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?

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.

05

I am still enrolling subjects...

If your study is eligible per Question 02, yes. You need to update the consent form using our current templates.

06

My study is federally funded (NIH, CDC)...

If FDA- or DOJ-regulated, it will not Transition for now, regardless of funding

07

My study was initially reviewed at Full Board

The type of initial IRB review does not impact whether a study transitions.

08

I am not sure if my study is FDA regulated...

It can be tricky to determine. Generally, studies involving drugs or devices (whether FDA-approved or investigational) are considered FDA-regulated.

09

What is the timeline to modify my consents

If your study is not transitioning, there is no need to update your consent forms to meet the new regulation. If your study is transitioning, then consent forms must be updated before the official transition takes place IF you are still consenting subjects.

10

I have more questions...

Contact us at http://www.irb.emory.edu/about/staff.html