**IRB Policy and Procedure**

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|  | **Wayne State University** **Institutional Review Board**  |
| **Subject**  | **IRB Document Retention for Research Protocols**  |
| **Form Date**  | November 3, 2006 (Rev. 03, 2015)  |
| **Approvals**  | 5/17/06 Steering Committee, 11/06/06 Administrative Review, 09/30/10 Administrative Review, 03/07/11 Administrative Review, 11/30/11 Administrative Approval; Administrative Approval 03, 2015; Administrative Approval 11/27/2019, IRB Approval 11/2024, IRB Approval 3/2025 |

# 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.

IRB records are maintained and stored in a secure manner to ensure the integrity and confidentiality of records.  When applicable, IRB records that are documented with an electronic signature must comply with 21 CFR Part 11, which defines the standards and controls necessary to maintain the integrity, security, and reliability of electronic records and signatures for FDA regulated research.

# Related Policies:

* 4-8 Closure of a Research Protocol
* 4-17 External IRB & Reliance Agreements for Multi-Site Research
* 4-20 Electronic Signatures on IRB Records- Compliance with 21 CFR Part 11 for FDA Regulated Research

# 1.0 IRB Procedures

## 1.1 Active/Open Protocols

As stated in the Code of Federal Regulations (CFR), all Institutional Review Board (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 IRB 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.

## 1.2 Closed/Expired Protocols

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

If a protocol is cancelled without participant enrollment, IRB records will be maintained for at least three (3) years after cancellation. VHA research records must be held in accordance with Veterans Affairs policy. The VHA record control schedule requires perpetual retention of research records (VHA research records cannot be destroyed).

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

## 1.3 Materials on File

 **Documents may include the following:**

* Research proposals/grant applications
* Investigator brochures
* Recruitment materials
* Required scientific/safety evaluations that accompany proposal
* HIPAA Summary Form
* Approved HIPAA Authorization document
* 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
* Audit reports
* 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,
	+ For research subject to the 2018 Requirements, the rationale for an expedited reviewer's determination that particular research appearing as a category on the expedited review list is more than minimal risk, and therefore not eligible for expedited review.
* For research involving reliance agreements: documentation specifying the responsibilities that an institution and an organization operating an IRB each will undertake to ensure compliance with the requirements of this policy, as described in IRB Policy 4-17 External IRB & Reliance Agreements for Multi-Site Research.

**IRB Operations Documents:**

* Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution
* Documentation specifying the responsibilities that the VHA facility and an organization operating as the VHA facility's IRB of Record each will undertake to ensure compliance with the requirements of this directive, such as an MOU or an IRB Authorization Agreement or IRB reliance agreement.
* List of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member’s chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution.
	+ IRB records must include a resume or Curriculum Vitae for each voting IRB member that is updated at the time of appointment or re-appointment.
* Written Procedures for the IRB

## 1.4 Confidentiality of IRB Research Records

All research materials or records kept in the IRB Administration Office are confidential and available only to appropriate WSU institutional officials, IRB Administration Office staff, regulatory officials, the Principal Investigator (PI), the PI’s designee (co-investigators, faculty sponsor/mentor), or regulatory personnel indicated for the approved IRB submission.

If a record is to be reviewed or copied by someone that is not either the WSU institutional official, IRB Administration Office staff, regulatory officials, the Principal Investigator (PI), the PI’s designee (co-investigators, faculty sponsor/mentor), or regulatory personnel indicated onthe approved IRB submission the PI must provide written approval giving permission to review and/or receive documents. Federal agencies with appropriate regulatory oversight [e.g., Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), Office of Civil Rights (OCR), etc.) may review IRB records. Monitors or inspectors conducting IRB file review are required to show picture ID indicating their credentials and provide documentation regarding their authority to review/inspect IRB records. Documentation, including date of inspection, name of inspector or monitor are noted in the IRB office Thfiles. Individuals that do not meet these criteria are not granted access to submission materials or information unless approved by the Principal Investigator indicating the purpose of review or need to access the record(s).

No original protocol materials may be taken from the IRB Administration Office without permission from the Director-HRPP or his/her designee.

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

## 1.5 Questions about record retention

For the IRB policy on PI record retention, please see IRB policy [6-1 Principal Investigator: Roles and Responsibilities](https://research.wayne.edu/irb/docs/doc122_policy_06-01_principal-investigator-roles-and-responsibilities_11_2019.doc) and IRB policy [4-8 Closure of a Research Protocol](https://research.wayne.edu/irb/docs/4-8-closure-of-a-research-protocol_final_revised_2_2022.doc). 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 IRB Policy, please see “Principal Investigator; Roles and Responsibilities” for specific guidance as it relates to this institution.

**2.0 Compliance with 21 CFR Part 11 for FDA Regulated Research:**

Use of Adobe Sign for Electronic Signatures on IRB Records:

To ensure compliance with 21 CFR Part 11 for the use of electronic signatures in clinical investigations, all document signatures required by investigators and IRB personnel that cannot be captured within the eProtocol electronic submission system must be documented using Adobe Sign whenever 21 CFR Part 11 compliance is required. For studies that are not in the eProtocol electronic submission system, paper submissions, which previously required the original ink signature, are no longer accepted. Investigators with studies that are not in the eProtocol electronic submission systemare currently required to provide an electronic signature on these IRB submission documents. IRB Personnel completing reviewer checklists must provide an electronic signature on all applicable reviewer forms.

All FDA regulated research must comply with 21 CFR Part 11. This applies to all personnel who create, maintain, and sign IRB records for studies that are not in the eProtocol using Adobe Sign, and IRB personnel who provide an electronic signature on reviewer checklists.

Additional details about compliance with 21 CFR Part 11 through Adobe Sign is available in IRB Policy 04-20 Electronic Signatures on IRB Records Compliance with 21 CFR Part 11 for FDA regulated research.

**2.1 Record Retention and Retrieval**

* **Adobe is not meant for long-term document storage.** IRB documents signed by Investigators or study team members through Adobe Sign must be downloaded and saved in the Investigator’s research file for appropriate record-keeping. IRB documents signed by IRB personnel through Adobe Sign must be downloaded and saved in the IRB file for appropriate record-keeping.
* Electronic IRB records and associated audit trails will be retained in accordance with this policy, IRB Policy 4-8 Closure of a Research Protocol and WSU Signature policies that govern contracts signed by the Sponsored Program Administration Office (https://policies.wayne.edu/administrative/04-06-Contract-Signatories-6th-release) and WSU Document Retention policies and applicable regulations.
* Records will be protected to prevent unauthorized access or alteration and will be retrievable in human-readable format upon request.

See IRB Policy 4-20 Electronic Signatures on IRB Records- Compliance with 21 CFR Part 11 for FDA regulated research for more information on electronic signatures on documents using Adobe Sign.