

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: protocol waivers
Date: Tuesday, February 12, 2019 1:32:33 PM
Attachments: [REDACTED]

Good afternoon –

Please see FDA's IRB waiver guidance from 2017.

<https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126500.pdf>

Additionally, there is very little discussion of protocol waivers in FDA guidance documents. While I am not aware of any discussion in a guidance document, FDA has addressed protocol waivers in Untitled and Warning Letters following FDA inspections, particularly to sponsors who have been found to give numerous protocol waivers. Since the effect is the same on the poolability of the data as protocol deviations, sponsors should discourage requests for protocol waivers. If many requests are received for a given study, the sponsor needs to reassess the protocol to determine if an amendment is necessary with regard to any requirement CIs find difficult to meet. A meeting with CIs may be necessary to determine if such requirements are too restrictive given the nature of the intended study population or present a major departure from standard medical practice that the CIs do not see as warranted for accruing the desired study endpoints.

Lastly, it is best to ask the sponsor to speak to the regulatory project manager of the IND at FDA for guidance to answer your question since it describes I/E criteria.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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From: [REDACTED]
Sent: Monday, February 11, 2019 4:38 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: protocol waivers

Hi,

I have a question regarding waivers.

If a protocol is in the process of being amended, however, is not yet IRB approved, can the IRB grant a waiver to enroll a subject that does not meet I/E for the current protocol.

There is an amendment that is with the IRB now that would include this subject, however, it is not approved. From all that I have read in the regs, IRBs are not allowed to grant waivers unless it is an emergency, which this is not.

Based on the IRB waiver, the sponsor allowed the subject to be enrolled. Is there any regulation or guidance that addresses this situation? Furthermore, if a Health Authority inspected either the site or the sponsor, would this be a finding?

Thank you.

