UNIVERSITY OF LINCOLN

Clinical Governance – Quality Manual
CGQM

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Approved by: Signature:	UREC See original

Version History	**Reason for change**

NOTE: This Clinical Governance Quality Manual is subject to regular review.

Please ensure that the version of this document is the most up to date.

OUT OF DATE DOCUMENTS MUST NOT BE USED AND HARD COPIES SHOULD BE DESTROYED

Contents

1. PURPOSE and SCOPE

Research studies which fall within the remit of the UK Policy Framework for Health and Social Care Research must be compliant with applicable legislation and regulatory standards.

The purpose of this Quality Manual is to document the University of Lincoln's Clinical Governance – Quality Management System (CG-QMS) for the governance of clinical research to ensure that all University of Lincoln researchers* and Lincoln Clinical Trial Unit (LinCTU) staff understand the necessary requirements and procedures covered by the standards set by ICH-GCP and any regulatory bodies.

*researchers as defined in the University of Lincoln Code of Practice for Research: Refers to any person who conducts research, including but not limited to as an employee; an independent contractor or consultant; a research student; a visiting or emeritus member of staff; or a member of staff on a joint clinical or honorary contract.

2. BACKGROUND

2.1 UK Policy Framework for Health and Social Care Research

The purpose of the UK Policy Framework for Health and Social Care Research is to provide a consistent framework and sets out principles of good practice in the management and conduct of health and social care research that take account of legal requirements and other standards.

The UK Policy Framework for Health and Social Care Research covers the four UK Health Departments: The Department of Health (England), the Department of Health (Northern Ireland), the Scottish Government Health and Social Care Directorates and the Department for Health and Social Services (Wales)).

UK Policy Framework for Health and Social Care Research

2.2 Health Research Authority

The core purpose of the Health Research Authority (HRA) is to protect and promote the interests of patients and the public in health and social care research.

To achieve this, they:

- make sure that research is ethically reviewed and approved
- promote transparency in research
- oversee a range of committees and services and
- provide independent recommendations on the processing of identifiable patient information where it is not always practical to obtain consent, for research and non-research projects.

These principles protect and promote the interests of patients, service users and the public in health and social care research, by describing ethical conduct and proportionate, assurance-based management of health and social care research, so as to support and facilitate high-quality research in the UK that has the confidence of patients, service users and the public.

It is for organisations and individuals that have responsibilities for health and social care research. This includes funders, sponsors, researchers and their employers, research sites and care providers.

2.3 MHRA

The Medicines and Healthcare Products Regulatory Agency (MHRA) inspect Clinical Trials of Investigational Medicinal Products (CTIMPs) conducted by both commercial and non-commercial organisations. GCP Inspectors assess whether organisation sponsoring and/or conducting CTIMPs have systems in place to meet the requirements of the Clinical Trials Regulations (now amended by The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019)

The University's CG-QMS meets the requirements of the Clinical Trials Regulations.

The University is registered with the MHRA to undertake CTIMPs and has been assigned number 54863

2.4 Good Clinical Practice (GCP)

Good Clinical Practice (GCP) is the international ethical, scientific and practical standard to which all clinical research is conducted.

GCP protects the rights, safety and wellbeing of study participants

Compliance with GCP assures patients and the public that the rights, safety and wellbeing of people taking part in studies are protected and that research data is reliable.

Both the HRA and the Medicines and Healthcare products Regulatory Agency (MHRA) advocate a proportionate approach to the application of GCP to the conduct of clinical trials and the appropriate training of staff involved, including those seeking consent from potential participants. Further guidance relating to GCP training may be obtained by contacting the University's Research Governance Manager sponsor@lincoln.ac.uk.

2.5 Human Tissue Licence (University of Lincoln)

Where clinical research involves Human Tissue coming to the University, researchers must comply with the Human Tissue Quality Manual and associated Human Tissue Quality Management System. Please contact HTOG@lincoln.ac.uk for further information

2.6 Integrated Research Application System

The Integrated Research Application System (IRAS) is a single system for applying for the permissions and approvals for health, social and community care research in the UK.

Research applicants are able to submit research applications to the HRA through IRAS including those for HRA Approval, applications for Research Ethics Committee (REC) review, as well as applications for the Confidentiality Advisory Group (CAG).

