Joint Research Office of Doncaster & Bassetlaw Hospitals NHS Foundation Trust, Rotherham Doncaster & South Humber NHS Foundation Trust and NHS Doncaster CCG	**Page 1 of 26**
Research Management & Governance	**SOP No. RM&G0002, Version 1**
Glossary of terms and acronyms	**Supersedes:** Not applicable
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Signatures:

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1 Purpose

The purpose of this SOP is to cover the definitions of acronyms and terms used within the Research Management & Governance SOPs. This SOP is designed to be a tool to be used alongside all other SOPs for this department.

2 Scope

This SOP covers all personnel who read any Research Management & Governance SOP.

3 Definitions

Adoption

The process by which a potentially eligible study is accepted for inclusion in the National Institute for Health Research Clinical Research Portfolio. ***National Institute for Health Research Coordinated System for Gaining NHS Permission (NIHR CSP) Operating Manual, 2012***

Adverse event (AE)

Any untoward medical occurrence in a subject to whom a medicinal product has been administered, including occurences which are not necessarily caused by or related to that product ***Medicines for human use (clinical trials) regulations 2004***

Adverse reaction (AR)

Any untoward and unintended response in a subject to Investigational Medicinal Product which is related to any dose administered to that subject. ***Medicines for human use (clinical trials) regulations 2004***

Anonymisation

The process of ensuring that data does not identify an individual directly, by removing the name, address, full post code and any other combination of details that might support identification. ***National Institute for Health Research Coordinated System for Gaining NHS Permission (NIHR CSP) Operating Manual, 2012***

Audit

A systematic and independent examination of trial related activities and documents to determine whether the evaluated trial related activities were conducted, and the data were recorded, analysed and accurately reported according to the protocol, Sponsor's Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s). ***ICH-GCP guidelines (CPMP/ICH/135/95)***

Caldicott Guardian
Caldicott Guardians are responsible for agreeing and reviewing internal protocols governing the protection and use of patient-identifiable information by the staff of their Organisations. ***National Institute for Health Research Coordinated System for Gaining NHS Permission (NIHR CSP) Operating Manual, 2012***

Case Report Form (CRF)
A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the Sponsor on each trial subject. ***ICH-GCP guidelines (CPMP/ICH/135/95)***

Chief Investigator (CI)
The investigator with overall responsibility for the research. In a multi-centre study, the Chief Investigator has coordinating responsibility for research at all sites. . ***National Institute for Health Research Coordinated System for Gaining NHS Permission (NIHR CSP) Operating Manual, 2012***

Clinical Trial of Investigational Medicinal Product (CTIMP)
Any investigation in human subjects intended to discover or verify the clinical, pharmacological and / or other pharmacodynamic effects of one or more investigational medicinal product(s), and/or to identify any adverse reactions to one or more investigational medicinal product(s) and / or to Study absorption, distribution, metabolism and excretion of one or more investigational medicinal product(s) with the object of ascertaining its (their) safety and / or efficacy. ***EU Directive 2001/20/EC, 4. April 2001***

Closedown
Closedown is the process that occurs at Study conclusion. This consists of notification of Study conclusion to relevant competent authority(ies), final report completion and maintenance and archiving of essential documents.

Compliance (in relation to trials)
Adherence to all the trial-related requirements, Good Clinical Practice (GCP) requirements, and the applicable regulatory requirements. ***ICH-GCP guidelines (CPMP/ICH/135/95)***

Consent
A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written signed and dated informed consent

form. ***National Institute for Health Research Coordinated System for Gaining NHS Permission (NIHR CSP) Operating Manual, 2012***

Coordinated System for gaining NHS Permission (CSP)
NIHR CSP is a system wihich standardises and streamlines the process of gaining NHS permission (also known as R&D approval) for commercial or non-commercial clinical research studies in England. ***National Institute for Health Research Coordinated System for Gaining NHS Permission (NIHR CSP) Operating Guidelines, 2012***

Data Monitoring Committee (DMC)
Most trials have a data monitoring committee that follows the progress of the trial and makes sure it is being run properly. The people on the data monitoring committee are independent. If they think that people are experiencing serious or unexpected side effects, or if evidence has emerged that one of the treatments being compared is clearly better than the others, they can advise that a trial is stopped[1].

