Ethical Issues in International Health Research and Epidemiology

John D. H. Porter, Carolyn Stephens, Anthony Kessel

This material was originally published in Ethics and Epidemiology (Second Edition) by Steven S. Coughlin, Tom L. Beauchamp, and Douglas L. Weed, and has been reproduced by permission of Oxford University Press.

http://www.oxfordscholarship.com/view/10.1093/acprof:oso/9780195322934.001.0001/acprof-9780195322934. For permission to reuse this material, please visit http://global.oup.com/academic/rights.

In this chapter we look at our divided world and explore issues such as the poverty of resources, health care infrastructure, research capability in developing countries, and the potential for exploitation that is inherent in this context and can occur through international research collaborations. We do not aim to repeat the well-rehearsed lists of ethical issues that can arise in international health research, but instead endeavour to grapple with these issues through the lens of the divided world, with an emphasis on the central role of the researcher.

In investigating research as we currently conduct it, we engage in descriptive ethics. But we also need to ask how we ought to be acting, which requires exploring systematically developed moral theories or normative ethics. Through the latter, research ethics may provide a guide towards changes in behaviour, which may help us understand better the nature of our individual and collective roles in international health research. The Nuffield Institute of Bioethics has recognized that we have a great deal to do in this area:
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. A sound ethical framework is a crucial safeguard to avoid possible exploitation of research participants in these circumstances (Quote from the Executive Summary of Nuffield Institute of Bioethics report on ‘The ethics of research related to healthcare in developing countries’ 2005 page xi) (1).

We argue here that ethics in international public health research needs to combine use of international understandings and guidelines with a close examination of how humans actually function in societies – both their own and in other peoples’.

Science itself is cultural and therefore embedded in a particular historical and social milieu (2). Part of the current historical and social milieu is the phenomenon of globalization, which has been defined as ‘the process of increasing economic, political and social interdependence and global integration that takes place as capital, traded goods, persons, concepts, images, ideas and values diffuse across state boundaries’ (3). This is particularly true in health where social, political, and economic forces are widening global inequalities in health leading to decreasing equity in resources, health protection, and health care (4).

Often values are being traded, not integrated, and different value systems are coming into conflict. This conflict is often linked to the global inequities and social injustice. These
divisions and differences need to be taken into account when creating research collaborations. Although globalization provides different ways of communicating in order to develop research proposals, how each of us should develop these collaborations continues to be an ethical question in international research. The creation of successful research collaborations and partnerships itself affects both how research subjects and communities are treated and how research teams operate (5).

Although low-income countries are gradually developing their own guidelines and ways of institutionalising ethics, most of the international research guidelines are currently presented within a western framework (6,7,8). We will discuss these changing value systems within international research after first looking briefly at international developments in research ethics.

**History of International Research and Ethical Issues**

Interest in the ethics of international health research accelerated in the early 1990s with the growth of international collaborations, led by the CIOMS guidelines and changes to the Declaration of Helsinki (9). From an international perspective, it is important to understand the history of the development of such guidelines.

Current regulations and guidelines are a direct consequence of research atrocities during the Second World War, and have evolved over the past 60 years. The history of research ethics shows the importance of remaining conscious to the problems of unethical research. By the beginning of the twentieth century the medical codes created by Thomas Percival circa 1800 (10) that consisted of the moral virtues of physicians with some mention of moral rules, rules of etiquette, and rules of professional conduct (11,12,13)
had become the dominant basis of professional ethics in the United States (13,14,15). In 1947 the British Medical Association (BMA) published its code of ethics, which essentially summarised the previous half-century’s work (11). The Nuremberg and Geneva Codes then expressed a new agenda based on the concept of human rights (16), and in 1964 the World Medical Association (WMA) published the Helsinki Declaration (7).

The Belmont Report of 1978, issued by the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, went beyond the Nuremberg Code (17) and the Helsinki Declaration to focus on informed consent, favorable risk-benefit ratios, and the need to ensure that vulnerable populations are not targeted for risky research (13). The report established the three main ethical principles in clinical research: respect for persons, beneficence, and justice (18).

In the 1980s there was an increase in international health research activity. In the early 1990s, the Council for International Organisation of Medical Sciences (CIOMS) worked with the World Health Organization (WHO) to develop two sets of international guidelines for international medical research (6,19). Controversies in the late 1990s around international HIV and TB trials (20,21) resulted in changes in the Helsinki Declaration and the CIOMS guidelines, and led to a working party report from the Nuffield Council of Bioethics in London (1,8).

