**TU IRB OFFICE PROCESS:**
**EXISTING PROTOCOLS APPROVED BEDFORE**
**the 2018 Common Rule effective date of January 19, 2018**

| EXEMPT | EXPEDITED | FULL BOARD |
|---|---|---|
| **PROCESS:** No need to notify PIs or do anything → PI still required to submit modification requests for review → keep for 3 years from the approval date *or* unless PI requested a later proposed end date *or* requested to close earlier *or* if it was described as a longitudinal study → shred. | **PROCESS:** Contact the PI after 2018CR effective date or at next annual review/modification to notify them that the 2018 CR <u>will</u> be applied and no more annual reviews needed → If still enrolling new subjects, PI must update to the 2018CR ICF → PI required to submit modification requests for review → send out documentation letter applying the 2018CR and dating the ICF with the approval date only and confirm/record PIs proposed end date on the letter → record project end date in database to contact PI 30-90 days before recorded end date → send PI email to choose: close out *or* extend the end date → keep protocol file for 3 years after protocol closed → shred | **PROCESS:** Contact the PI to notify them about the 2018 CR and inquire if they want to have it applied to their study → In most cases, If still enrolling new subjects, PI will not benefit from the 2018CR until the study meets Expedited Category 8a or 8c→ continue annual reviews until protocol meets criteria to end annual reviews – Expedited 8a or 8c (then follow the minimal requirements of EXPEDITED) *or* PI requests protocol to be closed out → When protocol transitions to 2018CR, send out approval/documentation letter applying the 2018 CR→ PI required to submit modification requests → keep protocol file for 3 years after protocol closed → shred |
| **EXEMPT Determination letter:** No additional correspondence needed but still required to submit modification requests for review. | **EXPEDITED Approval letter:** Documentation letter applying the 2018 CR and dating the ICF with the approval date only and confirm/record PIs proposed end date on the letter where PI will be notified by email 30-90 days before end date. PI is required to submit modification requests for review. | **FB Approval letter:** Continue 12-month approval and annual reviews until it meets the criteria for Expedited (8a or 8c)- Once 2018CR is applied, no annual reviews but still required to submit modification requests for review) → PIs get reminders 30-60 days before annual report is due. |
| | **Notes:** A 'final report' is not required for either the 2018 CR or the pre-2018 CR. Need to keep correspondence when PI requests to close the protocol → keep protocol file for 3-years after protocol closed → shred | **Notes: 1)** A 'final report' is not required on either the 2018 CR or the pre-2018 CR. Need to keep correspondence when PI requests to close the protocol. → keep protocol file for 3-years after protocol closed → shred |

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|---|---|---|
| **PROCESS:** Submitted with the latest version of the forms → initial review → if determined HSR, use the 2018CR list of Exempt categories → check researchers' IRB training → set up protocol number to register protocol → EXPEDITED review procedures on 'limited IRB review' if applicable EXEMPT category → send out EXEMPT determination letter → PI still required to submit modification requests for review → keep for 3 years from the approval date *or* unless PI requested a later proposed end date *or* requested to close earlier *or* if it was described as a longitudinal study → once officially closed, can shred. | **PROCESS:** Submitted with the latest version of the forms → initial review → if determined HSR → check researchers' IRB training → set up protocol number to register the protocol → Determined EXPEDITED - send out to Designated Reviewer for EXPEDITED review procedures → send out EXPEDITED approval letter with PIs proposed end date → record proposed end date in database to contact PI 30-90 days before end date → PI required to submit modification requests for review → send PI email to choose: close out *or* extend the end date → keep protocol file for 3 years after protocol closed → shred. | **PROCESS:** Submitted with the latest version of the forms → Initial review →determined HSR → check researchers' IRB training → set up protocol number to register the protocol → prepare protocol for next scheduled IRB meeting → PI still required to submit modification requests for review → annual reviews until protocol meets criteria to end annual reviews (then follow the minimal requirements of EXPEDITED) or requests protocol to be closed out → keep for 3 years after protocol closed → shred. |
| **EXEMPT Determination letter:** Explain that it will be approved/active for 3 years unless PI requested a later proposed end date *or* requested to close earlier *or* if it was described as a longitudinal study. | **EXPEDITED Approval letter:** No longer a 12-month approval - just 'approved' and no more annual reports due, but still required to submit modification requests for review. Add a line with their stated, "proposed end date of record" where they will be notified by email 30-90 days before end date. | **FB Approval letter:** If still enrolling new subjects, 12-month approval and annual reviews until it meets the criteria for Expedited-no annual reviews) but still required to submit modification requests for review. PIs get reminders 30-60 days before annual report is due. |
| | **Notes: 1)** A 'final report' is not required on the 2018 CR, just records of Continuing review. *Sponsor may still require a 'final report'. Keep correspondence when PI requests to close the protocol. **2)** If FDA or FF agency/dept. did not sign w/2018CR, need to follow pre-2018CR (*annual reviews). | **Notes: 1)** A 'final report' is not required on the 2018 CR, just records of Continuing review. *Sponsor may still require a 'final report'. Keep correspondence when PI requests to close the protocol. **2)** If FDA or FF agency/dept. did not sign w/2018CR, need to follow pre-2018CR (*annual reviews). |