Obtaining Informed Consent for Clinical Trials

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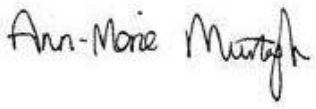
Signature and approval date	 31/12/2025

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1. BACKGROUND AND PURPOSE

This SOP describes the procedure for obtaining informed consent from, or on behalf of, a potential participant in a Clinical Trial sponsored by KHP.

This SOP has been developed in accordance with:

- ICH GCP E6 (R3), Section II. PRINCIPLES OF ICH GCP:
  - Principle 2, which states:
    - *Informed consent is an integral feature of the ethical conduct of a trial. Clinical trial participation should be voluntary and based on a consent process that ensures participants (or their legally acceptable representatives, where applicable) are well-informed.*
  - Principle 2.2, which states:
    - *The process and information provided should be designed to achieve the primary objective of enabling potential trial participants to evaluate the benefits, risks and burden of participating in the trial and to make an informed decision on whether or not to participate in the trial. The information provided during the informed consent process should be clear and concise so as to be understandable by potential participants or legally acceptable representatives.*

- The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025, Schedule 1, Part 1:
  - Paragraph 3, which states:
    - *(1) Subject to sub-paragraph (3), for the purposes of this Schedule, a person gives informed consent to take part, or that a participant is to take part, in a clinical trial only if his decision—*
    - *(a) is given freely after that person is informed of the nature, significance, implications and risks of the trial; and*
    - *(b) either—*
    - *(i) is evidenced in writing, dated and signed, or otherwise marked, by that person so as to indicate his consent, or*
    - *(ii) if the person is unable to sign or to mark a document so as to indicate his consent, is communicated (whether by talking, using sign language or any other means) in the presence of at least one witness and recorded in writing.*
    - *(2) For the purposes of this Schedule, references to informed consent—*
    - *(a) shall be construed in accordance with paragraph (1); and*
    - *(b) include references to informed consent given or refused by an adult unable by virtue of physical or mental incapacity to give informed consent, prior to the onset of that incapacity.*
    - *(3) Where sub-paragraph (4) applies, the protocol for the clinical trial for which consent is given may make provision for simplified arrangements for obtaining and evidencing consent, which shall include—*
    - *(a) the reason for obtaining consent using simplified arrangements;*
    - *(b) the information to be provided to the participant, and the means of providing that information; and*
    - *(c) the means by which consent shall be evidenced.*
    - *(4) This sub-paragraph applies where—*

- *(a) the investigational medicinal product or, if there is more than one, each of the investigational medicinal products, is authorised for use in the United Kingdom and is used in accordance with that authorisation;*
- *(b) the investigational medicinal product or, if there is more than one, each of the investigational medicinal products, is given to the participant in the course of that participant's routine health care; and*
- *(c) the participant receives no additional medication and undergoes no additional intervention or diagnostic procedure, solely for the purposes of the clinical trial.*

2. SCOPE

This SOP applies to all Clinical Trials sponsored by KHP where informed consent will be procured from participants.

This SOP does not apply to Clinical Trials where informed consent will not be procured from participants (i.e. emergency research, Clinical Trials using deferred consent models).

3. PROCEDURE

3.1 Overview of Consent Procedure

Task	Responsibility	Activity
1	Chief Investigator	Prior to submission of the Clinical Trial Authorisation (CTA), determine whether Simplified Arrangements for procuring informed consent are appropriate for the Clinical Trial. Where Simplified Arrangements are proposed, the justification and proposed consent approach shall be clearly documented in the Clinical Trial documentation, including the protocol, for regulatory and ethical review.
2	Chief Investigator	Ensure that the informed consent process for the Clinical Trial may commence only once all required central approvals are in place. These approvals include: • CTA approval • A favourable opinion from the REC • HRA approval The Chief Investigator shall ensure that approval records are filed in the TMF and made available to Principal Investigators in a timely manner.
3	Principal Investigator	Ensure that the informed consent process at a specific Trial Location may commence only once all required local approvals are in place.

