COMPETENCY FRAMEWORK FOR CLINICAL RESEARCH NURSES

A TOOL TO PROMOTE PATIENT SAFETY AND QUALITY DATA

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Acknowledgements

The Competency Working Group would like to acknowledge all those who commented on draft versions of the revised Framework and all those who contributed to the first edition of the Framework first published in 2008. The Working Group would also like to thank all those who supplied examples of how the Framework has been used in many different settings in the UK and in other parts of the world. This work would also not have been possible without the support of the NIHR, through representation from Clinical Research Facilities and Clinical Research Networks, and the Royal College of Nursing. We hope that the Framework will continue to have value to the many nurses working in clinical research.

Contents

Abbreviations

CF	Consent Form
CI	Chief Investigator
CRA	Clinical Research Associate
CRF	Case Report Form (not Clinical Research Facility)
CRN	Clinical Research Nurse
CRNA	Clinical Research Nurses Association
CRO	Clinical Research Organisation
DMC	Data Monitoring Committee
FDA	US Food and Drug Administration
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
IB	Investigator Brochure
ICR	Institute of Clinical Research
IRAS	Integrated Research Application System
KSF	Knowledge and Skills Framework
MHRA	Medicines and Healthcare products Regulatory Agency
NHS	National Health Service
NIGB	National Information Governance Board
NIHR	National Institute of Health Research
NIHR CSP	NIHR Coordinated System for gaining NHS permission
NRES	National Research Ethics Service
PI	Principal Investigator
PIS	Participant information sheet
PPI	Patient and public involvement
RCN	Royal College of Nursing
R&D	Research and Development
REC	Research Ethics Committee
SF	Study File
SOP	Standard Operating Procedure
TMF	Trial Master File
TSF	Trial Site File
UK	United Kingdom
UKCRC	United Kingdom Clinical Research Collaboration

Preface

Foreword

This last decade has seen major developments in research, which have changed completely the landscape of clinical research. Landmark policies, which have influenced and resulted in these changes, include the Research Governance Framework for Health and Social Care (March 2004) and Best Research for Best Health (2006), in association with European directives which have been translated into UK law. These polices and law, have provided us for the first time, with a defined infrastructure for the governance, delivery and implementation of clinical research, and resulted in enhanced engagement across the numerous disciplines within our health services.

Research is vital to the health and wealth of the population, and as such remains essential to the coalition Governments objectives for research in the NHS.

The result of these collective changes has been that research has now become a front-line, core service of the NHS. Inherent within these changes has been the role of the research nurse. Where the work of the research nurses is vital in delivering the vision for research in the United Kingdom. Consequently the number of clinic nurses who are involved and working in research has increased, (although overall numbers still remain low). The Clinical Research Nurse is now seen as an emerging nursing speciality.

In today's NHS, the scope and opportunities available for nurses in clinical research, are exciting and varied; although myths and misconceptions remain. Clinical research is a new and emerging discipline for nurses, which means that clarity on the role and responsibilities expected for nurses working in this discipline, and at different bands, needs to be provided.

This Competency Framework brings together the knowledge and skills of Clinical Research Nurses . It is designed to be comprehensive, giving an overview of the current expectations of the work of a Clinical Research Nurse, and at various levels of seniority. It consequently also provides clear structure for career development. One of the strengths of this documents is that it is adaptable to meet local requirements within all research settings.

The Competency Framework draws upon the expertise of numerous research nurses, working in a variety of different research settings. By pooling their wealth of experience and knowledge, this comprehensive document has been developed, accurately reflecting the work of Clinical Research Nurses.

We warmly congratulate this group in providing much needed guidance and structure to this new nursing discipline. We highly recommend this documents as an invaluable resource for all clinical researchers.

The CLRN Lead Research Nurses

Introduction to second edition

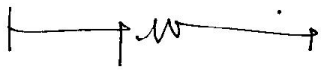
The planning, undertaking, closure and reporting of high quality clinical research is dependent upon the knowledge, skills and competence of the many individuals involved in making research possible. These attributes are developed through formal training, through supervision and mentorship, through ongoing personal development and through experience gained in practice. Together these contribute to the development of research practitioners who possess the competences required to help to guard against poor clinical and research practice and promote participant safety. This document offers the large and growing number of Clinical Research Nurses (CRNs) a framework which could help in the development of the skills, behaviour, knowledge and understanding required to support clinical research and to develop a career in research.

