

Specialist Competencies

Clinical Research Staff

Development Portfolio

Research Posts

Contact Details

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|---------------------------------|--|
| Name of Member of Staff: | |
| Job Title: | |
| Specialisation: | |
| CLRN Start Date: | |
| Line Manager: | |
| Trust: | |
| Place of Work (site): | |
| Department: | |
| Site Address: | |
| Work Contact Number: | |
| Work Mobile Number: | |
| Fax Number: | |
| Email Address: | |

Research Posts

CLRN INDUCTION PLAN/INITIAL OBJECTIVES

Welcome

We welcome you to your post and look forward to working with you in your new role.

We have developed this competency pack to assist your development, skills and knowledge within the clinical research field. The pack is based on the approved RCN/KSF linked competency framework for research staff.

Your post may be community or acute based and clinical practice will in conjunction with the Comprehensive Local Research Network and your employing organisation

This pack introduces the Comprehensive Local Research Network (CLRN) and it covers the competencies that may be required by research staff from a basic level to an advanced level. The competencies may not all be necessary for all staff and the levels of competency will vary according to your role within clinical research.

You will be able to develop your role and competencies within your job description, and there will also be your employer induction/development programme and a CLRN orientation document. This can be completed in conjunction with your line manager according to your role and responsibilities.

The National Institute Health Research

The National Institute for Health Research (NIHR) now brings together government support for research in the NHS in England, through the NIHR Clinical Research Network Coordinating Centre (NIHR CRN CC). 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 clinical trials.

The aims of the NIHR Clinical Research Network are to:

- Ensure patients and healthcare professionals from all parts of the country are able to participate in and benefit from clinical research
- 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.

Topic Specific Clinical Research Networks (TCRN)'s co-ordinate clinical trials for specific conditions:

A number of networks co-ordinate clinical trials for specific conditions. These are:

- **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 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.

Courses/induction areas that you may wish to consider in the first 12 weeks or that you may require to undertake your role. (This is for direction and not a complete or final list)

- Develop skills on searching for studies in your area of involvement using local systems
- An introduction to GCP/Fraud/Misconduct/Consent/Costing/
- Documentation on Standard Operating Procedures/Patients notes/medico legal aspects/Case Record Forms/SAE
- Research Governance
- Data management /site files/feasibility/ Roles and Responsibilities
- Research Passport/Letters of access/working in other areas
- Training needs Questionnaire after 3 months meeting 1-1 with CLRN lead Nurse
- Understanding Specialty Groups and networks and the CLRN
- Working knowledge of Share Point
- Meet CLRN staff across services
- Familiarise yourself with the NIHR/UKCRN
- Communication lists and email distribution list
- Research Ready /Local Enhanced Services
- Public Patient involvement
- Begin to identify barriers to research and discuss with CLRN team to enable and support development
- Presentation skills.
- Technical skills ECG/Phlebotomy /phlebotomy /spiromotory
- Organisation of own workload

Objectives:

Set CLRN objectives joint CLRN/Local within 3 months.

| Objective | Detail | Target Date | Target Reached (Date) |
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Expertise – Technical Competencies Development Portfolio

These competences have been taken from the COMPETENCY FRAMEWORK FOR CLINICAL RESEARCH NURSES Version 1 December 2008 and further information is to be found in the document if required.

The Development portfolio specialist management competencies will be assessed evidenced in your portfolio. You will need to collect evidence to support each competency relevant your practice. This must begin from the time of induction and is your responsibility to maintain.

The Development portfolio is designed to encourage individuals to develop the professional and technical skills, knowledge and experience, required to develop and deliver high standards of care.

Each competency has an optimum level of performance. The individual must produce evidence to demonstrate that they have achieved the competency. The competencies are development steps which guide the individual to the optimum level of performance and all or some may apply according to the role and responsibility of each individual. These will be agreed in the induction and development programme with your line manager and by CLRN support.

Each member of staff undertaking the technical competencies must complete a portfolio of evidence to accompany the documents. The methods of assessment are identified within the competencies. Evidence must be collected to support completion of competencies and can be gathered in preparation for the appraisal. Evidence is a way of demonstrating certain criteria has been achieved.

This competency structure is approved by the Royal College of Nursing (RCN) and is linked to KSF. It is a useful framework research staff and stimulates the collection of an evidence based portfolio.

