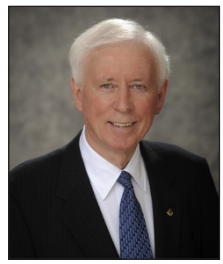
An updated Declaration of Helsinki will provide more protection

Cecil B Wilson



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Almost 50 years ago, the World Medical Association adopted the Declaration of Helsinki as an ethical guide for research involving human subjects. There are now proposed revisions under consideration that will provide additional protection for study participants as well as increased clarity regarding the responsibilities of those conducting the research. Making these changes is important in a complex environment where what is ethical is not always self-evident.

In a world where research involving human subjects increasingly includes study sites in multiple countries, it is crucial to have an international standard for research. The Declaration of Helsinki (DOH) is the key international document, the North Star if you will, that guides best practice for research. This month, the public comment period will conclude for proposed revisions of the DOH, and over the summer the draft document will be revised to reflect that input toward a finalized version.

Whenever discussing clinical trials, one should bear in mind that the truly astounding advances in development of medications and technical devices in recent decades would not be possible without research involving human subjects. Fortunately, the general public accepts the importance of research, and, in fact, many volunteer to participate out of a desire to help others. But that participation is dependent on having trust in those who conduct the research. The integrity of clinical trials rests in large part on physicians, who have an ethical duty to promote and safeguard the health and well-being of patients, including those who are involved in research.

In an effort to codify the importance of these dual imperatives of trust by patients and the duty of physicians, the World Medical Association (WMA) in 1964 adopted a statement of ethical principles for medical research involving human subjects: the DOH. The declaration requires that research be conducted only if the importance of the objective outweighs the inherent risks and burdens to the research subjects. Care must be taken to minimize those risks. Protocols for research must conform to generally accepted scientific principles. And study designs must be submitted to an independent research ethics committee for approval prior to initiating research.

> "Physicians have an ethical duty to promote and safeguard the health and well-being of patients."

The DOH requires that researchers take special care to protect the privacy of study subjects, and participation in trials should be voluntary. There must be adequate information, to which the participant must consent, that describes, for example, the aims of the study as well as its sources of funding and any discomfort it may entail. In addition, every clinical trial must be registered in a publicly accessible database before recruitment of the first subject.

In 2011, the WMA formed a workgroup to consider potential revisions to the DOH. The current effort, as has been the case with previous revisions, is aimed not at changing core ethical principles but at determining whether additional guidance is needed. The reality is that in the more and more complicated world of research, where scientific advances raise questions and new situations are present, what is ethical is not always clear.

From the beginning of its revision process, the WMA has sought to use methods that are thorough, transparent and reflective of diverse viewpoints. The association has held multiple expert conferences in countries such as the Netherlands, South Africa and Japan to receive insights and recommendations from a broad range of ethics scholars, academics, practicing physicians, government officials and those engaged in sponsoring clinical research.

At its meeting in April in Bali, Indonesia, the WMA Council, on the recommendation of the DOH workgroup, approved distribution of a draft version of the revised document for public comment. It is posted on the WMA web site (http://www.wma.net/). The changes proposed in the draft document incorporate increased protection for vulnerable groups—research populations who are disadvantaged and, as a result, are at an increased risk of incurring additional and greater harm. All future study participants will have stronger protection, and for the first time there will be a new provision for compensation for subjects harmed as a result of participation in research.

The proposed expanded requirements for post-study arrangements contain a requirement that participants be advised prior to a study that they will be informed of the results and, if needed, have access to treatments determined to be beneficial. The explicit ethical requirements for placebo use will be strengthened, particularly when a known effective treatment is available. Amendments have been made to clarify the qualifications and responsibilities of research ethics committees. And there is new wording that deals with research using human material or data contained in biobanks or similar repositories. In addition, the developers of the draft document have reorganized and restructured the document to improve readability while preserving the current character and length.

At the conclusion of the public comment period (15 June 2013), the DOH workgroup will strive to incorporate the input into the revised draft document at a meeting scheduled in Washington, DC in August. The workgroup will then present this new DOH to the WMA's ethics committee and council meetings in Fortaleza, Brazil, in October 2013 in anticipation of obtaining approval by the WMA Assembly at the same meeting.

Medical progress is dependent on research that ultimately includes studies involving human subjects. The DOH is the international standard that lays out the roadmap for trust and duty, so essential to the success of research. The anticipated revisions are important and will strengthen and preserve that roadmap.

Cecil B. Wilson is an internist in Winter Park, Florida, and the president of the World Medical Association, which is headquartered in Ferney-Voltaire, France.