

DEPARTMENT: INSTITUTIONAL REVIEW BOARD
POLICY NUMBER: 037
SECTION: INFORMED CONSENT PROCESS
REVIEW RESPONSIBILITY: IRB
EFFECTIVE DATE: AUGUST 13, 2003
REVISION DATE:
LAW IMPLEMENTED: 45 CFR 46.116, 46.117

SECTION: Approval and expiration dates informed consent document and stamping

1. The IRB Office shall affix the approval and expiration dates to all IRB approved informed consent documents. Copies of the current, dated documents are the ONLY versions that shall be used by investigators in obtaining consent. This procedure helps to ensure that only the current, approved informed consent documents are presented to subjects and also functions as a reminder to the investigators of the need for continuing review.
2. For projects approved by expedited review, the approval date for the informed consent document shall be the same as the date of the initial notice letter approving the protocol. The expiration date shall be one year (365 days) from the date of approval minus one day. Thus, as an example, if the initial approval notice letter is dated as approved on June 1, 2003, then the expiration date shall be May 31, 2004. No research may continue unless the appropriate request for renewal has been timely received and the project has received continuing review and approval. Any changes to the consent form during the course of the initial 365 day term, shall still be stamped to expire on the same date as the original expiration date. Upon renewal and approval, the current consent form shall be extended for another year term, but shall still retain the same day and month for its expiration date. Example: Consent form approved June 1, 2003, and expiration date is May 31, 2004. A change is made to the consent form on August 2, 2003. The revised consent form will still expire on May 31, 2004. A timely renewal is filed, the project receives continuing review and approval. The current consent form is stamped as expiring on May 31, 2005.
3. For projects approved by full committee review, the approval date for the informed consent document shall be the same as the date of the monthly full committee meeting at which the protocol was reviewed and approved. The date of approval of the protocol should match the date of approval of the informed consent document. The expiration date shall be one year (365) days minus one day. As an example: A protocol is reviewed at full committee and approved at the June 1, 2003 meeting. The approval date for the project shall be June 1, 2003, and the expiration date for the consent document shall be May 31, 2004. Any change to the consent form during the course of the initial term shall not modify the existing expiration date. Upon request for renewal, continuing review and approval, the new expiration date for the consent document shall be May 31, 2005.

4. Once an approval is granted, the Administrative Assistant assigned to full committee projects or the Administrative Assistant assigned to expedited/exempt review projects, shall stamp the lower right corner of the informed consent document. The stamp shall reflect the approval date, in handwriting, the Human Subjects internal number, example if 2003, then project would be number 03-.001 consecutively, and if the project is a renewed project that received continuing review and approval, the number shall be followed by an “R”, and the expiration date, noted as “Void After” shall be handwritten within the stamped area as described above.
5. The Administrative Assistant or student assistant shall copy the date stamped informed consent document and the final approval letter, and mail the documents to the Investigator. A copy of both should be retained in the IRB files. The investigator is notified in the final approval letter, that only current informed consent documents with the date of the IRB approval and expiration are to be copied and used for obtaining informed consent from subjects.