

Continuing Review

All projects reviewed and approved prior to January 21, 2019 remain under the old rule. These projects retain their existing level of review and all other IRB requirements, including continuing review requirements. Grandfathered projects will be provided information on transitioning to the new rules at the time of their continuing review date. Progress and Final Report Forms must be submitted 7 business days prior to the expiration date.

Exempt:

All exempt protocols will be closed automatically after one year from the most recent approval date unless a request is submitted in writing to keep the protocol open.

Expedited:

All expedited protocols must submit the Progress Report Form for annual review until enrollment of participants are no longer being conducted. SRU's IRB will evaluate the need for continuing review at the time of the next scheduled continuing review submission.

Full Board:

Same as expedited protocols.

Even when continuing review is not required for a protocol, the Principal Investigator (PI) must still:

- Submit amendments for protocol changes,
- Report unanticipated problems, adverse events or non-compliance, and
- Terminate the project once it ends, or when personal identifiers are removed from the data/biospecimens and all codes and keys are destroyed.

In the absence of the scheduled continuing review process for qualified expedited studies, SRU's IRB will send an annual email to the PI reminding them of these responsibilities. This email will be sent prior to the expiration date.

SRU's IRB may re-evaluate its continuing review or no continuing review decision depending on the type of change(s) proposed in an amendment (e.g., protocol change that increases subject risk), or as an outcome of the IRB's review of Reportable Events.