COMPETENCY FRAMEWORK FOR CLINICAL RESEARCH NURSES

A TOOL TO PROMOTE PATIENT SAFETY AND QUALITY DATA

SHORT VERSION

01/10/2011

Date for revision October 2013

Introduction to short version

This is the short version of the 'Competency Framework for Clinical Research Nurses'. This version is made available as a word document so the competences can be adapted and amended to meet local needs. This version of the Framework should be used alongside the full version, which includes more information about how the Framework was developed and how it might be used in practice.

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Chair
Competency Framework Working Group

Competence 1: To demonstrate understanding of the historical background, political influence and strategy regarding clinical research in the UK

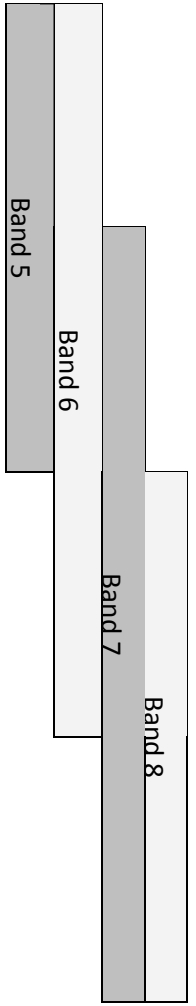
Skills and behaviours	Knowledge and understanding	KSF
• Understands the relevance of the historical development of clinical research to current research and policy. • Understands the current political context and relevant policy. • Champions the role of clinical research to the development of health, social care and the wealth of the nation. • Supporting and influencing the embedding of clinical research in NHS infrastructure / practice.	• History of ethics related to clinical research [2-18]. • Development of research ethics and governance [19-23]. • Methodological developments in clinical research [24-27]. • Political and strategic developments in clinical research [19, 28-34].	C1 C2 C3 C5 G5

Examples:

Band 5	Band 6	Band 7	Band 8
Recognises the importance of acknowledging the historical context with in which clinical research is undertaken.	Articulates the significance of major historical events, publications and policy developments in the evolution of clinical research, including political imperatives and government strategies.	Demonstrates comprehensive knowledge and understanding of the historical context, political influence and strategic developments relating to the evolution of clinical research.	Takes a leading role in supporting understanding of the historical and political context in which clinical research has developed and is currently being undertaken.

Assessment:

	Evidence of achievement
Level 1 Is competent with assistance and supervision	
Level 2 Is competent with supervision.	
Level 3 Is competent and autonomous with minimal assistance and supervision.	
Level 4+ Supports, trains and supervises others.	



Competence 2: To work within the regulation framework

2.1 Understands the role and remit of research ethics committees in the UK

Skills and behaviours	Knowledge and understanding	KSF
• Recognises the need to ensure that appropriate ethical opinions and governance approvals are obtained before any research activities are undertaken. • Articulates understanding of regulatory requirements. • Undertakes relevant educational activities [35-40].	• Structure and policy for the regulation of research [41-42]. • Roles and responsibilities of RECs [19, 31-32, 43-47]. • Structure and organisation of RECs and their membership [19, 41-44]. • Structure and organisation of R&D Departments, their membership and their roles and responsibilities [31-32]. • Processes for the submission of applications and their review [19, 29, 43-44, 46, 48-51]. • Local policies and procedures related to ethical review and research governance [29, 31-32, 48]. • Local and national policy developments [52-54]. • Roles and responsibilities of investigators and other members of the research team [31-32]. • Knowledge of procedures when breaches of protocol are identified or when fraud and misconduct is suspected [29, 39, 46, 48-49]. • Actions required when processes to protect participant confidentiality are not followed.	C1 C2 C3 C5 G5

Examples:

