HUMAN RESEARCH PROTECTION

Transitioning studies to *Exempt* under the Revised Common Rule

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Resource type GUIDANCE

This document outlines the option to transition an active study that was approved by the IRB under the Original Common Rule (45 CFR 46) regulation to IRB approval under the Revised Common Rule, which went into effect on January 21, 2019.

Eligibility criteria

If your study was approved by the Hennepin Healthcare IRB prior to January 21, 2019 as ***expedited review category 5*** (research involving data, documents, records, or specimens that have been collected, or will be collected solely for nonresearch purposes), it may now qualify under the Revised Common Rule as ***exempt research category 4*** (secondary research for which consent is not required: applies to secondary research uses of identifiable private information or identifiable biospecimens if specific criteria are met. [45CFR46.104(d)(4)])

IMPORTANT: Research that is subject to FDA regulation is NOT eligible for transition

Considerations for transitioning an existing study

For expedited approvals that were initially granted by the Hennepin Healthcare IRB prior to January 21, 2019:

- Some minimal risk research approved under expedited review may now qualify as exempt research under the Revised Common Rule
- Studies approved as exempt are not subject to IRB oversight and do not continuing IRB review; however, changes in study staff, study modifications that may affect exempt status, and study closure must be submitted via Cayuse HE.
- Before requesting to transition a study, consider how much longer IRB oversight will be needed; for example, when access and use of identifiable data is no longer needed, the study may be closed

Transition decision chart