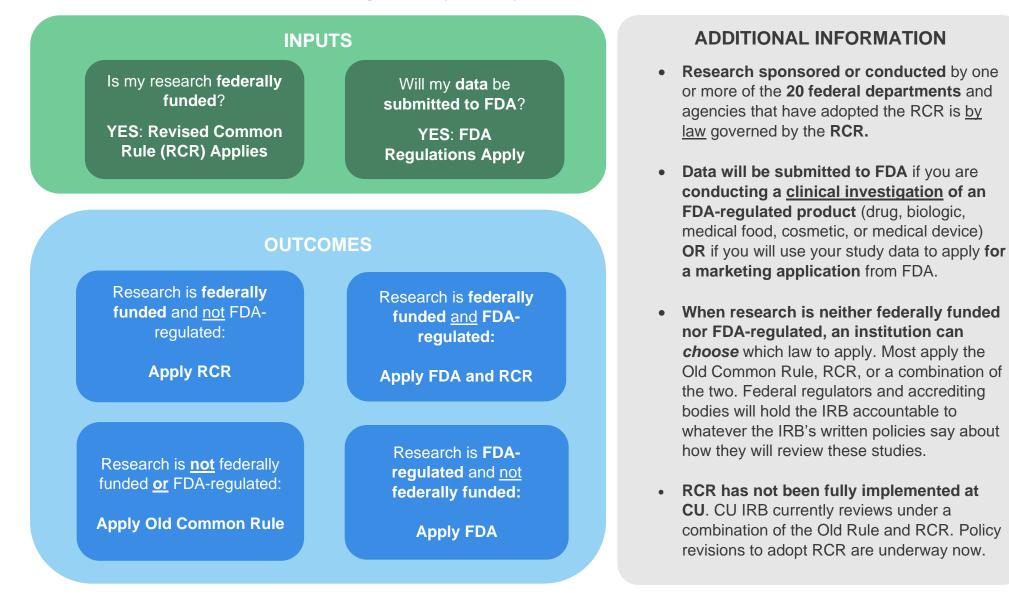
WHICH REGULATIONS APPLY TO MY STUDY?

To determine which set(s) of regulations apply to your human subjects research, answer two questions: "<u>What is the source of my funding</u>?" and "<u>Will my data be submitted to FDA</u>?"

The graphics below illustrate how <u>existing CU IRB</u> policies use the answers to these questions to determine which regulations apply to your study, how <u>upcoming IRB policy changes</u> will alter this regulatory analysis, and the <u>implications for CU investigators</u>.



Regulatory Analysis | Current State

IMPLICATIONS

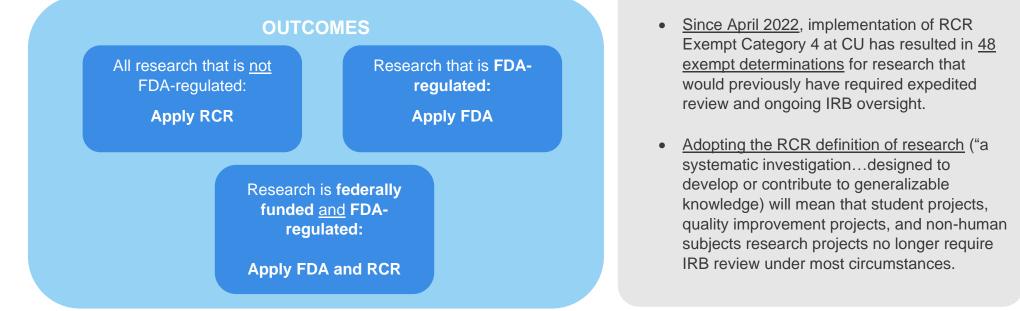
 Continuing review is eliminated for most expedited research under the RCR. FDA regulated research still requires continuing review but implementing the RCR at CU will prevent <u>105+ current studies AND future</u> <u>expedited studies</u> from submitting for continuing review.

Regardless of funding RCR Applies

INPUTS

Will my data be submitted to FDA?

YES: FDA Regulations Apply



Regulatory Analysis | Future State*

* The Regulatory Analysis will change again after FDA-regulated research is outsourced to an external IRB.

Last Updated: 10 February 2023.