

THE WORLD MEDICAL ASSOCIATION, INC.

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**TITLE: WMA SECRETARIAT REPORT
ON THE REVISION OF
PARAGRAPH 30 OF THE
DECLARATION OF HELSINKI**

Note

This report has been prepared by the WMA Secretariat to assist the Medical Ethics Committee in its analysis of the Workgroup Report on the Revision of Paragraph 30 of the Declaration of Helsinki (WG/DoH/Sept2003) and the comments on that Report that have been received to date (WG/DoH/Sept2003/COMM).

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

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1. Introduction

1.1 In early August 2003 the Workgroup Report on the Revision of Paragraph 30 of the Declaration of Helsinki (WG/DoH/Sept2003) was sent for comments to National Medical Associations, members of the WMA's DoH Advisory Panel and other interested parties. It was also posted on the WMA web site, where responses could be registered electronically. As of 1 September 2003, the deadline for responses, written comments have been received from 8 NMAs and 19 others. They have been collated in document WG/DoH/Sept2003/COMM.

1.2 Since there is considerable variance among the comments, the WMA Secretariat has attempted to find wording that reflects the spirit, if not the exact letter, of proposed changes on which there is general agreement. Where there are substantive differences, alternatives are suggested from which the Medical Ethics Committee can choose.

2. Considerations

2.1 As requested by the WMA Council in May 2003, the Workgroup developed both a proposed note of clarification and a proposed amended version of paragraph 30. Among those who have submitted comments there is no consensus as to which of these alternatives is preferable. Moreover, some respondents have stated that there should be no note of clarification or amendment to paragraph 30.

- 2.2 An amendment to paragraph 30 would have the advantage that its status would not be in doubt whereas, as the reception of the note of clarification to paragraph 29 has shown, there can be some uncertainty about the authority of such notes, especially when they are perceived to be somewhat inconsistent with the paragraph to which they refer.
- 2.3 On the other hand, in order to be consistent with the other paragraphs of the DoH, an amended version of paragraph 30 should not be too long. For such a complicated issue as is covered in that paragraph, a short statement is bound to omit considerations that some commentators feel are essential. For this reason, a note of clarification may be preferred since there is no need to limit its length.
- 2.4 It would be possible to have both an amended version of paragraph 30 and a note of clarification.
- 2.5 With regard to the substance of paragraph 30, it is clear from the responses that there are widely divergent views. The WMA Workgroup attempted to forge an acceptable compromise among these views. but in the opinion of several of the commentators it did not succeed. If indeed a compromise cannot be achieved, silence on the disputed issue is always an option. It should be noted that WMA By-laws require a majority vote of 75% in the General Assembly for amendments to documents of an ethical nature.
- 2.6 CURRENT (2002) VERSION OF PARAGRAPH 30

“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”.

3. Suggested Options

Option #1

Do not change paragraph 30, do not add a note of clarification, and postpone any further discussion of the Declaration of Helsinki either indefinitely or for a specific time period.

Option #2

Do not change paragraph 30 or add a note of clarification at this time, but continue and expand discussion of this paragraph among NMAs and other interested parties.

Option #3

Adopt one of the following notes of clarification to paragraph 30:

3.1 “This paragraph reflects the ethical principle that patients who take on the inconvenience and potential risks of a medical research study should have access to the best proven prophylactic, diagnostic and therapeutic methods that result from the study. The WMA realises that certain conditions need to be fulfilled before the requirements in this paragraph can be fully realised, for example:

- i. the study has identified a prophylactic, diagnostic or therapeutic method that is superior to other methods;
- ii. the results of the study are compatible with those of other studies of the same method, if any;
- iii. the appropriate authorities have approved the method for use;
- iv. the physician has determined that the method is appropriate for the patient.

Before undertaking a study, the physician should ensure that all patients the physician enters into the study will have access after their participation in the study to any available prophylactic, diagnostic or therapeutic methods that the study identifies as the most effective and appropriate for such patients. When obtaining the patient’s consent to enter the study the physician must explain the treatment options after the study and how they relate to the patient’s condition. Arrangements for the continuation of treatment beyond the study must be described in the study protocol (paragraph 13).”

3.2 “This paragraph reflects the ethical principle that patients who take on the inconvenience and potential risks of a medical research study should, wherever possible, receive interventions identified as beneficial in the study or access to other appropriate care. This is particularly important for patients with serious conditions for whom cessation of the study intervention could have severe consequences. The WMA realises that in certain situations, this principle cannot, or need not, be implemented. For example:

- i. There are situations in which it is not necessary to assure post-trial access to the study intervention, because, for example, of the transient nature of the condition under study.
- ii. There may also be situations in which it is simply not feasible to assure post-trial access to the study intervention. For example, the infrastructure needed to administer the treatment may not exist.
- iii. In many cases, a single trial will not identify the best-proven method. Even when a single trial provides definitive evidence of efficacy, that determination is usually possible only after the study, when the investigators, sponsor and the regulatory authorities have completed evaluation of the trial data.

Before undertaking a study, the physician should make every reasonable effort to ensure that all patients the physician enters into the study will have access after their participation in the study to any available prophylactic, diagnostic or therapeutic method that the study identifies as the most effective and appropriate for such patients, once the appropriate authorities have authorized it for use and the physician has determined that the method is appropriate for the patient.

When obtaining the patient's consent to enter the study the physician must explain the treatment options after the study and how they relate to the patient's condition and must state explicitly if it is foreseeable or likely that neither the sponsors nor other organizations will be able to provide effective and appropriate treatment to the patient after participation in the study. Any arrangements for the continuation of treatment beyond the study, or the reasons for their absence, should be described in the study protocol (paragraph 13). Host country governments and others with responsibilities for the research might also need to be involved in discussions about post-trial access to study interventions or other appropriate care."

Option #4

Adopt one of the following amendments to paragraph 30:

- 4.1** "Before undertaking a study, the physician should ensure that all patients the physician enters into the study will have access after their participation in the study to any available prophylactic, diagnostic or therapeutic methods that the study identifies as the most effective and appropriate for such patients. When obtaining the patient's consent to enter the study the physician must explain the treatment options after the study and how they relate to the patient's condition. Arrangements for the continuation of treatment beyond the study must be described in the study protocol (paragraph 13)."
- 4.2** "Before undertaking a study, the physician should make every reasonable effort to ensure that all patients the physician enters into the study will have access after their participation in the study to any available prophylactic, diagnostic or therapeutic methods that the study identifies as safe, effective and appropriate for such patients. When obtaining the patient's consent to enter the study the physician must explain the treatment options after the study and how they relate to the patient's condition and must state explicitly if it is foreseeable or likely that neither the sponsors nor other organizations will be able to provide effective and appropriate treatment to the patient after participation in the study. Any arrangements for the continuation of treatment beyond the study, or the reasons for their absence, should be described in the study protocol (paragraph 13)."

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