Commonly used Research Abbreviations and Terms

ABPI	Association of the British Pharmaceutical Industry: A trade association for UK pharmaceutical companies
ADR	Adverse Drug Reaction (also known as AR)
AE	Adverse Event
Amendment	A written description of a change or formal clarification Substantial amendments (See below under 'Substantial Amendment') to protocol, participant information/consent require REC, R&D, R&I, MHRA approval, Non-substantial amendments should be 'notified' to RED, R&D, MHRA
AMRC	Association of Medical Research Charities
AR	Adverse Reaction (also known as ADR)
ARSAC	Administration of Radioactive Substances Advisory Committee: Research studies wishing to administer radioactive medicinal products to human subjects need to obtain ARSAC approval before NHS R&D/R&I approval
ASR	Annual Safety Report: For studies involving the use of an Investigational Medicinal Product, this is the annual report which must be submitted to the MHRA detailing all SUSAR's and SAR's that have occurred in subjects on that study in the past year
ATMP	Advanced Therapy Medicinal Products
BP	Blood Pressure
BRC	Biomedical Research Centre: larger centre covering a number of topics with facilities and research active clinicians/academics/research nurses to run clinical projects
BRU	Biomedical Research Unit: topic-focused centre which usually combines facilities and research active clinicians/academics/research nurses to run clinical projects, e.g. respiratory BRU
C/O	Complains of
CA	Competent Authority: organisation approving the testing of new drugs/devices or approving the marketing licences, in the UK this is the MHRA
CC	Coordinating Centre
CCRN	Comprehensive Clinical Research Network
CF	Consent Form (also ICF, Informed Consent Form)
CFR	Code of Federal Regulations (US)
CI (i)	Chief Investigator: The lead investigator with overall responsibility for the research. In a multi-site study, the CI has coordinating responsibility for the research at all sites. The CI may also be the PI at the site in which they work. In the case of a single-site study, the CI and the PI will normally be the same person and are referred to as PI
CI (ii)	Coordinating Investigator
COREC	Central Office for Research Ethics Committees (replaced in 2007 by NRES)
CRA	Clinical Research Associate: usually a commercially employed person supporting the management of clinical studies, helps with obtaining R&D approval, site initiation, study monitoring and close out
CRF (i)	Case Report Forms: data collection tools provided by a sponsor on which the clinical data is recorded for each participant, such as weight, lab results, symptoms
CRF (ii)	Clinical Research Facility: hospital-like facility with consulting rooms, standard patient beds, ward medical equipment, research nurses supporting only research
CRN	Clinical Research Network
CRO	Clinical Research Organisation or Contract Research Organisation: A person or an organisation (commercial, academic or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions
CSAG	Clinical Studies Advisory Group
CSG	Clinical Studies Group

CSP	Coordinating System for gaining NHS Permissions: Standard process for adoption onto NIHR Portfolio of Studies in order to access NIHR CRN Support and funding; streamlines the process for gaining NHS permissions by collating the information for global and local approvals; researchers initiate this in IRAS by completing and submitting CSP Application Form
CTA (i)	Clinical Trials Administrator: person providing coordinating/secretarial support for running clinical studies
CTA (ii)	Clinical Trials Agreement: contract between the legal Sponsor and the hosting research sites
CTA (iii)	Clinical Trials Associate (similar to CRA): person involved in the management of a study from initiation, through conduct/monitoring to close-out
CTA (iv)	Clinical Trials Authorisation: The regulatory approval for clinical trial of a medicinal product issued by the MHRA
CTAAC	Clinical Trails Advisory and Awards Committee
CTD	Clinical Trial Document
CTIMP	Clinical Trail of an Investigational Medicinal Product
CTU	Clinical Trials Unit: Design and manage CTIMPs, sometimes in specialist clinical areas, such as Cancer, or types of trial, such as RCTs
CV	Curriculum Vitae
D&V	Diarrhoea and Vomiting
DeNDRoN	Dementias and Neurodegenerative Diseases Research Network; from April 2014 part of the Local Research Network
DH	Department of Health (for England)