In the case of a Clinical Trial of an Investigational Medicinal Product a Data Monitoring Committee can be defined as:

An independent data-monitoring committee that may be established by the Sponsor to assess at intervals, the progress of a Clinical Trial of an Investigational Medicinal Product, the safety data, and the critical efficacy endpoints, and to recommend to the Sponsor whether to continue, modify, or stop a trial[2].

These terms are consistent and the NIHR Research Support Services uses the term Data Monitoring Committee as defined by the NHS Library (Source 1).

[1] http://www.library.nhs.uk/KnowledgeManagement/Page.aspx?pagename=CCTGLOSS
[2] .ICH-GCP guidelines (CPMP/ICH/135/95)

Development Plan
Defines the capability items required to achieve the goals / missions / objectives outlined in an Organisation's Research Strategy. The Development plan assists the Lead / Director for R&D in planning requirements to achieve targeted capacity development and projected research activity as part of the R&D Operational Capability Statement. ***NIHR Research Support Services Project***

Employing Organisation
Organisation employing the Chief Investigator, Investigators or Researchers. Employers remain liable for the work of their employees. ***Research Governance Framework for Health and Social Care, 2nd Edition 2005***

Essential Documents
Essential Documents are those documents which individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the Investigator, Sponsor and monitor with the standards of Good Clinical Practice and with all applicable regulatory requirements. ***ICH-GCP guidelines (CPMP/ICH/135/95)***

Exception reporting
Exception reporting is the responsibility of the PI conducting the Study and consists of exception reporting by this individual to the R&D Office when relevant. An exception can be considered as any issue that has occurred / is occurring or any risk which may occur which the PI considers relevant to report to the R&D Office (the type of exceptions which the PI should escalate can be agreed prior to Study start) e.g. the Investigator requires advice or support on an issue which is not regarding an Internal Agreement or External Contract. ***NIHR Research Support Services Project***

External Agreement
An Agreement between an Organisation and relevant external parties for example between an Organisation and a Research Organisation. External Agreements may be required to confirm issues such as: indemnity, intellectual property, roles and responsibilities, data protection, confidentiality, financial and termination issues, standards of service and where applicable regulatory obligations. ***NIHR Research Support Services Project***

Funder
Organisation providing funding for a Study (through Agreements, grants or donations to an authorised member of the employing and/ or care Organisation). The main Funder typically has a key role in scientific quality assurance. In any case, it remains responsible for securing value for money. ***Research Governance Framework for Health and Social Care, 2nd Edition 2005***

Gene Therapy Advisory Committee (GTAC)
The Gene Therapy Advisory Committee, the national ethics committee for Clinical Trials involving medicinal products for gene therapy under Regulation 14(5). ***http://www.aapec.org.uk/documents/MHRA.pdf***

Good Clinical Practice (GCP)
The principles of Good Clinical Practice in Clinical Trials of Investigational Medicinal Products as set down in Articles 2-5 of the GCP Directive and implemented in the UK by Schedule 1 of the Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I.2004/1031) as amended by S.I. 2006/1928[1].

Good Clinical Practice is a set of internationally recognised ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting Clinical Trials of Investigational Medicinal Products that involve the participation of human subjects[2].

These terms are consistent and the NIHR Research Support Services uses the term Good Clinical Practice as defined by the MHRA (Source 1).

1. http://www.aapec.org.uk/documents/MHRA.pdf
2. EU Directive 2001/20/EC

Health Centre
Health centre means a health centre maintained under section 2 or 3 of the National Health Service Act 1977, section 36 of the National Health Service (Scotland) Act 1978 or Article 5 of the Health and Personal Social Services (Northern Ireland) Order 1972. ***http://www.opsi.gov.uk/si/si2004/20041031.htm***

Honorary Research Contract (HRC)
HRCs are required for researchers who are not employees of the NHS and whose activities could have a foreseeable and direct impact on patient care. ***National Institute for Health Research Coordinated System for Gaining NHS Permission (NIHR CSP) Operating Guidelines, 2012***

Hospital
Includes a clinic, nursing home or similar institution.
http://www.opsi.gov.uk/si/si2004/20041031.htm

Human Tissue Act (HTA) 2004
A regulatory framework for regulating the storage and use of human organs and tissue from the living and the removal, storage and use of organs from the deceased, for specified health related purposes and public display. ***National Institute for Health Research Coordinated System for Gaining NHS Permission (NIHR CSP) Operating Guidelines, 2012***

