Portsmouth Hospitals University NHS Trust

Standard Operating Procedure (SOP)

Recruiting and Consenting Patients into Clinical Research

For Completion by SOP Author	
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The definitive versions of all Portsmouth Hospitals University Trust SOPs, Templates and Forms for Research are online at https://www.porthosp.nhs.uk/research/

If you are reading this SOP in printed form then you are reading an uncontrolled document. You must therefore verify that the version number and date given below are the most recent, by cross-checking with the Trust research website before proceeding with implementation.

Portsmouth Hospitals University NHS Trust is committed to ensuring that, as far as is reasonably practicable, the way we provide services to the public and the way we treat our staff reflects their individual needs and does not discriminate against individuals or groups on any grounds. This SOP has been assessed accordingly.

CONTENTS

1 INTRODUCTION

As the drive for research increases, good standards for gaining informed consent not only ensure legal and ethical principles are adhered to but also promotes the wellbeing of individuals and the acceptability of participation in research studies i.e. not over burdening and being sensitive to individual needs for information.

The ethical principles of informed consent are fully outlined in the Declaration of Helsinki adopted in 1964 by the World Medical Association in relation to the conduct of medical research.

Each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, and any other relevant aspects of the study.

The potential participant must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without it compromising their medical care and treatment. Equally it is essential that potential participants are not over burdened with information. Information provided must meet the needs of the individual to ensure the information provided can be understood.

After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent.

The Medicines for Human Use (Clinical Trials) Regulations 2004 confirm that a person gives informed consent to take part in a clinical trial only if their decision is given freely after that person is informed of the nature, significance, implications and risks of the trial and either:

(1) is evidenced in writing, dated and signed or otherwise marked by that person so as to indicate consent, or
(2) If the person is unable to sign or to mark a document indicating consent, then it must be given orally in the presence of a witness and documented.

The UK Policy Framework for Health and Social Care Research (2017) defines the broad principles of good research practice and is key to ensuring that all health and social care research at Portsmouth Hospitals University NHS Trust is conducted to high scientific and ethical standards; informed consent is at the centre of ethical research.

2 PURPOSE

The purpose of this document is to describe the Standard Operating Procedures (SOP) for obtaining written informed consent from a potential study participant.

3 SCOPE

The principles outlined in this document apply to:

- All Investigators and Investigation Teams involved in the process of consenting potential study participants in research studies conducted at Portsmouth Hospitals NHS Trust, or at external sites for research sponsored by Portsmouth Hospitals University NHS Trust.

All relevant staff working on studies must be completely familiar with the recruitment and consent procedure. It is the personal responsibility of all staff to follow local NHS procedural documents.

The Trust recognises that some external sponsors, networks, funders and employers may require the use of their own SOPs for the good governance of research. In such cases it is the responsibility of the Portsmouth Hospitals University Trust user (including those individuals contracted to work on behalf of the Trust), to ensure that the external SOP is compatible with the procedure outlined below. If the external SOP contradicts the Trust's SOP then approval must be sought from a senior manager within the Research & Innovation Department at PHU.

In the event of an infection outbreak, flu pandemic or major incident, the Trust recognises that it may not be possible to adhere to all aspects of this document. In such circumstances, staff should take advice from their manager and all possible action must be taken to maintain ongoing patient and staff safety.

4 ABBREVIATIONS & DEFINITIONS

ICH GCP	International Committee on Harmonisation Good Clinical Practice
SOP	Standard Operating Procedure
PHU	Portsmouth Hospitals University NHS Trust
PI	Principal Investigator
CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
REC	Research Ethics Committee
HRA	Health Research Authority
MHRA	Medicines and Healthcare Products Regulatory Agency (the UK's competent authority)
AHP	Allied Health Professional
R&I	Research & Innovation
IRAS	Integrated Research Application System
CTA	Clinical Trials Assistant
RF	Research Fellow
RN	Research Nurse
RM	Research Midwife

5 DUTIES AND RESPONSIBILITIES

Investigator and investigation team are responsible for:

- Familiarising themselves with the study recruitment and consent procedure in the study protocol.
- Assessing a potential participant's cognitive ability to consent to the study.
- Ensuring that they have been appropriately delegated by the PI (or CI for single centre studies) to provide information to participants and receive their consent.
- Conveying information in a way that is easily understood by the potential study participant; providing and explaining complex protocol information in a way that is not ambiguous or confusing.
- Ensuring the participant is provided with the information sheet and informed consent form.
- Ensuring that the information sheet and informed consent form used have received approval from the relevant REC and the HRA (plus MHRA for CTIMPs and some device trials), provided on Trust headed paper, and are identifiable by a date and version number;
- Documenting the informed consent process in the medical notes, ensuring that informed consent is an ongoing process, which begins when initial contact is made and continues throughout the study.
- Ensuring a consent form is signed and dated by the study participant or their personal/professional legal representative and by the person who carried out the informed consent discussion.
- Ensuring a copy of the consent form is placed in the medical notes and a copy in the TMF/ISF; the type of file used will depend on the site type.

In addition, the Chief Investigator has overall responsibility for the maintenance of recruitment records as specified in this SOP and in accordance with the study protocol. This may be delegated to authorised personnel at their site and documented on the Site Delegation Log.

It is recognised that there will be studies that both provide information and receive consent electronically or by post without a delegated member of the research team having met with the participant e.g. online/postal questionnaires, mobile applications. Before adopting this approach it must have been approved by the REC and HRA. In these examples it is not practical to record their consent in their medical notes

6 PROCESS

The exact procedure for participant recruitment including the consent process should be detailed in the individual study protocol. Please note that there are additional sections for minors and incapacitated adults in 6.3 and 6.4 respectively.

The process starts from screening eligible patients for research studies. Best practice includes early discussion with the patient, answering their questions fully, asking if they understand, making a record in the notes and use of patient literature to enhance patient's understanding, but not as a substitute for discussion. *Note: there will be some cases where it has been agreed by an NHS ethics committee that a face to face meeting with the participant is not required, for example in studies involving online questionnaires where participation is considered implied consent. If you are unsure please contact the R&I Office for advice.*

The PI/CI, or appropriate RF/RN/RM/AHP/CTA, that has been delegated screening activities (on the delegation log) needs to review the hospital notes or other medical records to ensure the patient is eligible for participation in the study.

Under Part 3 of Schedule 1 to the Medicine for Human Use Act (implementing Article 3(2) to the EU Directive) the following conditions apply to the giving of informed consent by a capable adult:

1. The subject has had an interview with the investigator, or another member of the investigating team, in which he has been given the opportunity to understand the objectives, risks and inconveniences of the trial and the conditions under which it is to be conducted.
2. The subject has been informed of his right to withdraw from the trial at any time.
3. The subject has given his informed consent to taking part in the trial.
4. The subject may, without being subject to any resulting detriment, withdraw from the clinical trial at any time by revoking his informed consent.
5. The subject has been provided with a contact point where he may obtain further information about the trial.

Every person who is considered a potential candidate for the study should be recorded on the Participant Screening and enrolment log, regardless of how likely they are to give consent, or whether there might be other reasons that will prevent the person enrolling into the trial.

Consent from the participant, legal or personal representative should be sought before the patient is examined, treated or information is accessed or shared for research purposes.

The patient should be given as much time as they require to consider the study information provided and signing consent unless a minimum time e.g. 24 hours has been explicitly approved by the REC and HRA.

Once the patient has agreed to participate in the study, the informed consent form should be signed and personally dated by the patient and the appropriately delegated member of the research team that is authorised to receive consent.

Non-medical, Nursing, AHP and CTA staff are permitted to receive voluntary informed consent if authorised to do so by the Sponsor, Chief Investigator, PI and NHS Trust. Delegation of this task will be recorded on the study's delegation of authority and signature log after evidence of required training is documented using the forms listed in Section 8.

Each box requiring the participant's initials must be completed on the consent form by the participant. Each person's name should be clearly printed alongside their signature. The informed consent discussion should also be documented (including the versions and dates of the documents used) and dated in the participant's medical notes where they are a patient. A copy of the signed consent form must be kept in the patient's medical notes. A copy of the signed consent form will also be kept in the TMF/ISF; the type of file used will depend on the site type. The participant will be given a copy of the signed consent form and the information sheet to keep.

The consent process is ongoing and the participant's continued consent should be reaffirmed at each patient visit and documented in the medical notes. Should there be an amendment to the patient information sheet and informed consent form, and then if instructed to do so by the sponsor the patient must be re-consented following the same process.