		These approvals include: • Confirmation of capacity and capability by the R&D Dept. at the Trial Location • Completion of the SIV and Sponsor greenlight process in accordance with SOP 13.0 Study Set-Up and Initiation of an Investigator Site The Principal Investigator shall ensure that no consent-related activities take place until all approvals are confirmed and filed in the ISF.
4	Clinical Research Associate	Verify that Principal Investigators and all individuals delegated consent-related duties are appropriately trained prior to the start of participant consent activities. This training is typically delivered at the SIV in accordance with SOP 13.0 Study Set-Up and Initiation of an Investigator Site
5	Principal Investigator or delegate	Obtain informed consent from, or on behalf of, the participant prior to the conduct of any Clinical Trial-related activities involving the participant (excluding the consent process). Ensure that all individuals delegated consent-related duties are aware of and comply with this requirement Ensure that any failure to comply with this requirement is assessed and reported as a potential serious breach, in line with SOP 6.0 Notification of Serious Breach of Good Clinical Practice or Trial Protocol
6	Principal Investigator or delegate	Ensure that informed consent procured from each participant remains valid unless it is withdrawn by, or on behalf of, the participant. In the event of withdrawal: • Inform the CI • Save correspondence with the participant and the CI in the ISF
7	Chief Investigator or delegate	Ensure that informed consent procured from each participant remains valid unless it is withdrawn by, or on behalf of, the participant. In the event of withdrawal, save correspondence with the PI (or delegate) in the TMF. Where new information becomes available that may impact a participant's willingness to continue participation, or there's a change to the Clinical Trial, the Chief Investigator shall: • Submit a Modification • Share the documentation (including updated Clinical Trial documentation) for any approved Modifications with the Principal Investigators

8	Principal Investigator or delegate	For approved Modifications requiring participants to be re-consented, ensure participants are re-consented using the updated ICF and/or PIS.
9	Principal Investigator or delegate	Ensure that participants may withdraw consent at any time without penalty or loss of benefits. The Principal Investigator shall make a reasonable effort to ascertain the reason for withdrawal where appropriate, and shall ensure that any withdrawal of consent is clearly documented in the participant's records, and such records are saved in the ISF.
10	Principal Investigator or delegate	Where informed consent is not obtained from a potential participant, ensure that: • The records for the potential participant are updated to confirm that consent was not obtained, together with any reason provided • Clinical Trial screening records are updated accordingly, and such records are saved in the ISF
11	Clinical Research Associate	In accordance with the approved Monitoring Plan, verify through monitoring activities that the consent process has been conducted in compliance with the Clinical Trial documentation. Record activities per SOP 3.0 Clinical Trial Monitoring

3.2 Managing the Individuals that Procure Informed Consent

Task	Responsibility	Activity
1	Chief Investigator	Ensure that the informed consent process for the Clinical Trial is clearly defined, sufficiently detailed, and comprehensive, such that a potential participant (or their legally acceptable representative) is provided with all information necessary to make an informed decision regarding participation. The Clinical Trial documentation must include: • Clear specification of the knowledge, education, training, and experience required of researchers involved in any aspect of the consent process. • Any identity-verification requirements (e.g. use of cameras for remote consent discussions), which must be explicitly described in the protocol, where applicable. • Definition of minimum competency requirements for each stage of the consent process. Where consent is obtained through multiple steps, different requirements may be specified for different activities (e.g. information provision versus formal consent confirmation).

2	Clinical Research Associate	Deliver Clinical Trial-specific training on informed consent requirements to Principal Investigators and any individuals delegated responsibility for consenting, ordinarily at the Site Initiation Visit (SIV). Ensure that: • Attendance records and training materials are retained. • Evidence of training delivery is filed in the TMF
3	Principal Investigator	Ensure that the delegation log is accurately completed and maintained for all individuals undertaking consent-related activities on for the Clinical Trial. This includes, but is not limited to, conducting consent discussions and formally obtaining consent from or on behalf of participants. Note: The responsibility to record and act upon a participant's withdrawal of consent applies to all researchers and this responsibility does not require a separate delegation log entry. Ensure Trial Location Team training logs are updated to reflect the training.
4	Principal Investigator or delegate	During the consent process, record consent-related issues in a deviation log where the Principal Investigator determines that there may be a potential impact on participant safety, rights, or the integrity of Clinical Trial data.
5	Clinical Research Associate	In accordance with the Monitoring Plan, review and verify that: • The informed consent process has been conducted in line with the protocol and applicable regulatory requirements. • Consent activities have been performed by appropriately trained and delegated individuals. Record activities per SOP 3.0 Clinical Trial Monitoring

3.3 Managing the Individuals that Carry Out Capacity Assessments

Please note the following:

- Capacity is presumed for any participant who is over the age of 16 at the time informed consent is procured
- If informed consent was procured from a participant's legally acceptable representative, and that participant gains or regains capacity, the protocol will indicate whether the participant should be re-consented
- If informed consent was procured from a participant, and that participant loses capacity, the protocol will indicate whether the participant should be re-consented with the assistance of a legally acceptable representative

