



# THE DECLARATION OF HELSINKI THROUGH A FEMINIST LENS

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## Abstract

This commentary was submitted to the World Medical Association on behalf of the International Network on Feminist Approaches to Bioethics. Our submission included (1) a description of feminist research ethics, (2) suggestions for specific revisions to the Declaration, and (3) elements found in other international research ethics codes that are important from a feminist perspective. Our goals were to encourage the WMA to craft a declaration that: (1) conceptualizes issues of vulnerability in richer and more nuanced ways, (2) resists the influence of profit motives, and (3) extends the scope of responsibility for ethical research more broadly.<sup>1</sup>

## Introduction

This commentary was submitted to the World Medical Association (WMA) on behalf of the International Network on Feminist Approaches to Bioethics (FAB). The WMA solicited comments from FAB and other organizations for the

2008 revision of the Declaration of Helsinki. What follows are the suggestions made by the FAB Committee on the Declaration of Helsinki. Our submission consisted of three parts: (1) a description of feminist research ethics, (2) suggestions for specific revisions to the Declaration, and (3) elements found in other international research ethics codes not found in the Declaration that are important from a feminist perspective. Our goals, in general, were to encourage the WMA to craft a declaration that: (1) conceptualizes issues of vulnerability in richer and more nuanced ways, (2) resists the influence of profit motives, and (3) extends the scope of responsibility for ethical research more broadly.<sup>2</sup>

### **Distinctive features of a feminist perspective on research ethics**

Most research ethics codes, including the Declaration of Helsinki (hereafter, the Declaration), tend to focus on the behavior of researchers and the obligations of researchers and research ethics committees to subjects. These obligations typically begin when a study is already designed and submitted for ethical review and when the data are collected and analyzed. Feminist work in research ethics argues for broadening the scope of concern.

A feminist perspective on research ethics calls for directing our attention to features of the social and institutional context related to the research enterprise, including contextual features that may perpetuate patterns of inequality or power imbalance. For example, such features include operative norms and unquestioned assumptions in science and society, economic structures, and processes of decision making that structure research with humans. These norms, structures, and processes merit our attention and best efforts at remedy where they tarnish ethical ideals—above all, social equality and self-determination—for women and other groups. We offer some brief examples to illustrate.

Norms about “ideal” research subjects historically have contributed to the exclusion of women, given cyclical variation in hormones, body size and composition, or the use of contraceptives, all thought to compromise ideals of scientific rigor. In addition, it is often assumed that women’s frequent responsibility for child care renders them non-compliant in adhering to research regimens. Similarly, scientific norms that value homogeneity among research subjects have contributed to a failure to perform sex-specific analyses in studies where women have been included, for instance, in research on cardiovascular disease and HIV/AIDS. The still-operative assumption that researchers are active agents and subjects are passive participants has structured relationships between re-

searchers and potential and actual subjects in a way that undermines the moral agency of the latter—particularly women, people of color, and the poor—in a variety of ways: typically, excluding them from the design of research agendas and questions and from the process of ethical review and in deficient efforts to secure informed, voluntary consent. In addition to thwarting self-determination, these norms and assumptions perpetuate social inequality by leaving health care providers without sufficient information on the etiology, symptoms, and progression of diseases and conditions, preventive strategies and diagnostic testing, and the safety and efficacy of drugs and other interventions for women and others historically or currently excluded from research participation.

Related to the point noted previously regarding “active” researchers and “passive” subjects, entrenched assumptions regarding what constitute “research expertise” and/or “scientific literacy” have contributed to the design of decision-making processes that exclude the contributions of lay persons embedded in communities. Yet such people often have rich perspectives to contribute when it comes to important research questions and to the values that might be at stake in a proposed project.

Other features of decision-making processes in research raise concerns of justice that are of particular importance to feminist ethicists. Research ethics committees typically are expected to balance risks to the individual participants against the potential benefits to participants and to the society at large. However, whether by virtue of research regulations (such as those in the United States) or their mandate within a local institutional context, research ethics committees are not positioned to comprehensively assess the long-term implications for public policy or other potential risks to society. This is a source of great concern for populations who are in situations of vulnerability. One example of a potential long-term implication of research that would be beyond the mandate of many research ethics committees would be a research project or program of research (for example, in behavioral genetics) that could serve to stigmatize or to perpetuate discrimination against a particular social group.

