UC San Diego
INSTITUTIONAL REVIEW BOARD ADMINISTRATION

OIA-319 WORKSHEET: Approval Period

NUMBER	DATE	PAGE
OIA-319	09/06/2023	1 of 1

The purpose of this worksheet is to provide support for IRB reviewers when determining approval intervals. This worksheet, or equivalent, 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 Food and Drug Administration (FDA) jurisdiction.
- ☐ This research is expedited under category 8(b) or 9.

3 Regulation Jurisdiction B (If *one of the following is checked, continuing review is not required and study should not be assigned an expiration date. If none is checked go to Section 4.)*

- ☐ This research is not federally funded.
- ☐ This research is federally funded and was initially 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 Revised Common Rule.
- ☐ This research meets the requirements for an exempt category under *OIA-312 WORKSHEET: Exemption Determination*, or equivalent.

4 This research may require review more often than annually. *(Check any that apply. If none apply, go to Section 5. Checking a box in this section does not require that approval be granted for less than 1 year.)*

- ☐ Initial review of research involving greater than minimal risk with an exception to the requirement for informed consent for emergency research.
- ☐ Phase 1 study of a novel agent in which the risk of the agent in humans is not known.
- ☐ Review of reportable events that involve newly identified risks or increased risk.
- ☐ Other ***Explain:***

5 This research should be approved for 1 year