

**CLCH R&D Research Delivery Competency Framework**

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| **Your name:** |  |
| **Main Mentor/Co-mentor(s):** |  |
| **Baseline Assessment date:** |  |
| **1st Follow-up Assessment date**  *(suggested 6 months after baseline)* |  |
| **2nd Follow-up Assessment date**  *(suggested 12 months after baseline)* |  |

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**Introduction**

This competency framework was based on the National Institute for Health and Care Research (NIHR) Competency Framework for Research Delivery Staff (version 3, July 2024), developed by Clinical Research Network East Midlands, and adapted to the context of clinical community research conducted at the Central London Community Healthcare NHS Trust (CLCH).

This document is not limited to the use of research delivery staff. Research coordinators, managers, facilitators, fellows and non-research professionals are welcome to use.

The framework's objective is to enable staff to assess their research skills development in the community. Research competency frameworks completed in other NHS organisations are suitable to complement this current CLCH version.

As stated by the NIHR (2024), the competency framework will support staff to:

* Understand more clearly what is required from them
* Document their knowledge, skills, attributes and experience
* Identify learning needs and interests
* Provide evidence of achievement to support annual appraisals & promote fair and consistent assessment
* Demonstrate adherence to Good Clinical Practice (GCP)
* Recognise the contribution of every member of the research team
* Identify opportunities for personal development, training and career progression
* Can be used as evidence for health profession revalidation portfolio
* May form the basis for progression through NHS gateways (e.g. Agenda for Change)

**What are the competencies assessed in this framework?**

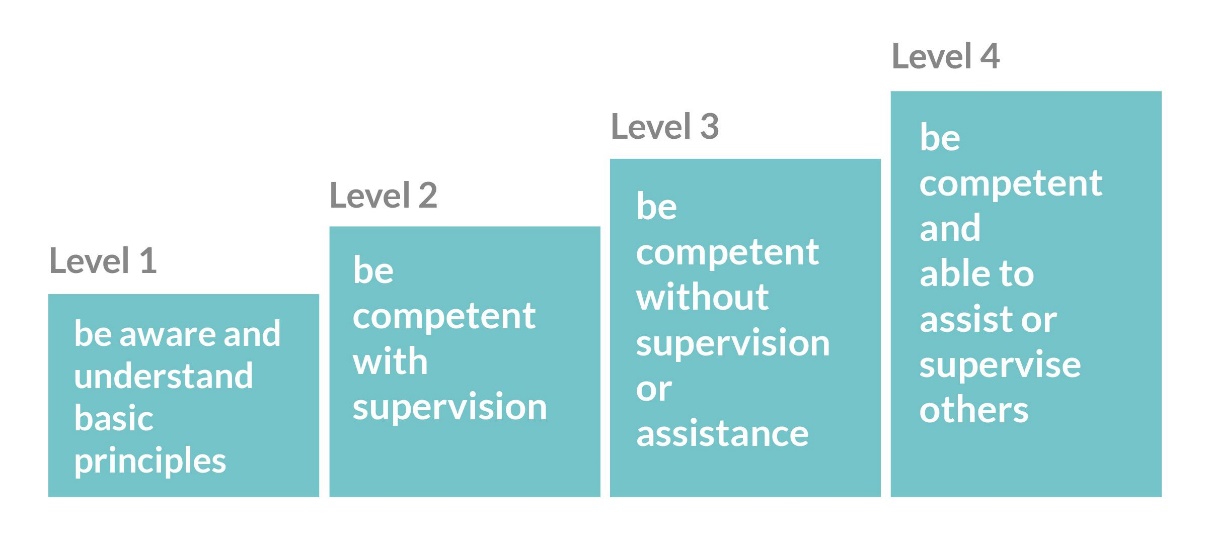
Please see below the competencies and the descriptions to be assessed in this framework.

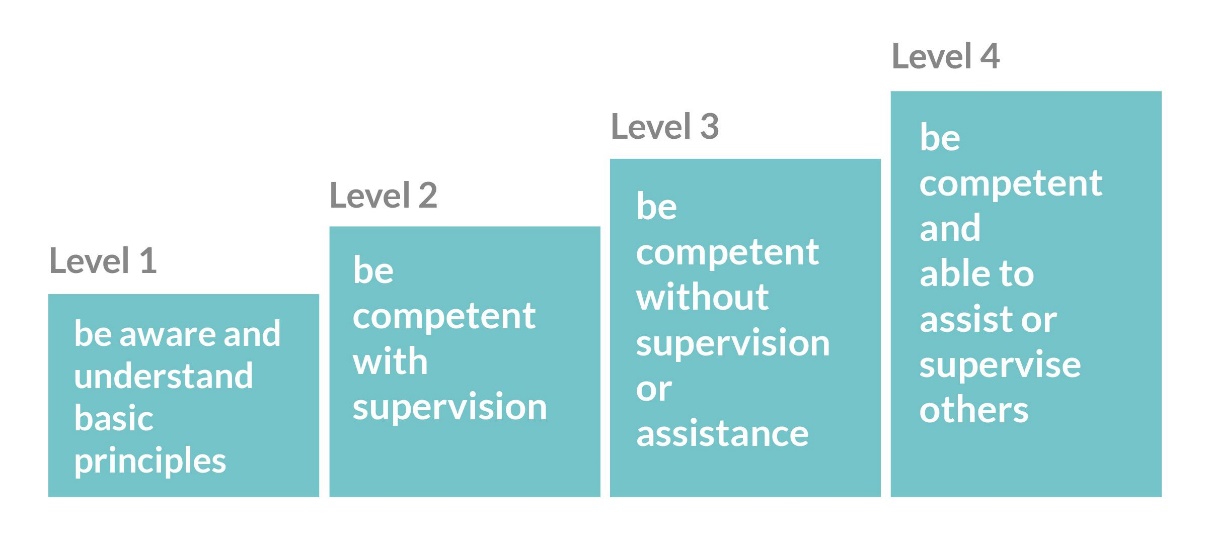
**Table.** Theme, competencies and description for the CLCH Research Competency Framework.

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| **Theme** | **Competency** | **Description** |
| **1 - Background to clinical research** | 1A – Guidance and Legislation | Demonstrate an understanding of the background and scope of the regulatory frameworks governing clinical research. |
| 1B – Research in the NHS | Demonstrate an awareness of the background, political influence, and strategy regarding clinical research in the NHS.  Discuss clinical research delivery aspects in the CLCH. |
| 1C – Study design | Demonstrate an understanding of the design and development of different types of clinical research studies and its feasibility to community setting. |
| **2 - Study Set-up** | 2A – Study feasibility and Set-up | Demonstrate an understanding how studies and sites are assessed for feasibility and how they contribute to the site-set up. |
| 2B – Study set-up | Identify and discuss the approvals required to conduct research in the NHS. |
| **3 – Study Conduct** | 3A – Key Personnel | Demonstrate an awareness of the roles and responsibilities of key personnel involved in clinical research. |
| 3B – Administration & Supplies | Recognise the importance of efficient research administrative tasks including the management of study supplies. |
| 3C – Consent | Demonstrate an understanding of valid informed consent in clinical research with different communities and acknowledge this is an ongoing process. |
| 3D – Protocol specific | Demonstrate an understanding of study-specific protocol requirements. |
| 3E – Managing profiles | Identify and prioritise tasks within studies. |
| **4 – Data management** | 4A – Data Protection | Apply the principles of data protection and secure handling of data. |
| 4B – Essential documents | Identify and appropriately utilise essential documents in the conduct of research studies. |
| 4C – Data & CRF Completion | Demonstrate accurate data capture and case report form (CRF) completing including timely submission of data. |
| 4D – Data Quality | Manage data queries and demonstrate an understanding of the role of monitoring, auditing and inspection in the maintenance of data quality. |
| 4E – Safety reporting | Demonstrate an understanding of the principles and process of Adverse Event reposting (AEs, SAEs and SUSARs). |
| 4F – Storage & Archiving | Apply the principles of secure storage and retention of data/study documentation. |
| **5 – Doing research in the community** | 5A – Clinical community research | Demonstrate an understanding of community needs and apply the clinical research principles to the community care setting. |

