



Procedure Name: Long-Term Storage Procedure for Closed Studies	Number: SOP 18 v1.0
Subject: Clinical Research	Effective Date: February 13, 2023
Linked Policy: Clinical Research Operations & Compliance Policy	Revised Date: February 13, 2023

PURPOSE:

This Standard Operating Procedure (SOP) outlines the procedure for requesting long-term storage for documents related to closed studies.

SCOPE:

This SOP applies to all persons involved with conducting clinical trials.

RESPONSIBILITY:

This SOP sets forth the requirements for requesting study-related documents to be stored in long-term storage facilities. In order to be considered for long-term storage, a study must be closed for a minimum of 2-3 years. Please review the contract with the business operations unit to determine how long an individual study must be retained on-site before being transferred to long term storage.

PROCEDURE:

Requesting Pickup

1. Ensure the study documents are safely stored in boxes. To request boxes, email the Office of Clinical Research (OCR) inbox at clinicalresearch@mfa.gwu.edu
 - If you are using your own boxes, each box MUST have handles and a lid or you will need to request Iron Mountain boxes.
2. If all documents are in boxes, email OCR to request one label per box. All boxes must have an approved Iron Mountain label in order to be included for pickup.
3. Once all boxes are packed and labeled, send a request for pickup to the OCR inbox.
 - All requests should also include a spreadsheet with the following information:
 - i. Iron Mountain label number
 - ii. Department Name
 - iii. PI Name
 - iv. Short Title



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<p>v. Date of Study Termination</p> <p>vi. Contact information for pickup</p> <ul style="list-style-type: none">• Name• Phone Number• Email Address <ul style="list-style-type: none">• You will also be provided with a Transmittal Sheet. This is separate from the internal tracking spreadsheet and will also need to be completed. We will provide this spreadsheet to Iron Mountain for their tracking purposes.• Department Name, PI Name, Short Title, and Date of Study Termination should also be written clearly on all boxes.• If any boxes are not Iron Mountain boxes, please provide the measurements for each box. <p>4. All studies entering long-term storage will be tracked by the Office of Clinical Research, but each individual department is responsible for retaining the study information and Iron Mountain label numbers for their own records.</p> <p>5. Pickups will be scheduled for the next available pickup date. The designated point of contact will be notified of the assigned pickup date and must be available on that date to ensure Iron Mountain can collect the boxes.</p> <p><u>Retrieving Documents</u></p> <p>Should study documents need to be retrieved from long-term storage at any time (i.e. in the event of an audit), email clinicalresearch@mfa.gwu.edu to request a return drop-off and provide the following information:</p> <ol style="list-style-type: none">1. Iron Mountain label number for each box requested2. Contact Information for drop off<ul style="list-style-type: none">• Name• Phone Number• Email Address



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*3 or fewer boxes will be shipped via UPS and can take 3-4 business days to arrive.

**4 or more boxes will be delivered by Iron Mountain on the next available Tuesday.