The initial preparation and subsequent revision of this Framework has highlighted the fact that CRNs in various clinical and geographical settings are involved in the different aspects of clinical research in different ways, taking different levels of responsibility and focusing their efforts on different parts of the research endeavour. For this reason it has not been possible to present an off-the-shelf set of competencies that would be relevant and meaningful to all CRNs. Rather, it is hoped that this document might offer a useful starting point for those developing local Competency Frameworks.

The future of clinical research in the UK is dependent on engagement with the NHS at all levels so it is hoped that this Framework will also be of use to clinical staff who support or line manage research nurses by helping to define the contribution and responsibilities of nurses involved in clinical research.

The development of the first edition of the Competency Framework began in the summer of 2007. After more than a year and after considerable effort by the members of the Working Group, the Competency Framework finally took shape and was published in December 2008. In undertaking this revision, the complexities of the roles of CRNs have again generated considerable challenges and much debate.

This is the second edition of what is anticipated will continue to be a regularly revised and updated Framework document that will evolve alongside changes in the context in which clinical research studies are planned, undertaken and reported. To help facilitate future revision, all suggestions, comments and examples of how this Framework has been amended and used should be sent to leslie.gelling@anglia.ac.uk.



Dr Leslie Gelling PhD MA BSc(Hons) RN FRSA - Chair, Competency Framework Working Group

What is a competency?

For the purposes of this document, a competency is defined as:

> "The ability to demonstrate the application of knowledge, understanding, practical and thinking skills to achieve effective performance in a professional or occupational role. This involves problem solving and being sufficiently flexible to meet changing demands."

The purpose of this competency framework is to enable an individual to:

- Understand more clearly what is expected of them,
- Identify personal development needs,
- Provide evidence of achievements to support career development and progression.

Competencies are the essential building blocks that shape nursing work in all clinical and practice settings. As practitioners acquire skills, knowledge, understanding and confidence in their field of practice they are able to demonstrate how they meet increasingly challenging levels of competence. For example, a nurse practising at Band 5 could be expected to participate in clinical research but at Band 7 they would be expected to manage studies and to offer expert advice to colleagues, researchers and others.

How to use this framework

In preparing this Competency Framework, the Working Group was keen to provide a framework that was sufficiently flexible to be of use to the many nurses working in clinical research. It is important to remember that these competencies may need to be adapted to meet local needs. In particular, it might be possible to amend the:

- Skills and behaviours
- Knowledge and understanding
- Band examples
- Additional reading, contextual information and websites

In adapting these competencies for local use, it is advised that interpretation and revision should not result in deviation from the core focus of these competencies. That is to support CRNs in the acquisition of the knowledge and practical skills required to fulfil their CRN role.

It should also be noted that the competencies presented in this document focus only on those skills unique to the role of CRNs. Clinical skills are assessed through different processes. There will, of course, be some overlap. For example, although effective communication is important to CRNs, it is not a competence unique to this role.

Explanatory notes

A 'Clinical Research Nurse' (CRN) refers to any nurse who is 'employed principally to undertake research within the clinical environment' [1]. This can include a variety of nursing roles but they all share the common feature that research is a central part of their employment.

'Skills and behaviours' describe the skills and behaviours that will be demonstrated in performing each competence.

'Knowledge and understanding' describes the essential knowledge and understanding required to demonstrate competence. Some examples of the knowledge and understanding that might be required to achieve a competence are given. This should not be considered an exhaustive list and should be amended to meet local needs.

The 'Knowledge and Skills Framework' (KSF) refers to a key part of the NHS agenda for personal development, career progression and pay. This document is produced as a tool to link the acquisition of appropriate knowledge and skills and to demonstrate competencies in a number of key tasks and concepts required to undertake the CRN role.

'Band' refers to the pay NHS band on which nurses are contracted to work. The majority of CRNs will be employed on Bands 5 to 8. It is accepted that some centres might not employ CRNs at Band 5 or Band 8. This again emphasises the need to amend these competencies for local use. The presentation of competencies for CRNs at Band 8 were not included in the first edition of the Framework but have been added to this second edition.