Indemnity

Indemnity provides protection against any action by an individual, a group or an Organisation that believe they received bad or negligent services, and incurred a loss as a result. Most professional bodies have professional indemnity cover; in some cases it is compulsory. The limit of an indemnity policy relates to the maximum amount of money that an individual or organisation will pay out in the event of a claim being made. ***National Institute for Health Research Coordinated System for Gaining NHS Permission (NIHR CSP) Operating Guidelines, 2012***

Inspection

The act by (a) regulatory authority(ies) of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authority(ies) to be related to the Clinical Trial of an Investigational Medicinal Product and that may be located at the site of the trial, at the Sponsor's and / or contract research Organisations (CRO's) facilities, or at other establishments deemed appropriate by the regulatory authority(ies)[1].

The term can also be defined as:

The act by a competent authority of conducting an official review of documents, facilities, records, quality assurance arrangements, and any other resources that are deemed by the competent authority to be related to the Clinical Trial of an Investigational Medicinal Product and that may be located at the site of the trial, at the Sponsor's and / or contract research Organisation's facilities, or at other establishments which the competent authority sees fit to inspect[2].

These terms are consistent and the NIHR Research Support Services uses the term Inspection as defined by the ICH-GCP Guidelines (Source 1).

*[1.] **ICH-GCP guidelines (CPMP/ICH/135/95)***
*[2.] **EU Directive 2001/20/EC, 4. April 2001***

Intellectual Property (IP)

IP can be described as the novel or previously undescribed tangible output of any intellectual activity. It has an owner and can be bought, sold or licensed and must be adequately protected. It can include inventions, industrial processes, software, data, written works, designs and images. ***National Institute for Health Research Coordinated System for Gaining NHS Permission (NIHR CSP) Operating Guidelines, 2012***

International Conference on Harmonisation (ICH)
International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use is a joint initiative involving both regulators and research-based industry focusing on the technical requirements for medicinal products containing new drugs. ***http://www.ich.org/cache/compo/276-254-1.html***

Interventional Study
For the purpose of studies conducted within Doncaster & Bassetlaw Hospitals NHS Foundation Trust, a non-interventional study is one that falls into one or more of the following categories:

- Clinical trials of investigational medicinal products (CTIMPs) falling within the scope of the EU Clinical Trials Directive and the Medicines for Human Use (Clinical Trials) Regulations 2004.
- Clinical trials or clinical investigations including but not limited to surgery, radiotherapy, imaging investigations, physiological investigations, mental health investigations or therapies and complementary or alternative therapies.
- Studies involving medical devices as detailed in the Medical Devices(Amendment) Regulations 2007.
- Studies involving the use of new human tissue sample or other human biological samples. ***Recording of research information in patient casenotes DBHft Policy CORP/COMM 17***

Investigational Medicinal Product
A pharmaceutical form of an active substance or placebo being tested, or to be tested, or used, or to be used, as a reference in a Clinical Trial, and includes a medicinal product which has a marketing authorisation but is, for the purposes of the trial:

(a) used or assembled (formulated or packaged) in a way different from the form of the product authorised under the authorisation

(b) used for an indication not included in the summary of product characteristics under the authorisation for that product, or

(c) used to gain further information about the form of that product as authorised under the authorisation. ***The Medicines for Human Use (Clinical Trials) Regulations 2004***

Investigator
Person responsible, individually or a leader of the researchers at a site, for the conduct of a Study at that site. For CTIMP involving medicines, an Investigator must be an authorised health professional[1].

In the case of a CTIMP an Investigator can be defined as:-

A doctor or a person following a profession agreed in the Member State for investigations because of the scientific background and the experience in patient care it requires. The Investigator is responsible for the conduct of a CTIMP at a trial site. If a trial is conducted by a team of individuals at a trial site, the Investigator is the leader responsible for the team and may be called the Principal Investigator[2].

The authorised health professional responsible for the conduct of that trial at a trial site, and if the trial is conducted by a team of authorised health professionals at a trial site, the Investigator is the leader responsible for that team[3].

