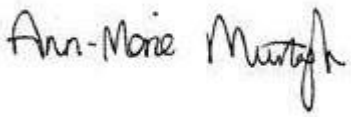
Sample Management in Clinical Trials

Document Details	
Document Type	Standard Operating Procedure
Document Name	KHP-CTO CT/SOP 20.0 Sample Management in Clinical Trials
Version	3.0
Effective from	28 Apr 2026
Review date	28 Apr 2029
Owner	King's Health Partners Clinical Trials Office
Prepared by	Kathryn Lobb, Quality Assurance Associate
Reviewed by	Craig Macpherson, Interim Non-Commercial Trials Manager
Approved by	Ann-Marie Murtagh, Director KHP-CTO
Signature and approval date	 29/12/2025

Contents

1. BACKGROUND AND PURPOSE

The purpose of this SOP is to describe the management of Human Biological Samples (HBS) collected for endpoint analysis in Clinical Trials in accordance with the study protocol, GCP and applicable regulations and associated guidance.

2. SCOPE

HBS collected for endpoint analysis in Clinical Trials sponsored by KHP. These include:

- HBS collected for endpoint analysis where the results are also used for standard of care
- HBS collected for endpoint analysis where the results are used solely for the Clinical Trial
- HBS collected in preparation for shipping to an external laboratory for endpoint analysis
- Safety monitoring

HBS collected for the following purposes are outside of the scope of this SOP:

- Endpoint analysis in Clinical Trials not sponsored by KHP
- Standard of care only
- Exploratory or translational research
- Contingency or confirmatory testing
- Biobanking / future use

3. PROCEDURE

3.1 General Sample Management Requirements

Task	Responsibility	Activity
1	Chief Investigator or delegate	Ensure that HBS requirements are clearly stated in the following Clinical Trial documents: • Protocol (which should list timepoints for HBS collection, include HBS type, detail total volume or number of HBS) • Informed Consent Form (which should identify whether consent has been given for the necessary and optional (if applicable) HBS to be collected) • Participant Information Sheet (which should explain the necessary and optional (if applicable) HBS to be collected) • Laboratory manual if applicable (which should detail instructions and processes for HBS analysis, include

		reagent standards, list equipment to be used, detail equipment maintenance and calibration) • Clinical Trial-specific SOPs for HBS if applicable (such SOPs may be required if SOP inclusion in the protocol is inappropriate) • Clinical Trial-specific instructions for participants if applicable (these should be submitted to REC for review)
2	Sole Sponsor/NHS Co-Sponsor R&D Dept.	Ensure that internal laboratories analysing HBS comply with GCP. The approach taken should include: • Quality Control measures • Quality Assurance measures (e.g. Clinical Trial monitoring)
3	Chief Investigator or delegate	Ensure any external laboratories are selected according to SOP 21.0 Vendor Selection and Oversight
4	Chief Investigator or delegate	If any changes are made to HBS management, ensure the appropriate Modification is submitted
5	Clinical Research Associate	Monitor HBS management at Trial Locations according to SOP 3.0 Clinical Trial Monitoring. Escalate any issues as appropriate. Record activities per SOP 3.0 Clinical Trial Monitoring.

3.2 Collecting HBS from Participants

Task	Responsibility	Activity
1	Chief Investigator or delegate	The Chief Investigator is responsible for ensuring that the Clinical Trial documentation clearly describes how HBS are to be obtained, including: • any training or competency requirements for individuals obtaining HBS; and • any equipment or materials required for HBS collection.
2	Sole Sponsor/NHS Co-Sponsor R&D Dept.	The Sole Sponsor/NHS Co-Sponsor R&D Dept. is responsible for reviewing the Sponsor-level HBS collection requirements and assessing the Partner Trust's capacity and capability to deliver them. This should be undertaken as part of the Sole Sponsor/NHS Co-Sponsor R&D Dept.'s review of the CTA Submission Package.

