|  |  |
| --- | --- |
| The purpose of this worksheet is to provide support for IRB reviewers when determining approval intervals. This worksheet is to be used. It does not need to be completed or retained.  When making this determination consider the nature and level of risks; degree of uncertainty regarding the risks; subject vulnerability; investigator experience; IRB’s experience with investigator or sponsor; projected rate of enrollment; and whether study involves novel procedures. | |
|  | |
| 1. Risk Level | |
|  | This research involves no more than minimal risk and would be reviewed under an expedited category if continuing review were required. ***(If Checked go to Section 2)*** |
|  | This research involves greater than minimal risk ***(If Checked go to Section 4)*** |
| **2. Regulatory Jurisdiction - A (*If none of the below are checked, go to Section 3*. If one or more items are checked, go to Section 4)** | |
|  | This research is funded by the Department of Justice |
|  | This research is subject to FDA jurisdiction |
|  | This research is federally funded and expedited under category 8(b) or 9. |
|  | This research is **not** federally funded and expedited under category 8(b). |
|  | |
| 3. Regulation Jurisdiction – B (If o*ne of the following is checked, continuing review is not required. If none are checked go to Section 4)* | |
|  | This research is not federally funded. |
|  | This research is federally funded and was initally approved after January 20, 2019 |
|  | This research is federally funded, was initially approved before January 20, 2019, and all remaining procedures are compliant with the requirements of the 2018 Common Rule |
|  | This research meets the requirements for an exempt category under WORKSHEET – Exemptions – HRP-312. |
|  |  |
| 4. This research may require review more often than annually *(check any that apply – if none apply, go to Section 5)* | |
|  | Initial review of research involving greater than minimal risk with an exception to the requirement for informed consent for emergency research should be approved for only six months |
|  | Phase 1 study of a novel agent where the risk of the agent in humans is not known |
|  | Review of informational items that involve newly identified risks or increased risk |
|  | Other: ***Explain*** |
|  | |
| 5. This research should be approved for 1 year | |
|  | |