Task	Responsibility	Activity
1	Chief Investigator	Note that ICH GCP E6 (R3) states that patients with severely impaired decision-making capacity are unable to provide informed consent (Principle 2.8.5). There is no statutory capacity-assessment methodology prescribed in the Regulations. Where it is anticipated that capacity assessments may be required for the Clinical Trial, the CI must ensure that a Clinical Trial-specific capacity assessment process is clearly defined in the protocol.
2	Chief Investigator or delegate	Develop all Clinical Trial documentation required to support the capacity assessment process, including any guidance, tools, or prompts to be used by assessors. Submit all capacity-assessment materials and a description of the assessment process as part of CTA Submission Package.
3	Clinical Research Associate	Ensure that Principal Investigators and any individuals delegated responsibility for assessing capacity receive appropriate Clinical Trial-specific training, ordinarily delivered at the Site Initiation Visit (SIV). Ensure that: • Attendance records and training materials are retained. • Evidence of training delivery is filed in the TMF
4	Principal Investigator	Ensure that the delegation log is accurately completed and maintained for all individuals undertaking capacity assessment-related activities for the Clinical Trial. This includes, but is not limited to, capacity discussions and formally assessing capacity for or on behalf of participants. Ensure Trial Location Team training logs are updated to reflect the training.
5	Principal Investigator or delegate	During capacity assessment: • Where capacity assessment is completed as part of the informed consent process for the Clinical Trial, document the assessment and the outcome in the participant's medical record • Record capacity assessment-related issues in a deviation log where the Principal Investigator determines that there may be a potential impact on participant safety, rights, or the integrity of Clinical Trial data

6	Clinical Research Associate	In accordance with the Monitoring Plan, review and verify that: • The capacity assessment process has been conducted in line with the protocol and applicable regulatory requirements. • Capacity assessment activities have been performed by appropriately trained and delegated individuals. Record activities per SOP 3.0 Clinical Trial Monitoring

3.4 Detailed Consent Procedure for Participants with Capacity

Task	Responsibility	Activity
1	Principal Investigator	Ensure that consent-related duties are appropriately delegated to suitably qualified and trained individuals. Generate and maintain a proportionate and up-to-date delegation log, in accordance with the Clinical Trial documentation, identifying those authorised to perform consent-related activities. Maintain a copy of the delegation log in the ISF.
2	Principal Investigator or delegate	Confirm the identity of the potential participant, particularly where consent is obtained remotely. Record confirmation that identity checks were completed as required. Provide the ICF, PIS, and any other approved participant-facing materials to the potential participant. Record in the potential participant's medical record: • The date information was provided • The materials supplied, including version numbers and issue dates where available Inform the potential participant about the Clinical Trial in a manner that facilitates their understanding, including the nature, purpose, risks, benefits, and burdens of participation, in line with ICH GCP E6 (R3) Principle 2.1. Document any substantive discussion of risks, benefits, and participant burden in the participant's medical record.
3	Principal Investigator or delegate	Where consent is obtained, record the participant's decision in accordance with the Clinical Trial documentation within the ISF. Record the consent decision in the participant's medical record.

4	Principal Investigator or delegate	Where consent is not obtained, record the participant's decision in accordance with the Clinical Trial documentation within the ISF. Record the consent decision in the participant's medical record.
5	Principal Investigator or delegate	In line with Trial Location practice and the Clinical Trial documentation, confirm ongoing consent at participant Clinical Trial visits where appropriate. If ongoing consent is confirmed at a participant Clinical Trial visit, record the confirmation in the participant's medical record and ISF.
6	Principal Investigator or delegate	If the Chief Investigator or delegate shares an approved Modification requiring participants to be re-consented, and the Trial Location R&D Dept. gives continued capacity and capability for the Modification; the Principal Investigator or delegate shall re-consent participants at Clinical Trial visits. If re-consent is confirmed at a participant Clinical Trial visit, record the confirmation in the participant's medical record and ISF.
7	Principal Investigator or delegate	Where consent is withdrawn, or re-consent is not obtained, make a reasonable effort to ascertain the reason(s) for withdrawal, in line with ICH GCP E6 (R3) Principle 2.9.2, and document any reasons provided in the participant's medical record and ISF. Inform the Chief Investigator of the participant's withdrawal.
8	Principal Investigator or delegate	Ensure that the participant continues to receive appropriate clinical care following withdrawal of consent. Where withdrawal of consent necessitates withdrawal of the IMP, follow the protocol and/or Investigator's Brochure or Summary of Product Characteristics to ensure safe discontinuation of the IMP.
9	Principal Investigator or delegate	Where a participant partially withdraws consent, clearly document in the participant's medical record which aspect(s) of the Clinical Trial consent has been withdrawn for, for example: • No further IMP administration • No further analysis of participant Human Biological Samples (HBS) • No further Clinical Trial follow-up visits • No further use of 'standard of care' clinical data for Clinical Trial purposes Inform the Chief Investigator of the participant's partial withdrawal, and the specific aspects consent has been withdrawn for.