These terms are consistent and the NIHR Research Support Services uses the term Inspection as defined by the EU Directive (Source 2). For the NIHR Research Support Services Guidelines, the term is applicable to all Studies, including those that are not CTIMPs.

1. Research Governance Framework for Health and Social Care
2. EU Directive 2001/20/EC, 4. April 2001
3. The Medicines for Human Use (Clinical Trials) Regulations 2004

Investigators Brochure (IB)
A document containing a summary of the clinical and non-clinical data relating to an investigational medicinal product which are relevant to the Study of the product in human subjects. ***National Institute for Health Research Coordinated System for Gaining NHS Permission (NIHR CSP) Operating Guidelines, 2012***

Leead Comprehensive Local Research Network (CLRN)
The lead CLRN is the CLRN nominated to take a lead in working with the Chief Investigator in the study setup phase. Within CSP, the lead CLRN is responsible for undertaking the study-wide governance review. ***National Institute for Health Research Coordinated System for Gaining NHS Permission (NIHR CSP) Operating Guidelines, 2012***

Letters of Access
Letters of Access, which enable NHS employees or staff with an honorary clinical contract (e.g. clinical academics) with one NHS Organisation to conduct research in another NHS Organisation. ***NIHR Research in the NHS- HR Good Practice Resource Pack***

Letters of Agreement
Letters of Agreement confirm the arrangements specified in Letters of Access. ***NIHR Research in the NHS- HR Good Practice Resource Pack***

Local criterion
A local criterion is a governance criterion that applies to a specific study site, and which is performed once for each Study site. ***National Institute for Health Research Coordinated System for Gaining NHS Permission (NIHR CSP) Operating Guidelines, 2012***

Medical Device
Medical devices may be classified as Class I, Class IIa, IIb and III, with Class III covering the highest risk products. Classification of a medical device will depend upon a series of factors, including: how long the device is intended to be in continuous use, whether or not the device is invasive or surgically invasive, whether the device is implantable or active whether or not the device contains a substance, which in its own right is considered to be a medicinal substance and has action ancillary to that of the device. ***National Institute for Health Research Coordinated System for Gaining NHS Permission (NIHR CSP) Operating Guidelines, 2012***

Medicines and Healthcare Products Regulatory Agency (MHRA)
The government agency which is responsible for ensuring that medicines and medical devices work, and are acceptably safe[1].

The MHRA can also be defined as:

MHRA (Medicines) is the competent authority for the UK in relation to the EU Directive and the Clinical Trials Regulations. MHRA (Devices) is the competent authority for the UK in relation to the Medical Devices Regulations 2002[2].

These terms are consistent and the NIHR Research Support Services uses the term Inspection as defined by the MHRA (Source 1). For the NIHR Research Support Services guidelines, the term is applicable to all Studies, including those that are not Clinical Trials of Investigational Medicinal Products.

[1.] http://www.mhra.gov.uk [2.] National Institute for Health Research Coordinated System for Gaining NHS Permission (NIHR CSP) Operating Guidelines, 2012

Mental Capacity Act (2005)
Provides a statutory framework to empower and protect vulnerable people who are not able to make their own decisions. It makes it clear who can take decisions, in which situations, and how they should go about this. ***National Institute for Health Research Coordinated System for Gaining NHS Permission (NIHR CSP) Operating Guidelines, 2012***

Monitor
Individual accountable for monitoring. ***ICH-GCP guidelines (CPMP/ICH/135/95)***

Monitoring
The act of overseeing the progress of a study, and of ensuring that it is conducted and recorded in accordance with the protocol, Standard Operating Guidelines (SOP's), Good Clinical Practice (GCP) and the applicable regulatory requirement(s). ***National Institute for Health Research Coordinated System for Gaining NHS Permission (NIHR CSP) Operating Guidelines, 2012***

Monitoring Report
A written report from the monitor to the Sponsor after each site visit and / or other trial-related communication according to the Sponsors SOPs. ***ICH-GCP guidelines (CPMP/ICH/135/95)***

Multicentre studies
Multicentre studies are those with more than one Participating Organisation, located within more than one CLRN. ***National Institute for Health Research Coordinated System for Gaining NHS Permission (NIHR CSP) Operating Guidelines, 2012***

National Information Governance Board for Health and Social Care (NIGB)
Replaced the Patient Information Advisory Group (PIAG) on 1 January 2009. ***National Institute for Health Research Coordinated System for Gaining NHS Permission (NIHR CSP) Operating Guidelines, 2012***