The narrowly defined scope of research ethics committees’ decision making raises at least one other major concern of justice for feminists. Research ethics committees, again by virtue of research regulations or their mandate within a given institutional setting, are prohibited from reviewing or requiring programs of research or a series of research projects. This poses problems for groups who historically have been understudied. For example, although recruitment may be justifiably limited in a particular study, that study’s results may justify expanding

the recruitment population in a subsequent study. Research ethics committees cannot require the subsequent studies, and the justice problem is that the subsequent studies are not performed. This, then, could serve to perpetuate inequalities, and in particular, health disparities for women.

Economic structures related to research funding can compromise the integrity of both researchers and research ethics committee members, all of whom are keenly aware of the need for research funding to support their institutions' financial viability. As well, the fear of legal liability has contributed to the exclusion and under-inclusion of pregnant women and often women of childbearing age. Exclusionary policies that put promising experimental treatments out of reach for women not only serve to undermine women's self-determination, but they also contribute to the development of health policy and standards of care that are not in all cases clearly applicable to women. The domination of affluent nations and the commercial interests of those who fund research, in setting research agendas and in funding research, lead to serious and indeed, fatal inattention to the health problems that plague people in resource-poor parts of the world. At the same time, these people can face exploitation as subjects in specific research projects that do not necessarily hold out the prospect of benefit for them or their countries.

Feminist ethicists, then, call for the following major reforms in research with humans:

1. Critical attention to social and scientific norms and assumptions that have served as barriers to the participation of women and others in situations of vulnerability;
2. More democratic and ^just^ processes in setting research agendas, designing programs of research, and in examining their ethical implications for human subjects and for society, including long-term potential for harm to the latter;
3. Transforming the systems for distributing resources for research, including building capacity in resource-poor countries to avoid exploitation and the perpetuation of global health disparities.

It is not only researchers and research ethics committees that hold responsibility for such reforms. Governments, elected officials, those who fund research, research institutions, and their systems of governance (within institutions and professional organizations), also have obligations to ensure that the essential effort to develop generalizable knowledge for the benefit of public health does not create or per-

petuate inequalities or relations of power or undermine the many other ethical ideals at stake in research.

### **Elements found in the other international research ethics codes that are important from a feminist perspective yet not found in the Declaration of Helsinki**

1. The importance of fair access to participation in research studies so that no group will be deprived of the benefits of research and so that all groups can better achieve social justice:
  - a. Other guidelines refer specifically to the exclusion of women of reproductive age or children in general and suggest special provisions when conducting research with them. They also refer to the need to refrain from over-studying some groups, especially the poor, while leaving others unstudied or understudied. There is also an explicit recognition that social disparities need to be addressed in research, as well as in any endeavor related to science and technology progress.
2. Vulnerability defined in a way that includes social inequity:
  - a. Other international instruments define vulnerability in a way that explicitly includes reference to social disparities. They also address the responsibility that both sponsors and investigators have in addressing it by conducting research that could worsen unjust conditions or create new inequities.
3. Other international codes explicitly describe the ethical obligations of external sponsors and investigators in externally sponsored collaborative research. These obligations include:
  - a. The need for international cooperation and responsibility on the part of affluent nations and sponsors to develop research agendas that address the health needs of low-resource countries and vulnerable populations;
  - b. The need for justice and equity when writing an agreement to conduct an international collaborative research project; including a robust ethical review that involves representatives from host countries that should advise on the best way to protect particular populations where the research is to be conducted and including members of communities who lack social, economic, or political power; it is also stated that the reviewers serving on the committee of the host

country, as well as those serving on the committee of the country where the sponsoring entity is based (government, pharmaceutical industry, or academic institution) should adhere to the same ethical standards. That is to say, every effort should be made to ensure that participants in research projects performed in resource-poor countries receive the same regimens as would be made available to participants in research performed in affluent countries.

- c. An equitable distribution of resources for and from research, particularly within resource-poor countries and among persons or groups in situations of vulnerability. This encompasses building capacity in resource-poor countries, providing sustainable assistance to persons and groups who took part in the research, and providing access to benefits derived from the research (including diagnostic or therapeutic methods). Care must be taken to ensure that such post-research benefits do not serve as coercive incentives for participation.

Although an important step was taken by the WMA in its last revision of the Declaration, when it added paragraphs 29 and 30, the notes of clarification weakened them. ^We are concerned^ that the allowance for the possibility of placebo controls and for the possibility that participants might not be given access to the benefits of the research after it has been completed will perpetuate global health inequalities.

