



An Orientation Guide for staff practicing in clinical research areas within the Essex & Hertfordshire Comprehensive Local Research Network

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<p>Welcome</p>	<p>We welcome you to your post and look forward to working with you in your new role.</p> <p>The Essex & Hertfordshire (E&H) Comprehensive Local Research Network (CLRN) has developed this orientation document to assist your personal and professional development. This is to provide direction for the acquisition of skills and knowledge required for the post within the clinical research field.</p> <p>The pack is supported by the approved by the Royal College of Nursing (RCN) Competency Framework For Research Staff which is linked to the NHS Knowledge and Skills Framework (KSF). Your post may be a community or acute setting based with research duties relating to clinical and/or non-clinical areas. Your research duties will mainly be in conjunction with the Comprehensive Local Research Network and your employing organisation.</p>
<p>Background</p>	<p>The National Institute for Health Research (NIHR) now brings together government support for high quality research in the NHS in England, through the NIHR Clinical Research Network Coordinating Centre (NIHR CRN CC).</p> <p>A new system for recording research conducted by the NIHR has been established. The NIHR has Clinical Networks which make it possible for all patients and health professionals across England to participate in relevant health research.</p> <p>The aims of the NIHR Clinical Research Network are to:</p> <p>Ensure patients and healthcare professionals from all parts of the country are able to participate in and benefit from clinical research</p> <ul style="list-style-type: none"> ▪ Integrate health research and patient care ▪ Improve the quality, speed and co-ordination of clinical research ▪ Increase collaboration with industry partners and ensure that the NHS can meet the health research needs of industry. <p>Topic Specific Clinical Research Networks (TCRN)s co-ordinate clinical trials for specific</p>

	<p>conditions:</p> <p>A number of networks co-ordinate clinical trials for specific conditions. These are:</p> <ul style="list-style-type: none"> ▪ Cancer - National Cancer Research Network (NCRN) ▪ Stroke - Stroke Research Network (SRN) ▪ Mental Health - Mental Health Research Network (MHRN) ▪ Diabetes - Diabetes Research Network (DRN) ▪ Medicines for Children - Medicine for Children Research Network (MCRN) ▪ Dementias and Neurodegenerative Diseases (Dementias and Neurodegenerative Diseases Research Network (DeNDRoN) ▪ A Primary Care Research Network (PCRN) focuses on health areas for which primary care has particular responsibility, including disease prevention, health promotion, screening, early diagnosis, and the clinical management of long term conditions. <p>Comprehensive Local Research Networks (CLRNs) are responsible for supporting the delivery of the NIHR portfolio studies across all areas of clinical need. The Essex & Hertfordshire CLRN comprises 17 NHS trusts (primary, secondary and mental health care) and 3 universities: Anglia Ruskin University, University of Essex and University of Hertfordshire.</p> <p>The CLRN has strong links with the two neighbouring East of England CLRNs (Norfolk Suffolk & Cambridgeshire and West Anglia), PCRN East of England, and the NIHR Research Design Service (RDS) for the East of England. The network contributes to the work of the East of England Research & Innovation Alliance that brings together key academic and NHS research stakeholders.</p>
<p>Structure CLRN</p>	<p>The E&H CLRN has a mixed model team by employing both a Central Team and deploying embedded CLRN funded staff throughout the Member Trusts where this has been deemed necessary and appropriate. A wider Core Team supports the Executive Team Please see Appendix 1 to illustrate the current core staff. The Lead Research Nurse (LRN) team supports a 'roaming' research team; organised into both generic and specialised research groups.</p>

