Document Title: Informed Consent for Research Studies

Document Number: R&D SOP003

Staff involved in development: *Job titles only*	Senior R&D Manager, R&D Operational Manager, Clinical Project Managers
Document owner:	Senior R&D Manager
Directorate:	Research and Development
Department:	Research and Development
For use by:	NHS Staff Trust-Wide
Review due:	July 2025
THIS IS A CONTROLLED DOCUMENT **Whilst this document may be printed, the electronic version maintained on the Trust's Intranet is the controlled copy. Any printed copies of this document are not controlled. ©Royal Papworth Hospital NHS Foundation Trust. Not to be reproduced without written permission.**	

Summary of Amendments

Version No:	Modification:
12.0	Minor amendments throughout

Key Points of this Document

- This document sets out the procedures to be followed by all Royal Papworth Staff who consent participants into research studies.

- It provides guidance on the legal requirements and the procedure of receiving informed consent when recruiting patients to research studies carried out at Royal Papworth.

1 Purpose and Content

a. This document defines the Trust's research procedures for the receiving of informed consent when recruiting participants for Research undertaken at Royal Papworth Hospital and PTUC.

b. The document details the requirements for informed consent as described in Good Clinical Practice (GCP: 'a standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected').

c. The document provides guidance on the processes involved in ensuring informed consent is in place before a patient's participation in research so as to comply with the Trust's Consent Policy DN306.

2 Roles & Responsibilities

a. This Policy applies to research that is conducted at the Trust.

b. Staff involved in the informed consent process for research must comply with the requirements set out in section 4.

c. The Principal Investigator of a research study is responsible for ensuring that the informed consent of study participants is obtained. The actual procedure may be delegated to a responsible member of the site's research team who is deemed to be appropriately qualified by knowledge and training.

d. The exact arrangements for receiving informed consent will be decided on a study-by-study basis in accordance with the studies' ethically approved protocol.

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.

4 Procedure

4.1 Who can take informed consent?

a. The responsibility for receiving informed consent lies with the Principal Investigator. These duties may be delegated and this must be documented on the study delegation log.

b. The Trust's position is that delegation of the taking of informed consent, to a suitably trained and experienced member of the research team is acceptable. They must have sufficient knowledge of the protocol of the research study. Approval for this will be on a trial-by-trial basis.

c. Receiving of informed consent for Clinical Trials of Investigational Medicinal Products (CTIMPs) must always be performed by the Principal Investigator, or other clinically qualified member of the research team (who are either medically qualified or who are non-medical prescribers).

4.2 Procedure – written consent (wet ink or e-signature)

a. When receiving informed consent the principles described in the ICH GCP Guidelines Section 4.8 should be observed.

b. Informed consent must be taken in accordance with the trial protocol and ethically approved process. Care must be taken to ensure the minimum time for participants to consider the information specified in the ethics application is allowed.

c. The most recent versions of the ethically approved patient information sheet and informed consent form must be given to the potential participant. The date this was carried out should be documented in the patient's medical records. Patient information sheets should include local contact details.

d. After the potential participant has received a copy of the trial's patient information sheet, the consent taker must discuss this information with the potential participant. The patient's privacy and dignity should be respected at all times and this includes consideration of the environment in which the discussion will take place.

e. Following full explanation of the study the consent taker must ensure the potential participant has fully understood the trial and given them the opportunity to ask questions and answer these completely. This must be fully documented in the patient's medical records as per the Informed Consent Competency Guidelines and SOP080 Study Data – Collection and Entry for CTIMPs

f. A potential participant may elect to have a family member or friend present during the discussions to obtain informed consent. No one can consent on behalf of a participant who is over 18 and has capacity.

g. Where adults lack the capacity to provide informed consent then reference should be made to the arrangements that have been provided for in the Research Ethics Committee approved protocol. If no such arrangements have been made a lack of capacity to consent would normally exclude participation in research trials.

h. Where adults lack the capacity to provide informed consent then reference should also be made to the Mental Capacity Act (2005) for non-CTIMPs and the Medicines for Human Use (Clinical Trials) Regulations for CTIMPs. A log of all the potential participants approached to take part in a trial should be kept to prevent a patient who has declined to participate from being approached again for that study. The reasons for declining should be documented if the participant is willing to provide this (see SOP031: Patient Recruitment).

i. If the protocol requires face-to-face informed consent, the consent taker must read out loud each statement on the informed consent form before asking the participant to confirm their acceptance of these by initialling the statement. The informed consent form must be signed and dated by the participant / delegated representative and the consent taker. Each person must also print their name on the form.

j. Where adults lack the capacity to physically sign the form then the informed consent process must be observed by a witness. The witness can be a next of kin or staff member who is not part of the research team. The consent form must be signed and dated by the consent taker and the witness on behalf of the participant. (See form FRM072 Informed Consent Form .

k. The original copy of the signed informed consent form is retained in the Site file, a copy is uploaded to the patient's medical records and a copy given to the patient. A copy of the patient information sheet is kept by the patient and another copy uploaded to the medical records.

l. Research procedures must not be carried out before the participant (or their legal representative) has signed the informed consent form.

m. Patients should be asked to reconfirm their decision to take part in a trial at each study visit. If there are any changes to the study or new potentially important information related to the study, then the participant may need to be re-consented following the procedure described above.

n. Participants should be reminded at each study visit that they can withdraw their consent at any time.

o. If a patient withdraws consent:

1. The sponsor must be informed who will advise on the requirements for keeping data and samples.
2. The explanation must be fully documented in the patient's healthcare records
3. The consent form must have WITHDRAWN written across, and the original consent form in the medical records must be replaced with the updated consent form.

p. For studies where it has been approved that consent can be undertaken remotely all procedures must be followed as detailed within the study documentation. For studies that implemented remote consent during the pandemic, this may be detailed within amendment documentation.

4.3 Procedure – verbal consent in emergency settings for adults with capacity

a. Verbal consent must be taken in accordance with the trial protocol and ethically approved process. Care must be taken to ensure the minimum time for participants to consider the information specified in the ethics application is allowed.

b. The patients must be given opportunity to ask any questions.

c. The verbal consent process must be clearly documented in the patients' health record.

d. In accordance with the trial protocol and ethically approved process, full written consent should be sought from the patient as soon as possible (as per Section 4.2).

4.4 Language considerations

a. The consent taker should ensure that they use clear and concise language in discussions. Medical terms and jargon should be avoided where possible and fully explained if used.

b. Where possible the Trust is committed to meeting the information needs of patients whose first language is not English. Interpretation and translation services will be made available as per the Trust's general patient consent policy.

c. Where a translator is required for the informed consent process, this should not be an immediate family member.

d. The IRAS form and protocol must be referred to, to see what resources have been made available by the sponsor.

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 active version approved 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 (2018)
Key related documents:	Trust Research Policy Consent Policy DN306

Equality Impact Assessment: Does this document impact on any of the following groups? If YES, state positive or negative, complete Equality Impact Assessment Form available in Disability Equality Scheme document DN192 and attach.

Groups	Disability	Race	Gender	Age	Sexual orientation	Religious & belief	Other
Yes/No	NO	NO	NO	NO	NO	NO	NO
Positive/Negative							
Review date:	July 2025						

I certify the contents of this SOP has been reviewed and ratified

DocuSigned by:
Dr Patrick Calvert
81A52758BFFF421...

Signed by Dr Patrick Calvert, Clinical Director of R&D

31-Jul-2022

Date