## **Recommendations for revisions to the current version of the Declaration**

Introductory notes:

1. We believe that the Declaration warrants two clarifications:
  - a. Clarification is required with respect to the scope of research that the Declaration is meant to address. A-1 states that “Medical research involving human subjects includes research on identifiable human material or identifiable data.” Does the WMA intend to imply that the standards set out in the Declaration do not apply to research using anonymous data? The way that anonymous data is obtained for research should have some oversight. We refer, for example, to the collection of research data from identifiable sources

- (e.g., medical records, databases, leftover tissue), that is made anonymous and turned over to researchers.
- b. The Declaration currently refers to both “experimentation” and “research.” It is not clear whether the terms are meant to be interchangeable in meaning or if “experimentation” is intended to be a subset of “research.” For instance, perhaps the WMA means by “experimentation” something along the lines of “physically or psychologically invasive research.” Clarification is required on this point as well.
2. What follows is the text of the WMA Declaration of Helsinki, including our suggestions for revision. New material and material moved to new areas have been indicated by an underline of the text.

## **WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI: ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS**

### **A. INTRODUCTION**

1. The World Medical Association has developed the Declaration of Helsinki as a statement of ethical principles to provide guidance to physicians, researchers, and other stakeholders in medical research involving human subjects. Medical research involving human subjects includes research on identifiable human material or identifiable data.
2. It is the duty of the researcher to promote and safeguard the health and welfare of the people who participate in research. The researcher's knowledge and conscience are dedicated to the fulfillment of this duty.
3. The Declaration of Geneva of the World Medical Association binds the physician with the words, “The health of my patient will be my first consideration,” and the International Code of Medical Ethics declares that, “A physician shall act only in the patient’s interest when providing medical care which might have the effect of weakening the physical, and mental condition of the patient.” When a physician is also a researcher, he or she must never undermine the health or well-being of a patient for the sake of research or tarnish the patient’s trust.

4. Medical progress is based on research that must ultimately rest in part on experimentation involving human subjects.
5. In medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society.
6. The primary purpose of medical research involving human subjects is to improve prophylactic, diagnostic, and therapeutic procedures and the understanding of the aetiology and pathogenesis of disease. Even the best proven prophylactic, diagnostic, and therapeutic methods must continuously be challenged through research for their effectiveness, efficiency, accessibility, and quality.
7. In current medical practice and in medical research, most prophylactic, diagnostic, and therapeutic procedures involve risks and burdens.
8. Medical research is subject to ethical standards that promote respect for all human beings and protect their health, bodily integrity, values, and rights.
9. Researchers must consider the context in which research occurs. Features of the research itself, the institutional environment, or the social and economic context can put participants in harm's way. Researchers must strive to be aware of these features of the research context and minimize potential harm. Special attention must be given to the background conditions that may interfere with a potential subject's ability to participate in research, such as work obligations, transportation, and child care considerations.
10. Some research populations are in situations of vulnerability and need special protection. In the context of research, the term "vulnerability" is typically associated with an inability (either total or partial) to protect one's own interests. This inability might arise, for example, from limited decision-making capacity, limited education, one's legal status, or one's power in a given society or community, based on its norms. Each of these attributes can diminish a person's ability to participate meaningfully and independently in the informed consent process. Particular concern should be paid to women and indigenous populations who, in many communities, may have little power. The particular needs of the economically and medically disadvantaged must be recognized. Special attention is



also required for those who cannot give or refuse consent for themselves, for those who may be subject to giving consent under duress, for those who will not benefit personally from the research, and for those for whom the research is combined with care.

11.#Vulnerability is not created solely by the attributes of individuals.

Research subjects may be rendered vulnerable by researchers, institutions, or environments which lack sufficient structures or resources for protection. ^Researchers and other responsible persons must strive to identify specific features of the research environment that may make persons vulnerable, to mitigate those features of the environment, and to implement protections for subjects against any remaining vulnerability^.

12.#Vulnerability is also associated with particular kinds of research.

Special scrutiny should be applied when: (1) the research involves initial experiences of translating new scientific advances into humans, especially when the intervention is novel and/or irreversible; (2) there is a known or credible risk of significant harm (death or serious disability being the clearest examples), and there is no potential of an offsetting direct medical benefit; or (3) the protocol raises ethical questions about research design or implementation for which there is no consensus.

13.#Researchers must take care not to use the concept of vulnerability to stereotype whole categories of individuals.

