

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: IRB Meetings
Date: Wednesday, May 01, 2019 9:36:56 AM

Good morning -

Research must involve no more than minimal risk for it to be eligible for expedited review procedures. It is possible that the fully convened IRB determines that the risk involved in the protocol amendment is greater than minimal risk and should not undergo expedited review based on the information received to date.

Each IRB is required to follow written procedures. 21 CFR 56.108 outlines the required elements of an IRB's written procedures. IRBs usually go beyond those itemized topics in their SOPs and include other matters as well. This would likely include whether the IRB/institutional human subject protection program restricts use of the expedited review procedures beyond those listed in the Federal Register notice published jointly by FDA and OHRP. It is conceivable that the fully convened IRB determines, in contradistinction to the IRB chair, that the protocol amendment is ineligible for expedited review based on its SOPs, without additional information.

The below FDA guidance documents will be helpful for you.

IRB Continuing Review - <https://www.fda.gov/media/83121/download>

IRB Written Procedures - <https://www.fda.gov/media/99271/download> (*May 2018)

IRB Meeting Minutes. - <https://www.fda.gov/media/94686/download> (*September 2017)

Q/A on IRBs - [Institutional Review Boards Frequently Asked Questions](#)

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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This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

-----Original Message-----

From: [REDACTED]
Sent: Tuesday, April 30, 2019 8:33 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>

Subject: Fwd: IRB Meetings

> Is the IRB required to review the criteria for IRB approval for a greater than minimal risk study at the IRB meeting? Does the criteria need to be discussed at the meeting and captured in the minutes? If the primary reviewer simply completes a checklist and does not discuss the criteria out loud at the IRB meeting - is this acceptable?

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