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You could be doing less work at continuing review!

Should I submit a Continuing Review or a Status Report for my research project?

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In the context of federal regulations governing human subjects research, Continuing Review and Research Status Report are essential components overseen by Institutional Review Boards (IRBs). Continuing Review and Research Status Report processes both contribute to the ongoing ethical oversight of research involving human subjects. These processes involve the submission of documentation to the IRB to facilitate the annual review and approval process. In both cases, investigators play a crucial role in providing accurate and timely information to the IRB about the progress of their research. However, most people don't know when to submit one or the other.

The primary purpose of Continuing Review is to assess whether the research continues to meet ethical standards and whether the risks and benefits remain acceptable. The Research Status Report is designed to provide the IRB with an update on the progress of the study, including any deviations or unanticipated issues.

If your new study was approved after 1/21/2019, and is considered minimal risk, Continuing Review is not required. Per Baystate policies, a Status Report can be submitted instead. This is a result of the revision of the federal regulations that govern Human Subjects Research Protections which are also known as The Common Rule. The revision of The Common Rule aimed at burden reduction states that continuing review is not required for:

- Research that is eligible for expedited review.
- Exempt research conditioned on limited IRB review.
- Research that has completed all interventions and now only includes analyzing data, even if the information or biospecimens are identifiable.
- Research that has completed all interventions and now only includes accessing follow-up clinical data from clinical care procedures.

Important to note: the IRB can override this default and still choose to require continuing review, as long as the IRB documents the decision and the rationale for this decision. Additionally, an exception to these regulations is that expedited submissions should submit a Continuing Review if they are a repository or registry.

However, the revision of the common rule eliminating Continuing Review for expedited studies is great because Status Reports are simply less work. The Status Report process at Baystate IRB requires an update of the current status of the research, updates to changes to funding, updated enrollment numbers, and current CITI/COIs for current study team members. The

Continuing Review process at Baystate IRB is much more in-depth, covering research status, updated research design/procedures, updates on subject selection/recruitment/vulnerable populations, updates on the risks/benefits, current consent documentation, and submission of current publications.

In the case that a researcher or study coordinator is unsure of whether or not to submit a Status Report or Continuing Review, the staff at Baystate IRB is ready to assist. Any analyst on staff will be happy to provide clarification and support as to whether or not your study qualifies for submission of Status Reports. All queries can be sent to the irbprotocolsubmissions@baystatehealth.org inbox.

[Refer to 45 CFR 46.109(f), 46.110, and 46.115(a)(8) of the revised Common Rule.]

In summary, while Continuing Review is a scheduled and comprehensive evaluation of the entire study protocol, Research Status Report is more focused, event-driven, and provides updates on specific aspects of the research. Both processes are essential for ensuring the ongoing protection of human subjects in research.

Revised Common Rule Q&As | HHS.gov