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| The purpose of this worksheet is to provide support for Designated Reviewers and IRB Staff conducting expedited and administrative review OF SUBMISSIONS for Initial Review, Modifications, and Continuing Review. This worksheet is intended to guide designated reviewers and IRB staff in determining whether to apply the Pre-2018 Common Rule Requirements or the 2018 Common Rule Requirements (Post 2018 Rule). | | | |
| **IRB Number**: | | |  |
| 1. **Submission Type** | | | |
|  | New Exempt Research ONLY  Funded by Federal Agency who has ***not*** adopted 2018 Common Rule **(Go to Section 4)**  All other funding types, including unfunded studies **(Go to Section 3)** | | |
|  | Initial Review of a study qualifying for Expedited review:  Funded by Federal Agency who has ***not*** adopted 2018 Common Rule **(Go to Section 4)**  All other funding types, including unfunded studies **(Go to Section 3)** | | |
|  | Initial review of a study reviewed by the convened board **(Go to Section 2)** | | |
|  | Modification or Continuing Review: (Choose One of the Below)  If approved prior to January 21, 2019 without the 3 burden reducing provisions and continuing under pre-2018 rule **(Go to Section 4)**  Determine if New Common Rule can be used **(Go to Section 2)** | | |
| 1. **Funding Type** | | | |
|  | Federal Agency which has adopted the 2018 Common Rule **(Complete Section 3)** | | |
|  | None/Department/Industry:  Sponsor/Investigator ***requests*** to transition to the 2018 Common Rule **(Complete Section 3)**  Sponsor/Investigator ***does not request*** to transition to the 2018 Common Rule **(Complete Section 4)** | | |
|  | Federal Agency which has not adopted the 2018 Common Rule **(Complete Section 4)** | | |
| 1. **2018 Common Rule** | | | |
|  | Apply the 2018 Common Rule provisions except for those pertaining to the review period | | |
|  | Denote that the 2018 Common Rule provisions are being applied through:  Apply 2018 Common Rule Global Tag in both the Admin and Committee Board (as applicable); and  Write that 2018 Common Rule will be used in reviewer’s notes | | |
|  | **Complete Section 5** | | |
| 1. **Pre-2018 Common Rule** | | | |
|  | | Apply the Pre-2018 Common Rule provisions. | |
|  | | Denote that the Pre-2018 Common Rule provisions are being applied through:  Apply Pre-2018 Common Rule Global Tag in both the Admin and Committee Board (as applicable); and  Write that Pre-2018 Common Rule will be used in reviewer’s notes | |
| 1. **Jurisdiction** | | | |
|  | FDA-regulated: (Check one)  Assign a continuing review date one year less one day from date of review.  Assign a continuing review date more frequently than one year.  Provide justification: | | |
|  | Not FDA-regulated | | |