**Core Competences**

**For Assistant Practitioners**

**Working in Clinical Research**

Appendix 1

**Learning Contract**

**Department Name: Trust wide Learning Time Scale: 24 months**

**Responsibilities of Learner:**

* Familiarise self with National and Trust guidelines for core units.
* Attend HPD for the completion of the theoretical components of the Assistant Practitioner Role
* Gain an understanding of the legal and ethical implications of the core units
* Acknowledge and accepts own limitations.
* Works within their own sphere of confidence and summons help when required.
* Understand the demands and needs of the service.
* Utilise all resources which are made available for learning and professional development.
* Be able to receive constructive feedback.
* Ensure that all course documentation is fully completed, and returned to LDS for verification and recorded onto ESR.
* Ensure that the agreed timeframe of, two years from commencement of HPD programme, is set with the assessor prior to commencing.

**Responsibilities of Mentor/Assessor:**

* Ensure the learner is working towards or has completed the HPD programme of study.
* Hold either the City & Guilds 730, A1, D32/33 assessors award, mentorship module or hold relevant post registration experience.
* Signpost the learner to relevant research and information to support evidence based practice.
* Facilitate supervised practice.
* Provide constructive feedback.
* Complete competency document as required
* Report unsafe practice
* Clarify with manager optional competences to be completed by TAP and assist with the development of these as required.

**Responsibilities of Department/Ward:**

* That the mentor has the appropriate qualification/occupational competency.
* Ensure time is allocated to learners training.
* Ensure that the department are fully informed of the role of the TAP/AP and competences to be achieved
* Identify optional competences required for the learner to achieve AP status
* Ensure that the department/unit understand the importance and need for the learner to have time for supervised practice & completion of the necessary documentation.
* Understand the implications of the learners training to the working of the service.
* Keep a record of competencies achieved in the staff member’s personnel file, and the dates for renewal of assessment.

I agree with the above learning contract:

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| --- | --- | --- |
| Signature of Learner | Print Name | Date |
| Signature of Mentor/Assessor | Print Name | Date |
| Signature of Manager | Print Name | Date |

Appendix 1

This competency links to the following dimensions and levels within the NHS Knowledge and Skills Framework (2004).

**KSF DIMENSIONS – Research Assistant Practitioner**

* Core 1 Communication – Level 3
* Core 2 Personal & People Development – Level 2
* Core 3 Health Safety & Security – Level 2
* Core 4 Service Improvement – Level 2
* Core 5 Quality – Level 2
* Core 6 Equality & Diversity – Level 2
* HWB2 Assessment and Care Planning to meet Health and Well Being Needs – Level 3
* HWB8 Undertake and report on routine biomedical investigations and/or interventions – Level 2
* G5 Organise specific aspects of services and/or projects – Level 2
* IK1 Modify, structure, maintain and present data and information – Level 2

**Key skill and competency framework for the Assistant Practitioner working in Clinical Research**

**Aim:**

* To ensure a quality and efficient service to clinical research participants
* To ensure the participant is safely and appropriately cared for
* To work in partnership with colleagues to ensure a holistic and team approach to care

**Entry Criteria:**

* Trainee Assistant Practitioner
* Minimum of 1 years experience in healthcare environment
* NVQ 3 in health or equivalent

The staff member must be prepared to undertake all Core Competencies (CC) and the relevant Specific Competencies (SC) in addition to the Higher Professional Diploma in Health and Wellbeing (HPD) to qualify as competent to undertake the Assistant Practitioner (AP) role.

**Core Competencies (Clinical Research) to be undertaken by all trainee Assistant Practitioners:**

* Communication
* Maintaining dignity of research participants
* Conduct assessment of participants in own work area
* Management of a caseload of research participants
* Early identification of an acutely ill participant
* Transferring care of the research participant at the end of study
* Personal and people development

**Research Specific Competencies to be undertaken by trainee Assistant Practitioner:**

* Good Clinical Practice certificate (NIHR on-line training <https://www.nihr.ac.uk/> or study day arranged via Research & Development Directorate, accessed via the Trust intranet).
* Valid Informed Consent certificate (NIHR on-line training <https://www.nihr.ac.uk/> or study day arranged via Research & Development Directorate, accessed via Trust intranet)
* IATA, dry ice training (study day arranged via Research & Development Directorate, accessed via Trust intranet)

**Study Specific Competencies to be undertaken by trainee Assistant Practitioner:**

* Venepuncture <https://royaldevonstaff.nhs.uk/venepuncture>

**Core Competence No 1**

**Communication**

**Aim:**

The Assistant Practitioner will be able to demonstrate advanced communication skills, enabling recognition and appropriate response to verbal and non-verbal communication. To be able to identify and address communication barriers and individual preferences throughout all care given.