NHS Permission letter
Letter confirming that NHS Permission has been given and the study can commence. ***National Institute for Health Research Coordinated System for Gaining NHS Permission (NIHR CSP) Operating Guidelines, 2012***

NHS Permission Signatory
An individual who can sign NHS Permission Letters on behalf of a member NHS Organisation. ***National Institute for Health Research Coordinated System for Gaining NHS Permission (NIHR CSP) Operating Guidelines, 2012***

NIHR Guideline
A Document which describes the standard procedures expected of any Organisation that manages research activity within the framework of NIHR Research Support Services. ***NIHR Research Support Services Project***

Non Interventional Study
For the purpose of studies conducted within Doncaster & Bassetlaw Hospitals NHS Foundation Trust, a non-interventional study is one that does not fall into any of the following categories:

- Clinical trials of investigational medicinal products (CTIMPs) falling within the scope of the EU Clinical Trials Directive and the Medicines for Human Use (Clinical Trials) Regulations 2004.
- Clinical trials or clinical investigations including but not limited to surgery, radiotherapy, imaging investigations, physiological investigations, mental health investigations or therapies and complementary or alternative therapies.
- Studies involving medical devices as detailed in the Medical Devices(Amendment) Regulations 2007.
- Studies involving the use of new human tissue sample or other human biological samples. ***Recording of research information in patient casenotes DBHft Policy CORP/COMM 17***

Organisation providing care
Organisation responsible for providing health or social care to patients and / or service users and carers participating in a Study. Health and social care Organisations remain liable for the quality of care, and for their duty towards anyone who might be harmed by a Study. ***Research Governance Framework for Health and Social Care, 2nd Edition 2005***

Outcome Indicators
Outcome Indicators are derived from information captured during the R&D process (as described by the Research Support Services standard processes) which demonstrate how R&D is being managed operationally. ***NIHR Research Support Services Project***

Oversight
Quality control checks or functions which ensure that all studies, whether they are subject to planned monitoring and / or auditing, have the proportionate amount of quality control in order to protect an Organisation. ***NIHR Research Support Services Project***

Participant
Patient, service user, carer, relative of the deceased, professional carer, other employee, or member of the public, who consents to take part in a Study. (In law, participants in Clinical Trials involving medicines are known as subjects). ***Research Governance Framework for Health and Social Care, 2nd Edition 2005***

Participating Organisation
Any Organisation participating in a research Study in a manner that means they are not acting as the Sponsor for that Study. Any involvement an Organisation may have in a Study from acting as a PIC, sharing data to hosting a Clinical Trial of an Investigational Medicinal Product when not acting as the Sponsor deems an Organisation a Participating Organisation. ***NIHR Research Support Services Project***

Peer review
An appropriate process of independent expert review has demonstrated that the research proposal is worthwhile, of high scientific quality and represents good value for money. ***Adapted from: Research Governance Framework and R&D Forum***

Pharmacovigilance
The process of: monitoring the use of medicines in everyday practice to identify previously unrecognised adverse effects or changes in the patterns of adverse effects; assessing the risks and benefits of medicines in order to determine what action, if any, is necessary is needed to improve their safe use; providing information to healthcare professionals and patients to optimise safe and effective use of medicines; and monitoring the impact of any action taken. ***National Institute for Health Research Coordinated System for Gaining NHS Permission (NIHR CSP) Operating Guidelines, 2012***

Portfolio study
A clinical trial or other well-designed study that is included in the NIHR CRN Portfolio and therefore can access CLRN infra-structure support. ***National Institute for Health Research Coordinated System for Gaining NHS Permission (NIHR CSP) Operating Guidelines, 2012***

Principal Investigator (PI)
The investigator responsible for the local research site. There should be one PI for each research site. In a single site study, the CI and PI will normally be the same person. ***National Institute for Health Research Coordinated System for Gaining NHS Permission (NIHR CSP) Operating Guidelines, 2012***

Protocol
A document that describes the objective(s), design, methodology, statistical considerations, and organisation of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents. Throughout the ICH GCP Guideline the term protocol refers to protocol and protocol amendments.[1]

The term Protocol can also be defined as:

A document that describes the objective(s), design, methodology, statistical considerations and organisation of a trial. The term protocol refers to the protocol, successive versions of the protocol and protocol amendments.[2]

These terms are consistent and the NIHR Research Support Services uses the term Protocol as defined by the ICH-GCP Guidelines (Source 1). ***[1.]ICH-GCP guidelines (CPMP/ICH/135/95) [2.] EU Directive 2001/20/EC, 4. April 2001***

Qualitative research
Research methods that use non–numeric information to systematically examine meanings and interpretation, focusing on 'how' and 'why' type questions such as how do people feel about issues or why do they behave in a particular way. ***Skills for Health***

Quality Assurance (QA)
All those planned and systematic actions that are established to ensure that the trial is performed and the data is generated, documented (recorded), and reported in compliance with Good Clinical Practice (GCP) and the applicable regulatory requirement(s). ***ICH-GCP guidelines (CPMP/ICH/135/95)***

Quality Control (QC)
The operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of the trial-related activities have been fulfilled. ***ICH-GCP guidelines (CPMP/ICH/135/95)***

Quantitative research
Research methods that gather information in numeric form and analyse numerical patterns. ***Skills for Health***

R&D Operational Capability Statement (RDOCS)
A public statement which provides operational information of an Organisation's research capability and capacity. It states the general services, systems,

equipment and resources currently available that support the overall aim of achieving the goals / missions / objectives outlined in an Organisation's Research Strategy. This includes detailing research support services currently provided by the Organisation or purchased elsewhere. It is a facilitation tool to improve collaboration and efficiency in research activity and quality.

It is suitable for use by research teams, partner Organisations, Executive Management staff and Research management and governance staff. ***NIHR Research Support Services Project***

Readiness Assessment
An assessment by an Organisation to manage Study risks (either itself or with support from a network or through an alliance). The assessment depends on the Study type and capabilities of the Organisation. ***NIHR Research Support Services Project***

Regulatory and Governance Advice Service
The UKCRC R&G Advice Service provides support for local advice providers and a route for handling more complex queries such as those involving more than one regulatory issue. It also provides access to a range of web-based resources including tool kits and Frequently Asked Questions. ***National Institute for Health Research Coordinated System for Gaining NHS Permission (NIHR CSP) Operating Guidelines, 2012***

Research Design Service (RDS)
The NIHR has established a new network of Research Design Service to help researchers develop and design high quality research proposals for submission to national, peer-reviewed funding competitions for applied health or social care research. ***NIHR website***
http://www.nihr.ac.uk/infrastructure/Pages/infrastructure_research_design_services.aspx

Research Ethics committee (REC)
Committee established to provide participants, researchers, funders, Sponsors, employers, care Organisations and professionals with an independent opinion on the extent to which proposals for a Study comply with recognised ethical standards. For Clinical Trials involving medicines, the ethics committee must be one recognised by the United Kingdom Ethics Committee Authority. ***Research Governance Framework for Health and Social Care, 2nd Edition 2005***

Research Passport
Provides a mechanism for assuring NHS Organisations of the pre-engagement checks conducted on a researcher; and other standardised procedures for

handling the HR arrangements for researchers. ***Research in the NHS HR Good Practice Resource Pack***

Research Strategy
A document that articulates an Organisation's vision for research usually specified over 2-5 years. It is aligned to an Organisation's values and objectives and provides a statement of commitment to providing high quality research. ***NIHR Research Support Services Project***

Researcher
Those conducting the Study. ***Research Governance Framework for Health and Social Care, 2nd Edition 2005***

Responsible Care Professional
Doctor, nurse, social worker or other practitioner formally responsible for the care of participants while they are taking part in the Study. ***Research Governance Framework for Health and Social Care, 2nd Edition 2005***

Serious Adverse Event / Reaction (SAE / SAR)
Any adverse event or adverse reaction that:

- Results in death
- Is life-threatening
- Requires hospitalisation or prolongation of existing hospitalisation
- Results in persistent or significicant disability or incapacity
- Consists of a congenital anomaly or birth defect. ***Medicines for human use (clinical trials) regulations 2004***

Service Level Agreement (SLA)
A communication document that makes clear what the supplier will deliver and what the Organisation will ensure. It is based on the conditions of contract and specification and does not in any way replace them.
http://www.pasa.nhs.uk/PASAWeb/Productsandservices/Agencystaffandoutsourcedservices/Agencyandtemporarystaff/PAS/SLA.htm

