



POLICY: End Approval Dates

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1. PURPOSE

- 1.1. This policy describes the calculation of the <End Approval Date>.

2. POLICY

- 2.1. The following research has no <End Approval Date>:
 - 2.1.1. Exempt research
 - 2.1.2. Research that does not require continuing review per “WORKSHEET: Criteria for Approval (HRP-400).”
- 2.2. For all other research:
 - 2.2.1. The Action Date is
 - 2.2.1.1. The date the convened IRB or <Designated Reviewer> made determination to approve the research.; or
 - 2.2.1.2. The date the IRB confirmed that the responsive materials met the requirements of a convened IRB or <Designated Reviewer> determination to conditionally approve the research.
 - 2.2.2. The Approval Interval is the period of approval granted by the convened IRB or <Designated Reviewer>. (e.g., 1 year, 6 months, 3 months)
 - 2.2.3. For initial review, the <End Approval Date> is the Action Date plus the approval interval minus one day.
 - 2.2.3.1. For example, if the research was approved for one year with an Action Date of April 15, 2020, the <End Approval Date> is April 14, 2021.
 - 2.2.4. For continuing review:
 - 2.2.4.1. When the Action Date is less than or equal to 30 days before the current <End Approval Date>, the new <End Approval Date> is the previous <End Approval Date> plus the current approval interval.
 - 2.2.4.2. When the Action Date is greater than 30 days before the current <End Approval Date>, the new <End Approval Date> is the Action Date plus the approval interval minus one day.
 - 2.2.5. For modifications, the <End Approval Date> is unchanged.

3. REFERENCES

- 3.1. 21 CFR §56.109(f)
- 3.2. 45 CFR §46.109(e)