

## 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. 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> made 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> determination that modifications were required to secure approval of the research.

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

2.4. 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)