Band 5	Band 6	Band 7	Band 8
• Understands the need for favourable ethical opinion and research and governance approval to be obtained before commencing research activities. • Has an awareness of the structure, roles and function of RECs and R&D Departments. • Knows how to raise concerns and report instances of protocol deviation.	• Contributes to the development of research protocols. • Has knowledge and understanding of structure, roles and function of RECs and R&D Departments. • Has Knowledge of local R&D policies and procedures. • Has familiarity with regulatory requirements. • Act as a knowledgeable resource and advisor to staff and researchers. • Contributes to supervision and meeting educational needs of staff.	• Provides comprehensive advice and guidance on matters relating to research ethics and governance. • Act as a resource to staff and contributes to the professional and educational development of staff. • Leads on the development and updating of local policies and procedures. • Leads on the professional and educational development of staff.	Demonstrates leadership by: • Act as an expert resource to staff and researchers. • Leading on the professional and educational development of staff. • Ensuring appropriate reporting at the organisation executive board level.

Assessment:

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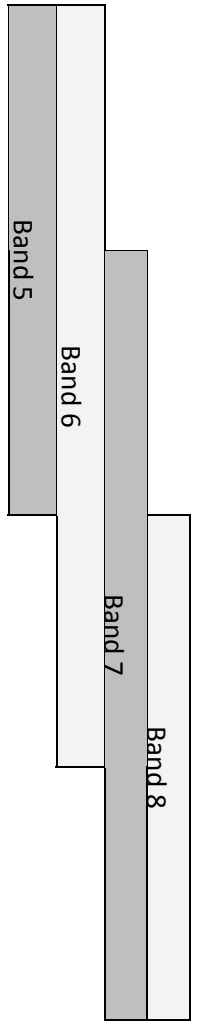

2.2 Contributes to the preparation of submissions for regulatory reviews

Skills and behaviours	Knowledge and understanding	KSF
• Aware of application processes and requirements for document management. • Leads or contributes to the preparation of paperwork and submission of applications.	• REC and R&D application processes (IRAS) [19, 44, 55-57]. • Other centralised permissions [58]. • Key documentation required to support REC and R&D submissions [19, 56]. • Protocol development. • Local review and reporting of research studies [59]. • Clinical Research Agreements [60-61]. • Risk assessment and feasibility. • Local and national policy developments. • Research sponsorship and researcher roles [31-32, 48, 56]. • Professional responsibilities and potential for conflict with research role [62].	C1 C2 C3 C5 G5 HWB2

Examples:

Band 5	Band 6	Band 7	Band 8
• Articulates the importance of clear, complete and accurate submissions. • Familiar with application processes.	• Act as a knowledgeable resource for staff and researchers making applications for regulatory approvals. • Raises concerns and seeks to address incomplete, inaccurate or misleading documentation. • Contributes to supervision and meeting the educational needs of staff.	• Act as expert resource for staff and researchers preparing submissions for regulatory approval. • Prepares, or makes significant contribution to the preparation of applications for regulatory approval. • Contributes to the professional and educational development of staff and researchers.	Demonstrates leadership by: • Ensuring that all processes, policies and standard operating procedures are in place. • Contributing to quality assurance. • Leading and taking responsibility for research in position of PI or CI.

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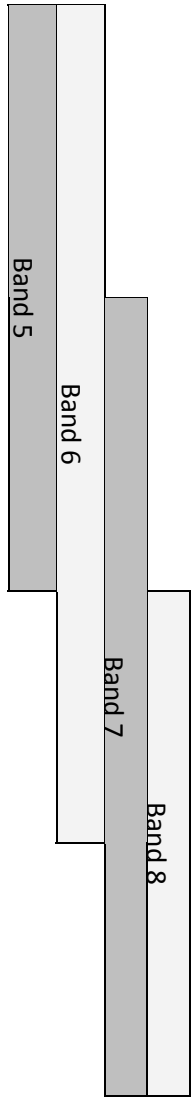

Competence 3: To understand, apply and promote the principles and practice of obtaining and maintaining valid informed consent

