Research Governance Office Sponsorship Standard Operating Procedures

Informed Consent

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1.0 Introduction and Scope

This Standard Operating Procedure (SOP) describes the process of obtaining informed consent from a trial participant and applies to all research (referred to as 'trial' hereafter) Sponsored by the University of Leicester (UoL), including individuals undertaking research at other sites in multi-centre research studies in England, Wales and Northern Ireland. For trials taking place in Scotland, and involving those who lack capacity to consent for themselves and/or involving children, the Health Research Authority (HRA) website should be consulted.

2.0 Definitions

Informed Consent is the process by which participants, or their legally acceptable representative ('representative'), voluntarily confirm their willingness to participate in a trial after having been informed of, and been provided with the opportunity to discuss, all aspects of the trial that are relevant to the participant's decisions to participate.

Typically, informed consent is a three-step process which involves;

1. The giving of information to the participant (or representative),
2. Having a detailed discussion and providing clarification of the information, and
3. Receiving the participant's/representative's verbal, written and/or electronic consent.

Informed consent must be obtained prior to the conduct of any trial related procedures.

3.0 Responsibilities

Research guidelines, including Good Clinical Practice (ICH-GCP), confirm that the Chief Investigator (CI) has overall responsibility for ensuring that all consent processes are undertaken by suitably qualified and trained personnel. The Principal Investigator (PI) holds responsibility locally. While the CI and PI may delegate the task of obtaining informed consent, they remain accountable for ensuring the approved process is followed.

All trial personnel obtaining informed consent must ensure that they are:

1. Trained and experienced (by qualification and/or undertaking informed consent training),
2. Completely familiar with all aspects of the trial described in the approved protocol (including all modifications), and
3. Are listed on the Delegation of Activities Log (SOP S-1010 applies).

The current, approved PIS and ICF must be available during the consent process. In most cases, a copy of the PIS should be provided in advance of the informed consent discussion/process.

4.0 Format and Content of Participant Information & Consent Forms

Varied approaches to the provision of information and the discussion about the trial can be used. This may include, for example, providing text in different formats, images and videos, and using telephone or video conferencing with investigator site

staff. 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.

The Health Research Authority (HRA) recommend the use of a template for writing a participant information sheet and consent form. The RGO has created a suite of templates which must be used when creating your participant documents, these are available from the RGO SharePoint webpages (UoL login required). Further information regarding informed consent can also be obtained from the Medical Research Council Website and HRA website.

How informed consent is obtained is subject to the Sponsor review process (i.e., it is expected that the Sponsor and ethics applications detail the specific process for obtaining informed consent, and outlines the types of personnel, and procedures involved) and researchers are reminded that it is their responsibility to use UoL approved software and processes.

NB: A consent form contains identifiable data.

4.1 Paper Informed Consent

Where paper-based consent is undertaken, the consenting researcher must:

- Ensure that black ballpoint/biro is used (to prevent the degradation of the ink);
- Ask the participant to read and then initial next to all the statements on the consent form **Note: Ticks or crosses in the statement boxes are not acceptable and will render the consent as invalid;**
- Ask the participant to clearly print their full name, and sign and date the consent form;
- File the original 'wet ink' signed ICF in the Investigator Site File (ISF);
- File a copy of the PIS and fully signed ICF in the participant's medical notes; and
- Provide a copy of the fully signed consent form to the participant.

When any of the above are not possible or appropriate, an alternative must be discussed and agreed with the Sponsor. This should happen during the Sponsor review, and where relevant, the risk assessment process.

4.2 Electronic Informed Consent

The Medicines and Healthcare products Regulatory Agency (MHRA) and HRA Joint Statement on "Seeking Consent by Electronic Methods" (September 2018) confirms that electronic methods may be used for seeking, confirming and documenting informed consent in trials. This includes the utilisation of online text or multimedia approaches as the main method of delivery of trial information to potential participants. For example, an electronic device such as a smartphone, tablet or computer may be used to convey information related to the trial and to seek and/or document informed consent. Paper-based methods should still be available for those unwilling or unable to use electronic methods.

The full statement can be found on the HRA website. Additional information can also be found on the following link.

The UoL's preferred platform for electronic consent is JISC. Completed consent forms should be downloaded and deleted from the platform as soon as possible and within 3 months.

4.3 Electronic signatures

Electronic signatures can be classified as "simple", "advanced" or "qualified" (defined below). The type of electronic signature that should be used depends on whether the recruitment and consent procedures taken as a whole (and considered as part of a proportionate approach) mean that you:

- Can trust that the person who signed is who they say they are (i.e., you should assure yourself of the identity of the individual);
- Can trust that the consent form they signed hasn't been altered;
- Can trust when the signature was applied; and
- Can demonstrate that trust if required.