IRAS enables applicants to enter the information about their project once instead of duplicating information in separate application forms and uses filters to ensure that the data collected and collated is appropriate to the type of study and the permissions and approvals required.

IRAS captures the information needed for the relevant approvals from the following review bodies:

- Administration of Radioactive Substances Advisory Committee (ARSAC)
- Confidentiality Advisory Group (CAG)
- Gene Therapy Advisory Committee (GTAC)
- Health Research Authority (HRA) for projects seeking HRA Approval
- Medicines and Healthcare products Regulatory Agency (MHRA)
- NHS / HSC R&D offices
- NHS / HSC Research Ethics Committees
- Her Majesty's Prison and Probation Service
- Social Care Research Ethics Committee

3. CLINICAL GOVERNANCE QUALITY MANAGEMENT SYSTEM (CG-QMS)

This Clinical Governance Quality Manual (CGQM) forms part of the University of Lincoln's Clinical Governance Quality Management System (CG-QMS) which relates to the governance of clinical research.

The successful implementation of the CG-QMS framework of policies and procedures (see section 5), seeks to ensure that all clinical research sponsored by the University of Lincoln or where the Lincoln Clinical Trial Unit (LinCTU) has managed in accordance with expected standards.

It is paramount that the research community and the public have confidence that all clinical research are conducted in accordance with any relevant framework, legislation and professional standards.

The key quality objectives are to establish an effective CGQMS that will:

- continue to evolve to demonstrate an enduring commitment to quality improvement
- provide a robust but practical framework for compliance
- be an integral component of the University's Code of Practice for Research
- have the confidence of and be fully embedded into practice by all researchers
- engender the highest levels of trust and confidence in our stakeholders and the broader public
- enhance the University's reputation for the delivery of research of the highest quality and ethical standards.

The University of Lincoln CG-QMS may be found at https://lncn.ac/clinicalSOPs

4. STANDARD OPERATING PROCEDURES (SOPS)

Clinical Governance

As part of the CG-QMS, the following suite of Clinical Governance SOPs (CG-SOPs), Record Forms and Work Instructions have been developed, detailing polices, and instructions on all processes that affect all clinical research.

All SOPs are written in accordance with applicable GCP requirements as outlined in Directives 2001/20/EC and 2005/20/EC (in the UK, these Directives were transposed into UK law by SI 2004/1031, SI 2006/1928) and subsequent amendments and when applicable Regulation 536/2014 and subsequent relevant SIs. Where applicable it incorporates elements of ICH GCP tripartite guidelines (E6)".

- RG-QMS RG01 Design and Review of Standard Operating Procedures
- RG-QMS RG02 Document Control – (QMS documents)
- RG-QMS RG03 Document Control – (Study documents)
- CG-QMS CGQM Clinical Governance - Quality Manual
- CG-QMS SOP CG01 Training
- CG-QMS SOP CG02 Sponsorship
- CG-QMS SOP CG03 Risk Assessment
- CG-QMS SOP CG04 Protocol Development
- CG-QMS SOP CG05 Ethics Applications
- CG-QMS SOP CG06 Regulatory Applications
- CG-QMS SOP CG07 Trial Master / Site File
- CG-QMS SOP CG08 Trial Initiation
- CG-QMS SOP CG09 Recruitment and Consent
- CG-QMS SOP CG10 Adverse Events and Safety Reporting
- CG-QMS SOP CG11 Serious Breach
- CG-QMS SOP CG12 Amendment
- CG-QMS SOP CG13 Monitoring and Audit
- CG-QMS SOP CG14 Trial Closure
- CG-QMS SOP CG15 Archiving (Clinical data)
- CG-QMS SOP CGD1 Data Protection and Confidentiality
- CG-QMS SOP CGD2 Data Management
- CG-QMS SOP CGD3 Data Storage , Security and Backup
- CG-QMS SOP CGD4 Database Design
- CG-QMS SOP CGD5 Case Report Form
- CG-QMS SOP CGD6 Randomisation
- CG-QMS SOP CGI1 ICT Purchasing
- CG-QMS SOP CGS1 Statistical Principles
- CG-QMS SOP CGS2 Statistical analysis plan
- CG-QMS SOP CGS3 Sample Size Calculations
- CG-QMS SOP CGS4 Health Economic Analysis Plan

- CG-QMS Data Monitoring Committee
- CG-QMS Trial Management Group
- CG-QMS Trial Steering Committee
- CG-QMS SOP CGIB1 Investigator Brochure

SOPs provide a uniform approach to the performance of specific functions to ensure continuity and consistency across the University and LinCTU.