<p>Purpose of the Development Pack</p>	<p>The purpose of this Orientation Guide is to provide a framework for your development with guidance on the following:</p> <ul style="list-style-type: none"> • Induction • Orientation • Professional & Personal Development • Ensure staff are orientated to the Hospital and primary care setting and aware of Trust links; • Ensure all staff possess the necessary knowledge and skills required to carry out their roles safely and effectively; • Highlight appropriate training objectives and identify and agree the support needed to attain them. <p>The orientation programme identifies expected standards, and specifies timeframes within which the necessary skills and knowledge to do your job should be demonstrated. This pack can be used in conjunction with other key documents and used to guide you as an individual within the research team. Other documents may include:</p> <ul style="list-style-type: none"> • Staff Induction checklist • Research competencies • Laboratory competencies • Individual Mandatory Training Record • KSF Evidence <p>Your induction programme will also include in-house study days which usually be phased into the first three - six months. These will constitute your documented training and development record and should be available at work so that you can add to them as appropriate. It will be used within the appraisal process. The Lead Research Nurse and your Manager will provide mentorship to support you.</p>
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<p>Philosophy</p>	<p>Each research participant will receive a high standard of care. This care will reflect their specific physical, psychological and spiritual needs and will encompass the whole person, their families and friends, in accordance with the Royal College of Nursing (RCN)'s research ethics framework.</p> <p>We recognise that our research participants have the right to informed consent, and we respect their right to withdraw from a study at any time. We will be advocates, acting always in participants' best interests.</p> <p>We believe that the rights of our participants are paramount, and our care is non-judgemental, based on ethical and moral principles, in accordance with the Code of Professional Conduct (NMC2008), the Declaration of Helsinki (2000) and the International Conference on Harmonisation Good Clinical Practice (ICH-GCP).</p> <p>We believe it is vital to foster good relationships in an atmosphere of respect, trust and honesty, protecting the research participants' right to privacy and confidentiality.</p> <p>Each member of the team will be valued and respected, and encouraged in their own professional development.</p> <p>The research team is a committed and dynamic force, working for the benefit of our patients/participants. We are in a privileged position of trust and will acknowledge this by providing the highest standard of care.</p> <p>We recognise that children have different needs from adults and should be cared for within a family focussed partnership approach.</p> <p>We will ensure that children will be provided with appropriate information to enable informed decisions and assent to be taken about their care and participation in the research process.</p> <p>We will ensure the research staff will undertake paediatric appropriate training in aspects such as informed and process consent and be suitably mentored by a registered children's nurse.</p> <p style="text-align: right;"><i>May 2009; adapted from ACRC (05)</i></p>
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<p>Roles & Responsibilities Definitions</p>	<p>Clinical for the purpose of this document may be defined as staff engaged in research activities that involve direct contact with patient's families and significant others in the clinical research pathway.</p> <p>A supervisor may be considered as an individual responsible for the supervision of another undertaking a task/action /activity in relation to clinical research.</p> <p>A manager may be considered an individual responsible for the management of another, identified in the job/role description.</p> <p>A practitioner may be considered as an allied health care professional.</p>
<p>Research Nurse (RN)</p>	<p>The Research Nurse (RN) will be responsible for particular studies they have been allocated.</p> <p>The RN will have an encompassing role in the clinical care of the patient, families and significant others throughout the study.</p> <p>The RN will contribute to the overall management of research studies ensuring best practice guidance is adhered to.</p> <p>The RN will have significant responsibility to ensure the professional care is provided to codes of conduct and best practice.</p> <p>The RN may have both technical and wider roles including administering prescribed medication.</p> <p>The RN will have been appointed for their previous experience, or particular interest in developing in the clinical research field.</p> <p>The CLRN funded RNs will be supported professionally by the CLRN Lead Research Nurse and Site Co-ordinator as well as by their employing Line Manager.</p> <p>The CLRN funded RNs are expected to contribute to the development of the local research service in their own department/service and other clinical areas within the trust.</p> <p>All CLRN funded staff are expected to, and are encouraged to, expand their skills by working cross-sectors and forging collaborative links with other disciplines and teams involved in clinical research.</p>

Clinical Trials Practitioner (CTP)	<p>The role of the clinical trials practitioner CTP is to support the facilitation of clinical trials under the guidance of the professional team. Some practitioners will be trained to undertake technical skills in the clinical research field in risk managed studies.</p> <p>The level of responsibility will vary according to experience and designated role. The CTP may have delegated responsibilities that support the facilitation of studies and assist the trials team in achieving best practice.</p>
Research Data Manager/Officer (RDM/O)	<p>The role of the RDM/O is to coordinate and facilitate all information identified with studies and to support the study teams. The RDM/O may also have direct contact with trials units, clinician's, patients, participants and families within this capacity. The level of responsibilities may vary according to experience, training and area of work, and risk managed studies.</p>
Research & management Governance teams	<p>To facilitate and manage all matters in the approval process and ensure ongoing governance is complied with.</p> <p>All CLRN funded staff are expected to work at all times within regulations as described in ICH-GCP and EU Directives and to proactively seek advice from the CLRN RM&G personnel, where necessary, on all matters relating to a study conduct compliance with the current regulatory framework and law.</p>
Responsibilities of all team members may include all or some the following:	<p>To become familiar with all aspects of the allocated study according to specific role and responsibilities.</p> <p>To ensure the study file has been set up and all documentation is in place as required by the Trust policy/procedure and study protocol.</p> <p>To liaise with appropriate members of the management team.</p> <p>To regularly update study process e.g. recruitment targets, start dates.</p> <p>To ensure identification and recording of any AEs, SAEs and other research related incidents according to local policy.</p> <p>To ensure Senior Research Nurse Manager is kept informed of progress of the study.</p> <p>To attend Core Team Meetings and Research Team Meetings as necessary.</p>

