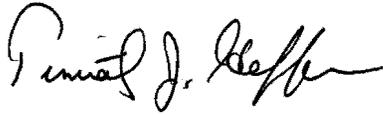


November 24, 2008

The Research and Development (R&D) Committee reviewed and approved on Thursday, November 19, 2008, the Memorandum of Understanding for Research Record Retention Agreement between the Harry s. Truman Memorial Veterans' Hospital and the University of Missouri Office of Research, Columbia, Missouri March 24, 2008.



TIMOTHY J. HOFFMAN, PHD



JOHN D. WHITED, MD

For Official Use Only

Memorandum of Understanding (MOU)

For

Research Record Retention Agreement

Between

Harry S. Truman Memorial Veterans' Hospital

and

University of Missouri Office of Research

Columbia, Missouri

March 24, 2008

Research Record Retention Agreement

Section 1. Introduction

The purpose of this MOU is to establish a procedure to store and archive paper research records that include or involve the Department of Veterans' Affairs (VA) personally identifiable information (PII) and/or personal health information (PHI) between the Harry S. Truman Memorial Veterans' Hospital (HSTMVH) and The Curators of the University of Missouri, on behalf of the University of Missouri (MU) Office of Research. This agreement will govern the relationship between the HSTMVH and MU, Office of Research in regard to investigator research record storage and archival of VA data collected during the conduct of studies approved by the HSTMVH Research and Development (R&D) Committee and the MU Health Sciences Institutional Review Board (HS-IRB). Pursuant to VHA 1200.5, research approved by the R&D Committee will be considered VA-approved research.

Section 2. Purpose

This agreement sets forth the roles and responsibilities of the HSTMVH and the MU Office of Research and staff that conduct VA-approved research and generate paper investigator research records that require retention and archival following study completion or closure by the R&D Committee. VA-approved research records may contain PII and/or PHI obtained from veteran and non-veteran participants; therefore, this agreement will delineate the security and co-management of these records by the HSTMVH and MU until time of destruction. The agreement will not apply to the removal of VA sensitive data (PII and/or PHI) authorized by the HSTMVH Director to off-site locations during the conduct of active VA-approved research studies by VA and/or MU investigators. This agreement also will not apply to administrative records for VA-approved research administered by MU through the Office of Sponsored Program Administration that does not contain VA sensitive data (PII and/or PHI).

Section 3. Research Record Retention Requirements

Pursuant to VHA Handbook 1200.5, investigators' VA-approved research records are the property and responsibility of the HSTMVH Research Office. The HSTMVH Director will determine where VA-approved research records will be securely stored and archived. VA-approved research records must be maintained for a minimum of five (5) years beyond the date of study closure and in accordance with applicable Food and Drug Administration (FDA) regulations, or as required by outside sponsors.

In accordance with Missouri state law such research records shall be retained for seven (7) years beyond the study closure date. In the case of FDA regulations (21CFR 312.62, 21CFR 812.140 and 21CFR 312.57) and sponsor-funded research studies, the record retention guidelines that will apply may be longer than those of the requirements of Missouri state law.

Per VA Directive 6600, the VA will enhance oversight and accountability of all VA data, including VA-approved research data that includes PII and/or PHI. Pursuant to VA Directive and Handbook 6502, the VA will secure and protect sensitive VA data, including VA research data with PII and/or PHI. VA-approved research records are required to be either stored within the covered entity (i.e., VA) in a limited-access, locked location that includes the protection of a smoke alarm and sprinkler system or at an off-site facility that meets all VA storage requirements, in accordance with National Archives and Records Administration (NARA) 36 CFR Part 1228.228.

Section 4. Retention Procedures

Those VA-approved research study records that include VA PII and/or PHI, but that otherwise also involve MU research personnel, sponsored research, and/or research subjects will be archived and stored by the HSTMVH in a site that meets the VA-approved NARA storage requirements. At the time of study closure, such records will be transferred by the investigator, or designee to the HSTMVH Research Office (VA Room B-43) for secure, traceable transport to the Federal Records Storage Center or other VA-approved off-site location, until the date of destruction. The duration of record retention and archival will be determined based on applicable requirements noted above. At the destruction date, the HSTMVH will send written notification to the investigator, or designee, and/or the MU Office of Research to obtain written permission to destroy sponsor-funded research records. Permanent record destruction will follow applicable VA-approved paper shredding procedures. The HSTMVH will provide written documentation of final record destruction to investigator or designee.

All record storage requirements applicable to VHA Handbook 1200.5, Missouri state law, FDA regulations, and sponsors will be adhered to by the HSTMVH. The Research Office will adhere to the most conservative applicable storage requirements and destruction deadlines (e.g., FDA storage requirements). The research records will be retained at the Federal Records Storage Center or VA-approved off-site storage site until the designated destruction date. The HSTMVH will follow the Missouri state law for record retention and archival requirements of investigator-initiated research and will not destroy FDA-regulated research records without prior authorization (described above).

Research investigators or their designee (e.g., MU School of Medicine, Office of Clinical Research), regulated by FDA, will be responsible for all communications with sponsors regarding receipt of authorization for destruction and communication of final disposition of research records. The HSTMVH Research Office will maintain an electronic database that delineates the location, content, and anticipated destruction date of research records. Annually, the HSTMVH will distribute an inventory of VA-approved research records stored at the applicable VA-approved off-site storage facility to investigators or their designee. VA and/or MU investigators, or designee(s) will verify the accuracy of the annual inventory, including the anticipated destruction date, and will notify the HSTMVH Research Office of any corrections.

At any time, the MU Office of Research investigators and/or authorized staff may request that VA-approved research records stored off-site be returned. The research records will be returned to the HSTMVH Research Office within 24 hours for temporary onsite use (in VA Room B043) and storage (in VA Room F036). VA-approved investigator research records, including VA sensitive data (PII and/or PHI), may not be temporarily or permanently removed to an off-site location that does not meet VA-approved NARA storage standards without the prior approval of the HSTMVH Director.

There will be no costs to MU Office of Research investigators and/or their academic departments for storage and archival of research records at a VA-approved off-site location. The HSTMVH Research Office will provide the VA and/or MU investigators, or designee with record storage boxes and directions for proper packing.

Section 5. Terms of Agreement

This agreement is subject to modification only by written agreement of both the HSTMVH and the MU Office of Research. A written request to modify or terminate this agreement may be initiated by either the HSTMVH or the MU Office of Research and will provide a minimum of three (3) months advance notice of such a request. The HSTMVH and the MU Office of Research must agree in writing that this agreement will be subject to renegotiation in the event new policy changes substantially enough to warrant renegotiation. This agreement will remain in effect for five (5) years unless a new agreement has been signed by both the HSTMVH and the MU Office of Research that supersedes this agreement, based on title and date of agreement.

Section 6. Signatory Authority

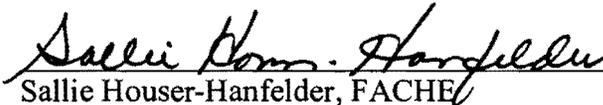
I agree to the terms of this MOU that delineates the current and proposed record retention policy between the HSTMVH and the MU Office of Research.



Robert D. Hall, JD, PhD
Interim Vice Chancellor for Research
MU Office of Research

1 April 2008

Date



Sallie Houser-Hanfelder, FACHE
Director, Harry S. Truman Memorial Veterans' Hospital

3-28-2008

Date