2018 Common Rule Updates to Continuing Review

Changes to Continuing Review Requirements for non-exempt research

The purpose of Continuing Review is to ensure that human subjects protections remain appropriate over the life of a study. For many minimal-risk studies this administrative step may not meaningfully enhance protection of research subjects. In recognition, the updated 2018 Common Rule outlines **exceptions** to the requirement of annual review by the IRB.

Accordingly, annual **continuing review is no longer required** for most minimal-risk research approved after January 21, 2019. However, the IRB or IRB reviewer may determine that continuing review is required to assure protection of human subjects or to address compliance concerns.

NOTE:

Ongoing research will continue to operate under the Pre-2018 Common Rule (or applicable FDA or Federal Agency regulations) until study closure or until the study is formally transitioned to the new 2018 Common Rule requirements.

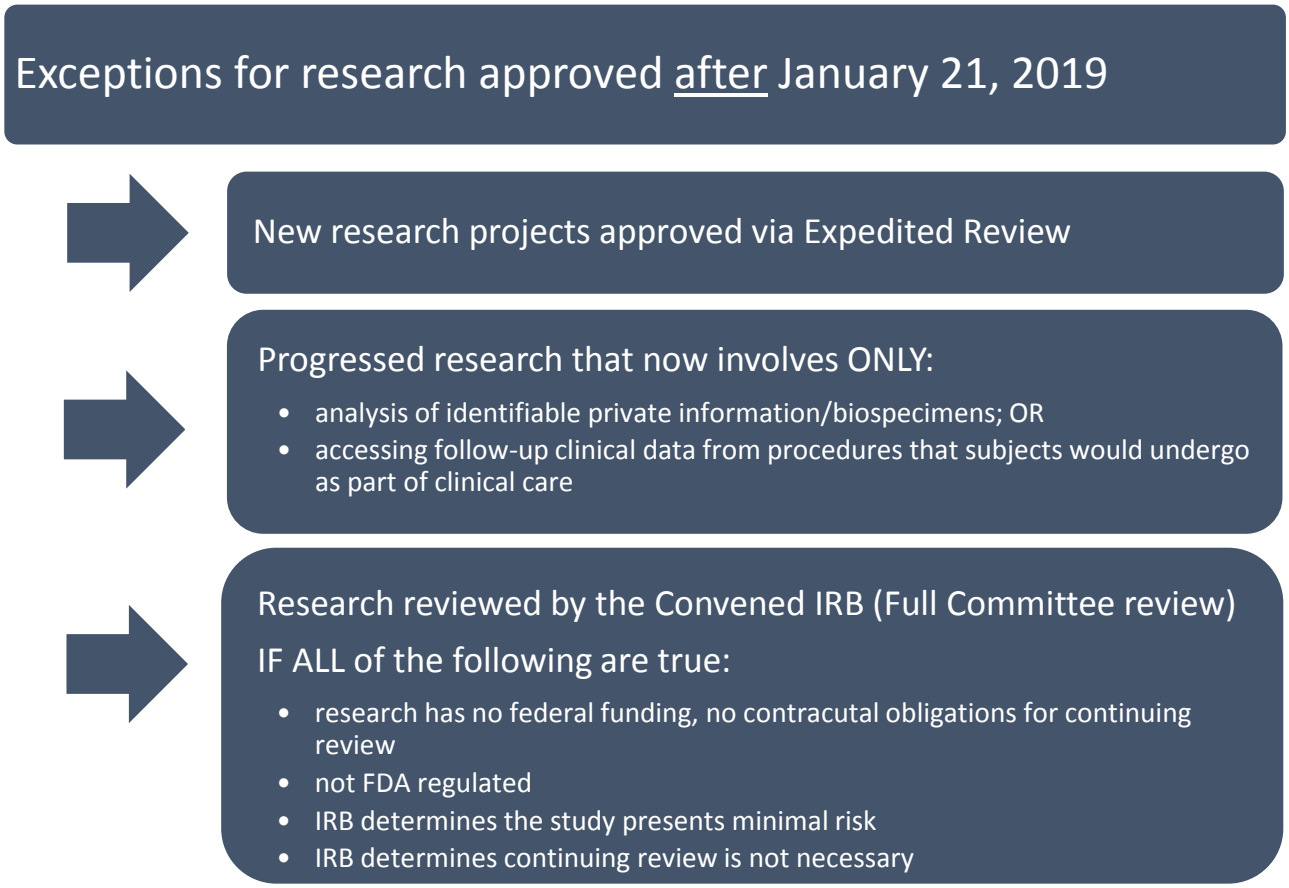
As transitioning to the 2018 Common Rule may require modifications to the study (e.g., revisions to the informed consent) each ongoing study will be assessed on a case-by-case basis for a determination of whether the project should be transitioned to the 2018 Common Rule requirements. This assessment will occur upon submission of an amendment action (i.e., continuing review or modification (other than a change to personnel-only)).

Exceptions to the Continuing Review Requirement

Exceptions for research approved before January 21, 2019

- Transitioned research* originally approved via Expedited Review
- Transitioned research that has progressed such that it now involves only:
  - analysis of identifiable private information/biospecimens; OR
  - accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care

*Transitioned research refers to studies approved under the prior regulations (i.e. approved before 1/21/19) that IRB Staff have formally transitioned to the new 2018 Common Rule. Studies are assessed for transition on a case-by-case basis upon submission of an amendment action (i.e., continuing review or modification (other than a change to personnel-only)).



Status Check in lieu of Continuing Review

ISU is responsible for oversight of all human subjects research, even when formal continuing review is not required. The IRB has implemented a brief "status check" process to ascertain the status of each protocol and to verify that no unapproved changes or unreported problems have occurred. This simple verification will occur at rolling three-year intervals until study completion. Researchers receive notification of the need for an upcoming status check electronically through IRBManager in advance of the three-year period end-date.

Document History

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