

| Wayne State University<br>Human Investigation Committee |   |
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| <b>Subject</b>  | <b>Document Retention for Research Protocols</b>  |
| <b>Form Date</b>  | November 3, 2006 (rev. 03/07/11)  |
| <b>Approvals</b>  | 5/17/06 Steering Committee, 11/06/06 Administrative Review, 09/30/10 Administrative Review 03/07/11 |

## Background

In accordance with 45 CFR 46.115(b); 38 CFR 16.11.115(B); 21 CFR 56.115(B); VHA Handbook 1200.5(7) and applicable state and local laws, all Wayne State University (WSU) Institutional Review Board (IRB) records must be retained and be accessible for inspection and copying by authorized representatives of appropriate federal agencies [Food and Drug Administration (FDA), Office of Human Research Protection (OHRP), Office of Research Oversight (ORO)], the Principal Investigator (PI) and his/her designees, and other administrative or department officials.

## HIC Procedures

### Active/Open Protocols

As stated in the Code of Federal Regulations (CFR), all IRB protocol materials must be organized to allow reconstruction of a complete history of all IRB actions related to the review and approval of the research study.

In compliance with the above-referenced regulations, the Human Investigation Committee (HIC) keeps complete materials for all active research protocols until they are closed and no research activities are being carried out with the participants. This means that the protocol materials will be kept until all changes to the research data or database have been completed.

### Closed/Expired Protocols

After a research protocol has been closed by the PI, or has expired, the HIC will keep all research documents for three (3) years in the HIC archive files. For those studies that have been conducted by the John D. Dingell Veterans Administration Medical Center (JDD VAMC), the documents will be held in accordance with VHA regulations.

If a protocol is cancelled without participant enrollment, IRB records will be maintained for at least three years after cancellation. For VA research, this period is five years.

For research sponsored by the Department of Defense (DoD), the agency may require submitting records to DoD for archiving.

### **Materials on File**

- Research proposals/grant applications
- Investigator brochures
- Recruitment materials
- Required scientific/safety evaluations that accompany proposal
- HIPAA Summary Form
- Approved HIPAA Authorization document
- Any proposed amendments
- IRB action on each amendment
- Progress reports submitted by investigators
- Reports of serious and unexpected adverse reactions and unexpected events, including research injuries
- Data and Safety Monitoring Board reports
- Documentation of protocol violations
- Documentation of non-compliance with applicable regulations
- Audit reports
- Record on continuing review activities
- Copies of all official correspondence between the IRB and investigators
- Copies of all official correspondence between the VAMC Research and Development Committee and the IRB
- Statements of significant new findings provided to participants
- Copies of all IRB approvals
- Original and any revised consent forms submitted
- Justification for using the expedited procedure
- Description of action taken by the review
- Any findings required by laws, regulations, codes, and guidance to be documented
- Justification for exemption determination

### **Confidentiality of HIC Research Records**

All research materials kept in the HIC office are confidential and available only to appropriate institutional officials, HIC staff members, regulatory officials, and the PI and his/her designee.

If a record is to be reviewed or copied by someone that is not an institutional official or HIC staff, that person must be either the PI or listed as key personnel on the protocol. If this is not the case, the PI must write a letter giving his/her designee permission to come to the HIC office to review or copy documents.

When a person comes to the HIC office to access a research protocol, picture identification must be presented to the HIC administrative staff or his/her designee and that person will be asked to sign a log.

No original protocol materials may be taken from the HIC office without permission from the Assistant Vice President for Research.

The HIC Office should be contacted in advance to schedule a mutually convenient time to access protocol materials for review and/or copying.

### **Questions about record retention**

It is always best to contact the sponsor for information regarding how long research study records should be retained as each sponsor has a different policy for record retention. For HIC Policy, please see "Principal Investigator; Roles and Responsibilities" for specific guidance as it relates to this institution.