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IRB PROCEDURE STATEMENT

Procedure: Approval and Expiration Dates for Informed Consent Documents

Procedure ID: 03-11-003

Effective: January 1, 2004
Revised: December 23, 2016

A. Background

OHRP recommends (Guidance on Written IRB Procedures) that IRBs affix the approval and expiration dates to all approved informed consent documents and stipulate that copies of these dated documents must be used in obtaining consent. This procedure helps ensure that only the current, IRB-approved informed consent documents are presented to subjects and serves as a reminder to the investigators of the need for continuing review.

B. Procedure

Note: This procedure applies to any new IRB application submitted for review after the procedure effective date listed above.

Upon notification of final approval of a new IRB application, a continuation request, or an amendment request resulting in new or revised consent documents, the Office of Research Compliance (ORC) will date all relevant consent documents with the date on which approval became effective and date on which the approval expires. The approval period will never be for more than, and may (e.g., for consent documents changing as the result of a modification request) be less than, 12 months.

A master copy of the dated documents will be provided to the PI and copies of these dated documents must be used in obtaining consent. This can be found in the "Board Documents" section in IRBNet.

For online consent documents, text equivalent to that of the IRB's approval stamp ("BGSU IRB – Approved – IRBNet ID #_____Effective_____/ Expires_____") will be required in the footer area of each document.