

CIOMS Working Group on the Revision of CIOMS 2002 International Ethical Guidelines for Biomedical Research Involving Human Subjects

Dear reader,

In 2010 the Executive Committee of CIOMS decided to revise the CIOMS Ethical Guidelines for Biomedical Research. The document was last revised in 2002. Since then, several developments have taken place, both in the field of biomedical research itself and in the field of research ethics. Among the latter developments is the recent revision of the Declaration of Helsinki in 2013.

The research and research ethics community, as well as the wider public, are now cordially invited to provide the Working Group of CIOMS with comments until **1 March 2016**. The Working Group will then process the comments and suggestions, and submit the final document to the Executive Committee of CIOMS. This Committee will approve the document.

The draft of the CIOMS guidelines can be downloaded here:

<http://www.cioms.ch/index.php/guidelines-test>

The Working Group

The [Working Group](#) consists of 10 members, one chair (President of CIOMS), four advisers (from WHO, UNESCO, COHRED and WMA) and one scientific secretary. The composition of the Working Group ensures that different cultural perspectives are present, members vary in age and expertise, and a gender balance is reached. One of the members represents the patient perspective. The group has met three times each year from September 2012 until September 2015.

Status of the current draft

The current version of the CIOMS guidelines is a draft. Although guidelines address specific issues, such as choice of the control, individual informed consent, and research with children, the CIOMS guidelines should be read and understood as a whole.

In the final version the Working Group will add introductory texts, a glossary and appendices.

Literature and guidance documents

The draft guidelines have been based on the results of literature searches and ethical reflection within the Working Group. Certain papers and guidelines have been particularly valuable for the current draft guidelines, such as the *Declaration of Helsinki* of the WMA, the *Ethical considerations in biomedical HIV prevention trials* of UNAIDS and *Standards and operational guidance for ethics review of health-related research with human participants* of the WHO. All sources used will be acknowledged in the final document.

Major changes

Most guidelines have been substantially revised. Guidelines have also been merged where possible. At the same time, new guidelines have been added to address new, pressing issues that require ethical guidance (such as disaster research or implementation research). The Working Group has also decided to merge the “Green Book” (the CIOMS Guidelines for Biomedical Research, 2002) with the “Blue Book” (the CIOMS Guidelines for Epidemiological Research, 2009) since the two guidelines substantially overlap each other. The scope of the guidelines has been broadened from biomedical research to health-related research with humans.

Providing feedback

The proposal of the Working Group is now open for comments.

<http://www.cioms.ch/index.php/guidelines-test>

Below each guideline there are two boxes: one for general comments and one for specific comments. Please provide us as much as possible with concrete, specific comments and text proposals. Since we expect to receive a great number of suggestions, we would like to caution that we will not be able to respond individually to each commentator.

We are grateful for your support of this important project and hope the revised CIOMS Guidelines will help to foster ethical research worldwide.

Yours sincerely,

Dr. J.J.M. van Delden

President of CIOMS