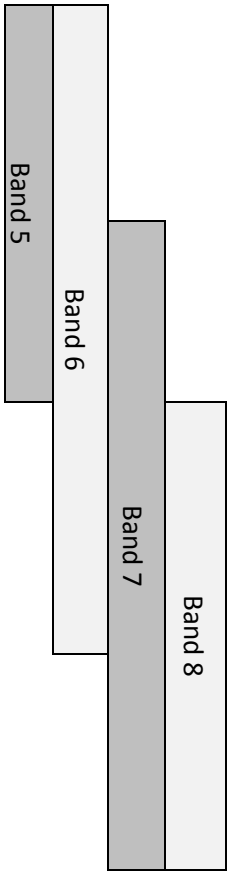
It is also acknowledged that there are a significant number of CRNs working in organisations other than the National Health Service (NHS) for whom Banding may have no relevance. CRNs or nurses working in these organisations will need to amend the Framework to meet their own needs and to reflect their own terms of employment and can use this Framework to demonstrate progression..

'Additional reading, contextual information and websites' will include specific reference to information pertinent to the area of practice within which the competence will be used. Where possible, reference is made to the different legislation in the devolved UK administrations. It should be noted that the list of additional information is not an exhaustive list but the content is offered as guidance to some of the key information and should be amended for local use.

Assessment

A suggested means of assessment has been included to enable CRNs to review and record their current level of performance within each competence. This process of assessment will best be achieved under the guidance of mentors or supervisors.

	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.	



Space is provided to record evidence of achievement. This evidence can include (but is not limited to):

- Evidence of everyday performance.
- Result of questioning whilst performing activities, at a review meeting or as a result of a formal assessment.
- Reflective practice journals.
- Supporting evidence from managers, colleagues, peers and clients.
- Publication and presentation.

Evidence must be:

- *Valid.* The evidence must relate directly and appropriately to the competence.
- *Sufficient.* The evidence should not be a one-off event but must demonstrate consistent achievement.
- *Authentic.* The evidence must be the CRN's own work or demonstrate the CRN's significant role in collaborative work.
- *Current.* The evidence must demonstrate currency and should not be reliant on work undertaken in the past.

This evidence should be collected and presented to demonstrate achievement of the performance criteria for each Band. For example, it is expected that a nurse performing at Band 7 would be able to demonstrate competence at the preceding Bands (5 and 6).

It is not necessary to demonstrate achievement of all the competencies at one Level before progressing to the next Level. For example, a CRN might progress rapidly through some competencies but might find others more challenging.

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.	

Band 5

Band 6

Band 7

Band 8

Competence 2: To work within the regulation framework

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

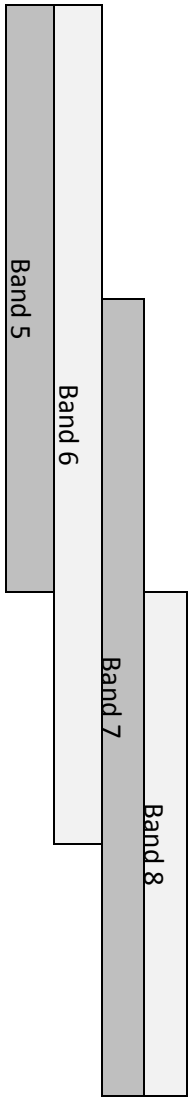
Skills and behaviours	Knowledge and understanding	KSF
• Recognises the need to ensure that appropriate ethical opinions and governance approvals are obtained before any research activities are undertaken. • Articulates understanding of regulatory requirements. • Undertakes relevant educational activities [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

	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.	



