STANDARD OPERATING PROCEDURE 7

Participant Information and Consent

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Author:	Claire Daffern, Quality Assurance (QA) Manager, Warwick Clinical Trials Unit (WCTU)		
WCTU Reviewers:	Alice Longe, Clinical Trial Manager, WCTU Lucy Eggleston, Clinical Trial Coordinator, WCTU Lauren Betteley, Clinical Trial Manager, WCTU		
Sponsor Reviewers:	Mathew Gane, Research Governance & QA Manager, Research & Impact Services (R&IS)		
WCTU approval:	Natalie Strickland, Head of Operations, WCTU		
Sponsor approval:	Carole Harris, Assistant Director, R&IS (Systems & Strategic Projects) & Head of Research Governance		
Review Lead:	WCTU QA Team		

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Revision Chronology:	Effective date:	Reason for change:
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	

STANDARD OPERATING PROCEDURE 7

Participant Information and Consent

1. Purpose and Scope

This Standard Operating Procedure (SOP) details procedures for providing information to potential research participants and obtaining consent from participants in various scenarios including:

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

The SOP also contains guidance from the Health Research Authority (HRA) regarding information which should be made available to participants at the end of a trial/study and National Institute for Health and care Research Health Technology Assessment (NIHR HTA) requirements for submission of trial/ study participant materials.

It also describes the procedure to follow to generate, review and approve new or amended versions of Participant Information Leaflets (PIL) and Consent Forms (CFs).

There is extensive guidance on the development of PIL and CFs 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/trial or facilitating recruitment from a study coordinating centre. It is also applicable to any externally sponsored studies where use of Warwick SOPs is agreed.

2. Definitions

Informed Consent	The EU Clinical Trials Directive (2001/20/EC) Article 2 defines informed consent in the following way: "informed consent: decision, which must be written, dated and signed, to take part in a clinical trial, taken freely after being duly informed of its nature, significance, implications and risks and appropriately documented, by any person capable of giving consent or, where the person is not capable of giving consent, by his or her legal representative; if the person concerned is unable to write, oral consent in the presence of at least one witness may be given in exceptional cases, as provided for in national legislation.
Participant Information Sheet/Leaflet (PIS/L) (For brevity/consistency purposes, the term PIS will be used in this document)	The participant information sheet/leaflet is used to explain the purpose of the research study and 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. In some cases, it will be appropriate to have the information sheet translated into a language other than English, or to provide an interpreter. This may be in paper or electronic format.

Investigator	A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the leader with responsibility for the team and may be called the Principal Investigator (PI)

3. Background

It is morally and professionally unacceptable to perform any research related procedure on someone without first obtaining their informed consent. However, there are occasions where exceptions arise.

Special conditions apply when research involves those in emergency situations, those who have mental incapacity and/or minors (see sections 4.3.3 and 4.3.4). In all cases, the study protocol should clearly describe the process to be followed which must always be approved by the relevant Research Ethics Committee (REC).

For Clinical Trials of Investigational Medicinal Products (CTIMPs), The Medicines for Human Use (Clinical Trials) Regulations 2004 must be followed in all situations. The Mental Capacity Act (MCA) 2005 will be applied if the research involves non-drug interventions, procedures, devices or investigations. Within the Act, sections 30 – 34 relate to research. 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 an application to the Confidentiality Advisory Group (CAG) is required.

Further details are available on the HRA website and SOP 43 'Seeking and Maintaining Approval from the CAG'.

It is important to remember that 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. Potential recruits to a research study must be given sufficient information and time to allow them to decide whether they want to take part.

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.

For more information refer to section 4.8 of the International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) guidelines. The HRA provide guidance on consent and the preparation of information for a range of different trial/ study participants along with an online tool to help understand specific requirements for vulnerable groups.

You are advised to refer to the University of Warwick Ethics and Research Code of Practice.

4. Procedure

4.1 Responsibilities

Chief Investigator (or delegate)	• Prepare materials to inform site teams of the study specific consent process • Provide appropriate training to sites (ongoing, as applicable) • Provide sites with updated materials (as required) • Maintain appropriate oversight of consenting process at each site
Investigator, or a person designated by the Investigator	• Ensure site staff are appropriately trained in study consent procedures • Ensure site staff delegated to obtain consent are listed on the site delegation log • Provide written and verbal information to potential participants • Provide oversight of recruitment activities at site • Ensure continuing consent is documented

4.2 When?

This SOP is applicable before recruitment begins, and during the recruitment and follow-up periods of a trial/research study. Appropriate consent must be obtained from all participants.

