reviews of proposed research undertaken by the pharmaceutical industry may be fully or partially confidential and therefore not comprehensively available to external review committees. Research ethics committees must be satisfied that appropriate scientific review of research has taken place.

8.5 There are concerns that, in a single ethics committee, the distinction between the review of the science and the ethics, which have quite different purposes, may be ill defined. We accept that it is not possible to entirely separate the processes of reviewing the science and the ethics of a research proposal. One depends to a degree on an appreciation of issues addressed by the other. Nevertheless, they should be undertaken as separate exercises. We conclude, therefore, that these two forms of review should, where possible, be kept separate. This may, but will not necessarily, require the establishment of separate committees.

1 Ferguson P (2001) Do researchers feel an LREC hinders research? **Bulletin of Medical Ethics**, 165 17–19.

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8.6 An ethics committee's primary task is to review the ethical acceptability of research proposals. Particular attention is usually paid to:

- the *predictable* risks involved in conducting the research
- the anticipated benefits for the participants in research and communities to which the research will be relevant
- the provisions within the design of the research relating to the care and protection of participants in research, including the treatment of any participant harmed by the research
- the procedures for recruitment and selection of participants in research (including details of the group to be investigated)
- the processes for obtaining genuine consent and provision for refusing consent or withdrawing it during research (including the adequacy of information given to participants and the acceptability of any inducements)
- the provisions for protecting the security and confidentiality of data about patients.

8.7 In the preceding chapters and the following chapter, we have examined in detail a number of issues that need to be considered by research ethics committees when reviewing externally-sponsored research. These include the appropriateness of procedures for giving information about the research to prospective communities. For example, in Chapters 6 we noted that it was necessary to draw on the expertise of a local research ethics committee to ensure that procedures for consent enabled prospective participants in any research to give genuine consent, and that any inducements to participate were appropriate (see paragraphs 6.32, 6.40). In Chapter 7 we recommended that, rather than requiring that a universal standard of care should always be provided to a control group during a clinical trial, a decision should be made in each case on what would be the most appropriate level of care to be provided. Such decisions can only be made in consultation with local researchers and local research ethics committees (see paragraphs 7.18, 7.29) and should be made by reference to the reasons and argument we set out in Chapter 7. In Chapter 9 we endorse the US National Bioethics Advisory Committee (NBAC) recommendation that researchers should have to justify the lack of arrangements for securing post-trial access for effective interventions for participants in a trial to the ethics review committee (see paragraph 9.31). We also conclude that an ethics review committee would need to be persuaded of the need to carry out a study involving a novel intervention to treat chronic disease in a locality where the availability of long-term treatment is unlikely.

8.8 The mere presence of a research ethics committee in a country is not enough to ensure that research will be adequately reviewed. Committees may be ineffective for a variety of reasons, including a lack of financial and human resources, and a lack of training in, and experience with, reviewing the ethics of research. In Box 8.1 the current capacity of a selection of countries to conduct such reviews is outlined.

Requirements for effective ethical review of research

8.9 As we have said, an effective system of ethical review is a crucial safeguard for participants in research. Research ethics committees are one component of a system for ensuring the protection of participants in research within a country. However, if there is little support for a system of ethical review amongst government officials, senior members of universities and research

BOX 8.1 Differing capacities to conduct ethical review

In some developing countries there are no research ethics committees. For example, Myanmar and Laos have no formal internal ethical review process for research related to healthcare.¹ Such countries may, however, have other mechanisms in place to provide a review of research, including the possibility of review by officials from the national Ministry of Health. In addition, a country without a committee may request a research ethics committee from neighbouring countries to review proposed research. For example, in Guinea Bissau, once the government has considered proposed research and decided that it is relevant, it is passed to the national ethics committee in The Gambia, for review.