**Entry requirement:**

* Trainee Assistant Practitioner / Assistant Practitioner

**Standard:**

The practitioner will:

* Communicate with individuals in a manner that is consistent with their level of understanding, culture, religion, spiritual beliefs, background and preferred way of communicating
* Recognise non-verbal communication and expressions of emotions and needs, responding in an appropriate manner
* Identify barriers to effective communication and use reflection to modify communication and relationship skills in response
* Interact in a manner that supports effective and accurate exchange of information and acknowledges individual choice and autonomy
* Offer appropriate support and privacy taking into account the participants privacy
* Identify and use a variety of appropriate communication methods

This competency links to the following dimensions within the NHS Knowledge and Skills Framework (2004):

* KSF C1 - Communication
* KSF C3 – Health, safety and security
* KSF C6 – Equality and diversity
* KSF HWB2 – Assessment and care planning to meet health and wellbeing needs

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| **Assessment criteria** | **Level of achievement** | **Comments** | **Coach** |
| Communicates effectively and appropriately |  |  |  |
| Recognises and responds to verbal and non-verbal communication |  |  |  |
| Considers the participant’s special requirements and adapts communication to the needs of the individual |  |  |  |
| Maintains the participant’s privacy and dignity |  |  |  |
| Considers religious, cultural and spiritual beliefs and respects individual choice |  |  |  |
| Identifies and responds to communication barriers |  |  |  |
| Employs a range of communication techniques including telephone, texts and email |  |  |  |
| Ensures all communication meets legal and organisational procedures |  |  |  |

**Core Competence No 2**

**Maintaining dignity of research participants**

**Aim:**

The Assistant Practitioner will be able to provide care that is culturally sensitive to age, social class, regional or group affiliation as well as ethnic, religious and national origins

**Entry requirement:**

* Trainee Assistant Practitioner / Assistant Practitioner

**Standard:**

The practitioner will:

* Provide care that is sensitive to individuals’ needs and preferences
* Maintain the privacy and dignity of participants at all times
* Recognise and respond to individuals’ diverse needs
* Act as a role model through evidence of good practice
* Manage and find solutions to conflicts

This competency links to the following dimensions within the NHS Knowledge and Skills Framework (2004):

* KSF C1 - Communication
* KSF C3 – Health, safety and security
* KSF C5 - Quality
* KSF C6 – Equality and diversity
* KSF HWB2 – Assessment and care planning to meet health and wellbeing needs

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| **Assessment criteria** | **Level of achievement** | **Comments** | **Coach** |
| Provide care that is culturally sensitive to age, social class, regional or group affiliation as well as ethnic, religious or national origins |  |  |  |
| Ensure that fundamental care is given |  |  |  |
| Actively engage with participants and carers in order to prevent problems |  |  |  |

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| Demonstrate an understanding of an individual’s medical condition, diagnosis, treatment and care |  |  |  |
| Work in partnership with individuals, key people both within and outside the organisation to promote the individual’s choice about their care |  |  |  |
| Support individuals to communicate their views about:   * Their priorities * Their needs * The factors that affect their health and wellbeing * Changes that they are experiencing |  |  |  |
| Develop solutions to deal with conflicts and dilemmas when promoting the individual’s rights and responsibilities |  |  |  |
| Act as a role model to demonstrate to others how to:   * Respect and balance the views * Identify preferences and wishes of individuals and key people * Support individuals to have as much control over their lives as possible * Support individuals to use their strengths and abilities * Acknowledge the dilemmas individuals face when balancing their own rights, preferences and responsibilities with those key people and others |  |  |  |
| Promote individuals’ rights to:   * Praise, comment and complain, acting on those in a fair and open manner, consistent with organisational requirements * Secure independent advice, support and advocacy when decisions are being made about their lives and futures |  |  |  |
| Provide care that is culturally sensitive to age, social class, regional or group affiliation as well as ethnic, religious or national origins |  |  |  |