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

After checks to determine eligibility have been performed

Before randomisation and any trial/ study-related procedures are performed*

Before baseline assessment is performed

**Any procedure that would not have been performed during normal management of the participant. This could include some eligibility checks.*

However, the consent process should not cease once initial consent is obtained. The practice of giving information about the trial/study to participants should be an on-going process performed by all members of the research team. This is particularly significant with the introduction of protocol amendments and the availability of important new information that may be relevant to the participant's willingness to continue taking part in the study. In these circumstances it may require the study participant to re-consent on an amended consent form in order to continue involvement in the study.

The timing of the signing of the consent form relative to the initiation of study procedures, and the process used to obtain consent, is subject to audit by governing bodies (e.g., Medicines and Healthcare products Regulatory Agency (MHRA)). Once consent is in place, study procedures may commence. The prospective participant should be provided with ample time and opportunity to read the PIS and discuss the study with family, friends or others. There are no fixed guidelines on the time to be allowed for consideration. Each study must be considered individually, and the time provided should be proportionate to the complexity of the study and the makeup of the patient group involved. Time

given for consideration and the reason for the particular approach must be documented in the protocol and approved by the REC.

In emergency situations **or** where a person lacks capacity to consent, but an intervention needs to be administered urgently, for example to an unconscious patient, time may not allow for gaining the written consent of a legal representative. In Clinical Trials of Investigational Medicinal Product (CTIMPs), The Medicines for Human Use (Clinical Trials) (Amendment No2) Regulations 2006 allows incapacitated adults to be entered into a study prior to consent being obtained (with certain provisions). In non-CTIMPs, the provisions within the Mental Capacity Act to involve such participants should be adhered to.

4.3 How?

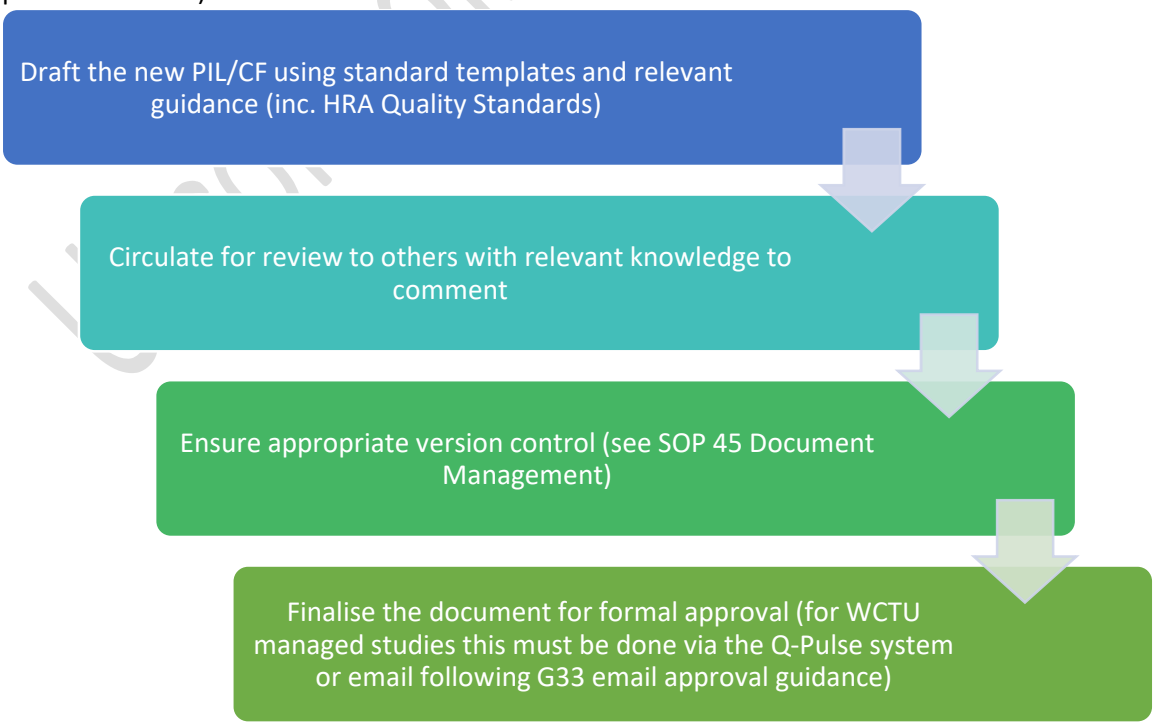
4.3.1 Procedure for the generation, review and approval of PIS and CFs

Written and verbal information must be given to potential participants in order for them to make an informed decision whether they wish to take part in a study. The written information must include key items defined by the Health Research Authority (HRA) - see also Appendix 1.

