Q&A-REVISED COMMON RULE

01

What studies have to transition?

Studies expiring after 1/21/19 that are in long-term follow-up or data analysis as of the latest continuing review (CR); or that are limited to secondary analysis of data/samples (excluding FDA- or DOJ-regulated studies, and ones with international sites)

02

Can I transition my study?

Maybe; your study must not be FDA- or DOJ-regulated, must not have international sites, and must not have significant recent compliance issues

03

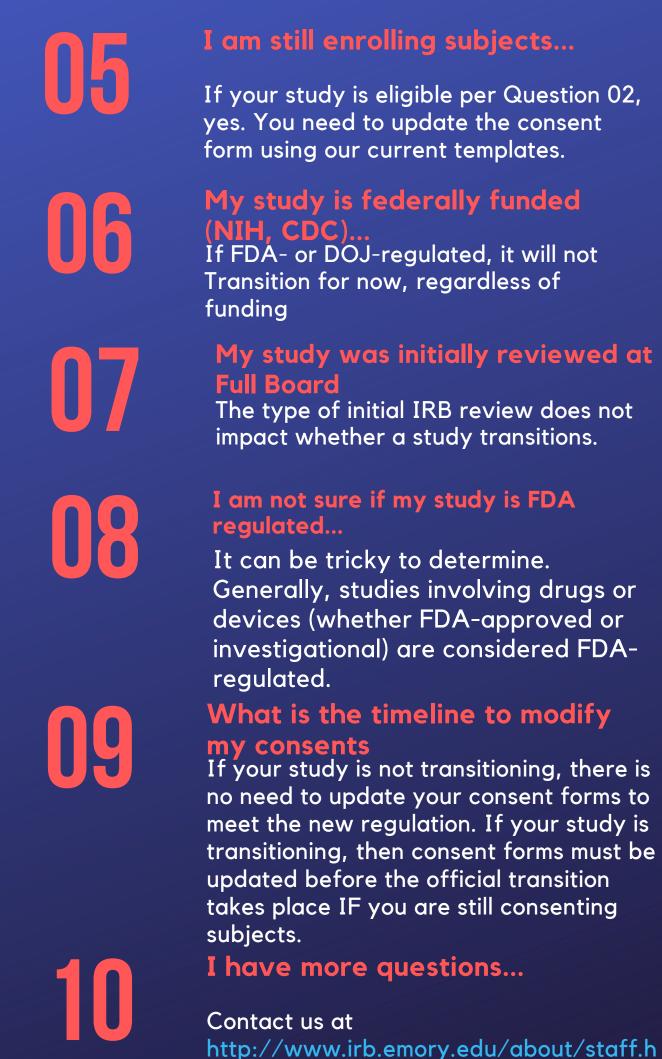
What documents do I need?

An amendment (AM) with the Attestation form if your study is required to transition; or an AM and a renewal submission if electing to transition

04

When can I transition? Is the IRB notifying us?

notifying us?
Submit your AM (and CR if electing to transition) 30 to 45 days before study expiration. The IRB will not send transition notifications for all studies, but will remind you if we receive a renewal application instead of a transition amendment.



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