DIPEx	Database of Individual Patient Experience – the DIPEx website has a range of open source videos of real patient experiences www.healthtalkonline.org
DNA	Did not attend
DPA	Data Protection Act
DQ	Data query
DRN	Diabetes Research Network; from April 2014 part of the Local Research Network
DSMB	Data and Safety Monitoring Board: An independent committee composed of clinical research experts and community representatives that reviews data whilst a clinical trial is in progress to ensure that participants are not being exposed to undue risk
ECG	Electrocardiogram
ECMC	Experimental Cancer Medicine Centre
EM	Experimental Medicine
EMA	The European Medicines Agency: A body of the European Union which has responsibility for the protection and promotion of public health through the evaluation and supervision of medicines for human use
EU	European Union
EudraCT	European Clinical Trials Database: A database of all clinical trials in Europe, held since 1994 in accordance with EU directive 2001/20/EC
FAQ	Frequently asked questions
FDA	Food and Drug Administration: the Competent Authority in the United States, giving authorisation to conduct clinical trials and issuing marketing licences
GAfREC	Governance Arrangements for Research Ethics Committees
GCP	Good Clinical Practice: A specific internationally recognised version of this is ICH-GCP (see below)
GLP	Good Laboratory Practice: standard for laboratories involved in pre-clinical analyses (e.g. animal, in vitro); does not apply to Laboratories analysing samples from clinical trials involving humans
GMP	Good Manufacturing Practice: quality assurance standard for producing IMP, medicinal products
GTAC	Gene Therapy Advisory Committee: the ethics committee for clinical studies using genetically modified products; usually no REC approval required
HEI	Higher Education Institution
HFEA	Human Fertilisation and Embryological Authority
HRC	Honorary Research Contract
HTA	Human Tissue Act or Human Tissue Authority

HTA	Health Technology Assessment – one of the NIHR research funding streams
IB	Investigator's Brochure: A compilation of clinical and pre-clinical pharmacological/biological data relevant to the use of the IMP(s) in human subjects (one single IB for all trials using the same IMP)
ICF	Informed Consent Form
ICH-GCP	International Conference on Harmonisation (Europe, USA, Japan); Defined standards for the terminology, design, conduct, monitoring, recording, analysis and reporting of a study. These standards give assurance that the reported results are accurate and credible and that the rights, integrity and confidentiality of all study participants have been protected throughout the study. Section E6 of ICH defines principles of Good Clinical Practice (referred to as ICH-GCP). Research teams on CTIMPs in the UK must follow GCP requirements as detailed in MfHU (CT) Statutory Instruments; all non-CTIMP studies conducted within the NHS adhere to GCP according to Research Governance Framework
IDMC	Independent Data Monitoring Committee
IMP	Investigational Medicinal Product: an unlicensed new drug, or an existing drug tested outside its licence, or existing drugs tested against each other for their efficacy/safety. The MHRA provide an algorithm to establish whether a study is a CTIMP: see the MHRA website http://www.mhra.gov.uk/home/groups/l-unit1/documents/websiteresources/con009394.pdf
IND	Investigational New Drug: sometimes used instead of IMP
Indemnity	Compensation for damage, loss or injury
Investigator	Researcher conducting the (clinical) study, those researchers leading the team are referred to as CI or PI
IRAS	Integrated Research Application System: A single, web-based system for completing applications for the permissions and approvals required for health and social care research in the UK. The various applications can be printed or submitted for this single system (includes REC, R&D/R&I, MHRA, GTAC, NIGB, ARSAC)
IRB	Independent Review Boards: US equivalent of authorised REC
IRMER	Ionising Radiation Medical Exposure Regulations: part of NHS R&D approval, usually done by the local hospital experts
ISF	Investigator Site File: A file designed for use in organising and collating all essential documentation required to conduct a study in accordance with the principles of GCP and the applicable regulatory requirements (e.g. REC approval letter/correspondence, MHRA approval, blank CRF, staff CVs, delegation of duties log etc.)