In some cases, it might be more appropriate to use other media to support the consent process, for example images, diagrams, audio, video or online materials etc. When using alternative formats, you should be mindful that some formats may unintentionally discriminate against people who are not comfortable with or who cannot use such technology.

PIS and CFs should be generated, reviewed and approved by study personnel with an appropriate level of knowledge and experience. It is also good practice to include input from a Patient and Public Involvement (PPI) representative in the review process.

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



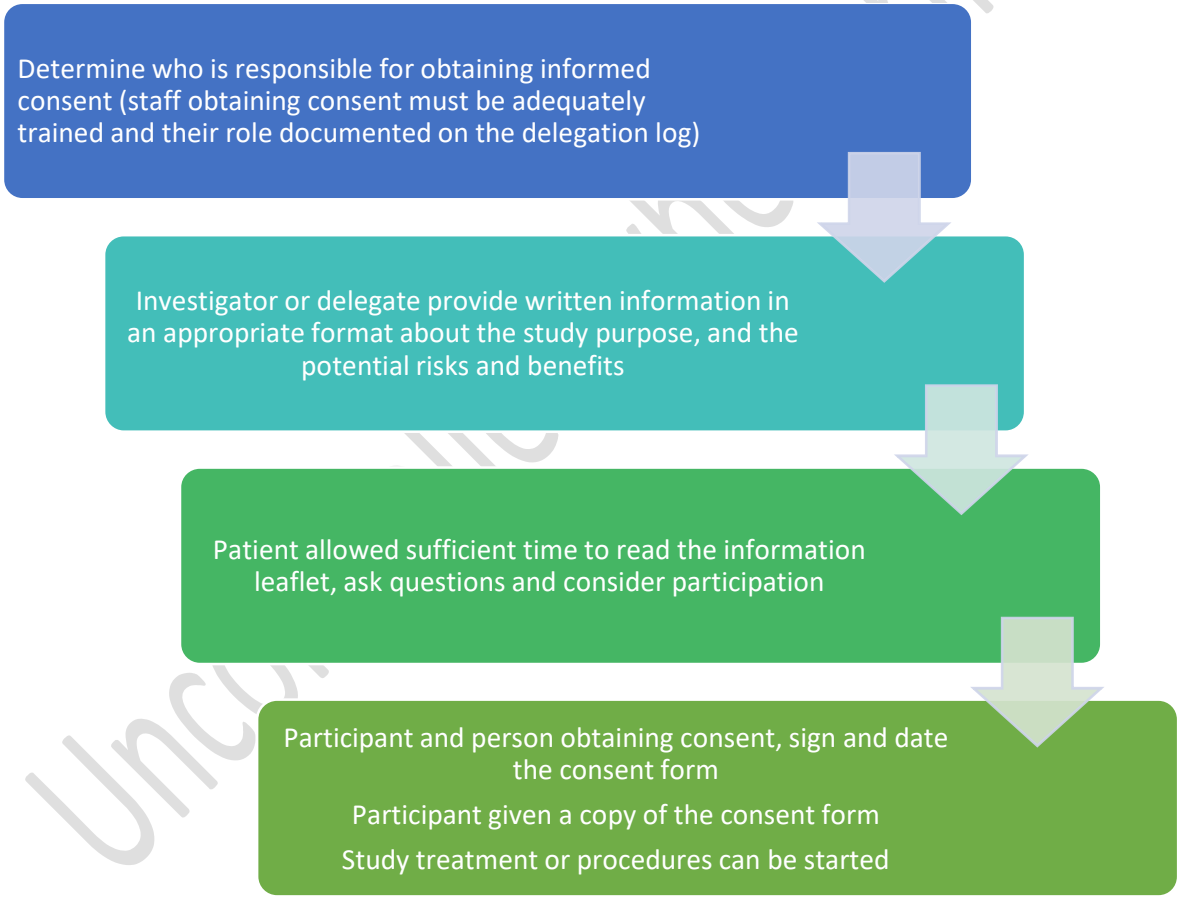
An Informed Consent Development Guide (G34) is available and should be referred to when producing a new Consent Form.

