

DECLARATION OF HELSINKI: NOTE OF CLARIFICATION ON PLACEBO-CONTROLLED TRIALS

The Declaration of Helsinki is one of the WMA's most well known position statements and acknowledged as the cornerstone of research ethics. Its current guideline on the ethical use of placebo-controlled trials has caused some confusion in the research world and for this reason the WMA Council decided to publish a note of clarification on the interpretation of this guideline. This extraordinary step was necessitated by the cancellation of the 53rd WMA General Assembly, which was due to take place during October 2001. The Assembly is the only body with the authority to adopt formal changes to the Declaration of Helsinki. The full text of the note of clarification reads:

"The WMA is concerned that paragraph 29 of the revised Declaration of Helsinki (October 2000) has led to diverse interpretations and possible confusion. It hereby affirms 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 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.

At the same meeting the WMA decided to appoint a panel of advisers, representative of all stakeholders in research, to assist the WMA in its continuing review of the Declaration of Helsinki.