
Procedure:
The purpose of this procedure is to provide guidance on stamping IRB approval and expiration dates on informed consent documents (ICDs) and calculating IRB expiration dates.

I. Investigator Responsibilities.
   A. Investigators submit all ICDs as a part of a new study submission for review and approval. It is recommended that the Investigator use the informed consent template located on the HRPP website at http://www.mc.vanderbilt.edu/irb/. All original consent documents are retained by the Investigator.
   B. Continuing reviews with no intent to enroll additional participants do not require the forwarding of the ICDs to the IRB for re-approval and stamping. However, the research study cannot be re-opened to enrollment without an amendment including a current ICD. If subjects were enrolled during the previous approval period, the Investigator is required to submit a copy of the most recently approved ICD.
   C. It is the Investigator's responsibility to only use those ICDs bearing approval and expiration dates when obtaining informed consent from research participants.

II. IRB Committee Responsibilities.
   A. The IRB Committee determines the appropriate review interval based on the federal regulations and HRPP policies and procedures regarding review and approval.
   B. For reviews that occur after initial approval, the IRB Committee verifies that the currently approved and correctly date-stamped ICDs have been submitted for review.

III. HRPP Regulatory Compliance Analyst (RCA) Responsibilities.
   A. Calculating the “Date of IRB Approval” on the ICDs.
      1. Approval at a convened meeting. When the convened IRB Committee approves the IRB application, the date of the convened IRB Committee meeting is the “Date of IRB Approval” stamped on the ICDs.
      2. Approval pending changes at a convened IRB Committee meeting. When the IRB application is approved with specific changes requested, pending review and approval by the Chair, the date that the changes are verified by the Chairperson or his or her designee is the “Date of IRB Approval” stamped on the ICDs.
      3. Expedited Review. When the IRB application is approved through an expedited review process, the date that final approval is extended by the Chairperson or his or her designee is the “Date of IRB Approval” stamped on the ICDs.
      4. Continuing Review. OHRP recognizes the logistical advantages of keeping the IRB approval period constant from year to year throughout the life of each project. When continuing review occurs annually and the IRB performs continuing review within 30 days before the IRB approval period expires, the IRB may retain the anniversary date as the date by
which the continuing review must occur.

5. **Amendments.** The “Date of IRB Approval” for amended ICDs is based on the type of review or determination as described above. For example, when an amendment is approved pending changes at a convened IRB Committee meeting; the date that the changes are verified by the Chairperson or his or her designee is the date of IRB approval stamped on the informed consent documents.

B. Calculating the “Date of IRB Expiration” on the ICDs

1. **Approval at a convened IRB Committee meeting.** Based on the approval period granted, the date of expiration is calculated from the date of the convened IRB Committee meeting. For example, if the committee meeting date is 2/01/2011, then the “Date of IRB Expiration” is 1/31/2012 for a 12-month review interval.

2. **Approval pending changes at a convened IRB Committee meeting.** Based on the approval period granted, the date of expiration is calculated from the date of the convened IRB Committee meeting. It is not calculated from the date the Chairperson or his or her designee verifies and grants final approval. For example, if the committee approves pending changes on 2/01/2011 and the CAL response is verified by the Chair on 3/1/2011, then the “Date of IRB Expiration” is 1/31/2012 for a 12-month review interval and 7/31/2011 for a 6 month review interval.

3. **Expedited review.** Since there is no convened meeting in an expedited review, the “Date of IRB Expiration” will be calculated based on the review interval determined by the Chair or his or her designee using the date that the initial IRB application or most recent Continuing Review Application was approved by the Chair or his or her designee.

4. **Amendments.** The approval date of an amendment does not affect the calculation of the expiration date unless the Committee increases or decreases the review interval.

C. Date Stamping of ICDs

1. The dates of IRB approval and expiration will match the dates indicated in the Final Approval Letter (FAL).

2. The RCA will stamp amended ICDs, when approved, retaining the original expiration date, unless the review period was changed.