**Assessment Levels**

Each competency is presented with examples of the knowledge, skills and behaviours that will be required for competent performance, and examples of how competence may be demonstrated based on a detailed review of research roles and responsibilities. However, these are by no means exhaustive and should be used as a guide rather than a mandate.





**How to evidence the competency levels and the mentorship?**

You will be assigned one main mentor and co-mentors if necessary. The mentor and co-mentors should be competent at least Level 4 in the relevant competency they are assessing you. The mentor/co-mentor should be trained at the university level.

The mentee can have one primary mentor and co-mentors; however, they need to be overseen by a member from the CLCH Research and Development team. The primary mentor may not be able to assess some competencies (e.g., phlebotomy / ECG / laboratory skills); they will look for co-mentors/training resources external to the team to provide the mentorship for the skill.

The mentee and the mentor will discuss the competencies and provide the assessment level together. The assessment should include the following to evidence reached level:

* Valid training/qualification certificates
* Accreditations
* Scored/answered questionnaires and interviews
* Previous completed competency frameworks
* Reflections through performance
* Observations from assessor (mentee being shadowed)
* Written feedback from senior staff, colleagues, patients and research participants
* Educational/research promotion materials created by the mentee
* Evidence that shows relevant knowledge and practice

The NIHR recommends the evidence to be used in the assessment should be **Valid & Relevant** to the competency being assessed, **Sufficient** to demonstrate constant achievement, **Authentic** to the mentee’s experience and **Current** to demonstrate the mentee is maintaining the skills up to date.

**The time frame and the schedule for the assessments**

The mentee can start the framework assessment at any career stage, independent of exposition to research practice.

The NIHR Competency Framework recommends that the assessment schedule should take up to 12 months to complete, with the mentee going through different learning and development assessments.

We recognise that some competencies can be developed in a shorter time, others in a longer time, depending on opportunities that the mentee will have to achieve the desired level. Considering this, the CLCH R&D Research Delivery Competency Framework proposes that the time and the schedule of the mentee’s learning and development should be agreed upon between the mentee and mentors, considering the available opportunities and tailoring the learning plans to the mentee's working and learning context.

Regular 1:2:1 sessions and appraisals with line managers can support this tailored approach, providing personalised feedback and goal setting. Additionally, it is considered beneficial to conduct level assessments every three to six months to ensure progress is tracked and areas for improvement are identified in a timely manner.

CLCH Competency Framework Matrix

Use this matrix to update your achieved levels after completing the assessment with your mentor(s).

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| **Assessment** | | |
| **Theme** | **Competency** | **Baseline** | **Follow-up 1** | **Follow-up 2** |
| **1 - Background to clinical research** | 1A – Guidance and Legislation | Level:  Date: | Level:  Date: | Level:  Date: |
| 1B – Research in the NHS | Level:  Date: | Level:  Date: | Level:  Date: |
| 1C – Study design | Level:  Date: | Level:  Date: | Level:  Date: |
| **2 - Study Set-up** | 2A – Study feasibility and Set-up | Level:  Date: | Level:  Date: | Level:  Date: |
| 2B – Study set-up | Level:  Date: | Level:  Date: | Level:  Date: |
| **3 – Study Conduct** | 3A – Key Personnel | Level:  Date: | Level:  Date: | Level:  Date: |
| 3B – Administration & Supplies | Level:  Date: | Level:  Date: | Level:  Date: |
| 3C – Consent | Level:  Date: | Level:  Date: | Level:  Date: |
| 3D – Protocol specific | Level:  Date: | Level:  Date: | Level:  Date: |
| 3E – Managing profiles | Level:  Date: | Level:  Date: | Level:  Date: |
| **4 – Data management** | 4A – Data Protection | Level:  Date: | Level:  Date: | Level:  Date: |
| 4B – Essential documents | Level:  Date: | Level:  Date: | Level:  Date: |
| 4C – Data & CRF Completion | Level:  Date: | Level:  Date: | Level:  Date: |
| 4D – Data Quality | Level:  Date: | Level:  Date: | Level:  Date: |
| 4E – Safety reporting | Level:  Date: | Level:  Date: | Level:  Date: |
| 4F – Storage & Archiving | Level:  Date: | Level:  Date: | Level:  Date: |
| **5 – Doing research in the community** | 5A – Clinical community research | Level:  Date: | Level:  Date: | Level:  Date: |

Foundations of clinical research: **Competency 1A** – Guidance and Legislation

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| **Knowledge** | | | | |
| Development of research ethics and governance related to clinical research principles of:   * [Declaration of Helsinki](https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/) * [Nuremberg Code](https://www.cirp.org/library/ethics/nuremberg/) * [International Conference of Harmonisation Good Clinical Practice (ICH GCP)](http://ichgcp.net/) * [UK Policy Framework for Health and Social Care Research](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/) * [The Future of Clinical Research Delivery: 2022 to 2025 implementation plan](https://www.gov.uk/government/publications/the-future-of-uk-clinical-research-delivery-2022-to-2025-implementation-plan/the-future-of-clinical-research-delivery-2022-to-2025-implementation-plan)   **Trainings:**   * [NIHR ICH GCP Certificate](https://www.nihr.ac.uk/career-development/clinical-research-courses-and-support/good-clinical-practice) | | | Relevant UK legislation:   * [Medicines for Human Use (Clinical Trials) Regulations 2004](http://www.legislation.gov.uk/uksi/2004/1031/contents/made) (SI 2004/1031) and [Amendment Regulations](http://www.legislation.gov.uk/uksi/2017/715/contents/made) 2017/No.715 * [Human Tissue Act](https://www.legislation.gov.uk/ukpga/2004/30/contents) * [Mental Capacity Act](https://www.legislation.gov.uk/ukpga/2005/9/contents) * [Role of MHRA in the regulation of CTIMP and medical devices research](https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about) * [Serious breaches](http://www.ct-toolkit.ac.uk/routemap/gcp-and-serious-breach-reporting/) in GCP; procedures when breaches of protocol are identified or when fraud/misconduct is suspected | |
| **Skills and Behaviours** | | | | |
| ● Completes GCP training and maintains GCP knowledge as per UK Law and Trust/Organisation policy  ● Applies the principles of GCP to everyday tasks and practices  ● Demonstrates knowledge in the background of clinical research (and clinical community research) and identifies the relevance of the regulatory frameworks that govern its conduct | | | | |
| **Examples of how competence may be demonstrated** | | | | |
| **Level 1**  [Complete Introduction to GCP course](https://www.nihr.ac.uk/career-development/clinical-research-courses-and-support/good-clinical-practice) (Certificate  of Attendance)  Identifies how the  principles of GCP are implemented using an everyday example | **Level 2**  Discusses how the  principles of GCP are implemented using everyday examples of  their working practices  Recognises their own limitations and attends/  completes relevant training | **Level 3**  Demonstrates a  comprehensive understanding of the  regulatory and legal  frameworks related to the planning, delivery and closure of clinical research studies  Demonstrates awareness of clinical community research  Recognises their own limitations and attends/  completes relevant training and is supportive in the training of others | | **Level 4**  Demonstrates leadership by:  - Providing comprehensive advice and guidance, tailoring to clinical community research  - Ensuring processes,  policies and standard operating procedures are in place to support compliance with regulatory requirements |

