

The controversies and national divisions over the text have continued. The US FDA rejected the 2000 and subsequent revisions, only recognizing the third (1989) revision, and in 2006 announced it would eliminate all reference to the Declaration. After consultation, which included expressions of concern, a final rule was issued on April 28, 2008 replacing the Declaration of Helsinki with Good Clinical Practice effective October 2008.

This has raised a number of concerns regarding the apparent weakening of protections for research subjects outside the United States.

The NIH training in human subject research participant protection no longer refers to the Declaration of Helsinki. The European Union similarly only cites the 1996 version in the EU Clinical Trials Directive published in 2001.

The European Commission, however, does refer to the 2000 revision.

While the Declaration has been a central document guiding research practice, its future has been called into question. Challenges include the apparent conflict between guides, such as the CIOMS and Nuffield Council documents. Another is whether it should concentrate on basic principles as opposed to being more prescriptive, and hence controversial. It has continually grown and faced more frequent revisions.

The recent controversies undermine the authority of the document, as does the apparent desertion by major bodies, and any rewording must embrace deeply and widely held values, since continual shifts in the text do not imply authority. the actual claims to authority particularly on a global level, by the insertion of the word "international" in article 10 has been challenged.

Carlson raises the question as to whether the document's utility should be more formally evaluated, rather than just relying on tradition.

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