**Core Competence No 3**

**Conduct assessment of participants in research work environment including screening, consent and routine follow up as outlined by research protocol.**

**Aim:**

The Assistant Practitioner will be able to demonstrate competence in carrying out the recruitment of participants into research studies and provide support and on-going assessment in accordance with research protocols

**Entry requirement:**

* Trainee Assistant Practitioner / Assistant Practitioner

**Standard:**

The practitioner will:

* Carry out recruitment of participants into relevant research studies, performing pre-screening, and screening activities
* Obtain and maintain valid informed consent appropriate for research activities
* Carry out and maintain assessment as outlined in study specific protocol schedules
* Maintain the privacy and dignity of research participants at all times
* Recognise and respond to individuals’ diverse needs
* Be able to use relevant and appropriate tools of assessment
* Record and report findings and outcomes

This competency links to the following dimensions within the NHS Knowledge and Skills Framework (2004):

* KSF C1 - Communication
* KSF C3 – Health, safety and security
* KSF C6 – Equality and diversity
* KSF HWB2 – Assessment and care planning to meet health and wellbeing needs
* KSF HMB8 – Biomedical investigations and interventions
* KSF IK1 – Information processing

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| **Assessment criteria** | **Level of achievement** | **Comments** | **Coach** |
| Communicate in a variety of ways with the participant and relevant others, in an environment that maximises privacy and dignity |  |  |  |
| Demonstrate a working knowledge and understanding of the clinical research environment, including a range of research methodologies |  |  |  |
| Demonstrate the ability to conduct clinical research activities in accordance with study protocols |  |  |  |
| Perform pre-screening activities in line with Ethical and Trust Approvals to identify potential participants |  |  |  |
| Identify suitable participants to invite for screening ensuring they have appropriate information leaflets, time to consider decision and invite to attend the research clinic |  |  |  |
| Greet the participant, introduce self and others, provide information on study schedules and venues and obtain contact details |  |  |  |
| Show awareness of Trust policy, ensuring good communication with participants with specific communication needs |  |  |  |
| Ensure participants understand the purpose of the research. Gain valid informed consent for the research using appropriate paperwork. Demonstrate appropriate recording of consent and filing of documentation:   * Hospital notes, EPIC, EDGE * Site files * CRF / eCRF |  |  |  |
| Provide information on how participants contact the research teams, access emergency numbers and contacts, and provide independent advice from the PALS team |  |  |  |
| Select valid and reliable assessment tools, strategies and care pathways for the required purpose and as outlined in specific research protocols   * Visual analogue scores * Quality of Life Questionnaires * Study specific participant diaries |  |  |  |
| Review and record the individual’s demographic details, history, medications. Identify specific problems relating to mobility, appointment times and transport, seeking advice as necessary |  |  |  |

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| Ensure that assessments are undertaken within the appropriate or required timelines |  |  |  |
| Undertake assessments within your own sphere of competence, involving the participant and / carer where appropriate. Seeking advice and support when needs of the participant or complexity of the case are beyond your competence and capability |  |  |  |
| Handle and process samples and specimens in line with:   * Trust Policies and Procedures – Infection control Policies * SOPs within specific research protocols * National and international legislation – COSSH, IATA, dry ice handling and shipping |  |  |  |
| Record and accurately document your findings and data according to research study specific requirements |  |  |  |
| Inform the relevant registered practitioner or Principle Investigator on the outcome of assessments, any action taken and make referrals as appropriate to ensure needs are met |  |  |  |

**Core Competence No 4**

**Manage a caseload of research participants**

**Aim:**

The Assistant Practitioner will be able to demonstrate competence in managing a caseload of research participants.

