UNIVERSITY OF WARWICK

STANDARD OPERATING PROCEDURE 07

Participant Information and Consent

Version:	4.0
Approval Date:	20/08/2026
Effective Date:	03/09/2026
Review Date:	02/09/2026
Review Lead:	Jo Grumett, Quality Assurance Manager, WCTU
WCTU Reviewers:	Jonathan Guck, Trial Manager, WCTU Deepthi Krovi, Clinical Trial Coordinator, WCTU Sara Wood, Trial Manager, WCTU
Sponsor Reviewers:	Mathew Gane, Research Governance & QA Manager, R&IS
WCTU approval:	Natalie Strickland, Head of Operations, WCTU
Sponsor approval:	Carole Harris, Assistant Director Research Culture, Governance and Compliance, R&IS

Revision Chronology:	Effective date:	Reason for change:
Version 4.0	3 September 2026	Biennial review. Move to new template. Reduce length of text and include signposting to available information. Updates in line with CT Regulations.
Version 3.0	12 March 2024	Biennial review: Addition of new HRA Quality Standards and Design and Review Principles for creating participant information. Web links updated.
Version 2.0	17 November 2021	Biennial review: Change to new format. Update web links. Updated information on obtaining consent remotely. Updates to guidance on producing PIL/CFs.
Version 1.7	24 July 2019	Biennial review: Multiple updates to text and web sites throughout the document. New sections 3.3.6.4 & 3.3.6.5
Version 1.6	19 July 2016	Addition of new sections (3.3.2.3, 3.3.6, 3.3.7, 3.3.8) and clarification of text (3.3.3, 3.3.4). Web links updated. Change to new format.
Version 1.5	6 January 2014	Addition of process to generate, review and approve documentation. Section order rearranged.
Version 1.4	31 October 2012	Biennial review: Update web links. Information on consent process for minors added.
Version 1.3	22 August 2010	Biennial review: Removal of reference to LREC approval only (section 3.1).
Version 1.2	22 August 2008	Addition of information relating to the Mental Capacity Act and obtaining consent from persons whose first language is not English.
Version 1.1	11 April 2008	Format change. Update web links. Updated NRES information. Incorporate new regulations.
Version 1.0	March 2006	

UNIVERSITY OF WARWICK

CONTENTS

1 Purpose and Scope

To detail procedures for providing information to potential research participants, obtaining consent from participants, and providing information to participants at the end of the study, in scenarios including:

- Adults with capacity
- Adults lacking capacity
- Emergency situations
- Minors
- Those whose first language is not English
- Remote consent
- Electronic consent

Guidance on the development of Participant Information Sheets (PIS) and Consent Forms (CF) is available from the Health Research Authority (HRA) website.

This SOP is applicable to University of Warwick staff involved in the recruitment of participants into a research study and to externally sponsored studies where use of Warwick SOPs is agreed.

2 Acronyms

CF	Consent Form
CI	Chief Investigator
CTIMP	Clinical Trials of Investigational Medicinal Product
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
GP	General Practitioner
HRA	Health Research Authority
ICH	International Conference on Harmonisation
IMP	Investigational Medicinal Product
ISF	Investigator Site File
MCA	Mental Capacity Act
MHRA	Medicines and Healthcare products Regulatory Agency
MRC	Medical Research Council
NETSCC	NIHR Evaluation, Trials and Studies Coordinating Centre
NIHR	National Institute for Health and care Research
PI	Principal Investigator
PIL/PIS	Participant Information Leaflet/Participant Information Sheet
PPI	Patient and Public Involvement
QA	Quality Assurance
REC	Research Ethics Committee
R&IS	Research & Impact Services
SOP	Standard Operating Procedure
TMG	Trial Management Group
WCTU	Warwick Clinical Trials Unit

3 Definitions

Informed Consent	A process by which a participant or legal representative voluntarily confirms their willingness to participate in a study after having been provided with sufficient information and the opportunity to discuss all aspects of the trial

	relevant to their decision to participate. Informed consent is documented by means of a written (paper or electronic), signed and dated informed consent form. Obtaining consent remotely may be considered when appropriate.
PIS	Used to explain the purpose of the study, what participants will be required to do and how participants will be involved. It should be in plain English, using language appropriate to the target audience. Documents may be translated into other languages. This may be in paper or electronic format. May be referred to as a PIL.