This section outlines the emergence of the field of research ethics within epidemiology and other health sciences in the late 20th century. It shows the dominance of guidelines
developed in wealthy Western societies. This links strongly to the dominant models of health research conducted internationally, which we discuss in the next section.

**Types of Research Being Conducted Internationally**

Research is ‘the systematic investigation into and study of materials, sources … in order to establish facts and reach new conclusions’ (*Oxford English Dictionary*), and science is ‘the systematic study and knowledge of natural and physical phenomena (*Collins English Dictionary*). Epidemiology is a core discipline within public health research, whose aim has been defined as ‘to generate organized community effort to address the public interest in health by applying scientific and technical knowledge to prevent disease and promote health’ (22). Epidemiology has further been described as ‘the study of the distribution and determinants of health related states or events in specified populations’ (23). It is a quantitative science that is considered by many to be among the most important disciplines in public health (22). Examples of classical epidemiological research include cohort studies and case-control studies. In addition to epidemiology, public health research contains many different disciplines and research approaches that includes: clinical research (e.g. drug and vaccine trials); laboratory research; social science research (qualitative studies); health systems research (inter-disciplinary); and policy research (trans-disciplinary). All these disciplines may be used in the creation of intervention studies, including clinical trials and community-based trials health services and operational research. Operational research has been defined as ‘the application of scientific methods of investigation to the study of complex human organisations and services’ (24).
For some, the most important aspect of research is not the ‘type of research’ being conducted but ‘how’ it is conducted and with whom. For example, some believe that epidemiology is becoming increasingly divorced from its important role in public health policy and practice (25). One reason is the lack of involvement of communities in the research process (26). These shifting sands have led to the creation of the term "popular epidemiology," a process that highlights social structural factors and involves social movements (27,28). Popular epidemiology seeks to return the knowledge creation process to ordinary people and is committed to assuring that the problem defined arises from within the community and that local people function as cornerstones in the research process (29,30). The essence of popular epidemiology is its commitment to the sharing of power with the people with and for whom researchers work (27). Popular epidemiology is about how we interact as researchers and the importance of the management of research studies. The emergence of popular epidemiology may in part be derived from some moral problems encountered in international research.

**How We Develop Research Internationally**

Many research materials report the stages involved in the creation of a research project, such as introduction (study plan and ethical considerations), definition of study objectives, selection of interventions (if any), allocation of interventions (e.g. randomised or not), choice of outcome measure(s), study population (criteria for selection, inclusion, exclusion criteria, size and compliance), implementation (community acceptance, staff recruitment and training and field organisation, data handling, quality control, and, finally, analysis and reporting (31). In addition to these stages, there is also the search for
funding, discussions with funding bodies and the creation of links and partnerships with local communities and other organizations.

Although some research disciplines (principally qualitative ones) study the process of the creation and management of research, little information on this subject had been published until recently (32). However, social scientists are now providing important insights into research processes in developing countries (33,34,35). Their studies highlight the different perspectives, approaches, and beliefs that distinguish international researchers and local populations. Little is also known about how Research Ethics Committees (RECs) function. A recent group of studies from Mexico, using both qualitative and quantitative methods, highlights the importance of structures, actions and processes of Mexican RECs, and suggests a need for audit of committees (36,37).

This section outlines very briefly a growing debate within international health research: there is now evidence suggesting that researchers are often very distant from research subjects – both culturally and in terms of interaction in the research process. But what does this mean for the development of ethics guidelines in international health research and how do researchers use the guidelines that exist? The following section outlines some of the current issues in ethical guideline development and implementation.

**Guidelines**

When planning research in developing countries, there are now many regulations and ethics guidelines for researchers to consult (38). Those available include international guidelines and conventions, directives, national laws or guidelines, regulations and guidelines for research sponsored by the pharmaceutical industry, guidelines produced by
funding agencies, institutional guidelines, and guidelines relating to a specific disease (1). These sources highlight the groups of stakeholders involved, which include lawyers, sponsors, researchers, civil servants, insurance brokers, study subjects and communities.

Every researcher is responsible for understanding the research process and what is required to create, undertake, manage and disseminate information to those people who can benefit from the research findings. Guidelines and regulations do not provide a simple rational basis for decision-making, but highlight the complexity and difficulty of ethical decision-making. For example, the executive summary from the Nuffield Council on Bioethics meeting on research in developing countries in 2004 indicates how difficult it was for the committee involved to apply the ethics guidelines:

‘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. For example, the guidelines vary with regard to the scope and level of detail of information to be provided in the consent process, the obligation to provide a universal standard of care to control groups, the use of placebos, and the extent to which research participants are owed access to successful therapeutics after research is complete. There is also variation with the degree of involvement of the host country in the review process.’(1).