Definitions;

- **Simple:** This could be a finger/stylus drawn signature, typed name, a tick box and declaration, a unique representation of characters or fingerprint scan.
- **Advanced:** Uniquely linked to the signatory and capable of identifying the signatory, allow the signatory to retain control, and are linked to data within the signature that can detect any changes made.
- **Qualified:** an advanced electronic signature uniquely linked to the signatory that is created by a qualified electronic signature creation device, and which is based on a qualified certificate for electronic signatures.

4.3.1 Clinical Trials of Investigational Medicinal Products (CTIMPs)

Under The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 sponsors can apply to use simplified arrangements for seeking and evidencing consent in low intervention CTIMPs, but consent must remain informed and evidenced.

The amended regulations do not permit consent to be waived or presumed. However, they do allow sponsors of eligible low intervention CTIMPs to use simplified arrangements for seeking and evidencing informed consent. These arrangements may include proportionate approaches to the information provided, the way consent discussions are undertaken, and the means by which consent is evidenced, provided that consent remains informed, freely given, explicit and prospectively obtained. Any such arrangements must be clearly described in the protocol and approved by a Research Ethics Committee.

Further guidance is available on the following HRA webpage.

For all other CTIMPs typewritten or scanned images of handwritten signatures should not normally be used. eSignatures that involve tracing the participants handwritten signature using a finger or stylus or biometric eSignatures should be used, as these allow direct comparison with eSignature/wet-ink signatures used for audit purposes or GCP inspection.

In clinical trials where consent is given remotely, it may not always be possible to verify that the participant is who they say they are. In such circumstances an advanced or qualified electronic signature should be used. Where a participant is required at some time point to visit a study site for purposes of the trial, then verification can be done in person using the information from official photo ID.

4.3.2 All other trials

A simple electronic signature may be adequate for the majority of non-CTIMP research that involves only negligible or minimal risk.

Where the research involves more than minimal risk or burden, simple eSignature that involve the participant tracing their handwritten signature using a finger or a stylus or biometric eSignature should be considered, as these allow direct comparison with wet signatures previously used by the participant.

For postal/online surveys or self-administered questionnaire-based research where identifiable personal data are to be collected, the participant must be able to actively signify their consent. This can be achieved by providing an explicit consent statement and a tick box within the questionnaire. In such cases a handwritten or biometric signature is not required.

5.0 Informed Consent Process

The following section outlines broad guidance for the informed consent process. It is not intended to be an exhaustive list. Further information about responsibilities and procedures can be found in

- Section 2.8 of ICH GCP E6(R3)
- HRA website

The approved informed consent process, as authorised by the Sponsor and relevant regulatory bodies, must be followed at all times. Any departure from the approved process must be documented as a protocol deviation (all trials; see SOP S-1012) and, for CTIMP and Medical Device trials, discussed with the Sponsor. All documentation and correspondence relating to issues with informed consent must be filed in the ISF and, where applicable, the Trial Master File (TMF). Any changes to the approved consent process must be submitted and authorised through the formal modification process (see SOP S-1018).

5.1 Provision of Participant Information

The participant must be provided with ‘sufficient time’ to read the participant information, and given an opportunity to discuss the trial with others. It is expected

that the process of consent and the time period allocated to participants regarding their decision to participate is detailed in the Sponsor and ethics application. Informed consent must be obtained prior to any research activity.

When describing the trial, the individual obtaining the consent should explain:

- Number of anticipated people taking part;
- Duration, number of visits involved (where and by whom), participant responsibilities;
- All procedures (e.g., tests/assessments) required;
- Potential benefits and risks as a result of participating;
- Details of the design and drug/placebo use including known safety profiles;
- Alternative treatment available;
- Participation is voluntary and the right to withdraw;
- Confidentiality will be maintained throughout should they participate and that medical records will be reviewed only by authorised personnel;
- Participation payment and compensation (if appropriate);
- Details of what will happen at the end of participation; and
- Funders and personnel who have reviewed the appropriateness of the trial to be conducted.

For participants where English is not their first language, where trial eligibility allows, it is important that the information is provided in a language that they can understand. Where PIS translation to other languages and/or use of an interpreter is required, this should be detailed within the Sponsor and ethics application. Where an interpreter is needed, this must be a Trust approved interpreter, using family members and members of the research team is not appropriate.

