**From:** OC GCP Questions
**To:** [redacted]
**Subject:** Declaration of Helsinki
**Date:** Tuesday, September 02, 2014 9:31:24 AM

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Good morning --

There is no formal guidance issued by FDA related to the DOH. However there is a 2008 Final Rule which discusses the DOH. The 2008 FDA Final Rule basically states that FDA will not require global trials to comply with the Declaration of Helsinki, but rather with Good Clinical Practice standards. Additionally, as noted in FDA's Preamble to the final Rule, Human Subject Protection; foreign clinical Studies Not Conducted Under an Investigational New Drug Application, "The Declaration of Helsinki is a document that is subject to change independent of FDA authority and, therefore could be modified to contain provisions that are inconsistent with U.S. laws and regulations." [See Federal Register vol. 73, No. 82, April 28, 2008, p. 22801] and the link below.

http://www.gpo.gov/fdsys/pkg/FR-2008-04-28/pdf/E8-9200.pdf

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA



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**From:** [redacted]
**Sent:** Saturday, August 30, 2014 5:46 PM
**To:** OC GCP Questions
**Subject:** Declaration of Helsinki

Hello-

Could you please send me the formal guidance document issued by the FDA, in which the rationale for dropping the DoH as a guidance document for protection of Human Subjects in Clinical Research is explained?

Thank you!

[redacted]