**Entry requirement:**

* Trainee Assistant Practitioner / Assistant Practitioner

**Standard:**

The practitioner will:

* Understand the relevant legislation around data protection and confidentiality when documenting care and communicating with internal and external research teams, healthcare professionals, sponsors and monitors
* Have an understanding of relevant information needed for participant care within study specific protocols and be able to provide this information when handing over care to other members of the research team
* Show on-going awareness of the participant’s condition and the usual and research specific pathways within their care
* Be able to manage a caseload of research participants, ensuring appropriate care is delivered by self and team
* Be a role model and mentor, delegating to and supporting other staff
* Be part of the multidisciplinary research team, recording and reporting findings and outcomes
* Know their capabilities and know when to refer to a registered practitioner

This competency links to the following dimensions within the NHS Knowledge and Skills Framework (2004):

* KSF C1 – Communication
* KSF C2 – Personal and people development
* KSF C3 – Health, safety and security
* KSF C4 – service improvement
* KSF C5 - Quality
* KSF C6 – Equality and diversity
* KSF HWB2 – Assessment and care planning to meet health and wellbeing needs
* KSF G5 – services and project management
* KSF IK1 – Information processing

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| **Assessment criteria** | **Level of achievement** | **Comments** | **Coach** |
| Present and record information relating to participant progress through research schedule of visits in a timely and professional manner |  |  |  |
| Participate in maintain effective communicate regarding caseload of participants with the research team |  |  |  |
| Identify the required information to manage the care for that group of participants questioning if information is unclear or lacks detail |  |  |  |
| Become familiar with end of study procedures. Ensure relevant information is shared with participants’ usual healthcare providers in Primary and Secondary settings and carers as appropriate |  |  |  |
| Have understanding of own capabilities, reporting to a registered practitioner if workload is assessed as unmanageable or requires skills that you do not possess |  |  |  |
| Ensure that other team members that you are working with understand how a participant’s care will be organised and delegate tasks to them that are within their skill base/experience |  |  |  |

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| Participate in team meetings and enter into proactive discussions regarding the planning of care and progress of the research participants |  |  |  |
| Ensure the registered practitioner with overall responsibility for the study is aware of changes in participants health or challenging issues associated with individual participants or your caseload |  |  |  |
| Ensure the practitioner with overall responsibility for the study is updated about end of study plans for participants and highlight any problems with these plans |  |  |  |
| Ensure that prior to the end of their study involvement, participants are aware of the process and how to access help if it should be required |  |  |  |
| Address concerns raised by participants and escalate these to a registered practitioner if you are not able to deal with them yourself |  |  |  |
| Continually prioritise the workload, demonstrate the ability to make safe decisions and communicate them to the team |  |  |  |
| Address shortfalls in the standards of acre delivered by other team members |  |  |  |
| Facilitate the knowledge and development of others |  |  |  |
| Identify and assess the potential risks involved in work activities and processes, to yourself and others |  |  |  |
| Act consistently as a role model in accordance with professional standards, current legislation, policies, procedures and quality initiatives |  |  |  |
| Communicate with other staff, participants and relatives in a form and manner appropriate to their level of understanding |  |  |  |
| Document care in accordance with policies, professional standards, current legislation, GCP and protocol specific requirements |  |  |  |

**Core Competence No 5**

**Early identification of an acutely ill participant**

**Aim:**

The Assistant Practitioner will be able to demonstrate competence in identifying and reacting to an individual who is acutely ill, taking appropriate action. Demonstrating when a how to refer them to a registered practitioner or summon help

**Entry requirement:**

* Trainee Assistant Practitioner / Assistant Practitioner
* Has been assessed competent in undertaking physiological measurements
* Has maintained mandatory training for basic life support

**Standard:**

The practitioner will:

* Have an understanding of the participant’s condition and the normal ranges within this
* Be able to identify observations outside the normal range
* Have an understanding of relevant information needed for appropriate care
* Accurately record and report findings and outcomes
* Know their capabilities and when to refer to a registered practitioner
* Know how to raise the alarm appropriately dependant on location
* Prepare and monitor individual until registered practitioner or emergency response teams arrive

This competency links to the following dimensions within the NHS Knowledge and Skills Framework (2004):

* KSF C1 – Communication
* KSF C2 – Personal and people development
* KSF C3 – Health, safety and security
* KSF C4 – service improvement
* KSF C5 - Quality
* KSF C6 – Equality and diversity
* KSF HWB2 – Assessment and care planning to meet health and wellbeing needs
* KSF G5 – services and project management
* KSF IK1 – Information processing