3	Principal Investigator or delegate	The Principal Investigator is responsible for ensuring that participant consent is respected and adhered to at each HBS collection event. In particular, the Principal Investigator shall ensure that: • Clinical Trial-specific HBS are obtained only after valid informed consent has been given, in accordance with the approved protocol and consent documentation • Optional HBS are collected only where explicit consent for those HBS has been obtained • All local clinical and safety requirements relating to HBS collection (for example, cannula placement or post-sampling observation) are followed, even where these are not explicitly specified in the Clinical Trial documentation, in order to minimise risk to participants • Any withdrawal of consent, whether in full or in part, is promptly documented in the participant's records and reflected in ongoing HBS collection activities
4	Principal Investigator or delegate	Where HBS are to be obtained by participants themselves, the Principal Investigator is responsible for ensuring that: • Participants are provided with all necessary materials required to obtain the HBS • Appropriate containers or packaging are provided to enable safe and secure transport of HBS from the participant's home to the Trial Location or laboratory, where applicable • Participants are given clear, appropriate instructions on the sampling process. The Principal Investigator shall ensure that the provision of materials and information is documented in the participant's records for each relevant sampling occasion.
5	Principal Investigator or delegate	Where the order of sampling is not specified in the Clinical Trial documentation, the Principal Investigator is responsible for determining and applying an appropriate sampling order, taking into account participant safety, scientific priority, and participant burden. Sampling should be prioritised in the following order: 1. Safety-related samples. 2. Primary endpoint samples. 3. Secondary endpoint samples. 4. Exploratory endpoint samples. The Principal Investigator shall also consider the invasiveness and overall burden of sampling on the participant when determining the order and extent of HBS collection.

		The Principal Investigator shall ensure that the time of HBS collection, together with any failure to obtain HBS (for example, due to cannula failure) and which HBS were not obtained, are accurately recorded in the participant's records.
6	Principal Investigator or delegate	The Principal Investigator is responsible for ensuring that significant issues relating to HBS are documented in a deviation log in a timely manner. In particular, the Principal Investigator shall ensure that: • Any missed safety-related HBS collections or assessments are treated as significant deviations • Any missed primary endpoint HBS collections are treated as significant deviations The Principal Investigator shall ensure that the deviation log is retained in the ISF.
7	Clinical Research Associate	The Clinical Research Associate is responsible for verifying, through monitoring activities, that the collection of HBS at Trial Locations is conducted in accordance with the approved Monitoring Plan, the protocol, and the participant's informed consent. Record activities per SOP 3.0 Clinical Trial Monitoring.
8	Principal Investigator or delegate	Where a participant's consent relating to the use of HBS changes at any point during participation, the Principal Investigator is responsible for ensuring that the change is managed and communicated appropriately. In particular, the Principal Investigator shall ensure that: • The Trial Location Team, and where relevant the laboratory team and/or Chief Investigator, are informed in a timely manner of any change in consent affecting HBS use • The change in consent (including withdrawal of consent or provision of new or amended consent), together with any reason provided by the participant, is accurately documented in the participant's records • The implications of the change are reflected in ongoing and future HBS collection, storage, analysis, or use, in accordance with the protocol and consent • A record of communication with the laboratory and/or Chief Investigator, where applicable, is retained in the ISF

3.3 Processing HBS

Task	Responsibility	Activity

1	Chief Investigator or delegate	Ensure any HBS processing requirements are clearly documented in the Clinical Trial documentation. The documentation should allow consistent processing by detailing: • Timelines after HBS collection • Temperature requirements • Centrifuge settings • Reagents or buffers to be used • Minimum aliquot size, aliquot number • Expected source of materials and equipment required for HBS processing (i.e. they'll be provided by the Sponsor, by the Trial Location, by an external provider)
2	Sole Sponsor/NHS Co-Sponsor R&D Dept.	The Sole Sponsor/NHS Co-Sponsor R&D Dept. is responsible for reviewing the Sponsor-level HBS processing requirements and assessing the Partner Trust's capacity and capability to deliver them. This should be undertaken as part of the Sole Sponsor/NHS Co-Sponsor R&D Dept.'s review of the CTA Submission Package.
3	Chief Investigator or delegate	If an external laboratory is required, the Chief Investigator is responsible for sharing the following with the external laboratory: • The HBS processing requirements • The appropriate Clinical Trial documentation • Any other information required by the external laboratory to enable it to determine if it can meet the HBS processing requirements
4	External laboratory	If an external laboratory is required, the external laboratory is responsible for determining whether it can meet the HBS processing requirements.
5	Sole Sponsor/Lead Co-Sponsor	If an external laboratory is required, the Sole Sponsor/Lead Co-Sponsor is responsible for negotiating the Service Level Agreement for HBS processing with the external laboratory.
6	External laboratory	The external laboratory is responsible for processing HBS in accordance with:

		• The HBS processing requirements • The Clinical Trial documentation • The Regulations The external laboratory is also responsible for: • Making contemporaneous records of HBS received, HBS processed, and HBS dispatched • Making records available for monitoring, audit, and oversight activities
7	Clinical Research Associate	The Clinical Research Associate is responsible for verifying, through monitoring activities, that the dispatch of HBS from Trial Locations to the external laboratory is conducted in accordance with the Clinical Trial documentation. Record activities per SOP 3.0 Clinical Trial Monitoring.