In India, there are clear and robust guidelines for externally-sponsored research, as well as for nationally funded research (see Appendix 1 Table 1). In addition to the national research ethics committee, there are many local and institutional review committees.² The quality of assessment, however, varies among the local committees.³

In Latin American countries, regulatory procedures for the evaluation of new medicinal products generally require both local scientific approval, and approval by an independent ethics committee. In Argentina, a single ethics review committee can approve multi-centre studies for centres which do not have their own ethics review committee. In Brazil, the number of research projects which have been approved has grown from 30 in 1995 to 430 in 1999, and national regulation for the ethical review of research proposals has recently been established.⁴ A federal resolution was approved in October 1996 by the National Council of Health, requiring that all research projects involving human participants receive ethical review.⁵

Research ethics procedures in Central and Eastern Europe vary greatly from one country to another, for largely historical reasons. Bulgaria, Hungary, Poland and Romania have national ethics committees as well as local ethics committees in hospitals. Albania and Lithuania have national ethics committees, while Estonia has two research ethics committees, in addition to a bioethics council and an ethics committee related to the planned Estonian Genome Project. The Czech Republic has institutional ethics committees while Russia has a committee in the Ministry of Health and another in the Academy of Medical Science: both are currently developing guidelines but are not yet reviewing research proposals. There is also a regional research committee in St. Petersburg. The Ukraine until recently has had no research ethics review system, and preparatory work here and in other Eastern European countries is supported by the Council of Europe.⁶

- 1 White N (2000) Personal communication, Wellcome – Mahidol University – Oxford Tropical Medicine Research Programme.
- 2 The ethical guidelines and the National Research Ethics Committee are the responsibility of the Indian Council of Medical Research, which had a budget of nearly US\$50 million in 1999–2000.
- 3 Personal communication, Working Party fact-finding meeting.
- 4 Brasil, Decreto 98 830, 15 Janeiro 1990 (Coleta por estrangeiros de dados e materiais científicos no Brasil).
- 5 The resolution sets out the terms of reference for the establishment and operation of ethics review boards and the creation of the Central Committee of Ethics in Clinical Research (CONEP) as an adjunct to the Ministry of Health. Research ethics committees must report to CONEP on a quarterly basis about the status of trials of new products.
- 6 Coker R and McKee M (2001) Ethical approval for health research in central and eastern Europe: an international survey, **Clinical Medicine**, 1(3) 197–9.

institutions, or local researchers, then research committees may not be established, or may be unable to function effectively due to a lack of training and resources, or a lack of independence. In some instances, researchers may submit research for approval in developing countries, only to have it 'approved' within a few days, with no amendments or changes proposed.² Under these circumstances concerns have been expressed that officials in developing countries do not recognise the need for effective ethical review and consider it to be simply a formality. Alternatively, the decisions of the research ethics committees may be ignored or overridden by government officials.

8.10 Furthermore, if a committee has limited independence and no clear framework of guidance to work within, there is a danger that they may take *ad hoc* rather than principled decisions, and

2 Melody Lin (2001) Personal communication, Office for Human Research Protections, US.

that these *ad hoc* decisions may reflect members' affiliations and interests, and pressure from host and foreign researchers, sponsors and local government or other administrative authorities. For example, a research ethics committee might find it difficult to refuse research that it considered inappropriate but which would bring a substantial funding to an institution or region. As we have said in paragraphs 5.25 and 5.28, the guidance on research related to healthcare can be ambiguous and difficult to apply in specific circumstances. For this reason we encourage countries to create national guidance for the clear and unambiguous application of existing international and national guidance. The need to provide training for members of research ethics committees so that they can act effectively is discussed below (paragraphs 8.26–8.29).

