



1201 Maryland Avenue SW, Suite 900, Washington, DC 20024  
202-962-9200, [www.bio.org](http://www.bio.org)

August 28, 2007

**The World Medical Association**

13, ch. du Levant  
CIB - Bâtiment A  
01210 Ferney-Voltaire  
France

Re: Declaration of Helsinki

Dear Sir or Madam:

The Biotechnology Industry Organization (BIO) represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and 31 other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products. BIO welcomes the World Medical Association's (WMA's) current initiative to reevaluate the Declaration of Helsinki (DOH), and appreciates the opportunity to provide comments.

In general, BIO supports the Declaration of Helsinki as a high level document that sets forth important guiding principles for the ethical conduct of clinical research. We recognize that well-accepted international standards for clinical research, including those published under the International Conference on Harmonization and associated with Good Clinical Practice, draw from the DOH.

BIO members are committed to protecting clinical research participants and to conducting only the highest quality research, irrespective of the location of a study. The importance that BIO assigns to human subject protection and ethics in clinical research is further exemplified by adoption of its Principles on Protecting Research and Research Participants, available on our website at <http://bio.org/bioethics/background/protect010303.asp>.

BIO has identified paragraphs 29 and 30 along with their accompanying Notes of Clarification as key areas that warrant further discussion. BIO requests an in-person meeting with the WMA to discuss in detail our specific concerns over these provisions. Please let us know if the WMA would be interested in such a meeting, and we can further

discuss making appropriate arrangements. Please feel free to contact me at 202-962-9200 or Katie McCarthy in my office at 202-962-6647.

Thank you for your attention to this important matter, and we look forward to hearing from you.

Sincerely,

/s/

Sara Radcliffe  
Vice President  
Science and Regulatory Affairs