MUSC
Medical University of South Carolina

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. Research records from the ERMA system are scanned and stored electronically on a secure MUSC server. Access to these records is limited to ORI personnel and other personnel as designed by the Institutional Official.

New studies in the eIRB system remain in the eIRB system which is maintained on a secure server owned by HSSC.

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 Veterans Affairs

For VAMC studies, all records, including the investigator's research records, must be retained until disposition instructions are approved by the National Archives and Records Administration and are published in VHA's Records Control Schedule (RCS 10-1). If a VA protocol is cancelled without participant enrollment, IRB records are 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. Guidance on Additional Requirements of Federal Funding Agencies

Please note that protocols conducted by MUSC and sponsored by any of the following federal agencies

- the Department of Defense (DOD),
- Department of Education,
- Department of Energy,
- Department of Justice (DOJ) / National Institute of Justice (NIJ) and Bureau of Prisons (BOP) or
- Environmental Protection Agency (EPA)

have additional operational and review requirements. In addition, protocols following the International Committee on Harmonisation – Good Clinical Practices (ICH-GHP) have additional requirements. Further information available on the MUSC IRB Resources & Guidance Webpage <http://research.musc.edu/ori/irb/resources.html>).

E. Memorandum of Understanding

In aspects where the MUSC IRB is being utilized by the Ralph H. Johnson VA Medical Center, both parties will abide by the agreements set forth in the current "Memorandum of Understanding Between The Ralph H. Johnson VA Medical Center And The Medical University of South Carolina Concerning Utilization of the Medical University of South Carolina's Institutional Review Boards".

F. 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 paper records is maintained in the IRB office for retrieval if documents are needed for audit purposes.