Document Title: Planning Patient and Public Involvement (PPI) in Clinical Research

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Summary of Amendments

Version Number	Modification:
V1.0	New SOP

Key Related Documents	Trust Policy DN001 Document Control Procedure

Key Points of this Document

1 Purpose and Contents

a. This Standard Operating Procedure (SOP) describes the process for including Patient and Public Involvement (PPI) in research studies managed by Papworth Trials Unit Collaboration (PTUC) or sponsored by Royal Papworth NHS Foundation Trust and is based on the UK Standards for Public Involvement in Research.

2 Roles & Responsibilities

This SOP applies to all personnel that are conducting research at the Trust.

a. Chief Investigator (CI) or delegate:

- Ensure PPI is planned prior to the submission for study funding
- Ensure PPI has been budgeted for in study funding
- Include PPI plan details in study protocol
- Ensure PPI is carried out as planned

b. PPI Clinical Project Manager:

- Support researchers in planning PPI
- Integrating PPI into Clinical Projects
- Project Oversight
- Stakeholder Engagement

c. PPI Coordinator

- Facilitating Engagement
- Supporting PPI Contributors
- Coordinating Activities
- Monitoring Impact

d. PPI representatives

- Advising on Research Design

- Improving Communication
- Shaping Services
- Representing Public Views
- Monitoring Impact

3 Policy

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

Abbreviations and definitions

CI	Chief Investigator
PPI	Patient and Public Involvement
SOP	Standard Operating Procedure

4 Procedure

4.1 Planning PPI

a. If required, support can be obtained from the PPI Clinical Project Manager and PPI Coordinator to help facilitate grant-related PPI activities, develop a PPI plan, and integrate PPI into the research application.

b. Royal Papworth Hospital has PPI representatives available to provide grant support.

c. Researchers across the Trust can request support for planning PPI in clinical and health research by emailing papworth.ppi@nhs.net. Early contact is essential to allow adequate time for planning and hosting a PPI meeting that facilitates meaningful engagement and delivers high-quality input.

d. Prior to initiating recruitment, researchers intending to establish a new PPI group must develop a clear role description and outline of responsibilities to ensure transparency and alignment of expectations.

e. All PPI activities are planned and delivered in line with Equality, Diversity and Inclusion (EDI) principles, including proactive efforts to involve individuals from diverse backgrounds, consideration of accessibility needs, and use of inclusive engagement methods.

4.2 Funding applications

a. Any specific funder requirements for PPI should be identified and made clear to the PPI Clinical Project Manager and PPI Coordinator during the planning stage.

b. The Trust advises researchers to engage PPI contributors during the early stages of developing their proposals. Funding bodies increasingly mandate the inclusion of PPI in grant applications.

c. PPI activities described in the application must be budgeted for appropriately. It is advisable that this should follow the NIHR Payment guidance for researchers and professionals (https://www.nihr.ac.uk/about-us/who-we-are/policies-and-guidelines/payment-guidance-researchers-and-professionals).

4.3 Design of the research:

PPI should be included in designing the research. Examples:

- Identify research priorities for patient population.
- Input into the research question to be studied.
- Assist with recruitment strategy.
- Identify patient centred outcomes.
- Advise on appropriateness of research methods.

4.4 Management of the research

Identify and implement appropriate PPI activities in the management of the research. Examples:

- Inclusion in Trial Steering Committee.
- Review of protocol.
- Assist with writing participant documents e.g. Participant information sheets, invitations and newsletters.

4.5 Undertaking the research

Identify activities that PPI representatives will assist with, such as conducting interviews, surveys, or focus groups.

4.6 Analysis of results

Identify and incorporate areas where PPI can provide input. Examples:

- PPI input into developing data priorities.
- PPI representatives involved in data analysis and interpretation.

4.7 Dissemination of the findings: key principles

Transparency and accessibility: Findings will be communicated in plain language, avoiding jargon, and using formats that are inclusive of varying literacy levels, languages, and digital access.

Timeliness: Updates and final results will be shared promptly, with clear timelines agreed upon during the study planning phase.

Recognition of contribution: PPI contributors will be acknowledged in dissemination materials (e.g., reports, presentations, publications) where appropriate, and their role in shaping the research will be highlighted.

Multiple formats: Dissemination may include written summaries, infographics, videos, webinars, community events, and social media posts, depending on audience needs.

Feedback loop: Opportunities will be provided for PPI contributors and community members to respond to findings, ask questions, and suggest future directions.

4.8 Remuneration for PPI

Ensure that PPI representatives are appropriately reimbursed for their time and direct expenses, such as travel and subsistence. Please contact the PPI Coordinator for an expense form. Please refer to the NIHR PPI payment guidelines which can be found online.

4.9 Data Protection

To uphold the principles of data protection and safeguard the personal information of PPI Representatives the following procedures must be followed:

4.9.1 Handling of Personal Contact Information in Publications

- Ensure personal information such as contact details are securely stored and only appropriate staff members can access.
- Electronic personal information should be stored in a password protected file on a secure NHS drive.
- Ensure that PPI Representatives understand what personal information they will be required to share, where this data will be held and who can access their data.
- The central email address papworth.ppi@nhs.net must be used as the default point of contact for all publications and presentations. Personal contact details of PPI Representatives must not be shared or published unless explicit consent has been obtained from both the individual concerned and the PPI Clinical Project Manager.
- For correspondence by post, please use the following address: **PPI Team, Research & Development, Royal Papworth Hospital NHS Foundation Trust, Papworth Road, Cambridge Biomedical Campus, Cambridge, CB2 0AY.** This address should be included in publications and presentations where a postal contact is required, ensuring consistency and safeguarding personal information.
- In cases where personal contact details have been inadvertently published, the responsible team must:
    - Immediately notify the affected individuals.
    - Contact the relevant journal or publisher to request removal or redaction of the personal data.
    - Monitor whether changes are reflected across associated platforms (e.g., PubMed) and follow up as necessary.

4.9.2 Use of Central Contact Information

- PPI Representatives must be given the choice to use either their personal contact or the central email address.

- The central email account will be managed and monitored by PPI Coordinator to ensure appropriate filtering and response.

4.9.3 Incident Response and Accountability

- Any breach or error involving personal data must be promptly reported to the Information Governance Officer.
- A formal apology and corrective action plan must be communicated to affected individuals.
- Staff involved in the incident should be supported and not held personally accountable where systemic or procedural issues are at fault.

4.10 Recording and evaluating PPI

a. Details of PPI should be included in all study protocols.

b. Researchers should have methods in place to document PPI that is carried out throughout the project and the impact this has had on the project. For example, meeting minutes, blogs documenting patient experiences and keeping tracked changes as evidence of how PPI input has changed documentation and feeding back to the PPI representatives.

c. There should be ongoing evaluation of the PPI plan throughout the project. It is the responsibility of the research team, to ensure the PPI plans are following what is detailed in the protocol and meet any funder milestones or reporting requirements.

d. The PPI representatives should be involved in the evaluation process.

e. It is important that the research team provide ongoing feedback to those involved in PPI activities. This should include documenting the PPI feedback that was provided and how this was implemented into the project, as well as a justification of why any suggestions were not possible to implement.

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) (Amendment) Regulations 2025 (and any subsequent 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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