Skills and behaviours	Knowledge and understanding	KSF
• Assures the provision of an environment conducive to obtaining valid informed consent. • Contributes to policy and practice development. • Aware of and is responsive to factors contributing to decision making during the consent process. • Assures patient safety by proactively managing any breaches of the informed consent process.	• Principles of informed consent for participation in research [18, 63-65]. • Roles of researchers, including CI and PI, in gaining and maintaining informed consent [31-32]. • Role of research nurses [31-32, 40, 66-69]. • Role of the REC [19, 42-43, 70-71]. • Key information required in PIS and CF [19, 72-75]. • Ongoing nature of informed consent. • Legal requirements related to gaining and maintaining valid informed consent, especially when participants lack capacity [76-80]. • Local policies and procedures relating to gaining and maintaining valid informed consent.	C1 C2 C3 C4 C5 C6 HWB2 HWB3

Examples:

Band 5	Band 6	Band 7	Band 8
• Effectively engages with research participants to ensure understanding of information about the research. • Demonstrates an awareness of the factors contributing to a participant's autonomous decision making during the consent process. • Complies with the informed consent processes as described in the approved protocol, including use of approved versions of PIS and CF. • Raises any concerns about the informed consent processes. • Recognises own learning needs and takes responsibility for maintaining up to date knowledge. • Provides evidence of training and understanding. • Recognises that informed consent is an ongoing process.	• Demonstrates a sound understanding of the need to identify issues which may impact on the process of gaining valid informed consent. Plans and implements actions to resolve these issues. • Receives informed consent when appropriate and as agreed in the approved protocol. • Supports participants through the consent process.	• Act as an expert resource to provide in-depth knowledge on aspects pertinent to acquiring and maintaining informed consent. • Contributes to the mentorship and monitoring of consent procedures. • Responsible for the reporting of poor consent processes that compromise patient safety and the study protocol.	Demonstrates leadership by: • Attending and reporting to corporate boards regarding governance, policy and service development related to research. • Holding responsibility for the training and monitoring of correct consent processes in research. • Developing systems to ensure that correct procedures are adhered to. • Contributing to the professional development and education of clinical research staff in the organisation.

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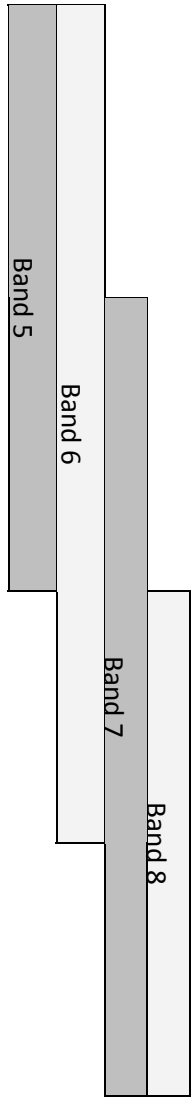

Competence 4: To apply professional knowledge and skills to facilitate efficient, safe and participant focused clinical research

4.1 Contribute to the development and facilitation of clinical research

Skills and behaviours	Knowledge and understanding	KSF
• Has an understanding of the research designs and methodologies used in clinical research. • Understands the implications for practice of the regulatory and legal frameworks related to the planning, delivery and closure of clinical research studies. • Has a comprehensive knowledge and understanding of the regulatory and legal frameworks related to the planning, undertaking and closure of clinical research studies. • Encourage, appreciate and value the contribution of study participants in all areas of research activity.	• The role of the National Institute of Health Research (NIHR) [48, 52, 81]. • The need for Quality Assurance [82-83]. • Phases of clinical research [84-85]. • Different research study designs: including protocol design and development; sample size and power; inclusion and exclusion criteria; randomisation; blinding and unblinding [49, 81, 86-88]. • Translational research [89-90]. • Multi-centre studies. • Management processes, from feasibility to closure [49, 91]. • Pharmacovigilance [92-93]. • Local, national and international dissemination of clinical research findings [94-97]. • Relevant UK legislation [76, 98-103]. • Professional codes of practice [62]. • Roles of licensing authorities and the licensing of investigational products [29, 104-105]. • Local requirements, policies and procedures.	C1 C2 C3 C5 G5