To provide verbal and written information and to offer support to patients/clients and families for the duration of their involvement in a study.

To assist in the informed consent process.

To be a point of contact for patients/clients and their families for their duration of their involvement in a study.

To attend regular updates re: education and training in aspects of the research process.

To refer patients/clients and their families onto other agencies as required.

With appropriate training, to take and process clinical samples for studies and dispatch to relevant department or trial centre as appropriate.

To work as part of the extended multidisciplinary team and maintain excellent links with staff in clinic, ward and treatment areas regarding protocol of care required for study patients.

To work at all times within regulations as described in IHC-GCP and EU Directives.

To cover the duties of other team members of the CLRN when required, including travelling to other sites and Trusts.

To attend relevant local, regional and national meetings related to specific trials.

To update and develop own clinical and theoretical skills in relation to study work.

To develop personal knowledge and skills in research, aiming to undertake own research with support.

To take opportunities to present and publish research findings undertaken when appropriate.

Ensure all duties are carried out to the highest possible standard of care

Adhere at all times to Trust policies and procedures, including the Equal Opportunities Policy.

Ensure the effective and efficient use of all Ward and Hospital resources.

Ensure that all duties are carried out to the highest possible standard and in accordance with the current quality initiatives within the work area.

Be aware of the responsibility to maintain a safe environment for patients, staff and visitors.

Be aware of your responsibilities under the Health and Safety at Work Act (1974)

Respect the confidentiality of all matters that you learn in the course of your employment and respect the requirements under the Data Protection Act (1998).

Be responsible for data quality and complying with the policies, procedures and accountability arrangements throughout the Trusts for maintaining accuracy and probity in recording of Trusts activities.

Comply with the requirement of the Freedom of Information Act 2000.

<p>Employment Policies - Local Trust Employment Contracts and CLRN context</p>	<p>Within your employing organisation contracts there are specific clause and responsibilities to consider which usually include:</p> <p>Sick leave; annual leave; absence; dress code; training, e.g. data protection, confidentiality, vulnerable adults, child protection, moving and handling; uniform policy and other mandatory requirements. These must be adhered to.</p> <p>In terms of the CLRN funded staff please consider the following:</p> <p>You are part of the networking organisation; therefore, your personal circumstance might impact on others who also contribute to the delivery of research. With that in mind, annual leave should be planned ahead as much as possible to enable the uninterrupted research support and service.</p> <p>Please report sickness and absence to your line manager and CLRN contact person if this applies, Early reporting will enable service to plan for absence where possible at the earliest opportunity. At the end of absence, it is the staff member's responsibility to report back to work.</p> <p>Uniform Policy This should be adhered in accordance with trust policy and clinical and non clinical areas of work, an ID Badge and the CLRN ID should be worn as identification of staff across Trusts.</p>
<p>Manager Meeting Record</p>	<p>You will meet with your Line Manager or representative on a regular basis to discuss and review your professional development and learning needs.</p> <p>It is suggested that these meetings will take place on a one-to-one base and be conducted regularly as agreed, more frequently initially.</p> <p>A formal meeting schedule and an annual appraisal will also be undertaken. You are welcome to discuss your particular requirements with the CLRN Research Nurse Lead and seek professional support and mentorship where necessary.</p>

