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| --- | --- | --- | --- |
| **Close-out Activities** | Yes | **No** | **Comments** |
| 1. Submit the Trial Sponsor’s notification of enrollment closure Closing to Enrollment letter (dated November 4, 2013) to all IRBs of Record within 2 weeks of receipt of the letter, or by November 18, 2013. |  |  |  |
| 1. Submit the NIH Official Letter addressed to the Trial Sponsor (dated October 30, 2013) to all IRBs of Record by November 18, 2013. |  |  |  |
| 1. It is not required that the ProTECT Subject EOS Notification Letter be submitted to the IRB for Spokes that did not enroll. This document entry can be waived in WebDCU. |  |  |  |
| 1. Data enter all CC events conducted through Nov. 3, 2013 into the WebDCU ProTECT Database on their own Community Consultation Summary Form. Notify Deneil ([dkolk@umich.edu](mailto:dkolk@umich.edu)) once you have completed all of your CC summary forms for verification. Any queries generated from the verification process must be resolved for this task to be complete. |  |  |  |
| 1. Data enter all PD events conducted through Nov. 3, 2013 into the WebDCU ProTECT Database on their own Public Disclosure Summary Form. Notify Deneil ([dkolk@umich.edu](mailto:dkolk@umich.edu)) once you have completed all of your PD summary forms for verification. Any queries generated from the verification process must be resolved for this task to be complete. |  |  |  |
| 1. Maintain regulatory compliance for the Spoke and all active study team members until end of study milestone tasks have been completed.\* |  |  |  |
| 1. Provide documentation of IRB acknowledgement of study closure in WebDCU under: **ProTECT IRB Close-out Acknowledgement**. |  |  |  |
| 1. Obtain PI signature on final Delegation of Authority log. Once all study team members are made inactive in the Project Spoke Team Member table and end dates are added to the Delegation of Authority log, please upload into WebDCU. |  |  |  |

\* Please note, we have allowed sites to inactivate team members with the exception of the Hub PI, Trial PI and Trial Primary Study Coordinator during this process