Examples:

Band 5	Band 6	Band 7	Band 8
• Consistently adheres to the study protocol design. • Raises concerns if design conflicts with regulatory frameworks and legal requirements or if research activities deviate from the study protocol. • Recognises own limitations and attends/completes relevant training (including GCP). Is supportive in the training of others. • Demonstrates an awareness of the need for patient and public involvement (PPI) in clinical research. This could include their involvement in any aspect of the research process.	• Act as a knowledgeable resource for staff, researchers, research participants and patients. • Contributes to the training and supervision of staff and researchers. • Contributes to the development of local policies related to all parts of the clinical research process. • Promotes and facilitates PPI in all aspects of clinical research. • Contributes to nurse led research.	• Act as an expert resource for staff, researchers, research participants and patients. • Demonstrates a detailed knowledge and understanding of different research designs and methodologies and the regulatory and legal frameworks related to clinical research studies. • Leads on the training and ensuring the appropriate supervision of staff. • Leading role in the development and updating of local policies and procedures. • Contributes to the development of national policies and procedures. • Leads in planning, conducting and supervising nurse led research.	Demonstrates leadership by: • Playing an integral role in R&D fora, (locally, nationally and internationally). • Contributing strategically on all areas of clinical research. • Political astuteness. • Professional leadership. • Efficient and effective networking skills. • Further development of clinical research. • Prioritising competing needs. • Contributing to the professional development and education of clinical research staff and organisations. • Contributing to or leading clinical research.

Assessment:

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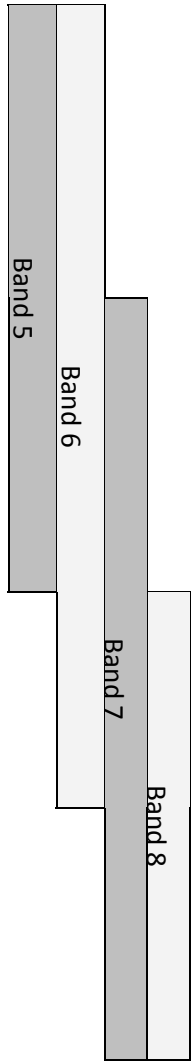

4.2 Contribute to effective and efficient use of resources

Skills and behaviours	Knowledge and understanding	KSF
• Has an awareness of the financial issues related to the planning and conducting of clinical research. • Recognises their role and contribution to the local and national strategic vision.	• Funding of research studies [106]. • Financial agreements [60-61]. • Financial management during the course of a clinical research study [91]. • Identification of costs [107]. • Role of the research funder [31-32]. • National and local research costing models. • Local employment policies and models of working.	C2 G5

Examples:

Band 5	Band 6	Band 7	Band 8
• Consistently operates within the financial constraints of the funding available for a clinical research study. • Alerts relevant personnel to potential escalating consumable and other costs associated with a clinical research study. • Is aware of different staff roles and responsibilities regarding resources.	• Contributes to the financial processes of planning, running and closing clinical research studies.	• Involved in the financial processes associated with coordinating research studies and grant applications. • Act as an expert resource for staff in relation to the financial management of clinical research studies. • Uses expert judgment in relation to competing demands for funding. • Involved in the management of staff as a resource.	Demonstrates leadership by: • Building alliances and working partnerships. • Enhancing Institutional reputation • Skill mix review. • Contributing to the professional development of the workforce. • Contributing to the acquisition of grant income and identification of other potential funding streams. • Cost recovery systems.