Where a subsequent amendment to the PIS or CF is required, the process described above should be followed for its review and approval. It may be appropriate to prepare a summary of the changes, so that those undertaking the review can easily identify what changes have been made. Ensure revised documents are approved internally before submission to REC (and MHRA if applicable) for their review. See SOP 6 'Amendments to Approved Study Documents' for more details.

4.3.2 Adults with capacity

Potential study participants, i.e., those who fulfil the inclusion/exclusion criteria of the study, will be identified and will be approached by either the investigator or designee as defined in 'Section 4.1 Responsibilities'

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



4.3.2.1 Informing the participant (capable adults)

Information should be provided to potential study participants in both an oral and written form. This advice is taken from HRA and there is extensive guidance available on their website.

- 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.

- Prior to the start of any study, written approval from the Research Ethics Committee (REC) will have been obtained for the use of the patient information sheet (see Appendix 1), the written consent form (see Appendix 2) and any other written information to be provided to participants.
- Information may be presented to potential participants using many formats and different media, including video, posters, recorded consultations, etc. All information presented to participants is subject to ethics approval (as above).

The information sheet and consent form 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. 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 trial/study records, as appropriate.

The HRA have produced guidance on preparing information for participants via their Design and Review Principles and these MUST be implemented (see Appendix 1). Ensure this guidance is referenced prior to producing any participant facing documents.

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.
- Any 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 information sheet and consent form should be identifiable by date and version number and be printed on headed paper associated with the particular Institution responsible for the study.

4.3.2.2 Obtaining informed consent (capable adults)

- In all cases, the consent process must be approved by the REC.
- When the person obtaining informed consent is satisfied that the participant has been fully informed and understands what study participation entails, the REC approved consent form should be personally signed and dated by the participant and by the authorised person who conducted the informed consent discussion (see Appendix 2 for examples of consent forms).
- Three copies of the signed and dated consent form should be made. The original form should be filed in the relevant section of the Investigator Site File (ISF). One copy should be given to the participant and the other copy should be filed in the participant's medical records.
- Participants should receive copies of all relevant, updated, and new information, regarding the study throughout their participation and re-consented if applicable. Full details of a patient's participation (discussions, interventions, study visits) in a study should be documented in their medical notes.
- It is good practice that the participant's General Practitioner should be informed in writing about their patient's participation in the study 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 along with provision of short summary information leaflets, with the opportunity to opt out with full consent being obtained subsequently or the study procedures may proceed without consent being in place until after the emergency has passed. In these situations, the proposed

consent process must be fully explained and justified in the study protocol and is only allowable when REC approval has been obtained. Details of the process followed and conversations with those participants recruited under emergency provisions should be fully documented in the patient's medical notes.

4.3.2.3 Changes in capacity

- If an adult with capacity gives informed consent to participate in a trial governed by the Medicines for Human Use (Clinical Trials) Regulations, 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 and the participant has lost capacity, a relevant legal representative should be approached for ongoing consent. For other types of research (i.e., non-drug studies), the provisions of the Mental Capacity Act will come into force and the procedure outlined in section 4.3.3 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 in the study.

4.3.2.4 Obtaining consent from capable adults with a disability which affects their ability to sign a Consent Form

If a potential participant with mental capacity is unable to provide written consent, for example due to an injury or disability (e.g., a visual impairment) which means they are unable to write, consent should be taken verbally in the presence of at least one witness (who should be independent of the study) 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 frail patients who indicate that they wish to take part in a study but want a next of Kin/friend to sign the consent form on their behalf.

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

4.3.3 Adults who lack capacity

There are two pieces of legislation regarding the involvement of incapacitated adults in research. The Medicines for Human Use (Clinical Trials) Regulations 2004 apply to all CTIMPs. For all other types of research, the Mental Capacity Act 2005 is in force (in England and Wales) and gives a framework for obtaining consent for research where participants lack capacity and cannot consent for themselves. The Mental Capacity Act (Northern Ireland) became law on 9th May 2016 for the involvement of adults not able to consent for themselves in non-CTIMP research. It is good practice to discuss specific

requirements with study sites in NI during the set-up phase of the study. Further information regarding NI procedures is available.