3.4 Labelling HBS

Task	Responsibility	Activity
1	Chief Investigator or delegate	The Chief Investigator is responsible for ensuring that appropriate, Clinical Trial-specific HBS labels are defined and made available for use across the Clinical Trial. The Chief Investigator shall ensure that each label supports unique identification and traceability of HBS and includes, as a minimum, the following information, where applicable: • The Clinical Trial identifier or acronym • The participant identifier • The date of HBS collection • The time of HBS collection, where required by the protocol • The type of HBS The Chief Investigator shall ensure that template HBS labels (or examples of label content) are retained in the TMF
2	Chief Investigator or delegate	Where HBS labels are to be completed by participants (for example, for HBS collected at home), the Chief Investigator is responsible for ensuring that the labels and any accompanying instructions for their completion are used only after a favourable opinion has been received from the REC. The Chief Investigator shall ensure that participant-completed labels and instructions are consistent with the approved participant

		information and consent documentation, and that REC-approved versions are made available to Trial Locations and retained in the TMF
3	Principal Investigator or delegate	The Principal Investigator is responsible for ensuring that each HBS is accurately labelled as soon as possible following HBS collection. The Principal Investigator shall ensure that: • Labelling is completed immediately after sampling and before the HBS leaves the collection area, wherever practicable • Labels are completed in accordance with the approved Clinical Trial label template and labelling requirements • The accuracy and completeness of the label are verified to ensure correct identification and traceability of the HBS
4	Principal Investigator or delegate	The Principal Investigator is responsible for ensuring that any significant issues relating to the labelling of HBS are documented in a timely manner. The Principal Investigator shall ensure that significant labelling issues (for example, missing, incorrect, illegible, or duplicated identifiers) are recorded in the deviation log. The Principal Investigator shall ensure that the deviation log is retained in the ISF.
5	Clinical Research Associate	The Clinical Research Associate is responsible for verifying, through monitoring activities, that HBS labelling at Trial Locations is conducted in accordance with the Clinical Trial documentation. Record activities per SOP 3.0 Clinical Trial Monitoring.

3.5 HBS Tracking

Task	Responsibility	Activity
1	Chief Investigator or delegate	Ensure the Clinical Trial documentation explains the chain of custody for HBS. The Chief Investigator shall ensure that: • Appropriate training and procedures are in place to support HBS tracking and chain of custody requirements at the Trial Locations • A HBS tracking system is implemented at the Trial Locations, which may be electronic or paper-based • The HBS tracking system supports monitoring

2	Principal Investigator or delegate	Maintain accurate and contemporaneous tracking of HBS at the Trial Location in accordance with the Clinical Trial documentation. The Principal Investigator shall ensure that: • All required HBS tracking information is recorded and kept up to date throughout the HBS lifecycle • The HBS tracking records are accessible and made available for monitoring
3	External laboratory or storage location	If an external laboratory or storage location is used, the external laboratory or storage location shall maintain accurate and contemporaneous tracking of HBS in accordance with the Clinical Trial documentation. The external laboratory or storage location shall ensure that: • All required HBS tracking information is recorded and kept up to date throughout the HBS lifecycle • The HBS tracking records are accessible and made available for monitoring
4	Clinical Research Associate	In accordance with the approved Monitoring Plan, verify through monitoring activities that HBS tracking at Trial Locations is conducted in line with Clinical Trial requirements. The Clinical Research Associate shall verify that: • HBS tracking records are complete, accurate, and consistent with Clinical Trial documentation • Any discrepancies, gaps, or significant issues identified in HBS tracking are appropriately documented and escalated in line with the monitoring and deviation management processes Record activities per SOP 3.0 Clinical Trial Monitoring.

