Document Title: Electronic Signatures for Authorisation of Documents

Document Number: R&D SOP086

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Summary of Amendments

Version Number	Modification:
1.0	New SOP
2.0	Reviewed for changes in regards to the new clinical trial E6 (R3 regs)

Key related documents:	Trust Policy DN001 Document Control Procedures SOP009 Project Management of Research Studies SOP024 Contract Negotiation & Review SOP055 Roles & Responsibilities for the Conduct of Research Studies including CTIMPS SOP066 Subcontracting of Research Activities

Key Points of this Document

1 Purpose and Contents

a. This SOP outlines the procedures to be followed by all Royal Papworth Hospital NHS Foundation Trust Staff who are involved in the preparation, review, and authorisation of key research documentation.

b. It provides guidance on the steps involved in the preparation of study feasibility, setup, initiation and operational documentation to ensure compliance with the Trust's policies.

c. This document confirms who may and may not provide their authorised signature to key research documentation and the formal process required to secure those signatures electronically.

d. This SOP relates to key research documentation for studies Sponsored by the Trust and for studies in which the Trust is a Participating Organisation.

2 Roles & Responsibilities

a. This SOP should be read in conjunction with the Trust policy *DN137_Board_of_Directors_-_Schedule_of_Decisions_reserved_for_the_Board_of_Directors_and_Scheme_of_Delegation,* SOP009: Project Management of Research Studies, SOP24 Contract Negotiation and Review, SOP66 Subcontracting of Research Activities and SOP055: Roles and Responsibilities for the Conduct of Research Studies and Clinical Trials including CTIMPs (Clinical Trials of Investigational Medicine Products), which defines the overall responsibilities of the Sponsor, Clinical Director of R&D, The Chief Investigator and Principal Investigators when conducting clinical research studies.

b. All staff managing research projects within the Research & Development department at Royal Papworth NHS Foundation Trust must comply with the requirements set out in Section 4.

c. Only those listed within the Trust's *DN137* may provide their signature physically, digitally and electronically on Study contractual documents and data-sharing agreements. A Principal Investigator (PI) must not sign these documents on the Trust's behalf.

d. Signatures on other key research documentation, physically, digitally and electronically should only be done so within the scope of that individual's professional conduct.

e. Those individuals listed within DN137 may delegate their responsibilities, confirmed in writing, to other individuals as appropriate.

f. Use of delegated or authorised signatures without the person's knowledge and consent is considered fraud.

3 Policy

a. This SOP is mandatory and, as per the Trust's Information Governance and Records Management framework, non-compliance with it may result in disciplinary procedures.

4 Procedure

4.1 Definitions

a) In 2018 the HRA and MHRA issued a Joint statement on seeking consent by electronic methods. A copy can be found here; https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/hra-mhra-econsent-statement-sept-18.pdf

b) The 'eIDAS' Regulation (EU) 2024/1183 establishes an EU-wide legal framework for electronic signatures. The Regulation, which is supplemented by the UK eIDAS Regulations (SI 2016/696), defines an electronic signature as 'data in electronic form which is attached to or logically associated with other electronic data, and which is used by the signatory to sign'.

c) Key Study Specific Research Documents - These are documents pertaining to the feasibility, setup, initiation, and conduct of a study that is either Sponsored and / or hosted at the Royal Papworth NHS Hospital Foundation Trust, that require a formalised signature for authorisation.

d) The MHRA has provided guidance on use of wet ink signatures and electronic signatures with regard to the COVID-19 pandemic;

https://www.gov.uk/guidance/approval-of-gxp-documents-when-working-from-home-during-the-coronavirus-covid-19-outbreak

4.2 Application of Electronic Signatures

a. Electronic signatures may be used instead of 'wet ink' / physical signatures.

The type of electronic signature that should be used depends on whether the process taken as a whole (and considered as part of a proportionate approach) mean that you:

- can trust that the person who signed is who they say they are
- can trust that the document they signed hasn't been altered
- can trust when the signature was applied
- can demonstrate that trust if required.

b. The system that is used for providing an electronic signature must be a recognised, legally binding format for the application of signatures, with the system requiring an account and login process to access and an audit trail available.

Docusign is one such system and is recommended for use for all RPH sponsored studies.

c. If an individual is delegated to sign a document on behalf of a colleague, then the delegated individual should apply their own signature to the documents in question and mark with 'PP'.

d. Approval of e-forms within OpenClinica: When entering the users name into a 'requested by', 'authorised by', 'reviewed by' or 'author' field within eForms; the time, date and users is recorded into the audit log. This makes it a valid method of providing an electronic signature within the eForms system. This approvals process is only applicable for e-forms within OpenClinica.
Note: OpenClinica has other digital signature systems, for investigator signatures, and within the eConsent module, which employ a 21 CFR Part 11-compliant system based on authenticated user credentials and which follow the requirements in 4.2.a.

4.3 Process for use Electronic Signatures

a. Only finalised versions of the document should be presented for signature.

b. When requesting an electronic signature via the approved electronic signature system, the document should be fully reviewed and checked for accuracy.

c. When arranging signatures for a contractual agreement, the finalised version should go via the R&D Governance team for logging and final review, prior to signature. Please use papworth.researchcontracts@nhs.net

d. The R&D Governance team should review the document uploaded to the chosen electronic signature system, prior to them re-directing the document directly to the authorised signatory.

e. The Sponsor/ person requiring a document to be electronically signed will be informed of the correct email address to send the document to i.e. the signee of the document, not a generic inbox account.

f. Copies of the fully signed documents should be saved down and stored in the study site file.

5 Risk Management / Liability / Monitoring & Audit

a. The R&D SOP Committee will ensure that this SOP and any future changes to this document are adequately disseminated.

b. The R&D Department will monitor adherence to this SOP via the routine audit and monitoring of individual clinical trials and the Trust's auditors will monitor this SOP as part of their audit of Research Governance. From time to time, the SOP may also be inspected by external regulatory agencies (e.g. Care Quality Commission, Medicines and Healthcare Regulatory Agency).

c. In exceptional circumstances it might be necessary to deviate from this SOP for which written approval of the Senior R&D Manager should be gained before any action is taken. SOP deviations should be recorded including details of alternative procedures followed and filed in the Investigator and Sponsor Master File.

d. The Research and Development Directorate is responsible for the ratification of this procedure.

Further Document Information

Approved by: *Management/Clinical Directorate Group*	Research and Development Directorate
Approval date: *(this version)*	Current approved version date
Ratified by Board of Directors/ Committee of the Board of Directors:	STET
Date:	N/A
This document supports: *Standards and legislation*	Medicines for Human Use (Clinical Trials) Regulations 2004 and all associated amendments. UK Policy Framework for Health and Social Care Research version 3.3 (07/11/17) and authorised amendments thereafter.

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Groups	Disability	Race	Gender	Age	Sexual orientation	Religious & belief	Other
Yes/No	NO	NO	NO	NO	NO	NO	NO
Positive/Negative							

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