Standard Operating Procedure – Trust-wide

NHS North Bristol NHS Trust

Informed Consent in Adult Research Setting

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Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the process by which North Bristol NHS Trust (NBT) staff receive informed consent from individuals wishing to participate in research where NBT is a participating site.

Key messages

All Researchers recruiting patients and/or healthy volunteers must, in addition to the clinical due diligence, also exercise holistic care due diligence in the preparation and execution of study visits.

You may also need to refer to the following policies and guidance

RI/QMS/SOP/005	Research Staff Training
RI/QMS/SOP/007c	Delegation of Responsibilities
RI/QMS/SOP/007d	Delegation of Responsibilities Log

Operational areas included

All trust areas undertaking research

Operational areas excluded

None

Who should read this?

This SOP should be used by all staff receiving informed consent for research studies within NBT, where NBT is a participating site.

Roles responsible for carrying out this procedure

The Principal Investigator (PI) is responsible for ensuring that informed consent is given by and documented for all participants enrolled in a research study in accordance with the protocol, approved study documentation and ethical approval.

Core accountabilities:

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Executive Sponsor	Dr Rebecca Smith
Approving Committee	Research & Innovation Group

Version history

Version Number	Effective Date	Summary of changes since previous version
1.0	05-05-21	N/A

1. PURPOSE AND SCOPE

The purpose of this Standard Operating Procedure is to describe the process that research staff will follow when receiving informed consent from patients or healthy volunteers wishing to participate in research at NBT, where NBT is a participating site.

Informed consent is defined as:

> "A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form." ICH GCP 1:28 (1997)

It should protect the research subject's rights and well-being, their autonomy and should be an on-going process of information exchange.

It is a legal requirement as stated in the Declaration of Helsinki, adopted by the World Medical Association in 1996 and Good Clinical Practice (ICH-GCP) and forms the foundation of ethical research.

2. DEFINITION Of TERMS

HRA	Health Research Authority
CI	Chief Investigator - The authorised health professional appointed by the sponsor of a research study, whether or not he/she is an Investigator at any particular site, who takes primary responsibility for the conduct and reporting of that study
CTIMP	Clinical Trial of Investigational Medicinal Product
EPR	Electronic Patient Record
ICF	Informed Consent Form
ICH GCP/ GCP	International Conference on Harmonisation guidelines for Good Clinical Practice
MHRA	Medicines and Healthcare Products Regulatory Authority
NBT	North Bristol NHS Trust
PI	Principal Investigator - The PI may be the CI. Where the research involves more than one site, the PI is the person at the site responsible for conducting the research to required standards
PIS	Participant Information Sheet
REC	Research Ethics Committee
SOP	Standard Operating Procedure
Sponsor	The sponsor is the individual, organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in

	place to set up, run and report a research project, as described in the UK Policy Framework for Health and Social Care Research.

3. ROLES AND RESPONSIBILITIES

The Principal Investigator (PI) is responsible for ensuring that informed consent is given by and documented for all participants enrolled in a research study in accordance with the protocol, approved study documentation and ethical approval.

The PI is also responsible for ensuring that where practical, health or social care professionals are notified of the participant's involvement in a research study. This notification can be by means of including a copy of the participant's signed informed consent form and associated PIS in their medical notes and/or by sending a letter to the General Practitioner (GP).

NBT staff are responsible for attending relevant informed consent and study specific training and only receiving consent if they feel confident and competent to do so, with a full understanding of the protocol and associated disease area.

4. WHO SHOULD USE THIS SOP

This SOP should be followed by all staff receiving informed consent for research studies within NBT where NBT is a participating site.

5. WHEN SHOULD THIS SOP BE USED

This SOP should be referred to for all research studies conducted at NBT where NBT is a participating site.

6. PROCEDURE

6.1. Authorised Personnel

All staff receiving consent should be an appropriate member of the research team. Requirement for GCP training will be dependent on the sponsor.

For CTIMPs consent should only be received by an appropriately qualified medical, nursing, midwifery or allied health professional who has undertaken appropriate GCP training. For non-CTIMPs consent can also be received by other staff who have undertaken appropriate valid informed consent training and if required by the sponsor, GCP.

All staff must be logged on the delegation log and signed off by the PI to perform informed consent tasks.

6.2. Training

Staff are required to undertake valid informed consent and study specific consent training prior to receiving consent.

All staff designated to receive consent must provide a copy of their CV, GCP certificate where applicable (see section 6.1) and sign the delegation log stating they will receive consent; this must be signed off by the PI.