10	Principal Investigator or delegate	If the Trial Location is responsible for any internal or external HBS processing, or any internal or external HBS storage, promptly inform the laboratory and storage location if consent for the storage, analysis, or use of participant HBS or results is withdrawn. Ensure that any required destruction, return, or restriction of use of HBS or results is completed and documented in the ISF (or documented in locations that are referenced in the ISF in the case of external laboratories or storage locations).
12	Clinical Research Associate	In accordance with the Monitoring Plan, review and verify adherence to the Clinical Trial consent process. Record activities per SOP 3.0 Clinical Trial Monitoring

3.5 Involvement of Witnesses when Procuring Informed Consent

Please note the following:

- The Regulations require that where a potential participant has capacity but is unable to sign or mark a consent document, consent may be given by other means (e.g. verbally, using sign language, or other communication methods), in the presence of at least one witness
- ICH GCP E6 (R3) Principle 2.8.9 further states that where a potential participant or a Legally Acceptable Representative is unable to read, an impartial witness must be present (either in person or remotely) for the entire informed consent discussion

Task	Responsibility	Activity
1	Chief Investigator	Ensure there's a specific field on the ICF for the witness to sign and date. This avoids any confusion about the role of the witness, which differs from the roles of the individual taking consent and the participant.
2	Principal Investigator or delegate	The Trial Location Teams should have established 'standard of care' processes for: • Identifying when a witness is required • Identifying a suitable witness
3	Principal Investigator or delegate	Identify the witness. Ask the witness if they're prepared to act in this role. During the conversation, if the Principal Investigator or delegate believes the witness has a conflict of interest, is biased or is partial; the Principal Investigator or delegate should refrain from procuring the witness's agreement to act in this role.

		During the conversation, if the Principal Investigator or delegate believes the witness is appropriate, ensure a record of the following is retained in the ISF: • How the witness was identified • The witness's agreement to act in this role
4	Principal Investigator or delegate	Ask the witness to read the PIS.
5	Principal Investigator or delegate	Following completion of the informed consent discussion in the presence of the witness, request that the witness confirms: • The information provided during the discussion was consistent with the PIS • The consent given by or on behalf of the participant was freely provided and valid The witness should sign and date the witness section of the consent form to confirm the above has taken place. If the witness cannot agree that the above has taken place, they should not sign the witness section of the consent form, and they should inform the Principal Investigator or delegate conducting the consent discussion of their concerns. These concerns should be addressed and documented in the ISF.
6	Clinical Research Associate	In accordance with the Monitoring Plan, if witness involvement is identified, confirm that: • Witness involvement complied with Clinical Trial-specific requirements • Appropriate documentation is present in the ISF and participant records Record activities per SOP 3.0 Clinical Trial Monitoring

3.6 Involvement of Translators when Procuring Informed Consent

Task	Responsibility	Activity
1	Principal Investigator or delegate	The Trial Location Teams should have established 'standard of care' arrangements for identifying when translation support is required to facilitate informed consent, and for identifying a suitable translator.
2	Principal Investigator or delegate	Identify the translator. Ask the translator if they're prepared to act in this role.

		During the conversation, if the Principal Investigator or delegate believes the translator has a conflict of interest, is biased or is partial; the Principal Investigator or delegate should refrain from procuring the translator's agreement to act in this role. During the conversation, if the Principal Investigator or delegate believes the translator is appropriate, ensure a record of the following is retained in the ISF: • How the translator was identified • The translator's agreement to act in this role
3	Principal Investigator or delegate	Ask the translator to read the PIS.
4	Principal Investigator or delegate	Following completion of the informed consent discussion using the translator, request that the translator confirms: • The information provided during the discussion was consistent with the PIS • The consent given by or on behalf of the participant was freely provided and valid The translator should sign and date the consent form to confirm the above has taken place (there won't be a 'translator section' on the form so signing and dating in any empty area on the form is acceptable). If the translator cannot agree that the above has taken place, they should not sign the consent form, and they should inform the Principal Investigator or delegate conducting the consent discussion of their concerns. These concerns should be addressed and documented in the ISF.
5	Clinical Research Associate	In accordance with the Monitoring Plan, if translator involvement is identified, confirm that: • Translator involvement complied with Clinical Trial-specific requirements • Appropriate documentation is present in the ISF and participant records Record activities per SOP 3.0 Clinical Trial Monitoring

3.7 Detailed Consent Procedure for Participants without Capacity

Please note the following:

- ICH GCP E6 (R3) recognises that some potential participants lack the capacity to provide informed consent for themselves. In such circumstances, **participants should still be informed about the Clinical Trial**, but in a manner that facilitates

their understanding, taking account of their age, maturity, and level of comprehension, and respecting their rights, safety, dignity, and well-being (Principle 2.1).

