South West Yorkshire Partnership NHS Foundation Trust

Glossary of Key Research Terms

The world of Research often has the habit of using some rather complicated and at times, confusing, language. See below for our guide of terms we feel you may find useful…

Annual Safety Report (ASR)	For studies using investigational medicinal products, this report must be submitted annually to the Medicines and Healthcare products Regulatory Agency (MHRA) detailing all Suspected Unexpected Serious Adverse Reactions (SUSARs) and Serious Adverse Reactions (SARs) that have occurred in the study in the past year (see "NHS acronyms" for help!)
Biomedical Research Unit (BRU)	A large centre which combines active research clinicians/academics/research nurses who run clinical projects.
Central Allocation system (CAS)	Can help identify a relevant Research Ethics Committee (REC) for your research project.
Chief Investigator (CI)	An individual who has the overall responsibility of a research project. They will coordinate the research if it takes part in multiple sites. The CI can also be the Principal Investigator (PI) for their site.
Clinical trials	Where new medicine or treatment is tested to see if it works properly. Clinical trials also consider whether the treatment will improve services. *See also Randomised Control Trials.*
Comprehensive Local Research Network (CLRN)	Support NHS portfolio studies only in local NHS trusts (25 in England). *See Non Portfolio/Portfolio Studies.*
Confidentiality	An ethical guideline states that confidential information must not be disclosed without consent, should be kept anonymous for the purposes of research and should only be accessed when absolutely necessary. *See also Personal Information and Sensitive Personal Information.*
Coordinated System for gaining NHS Permissions (CSP)	Process for adoption onto National Institution of Health

	Research (NIHR) Portfolio of Studies, it speeds up the process of gaining NHS permission. This is initiated by researchers through the use of Integrated Research
Data	Application System (IRAS), where they complete a Coordinated system for gaining NHS Permissions (CSP) application form.
Data protection	
	Information which can be qualitative (numbers) or quantitative (words e.g. from interviews).
	Data collected during a research project must be kept
Dissemination	securely and confidential (*see confidentiality)*. Researchers must be aware of the responsibilities they have and manage their data in accordance with the Data Protection Act.
Ethics	Sharing information about a project; this can happen during the project but usually happens at the end; for
Ethical Approval	example, research findings can be shared by publishing them or presenting them at conferences.
	Ensuring research is not potentially harmful to anybody.
European Medicines Agency (EMA)	Most research studies conducted within the NHS must be approved by a relevant Research Ethics Committee (REC; see FAQs). Any study which does not reach ethical requirements will not be approved and will therefore not be
European Clinical Trials Database (EudraCT)	able to go ahead.
	A European agency whose responsibilities involve protecting and promoting public health through evaluating
Honorary Research Contract (HRC)	and supervising medicines for human use.
	A database encompassing all clinical trials in Europe,
Hypothesis	which has been held since 1994.
	See “What is a research passport?” in FAQs.
Informed consent	
	A theory which can be tested by gathering data. For example; “The variability in service provision for self-harm

	will have an impact on patient outcomes."
Integrated Research Application System (IRAS)	Participants must provide informed written consent when taking part in research; they can do this by filling out a consent form (which will vary between projects). If the participant is a minor, their parent or caregiver must also give informed consent. All informed consent should make it clear to participants and parents/caregivers that they have the right to withdraw, without judgement, at any time during the study. The only exception where informed consent is not required from the participant is when they lack capacity to do so, seem willing to participate and informed consent is provided by the parent or caregiver.
Investigator Site File (ISF)	A single system used to apply for permission and approval for health and social care and community care research in the UK. It uses filters which certify whether or not the intended data collection is suitable for the study type. It also helps you meet regulatory and governance requirements. IRAS gathers all information required for all relevant approvals.
International Standard Randomised Control Trial Number (ISRCTN)	A file which contains all essential documentation (e.g. SSI forms, ethics/NHS Research and Development (R&D) approval) required to conduct the study in that particular site.
National Institute for Clinical Excellence (NICE)	For the purpose of randomising anonymous participants, a numeric system enabling the identification of participants and the Randomised Control Trials (RCTs) they have taken part which gives each participant a unique ID number.
National Information Governance Board for Health and Social Care Ethics and Confidentiality Committee (NIGB HSC ECC)	Decides which drugs can be used for NHS treatment.
National Institute for Health Research(NIHR)	Gives consent for the use of patient data without having to obtain informed consent.
National Research Ethics Service	

(NRES)	
Non-Portfolio Studies	Aims to manage and maintain research, research staff and infrastructure of NHS. They also fund NHS research.
	An umbrella service responsible for all Research Ethics Committees (RECs) in the UK.
Research and Development (R&D)	Non-Portfolio studies do not meet the eligibility criteria for the NIHR Portfolio. They are usually studies undertaken for education purposes (usually Masters/PhD level). Non-portfolio studies also include those that are funded via other departments and directorate funds. *See also Portfolio Studies.*
Participant	Investigation with the aim of improving services by gaining new information or knowledge.
	Refers to an individual taking part in research.
Participant Identification Centre (PIC)	Database devised to identify participants by a unique number, but does not hold information on recruitment, consent or study conduction.
Personal Information	Information which relates to an individual e.g. information that can identify an individual, health records, case files… See this personal data information chart for more details. *See also Sensitive Personal Information.*
Portfolio Studies	The National Institute for Health Research (NIHR) has a "Portfolio" of clinical research studies considered to be of a high quality, clearly relevant to the NHS and are eligible for support from the UK Clinical Research Network (UKCRN). The portfolios are comprised of four networks; England, Northern Ireland, Scotland and Wales. All four Portfolios are held in one single database; the UKCRN database. You can only apply for your study to be part of the portfolio if it meets the NIHR eligibility criteria. *See also Non-Portfolio studies.*
Protocol	A research plan; a protocol clarifies what you intend to do,
Principal Investigator (PI)	
Qualitative research	

