



**Royal Papworth Hospital**  
NHS Foundation Trust

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Dear Sir/Madam

Royal Papworth Hospital's sustainability strategy has a focus on delivering sustainable healthcare to the community we serve. A key area of focus is to minimise the use of resources such as paper with all departments in the hospital to become paper light. This is especially important in R&D because of the limited physical filing space we have available to us. We have therefore introduced an electronic Trial Master File (eTMF) system, which we are now using for our observational / non CTIMP studies. For externally Sponsored observational / non CTIMP studies we will therefore use an electronic Site File: please find attached a copy of the Site File Index for your information.

Please be reassured that essential patient documents such as signed Informed Consent Forms and living documents such as Study Delegation Logs will remain stored in paper files. Documents that are generated electronically will be saved direct to the electronic Site File. However, any documents with a wet ink signature that do not need to be retained as paper (e.g., File Notes), will be scanned using a dedicated eTMF scanner, saved electronically and the original copy destroyed via shredding.

**Security:** Only the research team has access to the electronic Site File and the drive where it is stored. The Royal Papworth Hospital IT department maintains a back-up of the information we store on this drive at all times.

**Scanning:** For documents that need to be scanned to create an electronic copy (i.e., documents with a wet ink signature), we use a dedicated eTMF scanner, which creates an auditable Scanning Log. When a document is scanned it is sent directly to the electronic Site File for the study and a record of the scanning event is automatically made on the Scanning Log for the study. This log is generated via the scanning profile for the study and is also stored in the electronic Site File. The log is in Excel format and shows comprehensive meta data for each scanning event including the date, time, user who scanned, the number of pages scanned, number of blank pages etc, thus maintaining an audit trail for all scanning activity for the study.

**Archiving process:** When an electronic Site File is ready to be archived the Screening/Enrolment/Recruitment Log will be printed off for paper archiving and deleted from the electronic Site File. The electronic Site File will be moved to the R&D Projects Archive by an authorised member of R&D staff and the R&D archiving database will be updated by the Archive Administrator. Notification to retrieve electronic documents must be made to the R&D Archive Administrator (papworth.randdadmin@nhs.net).

The following minimum document set will be archived as paper following the standard R&D paper archiving process:

- Signed Protocol Signature Page
- Signed Contracts (title and signature pages only)
- Study Delegation Log
- Study Training Log
- Screening/Enrolment/Randomisation Log
- Signed Informed Consent Forms

If you have any concerns regarding this, please do not hesitate to let us know.

Kind regards,

*Victoria Hughes*

18-03-2025

Victoria Hughes, Senior R&D Manager

Letter authorised for use from date of signature