CONTINUING REVIEW CONTENT RECOMMENDATIONS FOR SINGLE IRB REVIEW

Continuing Review Working Group of the
SMART IRB Harmonization Steering Committee.

February 27, 2021

Harmonized: This document underwent a review and input process from November 2020 to January 2021 and has now been finalized.

This table outlines recommendations for the information Reviewing IRBs should collect for continuing review and includes recommendations about who should provide the information to the Reviewing IRB. The content recommendations are based on the continuing review guidance issued by the Office for Human Research Protections and the U.S. Food and Drug Administration. The table is extracted from Single IRB Continuing Review Process: Recommendations for Harmonization, which was developed by the Continuing Review Working Group of the SMART IRB Harmonization Steering Committee; please see the full document for additional information.

OHRP/FDA Suggested Component	**Source**	**Who Provides Information to the Reviewing IRB***	**What Information Should be Provided to the Reviewing IRB**
Brief project summary: study status	Study sponsor (if one exists), applicable coordinating centers, and relying site investigators	Overall PI	The summary should identify the status of the overall study during the approval period and include • Enrollment status of the overall study, including whether ◦ Some sites or all sites have ongoing participant enrollment; ◦ Enrollment is complete, but study interventions are ongoing; ◦ Activities are limited to long-term follow-up of participants at some or all sites; or ◦ Enrollment is closed, study interventions are complete, and study activities are limited to data analysis • Notable subject experiences (e.g., complaints that could not be resolved by the study team, unanticipated problems) • Any delays in study activities • Expected activities for the upcoming year
The number of subjects accrued	Relying site investigators	Overall PI	The number of subjects enrolled and status of each subject by site.

Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, through grant number 3UL1TR002541-01S1.

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OHRP/FDA Suggested Component	Source	Who Provides Information to the Reviewing IRB*	What Information Should be Provided to the Reviewing IRB
A brief summary of any amendments to the research approved by the IRB since the IRB's initial review or the last continuing review	IRB records or study-wide records held by the Overall PI (or designee)	Overall PI	If IRB records already include a brief summary of amendments approved since the initial review or last continuing review, the IRB does not need to request this as part of the continuing review. If such a summary is needed, the Overall PI should provide it.
Any new and relevant information, published or unpublished, since the last IRB review, especially information about risks associated with the research	Study sponsor (if one exists), applicable coordinating centers, and relying site investigators	Overall PI	A summary of new and relevant information, published or unpublished, since the last IRB review (initial or continuing review, whichever was most recent) that includes a synopsis from the Overall PI of the relevance of this information to the study's risks, benefits, alternatives, and applicable informed consent documents.
A summary of both any unanticipated problems and available information regarding adverse events	Study sponsor (if one exists), applicable coordinating centers, and relying site investigators	Overall PI	Generally, IRBs do not request the submission of adverse events unless they constitute unanticipated problems. A summary of unanticipated problems and safety monitoring information that includes an analysis by the Overall PI of the unanticipated problems and adverse events, explaining whether the events have occurred at a higher rate or were more severe than previously expected or should be recategorized in terms of their relationship to any study procedures (e.g., previously thought to be unrelated but now viewed as related to a research intervention).

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OHRP/FDA Suggested Component	**Source**	**Who Provides Information to the Reviewing IRB***	**What Information Should be Provided to the Reviewing IRB**
A summary of any withdrawal of subjects from the research since the last IRB review, and the reasons for withdrawal, if known	Relying site PI	Overall PI	The number and reasons for subjects withdrawal at each site. This information would include, for example, how many subjects withdrew their consent to participate and why, as well as how many were withdrawn by study investigators (or others) due to safety concerns or compliance issues.
A summary of any complaints about the research from subjects or others since the last IRB review	Relying site PI	Overall PI	A summary of any complaints at each site that were unable to be resolved by the study team (or their institutions).
The latest version of the IRB-approved protocol and sample informed consent document(s)	IRB electronic submission system or Overall PI	Overall PI if requested	Reviewing IRBs can meet this expectation by using their electronic submission system (e.g., asking the Overall PI to confirm which consent documents will continue to be used for each site), requesting copies of the most recent consent forms each site has used with subject information redacted, or obtaining an attestation from the Overall PI that all sites are using the most current version(s).
Any proposed modifications to the informed consent document or protocol	*Not applicable*	*Not applicable*	*This is outside of the scope for this guidance.*

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For FDA-regulated research, the current Investigator's Brochure (IB), if available, including any modifications	Study sponsor (if one exists), applicable coordinating centers, or Overall PI	Overall PI	The most recent IB, if not previously provided, with an assessment of any effects on the study's risks, benefits, alternatives, or consent documents.
Any other significant information related to subject risk, such as the most recent report from any data safety and monitoring board (DSMB) or data monitoring committee (DMC) monitoring the research, if available	Study sponsor (if one exists), applicable coordinating centers, Relying Site PIs, or Overall PI	Overall PI	• Data safety monitoring reports or safety monitoring information either formal or informal to ensure the approved safety monitoring plan is being followed, that either the formal DSMB has determined the research is appropriate to continue based on their review, or that the informal review has not uncovered any additional study concerns. • A summary of any new and relevant information, published or unpublished, that has arisen since the last IRB review and synopsis from the Overall PI of the relevance of this information to the study's risks, benefits, alternatives, and applicable informed consent documents.

* In some cases, an IRB may allow a designee of the Overall PI, such as a coordinating center, to provide the information to the Reviewing IRB.

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