Incorporated into each of the SOPs, are the requirements for risk assessment, where appropriate, more detailed local procedures, training, audit and monitoring requirements, and sources of advice and further guidance.

Record Forms (RF) and Work Instructions (WI) accompany an SOP to provide further instruction or record as required by the SOP.

The University of Lincoln CG-SOPs may be found https://lncn.ac/clinicalSOPs

5. CLINICAL GOVERNANCE OVERSIGHT

RESPONSIBILITIES

5.1. Sponsor

All research falling under the remit of the Secretary of State for Health must have a formal sponsor. This includes all research in health and social care that involve NHS patients, their tissue or information. There are similar requirements for research involving social care practitioners, clients and resources, where this falls under the Secretary of State for Health's remit.

Any research outside the NHS should also have a sponsor to take on the specific responsibilities of the role.

Some funders may also require the allocation of a research sponsor as part of the application process.

The University of Lincoln will act as a research sponsor where the CI is employed by (or is a student of) the university, the university is managing the research, and no external staff have been involved in protocol development.

The University of Lincoln named sponsor is the Deputy Vice Chancellor Research & Innovation.

Where external staff or organisations are involved in the development or management of the research it may be more appropriate for another organisation to act as sponsor

All applications for research sponsorship will be reviewed by the Research Governance Team (RGT) prior to authorisation from the sponsor in accordance with the CG-QMS.

5.2. Research Governance manager / Sponsor Contact

The Research Governance Manager is the Document Controller and is responsible for managing the university's Clinical Governance Quality Manual and associated Clinical Governance Quality Management System and ensuring compliance with any policy, legislation and regulatory approvals.

5.3. Chief Investigator

The Chief Investigator (CI) is an individual who is responsible for the conduct of the whole project in the UK. The named CI should be a researcher who is professionally based in the UK, and:

- able to supervise the research effectively

Note: Students (including PGR students) cannot act as Chief Investigator

The Chief Investigator drives the research activity and have overall responsibility for their research projects – the governance and management of the research and their team

It is the responsibility of the Chief Investigator (CI) to request Sponsorship. However, it is recognised that this responsibility may be delegated to another member of the research team with sufficient knowledge of the research activity or, where the research is being conducted by a student (all levels), then the Academic Supervisor should act as the CI when applying for Sponsorship.

5.4. Principal Investigator

A Principal Investigator (PI) is an individual responsible for the conduct of the research at a research site. There should be one PI for each research site. In the case of a single-site study, the chief investigator and the PI will *normally* be the same person – unless it is student research, then the student may be named as PI.

5.5. Individual Researchers

All researchers must comply any relevant permissions, and CGQMS (section 3).

6. COMPLIANCE

It is important for the continuation of research, the reputation of its researchers and that of the University more broadly, that the University adheres and external approvals and adopts best practice, including robust and effective quality management, to its activities involving clinical research. If any staff or students knowingly breach any permissions, or the University's related policies and Clinical Governance Standard Operating Procedures, detailed in the CGQM, they may be subject to the University's Code of Practice for Dealing with Allegations of Research Misconduct.

7. GOVERNANCE FRAMEWORK

University Committee Structure

7.1. Academic Board (AB)

Academic Board is responsible for general issues relating to the research, scholarship, teaching and courses of the University, including criteria for the admission of students; the appointment and removal of internal and external examiners; policies and procedures for assessment and examination of the academic performance of students; the content of courses; the procedures for the award of qualifications and honorary academic titles; and the procedures for the expulsion of students for academic reasons. Such responsibilities shall be subject to the requirements of validating and accrediting bodies, as well as considering the development of the academic activities of the University and the resources needed to support them and for advising the Vice Chancellor and Board of Governors those matters; and advising on such other matters as the Board of Governors or the Vice Chancellor may refer to the Academic Board.