The HRA website contains further guidance relating to adults unable to consent for themselves in each UK nation.

N.B. Research in Scotland has a separate set of regulations contained in the Adults with Incapacity (Scotland) Act 2000 and therefore separate ethical approval will be required from a Scottish REC. The HRA provide guidance on the principles of consent in line with the Adults with incapacity (Scotland) Act.

Lack of capacity can be due to a range of causes, including (but not limited to) unconsciousness, dementia, learning difficulties, stroke, head injuries or mental health problems.

The study protocol should describe the proposed criteria and methods to assess the capacity of each potential participant to assess if they have the ability to provide consent personally or if an alternative method will be required. Screening tests may be used if (after discussion) it is deemed appropriate for a particular study, but these are not a definitive assessment of capacity. If a potential participant attains a score which would indicate that they have passed the screening test and they are able to communicate their understanding of the information given and the trained researcher has no other concerns, then the consent process can proceed.

However, if the researcher has *any* concerns regarding the individual's capacity and level of understanding of the information provided, then the process should be halted, and the individual not included in the study. Alternatively, where the protocol allows, the procedures in sections 4.3.3.1/4.3.3.2 should be followed.

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

4.3.3.1 Incapacitated adults in CTIMPs

Incapacitated adults are defined in The Medicines for Human Use (Clinical Trials) Regulations 2004 as "an adult unable by virtue of physical or mental incapacity to give informed consent".

In **non-emergency situations** where it is not possible to obtain consent from the participant themselves, a hierarchy is prescribed in the regulations to determine what type of legal representative should be approached, given all the relevant 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 trial/ 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 trial/ study who is either the doctor primarily responsible for the adult's medical treatment, or is a person nominated by the relevant health care provider

Refer to Schedule 1 of the Medicines for Human Use (Clinical Trials) Regulations 2004(S.I.2004:1031) which summarises the statutory requirements for informed consent of participants in CTIMPs.

The personal or professional legal representative must be given an Information Sheet which should have the same content as the Participant Information Sheet (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.

As with adults who have capacity, time must be allowed for consideration and for the representative to ask any questions which arise before the informed consent process can be completed. The representative and the person taking consent must each then sign and date the informed consent form.

If a participant who has been enrolled into a study whilst incapacitated then regains their capacity, the consent process for adults with capacity as described in section 4.3.2 must be followed, i.e., the investigator must fully explain the details of the trial/ study and give the participant the opportunity to make their own decision as to whether to continue in the trial/ study or withdraw. This decision should be documented by the participant signing an informed consent form or a withdrawal form.

In **emergency situations**, the Medicines for Human use (Clinical Trials) (Amendment No.2) Regulations 2006 made additional provision relating to trials involving incapacitated adults. Where the Investigational Medicinal Product (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. The amendment allows incapacitated adults to 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 a REC.

4.3.3.2 Incapacitated adults in all other research

For the purposes of the Mental Capacity Act, a person lacks capacity in relation to a matter if at the time they are unable to make a decision for themself in relation to the matter because of an impairment of, or a disturbance in, the functioning of the mind or brain, whether the impairment / disturbance is permanent or temporary.

It is a key principle of the 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, including blinking an eye or squeezing a hand.

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, carer or attorney acting under a legal Power of Attorney, as long as they are not paid to look after the person in question 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.

Whoever the person involved in the consultation process is, they must be provided with all the relevant information and must consider, so far as is reasonably ascertainable -

(a) the person's past and present wishes and feelings (and, in particular, any relevant written statement made by them when they had capacity),
(b) the beliefs and values that would be likely to influence their decision if they had capacity, and
(c) the other factors that they would be likely to consider if they were able to do so.

The person will then 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. However, if the potential participant indicates that they do not wish to take part in the study, then the consent process should be halted, and their wishes should be respected.

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 which gave approval for the research.

In all cases, as soon as 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.

The HRA provide comprehensive guidance on research in emergency settings

4.3.3.3 Adults who regain capacity during a study

If there is a possibility that adult participants might regain capacity during the course of a study, a plan must be in place to detail how you are going to involve them in the on-going consent process. In most cases it is appropriate to ask them to give their own consent when and if they are able. If you intend to ask participants who regain capacity for their on-going consent, you should:

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

4.3.4 Minors

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

Research involving children must normally only be carried out with the consent of a person who has parental authority and/or the child depending on the competence of the child.