<p>Orientation Visits</p> <p>These may vary according to a research site and specific role but they form part of professional development/training</p>	<p>Orientation to your working area</p> <p>Please ensure that in your first few days you familiarise yourself with the following:</p> <ul style="list-style-type: none"> • Fire Alarms/Location of fire exits/fire fighting equipment • Local First aider and location of first aid box • Telephone and bleep system • Use of 2222 system • Incident reporting <p>Please ensure you fully understand how to access policies, procedures and standard of conduct that are implemented by your employing organisation and your relevant professional body.</p> <p>All research staff will be given an opportunity to visit areas that may be of benefit to the development of knowledge and skill in the wider context of their role. These opportunities are across primary, secondary and tertiary care and can be facilitated by your line manager and CLRN links.</p> <p>Oncology Clinical Trials Laboratory - visit objectives:</p> <ul style="list-style-type: none"> • An overview of laboratory practice and the Health and Safety implications of sample handling. • Basic safe specimen handling • Use of centrifuge • Sample transfer, consider implications of how this works in primary care and across services etc • Waste management • Dry ice storage. <p>Clinical Research Facility (CRF) / Clinical Trials Unit (CTU) or a similar unit - visit objectives:</p> <ul style="list-style-type: none"> • To gain an understanding of the role of the CRF
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- To shadow a research nurse and gain understanding of their role
- To identify specific clinical skills required
- To communicate with patients and families recruited into studies
- To understand how CRF 'fits' with CLRN
- Identify own learning outcomes for visit
- This visit is arranged by your mentor as part of your induction.

Oncology Clinical Trials Unit/Specialist Oncology areas - visit objectives:

- To attend a variety of oncology clinics with an allocated research nurse
- To understand and take part in consent of patients into clinical trials
- To understand the differences between phase I, II and III drug trials
- To gain an understanding of *Good Clinical Practice (GCP)*
- This visit is arranged by your mentor as part of your induction
- Consider Visits to areas that are active in clinical research across services in all specialties
- Primary Care practice
- Laboratories
- Pharmacy.

Mandatory Records These courses will/may be mandatory with slight variation in the employing trust and the specific role, please ensure you are up to date.

<p>Introduction to Risk Management (inc slips, trips and falls) Safeguarding Children (level 1-3 according to role) Protecting Vulnerable Adults Infection Control and Hand Hygiene Training Fire Safety Training Equality & Diversity/Dignity at Work Information Governance /Security and Fraud Awareness Occupational Health Induction training Infection control training/hand hygiene (clinical staff) Moving and handling Resuscitation training</p>	<p>Trust Training all/or according to role</p>	<p>Annual/biannual</p>	<p>Due dates</p>
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When	Training	date/time/refresher	Achieved
Induction	Resuscitation training according to role. Discuss BLS/Anaphylaxis/adult/paediatric/advanced		
Induction	Get ID badge/smart card		
Induction	Ensure receive contract and understands		
Induction	Recording annual leave		
Induction	Reporting/recording absence		
Induction	Recording annual leave		
Induction	Reporting/recording absence		
Induction	Study allocation of time record		
Induction	Orientation tour		
Clinical research relevant	Venepuncture - practice - attain competency		
Clinical research relevant	Cannulation - practice - attain competency		
Clinical research relevant	Central line - practice - attain competency		
Clinical research relevant	Sampling - PK		
Clinical research relevant	Sampling - Processing		
Clinical research relevant	Sampling - advanced spinning		
Clinical research relevant	Sampling - transportation including dry ice		
Clinical research relevant	Sampling - recording of sample form/bottle		
Clinical research relevant	Sampling - storage/documentation/H&S		
Clinical research relevant	Spiromotomy - training pack		
Clinical research relevant	Requests for investigations i.e. CT /IMER		
Clinical research relevant	I.V. dosing		
Clinical research relevant	Infusion reactions		
Clinical research relevant	Anaphylaxis training		

General/Area Management	Freezer checks - 80, -40		
General/Area Management	Ordering food		
General/Area Management	Ordering supplies		
General/Area Management	Ordering stationary		
General/Area Management	Contacting IT helpdesk		
General/Area Management	Contacting estates - urgent repairs		
General/Area Management	Drugs - procedure/policy		
General/Area Management	Drugs - Checking procedures		
General/Area Management	Record documentation - read policy		
General/Area Management	Appraisal		
Information	Awareness of data protection and Caldicott, Trust information policies		
Information	Principles of data entry		
Research specific	Understand approval process /IRAS/SSI		
Research specific	Understand the SSI documentation and contribute to the collection of specific information in this process.		
Research specific	Understand research terminology		
Research specific	Understand and interpret research protocol		
Research specific	Complete GCP training		
Research specific	Advanced communication in clinical trials		
Research specific	Attend informed consent training		
Research specific	Attain competency to take/be involved in research consent		
Research specific	Attend legal issues training day		
Research specific	Attend an investigator meeting		
Research specific	Read role of clinical research nurse/clinical research		