Assessment:

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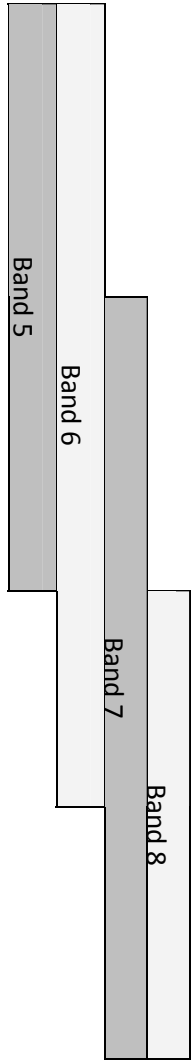

4.3 Facilitate the delivery of clinical research

Skills and behaviours	Knowledge and understanding	KSF
• Contributes to the delivery of clinical research protocols as a member of the research team. • Understands the rationale behind adherence to ethical approved study protocols. • Demonstrates safe and effective care of patients and/or research participants in research. • Awareness of policies relating to Investigational Medicinal Products (IMP). • Recognise the importance of accurate and comprehensive source documentation. • Demonstrate a good understanding of GCP in relation to direct patient/participant care.	• Local Medicines Policy. • Quality Assurance [82]. • Standard Operating Procedures (SOPs) [108]. • Relevant clinical skills in line with local procedures and national occupational standards [31-32]. • Knowledge of research study protocol. • Processes for participant recruitment. • Risk Management. • Public involvement in research [87]. • Importance of submitting recruitment figures to relevant bodies, including NIHR recruitment data [29, 52]. • Local organisational policies and procedures.	C1 C2 C3 C5 Ik2 G5 G6

Examples:

Band 5	Band 6	Band 7	Band 8
• Is able to correctly use and dispose of study supplies and equipment, in accordance with study protocol and relevant Standard Operating Procedures (SOPs). • Completes accurate paperwork associated with research study supplies. • Attends relevant training in relation to requirements of research study protocol. • Consistent application of relevant clinical and research skills. • Contributes to an active and effective research culture.	• Actively involved in the ordering of supplies, ensuring that resources (including staff and beds) are available for the effective conduct of the research study. • Ensures clear and accurate documentation is maintained on the arrival, use and disposal of research study supplies. • Advises staff and researchers, acting as a knowledgeable resource on matters relating to clinical practice and research, promoting an active and effective research culture. • Contributes to the development and training of staff and researchers. • Contributes to the development of SOPs.	• Takes a leading role in managing research studies. • Supports colleagues and researchers through the research study process, including clinical aspects associated with the research study. • Takes the lead on developing and updating SOPs. • Takes a leading role in activities of professional fora and networks. • Contribute to local recruitment strategies.	Demonstrates leadership by: • Having wider oversight and strategic vision. • Actively seeking to collaborate and share best practice to enhance delivery of clinical research. • Promoting effective recruitment strategies to increase recruitment in line with local and national targets.

Assessment:

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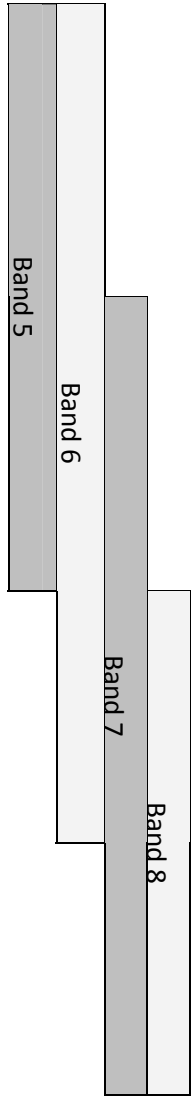