ISRCTN	International Standard Randomised Control Trial Number: A simple numeric system for the identification of trials and provides a unique number that can be used to track all publications and reports resulting from each trial; can be obtained from www.isrctn.org or www.controlledtrials.com/mrct
LRN	Local Research Network: LRNs are the primary vehicle for providing infrastructure to support study involvement at local NHS Trusts. There are 15 in England
MCA	Mental Capacity Act
mCIA	model Clinical Investigation Agreement: for medical devices, covers the running of the study, not design of protocol; standard template for the UK (use is not obligatory)
MCRN	Medicines for Children Research Network
mCTA	model Clinical Trial Agreement: for IMP studies with commercial sponsor/CRO conducted; standard template for the UK (use is not obligatory)
MfHU (CT)	Medicines for Human Use (Clinical Trials) Regulations: SI 2004: 1031 and subsequent amendments 2006:1928, 2006:2984, 2008:941, 2009:1164 and 2010:1882 are the UK Statutory Instruments translating EU directives 2001/20/EC and 2005/28/EC into UK law, laying down the legal requirements for conducting CTIMPs in the UK

MHRA	Medicines and Healthcare products Regulatory Agency: The UK Competent Authority (CA) and licensing authority for medicines and medical devices. It replaced both the Medical Devices Agency (MDA) and the medicines Control Agency (MCA) in April 2003
MHRN	Mental Health Research Network; fom April 2014 part of the Local Research Network
mNCA	model Non-Commercial Agreement: for clinical research studies; standard template for the UK (use is not obligatory)
Monitor	The person designated by the sponsor to perform site visits and conduct the monitoring process; e.g. check whether there are any deviations from the protocol and that all source data was transferred into the Case Report Forms correctly
MRC	Medical Research Council
Multi Centre Study	A study conducted according to a single protocol but carried out at more than one site and by more than one investigator; one CI oversees several local PIs
NCRN	National Cancer Research Network; from April 2014 part of the Local Research Network
ND	Not done
NHS	National Health Service
NICE	National Institute for health and Clinical Excellence (decides which drugs are accepted in NHS treatment)
NIGB	National Information Governance Board for Health and Social Care Ethics and Confidentiality Committee (NIGB HSC ECC): formerly PIAG, Gives approval for projects using patient data without obtaining consent
NIHR	National Institute for Health Research: established by Department of Health for England in 2006 to provide the framework through which DH will position, manage and maintain the research, research staff and infrastructure of the NHS in England as a virtual national research facility
NIHR CRN CC	National Institute for Health Research Clinical Research Network Coordinating Centre
NIHR IS	National Institute of Health Research Information Systems
NIMP	Non-Investigational Medicinal Product: product used alongside IMP but not directly under investigation in the research study, e.g. a challenge agent
NK	Not known
NOCRI	National Office for Clinical Research Infrastructure
Non-substantial amendments	Changes to the details of a study that have no significant implications for the subjects, the conduct, the management or the scientific value of the study (sometimes referred to as administrative amendments). Examples may be as follows: • Correction of typographical errors in the protocol or other study documentation • Amended contact details for the sponsor or project staff • Changes in funding arrangements • Appointment of new support staff • Changes in the documentation used to record study data • Changes in the logistical arrangements for transporting or storing samples
NRES	National Research Ethics Service: umbrella organisation responsible for all REC across the UK (replaced COREC in 2007)
OSCHR	The Office for Strategic Coordination of Health Research (UK wide)
PCF	Patient/Participant Consent Form
PCRN	Primary Care Research Network; from April 2014 part of the Local Research Network
PCT	Primary Care Trust (abolished 2013)
PI	Principal Investigator: The lead person at a single site designated as taking responsibility within the research team for the conduct of the study
PIAG	Patient Information Advisory Group (now NIGB)

PIC	Participant Identification Centre: NHS or other organisation which only identifies participants from a database etc, but recruitment/receiving consent and study conduct are managed elsewhere
PIS	Participant or Patient Information Sheet: An information leaflet given to those who have been invited to participate in a research study. The sheet is designed to provide the potential participant with sufficient information to allow that person to make an informed decision on whether or not they want to take part
PPI	Patient and Public Involvement
QA	Quality Assurance
QC	Quality Control
QLQ	Quality of Life Questionnaire
R&D	Research and Development: often name of Department within NHS hospitals giving permission to conduct projects on those facilities with patients/staff
R&I	Research & Innovation: alternative name for R&D
RCT	Randomised Controlled Trial: A randomised controlled trial (RCT) is a clinical study in which two (or more) forms of care are compared; the participants are allocated to one of the forms of care in the study, in an unbiased way