4 Background

In obtaining and documenting informed consent, the Investigator should comply with the applicable regulatory requirement(s) and should adhere to GCP and to the ethical principles that have their origin in the Declaration of Helsinki.

For CTIMPS, Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025) must be followed.

For non-CTIMPS, procedures, devices or investigations the MCA 2005 will be applied. An overview is available here: HRA: Mental Capacity Act

Both the Clinical Trials Regulations and the Mental Capacity Act have the same status in law.

There are scenarios where obtaining consent is not possible and if there is a need to access confidential patient information without consent in England and Wales, refer to: SOP 43 Seeking and Maintaining Approval from the CAG.

In some circumstances, for example questionnaire studies where individuals are identified as participants from a GP's list, consent may be 'implied' rather than explicit. Therefore, if a person responds to an unsolicited questionnaire, the fact that they have completed and returned the questionnaire implies their consent.

Consent is an ongoing process of information exchange, not just the provision of a signature. This process involves the giving of information, the discussion and clarification of the information and obtaining the participant's verbal and written consent, with sufficient information and time to allow them to decide whether they want to take part.

For more information refer to ICH GCP E6R3. The HRA provide guidance on consent and the preparation of information for different study participants, with an online tool to describe specific requirements for vulnerable groups.

Refer to the University of Warwick Ethics and Research Code of Practice.

5 Responsibilities

CI (or delegate)	• Prepare materials to inform staff of the consent process • Provide appropriate training to staff • Provide recruitment locations with any updated materials • Maintain oversight of consenting process at study locations
PI (or delegate)	• Ensure staff are appropriately trained in consent procedures • Ensure staff delegated to obtain consent are listed on the delegation/training log • Provide written and verbal information to potential participants

	• Provide oversight of recruitment activities at site • Ensure continuing consent is documented

6 When

Consenting procedures are applicable at all stages of a study.

For adults with capacity in non-emergency situations, informed consent must be obtained:

- After checks to determine eligibility
- Before randomisation
- Before study-related procedures that would not have been performed during routine management of the participant
- Before baseline assessment

The provision of information should be an on-going process performed by appropriate members of the research team. When new information becomes available and/or the protocol is updated, the participant may need to re-consent in order to continue involvement in the study.

Once consent is in place, study activities may commence. The prospective participant should be provided with sufficient time and opportunity to read the PIS and discuss the study with others.

7 How

7.1 Generation, review and approval of PIS and CFs

Refer to the Health Research Authority templates, ensuring key information is included.

Other media may be used to support the consent process (images, diagrams, audio, video, online materials).

PIS and CFs should be generated, reviewed and approved by study personnel with an appropriate level of knowledge and experience, and this should involve a PPI representative.

A process should also be undertaken and documented to cross-check these documents with others which contain study information, to ensure consistency across all documents (e.g., protocol and PIS).

It is essential that consenting procedures are thoroughly considered for the study during setup, clearly and consistently documented in the protocol, and approved by REC to ensure insurance requirements are met.

This process applies to any amendments made to the consenting materials (see SOP 6: Amendments to Approved Study Documents).

7.2 Adults with capacity

In the case of adults with capacity the following procedure should be followed:

- Determine who is responsible for obtaining informed consent
- Provide written information in an appropriate format
- Give sufficient time to read the materials, ask questions and consider participation
- Participant and person obtaining consent, sign and date the consent form
- Participant given a copy of the consent form

7.2.1 Informing the participant

Prior to the start of any study, written approval from the REC will be obtained for the consent process and use of the PIS, CF and other information to be provided to participants. The HRA have produced guidance on preparing information for participants via their Design and Review Principles and these must be implemented

Information should be provided to potential study participants in both an oral and written form.