7.2. Research Committee (RC)

Research Committee is a sub-committee of Academic Board convened to:

- Oversee the development of research activity, policy, culture and environment.
- Keep under review the research strategies of the University and its Colleges, in the light of internal and external contexts.
- Oversee the delivery of an excellent PGR student experience.
- Oversee the development of the University's REF strategy and monitor its implementation.
- Oversee the development and implementation of research ethics policies and procedures.

7.3. University Research Ethics Committee (UREC)

The University Research Ethics Committee (UREC) is established to have oversight of the principles and practices of ethical research conduct across the university, and University Human and non-Human Research Ethics Committees. It works in unison with the Research Committee to ensure that Ethics Committees are supported to implement, monitor and report on the ethical research conduct in their respective disciplines.

AB, RC and UREC all have Terms of Reference and a Full List of Members is available on the University of Lincoln portal.

7.4. Research Ethics

All clinical research projects conducted by University of Lincoln researchers requires a "favourable opinion" from a relevant Research Ethics Committee (REC) (University or Health Research Authority (HRA) NHS REC) and Medicines Health Regulatory Authority (MHRA) (where appropriate).

In addition, for projects where University of Lincoln is the Sponsor (as defined in the UK policy framework for health and social care research) Sponsors approval for the project is also required – see 9.4.

For projects that do not require a sponsor, applications should be submitted to the University Ethics Committee following the procedure set out following the University of Lincoln Research Ethics policy available on the University of Lincoln portal.

Researchers should also familiarise themselves with the University of Lincoln Research Ethics Policy available on the University of Lincoln portal.

7.5. Research Governance

Where University of Lincoln is the Sponsor (as defined in the UK policy framework for health and social care research) Sponsors approval for the project is also required.

Details of the sponsor review and approval process may found in CG-QMS SOP CG02 Sponsorship

8. REGISTRATION and TRAINING

All those involved in undertaking clinical research will in accordance with CG-QMS SOP CG01 Training:

- undertake training (relevant to their role
- receive and maintain awareness of training support materials
- have access to advice and guidance
- understand and adhere to the University's Clinical Governance Quality Management System
- comply with the requirements of the related policies and Standard Operating Procedures (SOPs)
- maintain a Research Training Portfolio (RTP) to record related training and development activities undertaken.

9. ADVICE and GUIDANCE

Further advice on any aspect of the CG-QMS or the policies and procedures in this CGQM may be sought from the Research Governance Manager (RGM). The RGM will seek advice directly from the HRA/MHRA, as appropriate.

10. MONITORING and AUDIT

Regular monitoring of the effectiveness of the implementation of this Quality Manual will be undertaken by the Chief Investigator, Principal Investigator, authorised staff from the Lincoln Clinical Trial Unit (LinCTU) and/or others nominated by the Research Governance Manager. In addition, regular audits will also be undertaken by the Research Governance Manager and the MHRA inspectors, as required, in accordance with SOP CG02 Monitoring and Audit.

11. COMPLAINTS

Any individual member of staff, student, or member of the public wishing to raise a complaint in relation to the clinical research should direct it to the Research Governance Manager in the first instance to sponsor@lincoln.ac.uk.

If the complaint is not resolved to the satisfaction of the complainant, it may be referred to the Deputy Registrar, on behalf of the Registrar, in accordance with the University's Complaints and Feedback Procedure available on the University of Lincoln webpage.

12. DEFINITIONS and ABBREVIATIONS

Academic Board (AB): Academic Board is responsible for general issues relating to the research, scholarship, teaching and courses of the University, including criteria for the admission of students; the appointment and removal of internal and external examiners; policies and procedures for assessment and examination of the academic performance of students; the content of courses; the procedures for the award of qualifications and honorary academic titles; and the procedures for the expulsion of students for academic reasons.

Adverse event: Any unfavourable or unintended symptom or sign, including change in laboratory results, temporarily associated with an investigational intervention during the conduct of a clinical trial. It does not matter whether this event is considered related or unrelated to the intervention.

Amendment: See also Substantial Amendment and Non-substantial Amendment

Amendment Tool: The amendment tool categorises each amendment and provides tailored guidance on submission, identifying any review bodies an amendment needs to be sent to, based on the changes that are being made to a study.