This document has been modified to enable easier navigation for referencing.

| History Of research | | | | | | |
|-------------------------------------|--|---|------------------------------|----------------------|------------|--------------|
| Development Step (1) | Competency statement: To demonstrate knowledge and understanding of the evolution of clinical research | Method of Assessment | Contextual Factor Reference | KSF LINK | Competency | |
| | | | | | Achieved | Not Achieved |
| Optimum Level of Performance | Demonstrates comprehensive knowledge and understanding of the historical background, political influence and strategic developments relating to the evolution of clinical research. | Discussion or written paper on political and strategic developments in clinical research | [12] [13] | | | |
| Development Stage | Has a comprehensive understanding of the historical background, political influence and strategic developments relating to research Articulates the significance of the major events and documents influencing the evolution of clinical research, including the political imperatives and government strategies. | Discussion or written evidence on the significance of the major events and documents influencing the evolution of clinical research, including Methodological developments in clinical research, the political imperatives and government strategies. | [14] [15] [16] [17] | C1 C2 C3 C5 | | |
| Development Stage | Broad understanding of the historical background, political influence and strategic developments relating to the evolution of clinical research. Is able to recognise the importance of acknowledging the context in which clinical research is undertaken. | Discussion or written evidence on the history of ethics related to clinical research. | [18] [19.1] [20] | G5 | | |

Design of Studies

| Development steps (2) | Competency statement: To Demonstrate Knowledge of the Design, Use and Types of Research Studies | Method of Assessment | Contextual Factors Reference | KSF LINK | Competency | |
|-------------------------------------|---|--|------------------------------|--|------------|--------------|
| | | | | | Achieved | Not Achieved |
| Optimum level of performance | Acts as an expert resource for staff, researchers, research participants and patients. | Documentary evidence of acting as a resource, trainer and developer of research and policies related to research. Written evidence of contribution to national policies and procedures. Discussion on the regulatory and legal frameworks related to clinical research studies | [8] | C1 C2 C3 C5 G5 | | |
| | Leads on the training and ensuring the appropriate supervision of staff. | | [9] | | | |
| | Leading role in the development and updating of local policies and procedures. | | [19.2] | | | |
| | Contributes to the development of national policies and procedures. | | [23] | | | |
| | Has a comprehensive knowledge and understanding of the different research designs and methodologies used in clinical research. | | [24] | | | |
| | | | [25] | | | |
| | Has a comprehensive knowledge and understanding of the regulatory and legal frameworks related to the planning, undertaking and closure of clinical research studies. | | [26] | | | |
| | | | [27] | | | |
| Development stage | Understands the rationale behind the different research designs and methodologies used in clinical research. | Discussion on the different research designs and methodologies used in clinical research and the implications for practice of the regulatory and legal frameworks. | [28] | | | |
| | Understands the implications for practice of the regulatory and legal frameworks related to the planning, undertaking and closure of clinical research studies. | | [29] | | | |
| | | | [30] | | | |
| | | | [31] | | | |
| | | | [32] | | | |

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| | <p>Acts as a knowledgeable resource for staff, researchers, research participants and patients.</p> <p>Contributes to the training and supervision of staff and researchers.</p> <p>Contributes to the development of local policies related to all parts of the clinical research process.</p> <p>Promotes and facilitates PPI in all aspects of clinical research.</p> | <p>Written evidence of :</p> <ul style="list-style-type: none"> ❖ Acting as a resource ❖ Contribution to the development of policies ❖ Promotion of PPI in clinical research | <p>[33]</p> <p>[34]</p> <p>[35]</p> <p>[36]</p> <p>[37]</p> <p>[38]</p> | | | |
| <p>Development Stage</p> | <p>Has an awareness and understanding of the research designs and methodologies used in clinical research.</p> <p>Has an awareness and understanding of the regulatory frameworks and legal requirements associated with the planning, undertaking and closure of clinical research studies.</p> <p>Consistently adheres to the study protocol design.</p> <p>Raises concerns if design conflicts with regulatory frameworks and legal requirements or if research activities deviate from the study protocol.</p> <p>Recognises own limitations and attends/completes relevant training (including GCP). Is supportive in the training of others.</p> | <p>Written evidence of:</p> <ul style="list-style-type: none"> ❖ Consistently adhering to the study protocol design ❖ Raising concerns if design conflicts with regulatory frameworks and legal requirements or if research activities deviate from the study protocol ❖ An awareness of the need for patient and public involvement (PPI) in clinical research | <p>[39]</p> <p>[40]</p> <p>[41]</p> <p>[42]</p> <p>[43]</p> <p>[44]</p> <p>[45]</p> <p>[46]</p> | | | |

