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>, but an abbreviated continuing review is requested every three years.
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 to conditionally approve 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, 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)