

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: IRB Guidelines
Date: Monday, July 01, 2019 1:25:45 PM
Attachments: [REDACTED]

Good morning –

I can give you information (resources) from an FDA perspective. Please see the links below.

FDA IRB Regulations - [eCFR — Code of Federal Regulations](#)

[Selected FDA GCP/Clinical Trial Guidance Documents | FDA](#) Please scroll down to the middle of the page for the IRB and Informed Consent guidances.

Please remember the OHRP follows 45 CFR 46 regulations and FDA follows CFR Part 56 for IRBs. The regulations are similar but slightly different.

Kind regards,

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From: [REDACTED]
Sent: Monday, July 01, 2019 10:52 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: IRB Guidelines

Good morning,

I am a newly adviser to the institutional review board [REDACTED] While searching for guidance, I came across the link: <https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/guidance-for-institutions-and-irbs/index.html>. However, this seems to be a draft from August 2016. Is there an update draft? Can you also lead me to any resources regarding IRBs?

I would like to learn the proper and compliant way an IRB should be run and make sure that [REDACTED] is aligned with that.

Any assistance would be greatly appreciated.

Thank you!

