Archiving Guidance for Researchers

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# Introduction

## The Academic & Clinical Central Office for Research & Development (ACCORD) is a joint office comprising clinical research management staff from NHS Lothian (NHSL) and the University of Edinburgh (UoE).

## This document applies to study Investigators, responsible for organising the archiving of research documentation for clinical research studies sponsored by NHSL and/or UoE, or studies hosted by NHSL.

Purpose

## **Archiving Request**

### E-mail ([LOTH.ArchivingRDO@nhs.scot](mailto:LOTH.ArchivingRDO@nhs.scot)) or telephone the R&D Administration Manager quoting the R&D study number. Contact details are available at [www.accord.scot](http://www.accord.scot).

### The R&D Administration Manager will provide further information and forms, including;

* Archiving Guidance for Researchers (GS005-W01)
* Archive Information Form (GS005-F01)
* Box Label template (GS005-T01)
* Price list and box sizes

### Investigator, or designee, will return e-mail to R&D Administration Manager, confirming agreement to conditions and specify how many boxes are required.

## **Collecting Boxes and Barcodes**

### Investigator, or designee, will agree when boxes can be collected from the R&D (ACCORD) office (Royal Infirmary Edinburgh - RIE). Where the research team is based at the Western General Hospital (WGH), it may be possible for the R&D Administration Manager to arrange delivery of boxes.

### The R&D Administration Manager will allocate boxes and barcodes for filled boxes.

### Any unused boxes should be returned to R&D (ACCORD) Office.

## **Completing the Archive Information Forms and Labelling Boxes**

### The Investigator, or designee, will complete each section of the Archive Information Form (GS005-F01);

* *Contact Name, Tel, E-mail* – details of person responsible for the boxes. (R&D Administration Manager MUST be informed if these details change during the archiving period)
* *Department* – name of Department responsible for study.
* *Address/Site* - study location.
* *Period of Retention (years)* – refer to study protocol for archiving period and/or SOP GS005 (Archiving Essential Study Documentation).
* *Documentation* –This should give enough detail to ensure that a person checking the box can confirm what is included. Ensure contents of the box are clearly documented as containing identifiable data, where applicable.

### Any media that may become obsolete will be documented on the form and highlighted to the R&D Administration Manager. Provisions should be made if the selected medium becomes obsolete during the archive period and require transfer to a more appropriate media format.

### Any boxes containing identifiable information should be documented and identifiable data should be enclosed in sealed and signed envelopes labelled as containing participant identifiable information.

### A separate form will be completed for each box.

### A specific list of contents should be kept by the person responsible for the box(es) (e.g. Investigator), as this paperwork may be required during a regulatory inspection by the Medicines and Healthcare products Regulatory Agency (MHRA).

### Archival materials will be packed by the investigator, or designee. Include a copy of the relevant Archive Information Form in each box.

### Complete 3 box labels for each box as per template GS005-T01.

### Affix completed labels to both short sides and the top of the box. Place barcode in appropriate section indicated on the side of the box.

## **Submitting Archive Information Forms**

### Two versions of the Archive Information Form (GS005-F01) are required.

* An electronic version renamed with appropriate barcode number, R&D reference number and study acronym or Principal Investigator (PI) name (e.g CA25267-2019/0001-PI name).
* A hard copy signed and initialled by the PI.

### When electronic forms are completed, e-mail this to the R&D Administration Manager.

### Completed signed hard copies will be collected by the R&D Administration Manager when checking archive boxes.

### Where checking of archive boxes has been delegated to a member of the research team, completed signed copies can be sent to the R&D Administration Manager via email.

## **Archiving Check**

### When the R&D Administration Manager receives electronic copies of the archive form(s), confirmation of funding for archiving will be sought from the R&D Finance Office.

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### Once approved, the R&D Administration Manager, or designee, will contact the Investigator, or designee, to agree an appropriate date/time to check archiving.

### The R&D Administration Manager, or designee, will check the contents of the boxes against the signed hard copy of the Archive Information Forms (GS005-F01), ensuring a copy of the appropriate Archive Information Form is in each box and that labels and barcodes are correctly positioned on the box.

### The R&D Administration Manager, or designee, will sign and date the hard copy of the form to confirm that an archiving check has been completed.

### The R&D Administration Manager may delegate the checking of archival box contents to a member of the research team. This cannot be the same member of the team responsible for packing the boxes.

### Where this task is delegated to the research team, the person responsible for will check the contents of the boxes against the signed hard copy of the Archive Information Forms (GS005-F01), ensuring a copy of the appropriate Archive Information Form is in each box and that labels and barcodes are correctly positioned on the box and sign and date the hard copy of the form to confirm that an archiving check has been completed before sending the forms(s) to the R&D Administration Manager.

### Once everything is checked and confirmed by the R&D Administration Manager, and before arranging box uplift, the Deputy R&D Director, the Principal R&D Manager or the Head of Research Governance will sign the Authorisations section on page 1 of the Archive Information Form (GS005-F01).

## **Box Uplift**

### Boxes awaiting uplift will be kept in a secure facility, i.e. a locked room.

### The Investigator, or designee, will agree the precise location details for pick up (room number, address, phone number of contact person for any queries), with the R&D Administration Manager.

### The R&D Administration Manager will contact Crown Records Management to arrange uplift.

### Crown Records Management will issue a receipt of the uplift to the contact person.

### The Investigator, or designee, will send a copy of this receipt to the R&D Administration Manager, for R&D (ACCORD) records.

## **Retrieval of Boxes from Archive and Return of Boxes to Archive**

### The Investigator, or designee, will contact the R&D Administration Manager to request retrieval of boxes. The request must be made by the PI, or the contact person named on the Archive Information Form (GS005-F01).

### The R&D Administration Manager will contact Crown Records Management to arrange delivery of the requested boxes.

### Retrieved boxes will be returned to the R&D (ACCORD) Office by Crown Records Management and must be accessed in the R&D (ACCORD) Office as per MHRA recommendations.

### Any information added or withdrawn from the boxes must be updated on the Archive Information Form (GS005-F01).

### When the required access has been completed, the R&D Administration Manager will check the content of the box(es) against GS005-F01 and arrange return of the archive boxes to Crown Records Management.

### Crown Records Management will issue receipts to the R&D Administration Manager for the retrieval and return to the archive.

### The Investigator, or designee, will inform the R&D Administration Manager if they require copies.

## **Destruction of Boxes/Minimum Retention Period**

### When the proposed date of destruction is imminent, the R&D Administration Manager will contact the PI and sponsor to confirm whether the boxes can be destroyed as detailed in SOP GS005 (Archiving Essential Study Documentation).

### For studies sponsored by NHSL or co-sponsored by NHSL & UoE, this authorisation will be given by the Deputy R&D Director.

References

* GS005 Archiving Essential Study Documentation
* GS005-F01 Archive Information Form
* GS005-T01 Box Label template