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| | Demonstrates an awareness of the need for patient and public involvement (PPI) in clinical research. This could include their involvement in any aspect of the research process, including in the preparation of Participant Information Sheets (PIS) and other study documentation. | | | | | |
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| Finance | | | | | | |
|-------------------------------------|---|--|---------------------------------------|----------|------------|--------------|
| Development steps (3) | Competency statement: To Demonstrate the Ability to Manage the Budget | Method of Assessment | Contextual Factors Reference | KSF LINK | Competency | |
| | | | | | Achieved | Not Achieved |
| Optimum Level of Performance | <p>Involved in the financial processes associated with coordinating research studies and grant applications.</p> <p>Acts as an expert resource for staff in relation to the financial management of clinical research studies.</p> <p>Uses expert judgment in relation to competing demands for funding.</p> <p>Has a comprehensive knowledge of the financial issues relating to the undertaking of clinical research.</p> | <p>Discussion or written evidence on:</p> <ul style="list-style-type: none"> ❖ Funding of research studies ❖ Financial agreements ❖ Financial management during the course of a clinical research study | <p>[19.3]</p> <p>[20]</p> <p>[47]</p> | C2 | | |
| Development Stage | <p>Contributes to the financial processes of planning, running and closing clinical research studies</p> <p>Understands the financial issues related to the undertaking of clinical research.</p> | <p>Discussion or written evidence on the Identification of costs.</p> | <p>[48]</p> <p>[49]</p> | G5 | | |
| Development Stage | <p>Consistently operates within the financial constraints of the funding available for a clinical research study.</p> <p>Alerts relevant personnel to potential escalating consumable and other costs associated with a clinical research study.</p> <p>Has an awareness of the financial issues related to the undertaking of clinical research?</p> | <p>Discussion or written evidence on:</p> <ul style="list-style-type: none"> ❖ The role of the research funder ❖ National and local research costing models | | | | |

| Research Process | | | | | | |
|-------------------------------------|--|--|------------------------------|----------------------|------------|--------------|
| Development Steps (4) | Competency statement: To Demonstrate the Ability to Undertake the Research Process | Method of Assessment | Contextual Factors Reference | KSF LINK | Competency | |
| | | | | | Achieved | Not achieved |
| Optimum Level of Performance | Manages research studies. | Discussion or written evidence on the ❖ Processes for participant recruitment. ❖ Risk Management. ❖ Public involvement in research. | [19.4] | C1 C2 C3 C5 | | |
| | An expert resource in the management of clinical research studies. Takes a leading role in managing research studies. | | [20] | | | |
| | Supports colleagues and researchers through the research study process, including clinical aspects associated with the research study. | | [29] | | | |
| | Takes the lead on developing and updating SOPs. Takes a leading role in activities of professional forum and networks. | | [31] | | | |
| | | | [32] | | | |
| Development Stage | Leads/coordinates the preparation, undertaking and closure of clinical research studies. | Discussion or written evidence on: ❖ Local Medicines Policy. ❖ Relevant clinical skills in line with local procedures and national occupational standards. ❖ Importance of submitting recruitment figures to relevant bodies, including UKCRN accrual data. | [41] | lk2 G5 G6 | | |
| | An expert resource, for staff and researchers, within the clinical research environment. Actively involved in the ordering of supplies, ensuring that resources (including staff and beds) are available for the effective conduct of the research study. | | [42] | | | |
| | | | [45] | | | |
| | | | [50] | | | |
| | | | [51] | | | |
| | Ensures clear and accurate documentation is maintained on the arrival, use and disposal of research study supplies. | | [52] | | | |
| | [53] | | | | | |
| | [54] | | | | | |

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| | <p>Advises staff and researchers, acting as a knowledgeable resource on matters relating to clinical practice and research, promoting an active and effective research culture.</p> <p>Contributes to the development and training of staff and researchers.</p> <p>Identifies own training needs.</p> <p>Contributes to the development of SOPs.</p> | | <p>[55]</p> <p>[56]</p> <p>[57]</p> <p>[58]</p> | | | |
| <p>Development Stage</p> | <p>Participates in clinical research study activities in accordance with the study protocol. Is able to correctly use and dispose of study supplies and equipment, in accordance with study protocol and relevant Standard Operating Procedures (SOPs).</p> <p>Completes accurate paperwork associated with research study supplies.</p> <p>Attends relevant training in relation to requirements of research study protocol.</p> <p>Consistent application of relevant clinical and research skills.</p> <p>Contributes to an active and effective research culture.</p> | <p>Discussion or written evidence on</p> <ul style="list-style-type: none"> ❖ Local organisational policies and procedures. ❖ NIHR Portfolio adoption processes. ❖ Knowledge of research study protocol. | | | | |