Information may be presented to potential participants using different media/formats, including video, posters, recorded consultations, etc.

The PIS and CF should be revised when necessary, i.e., when new information becomes available that may be relevant to the participant's consent. Any revisions should be approved by the REC **before** use, and the process of disseminating the information and any re-consent requirements agreed by the TMG. The participant should be informed of new information in a timely manner. The communication of this information should be documented in the participant's medical records and study records.

When approaching potential participants to obtain consent, the following points must also be considered:

- Neither the Investigator nor any member of the research team should coerce or unduly influence a participant to participate or to continue to participate in a study.
- Information imparted to the participant (written or verbal) should not contain any language that causes the participant to waive (or appear to waive) any legal rights, or that releases (or appears to release) the investigator, institution or sponsor from liability for negligence.
- The PIS and CF should be identifiable by date and version number and should include details of the institution responsible for the study.

7.2.2 Obtaining informed consent

When the person obtaining informed consent is satisfied that the participant has been fully informed and understands what study participation entails, the CF should be personally signed and dated by the participant and by the authorised person who conducted the discussion.

For paper forms, the original form should be filed in the ISF, one copy given to the participant and a copy filed in the participant's medical records. For electronic patient records and/or electronic ISFs, documents should be uploaded to the appropriate system.

Participants should receive copies of all relevant, new information, regarding the study throughout their participation and re-consented if applicable. Details of participation (discussions, interventions, study visits) should be documented in their medical records.

It is good practice that the participant's General Practitioner should be informed in writing about their patient's participation and receive appropriate information regarding the study. This requires the patient's consent.

In emergency situations where an adult has capacity, but time pressure does not allow for a lengthy consent process and reflection time, a brief verbal consent process may be possible with provision of summary information leaflets, with the opportunity to opt out. Full consent will be obtained subsequently after the emergency has passed. The proposed consent process must be explained and justified in the protocol and approved by REC. Details of the process and conversations with those participants recruited under emergency provisions should be fully documented in the patient's medical records. Consideration should be given to the process to follow when a participant dies before consent is obtained. See HRA guidance on research in emergency settings.

7.2.3 Changes in capacity

If an adult with capacity gives informed consent to participate in a CTIMP but subsequently becomes unable to give informed consent by virtue of physical or mental incapacity, the consent previously given when capable remains legally valid, provided the protocol does not change significantly. If there is a significant change to the protocol (e.g. which would affect participation or safety) and the participant has lost capacity, a relevant legal representative should be approached for ongoing consent.

For other types of research the provisions of the Mental Capacity Act will come into force and the procedure outlined in the Mental Capacity Act, Adults with Incapacity (Scotland) Act 2000, and/or Mental Capacity Act (Northern Ireland) must be followed.

If an adult with capacity refuses to give informed consent, and subsequently becomes unable to give informed consent, the refusal is legally binding. They cannot be entered into the study by seeking consent from a legal representative.

If there is a concern that participants may lose capacity during the course of a non-CTIMP study, discussions regarding their on-going options should be instigated. This should be done as early as possible so personal wishes can be considered.

The protocol should detail whether participants should be withdrawn from or remain in the study if a participant loses capacity, and this will be dependent on the requirements of their continuing involvement.

7.2.4 Capable adults with a disability affecting their ability to sign a CF

If a potential participant with mental capacity is unable to provide written consent, for example due to an injury or disability which means they are unable to write, consent should be taken verbally in the presence of a witness (who, where possible should be independent of the study delivery) and the reasons why this approach was taken must be recorded in writing. The witness may sign the consent form on behalf of the participant.

If the injury or disability is not permanent, the participant should be re-consented and personally sign a consent form as soon as it is feasible for them to do so.

This scenario may also occur with patients who indicate that they wish to take part in a study but want a family member/friend to sign the consent form on their behalf.