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| **Assessment criteria** | **Level of achievement** | **Comments** | **Coach** |
| Be compliant with mandatory training requirements for basic life support |  |  |  |
| Competent to monitor vital signs including blood pressure, heart rate and breathing |  |  |  |
| Demonstrate knowledge of the routine observations required and normal parameters |  |  |  |
| List possible signs of deterioration and describe appropriate actions |  |  |  |
| Take the immediate and appropriate actions when an acutely ill individual has been identified |  |  |  |
| Communicate concerns to appropriate personnel in a calm, professional and organised way |  |  |  |
| Demonstrate the appropriate way to raise the alarm dependant on location and site |  |  |  |
| Anticipate the needs of the attending personnel in preparation of the review |  |  |  |
| Display competence in continuing with monitoring whilst awaiting review |  |  |  |
| React appropriately to changes in an individual’s condition |  |  |  |
| Document care in accordance with professional standards and current legislation |  |  |  |

**Core Competence No 6**

**Transferring care of the research participant at the end of study involvement**

**Aim:**

The Assistant Practitioner will be able to demonstrate competence in transferring the care of the research participant from the research team back to the usual healthcare provider in Primary and Secondary care and the carers as appropriate

**Entry requirement:**

* Trainee Assistant Practitioner / Assistant Practitioner

**Standard:**

The practitioner will:

* Have an understanding of this transfer process
* Have an understanding of relevant information required to facilitate this process
* Be aware of the study and local requirements at the end of participants’ involvement in clinical research
* Show an awareness of services involved in this process, both primary and secondary care
* Know their capabilities and when to refer to a registered practitioner

*This competency links to the following dimensions within the NHS Knowledge and Skills Framework (2004)*:

* KSF C1 – Communication
* KSF C3 – Health, safety and security
* KSF C5 - Quality
* KSF HWB2 – Assessment and care planning to meet health and wellbeing needs
* KSF G5 – services and project management
* KSF IK1 – Information processing

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| **Assessment criteria** | **Level of achievement** | **Comments** | **Coach** |
| Act in a way that is consistent with legislation, policies and procedures for maintain the health, safety and security of participants |  |  |  |
| Clarify issues relating to transfer of participant care from the research team to participants’ usual healthcare providers and/ carers |  |  |  |
| Identify participants who are likely to have needs associated with this transfer of care and initiate early planning |  |  |  |
| Ensure that assessments have been completed |  |  |  |
| Have a working awareness of services supporting this transfer and facilitate appropriate communication and/ referral to other teams or agencies |  |  |  |
| Have understanding of own capabilities and seek advice or help from the registered practitioner as necessary |  |  |  |
| Ensure that referral letters are written and accurately reflect on-going needs relating to care and medication |  |  |  |
| Ensure that prior to the end of the study participants and / carers are aware of treatment plans, on-going care and/ medication needs |  |  |  |

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| Document care in accordance with policies, professional standards and current legislation |  |  |  |

**Core Competence No 7**

**Personal and people development, assessing Band 2/3 competence in the workplace using a range of methods**

**Aim:**

The Assistant Practitioner will be able to demonstrate competence in the basic principles of assessing competence of health care support staff working in their practice area.

**Entry requirement:**

* Trainee Assistant Practitioner / Assistant Practitioner
* Achieved or working towards Vocational Assessors Award (A1/D32)

**Standard:**

The practitioner will:

* Demonstrate competence in assessing Band 3/4 staff against agreed standards using a range of methods of assessment
* Be able to give feedback on staffs’ performance and decisions made
* Maintain their own Continuing Professional Development to ensure current and best practice is being achieved and taught

This competency links to the following dimensions within the NHS Knowledge and Skills Framework (2004):

* KSF C1 – Communication
* KSF C5 – Quality
* KSF C2 – Personal and people development

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| **Assessment criteria** | **Level of achievement** | **Comments** | **Coach** |
| Develop realistic plans with Band 3/4 staff for learning and assessment, including how and what will be assessed, together with a progress review |  |  |  |
| Judge and record evidence against criteria to make assessment decisions, a variety of evidence over a period of time |  |  |  |
| Review staffs’ levels of competence and identify what they need to do to be competent |  |  |  |
| Work with other staff involved in assessment process |  |  |  |
| Provide feedback and guidance to support staff on assessment decisions |  |  |  |
| Complete the A1 Vocational Assessors Award – Complete care certificate as per Trust requirements. |  |  |  |