- Where the participant is a Minor, assent should be sought where appropriate, **in addition to consent being provided by a Legally Acceptable Representative**.

- At the Clinical Trial design stage, **the CI may decide to include potential participants who lack capacity**. If so, the CI must ensure that:
  - The protocol explicitly states that only participants with capacity will be recruited
  - The inclusion/exclusion criteria clearly reflect this position
  - The CTA Submission Package explains the rationale (ethical, scientific, or practical)
  - The Trial Location Teams are trained to apply the criteria consistently and not to make ad-hoc judgments about capacity outside the protocol

Task	Responsibility	Activity
1	Chief Investigator	Ensure the Clinical Trial documentation supports the consenting of participants without capacity. Specify the process for seeking assent from participants without capacity in the protocol, including the process for circumstances where assent is not given. Specify whether participants who have their 16th birthday during the Clinical Trial should be approached for consent when they're 16 years old. Ensure a set of participant-facing materials have been adapted for potential participants without capacity. Submit all materials related to consenting participants without capacity as part of the CTA Submission Package.
2	Clinical Research Associate	Ensure that Principal Investigators and any individuals delegated responsibility for consenting participants without capacity receive appropriate Clinical Trial-specific training, ordinarily delivered at the Site Initiation Visit (SIV). Ensure that: • Attendance records and training materials are retained. • Evidence of training delivery is filed in the TMF
3	Principal Investigator	Ensure that duties relating to consenting participants without capacity are appropriately delegated to suitably qualified and trained individuals. Generate and maintain a proportionate and up-to-date delegation log, in accordance with the Clinical Trial documentation, identifying those authorised to consent participants without capacity.

		Maintain a copy of the delegation log in the ISF.
4	Principal Investigator or delegate	Carry out the capacity assessment and identify the potential participant without capacity to be consented.
5	Principal Investigator or delegate	Identify a Legally Acceptable Representative (LAR) who can consent on behalf of the participant without capacity - **see section 3.8: Involvement of Legally Acceptable Representatives when Procuring Informed Consent (below).**
6	Principal Investigator or delegate	Confirm the identity of the potential participant, particularly where assent is obtained remotely. Record confirmation that identity checks were completed as required. Provide the participant-facing materials (that have been adapted for potential participants without capacity) to the potential participant. Record in the potential participant's medical record: • The date information was provided • The materials supplied, including version numbers and issue dates where available Inform the potential participant about the Clinical Trial in a manner that facilitates their understanding, including the nature, purpose, risks, benefits, and burdens of participation, in line with ICH GCP E6 (R3) Principle 2.1. Document any substantive discussion of risks, benefits, and participant burden in the participant's medical record.
7	Principal Investigator or delegate	Where assent is obtained, record the participant's decision in accordance with the Clinical Trial documentation within the ISF. Record the assent decision in the participant's medical record.
8	Principal Investigator or delegate	Where assent is not obtained, record the participant's decision in accordance with the Clinical Trial documentation within the ISF. Record the assent decision in the participant's medical record.
9	Principal Investigator or delegate	In line with Trial Location practice and the Clinical Trial documentation, confirm the following at participant Clinical Trial visits where appropriate: • Ongoing assent from the participant • Ongoing consent from the LAR - **see section 3.8: Involvement of Legally Acceptable Representatives when Procuring Informed Consent (below).**

		If ongoing assent from the participant is confirmed, along with ongoing consent from the LAR, record the confirmation in the participant's medical record and ISF.
10	Principal Investigator or delegate	If the Chief Investigator or delegate shares an approved Modification requiring participants to be re-consented, and the Trial Location R&D Dept. gives continued capacity and capability for the Modification; the Principal Investigator or delegate shall re-procure: • Assent from the participant • Consent from the LAR - **see section 3.8 Involvement of Legally Acceptable Representatives when Procuring Informed Consent (below).** If assent is re-procured from the participant, and the LAR re-consents, record the confirmation in the participant's medical record and ISF.
11	Principal Investigator or delegate	Where assent or consent is withdrawn, or assent or consent could not be re-procured when required, make a reasonable effort to ascertain the reason(s) for withdrawal, in line with ICH GCP E6 (R3) Principle 2.9.2, and document any reasons provided in the participant's medical record and ISF. Inform the Chief Investigator of the participant's withdrawal.
12	Principal Investigator or delegate	Ensure that the participant continues to receive appropriate clinical care following withdrawal of assent or consent. Where withdrawal of assent or consent necessitates withdrawal of the IMP, follow the protocol and/or Investigator's Brochure or Summary of Product Characteristics to ensure safe discontinuation of the IMP.
13	Principal Investigator or delegate	If the Trial Location is responsible for any internal or external HBS processing, or any internal or external HBS storage, promptly inform the laboratory and storage location if assent or consent for the storage, analysis, or use of participant HBS or results is withdrawn. Ensure that any required destruction, return, or restriction of use of HBS or results is completed and documented in the ISF (or documented in locations that are referenced in the ISF in the case of external laboratories or storage locations).
14	Clinical Research Associate	In accordance with the Monitoring Plan, review and verify adherence to the Clinical Trial assent process. Record activities per SOP 3.0 Clinical Trial Monitoring