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| **Assessment**  *State evidence provided/seen, reflections and discussions, competency level achieved (1, 2, 3 or 4) and the learning and development plan for each assessment and re-assessment. If re-assessment is being taken to confirm the current level or progression to the next level, use a different page.* | |
| Baseline  Reflections and discussions:        Action and development plan(s): | |
| Follow-up 1  Reflections and discussions:              Action and development plan(s): | |
| Follow-up 2  Reflections and discussions:            Action and development plan(s):            *To continue, use a separate sheet.* | |
| **Mentee name:** | **Mentor/Co-mentor name:** |
| **Mentee signature:** | **Mentor/Co-mentor signature:** |
| **Date:** | **Date:** |

Foundations of clinical research: **Competency 1B** – Research in the NHS and in CLCH

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| **Knowledge** | | | |
| Political and strategic developments in clinical research:   * [NHS England: Maximising the benefits of research](https://www.england.nhs.uk/long-read/maximising-the-benefits-of-research/) * [Embedding research in the NHS](https://www.england.nhs.uk/aac/what-we-do/embedding-research-in-the-nhs/) * [Role of NIHR Research Delivery Networks](https://www.nihr.ac.uk/explore-nihr/support/clinical-research-network.htm) (RDN) * [NIHR North London Regional Research Delivery Network (RRDN)](https://rdn.nihr.ac.uk/region/north-london) * CLCH Research & Development   Research in the local NHS trust(s): [NIHR RDN portfolio](https://www.nihr.ac.uk/researchers/collaborations-services-and-support-for-your-research/run-your-study/crn-portfolio.htm) and non-NIHR portfolio research | | | |
| **Skills and Behaviours** | | | |
| * Aware of studies, and type of studies, taking place in their own Community Service/Department/CLCH * Aware of the Research Delivery Network (RDN) in which they work and the Network’s role in supporting research in their Trust/Organisation * Aware of the Research & Development (R&D) department and their role in supporting research at CLCH * Understands the relevance of historical development of clinical research to current research and policy | | | |
| **Examples of how competence may be demonstrated** | | | |
| **Level 1**  Aware that research is important to improve care  Aware that research is embedded in the NHS  Identifies how the principles of GCP are implemented using an everyday example | **Level 2**  Demonstrates  awareness of studies  in their own team/  department & wider  specialty area/CLCH  Discusses their individual contribution to delivering research | **Level 3**  Aware of the  research networks in  which they work and  can explain the network’s role in supporting research at CLCH  Aware of the  R&D department in supporting community clinical research  Demonstrates an understanding of the  historical and political  context in which clinical  research is being undertaken | **Level 4**  Demonstrates  leadership by:  - providing  comprehensive  information to support understanding of the  political context and  strategic developments  which influence research in the community care  - championing the role  of clinical research in  the development of  health and social care  - supporting and  influencing the  embedding of clinical  research in local NHS infrastructure/practice |

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| **Assessment**  *State evidence provided/seen, reflections and discussions, competency level achieved (1, 2, 3 or 4) and the learning and development plan for each assessment and re-assessment. If re-assessment is being taken to confirm the current level or progression to the next level, use a different page.* | |
| Baseline  Reflections and discussions:        Action and development plan(s): | |
| Follow-up 1  Reflections and discussions:              Action and development plan(s): | |
| Follow-up 2  Reflections and discussions:            Action and development plan(s):            *To continue, use a separate sheet.* | |
| **Mentee name:** | **Mentor/Co-mentor name:** |
| **Mentee signature:** | **Mentor/Co-mentor signature:** |
| **Date:** | **Date:** |

Foundations of clinical research: **Competency 1C** – Study design

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| **Knowledge** | | | | |
| * Clinical research process * [CLCH Research Process Toolkit](https://hub.clch.nhs.uk/section/Training-Learning-and-Development/pageResearch-process-Toolkit/_9ioOE) * [Common acronyms used in clinical research](https://www.nihr.ac.uk/glossary/) * [Phases of clinical research Preclinical, Phase I, II, III, IV](https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/what-clinical-trials-are/phases-of-clinical-trials) * Research study design including: **protocol design and development, sample size, inclusion and exclusion criteria, randomisation, blinding and unblinding** * [NIHR Clinical Trials Guide](https://www.nihr.ac.uk/clinical-trials-guide) | | | Clinical Trial Involving a Medicinal Product (CTIMP), Advanced Therapy Medicinal Product (ATMP) and Medical Device studies; pharmaceutical industry sponsored clinical trials drug discovery process and licensing of medicines in the UK and beyond   * Multi-centre studies * Qualitative and quantitative research * [Role and relevance of patient and public involvement in all stages of research process](https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/) | |
| **Skills and Behaviours** | | | | |
| * Identifies the research design and methodology used for trials/studies within the research team seeks opportunities to understand the relevance of the design methodology to their role & the wider research team | | | | |
| **Examples of how competence may be demonstrated** | | | | |
| **Level 1**  Explains the study that they support  Identifies the type, category and  phase of a study which they support (e.g. CTIMP/non-CTIMP/ATMP/Medical device/Phase I/II/III etc) and can explain how they know this and why it is relevant to know | **Level 2**  Discusses the design of a study that they  support (e.g. ‘double-blind’,  ‘randomised’, ‘placebo controlled’) and can explain what these terms mean | **Level 3**  Discusses different research designs and  methodologies,  explaining their relevance/implications  for members of the  research team  Demonstrates awareness of research designs and methodologies relevant and suitable to community care. | | **Level 4**  Has a comprehensive  understanding of the  research designs and  methodologies used in research and community care specific  Demonstrates  leadership by:  - providing  comprehensive  advice & guidance for  staff, researchers, patient, public  & participants  - contributing to  protocol design & review |

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| **Assessment**  *State evidence provided/seen, reflections and discussions, competency level achieved (1, 2, 3 or 4) and the learning and development plan for each assessment and re-assessment. If re-assessment is being taken to confirm the current level or progression to the next level, use a different page.* | |
| Baseline  Reflections and discussions:        Action and development plan(s): | |
| Follow-up 1  Reflections and discussions:              Action and development plan(s): | |
| Follow-up 2  Reflections and discussions:            Action and development plan(s):            *To continue, use a separate sheet.* | |
| **Mentee name:** | **Mentor/Co-mentor name:** |
| **Mentee signature:** | **Mentor/Co-mentor signature:** |
| **Date:** | **Date:** |

