From: OC GCP Questions
To: [redacted]
Subject: IRB and continuing review
Date: Wednesday, September 09, 2015 9:49:56 AM

Good morning ---

I consulted a few of my colleagues here in the office. Please see their thoughts below.

The IRB would need to follow its written procedures for expedited review. Those should outline how the IRB collects information and makes its determinations. They not only have to determine that it is minimal risk but also that it is on the list of study types that are eligible for expedited review. If they don't have a procedure for expedited review, that might be an issue.

The IRB will have to make a decision that the study is eligible but doing that might require obtaining information from the CI or sponsor. That should be in the written procedures.

It is not a simple one versus another answer.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Wednesday, September 09, 2015 8:00 AM
To: OC GCP Questions
Subject: Re: IRB and continuing review

Thanks for your prompt feedback Doreen. I re-read this (very useful) guidance again and we're still unable to fully resolve the specific question of which party actually makes the determination of whether a study qualifies for expedited review. The guidance uses a lot of passive voice description in the sections you highlighted and doesn't explicitly allocate the responsibility for this determination.

One interpretation would be that the IRB needs to collect the relevant information (applicable to the criteria in the federal register relating to expedited review) from the PI and then, based on this information, the IRB determines whether the study qualifies for expedited review.

Another interpretation might be that the sponsor (through) the PI needs to determine if their study qualifies for expedited review and the notify the IRB which review process to use: expedited or full board. In the case where a study did not qualify for expedited review but and expedited review was conducted, this would be considered non-compliance for the PI, and not the IRB.

Can you clarify which interpretation is aligned with FDA regulations 21 CFR part 56?

Many thanks once again,

[redacted]