

Institutional Review Board Human Research Protections (HRP)

2018 Common Rule Update: Cooperative Review in 2020

Version October 14, 2019

<u>The 2018 Common Rule</u> mandates single IRB review for all federally funded cooperative research. This latest 2018 Common Rule requirement will go into effect on January 19, 2020.

Namely, any institution located in the United States that is engaged in NON EXEMPT human subject cooperative research, that is also supported or conducted by the Department of Human and Health Services (DHHS) or an agency that has signed on to the 2018 Common Rule, must rely on a single IRB.

45 CFR 46.114(b)(1): "Any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States."

<u>Since the NIH has already mandated single IRB review for research that it funds (all competing grant applications for due dates on or after January 25, 2018),</u> this will not be a major change for many institutions. However, the 2020 requirement will apply to the other federal departments and agencies that have adopted the Common Rule.

What this means at UCI:

All non-exempt, cooperative studies approved by the UCI IRB on or after January 21, 2019 already follow the 2018 Common Rule, regardless of funding. For those studies under the 2018 Common Rule where a single IRB review process is not already in place, beginning on January 19, 2020, we anticipate that Human Research Protections (HRP) staff will initiate discussions with the study team about the single IRB review process at the time of continuing review or the next modification, whichever comes first.

Effective January 19, 2020:



Stay tuned for more information on this process — coming in 2020!