N.B. In CTIMPs, consent is not considered to be legal unless there is written evidence to show the consent process has been completed. This may be evidenced for example by the participant making a mark which is witnessed.

7.3 Adults who lack capacity

The HRA website contains Guidance for each UK Nation relating to adults unable to consent for themselves. Frameworks differ between each nation and therefore the Guidance should be followed for studies recruiting in England, Scotland, Wales and Northern Ireland.

The study protocol should describe the proposed criteria and methods to assess the capacity of potential participants to assess if they are able to provide consent personally or if an alternative method will be required.

The protocol should also detail the training requirements of those members of staff obtaining consent.

7.3.1 Next of Kin data

It may be necessary to collect and retain data from a participant's Next of Kin as part of the consent process. Consideration should be given to ensuring transparency regarding the data collected and the limited purpose. If the Next of Kin is informed via the participant, the rationale should be documented.

7.3.2 Incapacitated adults in CTIMPs

In non-emergency situations where it is not possible to obtain consent from the participant themselves, a hierarchy determines the type of legal representative that should be approached, given the study information, and asked to give informed consent on behalf of an incapacitated adult prior to their inclusion in a study:

1. Personal legal representative – a person not connected with the study who is suitable to act as the legal representative by virtue of their relationship with the adult and is available and willing to do so
2. Professional legal representative – a person not connected with the study who is either primarily responsible for the adult's medical treatment, or is a person nominated by the relevant health care provider

The legal representative must be given an Information Sheet which should have the same content as the PIS. This may be done by rewording the PIS to reflect the fact that they are consenting on behalf of the participant, e.g., amend "you will" to "your relative/friend will" or by adding an explanatory cover note to the front of the patient PIS.

Time must be allowed for consideration and for the representative to ask any questions which arise before the process can be completed. The representative and the person taking consent must sign and date the CF.

If a participant who has been enrolled into a study whilst incapacitated then regains their capacity, the consent process for adults with capacity should be followed.

Where the IMP needs to be administered urgently to a patient who is unconscious, time may not allow for the written consent of a legal representative to be obtained first. Incapacitated adults can be entered into a study prior to consent being obtained provided that:

Having regard to the nature of the study and the particular circumstances of the case, it is necessary to take action for the purpose of the trial as a matter of urgency but

- It is NOT reasonably practicable to obtain informed consent prior to entering the subject, and
- The action to be taken is carried out in accordance with a procedure approved by REC.

7.3.3 Incapacitated adults in all other research

It is a key principle of the Mental Capacity Act that all steps and decisions taken for someone who lacks capacity must be taken *in the person's best interests*.

It is the responsibility of the person obtaining consent to assess the capacity of each potential participant according to the requirements stated in the protocol.

Under the Mental Capacity Act, the following factors must be considered when assessing if someone has capacity to make a decision:

- Whether they can understand the information
- Whether they can retain the information related to the decision to be made i.e., are they able to retain the information long enough to enable them to make a decision
- Whether they can use or weigh that information as part of the process of making the decision

- Whether they can communicate that decision – by any means, (e.g. blinking an eye).

Any research involving a person lacking capacity that would otherwise have required consent from participants may only lawfully be carried out if a REC has given a favourable opinion.

In **non-emergency** situations agreement must be obtained from a consultee:

- A **personal consultee** may be a family member/friend, carer or attorney acting under a legal Power of Attorney, as long as they are not paid to look after the person and their interest in the welfare of the person is not a professional one.
- If no personal consultee is available, a person not connected with the research project should be approached – this person is usually known as a **nominated consultee** and is likely to be a registered medical practitioner who is not involved in the organisation or conduct of the research project.
- If a nominated consultee provides consent and then a personal consultee becomes available whilst the participant lacks capacity, the personal consultee should be approached to consider ongoing participation in the trial.