Researchers must make appropriate distinctions between individuals in a group who might have special characteristics that must be taken into account and those who do not, ^for example, by assessing individuals' particular capacities to give free and informed consent^.

14. Research investigators should be aware of the ethical, legal, and regulatory requirements for research on human subjects in their own countries, as well as applicable international requirements. No national, ethical, legal, or regulatory requirement should be allowed to reduce or eliminate any of the protections for human subjects set forth in this Declaration.

## B. BASIC PRINCIPLES FOR ALL MEDICAL RESEARCH

\* Due to their actual and/or potential general toxicity and large ecological footprint, all research and development of new medical practices, materials, tech-

niques, tools, or medications must be balanced by equivalent or greater efforts to reduce the overall environmental impact of health promotion efforts.\*

1. It is the duty of physicians and researchers in medical research to protect the life, health, privacy, and dignity of the human subject.
2. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and on adequate laboratory and where appropriate, animal experimentation.
- 3.\*The long-term environmental effects of the conduct of research, and of the likely products of research, must be considered. The precautionary principle should be used to balance potential harms and benefits where effects are uncertain. The welfare of animals used for research must be respected, and potential harm to species and biomes<sup>3</sup> must also be considered.\*
4. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol. Ideally, this protocol will be developed with the input from those who stand to benefit from it. This protocol should be submitted for consideration, comment, guidance, and where appropriate, approval to a specially appointed ethical review committee, which must be independent of the investigator, the sponsor, or any other kind of undue influence. This independent committee should be in conformity with the laws and regulations of the country in which the research experiment is performed. The ethical review committee should include representatives from the population from which subjects will be recruited or at least include reviewers who can represent their interests. The committee has the right to monitor ongoing research. The researcher has the obligation to provide monitoring information to the committee, especially any serious adverse events. The researcher also should submit to the committee for review, information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest, and incentives for subjects. To the extent possible, research findings should be disseminated to the subjects or to groups who represent their interests.

5. The research protocol always should contain a statement of the ethical considerations involved and should indicate the specific ways in which there is compliance with the principles enunciated in this Declaration.
6. Medical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person <sup>^(in some cases, non-physician health care personnel)^</sup>. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given consent. <sup>^Where other health care personnel have an active role in research, their responsibilities should be visible, recognized, and/or validated to ensure fairness in the research work environment and the protection of human subjects.^</sup>
7. Every medical research project involving human subjects should be preceded by careful assessment of predictable risks and burdens in comparison with foreseeable benefits to the subject or to others. <sup>\*Consideration must include potential risks and burdens for future generations and possible environmental harm resulting from any toxicity of the research or its products, potential increases in per capita ecological footprint, or cultural and social practices undermining environmental sustainability.\*</sup> This does not preclude the participation of healthy volunteers in medical research. The design of all studies should be publicly available.
8. Researchers and physicians should abstain from engaging in research projects involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Researchers and physicians should cease any investigation if the risks are found to outweigh the potential benefits or if there is conclusive proof of positive and beneficial results.
9. Medical research involving human subjects should only be conducted if the importance of the objective outweighs the inherent risks and burdens to the subject. This is especially important when the human subjects are healthy volunteers.
10. Medical research is only justified if there is a reasonable likelihood that the populations in which the research is performed stand to benefit from the results of the research.

11. Researchers must actively plan for and recruit women and other historically understudied groups to research. To achieve this goal, researchers must work to remove barriers to women's and other groups' participation in research, including, for example, restrictions relating to childbearing potential.
12. In international externally-sponsored research, investigators must submit the protocol for ethical and scientific review both in the host country and in the country where the sponsoring organization is based and should be subject to the same high ethical standards in both countries. The proposal should be responsive to the health needs and priorities of the host country.
13. The sponsors' obligations in international research studies should be clarified before the research begins and include ensuring the availability of health care services that are essential to the safe conduct of the research; treatment for subjects who suffer injury as a consequence of research interventions; and strengthening the capacity to design, conduct, and review biomedical research. Obligations of external sponsors to provide health care services will vary with the circumstances of particular studies and the needs of host countries. The agreed arrangements should be specified in the consent process and documented. The details of these arrangements should be agreed upon by the sponsor; officials of the host country; representatives of the institution where the research will be conducted; other interested parties such as ministries of health and when appropriate, the community from which subjects are to be drawn.
14. The subjects must be volunteers and informed participants in the research project. In the case of women of reproductive age, informed consent from the woman should suffice for the researcher and sponsor. Consent from the partner should only be sought when the research directly affects the partner or when it is culturally appropriate to do so. However, obtaining consent merely from a partner or an elder should never be regarded as sufficient.
15. Researchers and sponsors should not exclude women who are biologically capable of becoming pregnant from clinical trials of drugs, vaccines, and medical devices only on the basis of risks for a potential fetus. Proper access to effective pregnancy tests and contraceptive methods should be guaranteed to them prior to the study when

there is evidence or data that suggest that there is a potential risk to the fetus, pregnancy, or to the woman. Possibilities of termination of pregnancy and/or permanent medical follow up should be included in the informed consent process.