Research specific	Read principles of clinical research		
Research specific	Lead on one or more research study		
Research specific	Discuss ways of maximising recruitment		
Research specific	Contribute to a site visit		
Research specific	Contribute to a MTD study meeting		
Research specific	Costing 'Study costing and understanding study set up requirements'		
Research specific	Understanding resources associated with conducting research		
Research specific	Patient Public Involvement awareness of this		
Research specific	SharePoint - ability to use		
Research specific	Awareness of Mental Capacity Act		
Supervision	Understand staff rota and manage changes		
Supervision	Assist a team member with orientation plan		
Supervision	Complete informal clinical teaching sessions		
Supervision	Be involved in recruitment/selection process		
Supervision	Organise/allocate team responsibilities		

Examples of core Research Competencies in relation to practice

Competency	Requirement	Acceptable supporting evidence
1. Ability to take research consent in low risk non complex studies.	Attend the ethics and consent training day and evidence of ability to discuss key issues pertaining to research consent.	Certificate of attendance Presentation pertaining to consent issues
2. Ability to manage two concurrent low risk non complex studies.	Evidence of ability to manage two concurrent studies.	Written documentation from team lead
3. Good understanding of research governance including GCP in research.	Attend face to face GCP in research training. This must be for a minimum of 4 hours. Ability to discuss practice & GCP.	Certificate of attendance Presentation pertaining to GCP issues
4. Maintains and calibrates specialist equipment (e.g. blood glucose analysers).	At least one type of specialist equipment must be included.	Written competency sign off from team lead.
5. Ability to supervise members of the team.	Evidence of supervision of at least one person over an agreed time frame.	Written competency sign off from team lead.
6. Develops specialist knowledge in one or more areas.	Evidence of ability to teach others regarding key clinical knowledge in one or more specialist area using appropriate clinical/teaching skills and assessment.	One to one or group teaching of specialist knowledge, observed by a designated person and/or certificate of attendance.
7. Ability to deputise for team lead	Demonstrates ability to show team leadership, integration within and manage a team.	Evidence of acting as team lead. Evidence of responsibility as specialist link for area/team.
8. Have a signed off core research competency record (as appropriate to area/role)		Learning log, objective, team lead written assessments
<p>Definitions: low risk, non complex = research study involving questionnaires and/or baseline assessments and/or venepuncture collection and blood processing with a minimal risk of severe side effects and unknown risk.</p>		

Examples of acceptable evidence of learning for file

Activity and evidence	Evidence/Located/Reference:
1. Relevant reading i.e. journals, books etc	
2. Investigator meeting	
3. Relevant clinical learning sessions i.e. attending OPD clinic during induction where the purpose is to observe/learn rather than conduct research activity i.e. shadowing	
4. Study site set up meeting	
5. External relevant training	
6. Formal research training days/seminars	
7. Mandatory training/facilitation	
8. In house study specific i.e. reading protocol	
9. Formal academic learning i.e. module attendance	
10.	
11.	
12.	

Research Nurse Learning Hours' Log

Complete the record of assessment/re-assessment of competency as required for evidence

Title of Task/ Procedure	
Associated SOP/ Document version number if applicable	
TRAINING ASSESSMENT/reassessment	
date:	

To be retained in personal training folder

CURRICULUM VITAE Template

You are required to provide a CV when establishing/joining a new research project. Therefore we have provided a simple template to help you. Please complete and save an electronic copy.