Whoever the person involved in the consultation process is, they must be provided with all the relevant information and must consider:

- the person's past and present wishes and feelings (and, in particular, any relevant written statement made by them when they had capacity. Their wishes in relation to such statements should be respected.
- the beliefs and values that would be likely to influence their decision if they had capacity, and
- the other factors that they would be likely to consider if they were able to do so.

The person will be asked to sign a declaration stating that in their view the person who lacks capacity would have wanted to take part in the study.

In **emergency situations**, if it is not possible to consult with a consultee in sufficient time, then agreement should be obtained from an independent registered medical practitioner or comply with any other requirement of the REC.

In all cases, when the emergency situation has passed, arrangements should be made to seek consent or agreement from the participant or consultee (as appropriate) for continued participation in the study following the consent process detailed in the protocol and approved by the relevant REC.

7.3.4 Adults who regain capacity during a study

Where capacity may be regained during the course of a study, a plan must be in place to detail how they will be involved in the on-going consent process.

In most cases it is appropriate to ask them to give their own consent. If you intend to ask participants who regain capacity for their on-going consent:

- Inform the legal representative (CTIMPs) or consultee (other research) of this at the outset
- Prepare an appropriate PIS and CF for the participants that explains what has happened so far, and for the reasons for seeking their consent.
- Plan how you will handle a participant withdrawing consent at each stage of the study and tell them what they can expect.

7.4 Minors

Research should only include children where the relevant knowledge cannot be obtained through research in adults.

The requirements for consent, where participants are children and/or young people, depend on:

- The type of study
- In which UK nation it is taking place.

The HRA provides guidance on the legal frameworks and national requirements and should be consulted for study-specific requirements: The Principles of consent: UK Nations

Further guidance specific to obtaining consent from minors in CTIMPs and in emergency situations is available via HRA - Informing participants and seeking consent

7.5 Cluster Randomised Trials

In clinical trials where the randomisation is at the group rather than the individual level, individual consent is usually not possible. The protocol for cluster-randomised trials will need to state explicitly whether individual consent is possible, and at what stage it would be possible to obtain that consent. It will include whether, and how, it might be possible to opt out of the intervention(s). Individual consent is still required for data collection when confidential information is collected or when there is direct contact with individual participants for assessing outcome measures.

7.6 Consent from those whose first language is not English

When recruiting participants whose first language is not English, documents and materials may need to be translated into a language the participant does understand.

Accurate translation is required. An explanation of the translation process should be provided to the REC and the translated documents and back-translated versions should be available for REC review.

During the consent process an independent translator may be required to ensure the potential participant has a full understanding of the PIS, the issues, and risks and benefits of the trial prior to consenting. NHS Trusts may provide an independent translator to be present, alternatively external providers may be used e.g., Language Line Solutions.

The translator should not be a family member/non-professional translator. Potential participants must be allowed sufficient time to consider whether they wish to take part after a meeting with a translator. A second meeting with the translator may be required to ensure the person has understood the information provided, has had the opportunity to discuss their participation with others and is content to sign the consent form.

Consideration should be given to translation support which can be provided throughout participation in the trial.

7.7 Additional Considerations

7.7.1 Consent for the use of anonymised quotes from participants

If a researcher wishes to use anonymised quotes during an interview or focus group, this should be considered in advance. Explicit consent for any publication of quotes must be obtained and documented on the consent form.

7.7.2 Use of/holding personal identifiable data

Personal identifiable data may be required within a study for several reasons including (but not limited to) long term tracking, sending follow-up forms via the post, sending summary study reports to participants etc. Information as to why these data are required, how they will be collected and stored and who has access must be included in the PIS to ensure transparency. Retention of any personal identifiable data for use within a research study must comply with the UK GDPR.

7.7.3 Additional requirements for NIHR funded research

All participant materials must include the NIHR logo whenever possible, following the NIHR branding guidelines.