3.6 HBS Transport

Task	Responsibility	Activity
1	Chief Investigator or delegate	Where HBS are to be transported from one location to another, the Chief Investigator is responsible for ensuring that clear, Clinical Trial-specific shipment requirements are: • Detailed in the Clinical Trial documentation • Defined and communicated to the sending and receiving teams

		The Chief Investigator shall ensure that this information includes, as a minimum: • The required shipment conditions (for example, temperature control and time limits) • The approved packaging and packing requirements • Any restrictions on shipment timing or scheduling (for example, HBS to be dispatched on the day of collection)
2	Sole Sponsor/NHS Co-Sponsor R&D Dept.	The Sole Sponsor/NHS Co-Sponsor R&D Dept. is responsible for reviewing the Sponsor-level HBS transport requirements and assessing the Partner Trust's capacity and capability to deliver them. This should be undertaken as part of the Sole Sponsor/NHS Co-Sponsor R&D Dept.'s review of the CTA Submission Package.
3	Chief Investigator or delegate	If an external laboratory or storage location is required, the Chief Investigator is responsible for sharing the following with the external laboratory or storage location: • The HBS transport requirements • The appropriate Clinical Trial documentation • Any other information required by the external laboratory or storage location to enable it to determine if it can meet the HBS transport requirements
4	External laboratory or storage location	If an external laboratory or storage location is required, the external laboratory or storage location is responsible for determining whether it can meet the HBS transport requirements.
5	Sole Sponsor/ Lead Co-Sponsor	If an external laboratory or storage location is required, the Sole Sponsor/Lead Co-Sponsor is responsible for negotiating the Service Level Agreement for HBS transport with the external laboratory or storage location.
6	Sending team	Package and dispatch HBS in accordance with the HBS transport requirements. The sending team shall ensure that: • HBS are packaged in line with the HBS transport requirements • A shipment record is completed, documenting the date of shipment, the number and type of HBS dispatched, and the designated contact for confirmation of receipt • HBS tracking records are updated contemporaneously and made available for monitoring

7	Receiving team	Receive, inspect, and store HBS promptly and in accordance with the HBS transport requirements. The receiving team shall ensure that: • HBS are unpacked promptly on receipt and stored under the appropriate conditions specified in the HBS transport requirements • The date of shipment, together with the number and type of HBS received, is checked against the shipment documentation • Confirmation of receipt is provided to the designated contact in the sending team • Records of HBS receipt are retained and made available for monitoring
8	Clinical Research Associate	In accordance with the approved Monitoring Plan, verify through monitoring activities that HBS were transported from Trial Locations in accordance with the HBS transport requirements. The Clinical Research Associate shall verify that: • HBS transport activities (e.g. packaging, shipment, record-keeping) for HBS dispatched from Trial Locations are consistent with the Clinical Trial documentation • Any transport-related deviations or issues that come to light at Trial Locations are appropriately documented and escalated in line with the monitoring and deviation management processes Record activities per SOP 3.0 Clinical Trial Monitoring.

3.7 HBS Storage

Task	Responsibility	Activity
1	Chief Investigator or delegate	Where HBS are to be stored at a storage location, the Chief Investigator is responsible for ensuring that clear, Clinical Trial-specific storage requirements are: • Detailed in the Clinical Trial documentation • Defined and communicated to the storage location The Chief Investigator shall ensure that this information includes, as a minimum: • Storage conditions and controls • Identification and traceability requirements

		• Permitted use and retention parameters
2	Sole Sponsor/NHS Co-Sponsor R&D Dept.	The Sole Sponsor/NHS Co-Sponsor R&D Dept. is responsible for reviewing the Sponsor-level HBS storage requirements and assessing the Partner Trust's capacity and capability to deliver them. This should be undertaken as part of the Sole Sponsor/NHS Co-Sponsor R&D Dept.'s review of the CTA Submission Package.
3	Chief Investigator or delegate	If an external storage location is required, the Chief Investigator is responsible for sharing the following with the external storage location: • The HBS storage requirements • The appropriate Clinical Trial documentation • Any other information required by the external storage location to enable it to determine if it can meet the HBS storage requirements
4	External storage location	If an external storage location is required, the external storage location is responsible for determining whether it can meet the HBS storage requirements.
5	Sole Sponsor/ Lead Co-Sponsor	If an external storage location is required, the Sole Sponsor/Lead Co-Sponsor is responsible for negotiating the Service Level Agreement for HBS storage with the external storage location.
6	External storage location	The external storage location shall ensure that: • HBS are stored in accordance with the Clinical Trial documentation • Storage records (including, as a minimum, temperature logs, maintenance logs, and calibration records) are completed contemporaneously, kept up to date, and made available for monitoring • Any temperature excursion or other significant storage issue is documented as a deviation and made available for monitoring • Appropriate actions are taken in accordance with the protocol or established laboratory practice (for example, transfer of HBS to a validated back-up storage location following an excursion)