4.4 Contribute to the safe collection and storage of data and accurate completion of study documentation

Skills and behaviours	Knowledge and understanding	KSF
• Undertakes, supervises and manages the accurate and complete collection of data and insertion of data into Case Report Forms (CRFs) or other research storage formats. • Ensures the safe and secure storage of data. • Has a comprehensive understanding of the roles and responsibilities of key personnel within the clinical research environment. • Facilitating the monitoring process. • Ensures participant's confidentiality.	• Roles of those involved in all aspects of research [31-32, 66, 68, 109-111]. • Data insertion techniques, including the use of electronic data entry. • Audio and other media as means of data. • Source document verification. • Fraud and misconduct [112]. • Audit and monitoring of data [113]. • The process of inspections [113]. • Local and national policies and procedures relating to data collection and safe transfer [111, 114-120]. • Local Caldicott guardian and local information governance policy [121]. • Actions required when processes to protect confidentiality are not adhered to [116-117].	C1 C3 C5 Ik2 G5 HWB2

Examples:

Band 5	Band 6	Band 7	Band 8
• Evidence of accurate and complete data collection and entry. • Adherence to requirements of ethically approved protocol. • Raises concerns if inaccurate or incomplete data entry is suspected. • Takes appropriate action in event of adverse events. • Contributes to the safe and secure storage of research data. • Consistently works within own role and adheres to the roles and responsibilities documentation. • Understands the roles and responsibilities of others involved in clinical research. • Addresses non adherence to defined protocol/policies by timely and appropriate reporting. • Consistently adheres to requirements to protect confidentiality. • Raises concerns when processes to ensure confidentiality are not adhered to.	• Advises staff and researchers on data collection, data entry and safe data storage. • Responds to concerns if inaccurate or incomplete data entry is suspected. • Contributes to supervision and meeting the professional and educational needs of staff. • Contributes to study closure and archival preparation. • Act as a knowledgeable resource and contributes to the development and training of staff and researchers. • Contributes to the development and updating of local policies and procedures.	• Contributes to the development of local policies and procedures. • Ensures that local policies and procedures are followed by all members of the research team. • Contributes to the auditing and monitoring of research studies and responds to recommendations. • Takes an active lead in the setting up, coordination and management of clinical research studies. • Act as an expert resource for staff and researchers. • Takes an active role in developing and updating local and national policies and procedures. • Actively involved in local and national forums and networks related to clinical research and the nurse's role in that clinical research. • Ensures that processes and procedures for ensuring participant confidentiality are developed and adhered to.	Demonstrates leadership by: • Leading on the professional and educational development of staff. • Involvement in local implementation of national directives and policies. • Driving quality assurance measures and appropriate policies to enhance clinical research activity. • Involved in appropriate reporting at the organisational level.

Assessment:

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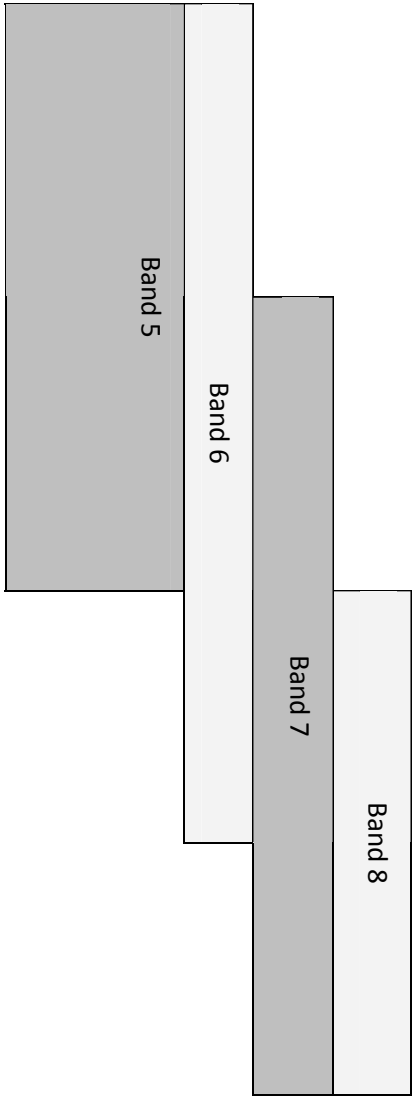

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