Policy Name: **Retention of Review Activities Records of the IRB**			
Approved			**Date: 11/01/08**
Effective Date: 02/20/09	**Page 1 of 2**	**Section: HRPP 2.6**	**Policy Number: N/A**
Replaces Policy: N/A			**Dated: N/A**

I. POLICY

A. Introduction

The Institutional Review Boards of MUSC have the responsibilities, Ethical Principles, Authority and Independence as specified in HRPP Guide Section 2.1, functions as specified in HRPP Guide Section 2.2 is comprised of a membership as specified in HRPP Guide Section 2.3, approves research activities as specified in HRPP Guide Section 2.4 in convened meetings as specified in HRPP Guide Section 2.5.

B. Federal Regulations for Retention of IRB Records

HHS regulations (45 CFR 46.115(b)) and FDA Regulations (21 CFR 56.115) require that IRB records be retained for at least 3 years. This includes protocols cancelled without participant enrollment. At the end of three years, records are boxed, labeled and sent to central storage for another 3 years.

Research records should be retained for a sufficient minimum period to allow evaluation and repetition by others of the results and to investigate an allegation of research misconduct. Usually [unless granted an exception by the Department of Health and Human Services (HHS) or the Office of Research Integrity (ORI)], this minimum period is six years

C. Department of Veteran's Affairs Policy

For VAMC studies, all records, including the investigator's research records, must be retained for a minimum of 5 years after the completion of the study and in accordance with VHA's Records Control Schedule (RCS 10-1), applicable FDA and DHHS regulations, or as required by outside sponsors. If a VA protocol is cancelled without participant enrollment, IRB records will be maintained for at least five years after cancellation. The local VA Research and Development Committee will have access to all IRB records related to VA Research

D. Inspection of Records

All records must be accessible for inspection and copying by authorized representatives of HHS and FDA at reasonable times and in a reasonable manner. A log of stored records is maintained in the IRB office for retrieval if files are needed for audit purposes.