- 8.11 The membership of research ethics committees requires careful consideration. The aim must be to achieve an independent, multi-disciplinary, efficient committee with sufficient expertise. Recent guidance from international bodies on the membership of research ethics committees is set out in Appendix 1 Table 4. With regard to attendance, in order to ensure that meetings are quorate, it is helpful to have more members than are required for a quorum. In the case of renewal of the membership, it is helpful to maintain a rotation of new members, not least because they inevitably take time to learn about the process of ethical review. We note that the inclusion of representatives of relevant religions may present difficulties if there are several religions represented within the host community. However, many theological scholars have given substantial thought to issues that need to be considered by ethics committees and their participation may be particularly valuable.
- 8.12 In some countries, it is considered an advantage to have a majority of members in a research ethics committee who are not professionals in the various fields covered by research (sometimes referred to as lay members).³ Their primary role is to reflect the values of the local communities and the local and national culture. Particular care will need to be taken to ensure that the interests of women and members of vulnerable populations are properly taken account of by research ethics committees. In countries which do not have research ethics committees, members of a committee from a neighbouring or sponsoring country may well have an incomplete understanding of the local conditions in the host country. As a consequence, any review may be inadequate. Moreover the geographical and social isolation from the communities under study may make any monitoring of the research difficult.
- 8.13 The independence of members of ethics committees is a common problem. In many developing countries, members of research ethics committees may not be able to afford to provide the necessary time and expertise to review research at no cost. Failure to provide appropriate remuneration may contribute to delay or to inadequate reviews. However, when committee members receive a fee for review, their independence may be compromised.
- 8.14 In many developing countries, there is often a limited number of people available who have the expertise and the time and who are able to bring to bear the kind of knowledge and care required to act as effective members of a research ethics committee. One example cited to the Working Party concerned the directors of two institutes who were members of each other's ethics committees, leading to a possible conflict of interest.⁴ Moreover, prospective reviewers with the appropriate scientific background may in fact be involved in the research, creating a potential conflict of interest. Where conflicts of interest are unavoidable, the procedures for managing them should be transparent, and may include the requirement that the conflict be declared and that a member be excluded from discussions when appropriate.

3 Lay members are individuals who represent a range of community and cultural values (and are not members of the specialist professions represented on research ethics committees, such as physicians, scientists, nurses and ethicists).

4 Das PK (2000) Personal communication, Vector Control Research Centre (VCRC), India.

- 8.15 Some research ethics committees meet infrequently, or at irregular intervals, which will delay review of research protocols. For example, if a committee meets only three or four times a year, a backlog of research proposals may build up. In some situations, sufficient funding will allow research ethics committees to meet more regularly, while in others, delays caused by a lack of infrastructure, for example difficulties of travel, may be more difficult to overcome.
- 8.16 **We recommend that all developing countries should have in place a properly constituted and functioning system for the independent ethical review of research. This will include the establishment of effective research ethics committees.** Developing countries may determine that the most appropriate means of reviewing externally-sponsored research is via an independent national research ethics committee. **In such circumstances the establishment, funding and proper operation of independent national research ethics committees should be the responsibility of national governments. No research should be conducted without review at the national or local level.**

Meeting the costs of research ethics committees

- 8.17 In developing countries, research ethics committees may have access to only limited administrative or financial support. Recent estimates suggest that the operating costs of one research ethics committee in the UK are £36,000 per annum, if both direct and indirect costs (such as time taken by committee members for review) are taken into account.⁵ This does not include start-up costs, reimbursement of costs of travel, costs of interacting with other committees, or of monitoring and evaluating approved projects. In the US, ethics review committees may cost up to US\$500,000 per annum to support.⁶ While the costs of running research ethics committees in developing countries will be much lower, such costs still represent a significant burden on limited resources.
- 8.18 To meet the financial costs, some research ethics committees receive regular funding from government. Others levy fees for reviewing research protocols. For example, in the UK, the Oxford regional research ethics committee charges pharmaceutical companies to conduct a review.⁷ Research ethics committees may charge a set fee for review or a variable fee, based on a proportion of the proposed research budget. While external sponsors generally recognise that set fees for reviewing research are a legitimate overhead cost, and some are encouraging such costs to be clearly identified in funding applications, they are often less willing to pay a proportion of the research budget for such review, particularly when this amounts to a significant sum.
- 8.19 Research ethics committees that levy fees may find it difficult to maintain their independence if fees are paid to the committee directly, rather than into a central fund, which can then be used for such matters as developing infrastructure, training and development for such committees. This possible weakening of independence may be the case even though the funds are intended for logistical support of the effective functioning of the committee. To meet this concern, in countries in which there is no central pool into which such levies may be paid, they could be paid to a local or national government and earmarked for support of research ethics committees.
- 8.20 Regardless of whether the financial support for research ethics committees comes from government, research institutions or as a result of levying fees for review, it is crucial that the independence of research ethics committees be maintained. **We conclude that there is a**

5 Squire SB (2001) Personal communication, Liverpool School of Tropical Medicine.

6 Wikler D (2000) Personal communication, World Health Organization.

7 Personal communication, Working Party fact-finding meeting in Oxford.

need for creative approaches to providing support, especially financial support, for research ethics committees, without compromising their independence. Sponsors should determine how they can meet the costs of ethical review without compromising the independence of the research ethics committee and should be responsible for meeting the costs of reviewing externally-sponsored research.

