



IRBMED Transition to Revised Common Rule Grid

Has Federal Sponsorship

Has No Federal Sponsorship

Initially Approved before
January 21, 2019

Remain under the pre-2018 Requirements

- A transition to **some** elements of the revised Common Rule, for reducing administrative burden or to improve human research protections, will not trigger the need to comply with all 2018 Requirements.
- For example, updating the consent to the updated template which reflects the 2018 Requirements

Initially Approved on or
after January 21, 2019

Comply with 2018 Requirements

- The eResearch application and Standard Informed Consent Template are updated to reflect 2018 Requirements.
- Study teams are required to post IRB-approved consent form for clinical trials online:
 - Clinicaltrials.gov or a docket folder on Regulations.gov
 - Must post after recruitment ends and no later than 60 days after last study visit by any subject
 - Tracking when to post the consent document is the study teams' responsibility

Comply with 2018 Requirements

- The eResearch application and Standard Informed Consent Template are updated to reflect 2018 Requirements.
- Study teams are **not** required to post IRB-approved consent form for clinical trials online.