

On November 22, 2019, [OHRP clarified](#) that cooperative¹ research supported or conducted by HHS and subject to the 2018 Requirements *are not required* to comply with the revised Common Rule's single IRB mandate. This clarification creates an exception to the single IRB mandate for:

1. Cooperative research conducted or supported by HHS agencies other than the National Institutes of Health (NIH), if an IRB approved the research before January 20, 2020, *or*
2. Cooperative research conducted or supported by NIH if either
 - a. the NIH single IRB policy does not apply, and the research was initially approved by an IRB before January 20, 2020, *or*
 - b. NIH excepted the research from its single IRB policy before January 20, 2020².

Because using a single IRB can be complex and not always more efficient, UCI will follow the single IRB requirement only for new cooperative research studies approved by the UCI IRB on or after January 20, 2020 that are:

1. Conducted or supported by an agency that has signed on to the 2018 Common Rule
2. Conducted or supported by the NIH

For all other cooperative studies approved by the UCI IRB on or after January 20, 2020 the single IRB requirement is optional and may be used as the Lead Researcher's discretion. Please note that we encourage Lead Researchers to discuss this option with IRB staff before making such a decision.

Additional Resources from HHS:

- [Read](#) the official regulatory text for the 2018 Requirements (45 CFR 46.114(b)(2)(ii))
- [Read](#) about the history of the revised Common Rule rulemaking process
- [Watch videos](#) summarizing the changes in the revised Common Rule
- [Read](#) Q&As about the revised Common Rule
- See the [list of guidance](#) (draft and final) that have been issued on the revised Common Rule
- [Review](#) revised Common Rule terms
- See [what agencies](#) have signed on to the 2018 Common Rule

Stay tuned for more information on this process – including two town hall meetings in 2020!

¹ 45 CFR 46.114 (a): Cooperative research projects are those projects covered by this policy that involve more than one institution.

² From HHS: The NIH policy on the use of a single IRB for multi-site research has been in effect since January 25, 2018. It requires all U.S. sites participating in NIH-funded multi-site (i.e., two or more sites) studies involving non-exempt human subjects research where the sites are following the same protocol to use a single IRB for the review. Exceptions to this policy are made where review by the proposed IRB is prohibited by a federal, tribal, or state law, regulation, or policy, or if there is a compelling justification for the exception. NIH determines whether to grant an exception after an assessment of the need. NIH's single IRB policy is largely coextensive with the Common Rule single IRB requirement, although NIH designed its policy to exclude certain categories of cooperative research (e.g., training protocols for activities that do not involve human subjects research at initiation).