- 8.21 The activities of research ethics committees need not be confined to approving or rejecting proposals for research. They may also play an educational or advisory role by suggesting modifications to proposals that are consistent with ethical requirements. In addition, research ethics committees should ideally play some supervisory or monitoring role once projects have begun. If unable to do so, an alternative is to appoint an independent monitor (for example a clinician), to monitor compliance with the agreed protocol and to ensure that the participants in the research project are suitably protected, but funding would need to be made available for this. In our view, it is highly desirable that research ethics committees throughout the world should request annual reports of progress from researchers. However, we recognise that many research ethics committees in both developed and developing countries do not currently have the resources to undertake such reviews. Therefore, we urge sponsors to allocate appropriate additional resources so as to facilitate the conduct of an annual review of research.

Reviewing research in the sponsoring country and the country in which the research is conducted

- 8.22 In order to ensure that acceptable ethical standards are observed in externally-sponsored research, research should be approved through a system of ethical review of research in both the host and the sponsoring country. As regards the latter, if a sponsor provides funding, it must have the means of ensuring that the funds are being used in a manner that is ethically acceptable. However, the country in which the research is to be conducted must also be satisfied about the ethical acceptability of the research. **We recommend that externally-sponsored research projects should be subject to independent ethical review in the sponsor's country(ies) in addition to the country(ies) in which the research is to be conducted.**
- 8.23 The imbalance in power resulting from inequalities in resources discussed in Chapter 4 may extend to relationships between research sponsors, researchers and research ethics committees in developed countries on the one hand, and research ethics committees in developing countries on the other. For example, commercial pressures may be applied to committees in developing countries to use the same structures and procedures for ethical review as in the sponsoring countries. Guidance on research ethics committees in fact sets out a number of possible structures for such committees (Appendix 1 Table 4). Developing countries should, therefore, be able to adopt the structure(s) for research ethics committees that they consider will allow them to provide effective ethical review.
- 8.24 Difficulties may also arise when research ethics committees in developing countries are asked to review research before it is reviewed in the country of the sponsor. This may cause committees in developing countries to employ scarce resources to review research that the sponsor subsequently decides not to fund. On the other hand, once research has been reviewed in the sponsor's country, some research ethics committees in developing countries may be placed under pressure to concur with the opinion of the committee in the sponsor's country, particularly when reviewing forms of research of which they have limited experience.
- 8.25 Should there be disagreement between committees in the developed and developing country(ies), negotiation between the committees may be required. There should be mechanisms available to

facilitate such negotiation. At present such mechanisms, which are likely to benefit both host and sponsoring research ethics committees, are rare. Where there are irreconcilable differences between research ethics committees, a committee may choose not to approve the research. If a committee from a sponsoring country does not approve the research, the sponsor cannot fund it. If a research ethics committee from a developing country does not approve the research, then the research cannot be conducted within that country.

