Guidance for the Transition of Studies approved before January 21, 2019, to the Revised Common Rule

The revised common rule will be effective as of January 21, 2019. For more information about these changes, read this link with the revised common rule text.

If your study was approved before January 21, 2019, your study will be transitioned to the revised common rule when submitting your continuing review if it is:

- Not an FDA regulated[1] or Department of Justice (DOJ) supported study, **and**
- In long term follow up (LTF) or data analysis only (DAO) as of the last continuing review, **or**
- A secondary analysis of identifiable data or biospecimens that are not going to be submitted to the FDA
- If the study is conducted at an international site, they are no longer under the local ethics committee's review

What do I need to do if I am required to transition my study to the revised common rule?
Nothing is required from you. The study analyst reviewing the continuing review application will complete the process after reviewing the information you submitted.

What if my study is no more than minimal risk[2] and I would like to transition it?
Fill out the attestation form (on next page), and attach it to your next continuing review, 30 to 45 days before expiration. The form should be attached to the last question of the continuing review submission.

If you are still enrolling subjects, you will need to submit a modification to update your consent to align with the revised common rule. Please, update your consent by using a consent form template on our website.

If you are planning to close the study in the next year, you may want to consider not transitioning to the Revised Common Rule.

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[1] The FDA has not aligned with the revised common rule to allow studies, IRB-approved as no more than minimal risk, to stop the requirement of submitting continuing review applications. FDA regulated research are those using a drug, device or biologic, approved for marketing or not, outlined under 21 CFR 312 (drugs), 21 CFR 812 (devices), and 21 CFR 600 (biologics). FDA regulations for informed consent (21 CFR 50) and Institutional Review Boards (21 CFR 56) also apply. For the purpose of this transition, we considered FDA regulated studies in which the data or specimens' analysis results will be submitted to the FDA.

[2] Minimal risk studies can be reviewed via expedited review because they present no more than minimal risk to human subjects, and involve only procedures listed in one or more of the expedited categories. Find the expedited categories here. This will not involve FDA regulated studies or studies funded by the DOJ.

Attestation Form

PI Name:
Study Name:
IRB#:

1. Is this study FDA regulated[1] or DOJ supported?	◯ Yes- **STOP**-your study cannot transition[1] ◯ No- Continue with question 2
2. Do you still need local ethics committee review?	◯ Yes- **STOP**-your study cannot transition[3] ◯ No- Continue with question 3
3. Do you have significant noncompliance issues?	◯ Yes- **STOP**-your study cannot transition[4] ◯ No- (or if a study conducted at the Atlanta VA)- Continue with question 4
4. Is this study still enrolling subjects via a consent process?	◯ Yes. If so, make sure you update your consent document using our new template**. Submit a new version of your consent in a modification**. ◯ No.
5. If yes, please add your rationale for why the data or biospecimens need to be in an identifiable form?	
6. Are you submitting your data to the FDA?	◯ Yes ◯ No

Any additional comments:

If you have additional questions, please refer to our Revised Common Rule page or contact any member of our staff, especially our staff leadership.

[3] Even if a study is in data analysis, if the study need international local site review it cannot transition.

[4] If you received a serious noncompliance, continuing non-compliance and unanticipated problem determination (not related to a safety event deemed as an unanticipated problem), your study cannot transition at this point. . If your study is being conducted at the VA, the single IRB mandate will not apply to your study, so you will be allowed to transition if applicable per our other requirements.