Furthermore, AI translations are not currently authorised by the HRA or the UoL; there must be evidence of human oversight and verification of the translation process. For guidance: https://www.hra.nhs.uk/about-us/news-updates/blog-ai-and-hra/

5.2 Recording Informed Consent

The participant (or representative, etc as required by the approved protocol) must sign and date the ICF.

The informed consent process must be documented in a detailed and chronological manner in the participant's medical records, trial workbook and/or on the Case Report Form (CRF) as contemporaneously as is feasible. Where others, such as personal or nominated consultee, professional representative or a witness have played an active role in assisting the participant, their involvement as either an advocate or witness should also be documented. We encourage the use of template stickers or template continuation sheets for documenting the process of consent within the medical notes to aid the consistency of the information recorded. The templates can then be populated with the specific detail relating to the consent process for any given participant. An example consent annotation sticker is available in Appendix 7.

5.3 Ongoing Informed Consent

The informed consent process does not cease once the ICF has been signed. The practice of giving information to the participants and reaffirming their continued willingness to participate in the trial should be on-going throughout the duration of a participant's involvement in the trial, and at each subsequent trial visit/appointment/contact with the participant (e.g., in the case of telephone follow-up calls).

5.4 Re-Consent

In certain circumstances it may be necessary to re-consent participants in order to confirm their continued involvement in the trial. A decision about the requirements for re-consenting some or all participants will form part of the Sponsor Green Light process for modifications.

For example, it is particularly important to re-consent participants when:

- There has been a modification to the trial protocol and associated participant information where the modification is likely to affect the risk: benefit ratio of the trial and/or a participant's decision about whether or not to take part in the trial;
- There has been an urgent safety measure; and/or
- New information which may be relevant to the participant's willingness to continue in the trial becomes available.

In most cases, all active participants should be re-consented. However, there may be instances where this is not required (e.g., the modification is not relevant to the participant because the new protocol procedure is to occur at a time point in the trial that the participant has already passed). In the case of re-consent, the consenting researcher must conduct a consultation with each active participant to ensure they are made aware of any changes and are able to ask any questions in order to make an informed decision regarding whether to provide consent and continue in the study, or to withdraw. They must then follow the consent process as detailed in Section 4.0.

6.0 Co-enrolment in Other Trials

Where it is possible/allowed that participants can take part in more than one trial at a time (i.e., co-enrolled), the inclusion criteria of the respective trial protocols must reflect this, otherwise it will be assumed that participants must only be in one trial at a time.

Care must be taken when screening and enrolling participants, and where necessary, explicit advice must be sought from the CIs of the trials in advance of informed consent being obtained. These discussions should be clearly documented in the medical records and will be handled on a case-by-case basis.

7.0 Attending research appointments in a fasted state

The requirement for participants to attend a screening visit whilst fasted (i.e., before written informed consent has been obtained), must be detailed in the protocol and

associated trial documents so that the Sponsor and regulatory authorities are aware of, and approve, this approach. It may be inappropriate to do this with vulnerable groups such as the elderly.

Participants must provide confirmation of their prior agreement to attended in a fasted state; it is recommended that a tear-off slip is provided at the end of an invitation letter or a statement is added to a reply slip/expression of interest form. An example is provided in Appendix 4.

8.0 Special Circumstances

8.1 Consent process for adults who lose or lack capacity

If a capable adult gives informed consent, but subsequently becomes unable to give ongoing informed consent due to physical or mental incapacity, **the original consent remains legally valid.**

If a capable adult refuses informed consent, the refusal is legally binding. They **must not be entered into the study** by seeking consent from a legal representative.

Adults who lack capacity to consent for themselves may only be included when there are **reasonable grounds to believe that the research could not be carried out effectively** if limited solely to individuals who have capacity. There must be reasonable grounds for believing that research of comparable effectiveness cannot be carried out if the trial has to be confined to, or relate only to, persons who do not have capacity to consent to taking part in it.

For CTIMPs, the consenting process is governed by The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 not the Mental Capacity Act. Provided there is no evidence of advanced refusal by the participant, consent must be obtained from a personal or professional legal representative in accordance with SOP S-1034.

All other trials must comply with the Mental Capacity Act.

8.2 Emergency Situations

In some emergency research the participant may be temporarily incapacitated (e.g., due to a stroke). The Statutory Instrument 2006. No 2984 and Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 allows for temporarily incapacitated adults to be entered into a CTIMP if:

- Treatment is urgent;
- The nature of the trial requires urgent decisions; and
- It is not reasonably practical to meet regulatory requirements.