The patient's GP will usually be informed of their patient's participation in the study using a letter that has been approved by the REC, HRA and the MHRA in the case of CTIMPs and some device studies. Not all studies require the GP to be notified and therefore if a letter has not been provided by the Sponsor then the R&I Office will be able to advise whether an exception has been approved in the study IRAS application.

Once consent is obtained the participant is enrolled onto the study and allocated a unique study participant number. There must be no duplication of study participant number in the project as a whole. You should be advised by the Sponsor as to how study participant numbers will be allocated i.e. through an electronic data capture, randomisation system or similar.

The date of enrolment is the date the consent was received. The exception for this would be where the participant is entered into the study in an emergency situation, in which case the date of enrolment would be the date they begin participation in the study. The allocation of a unique study participant number and any study related interventions must follow or be concurrent with this date.

For multi-site studies each participating site shall keep its own Participant Screening and Enrolment Log. The entries must be in chronological order.

6.1 Delegation of Responsibility for Informed Consent

The person delegated by the PI to receive consent will most often be a medically qualified investigator, unless the study is non-interventional that does not involve drugs or other treatments, or there is no randomisation to therapeutic modalities. For CTIMPs it is a requirement that the eligibility of the patient is confirmed by a medically qualified investigator that has been delegated to do so by the PI or CI on the trial delegation log.

The General Medical Council (GMC) recommends that when doctors delegate the task of informed consent it is their responsibility to ensure that the person delegated is:

- suitably trained and qualified
- has sufficient knowledge of the proposed investigation or treatment, and understands the risks
- acts in accordance with guidance as set out in GMC "Seeking Patients Consent ; the ethical considerations" (https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/consent)

In addition, a CI or PI for a research study may delegate responsibility for the informed consent process and/or responsibility for being the sole signatory on the Informed Consent Form and record the planned division of tasks in the Delegation Log.

In delegating responsibility for informed consent it is the responsibility of the CI/PI to ensure the following criteria are met:

- The designee is prepared to take on this additional responsibility and is competent to receive informed consent
- They have a comprehensive understanding of the study, potential pharmacological interactions/treatment toxicities and the associated disease area
- The designee should be fully aware of the risks and potential benefits of taking part in the clinical trial
- They should be qualified by experience and/or should have received appropriate training for this study and can evidence this using the forms listed in Section 8

- The delegation of responsibility for obtaining informed consent should be documented on the study's Delegation and Signature Log
- RF, RN, RM, CTA or AHP approval to receive informed consent has been approved in writing, if applicable, using the forms listed in Section 8 by the:
    1. Protocol (if not stated seek approval from the Sponsor)
    2. Principal Investigator (CTIMP or where CTA will consent)
    3. Senior Research Nurse (CTIMP or where CTA will consent)
- Confirmation that the REC does not explicitly exclude nurse or non-medic consent
- An effective line of communication is maintained back to the CI/PI who is ultimately the person responsible for the patient's care and for ensuring that subjects have fully understood what they are consenting to. Where questions arise during the consent process that the individual designated to receive consent can't answer the CI/PI must be consulted before the patient is enrolled into the study.
- All persons who obtain written informed consent must have a copy of their signed and dated CVs in the Study Site File and must have completed the Delegation and Signature Log
- Delegation of informed consent for CTIMPs to RFs, RNs, RMs and AHPs (Pay Band 6 and above only) is permitted where all the above criteria have been met and they have completed appropriate consent/assent training with an appropriate assessor. This decision will be made on a study by study basis by the Sponsor, PI and Lead RN.

6.2 The Mental Capacity Act 2005

The Mental Capacity Act provides the legal arrangements to enable adults lacking capacity to consent to take part in research other than Clinical Trials of Investigational Medicinal Products (CTIMPs) that would otherwise require the participant's consent.

The Mental Capacity act also enables adults with capacity to make arrangements or make their wishes known in advance, to deal with future situations where they lack capacity to consent to take part in research.

Where an adult lacks capacity to consent to take part in research, a personal consultee or legal representative should be consulted. The researcher must provide the consultee/legal representative with information about the research, and ask for advice on whether the person should take part in the research, and what the person's wishes would be likely to be if they had capacity.