2.2 Contributes to the preparation of submissions for regulatory reviews

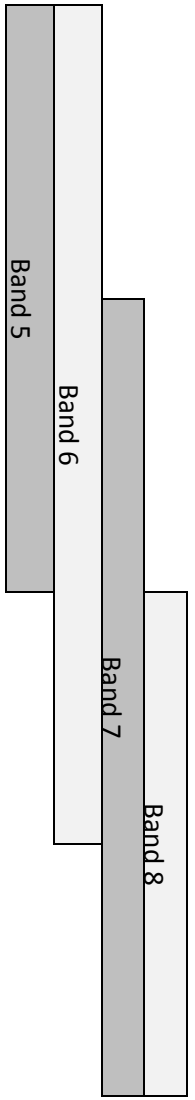
Skills and behaviours	Knowledge and understanding	KSF
• Aware of application processes and requirements for document management. • Leads or contributes to the preparation of paperwork and submission of applications.	• REC and R&D application processes (IRAS) [19, 44, 55-57]. • Other centralised permissions [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.

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

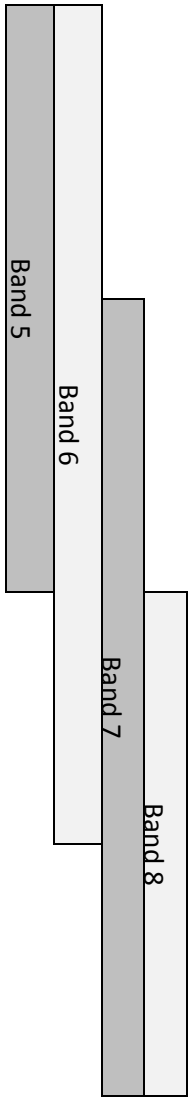
Skills and behaviours	Knowledge and understanding	KSF
• Assures the provision of an environment conducive to obtaining valid informed consent. • Contributes to policy and practice development. • Aware of and is responsive to factors contributing to decision making during the consent process. • Assures 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.

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 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	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.	

Band 5
Band 6
Band 7
Band 8

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

	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.	

Band 5
Band 6
Band 7
Band 8

4.3 Facilitate the delivery of clinical research

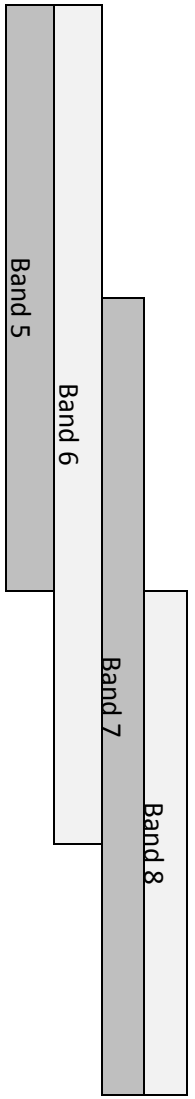
Skills and behaviours	Knowledge and understanding	KSF
• Contributes to the delivery of clinical research protocols as a member of the research team. • Understands the rationale behind adherence to ethical approved study protocols. • Demonstrates safe and effective care of patients and/or research participants 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

	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.	



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. • Is aware of own role limitations and escalates up when necessary. • 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

	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.	

Band 5

Band 6

Band 7

Band 8

References

1. United Kingdom Clinical Research Collaboration (UKCRC) Sub-committee for Nurses in Clinical Research. (2007) *Developing the best research professionals. Qualified graduate nurses: recommendations for preparing and supporting clinical academic nurses of the future*. London, UKCRC.

2. Spitz V. (2005) *Doctors from hell: the horrific account of Nazi experiments on humans*. Colorado, Sentient Publications.

3. *Nuremberg Code.* Available at: http://ohsr.od.nih.gov/guidelines/nuremberg.html. Last accessed: 11 July 2011.

4. Lifton RJ. (2000) *The Nazi doctors: medical killing and the psychology of genocide*. New York, Basic Books.

5. Katz J. (1996) The Nuremberg Code and the Nuremberg Trial: a reappraissal. *Journal of American Medical Association*. 276(20), 1662-1666.

6. Katz J. (1996) Human sacrifice and human experimentation: reflections at Nuremberg. Retrieved 9th May 2003, from the World Wide Web: http://www.law.yale.edu/outside/html/Publications/pub-katz.htm.

7. Post S. (1991) The echo of Nuremberg: Nazi data and ethics. *Journal of Medical Ethics*. 17(1), 42-44.

8. Kious BM. (2001) The Nuremberg Code: its history and implications. *Princeton Journal of Bioethics*. 4, 7-19.

9. Marrus MR. (1999) The Nuremberg doctors' trial in historical context. *Bulletin of the History of Medicine*. 73, 106-123.

