From: Less, Joanne
To: [redacted]
Subject: FW: Clarification for FDA-granted waiver
Date: Wednesday, July 29, 2020 12:26:34 PM

[redacted]

From: Less, Joanne
Sent: Wednesday, July 29, 2020 12:25 PM
To: David Borasky <dborasky@wcgclinical.com>
Cc: [redacted]
Subject: RE: Clarification for FDA-granted waiver

Hi, [redacted]

I'd doing ok. I hope both of you are too. We're having the same heat wave here too. It would be nice to be able to cool off at the beach or a lake. I'm sort of regretting that I sold my condo at VA Beach, although with all the reports of crowds, I'd be nervous to go.

From what you included below, it looks like the sponsor is conducting their study under an IND at both US and OUS sites. As you know, the IND requirements include review/approval by an IRB. However, for the OUS sites, the sponsor is anticipating that an IEC will be reviewing. Although the IEC membership and functions are similar to the requirements under 21 CFR 56, they may not meet all of FDA's requirements, so CDER/CBER may grant a waiver upon request by the study sponsor. See FDA's guidance entitled, "Waiver of IRB Requirements for Drug and Biological Product Studies" at https://www.fda.gov/media/75152/download. As stated in the guidance, the informed consent requirements would not be waived.

Hope this helps. Take care!

Joanne

From: [redacted]
Sent: Tuesday, July 28, 2020 3:04 PM
To: Less, Joanne <Joanne.Less@fda.hhs.gov>
Cc: [redacted]
Subject: Clarification for FDA-granted waiver

Ho Joanne – hope you are doing well. [redacted]

We received a letter from the FDA to a sponsor as part of a submission to our IRB. The letter from CDER has to do with a waiver, but the highlighted language has us puzzled. Here's the entire body of the letter.

Please refer to your investigational new drug application (IND) submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act for [investigational product].

We also refer to your [DATE] amendment requesting a waiver of the Institutional Review Board (IRB) requirements under 21 CFR Part 56 for the use of [investigational product] in a foreign investigational study or all foreign investigational studies conducted under this IND.

We have completed our review of your request and have determined that your submission justifies the requested waiver. Your waiver request is granted. Unless otherwise notified by FDA, this waiver applies to all current foreign clinical studies and all subsequent foreign clinical studies conducted under this IND that provide the same mechanism for ensuring the protection of the rights and welfare of human subjects as described in your submission.

Please reference this waiver in all subsequent protocol submissions for foreign clinical studies and maintain a list of all the foreign clinical studies to which this waiver applies, and their status, in the Annual Report for this IND.

This waiver does not apply to the requirement for obtaining informed consent from all subjects.

Please assure that all investigators attach a copy of this letter to the signed investigator statement (Form FDA 1572) in their records.

Waiving the requirement for IRB seems strange, especially since the need for informed consent and for human subject protection mechanisms is reinforced. Do you understand this wording and if so, can you translate it for us?

Stay cool!