RDS	Research Design Service: organisation with a number of experts who can help write the protocol/documents for NIHR grant applications
REC	Research Ethics Committee: authorised by NRES to review study documents for research taking place in the NHS, or social services. Some REC specialise in Clinical Trials, or topics such as research in children, MCA. See NRES website for more detail and other types of research http://www.nres.npsa.nhs.uk/ All Research in NHS/social services must have been reviewed by a UK REC
Research Passport	A system for HEI employed researchers/postgraduate students who need to undertake their research within the NHS organisations, which provides evidence of the pre-engagement checks undertaken on that person in line with NHS Employment Check Standards (among them CRB and occupational health checks)
RfPB	Research for Patient Benefit: NIHR research funding stream
RGF	Research Governance Framework: DH guidance for the conduct of research within the NHS in England (use 2nd edition, 2005)
RM&G	Research Management and Governance
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SDV	Source Data Verification: checking the original data record, such as lab reports, patient medical notes against what was transferred onto the CRF/into a database
Serious-ADR	Adverse drug reaction which falls in to one of the serious criteria and therefore warrants expedited reporting (serious = resulting in hospitalisation, prolonged hospitalisation, death, life-threatening, congenital anomaly/birth defect or persistent or significant disability/incapacity)
SHA	Strategic Health Authority (abolished 2013)
SI (i)	Statutory Instruments: document which defines UK law in on a specific topic, e.g. how to manage a clinical trial
SI (ii)	Sub-Investigator (as in ICH-GCP, ICH does not use the term Co-investigator
Site	The NHS organisation in which study activities and assessment are performed or the locations(s) where trial-related activities are actually conducted. Each site/Trust needs to give R&D approval
SLA	Service Level Agreement
SMO	Site Management Organisation
SmPC	Summary of Product Characteristics: smaller version of Investigator Brochure with details on pharmacological effects, side effects, but issued for a product that already holds a marketing licence
SOP	Standard Operating Procedure: detailed written instructions designed to achieve uniformity of the performance of a specific function
SRN	Stroke Research Network; from April 2014 part of the Local Research Network

SSA	Site Specific Assessment: An assessment performed to establish the suitability of a Principal Investigator and a site for the conduct of research; SSA will be performed by the Participating CLRN for each research site (NHS organisation), using an SSI form available is IRAS
SSI	Site Specific Information: local detail to inform SSA including qualifications/expertise of the PI and wider research team, study procedures, departmental capacity to absorb project (includes Pharmacy, Pathology, Radiology) and the departmental leads signatures; The SSI form is completed in IRAS
Substantial amendment	A substantial amendment can be defined as an amendment to the protocol or any other study specific documentation, the terms of the REC application or the terms of the CTA application (as applicable) that is likely to affect to a significant degree the: • The safety or physical or mental integrity of the subjects of the trial; • The scientific value of the trial; • The conduct or management of the trial; or • The quality or safety of any investigational medicinal product used in the trial Other changes to the particulars of a study that qualify as substantial amendments include: • A change of sponsor(s) • Appointment of a new Chief Investigator and • Extension of the research beyond the planned closing date for recruitment A substantial amendment may not be made to a research study without the favourable opinion from the REC that gave a favourable opinion for the study (the main REC) and as applicable the MHRA. The only exceptions to this rule are: • The Inclusion of a new research site or • The Appointment of a new PI at an individual site Both of these qualify as substantial amendments but as they require further SSA and approval from the REC there is no requirement for notice of amendment to the REC. These changes do still however need to be notified to the MHRA (as applicable)
SUSAR	Suspected Unexpected Serious Adverse Reaction: A Serious Adverse Reaction (SAR) which is Unexpected (i.e. its nature and severity is not consistent with the known information about that product from the Investigator's Brochure or the SmPC) and suspected, as it is not possible to be certain of causal relationship with the IMP
TCRN	Topic specific Clinical Research Network: includes DRN, DeNDRoN, NCRN, MCRN, MHRN and SRN. These ceased to exist from April 2014 when the new network structures were introduced which combined all topic specific networks with the comprehensive network for each geographical area to form 15 Local Research Networks
TMF	Trial Master File (file with essential documents held by the Chief Investigator/Sponsor organisation)
UKCRC	United Kingdom Clinical Research Collaboration
WHO	World Health Organisation
WMA	World Medical Association
WT	Weight