10. Grodin M. (1992) Historical origins of the Nuremberg Code. In: Annas G and Grodin M. (Editors). *The Nazi doctors and the Nuremberg Code*. New York, Oxford University Press.

11. Annas G and Grodin M. (1992) *The Nazi doctors and the Nuremberg Code*. New York, Oxford University Press.

12. Singer C and Underwood EA. (1962) *A short history of medicine*. Oxford, Clarendon Press.

13. Tadd W. (2000) The Declaration of Helsinki: why all the fuss? *Nursing Ethics*. 7(5), 439-450.

14. World Medical Association. (2001) World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. *Bulletin of the World Health Organisation*. 79(4), 373-374.

15. *International Conference on Harmonisation Good Clinical Practice.* Available at: http://ichgcp.net/. Last accessed: 11 July 2011.

16. Goliszek A. (2003) *In the name of science: a history of secret programs, medical research, and human experimentation*. New York, St Martin's Press.

17. Barth KL. (2005) *Human medical trials*. Greenhaven Press.

18. *Declaration of Helsinki.* Available at: www.wma.net/en/30publications/10policies/b3/index.html. Last accessed: 11 July 2011.

19. *National Research Ethics Service.* Available at: http://www.nres.nhs.uk/. Last accessed: 11 July 2011.

20. Shaw S, Boynton PM and Greenhalgh T. (2005) Research governance: where did it come from, what does it mean? *Journal of the Royal Society of Medicine*. 98(11), 496-502.

21. *Rawlins Review Report.* Available at: http://www.nhsconfed.org/Networks/HealthServiceResearchNetwork/ethics/Pages/Rawlins.aspx. Last accessed: 11 July 2011.

22. *A new pathway for the regulation and governance of health research.* Available at: http://www.acmedsci.ac.uk/index.php?pid=47&prid=88. Last accessed: 11 July 2011.

23. *History of research ethics.* Available at: http://research.unlv.edu/ORI-HSR/history-ethics.htm. Last accessed: 14 July 2011.

24. Jenkins J and Hubbard S. (1991) History of clinical trials. *Seminars in Oncology Nursing*. 7(4), 228-234.

25. Gehan EA and Schneiderman MA. (1990) Historical and methodological developments in clinical trials at the National Cancer Institute. *Statistics in Medicine*. 9(8), 871-880.

26. *The Evolution of the Clinical Trials Process – A Brief History Lesson.* Available at: http://www.psoriasiscouncil.org/chapter_pdfs/chapter_01.pdf. Last accessed: 14 July 2011.

27. *A brief history of clinical trials.* Available at: http://genome.wellcome.ac.uk/doc_WTD020948.html. Last accessed: 14 July 2011.

28. Hoey R. (2007) The EU Clinical Trial Directive: 3 years on. *The Lancet*. 369, 1777-1778.

29. *Medicines and Healthcare Products Regulatory Agency.* Available at: www.mhra.gov.uk. Last accessed: 11 July 2011.

30. *Directive 2001/20/EC of the European Parliament and of the Council 4 April 2001.* Available at: http://www.eortc.be/Services/Doc/clinical-EU-directive-04-April-01.pdf. Last accessed: 11 July 2011.

31. Department of Health. (2005) *Research governance framework for health and social care*. 2nd Edition. London, Department of Health.

32. Wales Office of Research and Development for Health and Social Care in Wales. (2009) *Research governance framework for health and social care in Wales*. 2nd Edition. Cardiff, National Assembly for Wales.

33. Department of Health. (2006) *Best research for best health: a new national health research strategy*. London, Department of Health.

34. Bioscience Innovation and Growth Team. (2003) *Improving national health, improving national wealth*. London, Department of Trade and Industry.

35. *Clinfield.* Available at: www.clinfield.com. Last accessed: 11 July 2011.

36. *Institute of Clinical Research.* Available at: www.icr-global.org. Last accessed: 11 July 2011.

37. *Royal College of Nursing - Research.* Available at: www.rcn.org.uk/research. Last accessed: 15 July 2011.

