

	<b>SOP: Approval Periods (Intervals) and End Dates</b>		
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## 1 PURPOSE

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

## 2 REVISIONS FROM PREVIOUS VERSION

2.1 None

## 3 SOP Statement

3.1 Exempt research is given a five-year determination period.

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

3.3 Use *Worksheet: Approval Period (Intervals) (HRP-302)*

3.4 As used in this policy:

3.4.1 The Action (Start) Date is:

3.4.1.1 The date the convened IRB or Designated Reviewer made a determination to Approve the research.; or

3.4.1.2 For new studies, 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 research.

3.4.2 The Approval Period (Interval) is the period of approval granted by the convened IRB or Designated Reviewer which is not to exceed one year. (e.g., 1 year, 6 months, 3 months)

3.5 For initial review, the End Approval Date is the Action (Start) Date plus the approval interval minus one day.

3.5.1 For example, if the research was approved for one year with an Action (Start) Date of April 15, 2020, the End Approval Date is April 14, 2021.

3.6 For continuing review, the new End Approval Date is the Action (Start) Date plus the approval interval minus one day.

3.7 For modifications, the End Approval Date is unchanged.

## 4 MATERIALS

4.1 *Worksheet: Approval Period (Intervals) (HRP-302)*

## 5 REFERENCES

5.1 21 CFR 56.109(f)

5.2 45 CFR 46.109(e)

5.3 AAHRPP II.2.D, II.2.F