Single Site Study
A Study with only one Participating Organisation. ***National Institute for Health Research Coordinated System for Gaining NHS Permission (NIHR CSP) Operating Guidelines, 2012***

Sponsor
Individual, Organisation or group taking on responsibility for securing arrangements to initiate, manage and finance a Study. (A group of individuals

and / or Organisations may take on sponsorship responsibilities and distribute them by agreement among the members of the group, provided that , collectively, they make arrangements to allocate all the responsibilities in this research governance framework that are relevant to the Study)[1].

The term Sponsor can also be defined as:

An individual, company, institution, or Organisation which takes responsibility for the initiation, management, and / or financing of a study.
The NIHR Research Support Services uses the term Sponsor as defined by the ICH-GCP Guidelines (Source 2). For the NIHR Research Support Services guidelines, the term is applicable to all Studies. [1.] ***Research Governance Framework for Health and Social Care, 2nd Edition 2005.*** [2.] ***ICH-GCP guidelines (CPMP/ICH/135/95).***

Standard Operating Procedure
Detailed, written instructions to achieve uniformity of the performance of a specific function. ***ICH-GCP guidelines (CPMP/ICH/135/95)***

Study Conclusion
The end of the Study which should be defined in the protocol. The Study conclusion is usually the last follow-up visit of the last patient. However, in studies that involve long-term follow-up when patients are no longer taking Study related medication and the data are obtained as part of usual care, this could be classified as a non-interventional phase, which would not need to be authorised under the regulations. ***NIHR Research Support Services Project***

Study-wide criterion
A study-wide criterion is a governance criterion that applies to all Study sites, and which is performed only once for the Study. ***National Institute for Health Research Coordinated System for Gaining NHS Permission (NIHR CSP) Operating Manual, 2012***

Subject
An individual who participates in a Clinical Trial as either a recipient of the investigational medicinal product or a control. ***EU Directive 2001/20/EC, 4. April 2001***

Suspected Serious Adverse Reaction (SSAR)
Any adverse reaction that is classed in nature as serious and which is consistent with the information about the medicinal product in question set out:

- In the case of a licenced product, the Summary of Product Characteristerics (SmPC) for that product

- In the case of any other investigational medicinal product the Investigator Brochure (IB) relating to the trial in question. ***Medicines for human use (clinical trials) regulations 2004***

Suspected Unexpected Serious Adverse Reactions (SUSAR)
Any adverse reaction that is classed in nature as serious and which is not consistent with the information about the medicinal product in question set out:

- In the case of a licenced product, the Summary of Product Characteristerics (SmPC) for that product
- In the case of any other investigational medicinal product the Investigator Brochure (IB) relating to the trial in question. ***Medicines for human use (clinical trials) regulations 2004***

Trial Management Group (TMG)
The Trial Management Group generally consists of those individuals responsible for the day-to-day management of the trial, such as:

a. The Chief Investigator.
b. A Statistician (if applicable).
c. The Study Coordinator.
d. The Research Nurse.
e. The Data Manager (if appropriate).

The TMG group should keep a close eye on all aspects of the conduct and progress of the trial and ensure that the protocol is adhered to and take action as necessary to safeguard participants and the trial itself.
http://www.nes.scot.nhs.uk/ct/monitoring/monitoring.htm

Trial Master File (TMF) (Also referred to as Site File)
Trial Master File contains all essential documents from all participating sites. Trial master files should be established at the beginning of the trial, both at the Investigator / institutions site and at the Sponsor's office. ***ICH-GCP guidelines (CPMP/ICH/135/95)***

Trial Steering Committee (TSC)
A committee, which makes sure the trial is running correctly. In the UK, this committee often included patient representatives as well as the researchers leading the trial, doctors and nurses.
http://www.library.nhs.uk/knowledgemanagement/Page.aspx?pagename=CCTSAFETY

Vulnerable Adults
Individuals whose willingness to volunteer in a study may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent. ***ICH-GCP guidelines (CPMP/ICH/135/95)***

