Policy
Department: HUMAN RESEARCH PROTECTIONS PROGRAM
Policy Number: IV.E
Section: Informed Consent Process
Review Responsibility: HRPP Policy and Procedure Committee
Original Creation Date: September 15, 2000
Revision Dates: February 9, 2004; July 1, 2015

Subject: Approval and Expiration Dates on Informed Consent Documents

Policy:
It is the policy of the Institutional Review Board (IRB) to stamp all IRB-approved informed consent documents with the Date IRB Approval and the Date of IRB Expiration.

I. The Office for Human Research Protections (OHRP) recommends that IRBs require approval and expiration dates on all approved informed consent documents and that only those documents bearing approval and expiration dates be used when obtaining informed consent from human participants. Effective May 1, 2001, the VU IRB required date stamping on ICDs for new IRB applications and continuing review applications.

II. Copies of the current, dated-stamped as approved documents are the only versions that may be used by Investigators in obtaining consent for research activities. This procedure helps assure that only the current, IRB-approved informed consent documents are presented to participants and serves as a reminder to the Investigators of the need for continuing review.

Date of IRB Approval. The approval date is the date that the IRB application and informed consent documents were initially reviewed and granted final approval by the IRB, unless one of the following apply:
A. If the Application has received a continuing review and approval of the research activities and informed consent documents, the date of the last continuing review approval is used.
B. If the IRB has approved a modification to the informed consent documents, the date of the IRB’s approval of the modification is used.
C. The “Date of IRB Approval”, which appears on the informed consent documents, is the date of approval for the most recent version of the informed consent documents.

III. Date of IRB Expiration. The expiration date is the date that signifies the end of the current IRB approval period. The Federal 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.