
The new Common Rule permits elimination of continuing review in certain circumstances. When assigning an initial, amendment, or continuing review submission for expedited review, IRB regulatory staff must select yes or no to the eResearch question “Is Continuing Review required for this application?” If the response is yes, staff must indicate why annual continuing review is required. The most common reasons for *requiring* annual review include:

- Ongoing study activity poses greater than minimal risk to subjects
- The research is subject to FDA regulation
- The research is subject to ICH-GCP standards

The selection of “No continuing review” may be appropriate for

- some initial applications that qualify for expedited review categories 1 through 7
- some amendment or continuing review applications for research
 - in which study activity is limited to data analysis and/or long-term follow-up
 - that qualifies for expedited review categories 1 through 7
- other circumstances

Once a submission has been assigned, the expedited reviewer will see the regulatory staff’s selection regarding whether annual continuing review is required. If staff have indicated that continuing review is required, the reviewer may choose to identify additional reasons for the requirement, such as that the study involves genetic analysis (using the free text field under the “other” line). However, keep in mind that if the expedited reviewer changes the response to the question from *yes (continuing review is required)* to *no (continuing review is not required)*, the eResearch system does not automatically generate an alert to IRB regulatory staff; therefore, reviewers who choose to change the response should create an issue within the submission to inform staff of the reasons for the change.

Contact the IRB for more information about regulatory and institutional requirements pertaining to annual continuing review.

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