

From: [OC GCP Questions](#)
To: [REDACTED]
Cc: [CDER DRUG INFO](#)
Subject: FW: Expanded access- continuing review
Date: Wednesday, November 13, 2019 6:29:00 PM
Attachments: [REDACTED]

Dear [REDACTED] -

Thank you for your question, which was forwarded to my office for a response. Your question did not specify the type of expanded access you are referring to (e.g., single patient, intermediate-size patient populations, or treatment IND/protocol use). I'm also not sure if your question is related to a single patient expanded access IND that initially utilized a Form FDA 3926 and for which concurrence by the IRB chairperson or another designated IRB member was used.

If your inquiry is related to single patient expanded access INDs, please see Q6 of FDA's guidance titled, "*Expanded Access to Investigational Drugs for Treatment Use – Questions and Answers*" found at <https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm351261.pdf>, which says that a physician submitting an individual patient expanded access IND using Form FDA 3926 may select the appropriate box on that form to request a waiver under § 56.105 of the requirements in § 56.108(c), which relate to full IRB review. FDA concludes that such a waiver is appropriate for individual patient expanded access INDs when the physician obtains concurrence by the IRB chairperson or another designated IRB member before treatment use begins. A physician submitting an individual patient expanded access IND using Form FDA 1571 may include a separate waiver request with the application. FDA also has guidance entitled, "Individual Patient Expanded Access Applications: Form FDA 3926" that can be found at <https://www.fda.gov/media/91160/download>.

In general, review of individual patient expanded access use by an IRB chairperson or other designated IRB member would follow a different review pathway that is neither full board, nor expedited, but rather one in which the IRB chairperson/other designated IRB member reviews the relevant information/documents (as determined by the IRB) and then his or her decision to concur or not (and/or any questions and responses) is documented. Concurrence by the IRB chairperson/other designated IRB member would also be appropriate for any changes/amendments, or continuing review should changes in the use, or the duration of the use continue, such that continuing review is required.

Unlike the single patient IND expanded access option for concurrence by the IRB chairperson/other designated IRB member, the initial and continuing review of an intermediate-size population expanded access use, or treatment IND/protocol use requires prospective IRB review and approval at a convened meeting of the IRB.

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp_questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at <http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriesToFDAonGoodClinicalPractice/default.htm> since we find that many questions and concerns are repeated over time.

Best Regards,

Janet
Janet Donnelly, RAC
Policy Analyst

Office of the Commissioner
Office of Good Clinical Practice
U.S. Food and Drug Administration



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.

From: OC GCP Questions

Sent: Friday, November 08, 2019 6:11 PM

To: [REDACTED]

Cc: CDER DRUG INFO <DRUGINFO@fda.hhs.gov>; [REDACTED]
[REDACTED]

Subject: FW: Expanded access- continuing review

Dear [REDACTED] -

Thank you for your question, which was forwarded to my office for a response. I wanted to let you know that we are working on a response and hope to get back to you next week. Thank you for your patience in our reply.

Have a wonderful weekend!

Best Regards,

Janet

Janet Donnelly, RAC

Policy Analyst

Office of the Commissioner

Office of Good Clinical Practice

U.S. Food and Drug Administration



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From: [REDACTED]

Sent: Monday, November 4, 2019 2:24 PM

To: CDER DRUG INFO <DRUGINFO@fda.hhs.gov>

Cc: [REDACTED]
[REDACTED]

Subject: Expanded access- continuing review

Good afternoon,

Do you have any guidance on how IRBs should address continuing review submission for an expanded access protocol? Specifically, can continuing review be conducted by expedited review or does continuing review need to take place at a convened meeting?

Thank you.