Guidelines need to be interpreted and specified for each research context, and the role and the integrity of the researcher is key in the process. Each researcher needs to ensure, on a minimal level, that the formalities required are completed in the host country as well as in the collaborating overseas country. Researchers need to ask themselves constantly whether they believe the research manoeuvre being employed is ethical. Regulations
and guidelines will provide assistance in this iterative process, but the decision-making ultimately is every party's responsibility. While research ethics are important in every context, they become particularly crucial when the balance of power between the researcher and the researched is skewed to the extent that we see in international research undertaken in low-income countries. The next section discusses this.

**Ethical Issues in International Research in Low-income Countries**

This section identifies and presents some key ethical issues that arise in international research. The controversy over the role of the drug Tenofovir in the prevention of HIV provides a story, which illustrates some of the current controversies inherent in international health research projects. It highlights the centrality of power dynamics within the milieu of different stakeholders and interests that come together in research collaborations that link rich with poor.

On Wednesday February 23rd 2005 Andrew Jack of the Financial Times wrote: ‘Testing Tenofovir on Cameroon prostitutes has landed researchers in a storm of criticism’ … The aim of the trial was to test whether Tenofovir could be used to stop AIDS infection. Such findings could revolutionise AIDS prevention. But attacks on the Cameroon study – and on similar research in half a dozen more countries – have raised broader issues about the economics and ethics of clinical trials in developing countries while the main beneficiaries are often in richer countries.’ (39)

Tenofovir is a powerful anti-retroviral (ARV) drug (marketed by Gilead) and approved for human use in 2001. A number of human studies were planned to investigate the drug for pre-exposure prophylaxis against HIV infection (PREP). The
countries involved included Botswana, Cambodia, Cameroon, Ghana, Malawi, Nigeria, Thailand and the United States. The study was funded by the US National Institutes of Health and the Gates Foundation, and planned to recruit 1000 sex workers to the trial. The trial was halted in August 2004 ‘… after the Cameroon leader judged that future support of trial participants – particularly if they were infected with HIV during the trial – was not sufficiently robust.’ (af-aids@eforums.healthdev.org).

Non-government organisations (NGOs) were also involved in the debate, and a representative from Medecins sans Frontieres (MSF) reportedly said: ‘Our concern is that these women who become infected receive adequate treatment. They must be guaranteed treatment by the trials sponsors’ (39). Following the suspension of the trial, the Global Campaign for Microbicides and the AIDS Vaccines Advocacy Coalition (AVAC) made its own statement: ‘Recently clinical trials have been launched in Africa, Asia and the United States to explore the potential use of oral Tenofovir as a ‘once a day’ pill to prevent HIV in uninfected individuals – an intervention know as pre-exposure prophylaxis (PREP). Yet concerns from a few activists opposed to these efforts have resulted in government decisions to halt the trial in Cambodia and the Cameroon.’ (www.avac.org).

The statement from AVAC later invokes assorted beliefs, assumptions and ethical imperatives. In a list of five points, AVAC states that the HIV pandemic is creating an urgent demand for safe and effective tools to treat HIV infection and to stop transmission; that this can only be achieved through responsible credible scientific studies; that the rights of vulnerable populations need to be protected; that
communities need to be involved in the conceptualisation and implementation of scientific studies; that rights of trial subjects need to be respected and that ‘they should be admired for their contribution to helping others’. Finally the AVAC statement indicated that researchers, and the organisations for whom they work, need to be held accountable for their studies.

The Tenofovir story demonstrates the different perspectives of the stakeholders involved (study subjects, research groups, NGOs, advocacy groups, governments, international agencies), and the overall complexity of the international research context. The use of ethics debate in international research collaborations provides a tool for presenting different positions, for debating particular research processes, while at the same time engaging with the individuals and groups involved in the research.

What are the general themes we can derive from the Tenofovir story? They include: social and cultural issues; priority-setting and equity; consent; ethical review of research; and standards of care. Each of these is discussed in turn in the following sub-sections.