3.8 Involvement of Legally Acceptable Representatives when Procuring Informed Consent

Please note that ICH GCP E6 (R3) recognises that some potential participants are unable to provide informed consent for themselves. In such circumstances, informed consent must be provided by a Legally Acceptable Representative (LAR), who acts in the participant's best interests, and consent must be obtained prior to the participant's involvement in the Clinical Trial (Principle 2.1).

LARs can be:

- A **Personal Representative** which is defined in UK legislation (for England, Wales. Northern Ireland and for Minors in Scotland) as:
    - A person other than a person connected with the conduct of the trial who, by virtue of their relationship with that adult or that Minor is suitable to act as their legal representative for the purposes of that trial and is available and willing to so act for these purposes.
    - Note: A person with parental responsibility for a Minor who is being considered for trial participation is suitable to act as a Personal Representative if they are available and willing to do so.
- A **Professional Representative:**
    - Which is defined in UK legislation (for England, Wales, Northern Ireland and for Minors in Scotland) as:
        - If there is no such person [to act as a Personal Representative], a person other than a person connected with the conduct of the clinical trial who is the doctor primarily responsible for the medical treatment provided to that adult or that Minor or a person nominated by the relevant health care provider.
    - And which is defined in UK legislation (for adults in Scotland) as:
        - Any guardian or welfare attorney who has the power to consent on behalf of an adult; or
        - If there is no such guardian or welfare attorney, the adult's nearest relative; or
        - If it is not reasonably practicable to contact a guardian or welfare attorney or the adult's nearest relative before the decision to enter the adult as a participant of a clinical trial is made, a person, other than a person connected with the conduct of the clinical trial, who is the doctor primarily responsible for the medical treatment provided to that adult or a person nominated by the relevant healthcare provider.

Task	Responsibility	Activity
1	Principal Investigator or delegate	The Trial Location Teams should have established 'standard of care' arrangements for identifying LARs when required.
2	Principal Investigator or delegate	Identify the appropriate LAR for the potential participant. Confirm that the individual is willing and able to act in the role of LAR.

		If, during the discussion, the PI or delegate considers that the proposed LAR has a conflict of interest, is not acting independently, or is otherwise unable to act in the participant's best interests, the PI or delegate must not proceed with obtaining consent from that individual. Where an individual is deemed appropriate to act as LAR, ensure that a record of the following is retained in the ISF: • How the LAR was identified (including whether they are acting as a Personal Representative or a Professional Representative) • The LAR's agreement to act in this role If a Professional Representative is acting as LAR, record the absence of a Personal Representative in the ISF.
3	Principal Investigator or delegate	Provide the approved PIS and any other approved participant-facing materials to the LAR, and allow sufficient time for the LAR to read, consider, and discuss the information prior to making a decision.
4	Principal Investigator or delegate	Following completion of the informed consent discussion with the LAR, confirm that the LAR: • Has received and understood the information provided • Has had the opportunity to ask questions and receive satisfactory answers • Is providing consent freely, in the best interests of the participant, and in accordance with the participant's presumed will, where known The LAR should sign and date the ICF where a participant with capacity would normally sign and date the ICF, noting they're signing on behalf of the participant. If the LAR is unable or unwilling to provide consent, consent must not be obtained, and the outcome and any relevant discussion should be documented in the ISF.
5	Clinical Research Associate	In accordance with the Monitoring Plan, if LAR involvement is identified, confirm that: • LAR involvement complied with Clinical Trial-specific requirements • Appropriate documentation is present in the ISF and participant records Record activities per SOP 3.0 Clinical Trial Monitoring

4. RELATED TEMPLATES

- SOP 3.0 Clinical Trial Monitoring
- SOP 6.0 Notification of Serious Breach of Good Clinical Practice or Trial Protocol
- SOP 13.0 Study Set-Up and Initiation of an Investigator Site