Developing capacity for reviewing the ethics of research

- 8.26 For research ethics committees to function effectively, committee members must receive adequate training. As many research ethics committees in developing countries have a rapid turnover of staff, regular training programmes for current and prospective members of committees are needed. A number of programmes are being established to develop expertise in the field of medical ethics and/or conducting ethical review. For example, the Fogarty International Centre of the National Institutes of Health (NIH) in the US is currently sponsoring training programmes in bioethics for faculties from developing countries. Towards the end of 2002, The Wellcome Trust will launch a funding initiative to support research into ethical and social aspects of conducting biomedical research in developing countries.⁸
- 8.27 The United Nations Development Programme (UNDP)/World Bank WHO Special Programme for Research and Training in Tropical Diseases (TDR) is addressing the need to strengthen the procedures for ethical review of research in developing countries through the training of key individuals in major research institutions.⁹ WHO's guidelines, which are available in Cambodian, English, French, German, Lao, Russian, Spanish, Thai, Turkish and Vietnamese, bring together previous recommendations concerning the minimum requirements for the proper functioning of ethics committees.¹⁰ The guidelines are currently being used in a number of regional fora which have been established to support the development of expertise in reviewing the ethics of research (see Box 8.2). In addition, regional workshops to train researchers and members of ethics review committees are currently conducted by the UNDP/United Nations Population Fund (UNFPA)/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction.
- 8.28 The Strategic Initiative for Developing Capacity in Ethical Review (SIDCER) is establishing networks within regions which will identify needs for training and education.¹¹ Each region has a forum, whose officers work with local governments, research institutions and participants in research and can represent the interests of research ethics committees at an international level (see Box 8.2).
- 8.29 Concerns have been expressed that training programmes for members of research ethics committees in developing countries, sponsored by a single developed country, may tend to reflect the views and procedures of the sponsoring country. **We recommend that international**

8 The majority of the research will take place in developing country locations where clinical or community oriented biomedical research is being done. An aim is to build capacity within developing countries to address ethical and social questions, and to increase the number of people with experience and training in this area.

9 Issues such as consent, standards of care and the protection of participants in research are part of a programme of training which also involves guidance on how to establish an effective research ethics committee.

10 World Health Organization (WHO) (2000) **Operational Guidelines for Ethics Committees that Review Biomedical Research**, WHO, Geneva. These guidelines define the role and composition of an ethics committee, detailing the requirements for submitting an application for review. Emphasis is placed on maintaining global ethical standards, while taking into account local variations in practice.

11 SIDCER was developed with contributions from WHO, European Forum for Good Clinical Practice (EFGCP), industry and CIOMS in conjunction with other institutions and associations. SIDCER works in co-operation with the established regional fora for ethical review and the WHO Regional Offices.

programmes and organisations, including WHO, continue to expand their current programmes for establishing, training and monitoring the development of research ethics committees. Funding should be provided to these international programmes for such purposes by bodies that sponsor research in developing countries.

BOX 8.2 Regional fora for developing the capacity for ethical review

A regional forum for ethics review committees in Asia and the Western Pacific (FERCAP) was established in January 2000. FERCAP has the objective of fostering an improved understanding and implementation of the ethical review of research by improving communication among ethics committees, acting as a collaborating centre and assisting in the implementation of relevant guidance. To date, it has sponsored a one-week training course in Bangkok in collaboration with a Thai and a Norwegian University.¹ Websites are being developed by FERCAP to assist in the dissemination of information. In addition to the regional fora, national bodies are being developed, for example FERCIT (the Forum for Ethical Review Committees in Thailand).

In Africa, a regional forum is being developed. PABIN (the Pan African Bioethics Initiative) aims to encourage the establishment of research ethics committees in countries in which they do not yet exist. It plans to conduct educational courses for members and potential members of research ethics committees in Africa.² The African Malaria Vaccine Testing Network (AMVTN) was set up in 1995 to assist in the planning and conduct of trials for a vaccine for malaria. It organises training courses in ethics for interested parties and will continue in this role, particularly while PABIN is developing.

In Russia and Eastern Europe, the Forum for Members of Ethics Committees in the Confederation of Independent States (FECCIS) was established in 2001. FECCIS plans to support the establishment of national and regional systems of ethical review, translate and distribute WHO's guidelines³ and develop training courses for medical students and research ethics committee members.⁴

Similar bodies have been set up in Latin America (The Latin American Forum of Ethics Committees in Health Research (FLACEIS)) and the Caribbean.

- 1 See FERCAP's objectives and activities at <http://www.fercap.org/> and 'The ethics of biomedical research' in **TDR News**, No. 63 (October 2000) at <http://www.who.int/tdr/publications/tdrnews/news63/ethics.htm>.
- 2 Chintu C (2001) Personal communication, PABIN.
- 3 World Health Organization (WHO) (2000) **Operational Guidelines for Ethics Committees that Review Biomedical Research**, WHO, Geneva.
- 4 The three-year plan for the Forum for Ethics Committees in the Confederation of Independent States (FECCIS) (2001–2003).