Transition to the New Rules

Can we transition?

FDA Regulated or Full Committee other than Cat 9, 8a, 8c

Minimal Risk, Expedite, Exempt, Full Committee (8a, 8c, 9)

Can't transition Old Rules Apply

Check below for KC requirements

Is the project still open to enrollment?

No

Yes

Only the Project Transition form needs to be completed.

Complete Transition form. If applicable, update consent forms.

Use the new common rule codes, and assign 158 or 159.

After Approval, see below