Portsmouth Hospitals NHS
NHS Trust

Standard Operating Procedure (SOP) for Preparation and Procedure to Archive

For Completion by SOP Author	
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If you are reading this SOP in printed form then you are reading an uncontrolled document. You must therefore verify that the version number and date given below are the most recent, by cross-checking with the Trust research website before proceeding with implementation.

Portsmouth Hospitals NHS Trust is committed to ensuring that, as far as is reasonably practical, the way we provide services to the public and the way we treat our staff reflects their individual needs

and does not discriminate against individuals or groups on any grounds. This SOP has been assessed accordingly

CONTENTS

1. INTRODUCTION

Archiving is the long-term storage of essential study documentation, held in the Trial Master File (TMF) and/or Investigator Site File (ISF), which individually and collectively permits the evaluation of the conduct of the study and the quality of the data.

All trial data must be accessible after the trial has finished for further analysis if required, for example, if an unexpected side effect occurs after the trial drug has been approved. Essential documents must be retained (archived) for sufficient periods to allow for audit and inspection by regulatory authorities and should be readily available upon request.

There are different regulatory requirements for the retention of tissue, data and essential documents at the end of a study. Therefore, Portsmouth Hospitals NHS Trust's position is to archive:

- Study records for all CTIMPs, Interventional and Observational studies for at least 15 years after receipt of notice to archive, unless otherwise specified by the Sponsor in writing.
- Study records for Advanced Therapy studies for at least 30 years after receipt of notice to archive, unless otherwise specified by the Sponsor in writing.
- Medical Records for pre-market authorisation study or paediatric CTIMP participants for 15 years, unless otherwise specified by the Sponsor in writing.
- Medical Records for all other study participant's for 5 years, unless otherwise specified by the Sponsor in writing.

Sponsor confirmation of agreement to destroy will be sought prior to destruction taking place for all of the above. Where no response is received from the Sponsor after two attempts at contact the decision will be taken to the Research Governance Group as to how to proceed.

Good Clinical Practice Guidelines (Section 5.5.12) state the 'Sponsor should inform the Investigator(s)/Institution(s) in writing of the need for record retention and should notify the Investigator(s)/Institution(s) in writing when the trial related records are no longer needed'. It is the responsibility of the Sponsor to inform the investigator(s)/Institution(s) when documents are no longer needed and can be destroyed.

2. PURPOSE

The purpose of this document is to provide the Standard Operating Procedure for the preparation and archiving of essential study documents.

3. SCOPE

This SOP applies to research studies both Sponsored and Hosted by Portsmouth Hospitals NHS Trust and for other sites for which PHT is responsible.

3.1. Who should use this SOP

- All individuals involved in research studies taking place within PHT; or
- All individuals involved in research studies taking place at another site, where PHT is the Sponsor.

The Trust recognises that some external sponsors, networks, funders and employers may require the use of their own SOPs for the good governance of research. In such cases it is the responsibility of the Portsmouth Hospitals Trust user (including those individuals contracted to work on behalf of the Trust), to ensure that the external SOP is compatible with the procedure outlined below. If the external SOP contradicts the Trust's procedure then approval must be sought in writing from the Director of Research.

In the event of an infection outbreak, flu pandemic or major incident, the Trust recognises that it may not be possible to adhere to all aspects of this document. In such circumstances, staff should take advice from their manager and all possible action must be taken to maintain ongoing patient and staff safety.

4. ABBREVIATIONS & DEFINITIONS

Archiving Facility: The commercial archive facility, deemed fit for purpose, used to maintain study records quality, integrity and confidentiality for the required retention period. Study records can be retrieved from this facility in a timely manner as required.

Chief Investigator (CI): A CI is the authorised Health Care Professional, whether or not he/she is an Investigator at any particular site, who takes primary responsibility for the conduct of the clinical research at all sites involved in the study.

CTIMP: Clinical Trial of an Investigational Medicinal Product.

EDGE: Clinical research management system utilised at Portsmouth Hospitals NHS Trust.

EPS: Local study database utilised at Portsmouth Hospitals NHS Trust.

