

THE HUMAN RESEARCH PROTECTION PROGRAM

THE COMMITTEE ON HUMAN RESEARCH (CHR)

DETERMINING EXPIRATION DATES – April 2007

The following excerpts were taken from:

Office for Human Research Protections
Department of Health and Human Services

Guidance on Continuing Review

Date: January 15, 2007

<http://www.hhs.gov/ohrp/humansubjects/guidance/contrev0107.htm>

HOW IS THE CONTINUING REVIEW DATE DETERMINED?

HHS regulations at 45 CFR 46.108(b) and 109(e) require, respectively, that (1) except when an expedited review procedure is used, each IRB must review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas; and (2) an IRB must conduct continuing review of research at intervals appropriate to the degree of risk, but not less frequently than once per year. The IRB should decide the frequency of continuing review for each study protocol necessary to ensure the continued protection of the rights and welfare of research subjects.

Several scenarios for determining the date of continuing review apply for protocols reviewed by the IRB at a convened meeting. To determine the date by which continuing review must occur, focus on the date of the convened meeting at which IRB approval occurs. (*These scenarios presume the IRB has determined that it will conduct continuing review no sooner than within 1 year.*)

The Expiration Date is the last day on which research may be conducted under the current approval.

Scenario 1: The IRB reviews and approves a protocol without any conditions at a convened meeting on October 1, 2005. Continuing review must occur within 1 year of the date of the meeting. The Expiration Date would be September 30, 2006.

Scenario 2: The IRB reviews a protocol at a convened meeting on October 1, 2005, and approves the protocol contingent on specific revisions the IRB Chair can verify. On October 31, 2005, the IRB Chair confirms that the required revisions were made. Continuing review must

occur within 1 year of the date of the convened IRB meeting at which the IRB reviewed the protocol. The Expiration Date would be September 30, 2006.

Scenario 3: The IRB reviews a study at a convened meeting on October 1, 2005, 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, 2005. At their October 29, 2005 meeting, the IRB completes its review and approves the study. Continuing review must occur within 1 year of the date of the convened meeting at which the IRB last reviewed and approved the protocol. The Expiration Date would be October 28, 2006.

The regulations make no provision for any grace period extending the conduct of research beyond the expiration date of IRB approval. Therefore, continuing review and re-approval of research must occur on or before the date when IRB approval expires. 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.

Scenario 4: The IRB reviews and approves a renewal application (i.e., continuing review) for the study described under Scenario 1 on September 10, 2006. Since continuing review occurred within 30 days prior to the Expiration Date (September 30, 2006), the new Expiration Date would be September 30, 2007.