7	Clinical Research Associate	In accordance with the approved Monitoring Plan, verify through monitoring activities that the storage of HBS is conducted in line with HBS storage requirements. The Clinical Research Associate shall verify that: • Storage conditions and records at the Trial Locations are consistent with the Clinical Trial documentation • Any storage-related deviations or issues at the Trial Locations have been appropriately documented and managed Record activities per SOP 3.0 Clinical Trial Monitoring.
8	Chief Investigator or delegate	Manage the external storage location's expectations with respect to the planned EoT date and any changes to the EoT date
9	External storage location	Prior to EoT, confirm with the Chief Investigator whether any Clinical Trial-specific HBS remain in storage. The external storage location shall ensure that: • The provisions in the Clinical Trial documentation are followed for HBS remaining in storage at EoT, unless the Chief Investigator instructs otherwise • HBS logs and tracking records are updated in a timely manner and made available for monitoring
10	Clinical Research Associate	In accordance with the approved Monitoring Plan, confirm at the Close Out Visit at each Trial Location that: • All HBS have been transferred, stored, or disposed of as required by the Clinical Trial documentation • Documentation supporting the final status of the HBS is complete and available in the ISF Record activities per SOP 3.0 Clinical Trial Monitoring.

3.8 Blinding Requirements (blinded trials only)

Task	Responsibility	Activity
1	Chief Investigator	Ensure that all individuals in the Clinical Trial Team with access to unblinded information are formally identified. The Chief Investigator shall ensure that:

		• All such individuals are explicitly listed on the delegation log, with their unblinded responsibilities clearly described • The delegation log is retained in the TMF and made available for monitoring
2	Principal Investigator	Ensure that all individuals in the Trial Location Team with access to unblinded information are formally identified. The Principal Investigator shall ensure that: • All such individuals are explicitly listed on the delegation log, with their unblinded responsibilities clearly described • The delegation log is retained in the ISF and made available for monitoring
3	Clinical Research Associate	In accordance with the approved Monitoring Plan, verify through monitoring activities that access to unblinded information is restricted to appropriately delegated individuals. The Clinical Research Associate shall verify that: • Unblinded data is communicated only to individuals listed on the delegation log as having unblinded responsibilities • Any inappropriate access to or disclosure of unblinded information is identified, documented, and escalated in line with the Clinical Trial's deviation and escalation processes Record activities per SOP 3.0 Clinical Trial Monitoring.
4	Any individual involved in the Clinical Trial	Any individual involved in the Clinical Trial shall report any unscheduled or accidental unblinding in accordance with SOP 6.0 Notification of Serious Breach of Good Clinical Practice or Trial Protocol

3.9 Sample Analysis

Sample analysis is covered by SOP 19.0 Laboratory Procedures and Sample Analysis in Clinical Trials.

3.10 HBS Disposal

Task	Responsibility	Activity
1	Chief Investigator	Prior to EoT: • Ensure that all required analysis of HBS has been completed • Confirm with the external storage location whether any

		Clinical Trial-specific HBS remain in storage. • Confirm with the external storage location that provisions in the Clinical Trial documentation are followed for HBS remaining in storage at EoT, or instruct the external storage location otherwise
2	Chief Investigator or delegate	Where the HBS are to be transferred to a tissue bank, provide the external storage location with: • Tissue bank details and contact information • HBS preparation, packaging and transport instructions
3	External storage location	Where the HBS are to be transferred to a tissue bank, ensure: • HBS are packaged in line with the HBS transport requirements • A shipment record is completed, documenting the date of shipment, the number and type of HBS dispatched, and the designated contact for confirmation of receipt • HBS tracking records are updated contemporaneously and made available for monitoring
4	External storage location	Where the external storage location must dispose of any HBS: • Disposal must take place within 12 months of EoT in accordance with the Clinical Trial documentation, participant consent, local SOPs and the Regulations. The external storage location must: • Document the date of disposal and the number and type of HBS disposed of • Update HBS tracking records contemporaneously and make them available for monitoring and audit
5	Clinical Research Associate	In accordance with the approved Monitoring Plan, verify at the Close Out Visit at each Trial Location that HBS tracking records confirm that no Clinical Trial-specific HBS remain in storage. Record activities per SOP 3.0 Clinical Trial Monitoring.