Archiving: is the process by which inactive information, in any format, is securely stored for long periods of time. Such information may – or may not – be used again in the future, but nonetheless should be stored until the end of its retention schedule.

Audit: The evaluation of a system, process or procedure in order to ascertain its effectiveness and the validity and reliability of the information.

CAPA: Corrective and Preventative Action used to bring about improvements to an organisation's processes and is often undertaken to eliminate causes of non-conformities or other undesirable situations.

Case Report Form (CRF) is a paper or electronic questionnaire specifically used in clinical trial research. The case report form is the tool used by the sponsor of the clinical trial to collect data from each participating patient.

CG-QMS: Clinical Governance - Quality Management System (See Quality Management System (QMS) and CG-SOP).

CG-SOP: Clinical Governance Standard Operating Procedures part of the CGQMS outlining standard procedures for management of clinical research, participants and data.

CGQM: Clinical Governance Quality Manual part of the CG-QMS (this document).

Chief Investigator (CI): is the overall lead researcher for a research project (Outside the UK the term Coordinating Investigator or Investigator may be used). In addition to their responsibilities if they are members of a research team, chief investigators are responsible for the overall conduct of a research project.

Child/Children: The Clinical Trials Regulation makes reference to those aged under 16 for the purposes of consent.

ClinicalTrials.gov: is a registry of clinical trials. It is run by the United States National Library of Medicine (NLM) at the National Institutes of Health, and is the largest clinical trials database, holding registrations from over 329,000 trials from 209 countries.

Clinical Trial Authorisation (CTA): In the UK, a Clinical Trial Authorisation (CTA) from Medicine and Healthcare Products Regulatory Agency (MHRA) is required for a Clinical Trial of an Investigational Medicinal Product (CTIMP). Trials with EU sites must be registered on the European Clinical Trials Database by obtaining a EudraCT number (see also EudraCT)

Clinical Trials of Investigational Medicinal Products (CTIMPs): A Clinical Trial of an Investigational Medicinal Product (CTIMP) is a clinical trial or study that is evaluating the safety or efficacy of a drug (Investigational Medicinal Product) or obtaining any other information about the drug e.g. how it is absorbed, distributed, metabolised or excreted.

Confidentiality Advisory Group (CAG): The Confidentiality Advisory Group (CAG) is an independent body which provides expert advice on the use of confidential patient information – including providing advice to us, the Health Research Authority (HRA). It also provides advice to the Secretary of State for Health for non-research uses.

Consent: This is either the consent of the person concerned (the participant), their nominated representative or (in the absence of either of these) the consent of a person in a qualifying relationship with the donor (e.g. spouse or partner; parent; child; etc.).

CV/Curriculum Vitae: A written overview of a person's experience and other qualifications.

Data Monitoring Committee (DMC): A data monitoring committee (DMC) – sometimes called a data and safety monitoring board (DSMB) – is an independent group of experts who monitor patient safety and treatment efficacy data while a clinical trial is ongoing.

Document Controller: Person responsible for storing, managing and tracking of documents which form part of a Quality Management System (see QMS).

Donor: Every human tissue source, whether living or deceased, of tissue, cells, organs or part organs.

DVC: Deputy Vice Chancellor.

Electronic Case Report Form (eCRF): See also Case Report Form

Electronic Data Capture (EDC): systems are computerised systems designed for the collection of clinical data in electronic format for use mainly in human clinical trials.

EudraCT: EudraCT (European Union Drug Regulating Authorities Clinical Trials Database) is the European database for all interventional clinical trials on medicinal products authorized in the European Union (EEA) and outside the EU/EEA if they are part of a Paediatric Investigation Plan (PIP).

Feasibility Study: See also Pilot Study

GafREC: Governance arrangements for research ethics committees is a policy document of the Devolved Administrations, the Health Research Authority and the UK Ethics Committee Authority. It describes what is expected from the research ethics committees that review research proposals relating to areas of responsibility of the Devolved Administrations and the Health Research Authority. It also explains when review by these committees is required.

Good Clinical Practice: A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected. Ethical and scientific quality standards for designing, conducting, recording and reporting trials that involve participation of human subjects to ensure that the rights, safety and wellbeing of the trial subjects are protected. Ensure the credibility of clinical trial data.