7.7.4 Seeking consent by electronic methods

The MHRA and HRA have published a joint statement, which sets out the legal and ethical requirements for seeking and documenting consent using electronic methods. It contains guidance and considerations:

- Can the signature be dated either manually by the participant or automatically by the eConsent system?
- Is it possible to verify to which version of the PIS and CF the electronic signature applies?
- Are methods in place to ensure that the person signing the electronic consent form is the person who will be participating in the research study?

Plans for obtaining consent using electronic methods must be discussed by the TMG and for WCTU studies, involve the QA and programming teams to ensure the proposed method is feasible and is not likely to lead to digital exclusion of any potential participant groups.

Should it be necessary to amend an electronic consent form (eCF) during a study:

- Ensure all eCF changes are discussed and agreed with a multidisciplinary team including trial manager, senior project manager, programmer, and a QA team member to ensure there is harmony between what the updated consent form needs to be capturing and how this is achieved and stored electronically.
- Create a new eCF for participants to provide ongoing consent after the consent form has been updated or for new participants to access. Ensure the new eCF is a separate electronic entity from the original eCF. The original eCF which will no longer be used should be stored for all those that completed it. Do not attempt to edit, amend or overwrite the original eCF and rename it as the new eCF as this will disturb the audit trail.
- For online studies, consider how the creation of a new eCF may affect other electronically automated processes e.g., if the sending of a text message to a participant is dependent upon completion of the eCF, ensure the system is now determining this based on completion of the new eCF.

7.7.5 Considerations where the participant is remote at the time of consent

There are some circumstances where face-to-face verification is not possible at the time of consent (e.g., self-referrals, postal consent where patients have not been identified by a healthcare professional). The conduct of a remote consent procedure would have to be approved by the relevant bodies (e.g., REC and MHRA). A risk-based approach should be followed if this process is being considered. In studies where remote consent procedures are implemented, researchers should consider methods to verify participant identity (as far as is practicably possible):

- Use a video link

- When the participant visits a study site for the purposes of the trial/ study then verification can be done in person using information from official photo ID
- Utilise general practices or other NHS sites local to the participant in order to verify their identity.
- Methods used to identify the identity of any legal representatives or consultees.

7.8 Information for participants at the end of a research study

The HRA have developed guidance to explain how and what information must be provided to participants, their legal representatives, consultees, relatives or close friends (where applicable), at the end of a trial/ study.

Sponsors/CIs will need to apply their judgement in applying the HRA guidance to a specific trial or research study.

As details of how study findings will be communicated to participants may not be known at the outset of a study, an additional information sheet outlining these details should be produced to deliver more up-to-date information.

See also SOP 22 'Publication and Dissemination' and SOP 28 'Transparency in Research Studies'.

7.9 Withdrawal of consent

A participant has the right to withdraw from a research study at any time without being subject to any form of detriment. Following withdrawal, no further protocol procedures should be undertaken (unless the participant agrees to continue with planned follow-up).

Data and samples already collected before withdrawal may be retained and used in the study analysis. The participant may request that no further data are added to the database, that any retained samples are destroyed and (on rare occasions) that previous data collected are not used. Processes must be in place to ensure clarity on the withdrawal status of each participant and the data which can and cannot be collected and retained.

Requests to delete data already collected are dealt with in accordance with the 'right to erasure' and are managed by the University's Legal and Compliance Services procedures which can be found here. Requests are submitted via a data subject right's form and should be forwarded to the Legal and Compliance team as soon as possible as a response to a request for erasure should be dealt with without undue delay, and at the latest within one month, to let the individual know whether the data in question has been erased, or that their request has been refused (if an exemption applies). Contact infocompliance@warwick.ac.uk.

The reason for withdrawal should be ascertained if possible and documented.

7.10 Simplified arrangements for consent

MHRA guidance sets out the legal requirements and ethical principles for using simplified arrangements to seek and evidence informed consent in low risk CTIMPs. Guidance via HRA is available here: Simplified arrangements for consent

8 Associated Templates and Documents

C01	ICF Checklist
C03	PIS Checklist
G37	Patient Accessibility Guidance