	why you intend to do it (usually by providing a simple easy to understand review of other related literature), where you intend to do it and when. It will also outline how you wish to analyse your data and how you wish to report the results.
	An individual who is designated to take charge of the conduct of a research project taking place in a single site.
Quantitative Research	Always textual data (e.g. interview transcripts or textual data following observations) which provides in depth information about any given "theme" or idea using. Sample sizes are usually small. An example of quantitative data would be interview data from a small number of patients in an inpatient unit about the quality of care they are receiving. Themes explored could include happiness of the patient, their relationships with the staff and how other experiences effect their perception of the care they are currently receiving.
Randomised Control Trials (RCTs)	Produces measurable data with set values, usually in the form of numbers. Sample sizes can vary from very few to thousands. For example, scores from the Becks Depression Inventory (BDI) can be used to measure depression.
Research & Development (R&D) Department	A type of interventional study where participants are randomly allocated to different conditions; e.g. for a clinical drugs trial, some participants may be in the "experimental" group (where they take the drug being tested) and the others may go in the "control" group and take a placebo. Such trials however, can often have more than two conditions. The more "arms" there are to the study, the more complicated the study can be! However, these types of trials are ideal for directly measuring the effect one condition can have over anther or more simply.
Research & Development (R&D) Approval	Usually the name of a department within the NHS which gives permission to conduct research in their particular NHS site with their patients/staff.
Research Design Service (RDS)	NHS research must be approved by the organisation it

	wishes to take place in. This is also known as NHS permission (see FAQs).
Research Ethics Committee (REC)	Organisation who employs individuals with expertise to help design research proposals for National Institute for Health Research (NIHR) grant applications. The RDS provide help and support on aspects of the proposal preparation process; this includes statistics, quantitative and qualitative research techniques, clinical trials, evidence synthesis, health economics, epidemiology, public and patient involvement, ethics and governance. There are 10 RDSs in each Strategic Health Authority Area; see their website for your closest RDS and their contact details.
Research for Patient Benefit (RfPB)	A stream of National Institute for Health Research (NIHR) funding for research projects. The funding available for an individual research project is up to £250k for 36 months.
Research Governance	Sets stands for research, improves research quality and encourages good practice. It applies to everybody who manages, takes part in, undertake, host and funds research.
Sensitive Personal Information (SPI)	Refers to information related to racial or ethnic origin, political opinions, convictions, physical or mental health condition, membership of trade unions, sexual life or religious or other similar beliefs *(see also "personal information").*
Service Evaluation	Aims to decide whether a service is doing what it's supposed to do and determine what standard a service is achieving This can be done by using questionnaires, interviews or focus groups with staff or service users to explore opinions of a service. For example using a questionnaire to determine how effective a web chat
Service User	
Site	
Site Specific Information (SSI) Form	
Sponsor	

	service is for emergency contraception.
	A person who uses or used to use a particular service.
	The locations research is conducted in within a particular NHS Trust hence each Trust must give NHS Research and Development (R&D) approval for research conducted in their site.
	A form (completed in the Integrated Research Application System (IRAS)) which must be filled out if you wish to conduct your research on multiple sites (see FAQs for more detail).
Suspected Unexpected Serious Adverse Reaction (SUSAR)	A person/team that supports and funds research. They have 7 main responsibilities (which must be agreed to by signing a contract on the Research and Development (R&D) form before the research is approved; 1) to discuss the research proposal with the Chief Investigator (CI) and agree on the sponsor, 2) agree the proposal is worth wile and of high scientific quality, 3) ensure any necessary indemnity or insurance arrangements will be in place before the research starts and renewed when necessary, 4) to ensure arrangements will be in place for the research team to access and support to deliver the research as proposed, 5) make sure arrangements to allocate responsibilities for the management, monitoring and reporting of the research are in place before the research begins, 6) ensure the duties of sponsors set out in the Research and Governance Framework for Health and Social Care will be undertaken in relation to the research and 7) to agree they understand that the summary of the study will be published on the National Ethics Service (NRES) website.
Topic Specific Research Network (TSRN)	
Trial Master File (TMF)	
User focussed monitoring (UFM)	A serious adverse reaction which is unexpected can occur in a research project; especially where new drugs are tested. It is where the severity is not consistent with the information already known about the product which caused it. It is suspected because it's not necessarily caused by the Investigational Medicinal Product (IMP).

Includes the Diabetes Research Network (DRN), Dementias and Neurodegenerative Diseases Research Network (DeNDRoN), National Cancer Research Network (NCRN), Medicines for Children Research Network (MCRN), Mental Health Research Network (MHRN) and Strokes Research Network (SRN).

Includes essential documentation required to conduct a research study within the NHS and is held by the Chief Investigator (CI).

An approach which means service users can monitor and or evaluate the service they have been provided. Service users are involved as they are the people who the service provides for therefore it is essential to gain feedback from them so we can continue to improve the service.