

VIEWPOINT

Paul Ndebele, PhD
Medical Research
Council of Zimbabwe,
Causeway, Harare,
Zimbabwe.



Viewpoint page 2143



Related article
page 2191

The Declaration of Helsinki, 50 Years Later

Fifty years and 7 revisions later, the 2013 version of the Declaration of Helsinki includes several important changes. By changing the format and including several subsections, the revised declaration enhances and improves clarity regarding specific issues. By having specific issues covered under these subsections, the declaration is now “bolder” in the way it addresses specific issues. The new formatting will also be welcomed by readers because the subsections improve the readability of the document. By so doing, the Declaration of Helsinki is a better and more important authority at what it is aimed at achieving—providing guidance on conducting medical research involving humans.

The increase in international studies over the past few decades has contributed to serious debate about the ethics of research conducted in various settings. Most of the debate centered on issues related to limited resources and justice: use of placebo and posttrial access to interventions. Through this and previous revisions, the World Medical Association (WMA) has demonstrated that the declaration is a living document that considers current issues in medical research. Important documents such as the declaration are expected to respond to new areas of need or areas that require revision.

The Declaration of Helsinki was born from the history of abuses of human research subjects. Over the years, research oversight has improved but has led to the underrepresentation of certain groups in research investigations.¹ This has disadvantaged such groups because they have not benefitted from some advances that others have experienced from the conduct of research. The new version of the declaration addresses this development in paragraph 13 by recommending that access to clinical trials for underrepresented groups needs be increased so these groups also can benefit from research. Instead of excluding groups that have been ordinarily excluded from research, such as minority groups, women, and children, researchers need to clearly justify why these groups have been excluded from research.

There are current discussions about compensation and treatment for individuals who are harmed as a result of their participation in research. Some funders of research have been unwilling to address this topic over the years.² However, India has issued a law that requires all trial participants to receive treatment and financial compensation for trial-related injuries or death. The law has disrupted the conduct of clinical trials supported by one of the major funders of medical research in that country.³ The issues of compensation and access to treatment for research-related injuries are important for limited-resource settings in which the majority of trial participants are not insured. By clearly stating that trial participants need to be treated and compensated for trial-related injuries, the new declaration

is likely to lead to further discussions by certain research funders who would like to avoid the cost of insuring trial participants. In the past some important stakeholders in medical research have preferred to adhere to older versions of the declaration as a way of avoiding dealing with certain provisions included in newer versions.⁴

The new version of the Declaration of Helsinki is more relevant to countries with limited resources because it includes clear terms that address issues of importance in these settings, such as posttrial access to interventions and care for participants from limited-resource settings. In limited-resource countries, there have been concerns that communities may be used for testing interventions that will not be accessible to their citizens because of high costs and other reasons such as logistical challenges in delivering the new interventions outside the research environment. The new version of the declaration is clear on the requirement to have plans for ensuring access to an intervention if it is proven to be effective. This requirement serves to recognize that research can play an additional role of improving access to care in limited-resource settings. In further recognition of the role of research in improving access to care in limited-resource settings, the new version of the declaration also addresses the issue of use of unproven interventions. The 2013 version of the Declaration of Helsinki recommends use of unproven interventions in cases for which proven interventions do not exist, after the physician has sought expert advice as well as the patient's informed consent.

The new version also addresses several issues related to the dissemination of health research information, including registration of trials in publicly accessible databases and publication of negative, inconclusive, and positive results. The nonpublication of research with inconclusive or negative findings is concerning and must be discouraged by all who sanction research. The scientific enterprise must acknowledge openly that science improves through failures and successes.

Informed consent is one of the hallmarks of ethical research and ensures that individuals can make decisions that are in their best interests. The new version of the declaration acknowledges that in some cases, such as in close-knit societies, informed consent needs to involve others such as community leaders and significant others. Community leaders can serve as additional layers of protection that researchers need to pass through before they reach the potential participants. By addressing this reality, the new version is emphasizing respect for culture and community norms as part of the research process.

With respect to individual participants in research, several studies have illustrated that individuals often agree to participate in clinical trials without full knowledge or understanding of the studies.⁵ The new version of the dec-

Corresponding

Author: Paul Ndebele, PhD, Medical Research Council of Zimbabwe, Cnr J. Tongogara/Mazowe St, PO Box CY573, Causeway, Harare, Zimbabwe (pndexas@yahoo.com).

laration encourages researchers to explain their studies using innovative ways, such as video and vignettes. The declaration also encourages that researchers need to assess understanding of the research interventions and purpose by potential research participants before engaging those individuals in their studies.

The issue of providing feedback to research participants after termination of study activities is part of respecting individuals who participate in research and also is part of demystifying research. Failure to provide feedback contributes to research fatigue in communities and perhaps lack of trust in research in other communities. The new version encourages researchers to plan for provision of feedback to participants and their communities.

Research ethics committees are recognized as an important part of research oversight systems. The new version of the declaration addresses many points that are of relevance to these committees. Paragraph 23 clearly articulates that all research protocols have to be reviewed by a well-constituted and competent committee before studies begin. Paragraph 23 further emphasizes that ethics committees should be transparent and should follow standards, policies, and national laws in performing their functions. This is consistent with the standards for research committees that were issued by the World Health Organization in 2011.⁶ Paragraph 23 is also clear on the need for research ethics committees to monitor ongoing research.

The Declaration of Helsinki is an international document that influences how research is conducted in all countries. By stating expectations for ethics committees, it is hoped that these committees will be further strengthened.

Recent years have seen increased international debate about the ethics of conducting medical research in developing countries. From a limited-resource setting perspective, the Council for International Organizations of Medical Sciences (CIOMS) guidelines⁷ were viewed more favorably than those of the Declaration of Helsinki because the CIOMS addresses issues of relevance to resource-limited settings. The new version of the Declaration of Helsinki has addressed many of the important issues relevant to conducting research in developing countries, such as the need to include underrepresented groups in research, the importance of effective research ethics committees, posttrial access to care, use of unproven interventions, and improving informed consent. By addressing these issues, the declaration has recognized the role of limited-resource settings in generating research data. The influence of the declaration in serving as an important international document for stakeholders in limited-resource settings should increase. For research ethics committees, funders, and participants in research, this version of the Declaration of Helsinki should be empowering given its emphasis on issues of justice.

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