Where the Clinical Trial Regulations apply (i.e. in CTIMPs), a minor is defined as someone under the age of 16. If a minor is enrolled in research the Regulations specify that consent must be obtained from someone with parental authority or a legal representative.

In other research the law states that anyone aged 16 and over is assumed to have capacity to consent. Under the age of 16 years a child who has been assessed as competent to consent may do so and that consent is valid. The agreement of a parent of a competent minor who has consented to take part in research should be sought (unless the minor specifically asks that the parent is not informed, and the protocol has been approved by the REC).

When parental consent has been given for a child or young person to participate in a study, agreement (or assent) of the child should still be sought and their refusal should be respected if they do not wish to do so.

When considering enrolling minors in a non-CTIMP trial, guidance produced by the HRA on obtaining consent from minors should be referred to.

Additional information on including minors in research in different UK regions is available on the HRA website

The Medicines for Human Use (Clinical Trials) Amendment (No. 2) Regulations of 2006 allow for the inclusion of minors in CTIMPs in emergency situations with certain provisions. It is lawful to recruit a minor prior to obtaining informed consent where the minor requires treatment in connection with the research as a matter of urgency and it is not reasonably practicable to obtain informed consent in advance. The procedures for recruitment must be approved by the relevant REC and informed consent must be obtained as soon as possible after the emergency has passed. Further guidance specific to obtaining consent from minors in CTIMPs is available via the HRA website.

4.3.5 Cluster Randomised Trials

In clinical trials where the randomisation is at the group rather than the individual level, known as cluster randomised trials, individual consent is usually not possible, and standard practice is not to seek individual consent but to seek consent from a 'cluster guardian'. However, Medical Research Council (MRC) guidelines on cluster randomised trials state that '*it is important to seek individual consent where 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. It may be necessary to discuss this process and take advice on a trial-by-trial basis with an external expert or senior colleague.

4.3.6 Obtaining consent from those whose first language is not English

ICH GCP guidelines require that 'the information that is given to the subject or their representative shall be in language understandable to the subject or their representative'. Therefore, when recruiting participants whose first language is not English, information sheets and consent forms 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. Some RECs may wish to see the translated and back-translated versions of the information sheet and consent form.

During the consent process an independent translator may be required to sit in on the meeting with the investigator 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 be able to provide an independent translator to be present during the consent meeting, alternatively external providers may be used e.g., Language Line Solutions

The translator should not be a family member/non-professional translator as there is the danger of incorrect or inconsistent translation. 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.

4.3.7 Additional considerations

4.3.7.1 Gaining consent for the use of anonymised quotes from trial/ study participants involved in qualitative research.

If a researcher wishes to use anonymised quotes obtained from a study participant 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.

4.3.7.2 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 this type of data is required, how it will be collected and stored and who has access to that data 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 General Data Protection Regulations (UK GDPR).

4.3.7.3 Additional requirements for NIHR HTA funded trials/ studies

All participant materials must include the NIHR logo whenever possible, following the NIHR branding guidelines. The appropriate logos should be accompanied by a funding statement such as the following:

"This project was funded by the National Institute for Health Research [name programme] (project number xx/xx/xx)."

The NIHR Programme Manager allocated to each trial/ study will be able to provide further clarification if needed.

4.3.7.4 Seeking consent by electronic methods

The MHRA and HRA have published a joint statement, supported by the Devolved Administrations around the UK, which sets out the legal and ethical requirements for seeking and documenting consent using electronic methods. It contains guidance on setting up electronic methods, including things to think about when using electronic methods to seek and document informed consent e.g.

- Can the signature be dated either manually by the participant or automatically by the eConsent system?
- Is it possible to verify which version of the information sheet and consent form the electronic signature applies to?
- For interventional studies, are there 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 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.
- Ideally, 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.

4.3.7.5 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 agencies (e.g., HRA, 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

4.3.8 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.

Given the wide range of settings involved in clinical trials and other interventional studies, sponsors/CIs will need to apply their judgement in applying the HRA guidance to a specific trial or research study. If in doubt, contact the manager of the relevant REC for advice.

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. In addition, the end of a study can be an anxious time for participants and this type of guidance is useful to ensure that they are provided with clear information concerning the options available to them at the end of their participation.

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

4.3.9 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 any planned follow up).

Any 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.