16. Researchers should include pregnant women in research when the research holds the prospect of direct benefit to the woman, direct benefit to the woman and the fetus, or when the proposed research presents no greater than minimal risk to the fetus and the research may produce important biomedical knowledge that cannot be obtained by other means. When possible, appropriate clinical studies on pregnant animals and non-pregnant women must be done to provide data on the likely risk of the research to pregnant women and their fetuses.
17. Fair access to participation in research studies should be taken into account when planning research. No group should be deprived from benefits derived from research that might concern them, nor from the benefits because of being a human subject. Researchers and sponsors should avoid conducting research exclusively with certain groups, such as the poor or the easily accessible.
18. The right of research subjects to safeguard their integrity always must be respected. Every precaution should be taken to respect the privacy of the subject, the confidentiality of the patient's information, and to minimize the impact of the study on the subject's physical, mental and social integrity, values, and on the personality of the subject.
19. In any research involving human subjects, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study, and the discomfort it may entail. Special attention should be given to the unique information needs of particular populations and individual potential participants, as well as to the methods used to deliver the information.
20. After ensuring that the subject has understood the information, the researcher then should obtain the subject's freely-given informed consent, preferably in writing. If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed. Persons who do not have authority to give consent (on

- the basis of cultural or other norms) should have a genuine opportunity to refuse participation. Such refusal should be honored.
21. When obtaining informed consent for the research project, the researcher should be particularly cautious if the subject is in a dependent relationship with the researcher or may consent under duress. This is a particular concern for researchers who are also physicians. In that case, the informed consent should be obtained by a well-informed researcher who is not engaged in the investigation, and who is completely independent of this relationship.
  22. For a research subject who is legally incompetent, or is physically or mentally incapable of giving consent for participation in research, the researcher must obtain informed consent from the legally authorized representative in accordance with applicable law. Members of these groups should not be included in research unless: (1) the research is necessary to promote the health of the individual human subject, or (2) the research is necessary to promote the health of the population represented by the individual human subject, and this research cannot be performed instead on legally competent persons.
  23. When a subject deemed legally incompetent, such as a minor child, is able to give assent to decisions about participation in research, the investigator must obtain that assent in addition to the consent of the legally authorized representative.
  24. Research on individuals from whom it is not possible to obtain consent, including proxy or advance consent, should be performed only if the physical/mental condition that prevents obtaining informed consent is a necessary characteristic of the research population. The specific reasons for involving research subjects with a condition that renders them unable to give informed consent should be stated in the experimental protocol for consideration and approval of the review committee. The protocol should state that consent to remain in the research should be obtained as soon as possible from the individual or a legally authorized surrogate.
  25. Both authors and publishers have ethical obligations. In publication of the results of research, the investigators are obliged to preserve the accuracy of the results. Negative, as well as positive results should be published or otherwise publicly available. Sources of funding, institutional affiliations, and any possible conflicts of interest should

be declared in the publication. Reports of experimentation not in accordance with the principles laid down in this Declaration or not having been registered in the national and/or international database of clinical trials, should not be accepted for publication.

26. Explicit consideration of the long-term implications for public policy that may be posed by research is essential. Because institutional research ethics committees are not positioned to conduct this form of review, other mechanisms for such review must be established.

