Standard Operating Procedure

INFORMED CONSENT FOR RESEARCH PURPOSES

SETTING Trustwide

AUDIENCE All staff receiving informed consent for research studies within University Hospitals Bristol & Weston NHS Foundation Trust (UHBW)

ISSUE To describe the process by which UHBW staff receive informed consent from individuals wishing to participate in research.

QUERIES Research Matron via email: Research@uhbw.nhs.uk

Document History

SOP number	SOP 027	**SOP Version**	1.0
Effective Date	28/05/2021	**Review Date**	28/05/2023

Review date	Version number	Version date	Effective date	Author/ Reviewer	Authorised by
Original SOP	1.0	15/MAR/2021	28/MAY/2021	Nicola Manning	Diana Benton on behalf of Trust Research Group

Version Number	Reason for change
Original V1.0	Original

1. Introduction

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.

This Standard Operating Procedure (SOP) describes the procedure for receiving written informed consent from patients or healthy volunteers participating in research studies within UHBW.

2. Purpose

The purpose of this SOP 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 UHBW.

3. Scope

In Scope: UHBW staff involved in receiving informed consent for research purposes.
Out scope: UHBW staff involved in other elements of the informed consent process for research purposes.

4. 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 GP.

UHBW 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.

5. Abbreviations and Definitions

Abbreviations	
CI	Chief Investigator
CTIMP	Clinical Trial of Investigational Medicinal Product
DMS	Document Management System
EPR	Electronic Patient Record
GCP	Good Clinical Practice
ICF	Informed Consent Form
ISF	Investigator Site File
MHRA	Medicines and Healthcare Products Regulatory Authority
PI	Principal Investigator
PIS	Participant Information Sheet
REC	Research Ethics Committee
R&I	Research & Innovation
SOP	Standard Operating Procedure
UHBW	University Hospitals Bristol and Weston NHS Foundation Trust

Definitions	
CI	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
PI	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

6. Procedure

6.1 Authorised personnel

All staff receiving consent should be an appropriate member of the research team and have up to date GCP training.

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 in addition to GCP.

All staff must be logged on the delegation log and signed off by the PI to perform informed consent tasks. Where it is known that named staff will undertake informed consent as part of the research, this person (s) should be named on the Study Site Information form prior to submitting the research for approval at site.

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 and sign the delegation log stating they will receive consent; this must be signed off by the PI.

Staff working on research studies who are not receiving consent should attend appropriate consent training to understand the process of consent to clinical trials and research.

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, be identifiable by a version date and/or number and be localised with the UHBW 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 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 patient will be given a copy of the PIS and signed consent form to keep and a copy should be placed in the patient's medical record or directly uploaded to the Electronic Patient Record (EPR) system.

The informed consent discussion should also be documented in the patient'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 trial and if appropriate an out-of-hours contact number should be provided.

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

Should new information become available during the course of the trial which may affect a participant's decision to continue, they should be re-consented using the amended approved PIS and ICF.

6.3 E-consent

In studies where an e-consent process is implemented the above procedure should be followed however completion and storage of consent documents should be undertaken in line with the study 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 Paediatrics

For guidance on receiving consent in a paediatric setting please refer to the W&C division SOP - Receiving Informed Consent in Paediatric Research Participants

6.7 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 UHBW 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 in the SOP

This SOP will be disseminated to applicable research staff (including R&I) and will be available on the R&I website.

All staff whose activities are subject to this SOP should ensure that they read and understand the content of the SOP. The personal training log of the individual (and the Investigator Site File/Trial Master File if required) should be completed to document that the content of this SOP has been read and understood as described in *SOP 007 Research Training*.

REFERENCES	N/A
RELATED DOCUMENTS AND PAGES	• SOP_008 Investigator Oversight • SOP_007 Research Training UHBW UHBW Research SOPs located at http://www.uhbristol.nhs.uk/research-innovation/for-researchers/templates-and-sops/ • SOP Receiving Informed Consent in Paediatric Research Participants (UHBW) • ICH GCP • Medicines for Human Use (Clinical Trials) regulations (2004) • Mental Capacity Act (2005) • MHRA, Good Clinical Practice Guide 2012
AUTHORISING BODY	Trust Research Group
SAFETY	N/A
QUERIES AND CONTACT	Contact the Research & Innovation Department on 0117 342 9873 or research@uhbw.nhs.uk