From: OC GCP Questions
To: [redacted]
Subject: External inquiry on ICH E6
Date: Thursday, December 17, 2015 10:38:20 AM

Good morning –

Your email was sent to my office for a response. Please see our answers below.

1. ICH E-6 5.9 does not specifically describe the actual financing. However it may include unrestricted grants from a regulated sponsor. You might want to consult with your legal department.

2. For restrictions on data from a non- US studies --ICH E6 has been adopted as guidance in the U.S., however, U.S. regulatory requirements (i.e., FDA regulations) must be met for studies conducted in the United States and if the studies are conducted under IND (even outside the US) all FDA regulations apply. For studies conducted outside of the U.S. but in ICH regions, compliance with the provisions of ICH E-6 generally assures that that the studies will be accepted for review by FDA as non-U.S., non-IND studies (under FDA's regulations related to accepting data from non-U.S., non-IND studies, e.g., 21 CFR 312.120. Please see the link below to the final rule for 312.120
   https://www.gpo.gov/fdsys/pkg/FR-2008-04-28/pdf/E8-9200.pdf

   Also please see the guidance link below for FDA Acceptance of Foreign Clinical Studies Not Conducted under an IND
   http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM294729.pdf

Kind regards,

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

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: CDER OMP
Sent: Wednesday, December 16, 2015 8:59 AM
To: OC GCP Questions
Subject: FW: External inquiry on ICH E6

Is OGCP available to respond to the inquiry below that we received via telephone?

[redacted]

It's a diagnostics company and his questions are:

1. In section 5.9 re financing—are there restrictions on types—in particular unrestricted grants?
2. The center they deal with is in Canada—are there restrictions on data from a non-US studies?