



**POLICY: End Approval Dates**

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**1. PURPOSE**

1.1. This policy describes the process for calculating the End Approval Date.

**2. POLICY**

2.1. Exempt research has no End Approval Date.

2.2. The remainder of this policy applies to non-exempt research.

2.3. As used in this policy:

2.3.1. The Action Date is:

2.3.1.1. The date the convened IRB or Designated Reviewer(s) made the determination to approve the research; or

2.3.1.2. The date the IRB confirmed that the responsive materials met the requirements of a convened IRB or Designated Reviewer(s) determination to conditionally approve the research.

2.3.2. The Approval Interval is the period of approval granted by the convened IRB or Designated Reviewer(s) (e.g. 1 year, 6 months, 3 months).

2.4. For initial review, the End Approval Date is the Action Date plus the approval interval minus one day.

2.4.1. 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.

2.5. For continuing review:

2.5.1. 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.

2.5.2. 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.

2.6. For modifications, the End Approval Date is unchanged.

**3. REFERENCES**

3.1. 21 CFR §56.109(f)

3.2. 45 CFR §46.109(e)