38. *National Institute for Health Research - Training.* Available at: http://www.nihr.ac.uk/Lists/Research%20Training%20Awards/awards_current.aspx. Last accessed: 15 July 2011.

39. *Royal College of Nursing Research Society.* Available at: www.rcn.org.uk/development/researchanddevelopment/rs. Last accessed:

40. Ledger T, Pulfrey A and Luke J. (2008) Developing clinical research nurses. *Nursing Management*. 15(2), 28-33.

41. *United Kingdom Clinical Research Collaboration - regulation and governance.* Available at: http://www.ukcrc.org/regulationgovernance/. Last accessed: 14 July 2011.

42. The Academy of Medical Sciences. (2011) *A new pathway for the regulation and governance of health research*. London, The Academocy of Medical Sciences.

43. Department of Health. (2011) *Governance arrangements for research ethics committees: a harmonised edition*. London, Department of Health.

44. National Research Ethics Service. (2009) *Standard Operating Procedures for Research Ethics Committees: version 4.0*. London, NRES.

45. Medical Research Council. (2005) *Research regulation and ethics: MRC position*. London, MRC.

46. Royal College of Nursing. (2009) *Research Ethics: RCN Guidance for Nurses*. London, Royal College of Nursing.

47. Murphy TF. (2004) *Case studies in biomedical research ethics*. Cambridge (Massachusetts), MIT Press.

48. *National Institute for Health Research Coordinated System for gaining NHS permission.* Available at: http://www.crncc.nihr.ac.uk/about_us/processes/csp. Last accessed: 11 July 2011.

49. *Medical Research Council and Department of Health Clinical Trials Tool Kit.* Available at: www.ct-toolkit.ac.uk. Last accessed: 11 July 2011.

50. Gelling L. (2010) Gaining access to the research site. In: Gerrish K and Lacey A. (Editors). *The Research Process in Nursing*. 6th Edition. Oxford, Wiley-Blackwell.

51. European Commission. (2003) *Detailed guidance on the application format and documentation to be submitted in an application for an Ethics Committee opinion on the clinical trial on medicinal products for human use*. Brussels, European Commission.

52. *National Institute for Health Research.* Available at: www.nihr.ac.uk. Last accessed: 11 July 2011.

53. *National Health Service Research and Development Forum.* Available at: www.rdforum.nhs.uk. Last accessed: 11 July 2011.

54. *National Institute for Social Care and Health Research (NISCHR).* Available at: http://wales.gov.uk/topics/health/research/nischr/?lang=en. Last accessed: 14 July 2011.

55. *Integrated Research Application System.* Available at: www.myresearchproject.org.uk/. Last accessed: 11 July 2011.

56. Smajdor A, Sydes MR, Gelling L and Wilkinson M. (2009) Applying for ethical approval for research in the United Kingdom. *British Medical Journal*. 339, 968-971.

57. National Research Ethics Service. (2008) *Defining research*. London, National Patient Safety Agency.

58. *All Wales Primary Care Research Management and Governance.* Available at: http://www.wales.nhs.uk/sites3/page.cfm?orgid=803&pid=36648. Last accessed: 18 July 2011.

59. Davies H. (2006) The importance of both research and its proper review: a historical perspective. *Research Ethics Review*. 2(2), 40-46.

60. *National Institute for Health Research - Model agreements.* Available at: http://www.nihr.ac.uk/industry/Pages/model_clinical_trials_agreement.aspx. Last accessed: 14 July 2011.

61. *Department of Health - Model clinical trials agreements.* Available at: http://www.dh.gov.uk/en/Aboutus/Researchanddevelopment/AtoZ/DH_4002073. Last accessed: 14 July 2011.

62. Nursing and Midwifery Council. (2008) *The Code: standards and conduct, performance and ethics for nurses and midwives*. London, NMC.

63. Foster C. (2001) *The ethics of medical research on humans*. Cambridge, Cambridge University Press.

64. Gelling L. (1999) Ethical principles in health care research. *Nursing Standard*. 13(36), 39-42.

65. Beauchamp TL and Childress JF. (2008) *Principles of biomedical ethics*. 6th Edition. Oxford, Oxford University Press.