5. CHANGE HISTORY

CHANGE HISTORY			
Date	Version Number	Change details	Approved by
11 Nov 2013	2.0	Change of branding from JCTO to KHP-CTO	Jackie Powell
28 Nov 2016	3.0	Update of template and glossary to standard format, updates due to HRA preferences, other minor updates	Jackie Pullen
01 Oct 2018	3.1	Updates to SOP scope to cover trials managed by the KHP-CTO	Jackie Pullen
18 Dec 2019	4.0	Replacing 'subject' with 'participant' throughout	Jackie Pullen
28 Feb 2023	4.1	Minor updates	Jackie Pullen
28 Apr 2026	5.0	• SOP template updated • Addition of ICH GCP E6 (R3) proportionality requirements • Addition of Chief Investigator responsibilities to ensure proportionate consent process with appropriate materials available	Ann-Marie Murtagh

6. GLOSSARY

Chief Investigator (CI) – The overall lead researcher for a Clinical Trial (Outside the UK the term 'Coordinating Investigator', 'Principal Investigator' or 'Investigator' may be used for the overall lead researcher for a Clinical Trial). Chief Investigators are responsible for the overall conduct of a Clinical Trial.

Clinical Research Associate (CRA) – A staff member employed by the KHP-CTO who conducts monitoring activities for a Clinical Trial, including but not limited to the initiation phase, routine phase, and close down phase.

Clinical Trial aka **Clinical Trial of an Investigational Medicinal Product (CTIMP) -** Any investigation in human participants (other than a non-interventional trial) intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more medicinal products and/or to identify any adverse reactions to one or more such products and to study absorption, distribution, metabolism and excretion of one or more such products with the object of ascertaining the safety and/or efficacy of those products. Includes clinical trials of ATMPs.

Clinical Trial Authorisation (CTA) – Authorisation from the Medicines and Healthcare products Regulatory Agency (MHRA) to conduct a Clinical Trial. No Clinical Trial can commence in the UK without both a CTA and a favourable ethical opinion. Applications to the MHRA and the Research Ethics Committee (REC) may be made in parallel.

Co-Sponsors – Two organisations that take responsibility for the initiation, management and financing (or arranging of the financing) in relation to a Clinical Trial. The Co-Sponsors agree how the Sponsor functions for the Clinical Trial are divided between themselves and document this accordingly.

CTA Submission Package - The CTA submission form and all necessary supporting documents for the CTA submission.

Good Clinical Practice (GCP) - An international ethical and scientific quality standard for designing, conducting, recording, and reporting Clinical Trials that involve human participants. It ensures the safety, well-being, and rights of participants are protected while maintaining the credibility and accuracy of trial data. GCP is crucial for safeguarding participants and ensuring Clinical Trials produce reliable, scientifically valid results.

Health Research Authority (HRA) – The national body in England responsible for protecting and promoting the interests of patients and the public in health and social care research.

Human Biological Samples (HBS) – Materials of human origin collected for clinical care or research purposes, which contain biological information about an individual. They typically include tissues, cells, blood, blood components, bodily fluids, DNA, RNA, and other derivatives obtained directly or indirectly from a human body.

ICH GCP E6 (R3) – The International Council for Harmonisation – Good Clinical Practice, Guideline E6 (Revision 3). This is an internationally recognised ethical and scientific quality standard for the design, conduct, oversight, recording, and reporting of Clinical Trials.

Informed Consent Form (ICF) - A document by which a participant formally records their voluntary agreement to take part in a Clinical Trial, having been provided with and understood the information set out in the Participant Information Sheet.

Integrated Research Application System (IRAS) - The online application system used to apply for most permissions and approvals for research in health and social care in the UK.

Investigational Medicinal Product (IMP) – A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a Clinical Trial. This includes products with marketing authorisation when used in a way different from the approved form, for an unapproved indication, or to gain further information about an approved use.

Investigator Site File (ISF) – The Trial Location-specific set of essential documents held at the Trial Location by the Principal Investigator, demonstrating how the trial was conducted at

that particular location and that the investigator complied with the protocol, Sponsor instructions, and GCP.

KHP-CTO Non-Commercial Team - Comprises the Non-Commercial Trials Manager, CRA(s), Clinical Trial Administrator(s), and Training Executive(s).

King's Health Partners (KHP) - King's College London, Guy's and St Thomas' NHS Foundation Trust, King's College Hospital NHS Foundation Trust, and South London and Maudsley NHS Foundation Trust.