Essential Documents: Those which individually and collectively:

- Permit the evaluation of the conduct of clinical research and the quality of the data produced.
- Serve to demonstrate the compliance of the Investigator, Research Team and Sponsor with the standards of Good Clinical Practice and with all regulatory requirements.
- When filed appropriately and in a timely manner greatly assist in the successful management of clinical research by the Investigator.
- Are usually audited or monitored by the Sponsor and inspected by regulatory authorities as part of the process to confirm the validity of the clinical research conduct and data collection.
- Section 8 of ICH GCP guidance (referenced) details the essential documents necessary for the conduct of clinical research.

Hosted: Refers to an externally sponsored study for which Portsmouth Hospitals NHS Trust are acting as a research site.

ICH GCP: International Committee on Harmonisation Good Clinical Practice.

Investigator Site File (ISF): The ISF forms part of the TMF but is held and managed at participating sites. This file may also hold confidential site information and should not be removed from the site until archiving, at which point, it must still remain in control of PHT as the research site.

Principal Investigator (PI): The authorised Health Care Professional who takes primary responsibility of the conduct of clinical research at each research site.

PHT: Portsmouth Hospitals NHS Trust.

R&D Office: The Research and Development Office at Portsmouth Hospitals NHS Trust.

Research Governance Group (RGG): Oversees the quality of the Trusts research activities, policies and procedures to ensure their compliance with Good Clinical Practice (GCP) and UK regulations.

Sponsor: In relation to clinical research, the person who takes responsibility for the initiation, management and financing (or arranging the financing) of that research.

Trial Master File (TMF): The TMF is a standard filing system which allows for the effective management, storage and location of essential study documents required for the conduct of clinical research in accordance with the principles of ICH GCP. The filing system may be in the form of a single project file or a number of files/filing cabinets, depending on size and complexity of the study.

5. DUTIES AND RESPONSIBILITIES

Chief Investigator (Trust-*Sponsored* Studies only)

- Notification to the R&D Office(s) that the study is ready to be archived.

Principal Investigators and Research Team

- Labeling of participant's medical records with Portsmouth Hospitals Clinical Trial stickers to ensure they are not destroyed until the required retention period is complete.
- Preparation of study files for archiving and completion of an Archiving Contents Form to document the contents of the box.
- Liaison with R&D Office to arrange archiving.
- Suggested retention of a file within the Department containing a record of all archived boxes in the form of a counter signed Archiving Contents Form.

R&D Office including Named Archivists or delegated persons

- Check of the contents of the archiving boxes against the Archiving Contents Form.
- Completion and retention of a log of archived boxes.
- Control of the transfer of boxes to the Archive Facility and within the Trust, where appropriate.
- Approval and control of archive box retrieval.
- Approval and implementation of archive box destruction.
- Contracting with appropriate archive facility.
- Overseeing and auditing the off-site archiving facility to ensure the location, construction, security, environment and administrative procedures are appropriate.
- Overseeing and control of e-archive (located on R&D Office G drive).

(The off-site archiving facility will only respond to requests made by the Named Archivists to ensure security of archived boxes).

Where the R&D Office is referenced in the SOP this will be the Named Archivist or Delegated Persons.

Medical Records Team

- Ensuring patient medical records are reviewed for a Clinical Trial Stickers prior to destruction and not destroyed until written evidence is received to confirm this can be undertaken.

Support Departments (e.g. Pathology and Pharmacy)

- Retain central records that may be relevant for trials e.g. calibration logs/training logs for a period of 15 years.