| Key Personnel | | | | | | | |
|------------------------------|--|---|------------------------------|----------|------------|--------------|----|
| Development steps (5) | Competency Statement: Demonstrate Knowledge of the Key Personnel Involved in the Research Process | Method of Assessment | Contextual Factors Reference | KSF LINK | Competency | | |
| | | | | | Achieved | Not achieved | |
| Optimum Level of Performance | <p>Has a comprehensive understanding of the roles and responsibilities of key personnel within the clinical research environment. Takes an active lead in the setting up, coordination and management of clinical research studies.</p> <p>Acts as an expert resource for staff and researchers.</p> <p>Takes an active role in developing and updating local and national policies and procedures.</p> <p>Actively involved in local and national forum and networks related to clinical research and the nurse's role in that clinical research.</p> | <p>Discussion or written evidence on the role of local and national research nurse forum and other relevant networks.</p> | [1] | C1 | | | |
| | | | [19.5] | | | | |
| | | | [20] | | | | C2 |
| | | | [32] | | | | C3 |
| | | | [41] | | | | C5 |
| Development Stage | <p>Acts as a knowledgeable resource and contributes to the development and training of staff and researchers.</p> <p>Contributes to the development and updating of local policies and procedures.</p> <p>Takes an active role in planning, undertaking and closing clinical research studies.</p> | <p>Discussion or written evidence on the roles of those involved in all aspects of research</p> | [45] | lk2 | | | |
| | | | [51] | | | | G5 |
| | | | [52] | | | | G6 |
| | | | [58] | | | | |
| Development Stage | <p>Has an understanding of the roles and responsibilities of key personnel within the clinical research environment. Consistently works within own role and adheres to the roles and responsibilities documentation.</p> <p>Is aware of own role limitations.</p> | <p>Discussion or written evidence on the roles and responsibilities of key personnel.</p> <p>Discussion on own role limitations</p> | [59] | | | | |

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| | <p>Involvement in the development of 'Delegation of Duties Log'.</p> <p>Familiar with roles and responsibilities of others involved in the clinical research and challenges non adherence to defined roles.</p> | | | | | |
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| Data Collection & Documentation | | | | | | |
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| Development Steps (6) | Competency Statement: Demonstrate the Ability to Collect Data and Complete Study Documentation | Method of Assessment | Contextual Factors Reference | KSF LINK | Competency | |
| | | | | | Achieved | Not achieved |
| Optimum level of performance | <p>Supervises and manages the accurate and complete collection of data and insertion of data into CRFs or other research storage formats. Contributes to the development of local policies and procedures.</p> <p>Ensuring that local policies and procedures are followed.</p> <p>Leads professional and educational development of staff. Contributes to the auditing and monitoring of research studies and responds recommendations.</p> | <p>Discussion or written evidence on:</p> <ul style="list-style-type: none"> ❖ Data insertion techniques, including the use of electronic data entry ❖ Audio and other media as means of data ❖ Source document verification | <p>[19.6]</p> <p>[38]</p> <p>[60]</p> <p>[61]</p> | <p>C1</p> <p>C3</p> <p>C5</p> | | |
| Development stage | <p>Supervises the accurate and complete collection of data and insertion of data into CRFs or other research storage formats. Responds to concerns if inaccurate or incomplete data entry is suspected.</p> <p>Advises staff and researchers on data collection and entry.</p> <p>Contributes to supervision and meeting the professional and educational needs of staff.</p> | <p>Discussion or written evidence on:</p> <ul style="list-style-type: none"> ❖ Fraud and misconduct ❖ Audit and monitoring of data | <p>[62]</p> <p>[63]</p> <p>[64]</p> <p>[65]</p> <p>[66]</p> <p>[67]</p> | <p>lk2</p> <p>G5</p> <p>HWB 2</p> | | |
| Development stage | <p>Undertakes the accurate and complete collection of data and insertion of data into Case Report Forms (CRFs) or other research storage formats.</p> | <p>Discussion or written evidence on local policies and procedures relating to data collection and timely transfer.</p> | | | | |