Requests to delete data already collected are dealt with in accordance with the 'right to erasure' (Article 17 UK GDPR) and need to be dealt with by the University's Legal and Compliance Services procedures which can be found here. Requests are submitted via a data subject right's form (available on the website) 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.

List of abbreviations

CF	Consent Form
CI	Chief Investigator
CTIMPs	Clinical Trials of Investigational Medicinal Products
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
MIS	Management Information System
MRC	Medical Research Council
NETSCC	NIHR Evaluation, Trials and Studies Coordinating Centre
NIHR	National Institute for Health and care Research

PI	Principal Investigator
PIL	Participant Information Leaflet
PPI	Patient and Public Involvement
QA	Quality Assurance
REC	Research Ethics Committee
R&IS	Research & Impact Services
SOP	Standard Operating Procedure
WCTU	Warwick Clinical Trials Unit

Template Documents

C01 ICF Checklist
C03 PIS Checklist
G02 Key Document Approval Guidance
T09 Key Document Approval Template
G05 PPI Data Protection
G28 Naming Convention Poster

Appendix

Appendix 1: Information to be provided to potential study participants (written and/or verbal)

Comprehensive Consent and participant information guidance is provided by the HRA and review of this guidance is strongly recommended before beginning to develop participant information. The PIS should take into account the HRA's Quality Standards which set out the minimum criteria that all participant information must meet. The HRA have also created 'Design and Review' principles to inform researchers and RECs what the important ethical considerations are for participant information and help to create information which meets the Quality Standards

HRA Quality Standards:

1. All acronyms and abbreviations are explained the first time they are used.

2. British English is used throughout.

3. The information starts with a summary of the study specific details, including:
   - an invitation to participate and an explanation on why the individual has been invited to take part
   - what the study is about and its aims?
   - who has been invited to participate and why?
   - what the participation will involve?
   - How long participation will last?
   - When, where, and how many times will each study activity be carried out?
   - potential risks and benefits of participation
   - an explanation that people invited do not have to take part, have the right to withdraw at a later date, including details about how to withdraw

4.The HRA UK General Data Protection Regulation (GDPR) transparency templates or an approved sponsor-specific UK GDPR statement is used. Generic approval to use a sponsor-specific template has been obtained after the applicant has explained how they used public involvement to develop their UK GDPR statement, and how it complies with UK GDPR transparency requirements.

5. Contact details for:
Someone who can provide more information and discuss the information provided
complaints or concerns*
A contact point for the duration of participation
At least one of these contacts must be able to point people directly to the sponsor's Data Protection Officer.
The contact details may include placeholders for localised information to be added after approval.

6. The sponsor has its own specific participant information template text (for use over multiple similar studies), which has been incorporated within the participant information material. Information is provided in the Integrated Research Application System (IRAS) application form to explain and justify both similarities and differences between the current presented project and those which have previously been approved using the same template participant information text.

7. Captions or alt-text and other appropriate accessible alternatives are used for images or graphics.

8. Where a video has been proposed, a transcript has been provided with the application. All videos should be subtitled.

9. In the IRAS application, it should be clear that people with relevant experience as patients, family members, carers or members of the public were involved in the development of the participant information. It should describe:

- who was involved
- how many people were involved
- how the feedback from public contributors was used to develop the information, including any sponsor-specific template text, and what changed because of the feedback

* The following details should be included in this section:
Head of Research Governance
Research & Impact Services
University House
University of Warwick
Coventry
CV4 8UW
Tel: 024 76 575733
Email: researchgovernance@warwick.ac.uk

This should be regarded as the basic minimum information to include in a patient information sheet, which can be supplemented if required. Information should clearly reflect the protocol and the language used should be suitable for a lay person. In the case of minors, information may be given in pictorial form. All technical words must be explained. The tone of the patient information sheet should be invitational and not coercive.

GDPR and transparency requirements must be considered, the HRA provide guidance

HRA Design and Review principles:

1. Involve public contributors in the design and review process to ensure that participant information is relevant and understandable for the intended audience

2. Information provided should be succinct, and the quantity proportionate to the complexity of the study

3. Language should be as clear as possible so that the key points of the information are easily understood

4. The format of the information should be appropriate for the intended audience

5. Written information should be formatted to optimise comprehension

6. Participant information should always be tailored to the intended study population

NOTE: Further details and explanations of these principles can be found on the HRA web site
The HRA also provide style guidance with some additional considerations to engage the reader and facilitate effective communication which should be referred to.