4 Acronyms

ABPI
Association of the British Pharmaceutical Industry

AE
Adverse Event

AHSN
Academic Health Science Network

AMRC
Association of Medical Research Charities

AR
Adverse Reaction

ARSAC
Administration of Radioactive Substances Advisory Committee

CCG
Clinical Commissioning Group

CCRN
Comprehensive Clinical Research Network

CHM
Commission on Human Medicine

CI
Chief Investigator

CLAHRC
Collaboration for Leadership in Applied Health Research and Care

CLRN
Comprehensive Local Research Network

CRF
Case report form

CRN
Clinical Research Network

CSO
Chief Scientist Office

CSP
Coordinated system for gaining NHS permission

CTA
Clinical Trial Authorisation

CTIMP
Clinical Trial Investigation of Medicinal Products

DBHft
Doncaster & Bassetlaw Hospitals NHS Foundation Trust

DeNDRoN
Dementias and Neurodegenerative Diseases Research Network

DoH
Department of Health

DPA
Data Protection Act

DRN
Diabetes Research Network

EAG
Expert Advisory Group

ECMCs
Experimental Cancer Medicine Centres

EME
Efficacy and Mechanism Evaluation programme - funded by MRC. Managed by NETSCC for NIHR

EORTC
European Organisation for Research and Treatment of Cancer

ETC
Excess Treatment Costs

EU
European Union

EudraCT
European Clinical Trials Database

GAfREC
Government Arrangements for Research Ethics Committees

GCP
Good Clinical Practice

GMP
Good Manufacturing Practice

GTAC
Gene Therapy Advisory Committee

HEI
Higher Educational Institution

HTA
Health Technology Assessment programme *(can also refer to Human Tissue Act)*

HTA
Human Tissue Act *(can also refer to Health Technology Assessment programme)*

HTD
Health Technology Devices

IB
Investigator's Brochure

ICF
Informed consent form

ICH GCP
International Conference on Harmonisation/Good Clinical Practice

IMPs
Investigational Medicinal Products

INVOLVE
Promoting public involvement in NHS public health and social care research

IP
Intellectual Property

IRAS
Intergrated Research Application System

IRMER
Ionising Radiation (Medical Exposure) Regulations 2000

ISA
Independent Safety Authority

LoA
Letter of Access

MCA
Mental Capacity Act

MCRN
Medicines for Children Research Network

mCTA
Model Clinical Trials Agreement

MHRA
Medicines and Healthcare products Regulatory Agency

MHRN
Mental Health Research Network

MPE
Medical Physics Expert

MRC
Medical Research Council

NCRI
National Cancer Research Institute

NCRN
National Cancer Research Network

NEYNL CLRN
North and East Yorkshire and Northern Lincolnshire Comprehensive Local Research Network

NICE
National Institute for Health & Clinical Excellence

NIGB
National Information Governance Board for Health and Social Care

NIHR
National Institute for Health Research

NOMS
National Offender Management Service

NRES
National Research Ethics Service

ONS
Officce for National Statistics

PAF

Portfolio Adoption Form

PCRN
Primary Care Research Network

PCRN – E
Primary Care Research Network – England

PI
Principal Investigator

PIC
Patient identification centre

PIS
Patient information sheet

PPI
Patient and Public Involvement

PSSRU LSE
Personal Social Services Unit London School of Economics

R&D
Research & Development

RAF
Research Applications Facilitator

RCP
Research Capability Programme

RCT
Randomised Control Trial

RDS
Research Design Service

RECs
Research Ethics Committees

RfPB
Research for Patient Benefit

RGF
Research Governance Framework for Health and Social Care

RM&G
Research Management & Governance

RC
Research costs

RP
Research Passport

RPA
Radiation Protection Advisor

RSS
Research Support Services

SAE
Serious Adverse Events

SAR
Serious Adverse Reaction

SDO
Service Delivery Organisation

SmPC
Summary of Product Characteristics

SOP
Standard Operating Procedure

SRN
Stroke Research Network

SSAR
Suspected Serious Adverse Reaction

SSC
Servicce Support Costs

SSI
Site specific information form

SUSAR
Suspected Unexpected Serious Adverse Reaction

SYCLRN
South Yorkshire Comprehensive Local Research Network

UCEA
Universities and Colleges Employers Association

UKCRC
UK Clinical Research Collaboration

5 Health and Safety

There are no health and safety risks associated with this SOP.