1. PURPOSE

1.1. This policy describes the calculation of the Expiration Date.

2. POLICY

2.1. Exempt research has no Expiration Date.

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

2.3. As used in this policy:

2.3.1. The Approval Date is

2.3.1.1. The date the convened IRB or Expedited Reviewer makes the determination to approve the research; or

2.3.1.2. The date the IRB confirms that the responsive materials met the requirements of a convened IRB or Expedited Reviewer determination to approve the research.

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

2.3.3. The approval period expires at 12:00 AM on the expiration date set forth in the IRB approval letter (i.e. the Expiration Date is the first date that the study is no longer approved).

2.4. For initial review.

2.4.1. Reviewer Action = Approved: The approval period is one year (unless otherwise indicated) from the Approval date (e.g. if approved on 4/15/2000, the Study Approval Date is 4/15/2000 and the Expiration Date is 4/15/2001). Note: the approval period may be 3 years if the study qualifies for the Discretionary policy.

2.4.2. Reviewer Action = Approved with Contingencies: the approval period starts on the date the reviewer approves the contingencies, and expires no later than one year from the date it was originally approved with contingencies (e.g. the Executive reviewer approved with contingencies on 4/15/2000. The contingencies were submitted and approved by the Office Board member on 5/1/2000, the study is Approval Date is 5/1/2000 and the Expiration Date is 5/1/2001).

2.4.3. Reviewer Action = Tabled at Convened Meeting: when the tabled response is approved at a subsequent convened meeting, the approval period starts from the date of the second meeting for the full period (e.g. a study is initially reviewed and tabled at the 6/2/2000 meeting, the tabled response is reviewed and approved at the 6/16/2000 meeting, the Approval Date is 6/16/2000 and the study Expiration Date is 6/16/2001). If during a subsequent meeting the motion is to Approve with Contingencies, refer to 2.4.2. to calculate the Approval and Expiration dates.

2.4.4. Reviewer Action = Needs Reply: if an Executive Reviewer’s motion is Needs Reply and the PI’s response is subsequently approved by an Executive Reviewer, the approval period will be one year from the approval date (e.g. a study is initially reviewed and Needs Reply is requested on 3/16/2000, the Needs Reply response is reviewed and approved on 3/25/2000 meeting, the Approval Date is 3/25/2000 and the study Expiration Date is 3/25/2001)

2.4.4.1. If the Needs Reply response is subsequently “Approved with Contingencies” by the Executive Reviewer see 2.4.2.

2.5. For continuing review:

2.5.1. The study Approval Date for continuing reviews is calculated identically as Initial Review as described in 2.4 above (Approved, Approved with Contingencies, Needs Reply, and Tabled).
2.5.2. The Expiration Date for continuing reviews is dependent on when the Continuing Review is submitted and when it is approved relative to the prior Expiration Date.

2.5.2.1. If the continuing review Submission and Approval Date is less than or equal to 30 days before the prior Expiration Date, the new Approval Date starts on the prior Expiration Date and the new Expiration Date is one year later (e.g. study is previously approved on 11/03/15 and expires on 11/03/16. The continuing review is submitted and approved on 10/30/16, meaning the new approval period starts on 11/03/16 and the new Expiration Date is 11/03/17).

2.5.2.1. If the continuing review Submission is less than or equal to 30 days before the prior Expiration Date, but the continuing review is not approved until after the prior Expiration Date, the new Expiration Date is the new Approval Date plus the approval interval. (e.g. study is previously approved on 11/03/15 and expires on 11/03/16. The continuing review submitted on 10/30/16, is not approved until 11/10/16. The new approval period starts on 11/10/16 and the new Expiration Date is 11/10/17).

2.5.2.2. If the Submission Date is greater than 30 days before the current Expiration Date, the new Expiration Date is the Approval Date plus the approval interval. (e.g. study is previously approved on 11/03/15 and expires on 11/03/16. The continuing review is approved on 10/02/16. The new approval period starts on 10/02/16 and the new Expiration Date is 10/02/17).

2.6. For modifications, the Expiration Date is unchanged.

3. REFERENCES

3.1. 21 CFR §56.109(f)
3.2. 45 CFR §46.109(e)