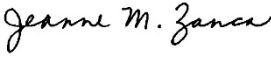



# KESSLER FOUNDATION

## *Policies and Procedures Manual*

<b>SUBJECT: Calculation of Approval and Expiration Dates</b>	<b>POLICY # 5040</b>
<b>APPROVED:</b>  _____ <b>Jeanne M. Zanca, MPT, PhD</b> <b>IRB Chair</b>   _____ <b>John DeLuca, PhD</b> <b>Senior Vice President for Research</b> 	<b>EFFECTIVE DATE:</b>  <b>January 20, 2026</b>  <b>REVISED DATE:</b>

### **PURPOSE**

To establish the procedure for how approval and expiration dates are calculated for initial applications, continuations, and amendments.

### **PROCEDURE**

#### **Initial or Continuing Review Applications**

1. Applications requiring full board review (review at a convened meeting)
  - a. Approval Date
    - i. If the review decision is “approved” (no modifications required), the date of approval is the date of the convened meeting at which the review decision to approve was made.
    - ii. If the review decision is “conditionally approved” (approved pending modifications) the date of approval is the date that all conditions have been met, as determined by the IRB Chair or their designee.
  - b. Expiration Date
    - i. The expiration date is one year from the date of approval (as specified above) minus one day, unless one of the following situations applies:
      1. The IRB committee may determine that review more often than annually is necessary for projects involving vulnerable populations, procedures with a high probability of physical or psychological risk, or other situations where more frequent monitoring is considered necessary to verify that the risk to benefit ratio of the project remains favorable. In such cases, the expiration date will be set by the IRB committee at a convened meeting in

collaboration with the IRB Chair. The expiration date and reasons for review more often than annually will be documented in the minutes of the convened meeting and communicated to investigators in writing.

2. If a project reviewed at a full board meeting is determined to meet criteria where further continuing review is not required (see 45 CFR Part 46.109(f)), the IRB committee will note this determination in the minutes and the approval letter will indicate that there is no expiration date for the approval unless otherwise prohibited (such as for clinical investigations subject to FDA regulation as specified at 25 CFR Part 56).

## 2. Applications qualifying for review via an expedited procedure

### a. Approval Date

- i. If the review decision is “approved” (no modifications required), the date of approval is the date that the project was determined to be approved by the IRB Chair or their designee.
- ii. If the review decision is “conditionally approved” (approved pending modifications) the date of approval is the date that all conditions have been met, as determined by the IRB Chair or their designee.

### b. Expiration Date

- i. In accordance with 45 CFR 46.109(f), projects qualifying for expedited review will not have an expiration date unless one of the following situations applies:
  1. The IRB committee determines that review more often than annually is necessary (see 1.b.i.1 above).
  2. The protocol otherwise requires review at least annually (as for clinical investigations subject to FDA regulation at 25 CFR Part 56).

## **Amendment Applications**

### 1. Applications requiring full board review (review at a convened meeting)

#### a. Approval Date

- i. The approval date will be established using the same procedure as specified above for initial or continuing review applications requiring full board review.

#### b. Expiration Date

- i. The expiration date will be unchanged from that established at the most recent initial or continuation review unless the amendment creates conditions where it is determined that review more often than annually is required (see IRB 1.b.i.1 above).

2. Applications qualifying for review via an expedited procedure

a. Approval Date

- i. The approval date will be established using the same procedure as specified above for initial or continuing review applications reviewed via an expedited procedure.

b. Expiration Date

- i. The expiration date will be unchanged from that established at the most recent initial or continuation review unless the amendment creates conditions where it is determined that review more often than annually is required (see IRB 1.b.i.1 above).