WCTU have produced a checklist (C03) to detail the expected information to be included in a PIS and an Informed Consent Development Guide (G34) to assist in the production of new consent forms. When preparing PIS(s) and consent forms for a new study/trial, it is advised that this checklist and guidance are referred to, to ensure all the relevant/necessary information is included. Some information is mandatory for all types of research projects, but other items (e.g., recording of interviews, use of anonymised quotes, collection/use of samples etc.) may also need to be included depending on the nature of the project.

Studies seeking approval from the University's Biomedical and Scientific Research Ethics Committee (BSREC) should check the BSREC web pages for template PIS and CF.

Copies of the patient information sheet and consent form must be submitted as part of the application for ethics approval. The ethics committee will also want to know what strategies will be used to seek out and disseminate new information that becomes available during the course of a research study, which might affect the participants' decision to continue to take part.

Template documents for studies approved via a University REC are also available via:

https://warwick.ac.uk/services/ris/research_integrity/researchethicscommittees/biomed

Other relevant information

HRA recommends the use of headed paper of the hospital/institution where the research is being carried out. All information sheets and consent forms must look professional, and have appropriate logos and contact details, such as the University and the study team; in some cases, these details might also include those of the hospital or local clinical contact. It is good practice for the coordinating team to request a copy of the initial version of the locally produced documentation with Trust logos inserted and file in the S/TMF.

Appendix 2: Example research study consent forms

(Form to be on headed paper)

Centre Name/Number:

Patient Identification Number for this trial/ study:

CONSENT FORM

Title of Project:

Name of Researcher:

Please initial each item

1. I confirm that I have read and understand the information sheet Version....., Dated..... for the above trial/study. I have had the opportunity to consider the information, ask questions and have had these questions answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐

3. (If appropriate) I understand that relevant sections of any of my medical notes and data collected during the study may be looked at by responsible individuals from [institution name], from regulatory authorities, or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐

4. (If appropriate) I understand that the information held and maintained by _____ [(enter name of organisation(s) that will be providing you with data, including any NHS/HSC organisations)] may be used to help contact me or provide information about my health status. ☐

5. (If appropriate) I agree to my General Practitioner being informed of my participation in the study. / I agree to my General Practitioner being involved in the study, including any necessary exchange of information about me between my GP and the research team. ☐

6. (If appropriate) I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers. ☐

7. I understand that the information will be stored securely and only used for medical research purposes and that I will not be identified in any way in the analysis and reporting of the results. ☐

7. I agree to take part in the above study. ☐

Name of Patient (Please PRINT)	Signature	Date
Name of person taking consent	Signature	Date

NB: Three copies should be made: Original to be retained in Investigator Site File, 1 copy for patient, 2nd copy for medical notes.

Footer to include document title, version number, date, and IRAS #

Appendix 3: Example qualitative study consent form

<To be printed on hospital headed paper>

QUALITATIVE SUB STUDY PATIENT CONSENT FORM

<<Insert study logo>>

<<Insert study name>>

Qualitative study - <<insert details>>

Name of Researcher: <*Insert name*>

Chief Investigator:

Please INITIAL boxes; do not tick

1. I confirm I have read and understood the Patient Information Sheet (*insert version no. and date*). ☐
2. I confirm that I have had the opportunity to ask questions, discuss the study and my questions have been answered satisfactorily. ☐
3. I understand that my participation is voluntary and that I am free to withdraw from the sub study at any time without giving a reason and without my medical care or legal rights being affected. ☐
4. I agree for my contact details to be held at Warwick Clinical Trials Unit for the purpose of contacting me to arrange an interview. ☐
5. I understand that the information will be used for medical research only and that I will not be identified in any way in the analysis and reporting of the results. ☐
6. I agree that I will complete an interview with a researcher which will be video/audio-recorded and that my name will not be used in any transcriptions. ☐
7. I agree that any free text quotes I provide during the interview may be used anonymously in future publications by the study group. ☐
8. I agree that authorised researchers engaged in relevant and authorised research may access anonymous data from this study. ☐
9. I understand that data collected for this study is covered by the UK General Data Protection Regulations and all data will be stored in a secure format. ☐
10. I agree to take part in this qualitative/interview study. ☐

Name of patient:

_____ Date: _____ Signature: _____

Name of person taking consent: *(if different from researcher)*

_____ Date: _____ Signature: _____

Name of researcher:

_____ Date: _____ Signature: _____