Document Title: Obtaining 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
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Summary of Amendments

Version No:	Modification:
12.0	Minor amendments throughout
13.0	- Replaced the term "patients" with "participants" - Included instructions specific to participants aged 16–17 - Added guidance for adults who are unable to provide a physical signature - Included additional instructions regarding remote consent and re-consent - Contains reference to Tissue Bank consent - reviewed for changes in regards to the new clinical trial R3 reg

Key related documents:	DN306 Consent to Examination or Treatment Policy SOP080 Study Data Collection and Entry

	SOP031: Participant Recruitment TPL015 Patient Information and Consent Form FRM072 Informed Consent Form

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 obtaining informed consent when recruiting participants to research studies carried out at Royal Papworth.

1 Purpose and Content

a. This document defines the Trust's research procedures for obtaining 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 obtained before an individual's participation in research.

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 obtaining 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 obtaining 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 the delegation of obtaining 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. Obtaining 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 obtaining informed consent, the principles described in the ICH GCP Guidelines should be observed.

b. Informed consent must be obtained 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 participant information sheet and consent form must be given to the potential participant. For interventional studies, the date this was carried out should be documented in the participant's medical records. Exceptions to this must be agreed by RGPAS and a file note added to the Trial Master File.

A log of all the potential participants approached to take part in a trial should be kept to prevent re-contacting those who have declined to participate. The reasons for declining should be documented if the participant is willing to provide this (see SOP031: Participant Recruitment).

d. After the potential participant has received a copy of the trial's participant information sheet, the consent taker must discuss this information with the potential participant. The participant'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 participant'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 apart from when they are physically unable to sign the form (see section 4.2.k).

g. If the protocol requires face-to-face informed consent, the consent taker should 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 own name on the form.

h. The original version of the signed informed consent form is retained in the paper Site File; a copy is uploaded to the participant's medical records and a copy given to the participant. A copy of the participant information sheet is kept by the participant and another copy uploaded to the medical records.

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

j. **Young people aged 16 or 17:** 16- and 17-year-olds may consent to research participation themselves if they are assessed as Gillick competent (possess sufficient understanding and maturity to comprehend the nature, purpose, and potential risks of the research). However, involving parents or legal representatives is encouraged.

k. Where adults do not have the ability to physically sign the consent form, they should provide oral consent using FRM072 Informed Consent Form – if independent signature is required. The informed consent process must be observed by a witness who can be a next of kin (NOK) or impartial witness (e.g. staff member who is not part of the research team). The witness needs to complete the initials of the participant in the box for each statement. The witness needs to print the participant's name. The consent form must be signed and dated by the witness on behalf of the participant, once this has been completed the consent taker should print, sign and date the consent form.

l. **Adults lacking capacity:**

1. 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.

2. 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.

m. **Remote Consent:** For studies where it has been approved that consent can be obtained remotely, all procedures must be followed as detailed within the study documentation. This may include justification for using remote consenting, verifying the identity of the adult potential participant (checking date of birth, address including post code and contact details, etc), and ensuring the provision and discussion of all necessary trial information. Participant Information Sheet and Consent Form (TPL015) can be sent electronically (e.g. Docusign or OpenClinica) or by post (with a prepaid envelope for returning the signed original consent form). All correspondence must be retained. For studies that implemented remote consent during the pandemic, this may be detailed within amendment documentation.

n. **Consent for donation to Tissue Bank**

The Trust has a clearly stated and understood policy towards the retention and use of tissues and blood for research and conforms to the Human Tissue Act 2004 and its subsequent amendments and guidelines. There are specific participant information sheets and consent forms to be used when patients wish to donate tissue to Papworth's Research Tissue Bank.

https://staff.royalpapworth.nhs.uk/research-and-development-tissue-bank

Prior to consenting patients to the Tissue Bank staff must be competent in obtaining consent and have completed the Tissue Bank training via the Learnzone. Recommendation is to refresh training every three years and/or following substantial changes to training presentation.

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

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

b. The potential participant must be given opportunity to ask any questions.

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

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

e. Re-Consent and withdrawal of consent. Participants should be re-consented with this revised version after regulatory approvals and reconfirmation of Trust Capacity & Capability. Section 4.2 should be followed for re-consent procedure.

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

g. If a participant 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 participant'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.

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 participants whose first language is not English. Interpretation and translation services will be made available as per the Trust's general consent policy.

c. Where a translator is required for the informed consent process, this should be used in line with the Trust policy DN514 Interpreting and Translation Services.

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 version 3.3 (07/11/17) and authorised amendments thereafter.

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							

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