Name:	
Present appointment: <i>(Job title, department, and organisation.)</i>	
Address: <i>(Full work address.)</i>	
Telephone number:	Email address:
Qualifications:	
Professional registration: <i>(Name of body, registration number and date of registration.)</i>	
Previous and other appointments: <i>(Include previous appointments in the last 5 years and other current appointments.)</i>	

Research experience: *(Summary of research experience, including the extent of your involvement. Refer to any specific clinical or research experience relevant to the current application.)*

Research training: *(Details of any relevant training in the design or conduct of research, for example in the Clinical Trials Regulations, Good Clinical Practice or other training appropriate to non-clinical research. Give the date of the training.)*

Signature:

Date:

Glossary	<p>Adverse event Any unfavourable or unintended sign, symptom or disease temporarily associated with the use of an investigational product, whether or not considered related to the investigational product e.g. Fractured tibia</p> <p>Anonymity A research participant's protection in a study so that no one, not even the researcher, can link the subject with the information given</p> <p>Assent An aspect of informed consent that pertains to protecting the rights of children as research subjects</p> <p>Benefice An obligation to do no harm and to maximise possible benefits</p> <p>Bias Any influence that may alter the outcome(s) of a study</p> <p>Close-ended item Question that may be answered with only one of a fixed number of choices</p> <p>Confidentiality Assurance that a research participant's identity cannot be linked to the information that was provided to the researcher</p> <p>Consistency Data are collected from each subject in the study in exactly the same way or as close to the same way as possible</p> <p>Control group The group in a experimental investigation that does not receive an intervention or treatment; the comparison group - may be placebo, standard treatment or nothing</p> <p>Correlation A statistical technique which shows how strongly pairs of variables are related</p> <p>Cross-sectional study A nonexperimental research design that looks at data at one point in time (the immediate present)</p> <p>Eligibility criteria Those characteristics that restrict the population to a homogeneous group of subjects (i.e. can dictate certain criteria such as age, medical history, current medication usage etc.)</p>
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<p>Evaluation research The use of scientific research methods and procedures for the purpose of making an evaluation</p> <p>Experimental design A research design that has the following properties: randomization, control and manipulation</p> <p>Experimental group The group in an experimental investigation that receives an intervention or treatment - tested against the control group</p> <p>External validity - The degree of the generalisation in clinical trials and experimental medicine</p> <p>Hypothesis A prediction about the relationship between two or more variables</p> <p>Informed consent An ethical principle that requires a researcher to obtain the voluntary participation of subjects after informing them of potential benefits and risks</p> <p>Internal validity The degree to which it can be inferred that the experimental treatment, rather than an uncontrolled condition, resulted in the observed effects</p> <p>Intervention Deals with whether or not the observer provokes actions from those who are being observed</p> <p>Likert scales Lists of statements on which respondents indicate whether they 'strongly agree', 'agree', 'disagree' or 'strongly disagree' may be a 3, 5 or 7 point scale.</p> <p>Longitudinal study A nonexperimental research design in which a researcher collects data from the same groups at different points in time</p> <p>Matching The process of selecting participants so that study group and a comparison group are similar or nearly similar in relation to preestablished variables, such as age and gender</p> <p>Mortality The loss of subjects from time 1 data collection to time 2 data collection (also known as drop outs)</p>

Null hypothesis A statement that there is no relationship between the variables and that any relationship observed is a function of chance or fluctuations in sampling

Open-ended item Questions that the respondent may answer in his or her own words

Parameter A characteristic of a population

Primary source Scholarly literature that is written by a person(s) who developed the theory or conducted the research

Prospective study Nonexperimental study that begins with an exploration of assumed causes and then moves forward in time to the presumed effect

Qualitative research Has no measurements or statistics but uses words, descriptions and quotes to explore nature and meaning of an experience. Useful in exploring an area about which very little is known.

Quality of Life a descriptive term that refers to an individual's emotional, social, and physical well-being, and their ability to function in the ordinary tasks of living

Quantitative research Usually contains numbers, proportions and statistics and is invaluable in measuring people's attitudes, their emotional and behavioural states. Also referred to as Empirical, Positivist or objective reality. Quantitative studies are concerned with cause and effect. Able to generalize findings to similar groups and predict future outcomes.

Randomization A sampling selection procedure in which each person or element in a population has an equal chance of being selected to either the experimental group or the control group

Reactivity The distortion created when those who are being observed change their behaviour because they know

that they are being observed

Peer-reviewed journal A scholarly journal that has a panel of external and internal reviewers or editors; the panel reviews submitted manuscripts for possible publication. The review panels use the same set of scholarly criteria to judge if the manuscripts are worthy of publication

Reliability The consistency or constancy of a measuring instrument

Representative sample A sample whose key characteristics closely approximate those of the population

Research The systematic, logical and empirical enquiry into the possible relationships among particular phenomena to produce verifiable knowledge

Retrospective study A nonexperimental-experimental research design that begins with the phenomenon of interest (dependent variable) in the present and examines its relationship to another variable (independent variable) in the past - ways of exploring including case notes review.