Study Set-up: **Competency 2A** – Study feasibility & Set-up

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| **Knowledge** | | | | |
| * Feasibility process * CLCH Research feasibility assessment * [Costing and funding research](https://www.nihr.ac.uk/research-funding/application-support/costing-research) * Site preparation including [Site Initiation Visits (SIV)](https://crnemwfd.nihr.ac.uk/pathways/commercial-studies-pathway/site-initiation-visit-siv) * Processes for participant recruitment | | | * Pathway planning * Risk assessment & feasibility * [Indemnity, financial & contractual agreements](https://www.myresearchproject.org.uk/help/hlptemplatesfor.aspx)   **Trainings:**  [Site File Management](https://learn.nihr.ac.uk/enrol/index.php?id=731) | |
| **Skills and Behaviours** | | | | |
| * Recognises the importance of planning prior to a study opening * Identifies opportunities to observe and later contribute to feasibility assessments * Understands related documents (e.g. local feasibility review, expression of interest forms) * Identifies patients for pre-screening/database searches * Attends MDT and/or clinical meetings and/or meetings with PIs/research staff * Liaises with R&D/support services to arrange set-up meetings (e.g. site initiation visits) | | | | |
| **Examples of how competence may be demonstrated** | | | | |
| **Level 1**  Obtains documents  for study set-up and stores them accordingly with local policies  Assists in the  organisation and  attends site initiation visits (SIV) or meets with  PIs/research staff to  discuss study set-up  Assists in the set-up of [site files](https://learn.nihr.ac.uk/course/view.php?id=731) compliant with research governance and GCP  requirements  Observes feasibility | **Level 2**  Assists in the  organisation of trial  documentation for  study set-up  Advises on/establishes trial [site files](https://learn.nihr.ac.uk/course/view.php?id=731) compliant with research governance and GCP requirements  Participates in  feasibility assessments/  meetings  Identifies research activities in different cost categories  Plans, facilitates and coordinates site initiation visit (SIV) | **Level 3**  Utilises patient pathway planning to assess study feasibility and identify study specific processes for recruitment/plan study schedule  Identifies relevant training for members of the CLCH research team in relation to the requirements of a new study protocol  Identifies and quantifies unmet NHS support costs  Identifies unplanned costs for the CLCH services  Evaluate the need and process Letter of Access | | **Level 4**  Undertakes risk and  feasibility assessments  Demonstrates leadership by:  - acting as a knowledge resource for staff &  researchers involved in assessing feasibility &  setting-up new studies - contributing to the supervision and education of staff involved in site set-up  - liaising with sponsor representatives and  responding to feedback regarding feasibility and/ or set-up |

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| **Assessment**  *State evidence provided/seen, reflections and discussions, competency level achieved (1, 2, 3 or 4) and the learning and development plan for each assessment and re-assessment. If re-assessment is being taken to confirm the current level or progression to the next level, use a different page.* | |
| Baseline  Reflections and discussions:        Action and development plan(s): | |
| Follow-up 1  Reflections and discussions:              Action and development plan(s): | |
| Follow-up 2  Reflections and discussions:            Action and development plan(s):            *To continue, use a separate sheet.* | |
| **Mentee name:** | **Mentor/Co-mentor name:** |
| **Mentee signature:** | **Mentor/Co-mentor signature:** |
| **Date:** | **Date:** |

Study Set-up: **Competency 2B** – Study Set-up

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| **Knowledge** | | | | |
| * Role and responsibilities of the [Health Research Authority (HRA)](https://www.hra.nhs.uk/about-us/what-we-do/) , including [Research Ethics Service (RES)](https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/research-ethics-service/) and [Research Ethics Committees (RECs)](https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/flagged-research-ethics-committees/) * Role and responsibilities of CLCH R&D department in assessing, arranging and confirming capacity and capability (CCC) to deliver research projects * Process of applying for an assessment of governance and legal compliance and independent ethical opinion (e.g. [HRA](https://www.hra.nhs.uk/), [REC](https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/research-ethics-committees-overview/), R&D, [MHRA/ Confidentiality Advisory Group](https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/confidentiality-advisory-group/) / [HerMajesty’s Prison and Probation Service](https://www.gov.uk/government/organisations/hm-prison-service) ) | | | * Key [documentation](https://www.hra.nhs.uk/planning-and-improving-research/research-planning/prepare-study-documentation/) required for HRA Approval * National policies & procedures related to [HRA approval](https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/hra-approval/) including the assessment criteria and standards for UK study wide governance * Regulatory requirements for [protocol](https://www.hra.nhs.uk/approvals-amendments/amending-approval/)   [amendments](https://www.hra.nhs.uk/approvals-amendments/amending-approval/) (substantial and non-substantial) termination and/or closure of a trial   * Regulatory reporting procedures when breaches of protocol are identified or when fraud/misconduct is suspected | |
| **Skills and Behaviours** | | | | |
| * Recognises the need to ensure that [HRA approval](https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/hra-approval/) , which may include appropriate and proportionate ethical opinion, is obtained before any research activities are undertaken in the NHS * Understands/utilises systems to apply for [HRA approval](https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/hra-approval/) / [REC](https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/research-ethics-committees-overview/) favourable opinion and other regulatory approvals (e.g. [IRAS](https://www.myresearchproject.org.uk/) ) * Assists with the acquisition/distribution/tracking of relevant trial documentation required for study set-up * Recognises the importance of clear, complete and accurate applications to the [HRA](https://www.hra.nhs.uk/) and is able to advise on this | | | | |
| **Examples of how competence may be demonstrated** | | | | |
| **Level 1**  Identifies the regulatory approvals that have been obtained/or need to be obtained for studies which they currently support | **Level 2**  Explains the process for gaining approval to  conduct clinical research identifies the specific  regulatory approvals  required for a new study and explains the  processes by which  these are obtained | **Level 3**  Demonstrates familiarity with regulatory requirements of CTIMP/ non-CTIMP/ATMP and Medical Device studies & approval processes  - Advises on/actively  contributes to the  preparation of applications for [HRA](https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/hra-approval/)  [approval](https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/hra-approval/)  - Discusses the [role &](https://www.hra.nhs.uk/about-us/what-we-do/)  [remit of HRA in England](https://www.hra.nhs.uk/about-us/what-we-do/) | | **Level 4**  Demonstrates leadership by:  - as a knowledgeable  resource for staff and  researchers making  applications for  regulatory approvals  - contributing to the  supervision and  educational needs of  staff involved in the  preparation of regulatory applications |

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| **Assessment**  *State evidence provided/seen, reflections and discussions, competency level achieved (1, 2, 3 or 4) and the learning and development plan for each assessment and re-assessment. If re-assessment is being taken to confirm the current level or progression to the next level, use a different page.* | |
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| Follow-up 2  Reflections and discussions:            Action and development plan(s):            *To continue, use a separate sheet.* | |
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| **Mentee signature:** | **Mentor/Co-mentor signature:** |
| **Date:** | **Date:** |

