START

On 20 Jan 19 is the study currently approved?

Will the study close before 21 Jan 2019?

Does the study now qualify as exempt or not research?

STOP

Deciding to convert an ONGOING study to the new Common Rule Requirements

Consider carefully: Must post consent form to TBD public website.

FDA regulated?

Consider carefully: Can not forgo Continuing review

Is the study a clinical trial under the new definition?

Is enrollment complete?

Is the study in data analysis only?

Is there a waiver of consent or documentation of consent?

Is all enrollment and data collection complete except for accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care?

CONVERT THE STUDY

Any study approved on or after 21 Jan 2019 must comply with new requirements.