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Dr. Otmar Kloiber
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**Proposed Revision of the Declaration of Helsinki:
Position Statement from TRREE Initiative**

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Dear Dr. Kloiber,

On May 15, 2012, the WMA issued a call for comments on the proposed revision of the Declaration of Helsinki (DoH). On behalf of the TRREE initiative, I am pleased to share with you our comments on this proposal.

While there is ample recognition that the DoH is a 'living document' which requires the broadest possible consensus in the medical and scientific community in order to be effective, there are grave concerns whether the proposed revisions are actually needed at this stage. The mere reference to the DoH as a 'living document', as outlined in the invitation to comment, is surely insufficient to justify another round of so called "reform". In this letter, I would like to urge the WMA most strongly to reconsider its plans to revise the DoH yet again. There is otherwise a real risk that the DoH would become little more than a fig leaf and might lose even some of its effectiveness in protecting vulnerable and disadvantaged populations against potentially unethical research.

First of all, as it has been mentioned in preparatory meetings during the last (2008) revision, the WMA cannot ignore the fact that the law has evolved in favor of a better protection of research participants. For instance, the Council of Europe Convention on Human Rights and Biomedicine states in article 2 that "the interests and welfare of the human being shall prevail over the sole interest of society or science". This principle is quite similar to paragraph 6 of the DoH. It is also grounded in the European Union regulation, for instance at article 2 of the COMMISSION DIRECTIVE 2005/28/EC stating that "The rights, safety and well-being of the trial subjects shall prevail over the interests of science and society". If the purpose of the revision would be to review the placebo rule in a more lenient way, the WMA should carefully assess the risk of being in violation of the European law and, thus, weakening the credibility of the DoH as the constitution of research ethics at the international level.

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Second, the DoH is often compared to the Universal Declaration of Human Rights in the protection of human participants. This is certainly true, especially in developing countries. In Africa, Asia or South America, the DoH appears as the main document of reference used by investigators and research ethics committees alike to protect the research participants. In spite of cultural, political and social differences, the principles rooted in the DoH are recognized worldwide as universal values to be respected when adapted to the local situation. The same is true for the Universal Declaration of Human Rights. Yet, while the DoH has been revised already 8 times since 1964, the Universal Declaration of Human Rights remains unchanged since its promulgation in 1948. This raises the question whether there is actually a pressing need to revise the DoH yet again at this point in time. Promoting the most fundamental principles in research ethics, the DoH should be somewhat more resilient against, and aloof from, the constant stream of biotechnological developments. While the world is undoubtedly changing, including the practice of medicine and society, the principles of research ethics should not necessarily be subject to the same kind and pace of change. They are there to provide the world with some degree of reliability.

This brings me to a third remark which is related to the motivation to revise the DoH again. It seems important to remind the WMA about the historical origins of the DoH in the early 1960s. At the time, the WMA was under pressure from the pharmaceutical industry and the research community with a strong influence of the USA (see for instance Lederer 2004; Lederer 2007). In the 2000 revision, we witnessed a paradigm shift when the WMA rejected the attempt to liberalize placebo control trials and instead placed its priority on the protection of the research participants before the interest of research and society. Some continue to regret this shift and wish to return to the original situation in which the DoH was meant to facilitate research in opposition to the Nuremberg Code, which was for many researchers considered to be too rigid and too strict. It is a matter of principle to resist such pressure on the basis that “In medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests” (DoH, paragraph 6).

Our last comment on the consultation is that it seems to be conducted exclusively in English which is rather unfortunate, as it excludes the voices of a sizeable number of leading world experts. This is confirmed by the fact the invitation to the “WMA Satellite Meeting during the 11th World Congress of Bioethics: Thinking ahead – The future of the Declaration of Helsinki”, which is scheduled to take place this June in Rotterdam, is advertised on the WMA website in English only. This could create a considerable bias as it excludes de facto a large group of researchers and RECs’ members who are particularly reliant on the DoH. This linguistic issue was already raised during the 2008 revision and led to an improvement in the DoH translation in French. It is important that the consultation is also conducted in French, Spanish, Portuguese and all the most common languages used by WMA members.

In conclusion, a revision of the Declaration of Helsinki seems unnecessary at this stage and raises more concerns than it provides solutions or improvements for medical practice. This being said, it would seem more proper for the WMA to consider a new approach in developing guiding documents in the field of research ethics. The DoH should remain unchanged to reinforce its influential role in defending the fundamental principles for the protection of research participants worldwide. Yet, the WMA could adopt specific guiding documents in given domains where the DoH does not provide clear solutions. This seems appropriate in traditional domains, such as research with children or with incapacitated adults, as well as in new ones, such as genomics or biobanking.

Rather than working on the revision of the DoH, the WMA should put its priority in identifying those fields in need of clarification and set up the proper procedure to develop the much needed guidance.

We wish to thank the WMA for its strong commitment in protecting the research participants worldwide while assuring the quality of health research. The Declaration of Helsinki has found the right balance between those sometimes conflicting interests and the WMA should be commended for this. We would like to thank you for giving us the opportunity to express our views with regard to the proposed revision, hoping that our arguments will be heard and the project abandoned.

Best regards,

Yours sincerely,



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