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| | <p>Evidence of accurate and complete data collection and entry.</p> <p>Adherence to requirements of ethically approved protocol.</p> <p>Raises concerns if inaccurate or incomplete data entry is suspected.</p> <p>Takes appropriate action in event of adverse events.</p> | | | | | |
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| Data Storage | | | | | | |
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| Development Steps (7) | Competency Statement: Demonstrate the Ability to Store Data | Method of Assessment | Contextual Factors Reference | KSF LINK | Competency | |
| | | | | | Achieved | Not achieved |
| Optimum Level of Performance | Supervises and manages the safe and secure storage of data. | Discussion or written evidence on policies and procedures for dealing with situations when data storage and archiving is inadequate | [19.7] | C1 C3 C5 G5 | | |
| | Contributes to ensuring that local policies and procedures, relating to data storage, are current and valid. | | [35] | | | |
| | Ensures adherence to local policies and procedures. | | [36] | | | |
| | Leads in the professional and educational development of colleagues. | | [37] | | | |
| | Advises on process of study closure and archiving of study documentation. | | [38] | | | |
| | | | [65] | | | |
| | | | [66] | | | |
| Development Stage | Ensures the safe and secure storage of data. Responsible for the safe and secure storage of research data within their own area of responsibility. | Discussion or written evidence on Local policies and procedures relating to data archiving. | [67] | | | |
| | Contributes to supervision and meeting the educational needs of staff. | | | | | |
| | Raises concern about poor data storage. | | | | | |
| | Contributes to study closure and preparation of archives. | | | | | |

| Development Stage | Ensures the safe and secure storage of data. Shows evidence of contributing to the safe and secure storage of research data. | <p>Discussion or written evidence on local policies and procedures relating to data storage, including:</p> <p>Discussion or written evidence on local policies and procedures relating to data storage, including:</p> <ul style="list-style-type: none"> ❖ CRFs ❖ Trial Master File (also Study File (SF) or Trial Site File (TSF)) ❖ Investigator Brochures (IBs) ❖ Human Tissue Samples | | | | |
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Section 8: to Work within, and adhere to, the Requirements of Research Ethics, Research Governance and Legislation

| Ethics | | | | | | |
|------------------------------|--|---|------------------------------|----------|------------|--------------|
| Development Steps (8) | Competency Statement: Demonstrate the Ability to Work with Research Ethics Committees | Method of Assessment | Contextual Factors Reference | KSF LINK | Competency | |
| | | | | | Achieved | Not achieved |
| Optimum Level of Performance | Provides comprehensive advice and guidance on matters relating to research ethics and governance. Acts as a resource to staff. Contributes to the professional and educational development of staff. | Discussion or written evidence of knowledge of procedures when local policies, approved protocols and legislative requirements are not adhered to, including instances of fraud and misconduct. | [8] | | | |
| | | | [9] | | | |
| | | | [19.8] | | | |
| | | | [20] | | | |
| Development Stage | Knowledge and understanding of structure, roles and function of RECs and R&D Departments. Knowledge of local R&D policies and procedures. Familiarity with legislative requirements relevant to research ethics, the function of RECs and R&D Departments. Provides advice to staff and researchers. Contributes to the development and updating of local policies and procedures relating to research governance. | Discussion or written evidence on: ❖ Local and national policy developments. ❖ Local policies and procedures related to ethical review and research governance. | [23] | C1 | | |
| | | | [32] | C2 | | |
| | | | [35] | C3 | | |
| | | | [36] | C5 | | |
| | | | [37] | G5 | | |
| | | | [38] | | | |
| | | | [39] | | | |
| Development Stage | Awareness of the structure, roles and function of RECs and R&D Departments Recognises the need to ensure that appropriate ethical opinions and governance approvals are acquired before any research activities are undertaken. | Discussion or written evidence of roles and responsibilities of: ❖ NRES | [48] | | | |
| | | | [60] | | | |

