**Archiving Log**

Archiving arrangements for research study documentation should be discussed with the study Sponsor.

NHS Greater Glasgow & Clyde require that once archiving retention has been established, the study documents are archived in a secure place and are accessible for audit and monitoring purposes.

The original archiving log should be retained in the study site file, a copy kept by the Investigator at the study site and a copy sent to the R&D Department.

**Type of study:**

|  |  |
| --- | --- |
| **Study title/acronym:** |  |
| **R&D reference** |  |
| **Chief/Principal Investigator** |  |
| **Individual responsible for archiving** |  |
| **Date study opened** |  |
| **Date study closed** |  |
| **Where documents archived** |  |
| **Archived until**  **(5 years after study close out or end of study as defined in study protocol)** |  |
| **Date destroyed** |  |
| **Destroyed by** |  |

**The documents archived should reflect the documents retained in the study file**

**Documents archived:**

1. Contact information

2. Study correspondence

3. Protocol and related documents

4. Ethics

5. NHS GG&C Board Approval documents

6. Sponsor

7. Safety Information/Reporting

8. Study documents

9. GCP

10. Amendments: numbered

11. Screening and Recruitment

12. Body fluid/tissue sample retention

13. Investigator meetings

14. Equipment

15. Archiving

16. File notes

17. Other (state)………………………………………………………………

Document(s) retrieved and reason for retrieval: Responsible person:

|  |  |
| --- | --- |
|  |  |
| Date retrieved: | Date returned to archive: |