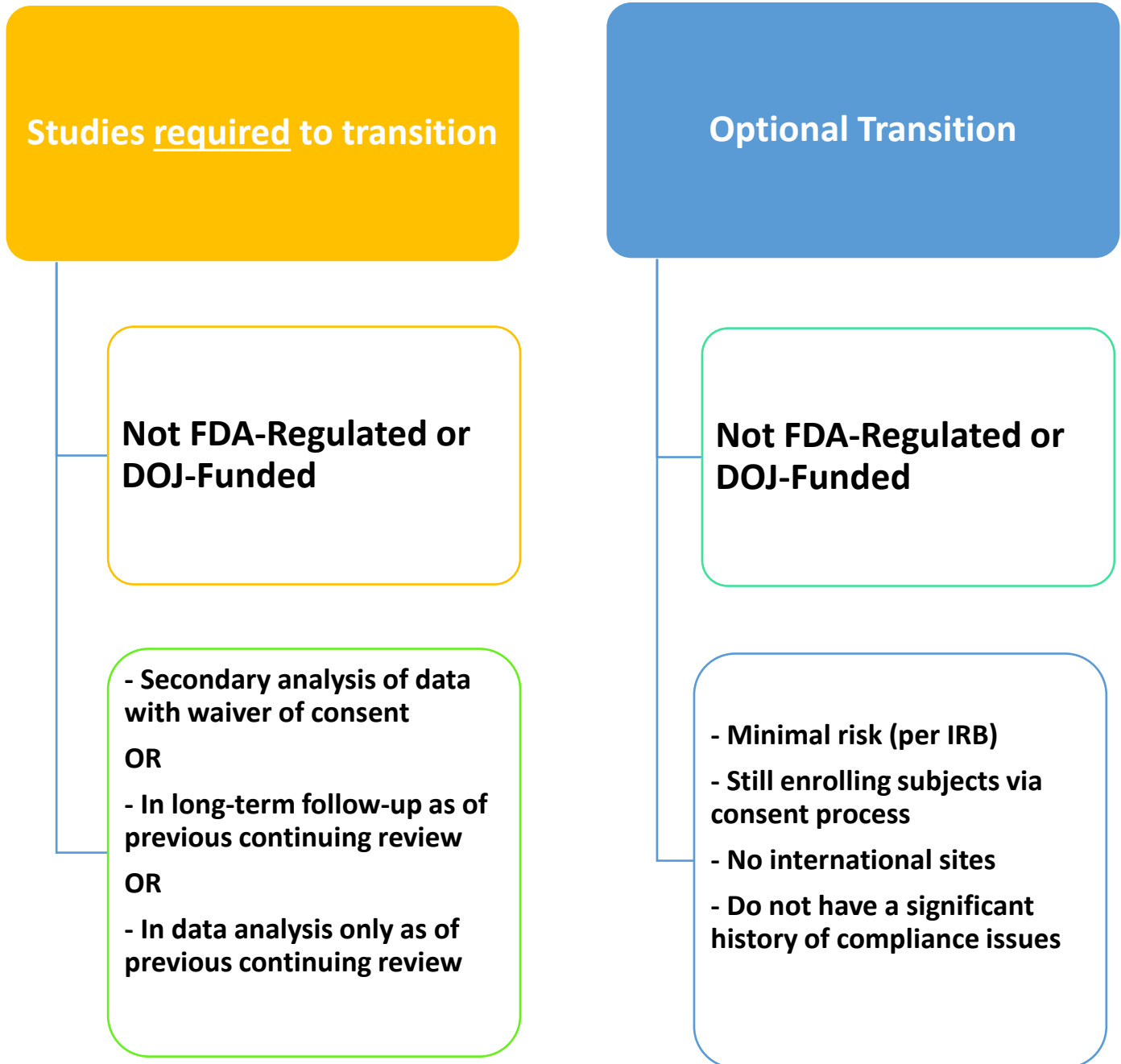


## What studies will – or can – transition to the 2018 Common Rule?



## 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.