6. PROCESS

6.1. Preparation for archive (both Sponsored and Hosted studies)

The Research Team should:

- Contact the R&D Office to request archiving boxes and Archiving Contents Forms. Prepare the study files for archive as outlined below, unless otherwise agreed by the Name Archivist:
    - Folders should not be overfilled or damaged.
    - All folders should be clearly identified.
    - Paper-clips and rubber bands should be removed (staples can be left if they are not too close to the wording so that any rust that may develop would not obscure the data).
    - All plastic wallets should be removed as they may remove ink from documents.
    - Documents on Compact Disk (CD) or other electronic media should be printed and archived in paper format where practicable OR transferred into the e-archive controlled by the R&D Office. Where records are held centrally such as electronic CRF databases this should be referred to the Named Archivist for risk assessment and confirmation of what action to take, if any.
    - Faxes or emails on thermal paper should be photocopied onto standard paper as they will deteriorate over time and may become unreadable.
    - Electrocardiogram (ECG) reports on thermal paper should be copied onto standard paper, in consultation with the Sponsor.
    - Emails which record decisions made regarding study participants should be printed and archived as these are still source documents.
    - Where required, ensure calibration and training logs are included in the site file.

- Fill archive boxes with all prepared study files. It is advisable that only one study is included per box.
- Complete the Archiving Contents Form accurately detailing the documents held in the box.
    - No abbreviations should be used e.g. ISF should be Investigator Site File.
    - The folder containing the ethics approval letters should be indicated.
    - If a Case Report Form (CRF) folder is included in a box the Archiving Contents Form should show the patient numbers contained within this. Ranges can be used if numbers are consecutive e.g. 001-085 to enable identification of which CRFs are held in which box.

6.2. Procedure to archive

The Research Team should:

- Contact the R&D Office to arrange an appointment for the prepared archiving boxes to be brought over for the final stages of the archiving process to be undertaken.

The R&D Office and Research Team should:

- Identify, collect and add any folders from Support Departments e.g. Pharmacy, Pathology, Radiology etc. to the box and to the Archiving Contents Form as required.

The R&D Office should, in the designated appointment time slot:

- Double check the contents of the box matches that listed on the Archiving Contents Form and countersign as confirmation.
- Allocate the box a number, record this on the top of the Archiving Contents Form and add the details to the Archiving Database (Research Office - G Drive).
- Log if any study information has been saved in the e-archive on the e-archive tab within the Archiving Database.
- Take a scanned copy of the Archiving Contents Form and save this in the 'End of Study, Close Out & Archiving' sub-folder of the study folder (Research Office - G Drive).

- Give the **Research Team** a copy of the countersigned Archiving Contents Form which should be retained within the department. The original copy will be placed in the archive box.
- Complete the Deposit Schedule.
- Seal the box.
- Check whether the study has been closed out fully.
    - If **the R&D Office** has not received the end of study declaration form, acknowledgment of the end of study declaration from REC and confirmation from the Sponsor that the study can be archived, the study will be sent to the Archive Facility for **storage** and can be recalled by the local study team for close-out/addition of documents as required.
        - EDGE status: Completed

    - If **the R&D Office** has received the end of study declaration form, acknowledgment of the end of study declaration from REC and confirmation from the Sponsor that the study can be archived, the study will be sent to the archive facility as **archived** and access will be restricted by the Named Archivist via the Research Office.
        - EDGE status: Archived

The final reports as required by MHRA/REC are not required for archive as they are often not available for some time after the study closes. Therefore the report can be added to the archive box at a later date or held electronically in the e-archive as long as it is easily retrievable if requested.

The R&D Office should:

- Arrange for the transfer of the box to the Archive Facility.
- Ensure responsibility of the box has been transferred to the Archive Facility e.g. signature on the deposit schedule.
- Record on the Archive Database the date the box was sent to the Archive Facility.

The Archive Facility will retain the boxes until recalled by the R&D Office or until one month before the destruction date when they will contact the R&D Office for confirmation on how to proceed before any action is taken.

6.3. Procedure for archive at Sponsor - arranged Archive Facility (Hosted studies only)

(This is to be agreed in writing or in the Contract/Clinical Trials Agreement)

- An external sponsor can arrange archiving on behalf of Portsmouth Hospitals NHS Trust. The arrangement should be agreed and documented between the sponsor and PHT.
- Documents must go directly from PHT to the archiving facility and permission must be granted by PHT for access to the documents. The Sponsor must not have uncontrolled access.

The Research Team should follow the Sponsor process for preparation to archive and archiving.