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| | <p>Articulates understanding of ethical requirements and processes and demonstrates an awareness of regulatory and legal requirements relating to research ethics and governance.</p> <p>Attends relevant educational opportunities relating to research ethics and governance.</p> | <ul style="list-style-type: none"> ❖ RECs ❖ Main Rec ❖ Investigators and members of the Research Team <p>Structure and organisation of RECs and their membership.</p> <p>Structure and organisation of R&D Departments and their membership.</p> <p>Processes for the submission of applications and their review.</p> | <p>[68]</p> <p>[69]</p> <p>[70]</p> <p>[71]</p> <p>[72]</p> <p>[73]</p> <p>[74]</p> <p>[75]</p> <p>[76]</p> <p>[77]</p> <p>[78]</p> <p>[79]</p> | | | |
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| Ethics and Governance Documentation & Submission | | | | | | |
|--|--|--|------------------------------|----------|------------|--------------|
| Development Steps (9) | Competency Statement: Demonstrate the Ability to Seek Ethical Opinion and Governance Approval: Preparation of Documentation and Submissions Throughout the Research Study | Method of Assessment | Contextual Factors Reference | KSF LINK | Competency | |
| | | | | | Achieved | Not achieved |
| Optimum Level of Performance | <p>Leads or make significant contribution to the preparation of documentation and submission of application to REC and R&D Department, as agreed within the research team. Prepares, or makes significant contribution to the preparation, of application to REC or R&D Department.</p> <p>Submits, or contributes to the submission, of application to REC or R&D Department.</p> <p>Acts as an expert resource for staff and researchers preparing a submission to a REC and R&D Department.</p> <p>Leads or contributes to the professional and educational development of staff and researchers.</p> | <p>Discussion or written evidence on REC and R&D application processes using the Integrated Research Application System (IRAS).</p> <p>Key documentation required to support REC and R&D submissions.</p> <p>Protocol development.</p> | [32] | C1 | | |
| | | | [48] | | | |
| | | | [48] | | | |
| | | | [49] | | | |
| Development Stage | <p>Contributes to the preparation of paperwork and submission of application to REC and R&D Department, as agreed within the research team. Documentation is clear, complete and accurate.</p> <p>Acts as a knowledgeable resource for staff and researchers making a submission to a REC or R&D Department.</p> <p>Raises concerns about incomplete, inaccurate or misleading documentation. Contributes to supervision and meeting the educational needs of staff.</p> | <p>Discussion or written evidence on</p> <p>Local review and reporting of research studies.</p> <p>Clinical Research Studies Agreements.</p> <p>Risk assessment.</p> | [69] | G5 | | |
| | | | [70] | HWB 2 | | |
| | | | [77] | | | |
| | | | [80] | | | |
| | | | [81] | | | |

Annex J

| Development Stage | <p>Aware of application processes and requirements for document management. Articulates the importance of clear, complete and accurate application form and supporting documentation.</p> <p>Familiar with application processes.</p> | <p>Discussion or written evidence on Local and national policy developments.</p> <p>Professional and educational requirements.</p> <p>Research sponsorship.</p> | | | | |
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| Confidentiality | | | | | | |
|------------------------------|---|--|------------------------------|----------|------------|--------------|
| Development Steps (10) | Competency Statement: Demonstrate the Ability to Ensure Participant Confidentiality | Method of Assessment | Contextual Factors Reference | KSF LINK | Competency | |
| | | | | | Achieved | Not achieved |
| Optimum Level of Performance | Ensures protection of a research participant's confidentiality. | Discussion or written evidence on Processes and actions required when processes to protect participant confidentiality are not followed. Safe transfer of data. | [19] | C1 | | |
| | Leads on the development and updating of local policies and procedures. | | [36] | | | |
| | Ensures that processes and procedures for participant confidentiality are developed and followed. | | [37] | | | |
| | Leads professional and educational development of staff. | | [38] | | | |
| Development Stage | Ensures protection of a research participant's confidentiality. | Discussion or written evidence on Local policies, procedures and protocols. Local and national policy developments. | [65] | C2 | | |
| | Acts as a knowledgeable resource and advisor to staff and researchers. | | [70] | C3 | | |
| | Contributes to supervision and meeting the educational needs of staff. | | [82] | C5 | | |
| | Contributes to the development and updating of local policies and procedures. | | [83] | | | |
| Development Stage | Ensures protection of a research participant's confidentiality. | Discussion or written evidence on Relevant legislation. Local Caldicott guardian. | | | | |
| | Consistently adheres to the requirement to protect a | | | | | |