Health Economic Analysis Plan (HEAP): All clinical trials, using LinCTU, with a health economic analysis must have a Health Economic Analysis Plan (HEAP). HEAP is a comprehensive description of the methods and presentation of data analysis proposed.

Health Research Authority (HRA): The HRA protects and promotes the interests of patients and the public in health and social care research.

Human samples, tissue and material: All material derived from a human (cellular and acellular) that may be acquired, stored and used in research.

ICH-GCP: See also Good Clinical Practice

Independent Data Monitoring Committee (DMC): see also Data Monitoring Committee

IRAS: The Integrated Research Application System (IRAS) is a single system for applying for the permissions and approvals for health and social care / community care research in the UK.

ISO 27001: is the international standard that describes the specifications for implementing an information security management system (ISMS).

Investigator Brochure (IB): See also Investigational Medical Product Dossier (IMPD)

Investigational Medical Product Dossier (IMPD)

Investigator Site File: is the collection of essential documents which allows the conduct of a clinical trial to be reconstructed and evaluated. It is basically the story of how the trial was conducted and managed at a specific site.

LEAS: Lincoln Ethics Application System – system to apply for University of Lincoln ethics

LinCTU: Lincoln Clinical Trials Unit

Medical Device: means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more specific medical purpose.

Medicines and Healthcare products Regulatory Agency (MHRA): regulates medicines, medical devices and blood components for transfusion in the UK.

Monitoring: is defined as the act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, SOPs, The Principles of GCP, and the Medicines for Human Use (Clinical Trails) Regulations - where applicable.

Non-Substantial Amendment: A non-substantial amendment is defined as a change to the details of the study which will have no significant implications for participants, the scientific value, conduct or management of the trial, or quality and safety of the Investigational Medicinal Product in a CTIMP.

Pilot Study: A pilot study can be defined as a 'small study to test research protocols, data collection instruments, sample recruitment strategies, and other research techniques in preparation for a larger study

Principal Investigator (PI): An individual responsible for the conduct of the research at a research site. There should be one PI for each research site. In the case of a single-site study, the chief investigator and the PI will normally be the same person.

Quality Assurance (QA): consists of planned, systematic activities that are conducted to ensure that a trial is performed—and that trial data are generated, documented, and reported—in compliance with the protocol, Good Clinical Practice (GCP) guidelines, and all other applicable regulatory standards.

Quality Management System (QMS): Centralised governance framework policies, procedures, training, provision of advice and guidance, documentation and data records.

Protocol: is a document that describes how a clinical trial will be conducted (the objective(s), design, methodology, statistical considerations and organisation of a clinical trial,) and ensures the safety of the trial subjects and integrity of the data collected.

Protocol Deviation: can be described as any departure from the approved trial protocol.

Randomisation: is the process of assigning patients by chance to groups that receive different treatments. In the simplest trial design, the investigational group receives the new treatment, and the control group receives standard therapy. Randomisation helps prevent bias.

Randomised Controlled Trial (RCT) A study in which a number of similar people are randomly assigned to 2 (or more) groups to test a specific drug, treatment or other intervention.

Randomised Cross-Over Trial: is a specific type of RCT where you assess 2 or more interventions. In this design, all participants receive all the interventions, but the order in which they get the interventions is randomised.

Record Form: A way of documenting that the policies, procedures, and work instructions have been followed in accordance with a related SOP.

Relevant Material: Human samples that consist of or contain human cells. It excludes gametes and embryos, hair and nail from a living person; cell lines which have divided outside the human body and extracted DNA and RNA.

Research Committee (RC): Research Committee is a sub-committee of Academic Board with specific monitoring responsibilities and oversight of both research and enterprise in relating to the strategic plan, KPI and strategic objectives.

Research Ethics Committee (REC): a group of people appointed to review research proposals to assess formally if the research is ethical. This means the research must conform to recognised ethical standards, which includes respecting the dignity, rights, safety and well-being of the people who take part. All Clinical Research either led by the University of Lincoln or supported by LinCTU, requires a favourable ethical opinion from either a GafREC recognised committee, or relevant university ethics committee.

Research Governance Manager: Person responsible for research governance.

Research Training Portfolio (RTP): A record of documentation regarding the training received and training support materials relating to the acquisition, storage, use and disposal of human samples in research, which is required to be constantly maintained and updated.