- No original or photocopied documents should be taken by the Sponsor unless explicit consent has been given by the participant. Portsmouth Hospitals NHS Trust should always retain control of the original documentation held in the ISF to ensure the Sponsor does not have uncontrolled access to the source data.

The R&D Office should:

- Confirm that the Sponsor is unable to have direct access to the essential documents at the Sponsor-arranged archiving facility. (The Investigator Site File should never be sent directly to the Sponsor for archiving except where the Sponsor and CI/PI are the same).
- Act as signatory on any documentation to archive the study; the signatory should be one of the Named Archivists. It should not be a member of the research team.

- Double check the contents of the box matches that listed on the Archiving Contents Form and sign as confirmation.
- Take a scanned copy of the Sponsor paperwork and save this in the 'End of Study, Close Out & Archiving' sub-folder of the study folder (Research Office - G Drive). Give the **Research Team** a copy of the countersigned Sponsor paperwork which should be retained within the department. The original copy will be placed in the archive box.
- Add the details of the archive box to the Archiving Database (Research Office - G Drive).
- Log if any study information has been saved in the e-archive on the e-archive tab in the Archiving Database.
- Arrange for the transfer of the box to the Archive Facility requested in line with Sponsor process.
- Hold the box in the R&D Office to await collection.
- Ensure the representative of the Archive Facility provides confirmation that the responsibility of the box has been transferred to the Archive Facility e.g. signature on pick-up request form.
- Record on the Archive Database the date the box was sent to the Archive Facility and state the address of the facility in the comments box.

6.4. Procedure for archive where PHT are Sponsor for external sites

- In most cases PHT will delegate responsibility for archiving to the host site in the Clinical Trial Agreement or in writing.
- The **R&D Office** will have oversight of the archiving procedures and ensure the name and location of essential study documentation storage is logged on the Archiving Database.
- External sites that require PHT to archive on their behalf will be provided with guidance on the archiving process to follow including instructions to be followed to ensure PHT can't access the files directly, they will remain only accessible by the site themselves.

6.5. Procedure for Retrieval:

Archived Boxes

- For retrieval of a box which has been **archived** the requester must provide **the R&D Office** with a reason as to why they need access to the archived material. These may include:
    - o Addition of documents
    - o Review of information
    - o Access for data audits or inspections

  No documents can be removed but copies can be provided/taken.
  No alterations to study data can be made.

- **The R&D Office** will assess the request and either approve or reject it based on the above criteria. Advice will be sought from the Research Governance Group if there is uncertainty as to whether a request should be approved or rejected. The decision will be recorded using the Retrieval Progress Report. If approved, the R&D Office will facilitate the return of the box to the R&D office.
- **The R&D Office** will log the retrieval reason on the Archiving Database along with the date it is returned.
    - The box must remain within the **R&D Office** after retrieval to ensure access is supervised as the Named Archivist retains responsibility for it and its contents. It cannot be taken back to the department.

Stored Boxes

- For retrieval of a box which has been **stored** the requester must provide **the R&D Office** with a reason as to why you require access to the stored material.
- **The R&D Office** will log the retrieval reason on the Archiving Database along with the date it is returned to the office.

- **The Research Team** is allowed to take the box back to the department if required but must sign the Archiving/Storage Box Location Form to confirm where it is to be held.
- **The R&D Office** will track the transfer of the box back to the department using the Archiving/Storage Box Location Form and will log the location on the Archiving Database.
- **The Research Team** should inform the R&D Office if the box is moved from this location at any point to ensure it is traceable.

- For both **archived** and **stored** boxes the R&D Office will re-sign the Archiving Contents Form before return to the Archive Facility to confirm the contents of the box.
- **The R&D Office** will record the date the box was returned to the Archive Facility on the Archiving Database.

6.6. Procedure for Destruction (Hosted studies)

- When the archiving period for a study has been completed **the R&D Office** will write to the Sponsor to ask for permission to destroy boxes.
- **The R&D Office** will notify the PI, where possible, of the intent to destroy study boxes.
- Once agreement from the Sponsor has been received sign off by an appropriate senior manager at PHT will be sought and the process documented.
- Destruction will then be completed by the Archive Facility at our instruction. Exceptions may be escalated and agreed by Research Governance Group.