Study conduct: **Competency 3A** – Key Personnel

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| **Knowledge** | | | |
| * [Role and responsibilities](https://www.hra.nhs.uk/planning-and-improving-research/research-planning/roles-and-responsibilities/) of Sponsor and [Chief Investigator (CI)](https://www.hra.nhs.uk/planning-and-improving-research/research-planning/roles-and-responsibilities/mhra-and-hra-position-who-can-act-chief-investigator/) * Site staff & their responsibilities including [Principal Investigator (PI)](https://www.hra.nhs.uk/planning-and-improving-research/research-planning/roles-and-responsibilities/) , research delivery staff & research participants * Delegation of duties log and documentation of this process * The role and remit of sponsor delegates: Contract Research Organisations (CRO); [Clinical Trials Units (CTU)](https://www.ukcrc.org/research-infrastructure/clinical-trials-units/) * Trial Management, Trial Steering Groups, Data Monitoring and Safety Committees | | | |
| **Skills and Behaviours** | | | |
| * Contributes to the delivery of clinical research protocols as a member of the research team * Identifies and consistently works within the scope of their own role and delegates duties * Aware of the limitations of their own role and seeks help and support appropriately * Maintains up-to-date delegation of duties log, records, CVs and training * Establishes and maintains effective working relationships with relevant individuals and organisations * Actively contributes to research team meetings | | | |
| **Examples of how competence may be demonstrated** | | | |
| **Level 1**  Completes the  Delegation of duties log for a new trial and  Demonstrates understanding of  delegated duties  Consistently seeks  help and support from  members of the research team  Can identify key  personnel within the  clinical research team  Attends relevant training in relation to  the requirements of the study protocol | **Level 2**  Able to differentiate between the roles and  delegated duties of key  personnel within the  clinical research team  Articulates their own responsibilities and  recognises the boundary of their own role and when to refer to others  Consistently works within the scope of their own role and delegated duties; seeks help from appropriate members  of the team  Identify relevant training for the requirements of the study protocol | **Level 3**  Consistently works within the scope of their own role and delegated duties  Promotes team working  Demonstrates a  comprehensive  understanding of the  roles and responsibilities  of key personnel within  the clinical research  environment  Establishes and  maintains effective working relations with  relevant individuals and  organisations | **Level 4**  Ensures comprehensive induction is provided for all new staff  Demonstrates  leadership by:  - contributing to the  development and  training of colleagues  - efficient and effective  networking  - proactively monitoring  and dealing with  issues appropriately |

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| **Assessment**  *State evidence provided/seen, reflections and discussions, competency level achieved (1, 2, 3 or 4) and the learning and development plan for each assessment and re-assessment. If re-assessment is being taken to confirm the current level or progression to the next level, use a different page.* | |
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| **Mentee signature:** | **Mentor/Co-mentor signature:** |
| **Date:** | **Date:** |

Study conduct: **Competency 3B** – Administration & Supplies

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| **Knowledge** | | | |
| * Ordering and maintaining study supplies (e.g. case report forms (CRFs), questionnaires, sample kits) * Administrative skills: managing telephone enquiries/photocopying/scanning/filing * Acquisition and return of clinical records (e.g. medical records –SystemOne, EMIS, Lilie IDOX), includes access and appropriate permissions to Electronic Patient Records (EPR’s) in line with GDPR * In-house documentation systems * Sponsor documentation systems | | | |
| **Skills and Behaviours** | | | |
| * Maintains sufficient stocks of documentation and equipment, understanding the community service aspect (researching at people’s home, health centres, community hospitals, etc) * Manages telephone enquiries including timely and appropriate referral and documentation * Demonstrates proficiency with ICT applications: Microsoft Office, [Edge](https://www.edge.nhs.uk/), NIHR sytems, relevant internal systems * Maintains effective communication using a variety of media including telephone, email, face to face meetings etc * Actively manages day to day queries – liaising with team members and documents these appropriately | | | |
| **Examples of how competence may be demonstrated** | | | |
| **Level 1**  Consistently seeks appropriate support/  referral to manage email and telephone enquiries  Completes administrative tasks efficiently  Organises research documentation in  clinical records/EPR’s  Completes accurate documentation  associated with research study supplies | **Level 2**  Establishes and/or  maintains in-house and  sponsor documentation systems  Orders supplies and  ensures they are available when required  Ensures clear and  accurate documentation  is maintained on the  arrival, use and disposal of research study  supplies  Establishes and/or  maintains accurate contacts | **Level 3**  Contributes to the  effective and efficient  use of resources, specialising in the community research aspect  Proactively manages study supplies and ensures that necessary staff and facilities and equipment (valid service contract checks) are available (e.g. clinic room) for the effective conduct of the study  Consistently manages day to day queries and liaises appropriately to ensure their effective resolution | **Level 4**  Demonstrates  leadership by:  1) Managing a research team with attention to  skill mix  2) Being aware of the  financial constraints  of the funding available for a clinical research study  3) Management of equipment and service contracts (freezers, centrifuges, ECG’s etc) |

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| **Assessment**  *State evidence provided/seen, reflections and discussions, competency level achieved (1, 2, 3 or 4) and the learning and development plan for each assessment and re-assessment. If re-assessment is being taken to confirm the current level or progression to the next level, use a different page.* | |
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| **Mentee signature:** | **Mentor/Co-mentor signature:** |
| **Date:** | **Date:** |

Study conduct: **Competency 3C** – Consent

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| **Knowledge** | | | |
| * Principles of informed consent for participation in research – legal and governance requirements * Information and key components of [patient information sheets (PIS)](https://www.hra-decisiontools.org.uk/consent/content-sheet.html) and [informed consent forms (ICF)](https://www.hra-decisiontools.org.uk/consent/content-form.html) * Preparation of PIS and informed consent forms for local use (version control, Trust ‘headed paper’ etc) * Study specific documentation – what signatures are required; copies – how many and to whom; documenting the process of informed consent * Storage of the signed informed consent form * Team roles and responsibilities in gaining and maintaining informed consent * The need to reaffirm willingness to continue throughout the study   **Training**  [Informed consent courses:](https://learn.nihr.ac.uk/course/view.php?id=1238) with different communities, children, including adults lacking capacity and remote consent | | | |
| **Skills and Behaviours** | | | |
| * Recognises the need to ensure that informed consent has been obtained and maintained; proactively seeks information to support this before undertaking study-related activities * Prepares/tracks patient information sheets (PIS) and informed consent forms with attention to version control * Assures patient safety by recognising and raising any concerns with the informed consent process * Understands and administers capacity assessments as appropriate (formal and informal) * Attends and maintains valid informed consent training as per CLCH Research Governance Policy | | | |
| **Examples of how competence may be demonstrated** | | | |
| **Level 1**  Complete Informed Consent [training](https://learn.nihr.ac.uk/course/view.php?id=1238)  Acknowledges the  need for consent in  clinical research  Identifies evidence of  the consent process in  source data | **Level 2**  Provides a brief overview of the consent process  for a specified study and  can explain who can be involved & how informed consent is documented  Can describe their role in the process of obtaining informed consent  Proactively seeks documentation to  confirm informed consent has been provided by the  participant  Identifies errors/  concerns in documents | **Level 3**  Clearly articulates their role and the roles of other team members in the informed consent process; fulfils but does not exceed their delegated duties  Reports any concerns with informed consent processes in a timely & appropriate manner; can cite examples from practice  Can identify immediate action to be taken  Applies capacity assessment process on  each study contact | **Level 4**  Demonstrates  leadership by:  - acting as a knowledgeable  resource and role model for staff and researchers regarding the contribution of research delivery staff to the informed consent process  - being recognised as  a staff support for valid informed consent issues |

