**Appendix D**

 **Form D (Parts 1, 2, 3)**

**Request for Retrieval of Research Documentation for Destruction at Expiry of Archiving**

**FORM D: PART 1**

**Name of person requesting information…………………………………………………………………**

**Contact telephone number………………………………………………………………………………… UHL EDGE ID Number/REC Ref ………………………………………………………………………………**

**LMB Barcode………………………………………………………………………………………………… Box Reference ……………………………………………………………………………………………….**

**Contact details at site for delivery**

**Name………………………………………………………….. Tel:…………………………………….. Full details of location………………………………………………………………………….**

**………………………………………………………………………………………………………**

**Name and Full Billing Address for Invoice**

**Cost Code…………… Name of Holder (PRINT)…………………………………………………………. Signature of Holder………………………………………………………………………………………….. Full Billing Address & Contact Telephone Number**

**…………………………………………………………………………………………………………………….**

**…………………………………………………………………………………………………………………….**

**Form Completed by (print name):…………………………………………………**

**Job Title: …………………………………………….**

**Signed: ………………………… Date: ……………….**

**For R&I Office purposes only:-**

**Date confirmation received from Stor-a-File that collection has been completed:…………………**

**Name:………………………………………………….**

**Signature:………………………………………………**

**Date:……………………………………………………**

**CONFIRMATION OF DESTRUCTION OF PAPER FORMAT RECORDS**

**FORM D: PART 2**

**Records Destruction Form**

**1. Short Study Title: …………………………………………………………………………………………..**

**2. Edge Number ………….**

 **IRAS Ref: ………………**

**3. Site ………………………………………………………**

**4. Date confirmation received from Sponsor that study archiving period expired --/--/----**

**5. Details of all Records Destroyed**

**6. Date of Destruction --/--/----**

 **7. Confirmation of process of destruction …………………………………………………………………….**

**8. CI/ Delegated Individual confirming destruction completion**

**Name:……………………………………………………………………………...**

**Role:………………………………………………………………………………..**

**Signature:…………………………………………………...............................**

**Date:………………………………………………………………………………..**

**Guidance Document for FORM D PART 2 Confirmation of destruction of paper format documents**

Form completion instructions:

1. Short Study title as listed on IRAS application
2. Enter Sponsor assigned EDGE number for the study

Enter IRAS reference number

1. Site: enter details of site. For multicentre studies a completed form will be required for each collaborating centre
2. Enter date of Sponsor email confirming that archiving period is complete. A copy of this email should be filed in the archiving section of the Trial Master File/Investigator site file/s
3. Details of all documents destroyed should be listed. For example (paper format)
* Site File/Trial Master File Volumes 1 to 5.
* Pharmacy File Volume 1 and 2
* Case report forms for all subjects (list details).

**NB**. **Where consent for future research is in place, consent forms must be retained for the period stated within the IRAS application. Anonymised datasets and samples covered by this consent may be retained.**

1. Complete date that all records were destroyed
2. Confirmation of process of destruction e.g. via confidential waste bins/ collection by Universities disposal process
3. CI/delegated individual to sign and date form

**CONFIRMATION OF DESTRUCTION OF DIGITAL/ELECTRONIC FORMAT RECORDS**

**FORM D PART 3 If not applicable tick box** [ ]

**Records Destruction Form**

**1. Short Study Title: …………………………………………………………………………………………..**

**2. Edge Number: ………….**

 **IRAS Ref: ………………**

**3. Site: ………………………………………………………**

**4. Date confirmation received from Sponsor that study archiving period expired: --/--/----**

**5. Details of all Records Destroyed:**

**6. Date of Destruction: --/--/----**

 **7. Confirmation of process of destruction: …………………………………………………………………….**

**8. CI/Delegated Individual confirming destruction completion**

**Name:……………………………………………………………………………...**

**Role:………………………………………………………………………………..**

**Signature:…………………………………………………...............................**

**Date:………………………………………………………………………………..**

**R&I Office Use Only:**

**Name**:…………………………………………………………. **Signature**:…………………………………………………................

**Date**:………………………

**Guidance document for Form D PART 3 Confirmation of Destruction of Digital Format Records/Databases**

Form completion instructions:

1. Short Study title as listed on IRAS application
2. Enter Sponsor assigned EDGE number for the study

Enter IRAS reference number

1. Site: enter details of site. For multicentre studies a completed form will be required for each collaborating centre
2. Enter date of Sponsor email confirming that archiving period is complete. A copy of this email should be filed in the archiving section of the Trial Master File/Investigator site file/s
3. Details of all records destroyed should be listed. It is very easy for multiple copies of digital information to exist, therefore it is vital that all various locations that records could be stored, have been considered. The Investigator must ensure that all copies of archived study data held in any format i.e. virtual platforms e.g. Cloud based, APPS or on individual devices, hard drives, cd, usb sticks and computer servers are permanently deleted

**NB**. **Where consent for future research is in place, consent forms/ eConsent must be retained for the period stated within the IRAS application. Anonymised datasets and samples covered by this consent may be retained.**

1. Complete date that all records were destroyed
2. Confirmation of process of destruction e.g. storage device securely wiped/CD destroyed / virtual platform records deleted.
3. CI/delegated individual to sign and date form