**Social and cultural issues**

By the nature of much work in international health, many researchers move across cultures. A society is made up of all the skills, feelings, values, and beliefs that are learned, shared, and taught by its members from one generation to the next (40). This applies to the local culture of the population to be studied but also to the culture of the research team and of the sponsoring agency or national government. Researchers need to be asking themselves the following kinds of questions: How much consideration has
there been in the process of developing a protocol on social and cultural issues within the
particular countries involved? Whose perspectives have been respected and considered
unimportant? Whose perspective has ultimately been felt to be most important? Which
group has funded the project, and for whom is the work to be conducted?

Crossing social and cultural boundaries challenges our norms, lifestyles and ways of
seeing the world. A globalized world requires us to come to grips with the huge
disparities between the rich and poor. This is an important theme within all international
health research (4). Is scientific research the most appropriate way to address the health
problems in a particular country? In the north we often (though not always) think it is,
and if we have collaborators in the south, then they also may think that it is an
appropriate approach. At the same time, they may have different processes and methods
for conducting the work, which may include different priorities (26).

Priority and equity
Research in developing countries should be responsive to the health needs and the
priorities of the community in which it is to be carried out. (Guidelines 8. CIOMS) (6).
Ninety percent of all medical research conducted is on those diseases that cause 10% of
the global burden of disease (4,41). Our task as researchers is to ally ourselves with
approaches that help reduce these inequities because a reduction of inequity produces
better health (4,42). Health related research needs to be allied to each country’s health
priorities. International organizations such as the United Nations (UN), the World Health
Organization (WHO) and the World Bank identify international health priorities.
Currently the focus is on the Millenium Development Goals (MDGs) and the reduction of
poverty (43), but each country and each research group creates its own priorities within these goals and tries to ensure that the goals themselves do not impede creative work.

Although we can speak meaningfully of setting priorities internationally, international priorities cannot and should not be the same for each country. Each country has its own unique context, its own unique identity and ways of working. Health priorities are ultimately created in each country through the government and its relationships with international organizations and other stakeholders. However, international research groups also influence decision making within countries. The researcher should be asking how these priorities are created and who influences these decisions.

**Consent**

Research subjects need to understand and give consent to participation in research studies, as is discussed by Anna Mastroianni and Jeffrey Kahn in chapter 4. This is affected by social and cultural issues (34,44). Guidance from the different bodies agrees that each research participant must be adequately informed about the ‘nature, significance, implications and risks associated with a research trial,’ and that in the majority of cases, informed consent should be sought from each potential research participant. Some guidelines stress the importance of respecting cultural beliefs and norms, which means that in certain situations community consent may be appropriate, though it is important not to assume that individual consent is thereby not required (8). The default position should always be individual-subject consent.

International guidelines published by the Council for International Organisations of Medical Sciences (CIOMS) 2002, World Medical Association (WMA) 2000, Council of
Europe (CoE) 2004, European Union (EU) 2001, European Group on Ethics in Science and New Technologies (EGE) 2003, and Nuffield Council on Bioethics (NCOB) 2002 all address the issue of consent in international research. The areas they cover include who should give consent, how it should be recorded, provision of information, inducements and concepts of ‘genuine consent’ (1). These documents supply a significant body of good advice, though it cannot always be taken as authoritative for epidemiology. The degree of detail of information required varies between the guidelines and indicates the increasing bureaucracy around international trials. For example, the Helsinki Declaration of 2000 states that each potential subject must be adequately informed about: “The aim of the study and methods to be used, the sources of funding and possible conflicts of interest, the institutional affiliations of the researchers; the anticipated benefits and potential risks and the follow-up of the study, the discomfort it might entail, and the right to abstain from taking part in the study, or to withdraw from it at any time without any reprisals” (7). As consent becomes an increasingly bureaucratic process, there is a potential to completely miss the point of consent, which is the creation of relationship and understanding.

**Ethical review of research**

If countries want to be involved in the funds that come through international research collaborations they must have functioning research ethics committees. For those of us living in wealthy industrialized countries, it is important to remember the long historical process that led to the creation of ethics committees in North America and Europe, as discussed by Robert Levine in chapter 12. RECs have huge responsibilities that are often compromised of their ability to act due to competing interests. As Figure 1 shows, ethical decision making involves different tensions that include power equalization, reflection on
ethics, reconciliation between personal interest and values, and democratic dialogue (13,45). An inappropriate balance in any of these areas will lead to poor decision making and unethical research. It is also clear that local and national RECs are being increasingly directed by outside influences, including international regulations as well as international research collaborations (46). There is a need to keep this process under review and not to assume that ethics committees are able to do the job they were established to perform. Sometimes, the process or structure of the committee needs to change, and there have been suggestions that regular audit may be needed (36,37).