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**Scenarios for Determining Dates of Approval and Expiration**

**Scenario 1:** The IRB reviews and approves a study for one year, without any conditions, at a convened meeting on October 1, 2012. The date of IRB approval is October 1, 2012 and the date of IRB expiration is September 30, 2013. Continuing review must occur within one year of the date of the meeting that is, by September 30, 2013.

If Continuing review occurs within 30 days of October 1, 2013, the original anniversary date may be retained. Therefore, the new approval date is October 1, 2013, and for a one year approval, the expiration date is September 30, 2014.

However, if the IRB approves the study for six months, the date of IRB approval is October 1, 2012 and the date of expiration is March 31, 2013. Continuing review must occur within six months of the date of the meeting, that is, by March 31, 2013.

If Continuing review occurs within 30 days of April 1, 2013, the original anniversary date may be maintained. Therefore, the new approval date is April 1, 2013, and for a six month approval, the expiration date is September 30, 2013.
**Scenario 2:** The IRB reviews a study at a convened meeting on October 1, 2012, and approves the study for one year, contingent on specific minor conditions the IRB chair or his or her designee can verify. On October 31, 2012, the IRB chair or designee confirms that the required minor changes were made. The date of approval is October 31, 2012 and the date of expiration is September 30, 2013. Continuing review must occur within one year of the date of the convened IRB meeting at which the IRB reviewed and approved the study, that is, by September 30, 2013.

If Continuing review occurs within 30 days of October 1, 2013, the original anniversary date may be maintained. Therefore, the new approval date is October 1, 2013, and for a one-year approval, the expiration date is September 30, 2014.

However, if the IRB approves the study for a period of six months, the date of IRB approval is October 31, 2012 and the date of expiration is March 31, 2013. Continuing review must occur within six months of the date of the meeting, that is, by March 31, 2013.

If Continuing review occurs within 30 days of April 1, 2013, the original anniversary date may be maintained. Therefore, the new approval date is April 1, 2013, and for a six-month approval, the expiration date is September 30, 2013.

**Scenario 3:** The IRB reviews a study at a convened meeting on October 1, 2012, and has serious concerns or lacks significant information that requires IRB review of the study at subsequent convened meetings on October 15 and October 29, 2012. On October 29, 2012, the IRB completes its review and approves the study for one year. The date of IRB approval is October 29, 2012 and the date of expiration is October 28, 2013. Continuing review must occur within one year of the date of the convened meeting at which the IRB reviewed and approved the study, that is, by October 28, 2013.

If Continuing review occurs within 30 days of October 29, 2013, the original anniversary date may be maintained. Therefore, the new approval date is October 29, 2013, and for a one-year approval, the expiration date is October 28, 2014.

However, if the IRB approves the study for a period of three months, the date of IRB approval is October 31, 2012 and the date of expiration is January 30, 2013. Continuing review must occur within three months of the date of the convened meeting at which the IRB reviewed and approved the study, that is, by January 30, 2013.

If Continuing review occurs within 30 days of January 31, 2013, the original anniversary date may be maintained. Therefore, the new approval date is January 31, 2013, and for a three-month approval, the expiration date is April 30, 2013.

**Scenario 4:** The IRB reviews and approves a study at a convened meeting on January 2, 2013 for a period of one year. The PI submits an amendment to the approved study, which is reviewed and approved at a convened meeting on November 1, 2013. The Committee did not change the review period. Therefore, the new date of approval is November 1, 2013 and the date of expiration is January 1, 2014. Continuing review must occur by January 1, 2014.

However, if the IRB approves the amendment on November 1, 2013 contingent on specific minor conditions the IRB chair or his or her designee can verify, and the Chair verifies the changes on November 20, 2013. The IRB date of approval is November 20, 2013. The date of expiration remains unchanged at January 1, 2014.