Once capacity is regained the participant must be consented as detailed in the application process. Where consent is withheld, the participant must be withdrawn. Samples and data collected up to this point may be retained with the consent of the participant or legal representative.

Further advice can be found in the toolkit on the HRA website

8.3 Consent process where a witness is required

Some participants will have the capacity to provide informed consent but may be unable to read the consent materials in their standard format. In these instances, the research team must ensure that the participant receives all required information in a format they can understand (e.g., verbal explanation, large print, audio, or other accessible formats). Others may fully understand the consent materials but be unable to sign the consent form due to physical limitations (e.g., severe tremors or an inability to write). Where it is anticipated that this situation will occur regularly, the study should include a consent form that allows for witnessed consent from the outset. This must be incorporated into the approved consent materials. If this requirement is identified during trial delivery, a modification must be submitted to add a witnessed consent option.

If such situations are not expected and therefore occur only as an exception, a single witnessed-consent episode may be undertaken. In these cases, a detailed Site File Note must be completed and filed appropriately within the ISF. The documentation must clearly describe the process used to confirm the participant's understanding, and the witness must attest to this by signing the consent form.

Occasionally, a witness may be involved in the consent of a participant on an ad-hoc basis. The reasons for using a witness must be fully documented in the participant's medical notes and included in the Case Report Form. Where witness consent is required, please contact the RGO.

9.0 Consent process for minors

9.1 Consent for under 16s

The Medicines for Human Use (Clinical Trials) Regulations prohibit children under the age of 16 from giving consent to take part in a CTIMP.

Those who are able to give consent on behalf of children/young people, to take part in a CTIMP, in the UK are:

- A parent or someone with parental responsibility (agreement of only one parent is required);
- A personal legal representative (i.e., a person not connected with the conduct of the trial who is suitable to act as the legal representative by virtue of their relationship with the child/young person, and is available and willing to do so); or
- Where a personal legal representative is not available, a professional legal representative (i.e., a doctor responsible for the medical treatment of the child/young person if they are independent of the study, or a person nominated by the healthcare provider).

A legal representative should only ever be approached if someone with parental responsibility cannot be contacted prior to the proposed inclusion of the child/young person, by reason of the urgent nature of the treatment provided as part of the trial.

You must ensure that parents or legal representatives:

- Understand that you are asking them to give consent on behalf of the child/young person;
- Understand the objectives, risks and inconveniences of the trial and the conditions under which it is to be conducted;
- Have been informed of the right to withdraw the child/young person from the trial at any time; and
- Have a contact point where further information about the trial can be obtained.

Children and young people should be involved in the decision-making process whenever possible. Researchers must ensure that they receive information about the trial, which is written in a format that is understandable to them.

The child can however, refuse to participate or withdraw from the trial independently and by any form of communication (i.e., their withdrawal can be behavioural).

Further advice on the consent of minors can be found on the HRA Website and further training may also be available via the NIHR.

9.2 Consent for over 16s

In general, young people over 16 are presumed to be capable of giving consent to participate in CTIMPs.

Any young person, over 16, who is not considered capable of giving consent, should only be included in a CTIMP in the UK in line with the adult provisions of the Medicines for Human Use (Clinical Trials) Regulations.

For non-CTIMPs there is no statute governing a child's right to consent to take part in research.

10.0 Withdrawal of consent

A participant has the right to withdraw from a trial at any time without their future medical care, working conditions, or legal rights being affected. Following withdrawal, no further protocol procedures should be undertaken unless the participant agrees to being followed-up. It should be clearly documented whether the participant has withdrawn from specific trial assessments, or the trial as a whole. Data and samples collected up to the point of withdrawal should be retained.

11.0 Training

The trial protocol and application documents must provide sufficient detail about the types and roles of trial personnel who will be obtaining informed consent. This is because, some types of trials may prohibit non-medics from performing this task. Specific advice should be sought from the RGO.

Where applicable, researchers must complete specific training on the process of informed consent (SOP S-1020 applies).

12.0 Development Record

The table below summarises the revisions introduced in this version. Full historical change records are available within archived SOP versions.

Date	Version number	Description of changes
April 2026	5.0	• Removed Office Address • Refined wording throughout to aid clarity and avoid repetition • Provided guidance on when re-consent may be required. • Removed appendix 2 & 3 • Appendix 4 amended to a pre-consent fasting reply slip example from generic pre-consent activity proforma • Removed responsibilities table as responsibilities are laid out within the body of the SOP. • Removed full historical SOP review record; only the latest approved revision is now displayed, with prior versions retained in the document archive.