6.3 CTIMPs involving minors and incapacitated adults

The Medicines for Human Use (Clinical Trials) Regulations 2004 make legal provision for participation in CTIMPs by adults lacking capacity to consent. In the case of minors or incapacitated adults requiring a legal representative, the personal/professional legal representative must have the opportunity of an interview with the Investigator or a member of the investigation team. They will have been given the opportunity to understand the objectives, risks and inconveniences of the trial and the conditions under which it is to be conducted.

6.4 Consent of Minors

Under the Regulations a "minor" is a person under the age of 16 years. All guidance, advice and statutory provisions previously documented in this SOP apply and in addition extra care and consideration must be applied.

All relevant information must be provided in appropriate written or pictorial form according to their capacity of understanding. The role and responsibilities of those with parental responsibility, guardians and carers must be clearly explained and understood.

Where a minor volunteers consent, a parent or carer with legal responsibility for the minor should also be asked for their assent.
Where it is judged a minor is unable to consent, assent should be obtained, whilst consent should be received from the parent or guardian with legal responsibility for the minor.

The study must be designed to minimise pain, discomfort, fear and any other foreseeable risks in relation to the disease and the minor's stage of development. The risk threshold and the degree of distress have to be specifically defined and constantly monitored. The interests of the participant always prevail over those of science and society.

As soon as the minor reaches 16 years of age they should be asked to re-consent to enable continued participation in the clinical study.

6.5 Consent of Minors in an Emergency Situation

Where treatment needs to be administered to a minor urgently, time may not allow for written consent to be received from either a parent with parental responsibility or legal representative. In such circumstances where it is necessary to take action for the purpose of the study but not reasonably practicable to obtain consent prior to treating the participant action must be carried out in accordance with the procedure approved by the Ethics committee (Medicines for Human Use (Clinical Trials) Act (S.I.2006/2984).

When a minor is treated without prior informed consent from an individual with parental responsibility or legal representative, informed consent must be sought as soon as practicable after the initial emergency has passed. Where informed consent is withheld the minor must be withdrawn from the trial, clear documentation must indicate whether the patient has withdrawn from treatment alone or treatment and follow-up. If the minor has withdrawn completely from the study all samples must be destroyed and the action clearly documented within their medical notes.

6.6 Consent of Incapacitated Adults

All non-CTIMP research studies must comply with the Mental Capacity Act 2005. For CTIMPs there is specific provision for including adults lacking capacity in CTIMPs in Schedule 1 of the Medicines for Human Use (Clinical Trials) Regulations 2004.

All guidance, advice and statutory provisions previously documented in this SOP apply and in addition extra care and consideration must be practiced.

There must first be reasonable grounds for believing that research of comparable effectiveness cannot be carried out if the study has to be confined to, or relate only to, persons who do not have capacity to consent to taking part in. This assessment is made by the Sponsor and NHS ethics committee.

Once a subject has been assessed and identified as potentially eligible for a particular study and is agreeable, the PI, CI or delegated RF/RN/RM/AHP should discuss the process for determining which legally designated representative, parent, guardian or carer should be approached to introduce the study.

Informed consent given by a legal or personal designated representative shall represent the presumed will of an incapacitated adult.

The clinical study must be designed to minimise pain, discomfort, fear and any other foreseeable risk in relation to the disease and the cognitive abilities of the subject.
The risk threshold and the degree of distress have to be specifically defined and constantly monitored.

The interests of the participant always prevail over those of science and society.

6.7 Consent of Incapacitated Adults in an Emergency Situation

Where incapacitated adults require treatment in an emergency situation, time may not allow for the receiving of written informed consent of the patient or of a personal consultee to be obtained prior to treatment. The Medicines for Human Use (Clinical Trials) Regulations (S.I.2006/2984) ascertain administration of a medical product without prior written consent may occur when it is deemed necessary to take action for the purpose of the study as a matter or urgency, whilst not reasonably practicable to receive informed consent. All treatment therefore must be carried out in accordance with procedures approved by the ethics committee documented in the study protocol.

Where it is no longer necessary to take action as a matter of urgency this exemption does not apply, all usual conditions for obtaining informed consent must be adhered too. Retrospective informed consent must be sought as soon as the initial emergency is over. Where consent is withheld the individual must be withdrawn from the study. Documentation must indicate whether the patient has withdrawn from treatment alone or both treatment and follow-up. If the individual has withdrawn completely all study samples must be destroyed and the action clearly documented within their medical notes.

