

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: RE: Question: FDA support of 2013 Declaration of Helsinki
Date: Monday, March 31, 2014 11:10:44 AM

Ms. [redacted]:

Thank you for your query on the 2013 version of the Declaration of Helsinki. 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] This remains true.

You'll also note in FDA's Preamble to the draft Rule, Human Subject Protection; Acceptance of Data From Clinical Studies for Medical Devices, that the Declaration of Helsinki is listed as a document identifying ethical and other principles that provide assurance of the quality and integrity of clinical data and adequate protection of human subjects. [See Federal Register vol. 78, No. 37, February 25, 2013, p. 12665-6]

I hope this is helpful.

Sincerely,

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From: [redacted]
Sent: Tuesday, March 25, 2014 4:57 PM
To: OC GCP Questions
Subject: Question: FDA support of 2013 Declaration of Helsinki

A GCP question regarding FDA support of 2013 Declaration of Helsinki.

The Declaration of Helsinki was recently updated in October 2013 with some updates e.g. Protection of vulnerable groups, Use of comparators and placebos, Post-study/trial arrangements, requirement to fully compensate injuries incurred by patients during the trial.

I am aware of an FDA notice from 2008 in which it stated that FDA will not require global trials to comply with the Declaration of Helsinki, but rather the Good Clinical Practice standard (e.g. Informed Consent regulation). In the FDA notice it states that FDA does not fully support the 2000 or later versions of the Declaration because it contains certain statements that may be inconsistent with US law and policy (e.g. concerning use of placebos in clinical trials).

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

I would like to ask if the FDA supports the 2013 Declaration of Helsinki in respect that global studies would be expected to comply with the updated Declaration or if FDA is continuing to accept that the principles of the Declaration are reflected in the Good Clinical Practice standard (e.g. Informed Consent regulation).

Kind regards,
[redacted]