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|--|--|---|--|--|--|--|
| | research participant's confidentiality. Raises concerns when confidentiality requirements are not adhered to. | Maintaining confidentiality for research participants involved in research Professional and educational requirements. | | | | |
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| Regulatory Requirements | | | | | | |
|-------------------------------------|---|--|--|----------------------------------|------------|--------------|
| Development Steps 11. | Competency statement Demonstrate the ability to understand and apply in practice the legal and regulatory requirements related to gaining and maintaining valid informed consent. This will include, where appropriate, children, young people and vulnerable adults. | Method of assessment | Contextual Factors Reference | KSF LINK | Competency | |
| | | | | | Achieved | Not achieved |
| Optimum level of performance | Acts as an expert resource to provide in-depth knowledge on aspects pertinent to acquiring and maintaining informed consent. | Discussion or written evidence on Legal requirements related to gaining and maintaining valid informed consent. Local policies and procedures relating to gaining and maintaining valid informed consent. | [8] [12] | C1 | | |
| Development stage | Demonstrates a sound understanding of the need to identify issues which may impact on the process of gaining valid informed consent. Plans and implements actions to resolve these issues. | Discussion or written evidence on Key information required in PIS. Key components of CF. Ongoing nature of informed consent. | [19.9] [21] [23] [66] | C2 C3 C4 C5 | | |
| Development stage | Effectively engages with research participants and others to ensure their understanding of information about research. Demonstrates an awareness of the factors contributing to a participant’s autonomous decision making during the consent process. Complies with the informed consent processes as described in the approved protocol, including use of | Discussion or written evidence on Principles of informed consent for participation in research. Roles of researchers, including CI and PI, in gaining and maintaining informed consent. | [84] [85] | HWB 2 | | |

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|--|--|--|--|--|--|--|
| | <p>approved versions of PIS and Consent Form (CF).</p> <p>Raises any concerns about the informed consent processes.</p> <p>Recognises own learning needs and takes responsibility for maintaining up to date knowledge.</p> <p>Provides evidence of training and understanding.</p> <p>Takes informed consent when appropriate and as agreed in the approved protocol.</p> | | | | | |
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Expertise -Technical Competencies

Development Portfolio

| Please complete one of these sheets as work is in progress and discussed with a supervisor and insert to each section as evidence is collected and discussed under relevant headings | | | |
|---|---------------------------|----------|-------------------------------------|
| Name Section of Competency | Level Achieved /discussed | Comments | Identified work /evidence collected |
| Assessor Name | Designation | Date | Review date |

Appendix 1

| Section | Number | Contextual Factor | Version | Revised Date |
|---------|--------|--|---------|--------------|
| | 1 | | | |
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| | 7 | | | |
| | 8 | Mental Capacity Act 2005 | | 2005 |
| | 9 | Adults with Incapacity (Scotland) Act 2000 | | 2000 |
| | 10 | | | |
| | 11 | | | |
| | 12 | Declaration of Helsinki | | |
| | 13 | Nuremberg Code | | |
| | 14 | 'The Nazi Doctors and the Nuremberg Code' | | |
| | 15 | 'Human Medical Trials' | | |
| | 16 | 'In the Name of Science' | | |
| | 17 | 'Research Governance: Where did it come from, what does it mean?' | | |
| | 18 | International Conference on Harmonisation good Clinical Practice (GCP) | | |
| | 19.1 | GCP, Including Section 2 | | |
| | 19.2 | GCP, Including sections: (4.9.2), (5.4 – 5.5), (6 – 7) and (8.3.14) | | |
| | 19.3 | GCP, including sections: (1.17), (4.9.6), (5.9) and (8.2.4) | | |
| | 19.4 | GCP, Including sections: (4.9.2), (5.4 – 5.5), (6-7), (8.3.14) | | |
| | 19.5 | GCP, Including sections: (4-5) and (5.2) | | |
| | 19.6 | GCP, Including sections: (4.9), (4.11), (5.18.4), (6.8.4) and (6.10) | | |
| | 19.7 | GCP, Including sections: (4.9.5) and (8) | | |
| | 19.8 | GCP, Including sections: (3) | | |
| | 19.9 | GCP, Including sections: (4.8.2), (4.8.7 – 4.8.11) and (8.3) | | |
| | 20 | 'Research Governance Framework for Health and Social Care' | | |
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| | 22 | | | |
| | 23 | Medicines for Human Use (Clinical Trials) Regulations | | 2004 |
| | 24 | 'Clinical Trials: A Practical Guide to Design, Analysis and Reporting' | | |
| | 25 | 'Clinical Trials Explained: A Guide to Clinical Trials in the NHS for Healthcare Professionals' | | |
| | 26 | 'Real World Research' | | |
| | 27 | 'The Research Process in Nursing' | | |
| | 28 | 'Essentials of Nursing Research: Methods, Appraisal and Utilization' | | |
| | 29 | 'Principles of Clinical Research' | | |
| | 30 | 'Best Research for Best Health' | | |
| | | 'Best Research for Best Health – Implementation Plan 3.3 – NIHR Faculty Membership' | 5 | Jul 09 |
| | | 'Best Research for Best Health – Implementation Plan 3.5 – NIHR Faculty Leadership Programme' | 5 | Jul 09 |
| | | 'Best Research for Best Health – Implementation Plan 4.1b – Bureaucracy Busting: Ensuring Good Governance through Networks' | 5 | Jul 09 |
| | | 'Best Research for Best Health – Implementation Plan 5.1 – NIHR Clinical Research Network' | 9 | Jul 09 |
| | | 'Best Research for Best Health – Implementation Plan 5.1a – NIHR Comprehensive Clinical Research Network' | 8 | Jul 09 |
| | | 'Best Research for Best Health – Implementation Plan 5.9 – NIHR Research Design Service' | 4 | Jul 09 |
| | | 'Best Research for Best Health – Implementation Plan 6.4 – NIHR Invention for Innovation Programme' | 8 | Jul 09 |
| | | 'Best Research for Best Health – Implementation Plan 6.6 – Research Units' | 8 | Jul 09 |
| | 31 | National Institute of Health Research (NIHR) | | |
| | 32 | National Institute of Health Research Clinical Comprehensive Research Network (NIHR CRN) | | |
| | 33 | MRC – 'Good Research Practice' | | |
| | 34 | MRC – 'Guidelines for Good Clinical Practice in Clinical Trials' | | |
| | 35 | MRC and Department of Health Clinical Trials Tool Kit | | |
| | 36 | Human Tissue Act 2004 | | 2004 |
| | 37 | Human Tissue (Scotland) Act 2006 | | 2006 |
| | 38 | Data Protection Act 1998 | | 1998 |
| | 39 | Medicines and Healthcare Products Regulatory Agency | | |
| | 40 | US Food and Drug Administration (FDA) | | |
| | 41 | 'The Code: Standards and Conduct, Performance and Ethics for Nurses and Midwives' | | |
| | 41.1 | Nursing & Midwifery Council (NMC) – 'The Code: Standards and Conduct, Performance and Ethics for Nurses and Midwives' | | |