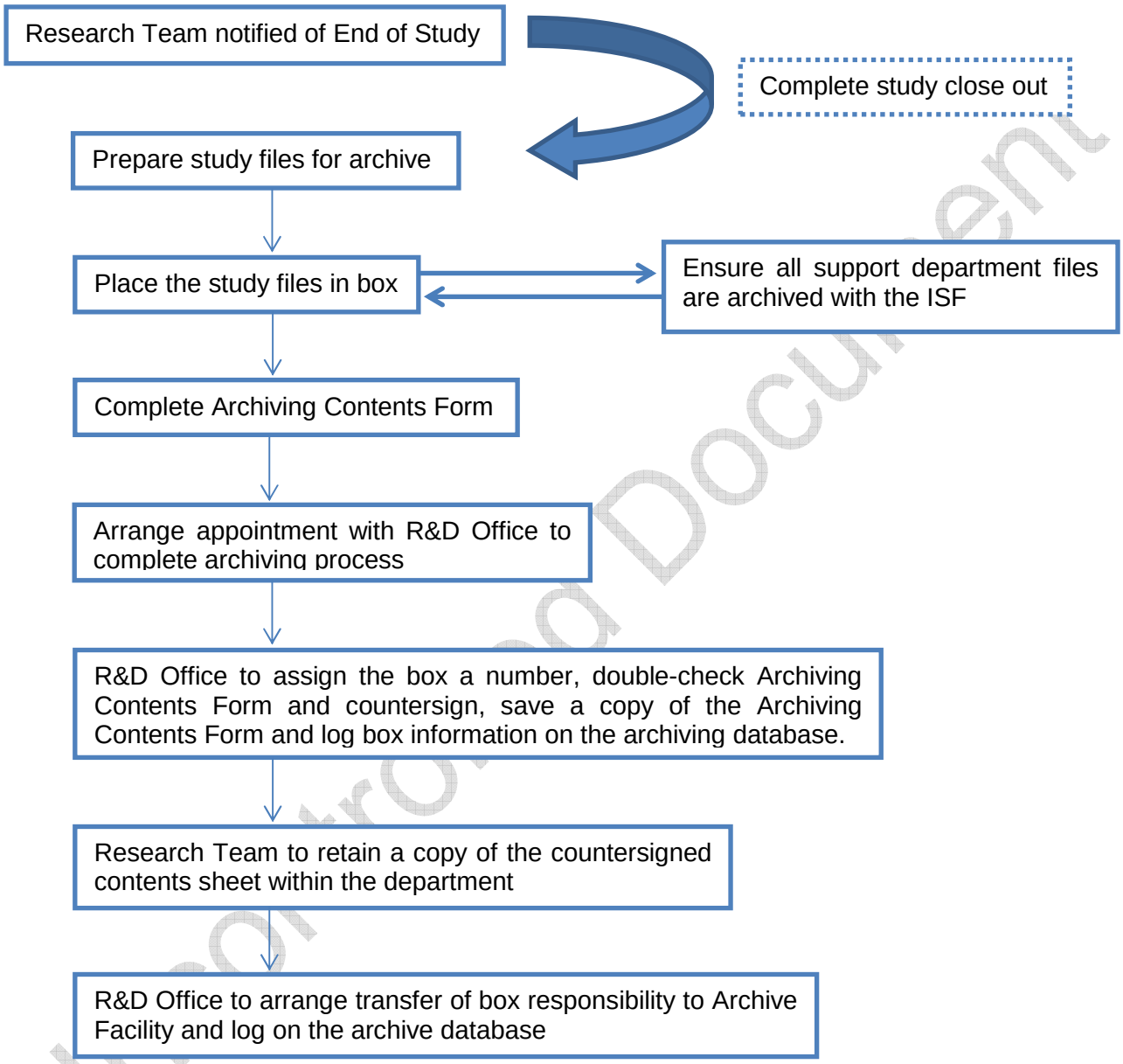
6.7. Procedure for Destruction (Sponsored studies)

- When the archiving period for a study has been completed **the R&D Office** will write to the CI and PI to ask for permission to destroy boxes, where possible.
- Once agreement has been received sign off by an appropriate senior manager at PHT will be sought and the process documented.
- Destruction will then be completed by the Archive Facility at our instruction. Exceptions may be escalated and agreed by Research Governance Group.
- **The R&D Office** will contact all external study sites that the archive period is complete and that they give permission for the study documentation to be destroyed.

