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

### Required 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
- Not a "clinical trial" per NIH or Common Rule definition
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
- 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)
- Include revised ICF to include new elements, if still enrolling subjects