**Transition to Revised Common Rule Appendix**

|  |
| --- |
| On January 21, 2019, the DHHS Office of Human Research Protections (OHRP) revised Common Rule went into effect. Research protocols approved before January 21, 2019 may be transitioned to the Revised Common Rule regulations if the following criteria are met.  |
|  | Is the study sponsored by a Federal Agency | [ ] No **– STOP**, the research does not qualify  for transition to the revised Common Rule[ ] Yes  |
|  | Was the study approved prior to January 21, 2019? | [ ] No **– STOP**, the research does not qualify  for transition to the revised Common Rule[ ] Yes  |
|  | Is the study a drug or device study subject to FDA regulations? | [ ] No[ ] Yes **– STOP**, the research does not qualify  for transition to the revised Common Rule |
|  | Is the study closed to enrollment? | [ ] No **– STOP**, the research does not qualify  for transition to the revised Common Rule[ ] Yes  |
|  | Is the study in data analysis only? | [ ] No **– STOP**, the research does not qualify  for transition to the revised Common Rule[ ] Yes  |
| Please note Under the revised Common Rule, all Federally Sponsored research that meets the definition of a clinical trial must post the consent form to a Federal website.If you answered Yes to number 1, 2 and 4 your study meets criteria to be transferred to the revised Common Rule. Please include this completed Appendix with your submission documents.Please do not submit an amendment solely to request the transition of your study to the revised Common Rule.You can receive submission guidance by e-mailing your questions to irbquestions@wayne.edu |