6.8. Procedure for archive of Medical Records

- Study participants hospital medical records are source data and must be retained for the same retention period as the essential study documentation for research purposes.
- Study participants medical records are labelled with a Research Sticker by **the Research Team** to indicate this patient is part of a study and to ensure the **Medical Records Team** can identify the notes as not to be destroyed.
- After labelling, the notes can be archived in the hospital/clinic filing system with appropriate note tracking facilities. All data can be made available if requested by relevant authorities.
- **The Medical Records Team** must ensure the **R&D Office** is notified of any medical records to be destroyed that are identified by a Research Sticker.

Preparation and Procedure to Archive Pathway Overview



7. TRAINING REQUIREMENTS

All research staff should be trained in this procedure. Evidence of training shall be required for the R&D Office Named Archivists.

The Research Department will endeavour to notify individuals of SOP developments that may be relevant to them. Updates on SOPs will feature in research newsletters and communications. It is the responsibility of all research active staff to ensure that they read the issued updates that may be relevant to them.

When a new SOP is authorised, or when an existing SOP is revised, self directed training must be carried out by all staff to which the SOP is relevant and this training documented in their training record. A template is provided to support this process. A study specific SOP training plan will be developed for investigators on high risk PHT Sponsored studies.

Staff should take time to read and fully understand the SOP and relevant documents, ensuring that they are able to implement the SOP when required. If clarification is needed then the trainee should approach their line manager and the SOP Controller who will arrange additional training. All staff should complete their training prior to the published implementation date which will normally be between 2-6 weeks after publication.

All staff are responsible for maintaining their own SOP training Records and copies must be made available to line managers, the SOP Controller, GCP Inspector or study monitors and sponsors on request.

8. REFERENCES AND ASSOCIATED DOCUMENTATION

Reference:
Medicines for Human Use (Clinical Trials) Regulations 2004.
http://www.legislation.gov.uk/uksi/2004/1031/contents
International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). Good Clinical Practice. http://www.ichgcp.net

9. VERSION HISTORY LOG

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Details of Significant Changes
1.0	18/11/2014	New Document
1.1	07/04/2016	Additional information regarding SOP training added
1.2	12/11/2018	1. Location of archiving contents form changed from Archiving folder to archiving sub folder of the study folder 2. Section 6.3 updated to provide clarity around sponsor-arranged archiving and advise photocopies of original documents must not be taken by the sponsor.

10. APPENDICES

10.1. Training Record

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Appendix 1

CONFIRMATION OF SOP TRAINING RECORD

A copy of this record may be kept in your personal training file to confirm your training in a specific SOP. The research department or your line manager may request copies to verify your training. If required by a study Sponsor a record may also need to be kept in the Trial Master Files (TMF) or Investigator Site Files (ISF).

SOP Details: To be completed by the SOP Controller	
Title of SOP	Preparation and Procedure to Archive
Reference Number	PHT/RDSOP/011
Version	1.2 12 Nov 2018
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Personnel Details	
Name	
Job Title & Research Role	
Date of Training	
Nature of Training	Self Directed/Delivered by etc
Records of any meetings to clarify details in SOP	

Signatures
I confirm that I have read and consider myself to be sufficiently trained in the above Standard Operating Procedure with regards to my individual roles and responsibilities Signature of Trainee …… Date ……
I confirm training in the above SOP was delivered as recorded above and that the trainee may be considered sufficiently trained in their roles and responsibilities

Signature of Trainer …… Date …….

Additional Notes & Signatures

Signature of Trainer (where appropriate)

I confirm training in the above SOP was delivered as recorded above and that the trainee may be considered sufficiently trained in their roles and responsibilities

Signature of Trainer …… Date …….