Review of the literature An extensive, systematic, and critical review of the most important published scholarly literature on a particular topic.

Risk-benefit ratio The extent to which the benefits of the study are maximised and the risks are minimised such that the subjects are protected from harm during the study

Sample The number, within a given population, who are selected to participate in the research study.

Secondary data Refers to all types of clinical and non-clinical information that has already been collected and assembled for some other purpose and that was subsequently cleaned of any person-identifiable information so it can be used by researchers. Local guidance will apply to accessing and handling such data and obtaining consent to

access and use.

Secondary source Scholarly material written by a person(s) other than the individual who developed the theory or conducted the research.

Selection bias The bias towards selecting research participants in way it results in a non- representative sample. It can seriously impact on internal validity threat that arises when pre-treatment differences between the experimental group and the control group are present.

Serious Adverse Event Adverse event that is life threatening, requires in-patient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, a congenital abnormality or birth defect.

Time series design A quasi-experimental design used to determine trends before and after an experimental treatment. Measurements are taken several times before the introduction of the experimental treatment, the treatment is introduced, and measurements are taken again at specific times afterwards

Validity Determination of whether a measurement instrument actually measures what it is purported to measure - e.g. thermometer

Visual analogue scale visual rating scale e.g. 'pain thermometer'

Acronyms	ACCI	Addenbrooke's Centre for Clinical Investigation
	AE	Adverse Event
	CI	Chief Investigator
	CRF	Case Report Form/Case Record Form (eCRF: electronic CRF)
	CTA	Clinical Trials Assistant/Authorisation
	DoH	Department of Health
	GCP	Good Clinical Practice
	GMC	General Medical Council
	GSK	GlaxoSmithKline
	HADS	Hospital Anxiety and Depression Scale
	ICH	International Conference on Harmonisation
	ICR	Institute of Clinical Research
	IRAS	Integrated Research Application System
	IVRS	Interactive Voice Recognition System
	MHRA	Medicines and Healthcare Products Regulatory Agency
	MRC	Medical Research Council
	NIHR	National Institute for Health Research
	QOL	Quality of Life
	QP	Qualified Person

PI	Principal Investigator
RCT	Randomised Controlled Trial
R&D	Research and Development
REC	Research Ethics Committee
SAB	Scientific Advisory Board
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
SSI	Study Site Information
SUSAR	Suspected unexpected serious adverse reaction
WTCRF	Wellcome Trust Clinical Research Facility

Useful Websites

<http://essex-herts.crncc.nihr.ac.uk> - This is a home page of the Essex & Hertfordshire CLRN. Please monitor announcements, training opportunities and general updates. You will also be receiving weekly staff bulletin and our quarterly newsletter.

www.nihr.ac.uk - This is a home page of the NIHR. This site contains information about important announcements relevant to the NHS research, the NIHR Faculty, research funding and general opportunities for research.

www.crncc.nihr.ac.uk - NIHR Clinical Research Network - the parent organisation of all research networks funded via the NIHR. Contains information about networks, research governance, career opportunities and training. Importantly, this site links to the NIHR portfolio studies portal.

www.ukcrc.org - UK Clinical Research Collaboration webpage. Contains high quality information about research, research career pathways, best practice in research management and public engagement.

www.ich.org - The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is a unique project that brings together the regulatory authorities of Europe, Japan and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration. The purpose is to make recommendations on ways to achieve greater harmonisation in the interpretation and application of technical guidelines and requirements for product registration in order to reduce or obviate the need to duplicate the testing carried out during the research and development of new medicines.

www.library.nhs.uk You can log-on with your ATHENS password to conduct literature searches.

www.wtcrf.cam.ac.uk The Wellcome Trust Clinical Research Facility in Cambridge. Useful information about education and their dedicated research facilities.

www.rcn.org.uk/development/researchanddevelopment The RCN's dedicated site for all things R&D, including events, competency framework and the option to join their weekly news bulletin.

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