

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,

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Office of the Commissioner, FDA

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From: FYXUMXQ
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,