

Florida State University Policy 7-IRB-37

Title of Policy: Approval and expiration dates informed consent document and stamping

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

Effective Date: Readopted –January 1, 2015

Revision History: New August 13, 2003

Revised _____

I. INTRODUCTION

This policy states the responsibilities and procedure the IRB follows for approving and dating informed consent documents.

II. POLICY

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 set 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.
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.

Once an approval is granted, the Program Coordinator assigned to full committee projects or the Program Associate assigned to expedited/exempt review projects, shall add a footer or stamp the lower right corner of the informed consent document. The footer or stamp shall reflect the approval date, 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”.

4. The student assistant shall copy the date stamped informed consent document and the final approval letter for the file, and transmit 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.

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.116, 46.117