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| **Assessment**  *State evidence provided/seen, reflections and discussions, competency level achieved (1, 2, 3 or 4) and the learning and development plan for each assessment and re-assessment. If re-assessment is being taken to confirm the current level or progression to the next level, use a different page.* | |
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| **Mentee signature:** | **Mentor/Co-mentor signature:** |
| **Date:** | **Date:** |

Study conduct: **Competency 3D** – Protocol Specific

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| **Knowledge** | | | | |
| * [Protocol](https://www.myresearchproject.org.uk/help/hlptemplatesfor.aspx#Protocol) – main sections; extracting information / study specific requirements; eligibility criteria & schedule of events * Randomisation process * Awareness of patient pathway planning * Screening and eligibility * Safe handling of samples, including storage as per protocol ([Human Tissues Act](https://www.legislation.gov.uk/ukpga/2004/30/contents)) * Ordering couriers, packaging and shipment of samples (handling of dry ice if applicable) as per protocol * Processes for participant recruitment – screening, randomisation and patient pathway * Equipment and supplies including investigational medicinal product   **Trainings:**  [Protocol design](https://learn.nihr.ac.uk/course/view.php?id=985) | | | | |
| **Skills and Behaviours** | | | | |
| * Understands the rationale behind adherence to ethically approved study protocols * Verifies inclusion/exclusion criteria of subjects recruited into trials and ensures that all relevant baseline data has been recorded * Randomises/registers patients to trials according to the protocol requirements * Assists in ensuring protocol-required tests/procedures are completed according to the protocol schedule | | * Liaises with support services to book tests/procedures * Plans study visits/follow-up schedules * Identifies protocol schedule of events * Develops checklists/workbooks/flowcharts * Arranges couriering of samples * Articulates study protocol procedures with community service demands | | |
| **Examples of how competence may be demonstrated** | | | | |
| **Level 1**  Explain the duties to be delegated and the purpose of the research study  Demonstrates an  awareness of the  eligibility criteria of a  protocol(s)  Lists content sections  of chosen protocol(s)  Understands superseded protocol and related documents processing and archiving | **Level 2**  Demonstrates  effective use of  protocols by referring to  appropriate sections as  required  Aware of how to raise  concerns and report  instances of suspected  protocol deviation  Plans and implements  a recruitment strategy  to ensure recruitment  adheres to time and  target | | **Level 3**  Ensure the team adheres to study protocol  Plans patient pathway  for trial identifying  service and resource challenges  Contributes to the  development of policies  and standard operating  procedures (SOPs) to  support adherence to  protocols  Identify/action protocol deviation or violation | **Level 4**  Demonstrates  leadership by:  - providing  comprehensive  guidance and  contributing to the  training and development  of colleagues  - effective networking  across clinical  departments  - corrective action  planning for any  deviations or violation |

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| **Assessment**  *State evidence provided/seen, reflections and discussions, competency level achieved (1, 2, 3 or 4) and the learning and development plan for each assessment and re-assessment. If re-assessment is being taken to confirm the current level or progression to the next level, use a different page.* | |
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Study conduct: **Competency 3E** – Managing Profiles

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| **Knowledge** | | | |
| * Prioritising work * Planning workload * Time management * Reviewing & reassessing priorities & workload * Implications of tasks on study timelines & workload | | | |
| **Skills and Behaviours** | | | |
| * Identifies workload priorities * Plans workload * Identifies and alerts team members to expected delays or competing priorities * Identifies skills required to complete a task successfully * Undertakes appropriate delegation of study responsibilities | | | |
| **Examples of how competence may be demonstrated** | | | |
| **Level 1**  Undertakes identified  tasks/activities within  predefined time frames (requires assistance to  define priorities and  time frame) | **Level 2**  Plans work and  identifies priorities  Seeks support and assistance appropriately to meet  deadlines  Anticipates workload  (e.g. monthly/recurring  tasks)  Aware of the need to  have a recruitment  strategy | **Level 3**  Responds flexibly to  changes in workload/priorities  Recognises changing  demands and can  respond efficiently  Delegates appropriately  Aware of the need to  have a recruitment  strategy and why this  should be amended | **Level 4**  Demonstrates  leadership by:  - providing  comprehensive advice  and guidance  - delegating tasks  appropriately and  providing constructive  feedback  - proactively working  with the research team; taking action when the recruitment strategy is not effective |

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| **Assessment**  *State evidence provided/seen, reflections and discussions, competency level achieved (1, 2, 3 or 4) and the learning and development plan for each assessment and re-assessment. If re-assessment is being taken to confirm the current level or progression to the next level, use a different page.* | |
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Data management: **Competency 4A** – Data Protection

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| **Knowledge** | | | | |
| * Maintaining confidentiality for patients in clinical trials and studies * Actions required when data protection processes are not adhered to * Local and national policies and procedures relating to data collection, storing and secure transfer including: | | | | |
| [Data Protection Act](https://www.legislation.gov.uk/ukpga/1998/29/contents)  [Confidentiality NHS Code of Practice](https://www.gov.uk/government/publications/confidentiality-nhs-code-of-practice)  [Caldicott report](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1769982/) and local Caldicott guardian | | | [Freedom of Information](https://www.legislation.gov.uk/ukpga/2000/36/contents)  [Human Rights Act](https://www.legislation.gov.uk/ukpga/1998/42/contents)  Information Governance  GDPR (Refer to section 4A, [Induction Manual](https://docs.google.com/document/d/1vGQlC6SI0boZfuUqR590puNIjGh-Oz_ISQ9K73WF7Do/edit)) | |
| **Skills and Behaviours** | | | | |
| * Respects participant confidentiality * Ensures participant confidentiality is maintained * Takes responsibility for the safe and secure storage of data * Recognises poor practice relating to data storage and raises concerns | | | | |
| **Examples of how competence may be demonstrated** | | | | |
| **Level 1**  Understands and  explains own role in  maintaining  confidentiality and  protecting data  Contributes to the safe and secure storage of data by returning documents to storage location after use  Aware of the risks of sharing data as per  protocol | **Level 2**  Identifies and  describes measures  taken to maintain  confidentiality of data  Understands the role of the Information Governance (IG) in research in the Trust | **Level 3**  Consistently adheres  to requirements to  protect confidentiality  and data  Raises concerns  when processes to  ensure confidentiality  are not adhered to  Gather IG approval if needed | | **Level 4**  Demonstrates  leadership by:  - ensuring processes and procedures for maintaining participant  confidentiality are developed and adhered  to by all members of the  research team  -Follows the CLCH Research Governance Policy SOP for the reporting of breaches of participant confidential information  - providing expert  advice on different  methods for transferring  patient identifiable  information |

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Data management: **Competency 4B** – Essential Documents