### C. ADDITIONAL PRINCIPLES FOR MEDICAL RESEARCH COMBINED WITH MEDICAL CARE

27. The physician-researcher may combine medical research with medical care, only to the extent that the research is justified by its potential prophylactic, diagnostic, or therapeutic value. When medical research is combined with medical care, additional standards apply to protect the patients who are research subjects.
28. The benefits, risks, burdens, and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods. This does not exclude the use of placebo or no treatment, in studies where no proven prophylactic, diagnostic, or therapeutic method exists. (See note of clarification for paragraph 28.)
29. At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic, and therapeutic methods identified by the study. (See note of clarification for paragraph 29.)
30. The physician-researcher should fully inform the patient which interventions are requested or required solely for the purposes of research. The refusal of a patient to participate in research must never interfere with the patient-physician relationship or access to future medical care.
31. In the treatment of a patient, where proven prophylactic, diagnostic, and therapeutic methods do not exist or have been ineffective, the physician, with informed consent from the patient, must be free to use unproven or new prophylactic, diagnostic, and therapeutic measures, if in the physician's judgment it offers hope of saving life, re-establishing health, or alleviating suffering. Where possible,

these measures should be made the object of research, designed to evaluate their safety and efficacy. In all cases, new information should be recorded and where appropriate, published. The other relevant guidelines of this Declaration should be followed.

**Note: Note of clarification on paragraph 28 of the WMA Declaration of Helsinki**

The WMA hereby reaffirms its position that extreme care must be taken in making use of a placebo-controlled trial and that in general, this methodology should only be used in the absence of existing proven therapy. However, a placebo-controlled trial may be ethically acceptable, even if proven therapy is available, under the following circumstances:

- Where for compelling and scientifically sound methodological reasons, its use is necessary to determine the efficacy or safety of a prophylactic, diagnostic, or therapeutic method; or
- Where a prophylactic, diagnostic, or therapeutic method is being investigated for a minor condition, and the patients who receive a placebo will not be subject to any additional risk of serious or irreversible harm.

All other provisions of the Declaration of Helsinki must be adhered to, especially the need for appropriate ethical and scientific review.

**Note: Note of clarification on paragraph 29 of the WMA Declaration of Helsinki**

The WMA hereby reaffirms its position that it is necessary during the study planning process to identify post-trial access by study participants to prophylactic, diagnostic, and therapeutic procedures identified as beneficial in the study or access to other appropriate care. Post-trial access arrangements or other care must be described in the study protocol so the ethical review committee may consider such arrangements during its review.

The Declaration of Helsinki (Document 17.C) is an official policy document of the World Medical Association, the global representative body for physicians. It was first adopted in 1964 (Helsinki, Finland) and revised in 1975 (Tokyo, Japan), 1983 (Venice, Italy), 1989 (Hong Kong), 1996 (Somerset-West, South Africa), and 2000 (Edinburgh, Scotland). Note of clarification on Paragraph 29 added by the WMA General Assembly, Washington 2002.



## Notes

1. *Editor's Note:* In the summer of 2006, the World Medical Association invited FAB to submit suggestions for revisions to the Declaration of Helsinki. What appears here is the document submitted by FAB's review committee to the WMA in Fall 2008, with some additions suggested by the IJFAB editorial office. The process of revision continues. After this issue of IJFAB went to the printer, the WMA circulated a revised draft of the Declaration, responding in part to FAB's commentary. The WMA has solicited a second round of comments, and the final version of the revised Declaration is expected to appear in 2008.

2. The anonymous IJFAB reviewers of this manuscript suggested several helpful revisions to this document that were not included in our original submission to the WMA. One such suggestion was a change from the use of the term *subject* to the term *participant*. Because there was some ambivalence within our group on this point and because we did not wish to distract the WMA from the many other changes for which we argued, we opted to retain the use of the term *subject*. Although one member of the group believes that the term *subject* should be retained because it highlights the inequalities between researchers and those enrolled in research, others argued that moving to the term *participant* reflects an important move in the moral discourse for it aims to narrow this power gap. Because of this disagreement among authors, we retained the term *subject* in the version of the commentary you see here.

Another reviewer noted, quite rightly, that the current reference to "appropriate caution" regarding protections to the environment was too vague. In proposing revisions to the Declaration on this issue, we were influenced by several suggestions of our colleague Andrew Jameton. However, the authors remain responsible for what is published here. These additions are set off in the text by an \* before and after the text.

There were several other helpful suggestions made by reviewers that strengthened this manuscript. But again, these textual additions did not appear in our original submission to the WMA, so we felt it was important to indicate them as such in the commentary. Therefore, any other changes made as a result of reviewer comments are designated by a ^ before and after the insertion.

Finally, in Part III of this version of the document, we have changed the order of three principles. This is indicated by a # at the start of each of the three principles.

3. A biome is a complex biotic community characterized by distinctive plant and animal species and maintained under the climatic conditions of the region, especially such a community that has developed to climax. (Dictionary.com)