Research: A study which addresses clearly defined questions, aims and objectives in order to discover and interpret new information or reach new understanding of the structure, function and disorders of the human body. Research attempts to derive new knowledge and includes studies that aim to generate hypotheses, as well as studies that aim to test them or develop practical applications of new knowledge.

Research Tissue Bank (RTB): A research tissue bank or biobank is a collection of human tissue or other biological material, which is stored for potential research use beyond the life of a specific project with ethical approval or for which ethical approval is pending.

Researcher: Refers to any person(s) who conducts research, including but not limited to as an employee; an independent contractor or consultant; a research student; a visiting or emeritus member of staff; or a member of staff on a joint clinical or honorary contract.

Risk Assessment:

Sample Size: number of participants in a clinical study to provide a reliable answer to the hypothesis being tested.

Serious Adverse Event (SAE): SAE is short for Serious Adverse Event. An SAE is any untoward medical occurrence in a patient or trial subject, which does not have a causal relationship with the treatment, and:

- is fatal, and/or
- is life-threatening for the subject, and/or
- makes hospital admission or an extension of the admission necessary, and/or
- causes persistent or significant invalidity or work disability, and/or
- manifests itself in a congenital abnormality or malformation, and/or
- could, according to the person that carries out the research, have developed to a serious undesired medical event, but was however prevented due to premature interference.

Serious Adverse Device Effect (SADE): Unanticipated adverse device effect is any serious adverse effect on health or safety, any life-threatening problem or death caused by, or associated with a device

Serious Adverse Reaction (SAR): See also SAE

Serious Breach: is a breach that is likely to affect to a significant degree: the safety or physical or mental integrity of the participants; or. the scientific value of the trial.

Substantial Amendment: A substantial amendment is defined as a change to the protocol or any other supporting documentation (e.g. participant information sheet, participant consent form), that is likely to affect to a significant degree any of the following:

- The safety, physical or mental integrity of the participants.
- The scientific value of the study.
- The conduct or management of the study.
- The quality or safety of any investigational medicinal product (IMP) used.

Summary of Product Characteristics (SmPC) is a description of a medicinal product's properties and the conditions attached to its use. It explains how to use and prescribe a medicine. It is used by healthcare professionals, such as doctors, nurses and pharmacists.

Suspected Unexpected Serious Adverse Reaction (SUSAR): is the term used to refer to an adverse event that occurs in a clinical trial subject, which is assessed by the sponsor and or study investigator as being unexpected, serious and as having a reasonable possibility of a causal relationship with the study drug.

Sponsor: The organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project.

Sponsor Legal Representative: If a sponsor(s) of a CTIMP is not established in the UK or on an approved country list (which initially includes EU / European Economic Area (EEA) countries), it is a statutory requirement to appoint a legal representative based in the UK or a country on the approved country list for the purposes of the trial.

Standard Operating Procedure (SOP): Detailed, written instructions to achieve uniformity of the performance of a specific function which is an integral part of a quality management system. In the context of research using human samples, SOPs document all the processes that affect the quality and safety of those samples (e.g. acquisition, storage, transfer, and disposal). In the context of clinical studies and trials, SOPs document all the processes that affect the quality of the study/trial and the safety of participants.

Statistical Analysis Plan (SAP): gives a detailed description of the endpoints in the study and the corresponding analyses.

Trial Master File: is the collection of essential documents which allows the conduct of a clinical trial to be reconstructed and evaluated. It is basically the story of how the trial was conducted and managed.

Trial Steering Group/Committee (TSG / TSC)

Terms of Reference (ToR): Define the purpose and structure of a committee.

University Research Ethics Committee (UREC): The University Research Ethics Committee (UREC) is established to have oversight of the principles and practices of ethical research conduct across the university, and University Human and Animal* (needs naming) Research Ethics Committees.

UOL: University of Lincoln.

Valid Consent: Consent which has been given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question. Valid consent is explained in detail in CoP Code A: Guiding principles and the fundamental principle of consent.

Work Instruction: a document which spells how a job will be done. The instructions are the most detailed part of a QMS. A work instruction may be in the form of a detailed drawing, recipe, routing sheet, specific job function (for example, turn nut four turns clockwise), photograph, video, or simply a sample for comparison or conformity.