From: [OC GCP Questions]
To: [redacted]
Subject: Waiver of IRB
Date: Monday, September 08, 2014 3:18:27 PM

Good afternoon –

Please contact the review division that is overseeing the IND and/or the FDA project manager of the IND to discuss waiver possibilities and the process.

Thank you,

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

From: [redacted]
Sent: Friday, September 05, 2014 12:39 PM
To: OC GCP Questions
Subject: Waiver of IRB

We have a Canadian site that has participated in our phase 3 global study for the last 2 years and the PI signed the 1572. Now, their REB is asking for a Waiver of IRB in order to approve a protocol change since an REB is not an IRB and therefore needs to have a Waiver of IRB for not being able to strictly comply with Part 56. The REB complies with ICH E6 for GCPs. Is it possible to get a Waiver of IRB if the 1572 has already been signed?

What is the process for obtaining a Waiver, is the request made to the Division which holds our IND or to another FDA office. How long would it take to get this waiver.

Thank you,

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