

Glasgow Clinical Trials Unit Guideline

Guideline number	57.005B	Version	2.0
Title	GCRF Archiving Process		

This guidance document describes the Glasgow Clinical Research Facility (GCRF) Investigator Site File (ISF) archiving process. Studies hosted by GCRF can be archived once close-out visit is complete. If required for regulatory inspection or external/internal audit purposes, the archived boxes can be retrieved within 24 hours. More than one study can be archived in the same box so long as the retention period is the same.

GCRF hosted studies are archived following one of the processes detailed below:

1. Sponsor provides archiving at third party facility.
2. ISF archived at NHS GG&C archiving facility, Iron Mountain.

Study correspondence may be saved to CD. Sponsor must approve this before archiving process begins. If the approval is not granted then all correspondence must be printed and filed.

Archived boxes are stored at the following IM sites:

Nettlehill Road	Argyll House
Houston Industrial Estate	26 Helen Street
Livingston	Glasgow
EH54 5DL	G51 3LJ

1. Sponsor archiving process

- 1.1. The contract or protocol will confirm if the ISF is to be archived using the study sponsor process.
- 1.2. The ISF should never be sent to sponsor.
- 1.3. The ISF should never leave GCRF site with a sponsor representative.
- 1.4. The ISF should never be packed away by a sponsor representative.
- 1.5. Sponsor will provide boxes, courier, details of third party archiving facility, retrieval process and may also provide paperwork to complete.
- 1.6. GCRF staff must pack the boxes and complete either sponsor paperwork or Form 57.005A with contents of each box.
- 1.7. Sponsor will provide courier details to arrange pick-up of boxes to third party facility.
- 1.8. Archiving details must be recorded on EDGE including retrieval process.

2. Iron Mountain Archiving

- 2.1. Once a study is ready to be archived. All documentation should be removed from folders, plastic wallets and bound together with plastic and nylon treasury tags.
- 2.2. Iron Mountain boxes should be full but not exceed capacity limit.
- 2.3. Lead study nurse must confirm study documentation is ready to be archived.
- 2.4. Form 57.005A must be completed with the contents of each box, and must include the end date of study and retention period.
- 2.5. Locate Iron Mountain barcode stickers kept in Administration Areas at each site QEUH, GRI and GGH.

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- 2.6. Allocate each box an IM barcode sticker label, the adjoining smaller barcode should be added to Form 57.005A.
- 2.7. Scan Form 57.005A and save in study e-folder.
- 2.8. Record archiving details to EDGE study record and upload Form 57.005A.
- 2.9. Once boxes are labelled and contents ready, log on to iron Mountain Connect to record the contents of the box and arrange pick-up with IM.

3. Add new archive box and arrange collection using Iron Mountain system

- 3.1. Go to www.ironmountainconnect.com
- 3.2. Logon using account details on Contact and Account list.
- 3.3. Click **Record Management**
- 3.4. Click **Collections, Add records**
- 3.5. **Click Collection List (Add Records)**
- 3.6. **Click Add Box**
- 3.7. **Click Box Size**
- 3.8. Enter **SKP Box Number** (barcode number)
- 3.9. Enter **Customer Box Number** (2 of 4)
- 3.10. Select Box **Division** (GCRF)
- 3.11. Select Box **Department** (Studies)
- 3.12. Enter **Major Description** (R&I Number)
- 3.13. Enter **Minor Description** (Study Short Title)
- 3.14. Enter **Destruction Date (format DD/MM/YYYY)**
- 3.15. Enter Long **Description** (record ALL contents of box)
- 3.16. Click Save & **AddRepeat** until all boxes have been recorded
- 3.17. Click Quick Collection **Order**
- 3.18. Select **Either New or Refile** and enter no. of boxes
- 3.19. **click Add to Basket**
- 3.20. **Click Collection**
- 3.21. **Click Next**
- 3.22. Confirm collection address, date and email address (should address be different click change address and find suitable address).
- 3.23. Click **Place Your Order**
- 3.24. Confirmation email will be sent

4. Retrieve box from Iron Mountain

- 4.1. Records management
- 4.2. Enter **R&I Reference** or **Study Title** in search field
- 4.3. Grid will appear with all boxes with this reference
- 4.4. Click on box to see further details of box
- 4.5. Click Add to Basket and Close
- 4.6. Click Retrievals
- 4.7. Instructions will appear Click Next
- 4.8. Confirm delivery address, date, and email address (should address be different click change address and find suitable address).
- 4.9. Click Place Your Order

5. Order Iron Mountain Boxes

- 5.1. Click Records Management
- 5.2. Click **Order Supplies**
- 5.3. Create supply order by entering the Quantity of the Item to be ordered and add to basket.
- 5.4. Click Supplies
- 5.5. Invoice to Division – choose the GCRF
- 5.6. Invoice to Department – choose Supplies
- 5.7. Click Next
- 5.8. Check address, Date and email address
- 5.9. Click **Place Your Order**

Guideline signatories

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Document history

Version	Date	Description
1.0	11/12/2017	First creation
2.0	03/08/2023	Update to GCTU Guidance template v1.0 Minor admin changes

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