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| **Knowledge** | | | | |
| * Version control and document tracking * Title, purpose and storage location of essential documents including: | | | | |
| **Source documents**  **Screening logs**  **Participant ID logs**  **Investigator Brochure**  **Regulatory approvals and** [**amendments**](https://www.hra.nhs.uk/approvals-amendments/amending-approval/)  **GCP Certificates /** [**Investigator CV**](https://www.hra.nhs.uk/planning-and-improving-research/best-practice/investigators-cv/)  **File notes Insurance and Indemnity confirmation** | | **Patient information literature**  [**Study Protocol**](https://www.hra.nhs.uk/planning-and-improving-research/research-planning/protocol/)  **Case Report Forms (CRFs)**  **Contracts ([mNCA](https://www.myresearchproject.org.uk/help/help%20documents/mNCA-Guidance_July_2022.pdf), disclosure)**  [**Confirmation of Capacity and Capability (CCC)**](https://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/capacity-capability/)  **Reports and Communications**  [**Delegation of Duties Log**](https://myresearchproject.org.uk/help/help%20documents/Signature_And_Delegation_Log_Template_v1-2.docx) | | |
| **Skills and Behaviours** | | | | |
| * Establishes trial [site files](https://learn.nihr.ac.uk/course/view.php?id=731) that are compliant with research governance and GCP requirements * Maintains and updates essential documents in the site file * Recognises the importance of accurate and comprehensive documentation and source data verification | | | | |
| **Examples of how competence may be demonstrated** | | | | |
| **Level 1**  Identifies and  discusses the purpose  of key research  documents ([site files](https://learn.nihr.ac.uk/course/view.php?id=731) ,  CRFs, investigator  brochure, source data)  Assists in creating  and maintaining research  files according to local  standard operating  procedures (SOPs)  Raises concerns if  incomplete, inaccurate  or misleading  documentation is  Identified  Understands the relation between amendments to the protocol and the CCC | **Level 2**  Describes the  purpose of and  provides examples of  essential documents  Raises concerns if  incomplete, inaccurate  or misleading  documentation is  identified  Demonstrates the use  of correct versions of  documentation and  implements document  tracking according to  local SOPs  Process notification of amendments with the PI and | | **Level 3**  Creates and  maintains research files  according to local  SOPs  Responds to concerns  if inaccurate or incomplete documentation is identified  Successfully implement Amendments to the protocol and | **Level 4**  Demonstrates  leadership by:  - acting as a  knowledgeable resource for staff  - meeting the  supervision and  educational needs of  research staff utilising  essential documents  - ensuring processes,  policies and SOPs are  developed and reviewed to support compliance with regulatory requirements |

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| **Assessment**  *State evidence provided/seen, reflections and discussions, competency level achieved (1, 2, 3 or 4) and the learning and development plan for each assessment and re-assessment. If re-assessment is being taken to confirm the current level or progression to the next level, use a different page.* | |
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| **Date:** | **Date:** |

Data management: **Competency 4C** – Data & CRF Completion

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| **Knowledge** | | | |
| * Data media (paper based/web-based/audio/images etc.) * Accurate completion of CRFs (paper and electronic) * Source document verification * IT systems: Network, Trust and Sponsor specific applications including Microsoft Office, [NIHR Google Hub](http://hub.nihr.ac.uk/) , [Edge](http://www.edge.nhs.uk/) and study exclusive databases * Importance of submission of recruitment figures to relevant bodies including [NIHR recruitment data](https://www.nihr.ac.uk/researchers/collaborations-services-and-support-for-your-research/run-your-study/performance-monitoring.htm) | | | |
| **Skills and Behaviours** | | | |
| * Transcribes/exports data from medical records to CRF (paper and electronic) * Liaises with trial coordinators, research professionals and clinicians to ensure accurate and complete data collection * Identifies and resolves missing data and/or discrepancies in data * Shares findings of audits with the research team to raise awareness and reduce data errors/omissions * Demonstrates proficiency in essential IT skills: store, save and manage electronic files & use Trust/Network based IT systems (e.g. patient records; [Edge](http://www.edge.nhs.uk/) ) as well as sponsor specific applications (e.g. CRFs) * Recognises the importance of accurate and comprehensive documentation and source data verification * Shows attention to detail and accurate data recording | | | |
| **Examples of how competence may be demonstrated** | | | |
| **Level 1**  Evidence of accurate  data entry | **Level 2**  Evidence of  accurate and complete  data entry  Raises concerns  and seeks to address  incomplete, inaccurate or  misleading data entry  Contributes to the  collection and reporting  of local recruitment data | **Level 3**  Undertakes and  manages the accurate  and complete collection  of data, and insertion  of data into case report  forms or other research  storage formats  Responds to concerns if  inaccurate or incomplete  data entry is identified  Manages the collection  and reporting of local  recruitment data | **Level 4**  Demonstrates leadership By:  - Undertaking,  supervising & managing the accurate & complete collection & transcription of data  - disseminating  recruitment data  - strategic planning to  promote effective  recruitment in line with time and target  - ensuring that local  policies and SOPs are  followed by all members of the research team  - contributing to the  development of SOPs  and ongoing updates |

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| **Assessment**  *State evidence provided/seen, reflections and discussions, competency level achieved (1, 2, 3 or 4) and the learning and development plan for each assessment and re-assessment. If re-assessment is being taken to confirm the current level or progression to the next level, use a different page.* | |
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| **Date:** | **Date:** |

Data management: **Competency 4D** – Data Quality

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| **Knowledge** | | | |
| • Monitoring visits and the role of monitor  • Audit and inspections  • Local processes for auditing and monitoring study data  • Data queries  • Protocol deviation/violation  Training: [NIHR Data Quality in Research](https://learn.nihr.ac.uk/enrol/index.php?id=477) | | | |
| **Skills and Behaviours** | | | |
| • Acknowledges the purpose of monitoring visits and responds to recommendations appropriately  • Organises and prepares visits by trial monitors (as per protocol)  • Liaises with Clinical Trials Units/Coordinating Centres regarding data queries  • Checks and resolves data queries  • Conducts quality assurance of documentation and/or audit as necessary  Recognises the importance of accurate and comprehensive documentation and source data verification | | | |
| **Examples of how competence may be demonstrated** | | | |
| **Level 1**  - Prepares  documents and  facilities for  monitoring visits  - Contributes to  the resolution of  data queries | **Level 2**  - Identifies errors and  inconsistencies  between case report  forms (CRFs) and  source data and seeks  to resolve these  - Prepares documents  and facilities for  monitoring visits and  works with the study  monitor during visit  - Responds to data  queries in a timely  manner and seeks to  resolve them  - Responds to  audit/monitoring  recommendations | **Level 3**  - Proactively manages  errors/inconsistencies  between CRFs and  source data to avoid data  queries  - Responds to data  queries in a timely  manner and seeks to  identify patterns/trends  in missing data to prevent  recurrence  - Participate in the  auditing and monitoring  of research studies | **Level 4**  Contributes to auditing & monitoring of research studies and proposes recommendations  Demonstrate leadership by:  - undertaking, supervising & managing the accurate & complete collection/transcription of data  - contributing to the  development of &  ensuring local policies  & SOP followed by all members of team  - proactively monitor the frequency & nature of data queries & seeks  to reduce team data query rates |

