What studies will – or can – transition to the 2018 Common Rule?

Studies required to transition

- Not FDA-Regulated or DOJ-Funded
  - Secondary analysis of data with waiver of consent
    OR
  - In long-term follow-up as of previous continuing review
    OR
  - In data analysis only as of previous continuing review

Optional Transition

- Not FDA-Regulated or DOJ-Funded
  - Minimal risk (per IRB)
  - Still enrolling subjects via consent process
  - No international sites
  - Do not have a significant history of compliance issues
How to Transition Existing Studies to the 2018 Common Rule

Studies required to transition

Transition will occur 45 to 30 days before study expiration

- Do not submit continuing review
- Submit an amendment (AM) with attestation form, stating how much longer study will likely remain open. You don’t need so submit an attestation form every year
- The study will not require continuing review in the future.

Study Team-Requested Transition

Transition should occur 45 to 30 days before study expiration

- Submit a continuing review (CR) application as usual
- Submit an amendment (AM) with attestation form, stating when the study will close (approximate date). You don’t need so submit an attestation form every year
- Include revised ICF to include new elements, if still enrolling subjects
- The study will not require continuing review in the future.