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|  | **University Hospital of Brooklyn****College of Medicine****College of Health Related Professions****College of Nursing****School of Graduate Studies****Graduate Program in Public Health** | **Guidance for Retention and Destruction****Of IRB Records** |
| For more information please contact the IRB at 718-613-8480 or IRB@downstate.edu. **KEY POINTS:*** + - * IRB records must be securely retained for the retention periods specified within state and federal regulations.
			* Access to IRB records is only permitted to those with a legitimate need for access.
			* The retention period for each IRB record varies depending on the nature of the documentation.
			* Active IRB records must be securely stored and be readily available.
			* Only the individuals designated in the guidance may destroy IRB records.
			* Before destroying any IRB record, such records must be listed on a Records Management Certificate of Destruction form and approved by the Records Management Officer or Designee.
			* After destruction, the IRB files the certificate with Records Management Officer and Central Stores within thirty (30) days of destruction.
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Table of Contents

[Introduction 3](#_Toc508358761)

[Minimal Retention Period for Research Records 3](#_Toc508358762)

[Retention and Disposition Of IRB Records 4](#_Toc508358763)

[Historical Records 4](#_Toc508358764)

[Legal Hold or Audit 4](#_Toc508358765)

[IRB Records Storage 5](#_Toc508358766)

[IRB Records Stored Off-Site 5](#_Toc508358767)

[Destruction of IRB Records 5](#_Toc508358768)

[Appendices 7](#_Toc508358769)

[References 7](#_Toc508358770)

[Authors 7](#_Toc508358771)

[Review and Approval History 8](#_Toc508358772)

# Introduction

IRB records must be securely retained for the retention periods specified within state and federal regulations.

IRB records should not be retained unless they serve a legal, operational or historical value to Downstate. Retaining records when there is no legal requirements may subject Downstate to additional burdens.

This document provides guidance for the SUNY Downstate IRB. Additional guidance or policy may apply to investigator’s records that go beyond the scope of this guidance; however, some minimal retention periods are provided below.

# Minimal Retention Period for Research Records

Downstate faculty should consult with FDA regulations, State Retention Policies, Downstate guidance and their departmental policies for additional information. Research records and specimens must be securely stored in accordance with the research procedures,

IRB approved documents, and Downstate policies. Research records and specimens may not be destroyed unless in conformity with Downstate policies, and when applicable other requirements of sponsors or external research sites. In general, research retention periods are described below, but may differ depending on the details of the study. Some of the minimum retention periods are provided below:

* Records relating to a specific research activity, including research records collected by investigators must be maintained for at least three years after completion of the research. This minimum retention period applies whether or not any research participants were enrolled in the study.
* If the research is FDA regulated, records should be retained for at least two years after approval of the investigational agent by FDA; if it is not approved, records should be retained at least two years after the study is terminated and FDA is notified. However, the FDA requirements for record retention differ and the individual pharmaceutical or device manufacturing companies sponsoring the research may have their own policies on record retention to which the investigators may be subject. Consult with the sponsor before destroying any records.
* Research participants' signed HIPAA Research Authorization forms must be kept for a minimum of six years after such authorization last was in effect.
* Records concerning controlled substance research must be maintained for five years after completion of the study.
* When research takes place an external site, the PI must follow the longer specified retention period of either the external site or Downstate.

Access to IRB Records

Inspection or access to or copying of IRB records, whether paper or electronic, is limited to the investigators approved by the IRB to have access to the records, those performing healthcare operations activities, Institutional Official, Operations Manager, IRB Members, IRB administrative staff, authorized officials (e.g., auditors, legal counsel, external consultants, accreditation bodies), officials of federal and state regulatory agencies (e.g., OHRP, FDA, OCR, NYSDOH, etc.), and sponsors with legitimate need for access or as determined the IRB, Privacy Officer, Institutional Official, Operations Manager, or General Counsel; those who are external to Downstate and not part of a regulatory body may be required to establish a Business Associate Agreement. Consult the Privacy Officer to make this determination. All other access to IRB records is prohibited.

# Retention and Disposition Of IRB Records

IRB records must be securely maintained to protect confidentiality and privacy for a minimum of **three (3) years, and records related to research which is conducted must be retained for at least three (3) years after completion of the research; however,** it is recommended IRB records be retained for up to 10 years, when practicable.

If the research takes place at an external site, the IRB may be required to follow longer retention periods, as outlined in any IRB Authorization (Reliance) Agreement.

It is not practicable to destroy electronic IRB records; however, these must be stored in a secure manner. Any electronic IRB records which contain Protected Health Information must be maintained in accordance to information security requirements, as described in the [IRB Guidance on Data Security.](http://research.downstate.edu/irb/irb-policies.html)

## Historical Records

**Do not destroy any IRB records that may have important historical value.**

## Legal Hold or Audit

The SUNY Downstate Office of General Counsel will notify the Department or IRB of any litigation holds and follow-up when records are no longer subject to a legal hold.

Research records may also be used for audit purposes.

If IRB records are part of a legal hold or audit, please hold the IRB records **until the hold is lifted or they are no longer needed for an audit**. Please consult the SUNY Downstate Office of General Counsel or the group performing an audit if you have any questions.

# IRB Records Storage

Active paper IRB study files are kept secure in filing cabinets in the IRB office or archival locations approved by the SUNY Research Foundation. All DMC storage sites are closed and locked when unattended.

Any paper IRB records that are removed from the IRB Office for archival purposes are placed in coded storage boxes. A list of materials in each box is maintained on a spreadsheet in the IRB office electronic records and is stored in a secure folder behind the Downstate firewall.