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| | 42 | Institute of Clinical Research (ICR) Training Opportunities | | |
| | 43 | CONSORT Statements (Consolidated Statements of Reporting Trials) | | 2001 |
| | 44 | EudraCT | | |
| | 45 | NHS Research & Development (R&D) Forum | | |
| | 46 | 'A Guide to Efficient Trial Management' | | |
| | 47 | National Institute for Health and Research (NIHR) Costing Template | | |
| | | Local Organisations, including: | | |
| | 48 | Comprehensive Clinical Research Network (CCRN) | | |
| | | Universities | | |
| | 49 | NHS Organisations | | |
| | | Charitable Organisations | | |
| | | Industry and Commercial Organisations | | |
| | 46 | 'A Guide to Efficient Trial Management' | | |
| | 50 | Good Laboratory Practice (GLP) | | |
| | 51 | Royal College of Nursing (RCN) | | |
| | 52 | Clinical Research Nurses Association (CRNA) | | |
| | 53 | INVOLVE | | |
| | 54 | 'Conference Presentations: A Guide to Writing the Abstract' | | |
| | 55 | 'From Conference Presentation to Journal Publication: A Guide' | | |
| | 56 | 'Writing for Publication: Pressures and Support Strategies' | | |
| | 57 | 'Writing for Publication: A Practical Guide' | | |
| | 58 | Medical Research Council (MRC) Experimental Medicine Tool Kit | | |
| | 59 | | | |
| | 60 | 'Fraud and Misconduct in Biomedical Research' | | |
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| | 65 | Medical Research Council (MRC) Data and Tissues Tool Kit | | |
| | 66 | | | |
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| | 68 | 'Governance Arrangements for Research Ethics Committees' | | |
| | 69 | 'Standard Operating Procedure for Research Ethics Committees' | | |

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| | 70 | National Research Ethics Service (NRES) | | |
| | 71 | National Institute of Health Research (NIHR) Coordination Systems for NHS Permissions (CSP) | | |
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| | 74 | | | |
| | 75 | | | |
| | 76 | 'Case Studies in Biomedical Research Ethics' | | |
| | 77 | 'Principles of Biomedical Ethics' | | |
| | 78 | Healthcare Commission Standards | | |
| | 79 | | | |
| | 80 | International Research Application System (IRAS) | | |
| | 81 | 'The Importance of Both Research and its Proper Review' | | |
| | 82 | Human Rights Act 1992 | | 1992 |
| | 83 | Caldicott Report 1997 | | 1997 |
| | | Industry and Commercial Organisation | | |
| | | Universities | | |