3.11 HBS Records Requirements

Task	Responsibility	Activity
1	Chief Investigator or delegate	The Chief Investigator shall ensure that records required to support HBS collected for safety assessments and endpoint analysis are clearly defined within the Clinical Trial documentation, including identification of any additional laboratory records required beyond

		standard source data. Ensure the Sponsor-level HBS collection, processing, transport and storage records, and any deviations, are stored in the TMF.
2	Principal Investigator or delegate	The Principal Investigator shall ensure that the Trial Location-level HBS collection, processing, transport and storage records, and any deviations, are stored in the ISF.
3	External laboratory or storage location	Where an external laboratory or storage location is used, the external laboratory or storage location shall maintain complete, accurate, and contemporaneous records relating to the receipt, processing, storage, transfer, and disposal of HBS, in accordance with the Clinical Trial documentation.
4	External laboratory	Where an external laboratory is used and the results of HBS analysis are required to support standard of care for participants, these results must be transposed into the participant's medical records in a timely manner to support participant safety and continuity of care.
5	Chief Investigator or delegate	Where an external laboratory or storage location is used and relevant records (for example, equipment calibration records or laboratory training records) are not held in the ISF/TMF; the location of these records must be clearly referenced within the TMF to enable inspection, audit, and research transparency.
6	Clinical Research Associate	The Clinical Research Associate, in accordance with the approved Monitoring Plan, shall verify that HBS records meet trial, inspection, audit, and transparency requirements. Ensure records are prepared for archiving in line with SOP 4.0 Archiving of Clinical Trial Data and Essential Documentation Record activities per SOP 3.0 Clinical Trial Monitoring

4. RELATED TEMPLATES AND SOPS

- Disposal Form template
- Fridge Freezer Sample Transfer Log template
- Nitrogen Vessel Storage Log template
- Sample Tracking Log template
- Temperature Log template

- SOP 3.0 Clinical Trial Monitoring
- SOP 4.0 Archiving of Clinical Trial Data and Essential Documentation

- SOP 6.0 Notification of Serious Breach of Good Clinical Practice or Trial Protocol
- SOP 19.0 Laboratory Procedures and Sample Analysis in Clinical Trials
- SOP 21.0 Vendor Selection and Oversight

5. CHANGE HISTORY

Change History			
Date	Version Number	Change details	Approved by
05 Jan 2021	2.0	Updated procedure for poorly labelled samples	Jackie Pullen
19 May 2023	2.1	Minor amendments	Jackie Pullen
01 Jan 2026	3.0	• Move to new template • Incorporation of ICH GCP E6 (R3) proportionality requirements for primary and secondary endpoint analysis of HBS • Clarification of HBS management expectations (inc. HBS transfer at EoT) for external vendors	Ann-Marie Murtagh

6. GLOSSARY

Advanced Therapy Medicinal Product (ATMP) - A medicine based on genes, cells, or engineered tissues that is intended to treat, prevent, or diagnose disease by modifying biological functions at a cellular or genetic level.

Blinding - A procedure in which information about a participant's assigned treatment is deliberately withheld from one or more parties involved in a Clinical Trial, to minimise bias in treatment administration, assessment of outcomes, and data interpretation.

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.

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

Close Out Visit (COV) - A monitoring visit conducted at the end of a Clinical Trial at a Trial Location to confirm that all Clinical Trial activities have been completed in accordance with the protocol and regulatory requirements. It typically includes verification that essential documents are complete and archived, investigational product accountability is resolved, outstanding data queries are addressed, and any remaining HBS are managed or disposed of appropriately.

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.

Curriculum Vitae (CV) - A summary of a person's education, professional history and job qualifications.

End of Trial (EoT) – The end of the trial as defined in the protocol. The end of the trial is typically expressed as a condition-based event, not a predetermined date.

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.

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.

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.

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.

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.

Sole Sponsor/NHS Co-Sponsor R&D Dept. – The R&D Dept. at the Partner Trust that's sponsoring or co-sponsoring the Clinical Trial.

Sole Sponsor/NHS Co-Sponsor Representative – The appropriate signatory at the Partner Trust that's sponsoring or co-sponsoring 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.

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.

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.