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

Studies <u>required</u> to transition

Optional Transition

Not FDA-Regulated or DOJ-Funded

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- 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

- 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.