WHICH REGULATIONS APPLY TO MY STUDY?

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

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

Regulatory Analysis | Current State

INPUTS

Is my research **federally funded**?

YES: **Revised Common Rule (RCR) Applies**

Will my **data** be **submitted to FDA**?

YES: **FDA Regulations Apply**

OUTCOMES

Research is **federally funded** and not FDA-regulated:

Apply RCR

Research is **federally funded** and **FDA-regulated:**

Apply FDA and RCR

Research is **not** federally funded **or** FDA-regulated:

Apply Old Common Rule

Research is **FDA-regulated** and not **federally funded:**

Apply FDA

ADDITIONAL INFORMATION

- **Research sponsored or conducted** by one or more of the **20 federal departments** and agencies that have adopted the RCR is by law governed by the **RCR.**
- **Data will be submitted to FDA** if you are **conducting a clinical investigation of an FDA-regulated product** (drug, biologic, medical food, cosmetic, or medical device) **OR** if you will use your study data to apply **for a marketing application** from FDA.
- **When research is neither federally funded nor FDA-regulated, an institution can *choose*** which law to apply. Most apply the Old Common Rule, RCR, or a combination of the two. Federal regulators and accrediting bodies will hold the IRB accountable to whatever the IRB's written policies say about how they will review these studies.
- **RCR has not been fully implemented at CU**. CU IRB currently reviews under a combination of the Old Rule and RCR. Policy revisions to adopt RCR are underway now.

Regulatory Analysis | Future State*

INPUTS

Regardless of funding

RCR Applies

Will my **data** be **submitted to FDA**?

YES: **FDA Regulations Apply**

OUTCOMES

All research that is not FDA-regulated:

Apply RCR

Research that is **FDA-regulated:**

Apply FDA

Research is **federally funded** and **FDA-regulated:**

Apply FDA and RCR

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 105+ current studies AND future expedited studies from submitting for continuing review.
- Since April 2022, implementation of RCR Exempt Category 4 at CU has resulted in 48 exempt determinations for research that would previously have required expedited review and ongoing IRB oversight.
- Adopting the RCR definition of research ("a systematic investigation…designed to develop or contribute to generalizable knowledge) will mean that student projects, quality improvement projects, and non-human subjects research projects no longer require IRB review under most circumstances.

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

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