

THE WORLD MEDICAL ASSOCIATION, INC.

WORKGROUP REPORT ON THE REVISION OF PARAGRAPH 30 OF THE DECLARATION OF HELSINKI

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1. Background

Following the adoption by the World Medical Association Assembly in October 2000 of a substantially revised version of the *Declaration of Helsinki* (DoH), concerns were voiced about a few of its provisions, especially paragraph 29 dealing with the use of placebos in clinical trials and paragraph 30 on continuing care of research subjects. Para. 29 was addressed in a note of clarification adopted by the Assembly in October 2002. This report deals with para. 30.

At its October 2001 meeting, the WMA Council established a workgroup to determine whether, in addition to the note of clarification on para. 29 of the Declaration of Helsinki, further notes of clarification were warranted, in particular on paras. 6, 19 and 30. The report of the workgroup to the May 2002 Council meeting recommended that no note of clarification was needed for para. 6 and that para. 19 required further study. It suggested a note of clarification for para. 30, but Council rejected that draft note of clarification, at least partly because of the perception that, as formulated, it would compromise para. 19. It was agreed not to change para. 19 and the workgroup was asked to continue its work on para. 30.

The workgroup provided progress reports at Council meetings in October 2002 and May 2003. At the latter meeting it was asked to draft, after appropriate consultation, either an amendment or a note of clarification to para. 30.

In August 2003 the workgroup produced its report, which was distributed to NMAs and other stakeholders for comment. The report included background considerations regarding the perceived need for a change to para. 30 and both a proposed note of clarification and a proposed amended version of para. 30.

Many comments were received in reaction to this report. Immediately prior to the Helsinki Assembly meetings, the WMA Secretariat compiled these comments and prepared a new report for Assembly participants outlining the options for dealing with para. 30, including two alternative notes of clarification and two alternative amended versions (www.wma.net/e/ethicsunit/pdf/secretariat_report_rev_paragraph30.pdf). After considerable discussion at the Medical Ethics Committee and Council meetings, Council chose not to change para. 30 or add a note of clarification at this time but to continue and expand discussion of this

paragraph among NMAs and other interested parties. Council formed a new workgroup, consisting of Drs. Sir David Carter (U.K.), Dirceu Greco (Brazil), Otmar Kloiber (Germany), Kgosi Letlape (South Africa) and John Nelson (U.S.A.), to oversee this work.

The workgroup communicated electronically during November and December 2003 and has prepared this report for consultation with NMAs and other interested parties. In March 2004 the workgroup will review the comments received and prepare a report for the WMA Medical Ethics Committee and Council when they meet in May.

2. Considerations

The discussion of para. 30 has generated considerable interest and concern in many quarters. Council's decision at Helsinki to continue the discussion was reported and commented on in numerous journals, including editorials in the *Lancet* and the *Canadian Medical Association Journal*. Many individuals and groups are waiting anxiously for the WMA to come to a definitive resolution of this matter.

It was evident before and during the Helsinki meetings that there are widely differing views, both within the WMA and outside, as to how to deal with para. 30. These views can be summarized as follows:

- Para. 30 should not be changed – the ethical principle it states is correct, and all those responsible for medical research should strive to overcome the practical obstacles to its implementation.
- Para. 30 should be left unchanged, but a note of clarification should be added that would specify one or more of the following items: the conditions required for implementing the principle stated in the paragraph; the need for informing the research subject about provisions for continuing care; the role of the ethics committee in determining the appropriateness of any continuing care provisions. Two alternative proposed notes of clarification were included in the secretariat report to the Helsinki meetings.
- Para. 30 should be amended – suggestions for amendment range from a relatively minor clarification of the ethical principle stated there to a qualification/limitation of the principle to a deletion of the principle and its replacement by another principle and/or operating procedure(s). Two alternative proposals were included in the secretariat report to the Helsinki meetings.

The workgroup acknowledges that the current wording of para. 30 is not perfect. It is convinced, however, that there are overriding reasons for not proposing an amended version of the paragraph. These include:

- agreement with the spirit, if not the exact wording, of the paragraph;
- the difficulty of achieving the required 75% approval for any change;
- the need for stability (the DoH should be amended only when absolutely necessary).

The workgroup has considered several alternative, but not mutually exclusive, approaches for resolving the disagreements about para. 30:

- Add the following preamble explaining that the Declaration is a set of ethical guidelines, not laws or regulations. "As a statement of principles, the Declaration of Helsinki is intended to establish high ethical standards that guide physicians and other participants in medical research involving human subjects. These ethical principles provide the basis of moral reflection on the means and goals of research involving human subjects, distinct from national legal and regulatory requirements. Interpreting the provisions of the Declaration regarding the design, conduct or completion of the research requires careful balancing of all of the Declaration's ethical principles. Differences in interpretation should be resolved by physicians and other participants involved in the research who are most familiar with all relevant factors, including the needs of research participants and of the host population."
- Add a note of clarification that reaffirms the intention of para. 30 but avoids the possibility of misinterpretation. The note would emphasise the ethical obligation on those conducting studies to explain to potential research subjects what is being proposed and its rationale, to provide a comprehensive explanation of potential risks and benefits, and to give a detailed explanation of what will and will not be available in terms of prevention, diagnosis and treatment for the individual concerned.
- Do not make any changes or additions to the Declaration of Helsinki. If it is felt that the WMA should expand its treatment of equitable access to health care, in the research context as elsewhere, this should be done in a separate document apart from the Declaration of Helsinki.

3. Conclusions

1. The workgroup recommends that para. 30 not be amended.
2. The workgroup has not yet achieved consensus on an alternative approach to para. 30. Before making its report to the WMA Medical Ethics Committee and Council, the workgroup requests comments and suggestions from NMAs and interested parties on the three alternatives described above or any other.