

Revised Common Rule

Quick Reference

Key Changes

- Definition of human subject research expanded
- New and revised exemptions
- New “limited IRB review” required for some exemption categories
- New ICF elements
- Continuing review is not required for minimal risk studies, and they will not have an expiration date
- Grant reviews are no longer required
- Waiver of consent is no longer needed for screening and recruitment purposes
- When state law does not define who can be a LAR, institutional policy may be followed
- Single IRB requirement for multisite research is effective in 2020 (already required by NIH)
- Option to apply OHRP regulations to non-federally funded research removed (i.e., option to “check the box” on the FWA no longer exists)

The revised Common Rule does NOT apply to research that is:

FDA regulated



Department of Justice funded



Non-federally funded



Not funded



Health Canada-only regulated



Frequently Asked Questions

Can a study approved under the FDA regulations elect to follow the revised Common Rule?

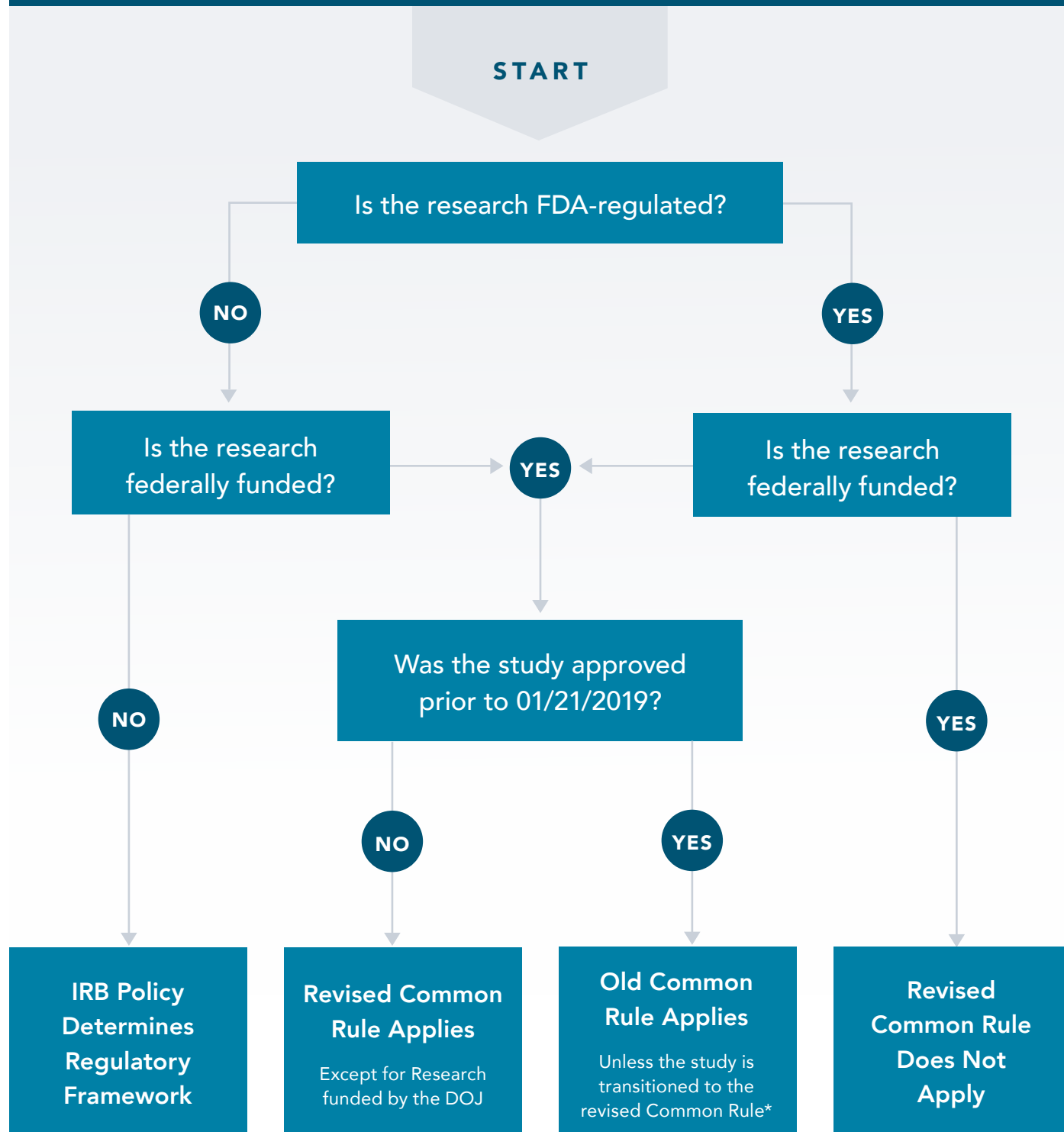
FDA-regulated research that is not federally funded may incorporate the consent provisions in the revised Common Rule. Other provisions such as the new exemptions, changes in continuing review, and the new waiver criteria cannot be voluntarily applied to FDA-regulated research.

Can a study or site that is not subject to the revised Common Rule add the key information and new elements to their ICF? Yes, studies that are FDA-regulated or approved under the old Common Rule can add the key information and consent elements to their ICFs. However, making these revisions to the ICF will not transition the study to the revised Common Rule.

Can a study approved under the old Common Rule transition to the revised Common Rule?

Research that is not FDA-regulated may be transitioned to the revised Common Rule.

Do I Need to Comply With the Revised Common Rule?



*DOJ-funded research cannot be transitioned