International guidelines help to clarify the role of RECs. For example, the Helsinki Declaration and the International Guidelines for Biomedical Research (CIOMS) have established that RECs exist to ensure, that proposed research will not expose participants to unacceptable risks and practices. Also, they must ensure that the potential participants can evaluate the expected consequences of their involvement and decide for themselves whether to participate (6,7,36). These guidelines state that a REC should operate inside a defined framework that includes ‘membership and size of committee, working rules, and ethical, legal and regulatory requirements for research on human subjects in the country where it is situated as well as applicable international requirements’ (6,7). International guidelines stress the importance of the review of scientific research (1), but some countries have no established system for review, rendering the maintenance of an ethical review process expensive. There is currently a lack of information in many countries about the processes and standards of their ethics committees (47,48).

The working party from the Nuffield Council on Bioethics recommended that all countries establish an effective system for the ethical review of research that is
independent of government and sponsors of research (8). Adequate provision should be made for training all professionals involved in the ethics of research. This recommendation brings with it a responsibility on the part of industrialized countries to help train ethics committees in poorer countries. It also emphasizes the importance of the independence of impartially constructed committees.

**Standards of care**

In the late 1990s the issue of standards of care was highlighted through the publication of clinical trials investigating the prevention of the transmission of HIV from mother to child (20,21). This issue relates to the treatment that participants in a control group should receive as part of a trial. Some would argue that participants in trials should receive the same standard of care as those people in countries sponsoring the research (8). But who determines the best standard of care, and which criteria are to be used? In deciding which standard of care is best, the context of the research is critical. As the Nuffield Report indicates: ‘The context of the research in different countries must be critically assessed to establish whether or not it provides a morally relevant reason for offering a different standard of care’ (8). In the quest for equality and equity, it is important to realize that people and countries are different and that local socio-political, financial, infrastructural, and cultural circumstances are important (9). Equality does not mean that people must always be treated identically but that ‘for every difference in the way men are treated, a reason should be given that is relevant’. (8,49).

Guidelines have continued to adapt following the revision of the Helsinki Declaration. The debate has proved productive and led to several new perspectives. In 2002 the Nuffield Council recommended the following: ‘The minimum standard of care that
should be offered is the best intervention available as part of the national public health system.’(1).

*Externally sponsored research*

In many cases funding for international research comes from outside a low-income country in which the research is to be carried out. For example, the Tenofovir study (see Box 2) was conducted in several different countries and funded by the National Institutes of Health (NIH) and the Gates Foundation. This leads to conflicts and tensions around control of the processes of research. The ethics review process attempts to deal with some of these issues, but each research group and funding agency has a responsibility to ensure that individual research subjects are not compromised in the process. Respect for difference means that sponsoring agencies need to accept and negotiate various possible different approaches to the research process.

The Declaration of Helsinki (Clause 13) stresses the importance of ethics review, but does not recognize a special responsibility for ethics review in the host country (9). In contrast, the Nuffield Council on Bioethics Report of 2002 recommends that externally sponsored research projects be subject to independent ethical review in the sponsor’s country in addition to the host country. This ensures that all countries are represented in the research ethics discussions.

Current international guidelines provide differing information and stimulate debate without providing a solution to various conflicting approaches. A main point of disagreement in the guidelines and regulations concerns the degree of involvement of the host country in the review process. The CIOMS guidelines call for representation from
host countries, whereas the Council of Europe requires ethical review by an independent ethics committee ‘in each State in which any research activity is to take place’ (CoE 2004 Article 9). The Nuffield Council 2002 recommends that research should be reviewed in both the sponsoring country and the host country where research takes place (8).

There is little information available on how these processes actually work. The Nuffield Guidelines are useful in providing scenarios to help the reader address the issues in particular contexts, but more work is needed to support the research and better understand the differing processes.

**What happens when the research is over?**

‘Wherever possible, the results of trials where the interventions prove to be effective must be translated to improve healthcare for communities in which they were undertaken’ (1).

It is no longer appropriate to conduct research in a particular setting and then simply leave with the data. The process of conducting ethical research is about the creation of relationships with each of the stakeholders involved including study subjects and communities. At the completion of the study there needs to be a clear understanding of how the community involved will benefit from the research conducted. For example, in the case of Tenofovir (39), important questions include: Will the community receive the drug if it is found to be efficacious? Will the placebo group receive the intervention and for how long? Who should pay for and supply the treatment or intervention?

