From: OC GCP Questions
To: [redacted]
Subject: HELSINKI DECLARATION LAST VERSION in INDS CLINICAL PROTOCOL
Date: Friday, January 23, 2015 11:04:35 AM

Good morning --

There is no formal guidance issued by FDA related to the DOH as the declaration is independent of FDA regulations. 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

From: [redacted]
Sent: Thursday, January 22, 2015 4:25 PM
To: OC GCP Questions
Subject: HELSINKI DECLARATION LAST VERSION in INDS CLINICAL PROTOCOL

Dear FDA:

I would like to check with you:
if it is mandatory by FDA, to mention in a written IND protocol the Helsinki declaration version at which the protocol was designed?
In other words the written protocol has to make the reference to the Helsinki declaration last version?

[redacted]