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| **Assessment**  *State evidence provided/seen, reflections and discussions, competency level achieved (1, 2, 3 or 4) and the learning and development plan for each assessment and re-assessment. If re-assessment is being taken to confirm the current level or progression to the next level, use a different page.* | |
| Baseline  Reflections and discussions:        Action and development plan(s): | |
| Follow-up 1  Reflections and discussions:              Action and development plan(s): | |
| Follow-up 2  Reflections and discussions:            Action and development plan(s):            *To continue, use a separate sheet.* | |
| **Mentee name:** | **Mentor/Co-mentor name:** |
| **Mentee signature:** | **Mentor/Co-mentor signature:** |
| **Date:** | **Date:** |

Data management: **Competency 4E** – Safety Reporting

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| **Knowledge** | | | |
| * [Definition](https://www.nihr.ac.uk/glossary) of AE/SAE/SUSAR; timelines for reporting to sponsor and host * Preparation of safety reports * Medical terminology and common acronyms   Training: [The Safety Reporting Journey](https://learn.nihr.ac.uk/course/view.php?id=939) | | | |
| **Skills and Behaviours** | | | |
| * Recognises the importance of safety reporting in clinical research * Prepares adverse event forms in liaison with clinical staff and recognises the importance of ensuring the process continues through to completion * Works with the research team to ensure safety reporting timelines are adhered to * Demonstrates effective communication with wider clinical teams | | | |
| **Examples of how competence may be demonstrated** | | | |
| **Level 1**  Completes [The Safety Reporting Journey](https://learn.nihr.ac.uk/course/view.php?id=939) eLearning  Is able to discuss the  link between adverse  event reporting and  patient safety  [Defines](http://www.ct-toolkit.ac.uk/routemap/safety-reporting/) the terms  AEs, SAEs, and  SUSARs and provides  an example of each | **Level 2**  Describes the  difference between  AEs, SAEs, and  SUSARs citing  examples from practice  Consistently takes  appropriate action  (within the scope of  delegated duties) when  an adverse event  occurs or is discovered,  including timely and  appropriate referral  Assists in the  preparation of adverse  event reports | **Level 3**  Identifies and  consistently takes  appropriate action  (within the scope of  delegated duties) when  an adverse event occurs  Prepares initial and  follow-up adverse event  reports in liaison with  clinical staff  Discusses the  principle of unblinding  and explains local/study  specific processes | **Level 4**  Demonstrates a  comprehensive  understanding of safety  reporting requirements  in clinical trials  Demonstrates  leadership by:  - providing  comprehensive  advice and timely  guidance  - contributing to the  supervision and  educational needs of  research staff involved in safety reporting |

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| **Assessment**  *State evidence provided/seen, reflections and discussions, competency level achieved (1, 2, 3 or 4) and the learning and development plan for each assessment and re-assessment. If re-assessment is being taken to confirm the current level or progression to the next level, use a different page.* | |
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| Follow-up 2  Reflections and discussions:            Action and development plan(s):            *To continue, use a separate sheet.* | |
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| **Mentee signature:** | **Mentor/Co-mentor signature:** |
| **Date:** | **Date:** |

Data management: **Competency 4F** – Storage & Archiving

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| **Knowledge** | | | |
| * Filing systems * [Site Master File](https://learn.nihr.ac.uk/course/view.php?id=731) /Essential Documents * Storage of trial Site File, Case Report Forms (CRFs) and Investigator Brochure * Storage of completed informed consent forms * Archiving of data following study closure * Local Trust and Trial Archiving standard operating procedures (SOPs) * Agreed contracts and costs of archiving | | | |
| **Skills and Behaviours** | | | |
| * Ensures secure filing and storage of study documentation in accordance with research governance requirements * Recognises the importance of maintaining secure storage and retention of data | | | |
| **Examples of how competence may be demonstrated** | | | |
| **Level 1**  Watch Archiving a [Research Study](https://learn.nihr.ac.uk/course/view.php?id=921) Video  Maintains in-house  filing systems  Returns files/data to  original storage location  after use | **Level 2**  Contributes to study  closure and preparation  of documents for  archiving | **Level 3**  Plans for the secure  storage of data at the  end of study  Participates in archiving  of studies liaising with  the sponsor and R&D | **Level 4**  Demonstrates  leadership by:  - providing  comprehensive advice  and guidance  - ensuring processes and SOPs are in place and adhered to  - is fully conversant  with how to recall  archived data |

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| **Assessment**  *State evidence provided/seen, reflections and discussions, competency level achieved (1, 2, 3 or 4) and the learning and development plan for each assessment and re-assessment. If re-assessment is being taken to confirm the current level or progression to the next level, use a different page.* | |
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Doing clinical research at the community: **Competency 5A** – Clinical community research

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| **Knowledge** | | | |
| * Understanding communities' health and social needs, building partnerships, and ensuring cultural competence and ethical practices in community research * Managing resources, logistics, and requirements to maintain the research quality and integrity * Understanding the [decentralisation of clinical trials](https://www.nihr.ac.uk/support-and-services/industry/spotlights/decentralised-clinical-trials) and the benefits of technology in terms of utilising remote monitoring, telemedicine, data protection actions to conduct trials effectively * Adopting good laboratory practices, handling samples correctly, and maintaining laboratory systems to uphold the quality and reliability of research data collected in the people’s home, health centres and community hospitals | | | |
| **Skills and Behaviours** | | | |
| * Advocates for [clinical community research](https://www.nihr.ac.uk/support-and-services/industry/spotlights/research-beyond-the-hospital), through actions such as promoting engagement, acknowledging community service needs and population demands, development themselves and the team and seeking actions to improve access to the available opportunities | | | |
| **Examples of how competence may be demonstrated** | | | |
| **Level 1**  Shows awareness of communities' health and social needs by attending training  Shows awareness of different research designs and methods and their suitability to be implemented in community healthcare services  Shows awareness of the safety reporting/management and escalation of the research study conducted in the community  Understands CLCH Lone Working Policy | **Level 2**  Performs study feasibility assessment considering community services structure  Performs screening, gains informed consent and enrols participants recruited in different community environments (e.g. people’s home, [remotely](https://learn.nihr.ac.uk/course/view.php?id=1412))  Successfully collects research data through data capture systems and assesses its suitability to the research environment  Reports and follow-up with concerns on the research protocol logistics | **Level 3**  Demonstrate proficiency in technology to maintain data integrity in research conducted in the community  Successfully engage and collaborate with different service teams and organisations to guarantee clinical research delivery (e.g. patient transport, translation services, non-CLCH research visits)  Assess potential risks (to patients and study integrity) prior study commence  Successfully manages essential research equipment, materials and resources | **Level 4**  Shows leadership by:  -Creating and working collaboratively with partners to resolve issues  -mentoring professionals interested in advance in community clinical research  -induct professionals to best practices in managing samples collected in the community settings |

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| **Assessment**  *State evidence provided/seen, reflections and discussions, competency level achieved (1, 2, 3 or 4) and the learning and development plan for each assessment and re-assessment. If re-assessment is being taken to confirm the current level or progression to the next level, use a different page.* | |
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**NOTES**