7 TRAINING REQUIREMENTS

Regular GCP for research training is hosted by the Trust R&I Department and includes the informed consent process. Training is delivered by specialist GCP trainers according to NIHR training. The training should be attended by all research active staff. Attendees will be registered via the R&I Department and certificates of attendance issued by the GCP trainer at the end of the course. Investigators who fail to complete the training will be followed up by a member of the R&I Department.

"The Research Dept., will endeavour to notify staff of SOP developments that may be relevant to them. SOPs are available on the Research department website. Updates on SOPs will feature in Research newsletters and communications and disseminate at local research meetings. It is the responsibility of all research active staff to ensure that they read the issued updates that may be relevant to them.

When a new SOP is authorised, or when an existing SOP is revised, self directed training must be carried out by all staff to which the SOP is relevant and this training documented in their training record. A template is provided to support this process. A study specific SOP training plan will be developed for investigators on high risk PHU Sponsored studies.

Staff should take time to read and fully understand the SOP and relevant documents, ensuring that they are able to implement the SOP when required. If clarification is needed then the trainee should approach their line manager and the SOP Controller who will arrange additional training.

All staff should complete their training prior to the published implementation date which will normally be between 2-6 weeks after publication.

All staff are responsible for maintaining their own SOP Training Records and copies must be made available to line managers, the SOP Controller or study monitors on request."

8 REFERENCES AND ASSOCIATED DOCUMENTATION

Associated Documents

- Delegation of Consent Form: Clinical Trial Assistant. [online] Available: https://www.porthosp.nhs.uk/research/sops-and-templates.htm [Accessed February 2020]

- Document: Delegation of Consent Form: CTIMP [online] Available: https://www.porthosp.nhs.uk/research/sops-and-templates.htm [Accessed February 2020]

References

- Statutory Instrument 2004: 1031. The Medicines for Human Use (Clinical Trials) Regulations 2004. [online] Available: http://www.legislation.gov.uk/uksi/2004/1031/contents/made [Accessed February 2020]

- Mental Capacity Act 2005 [online] Available: http://www.legislation.gov.uk/ukpga/2005/9 [Accessed February 2020)

- Human Tissue Act 2004 [online] Available: http://www.legislation.gov.uk/ukpga/2004/30/contents [Accessed February 2020

9 VERSION HISTORY LOG

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Details of Significant Changes
1.0	01/07/2012	N/A
1.1	07/04/2016	Removal of sentence regarding patient withdrawal, additional information regarding SOP training added
2.0	14/11/2017	Re-write of the SOP to update in line with introduction of the UK Policy Framework for Health and Social Care Research (2017). The policy has also been updated to introduce CTA consent on studies with limited risk as defined in this SOP.
3.0	13/08/2020	Review of SOP in accordance with review date. Updated Medicines for Human Use regulation, documentation references and language.

10 APPENDICES

CONFIRMATION OF SOP TRAINING RECORD

A copy of this record may be kept in your personal training file to confirm your training in a specific SOP. The research department or your line manager may request copies to verify your training. If required by a study Sponsor a record may also need to be kept in the Trial Master Files (TMF) or Investigator Site Files (ISF).

SOP Details: To be completed by the SOP Controller	
Title of SOP	Recruiting and Consenting into Clinical Research
Reference Number	PHT/RDSOP/005
Version	V 3.0, 13th August
Issue Date	13th August 2020
Implementation Date	13th September 2020

Personnel Details	
Name	
Job Title & Research Role	
Date of Training	
Nature of Training	Self Directed/Delivered by etc
Records of any meetings to clarify details in SOP	

Signatures
I confirm that I have read and consider myself to be sufficiently trained in the above Standard Operating Procedure with regards to my individual roles and responsibilities Signature of Trainee …… Date ……
I confirm training in the above SOP was delivered as recorded above and that the trainee may be considered sufficiently trained in their roles and responsibilities Signature of Trainer …… Date ……

Additional Notes & Signatures
Signature of Trainer (where appropriate) I confirm training in the above SOP was delivered as recorded above and that the trainee may be considered sufficiently trained in their roles and responsibilities Signature of Trainer …… Date …….