IRB records that do not require the original source documentation (e.g., records or documents with signatures for FDA regulated clinical investigations, etc.) may be scanned for electronic storage. However, Protected Healthcare Information (PHI) cannot be stored on any system external to Downstate unless a Business Associate’s Agreement (BAA) is in place, unless the PHI is redacted.

Any IRB records that do not require the original source documentation (e.g., records or documents with signatures for FDA regulated clinical investigations, etc.) may be scanned for electronic storage.

Documents that are scanned for electronic storage must be reviewed by an IRB office member, IRB Member, or designated consultant to discern the quality of the scan. If the scan is not legible, it must be re-scanned before it is stored. All electronic records must be stored in either a folder on the IRB shared drive behind the Downstate Firewall or within the secured IRB application and processing system [[IRBNet](https://www.irbnet.org/release/faq.html#data_security), [ClickSoftware](https://www.clicksoftware.com/wp-content/uploads/2016/08/160725-Information-Security-Program.pdf) (SUNY PACS), etc.].

## IRB Records Stored Off-Site

The IRB may use off-site locations managed by a SUNY-RF Contractor that is responsible for coordinating all records stored off-site. The IRB must create a list, in Excel format, of materials in each box that contains at minimum:

1. Box identifier e.g. bar code
2. Description of content and record (IRB #, Study Name, PI)
3. Any folder which contains study files within the box must be labeled with the IRB study #
4. Date of future destruction (if known), based on all records in the box.

The list must be retained by the IRB in electronic format behind the Downstate Firewall.

It is recommended that a copy of the list should be included in the storage box.

# Destruction of IRB Records

The IRB office staff or IRB members may destroy incidental copies of IRB records, when they are no longer needed, using the Shred-It system.

Before any official IRB record is destroyed the following must occur:

1. Verify the retention requirement period has passed for the IRB record.
	1. This may be confirmed by reviewing IRB records.
	2. For exempt studies which are not officially closed, an investigator on the study must be contacted by the IRB Office to verify the study has been closed for at least 3 years.
		1. If none of the investigators are employed at Downstate at the time of the inquiry, the IRB Office must confirm with the Department Chair or Dean that the records can be destroyed. A record of such confirmations shall be retained indefinitely.
		2. Any records that are not eligible for destruction must be permanently archived until it can be determined they can be destroyed.
2. Complete a Records Management Certificate of Destruction. This form may be completed by any of the following individuals:
	1. IRB Office Staff or IRB Member
	2. IRB Records Coordinator
	3. Consultant under a contract with the SUNY RF
	4. Off-site storage facility
3. Obtain the signature of the following individuals:
	1. Department Records Coordinator
	2. Supervisor/Director/Department Head
	3. Records Management Officer or Designee

1. Any of the above individuals may destroy the records and complete the certification of destruction.
	1. Paper records must be shredded via Shred-It program or any other program approved by the SUNY RF.
	2. Electronic records may only be destroyed in accordance with DMC Data Security Policies.
	3. The person destroying the records must complete the Certificate of Destruction and provide a copy to the IRB within five (5) business days from the date of destruction.
	4. The IRB files the certificate with Records Management Officer and Central Stores within thirty (30) days of destruction.

# Appendices

Records Management Certificate of Destruction

Records Management Certificate of Destruction – Supplement Form A

# References

* [ClickSoftware: Information Security Program](https://www.clicksoftware.com/wp-content/uploads/2016/08/160725-Information-Security-Program.pdf)
* [DMC Office of Compliance and Audit Services HIPAA Policy](http://www.downstate.edu/compliance/policies.html)
* [General Retention and Disposition Schedule for New York State Government Records](http://www.archives.nysed.gov/common/archives/files/mr_pub_genschedule.pdf)
* Greater New York Hospital Association Record Retention Grid.
* [HHS 42 CFR Part 50; HHS 42 CFR Part 94 - Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors](https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=3&cad=rja&uact=8&ved=0ahUKEwil28n8j5nMAhXIVj4KHVVzDGMQFggsMAI&url=https%3A%2F%2Fwww.gpo.gov%2Ffdsys%2Fpkg%2FFR-2011-08-25%2Fpdf%2F2011-21633.pdf&usg=AFQjCNEeQblIuCETRXpzp6IeEQRVIYdUOw&sig2=rHVwXEUeojwWm1NQwSYH5Q)
* [HHS 45 CFR 2 –Confidentiality of Alcohol and Drug Abuse Patient Records](http://www.ecfr.gov/cgi-bin/text-idx?rgn=div5;node=42%3A1.0.1.1.2)
* [HHS 45 CFR 46.115](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html)
* [HHS 21 CFR 56.115](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.115)
	+ [IRB-01 policy](http://research.downstate.edu/irb/irb-policies.html)
	+ [IRBNet FAQs on Information Security](https://www.irbnet.org/release/faq.html#data_security)
* [Legal Proceeding Preparation (E-Discovery) Procedure](http://www.suny.edu/sunypp/documents.cfm?doc_id=752)
* [Record Retention and Disposition policy of SUNY](http://www.suny.edu/sunypp/documents.cfm?doc_id=650)
* [State University of New York Records Retention and Disposition Schedule](http://www.suny.edu/sunypp/documents.cfm?doc_id=650#appendicies)
* [SUNY Records Retention](http://system.suny.edu/compliance/topics/records/records-retention/records-retention-schedule/)
* [SUNY Retention and Disposition Schedule](http://system.suny.edu/compliance/topics/records/records-retention/records-retention-schedule/#sunystateoppolicyschedules)

# Authors

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# Review and Approval History

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