Copies of certificates and competencies for any training should be held on record and produced upon request.

6.3. Consent Procedure

Consent must be received prior to any research related procedures taking place.

The participant must receive an up to date version of the Participant Information Sheet (PIS) relating to all aspects of the study. The PIS must have received Research Ethics Committee (REC) approval, HRA and MHRA Approvals where appropriate. All PIS's in use must be identifiable by a version date and number and be localised with the NBT header.

The participant should be given adequate time to consider the information in line with the study protocol.

The information should be presented verbally to the participant by the study team member receiving consent using non-technical language and other resources as appropriate. Other resources, as per protocol and appropriate approvals, may include video, diagrams, consent script or frequently asked questions documents.

Adequate time should be given for the participant to ask questions and have these answered to their satisfaction by a member of the study team.

Once a participant has agreed to participate in the study, the Informed Consent Form (ICF) should be completed as per protocol, signed and personally dated by:

- The participant
- The PI or delegated responsible person

Each person's name should be clearly printed and each person must date his or her own signature only.

The original signed informed consent form will be kept in the study file. The participant will be given a copy of the PIS and signed consent form to keep and a copy should be placed in the participant's medical record or directly uploaded to the Electronic Patient Record (EPR) system.

The informed consent discussion should also be documented in the participant's medical record. In the case of healthy volunteers where no medical records are available,

documentation of the informed consent discussion should be available in the EPR or within the participant's study notes in agreement with the sponsor.

All subjects must be provided with contact details to obtain further information about the study and if appropriate an out-of-hours contact number should be provided.

At all follow-up study visits, research staff must verbally check if the participant is willing to continue in the study and the response must be recorded.

Should new information become available during the course of the study which results in an amendment, participants will need to make an informed decision as to whether they wish to continue in the study. Participants should be provided with a copy of any updated participant facing information (e.g. PIS and ICF) before attending their next study appointment. At the study appointment participants will need to be reconsented using the new, HRA/REC approved paperwork in line with the protocol.

6.4. E-Consent

In studies where an e-consent process is implemented the study specific guidance should be followed in line with the REC/HRA approved study protocol. E-consent may include electronic signatures if conducted remotely or may be in the form of a signature on a tablet or other e-consent compatible device. All consent documentation will need to be printed for storage in the ISF and a copy provided to the participant. Any other storage requirements will be dictated by the protocol.

6.5. Establishing Capacity

Prior to receiving consent the study team member must establish that the participant has capacity to provide consent at that time. If there are concerns regarding a participant's capacity, expert advice must be sought.

Adults lacking capacity may only be approached for studies where provision is made in the protocol and approved by REC. In the case of a CTIMP the Medicines for Human Use (Clinical Trials) regulations (2004) should be followed. In non-CTIMP studies, the Mental Capacity Act (2005) should be used to guide the process. In all studies the presumed will of the participant should inform any decisions made on their behalf.

6.6. Translated Documents

It is the responsibility of the Sponsor to provide translated PIS and ICF's with assurance that they mirror the English version. If localisation of the text is required the Sponsor must clearly indicate where this is needed and the document must then display the NBT header. The translated ICF can be signed by both the participant and study team member receiving consent. A note to file should be added, explaining whilst the person taking consent doesn't understand the translated text it has been assured it is the exact version as written in

English. Any local process in relation to the use of translated PIS/ICF's must also be agreed with the Sponsor.

7. DISSEMINATION AND TRAINING

SOPs will be distributed in accordance with the SOP on Preparation of Research SOPs (RI/QMS/SOP/001).

This SOP and any associated templates and forms will be uploaded to the Trust website (www.nbt.nhs.uk/research) and the Managed Learning Environment (MLE) system on the Trust intranet shortly after having been released.

All staff whose activities are subject to this SOP should ensure that they read and understand the content of this SOP. The training log within the Investigator Site File/Trial Master File should be completed to document that members of staff have read and understood the content of this SOP.

8. REFERENCES

- Health Research Authority
  UK Policy Framework for Health and Social Care Research
  www.hra.nhs.uk

- ICH Secretariat
  Guidelines for Good Clinical Practice (E6 R2, Step 4, 2016)
  www.ich.org

- MHRA
  Clinical Trials for Medicines
  www.gov.uk/guidance/clinical-trials-for-medicines-manage-your-authorisation-report-safety-issues

- UK Government
  Medicines for Human Use (Clinical Trials) Regulations 2004
  www.legislation.gov.uk

- UK Government
  Mental Capacity Act 2005
  www.legislation.gov.uk