

SOP: Approval Review and End Dates	
Section III: IRB Protocols	
Number	Date
IRB III-005	9/13/2025

1. PURPOSE

1.1. This SOP describes the calculation of the approval period and approval end date.

2. REVISION FROM PREVIOUS VERSIONS

2.1. None

3. SOP STATEMENT

- 3.1. Exempt research does not have an expiration date; however, research compliance staff assigned to the IRB may reach out to PIs of exempt protocols on a periodic basis to confirm whether their exempt work is ongoing or may be closed.
- 3.2. The remainder of this policy applies to non-exempt research, including both expedited and convened reviews.

4. RESPONSIBILITIES

4.1. The research compliance staff assigned to the IRB is responsible for carrying out these procedures.

5. PROCEDURE

- 5.1. As used in this policy for approval review and end dates:
 - 5.1.1. The Action (Start) Date is:
 - 5.1.1.1. The date the convened IRB or designated reviewer made a determination to approve the research; or
 - 5.1.1.2. The date the IRB confirmed requested modifications met the requirements of a convened IRB, or the designated reviewer determined required modifications were completed to secure approval of research.
 - 5.1.2. The Approval Period (Interval) is the time frame of approval granted by the convened IRB or designated reviewer, which is not to exceed one year.
- 5.2. For initial review, the End Approval Date is the Action (Start) Date plus the approval interval minus one day.
 - 5.2.1. For example, if the research was approved for one year with an Action (Start) Date of April15, the End Approval Date is April 14 of the following year.
- 5.3. For continuing review, the new End Approval Date is the Action (Start) Date plus the approval interval minus one day.
- 5.4. For amendments, the End Approval Date does not change from the date originally assigned to the study.

5.5. Notification of renewal status will be issued 31 calendar days prior to the expiration date via the Cayuse electronic system. See TAMUK SOP: Expiration of IRB Approval (IRB SOP III-006) for renewals in the "expired" status.

6. REFERENCES

6.1. <u>21 CFR 56.109</u>(f)

6.2. <u>45 CFR 46.109(e)</u>

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