King's Health Partners Clinical Trials Office (KHP-CTO) – The department established by KHP to 1) undertake the governance, contracting and financial management for commercial research hosted by KHP, and 2) undertake the monitoring and regulatory oversight for non-commercial research sponsored by KHP.

Legally Acceptable Representative (LAR) – An individual or body authorised under applicable UK law to give informed consent on behalf of a potential Clinical Trial participant who lacks the capacity to consent for themselves.

Medicines & Healthcare products Regulatory Agency (MHRA) – The UK government agency responsible for regulating medicines, medical devices, and Clinical Trials. In the context of Clinical Trials, the MHRA i) acts as the licensing authority for Clinical Trials, ii) reviews the scientific, quality, and safety aspects of a Clinical Trial application, iii) issues CTAs, iv) oversees GCP and GMP inspections, v) monitors pharmacovigilance and safety reporting, and vi) enforces compliance with UK medicines legislation.

Minor – A person under the age of 16 years.

Modification - Any change to a Clinical Trial after initial approval that affects the information or conditions on which the Clinical Trial was authorised. Includes minor modifications, Modifications of an Important Detail (MOIDs), Route A and Route B substantial modifications.

Monitoring Plan - A Sponsor-approved document that sets out how Clinical Trial monitoring will be conducted, managed, and documented, using a risk-based approach to ensure participant safety, data integrity, and compliance with the approved protocol and applicable regulations.

New Rules Trial - A Clinical Trial where the application to approve it is submitted after 28 April 2026.

Old Rules Trial – A Clinical Trial where the application to approve it is submitted before 28 April 2026.

Participant Information Sheet (PIS) - A document provided to potential Clinical Trial participants that clearly explains the purpose, procedures, risks, benefits, and practical implications of taking part in a Clinical Trial, enabling them to make an informed decision about participation.

Partner Trusts – Guy's and St Thomas' NHS Foundation Trust, King's College Hospital NHS Foundation Trust, and South London and Maudsley NHS Foundation Trust.

Principal Investigator (PI) – The individual at a Trial Location who has primary responsibility for the conduct of the Clinical Trial at that Trial Location.

Regulations – Statutory Instrument 2025 No. 538: The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025, and the Human Tissue Act 2004.

Research & Development Department (R&D Dept.) – The NHS department at a Trial Location that's responsible for research and development at that Trial Location.

Research Ethics Committee (REC) – A national independent body consisting of healthcare professionals and non-medical members, whose responsibility is to protect the rights, safety and well-being of human subjects involved in a Clinical Trial, and to provide public assurance of that protection by, among other things, expressing an opinion on the Clinical Trial protocol, the suitability of the investigators and the adequacy of facilities, and on the methods and documents to be used to inform Clinical Trial participants and obtain their informed consent.

Simplified Arrangements - A risk-proportionate approach to seeking and documenting participant consent in certain lower-risk Clinical Trials, where the trial design, Investigational Medicinal Product use, and procedures do not materially increase risk or burden beyond standard care. Under simplified arrangements, the content, format, and process for providing information and recording consent may be streamlined, focusing on what differs from routine treatment, rather than using full, standalone consent documentation.

Site Initiation Visit (SIV) - A formal visit conducted by the Sponsor or their representative before a Trial Location begins participant recruitment, to confirm that the Trial Location is fully prepared to conduct the Clinical Trial in accordance with the approved protocol, regulatory requirements, and GCP.

Sponsor - The person or body who takes on ultimate responsibility for the initiation, management and financing (or arranging of the financing) of a Clinical Trial. The Regulations allow for two or more persons or bodies to take on responsibility for Sponsor functions.

Sponsor Team – The team selected by the CI to undertake the sponsorship functions of the Clinical Trial.

Standard Operating Procedures (SOPs) - Detailed, written instructions to achieve uniformity of the performance of a specific function. SOPs are the basis upon which Quality Systems and Processes are conducted and monitored against.

Trial Location - Means a hospital, health centre, surgery or other establishment, or facility or premises at or from which a Clinical Trial, or any part of such a Clinical Trial, is conducted.

Trial Location Team - The team selected by the PI to undertake the Trial Location functions of the Clinical Trial.

Trial Master File (TMF) - A standard filing system which contains all essential documents which individually and collectively permits the evaluation of the conduct of a Clinical Trial and the quality of the data produced. The filing system can be in the form of a single project file or a number of files/filing cabinets, depending on what is deemed most appropriate for a particular Clinical Trial given its size and complexity. The regulatory documents and approvals within the TMF will be maintained alongside Case Report Forms and source documentation.

Witness – A third party who's not involved in the Clinical Trial, such as a Trial Location employee who's not involved in the Clinical Trial, a relative of the participant, or a person similarly uninvolved in the Clinical Trial.