As part of the preparation of the protocol there needs to be close collaboration between the researcher and the stakeholders, particularly with the communities that are receiving
the intervention. These discussions need to be linked to national health priorities and the local priorities of those communities. The research needs to be seen as part of a larger public health agenda for improving the health of the population. A critical part of the engagement must include a precise understanding of investigator responsibility once the research is finished. Consideration of what happens when the research is over is not limited to provision of drugs or other interventions after the study has ceased. Thought must be given to impact of the research on issues of equity of healthcare provision and ongoing issues of capacity building and the training and support of staff.

**Conclusions**

When crossing international borders and boundaries it is important to understand that particular ways of thinking are not present in all countries. Each context, like each individual, is unique. If we are from a developed country, we may be projecting our values onto countries that may have different beliefs and values. In international health research, guidelines and declarations provide us with some information, but each researcher and each institution sponsoring research needs to reflect morally on the often conflicting advice in order to find his or her own way through the plethora of codes, guidelines and recommendations. The whole process of research, from the idea of the study, through the development of the protocol, discussions with stakeholders, ethics committees, funding activities, the research itself, and the results and the dissemination are all points of reflection for each researcher. Each of us needs to be satisfied that our contribution, the contribution of our team of researchers, and ultimately with the impact of the work on the communities involved can be morally justified. The Nuffield Council highlights four principles to use when considering research work related to healthcare in developing countries: 1) The duty to alleviate suffering; 2) The duty to show respect for
persons; 3) The duty to be sensitive to cultural differences; and 4) The duty not to exploit the vulnerable (8).

Benatar and Singer (4) also suggest a list of requirements to consider for making moral progress in international health research. These include: educating researchers and members of research ethics committees about research ethics; ensuring that international researchers understand and are sensitive to the social, economic and political milieu that frames the context in which their research is taking place; involving members of the host country in the design and conduct of the trial; ensuring that trials are of direct relevance to the health needs of the host country and that the balance of benefits and burdens of the project are fairly distributed; conducting prior evaluation by a local committee or governing body of whether the study findings can, and will, be incorporated into the local healthcare system; providing subjects with care of treatment they would not ordinarily get in the country where the trial is carried out; ensuring existing disparities are not more deeply entrenched by inappropriate deflection of local human or material resources away from the healthcare system in the host country towards the research project; and ensuring that research produces benefits for the practice setting and builds the capacity of healthcare professionals in the host country.

These requirements stress the importance of connecting with the values that underpin local communities, which are often far from obvious. The roots of communities are essential to understand in the creation of a morally appropriate relationship. We need to respect differences and find a way of actively encouraging dialogue, group discussion and ultimately translation of information. If we are unable to listen, learn, translate, and respect, we will fail to be ethical researchers. We should go beyond our current research
ethics approach. As Benatar and Singer note, ‘There is a need to go beyond the reactive research ethics of the past. A new, proactive research ethic must be concerned with the greatest ethical challenge – the huge inequities in global health’ (4).

* In this chapter we have explored the ethical issues that arise in the course of undertaking epidemiological and international health research. At the outset we explained that it was not our intention to provide another set of ethics guidelines or benchmarks for researchers. Already, a number of such documents exist, and we have signposted the reader towards these, as well as outlining milestones in the historical development of key guidelines.

The chapter has instead focused on ethical issues that the researcher inevitably has to grapple with during the conduct of research. These include: how to plan and develop international research; the value systems of different cultures and countries; particular issues in low-income countries such as those around priority-setting, equity and consent; external sponsorship and ethical review of research; and what happens when the research is over.

Most significantly, however, we have tried to convey that, although following guidelines and adhering to the law are both important, what is perhaps critical is that the researcher approaches the research with an open mind and willing heart. There is no replacement whatsoever for thoughtfulness, sensitivity, and treating people with respect and dignity.
REFERENCES


10. Percival T. Medical Ethics or a code of institutes and precepts adapted to the professional conduct of physicians and surgeons. Manchester: Johnson J, Bickerstaff R, 1803.


13. Valdez-Martinez E. Medical Research Committees in Mexico: their role in the ethics of scientific research. DrPH thesis. London School of Hygiene and Tropical Medicine. Faculty of Medicine, London University, 2004.


33. Molyneux CS, Wassenaar D, Marsh K. Even if they ask you to stand by a tree all day, you will have to do it (laughter)! Soc Sci Med 2005;61:443-454.


Democratic dialogue

Reflection on ethics

Reconciliation between personal interest and values

Ethical decision making

Power equalization

Figure 1  Tensions in ethical decision making (13)