66. Spilsbury K, Petherick E, Cullum N, Nelson A, Nixon J and Mason S. (2008) The role and potential contribution of clinical research nurses to clinical trials. *Journal of Clinical Nursing*. 17(4), 549-557.

67. Hill G and MacArthur J. (2006) Professional issues associated with the role of the research nurse. *Nursing Standard*. 20(39), 41-47.

68. Chatfield D and Gelling L. (2001) Informed consent to research: the role of the research nurse. *Clinical Research Focus*. 12(7), 5-11.

69. Gordon C. (2008) Exploring the new speciality of clinical research nursing. *Nursing Times*. 104(29), 34-35.

70. Gelling L. (1999) Role of the research ethics committee. *Nurse Education Today*. 19, 564-569.

71. McGuinness S. (2008) Research ethics committees: the role of ethics in a regulatory authority. *Journal of Medic Ethics*. 34(9), 695-700.

72. Royal College of Nursing. (2011) *Informed Consent in Health and Social Care Research: RCN Guidance for Nurses*. London, Royal College of Nursing.

73. National Research Ethics Service. (2011) *Information sheets and consent forms: guidance for reseachers and reviewers*. London, NRES.

74. *Language Awareness Infrastrcuture Support Services.* Available at: http://www.llais.org/. Last accessed: 11 July 2011.

75. Franck L and Winter I. (2004) Research participant information sheets are difficult to read. *Bulletin of Medical Ethics*. 195, 13-16.

76. *Mental Capacity Act 2005.* Available at: www.opsi.gov.uk/ACTS/acts2005/ukpga_20050009_en_1. Last accessed: 11 July 2011.

77. *Adults lacking capacity - on-line toolkit.* Available at: http://www.nres.npsa.nhs.uk/news-and-publications/news/release-of-adults-lacking-capacity-toolkit/. Last accessed: 11 July 2011.

78. Menon D and Chatfield D. (2011) *A guide for critical care settings: Mental Capacity Act 2005*. London, Intensive Care Society.

79. Department for Constitutional Affairs. (2007) *Mental Capacity Act 2005: Code of Practice*. London, Department for Constitutional Affairs.

80. *National Research Ethics Service.* Available at: http://www.nres.npsa.nhs.uk/news-and-publications/news/release-of-adults-lacking-capacity-toolkit/. Last accessed:

81. *National Institute for Health Research - Research Support Services.* Available at: http://www.nihr.ac.uk/systems/Pages/Research_Support_Services.aspx. Last accessed: 11 July 2011.

82. *British Association of Research Quality Assurance.* Available at: http://www.barqa.com/. Last accessed:

83. Medical Research Council. (2005) *Good research practice*. London, MRC.

84. Kerr DJ, Knox K, Robertson DC, Stewart D and Watson R. (2006) *Clinical trials explained: a guide to clinical trials in the NHS for healthcare professionals*. London, BMJ Books.

85. Giovanna ID and Hayes G. (2001) *Principles of clinical research*. Petersfield, Wrighton Biomedical Publishing Ltd.

86. Wang D and Bakhai A. (2006) *Clinical trials: a practical guide to design, analysis and reporting*. London, Remedica.

87. *INVOLVE.* Available at: www.invo.org.uk. Last accessed: 11 July 2011.

88. *NIHR Research Support Services.* Available at: http://www.nihr.ac.uk/systems/Pages/Research_Support_Services.aspx. Last accessed: 11 July 2011.

89. *Medical Research Council - Translational Research.* Available at: http://www.mrc.ac.uk/Ourresearch/ResearchInitiatives/Translationalresearch/index.htm. Last accessed: 14 July 2011.

90. *Wellcome Trust - what is translational research?* Available at: http://www.wellcome.ac.uk/Funding/Technology-transfer/WTD027704.htm. Last accessed: 14 July 2011.

91. Farrell B. (2006) *A guide to efficient trial management*. London, UK Trial Management Network.

92. *Pharmacovigilance and drug safety.* Available at: http://www.pharmacovigilance.org.uk/. Last accessed: 14 July 2011.

93. *Medicines and Healthcare products Regulatory Agency - Good pharmacovigilance practice.* Available at: http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodPharmacovigilancePractice/index.htm. Last accessed: 14 July 2011.

94. Happell B. (2008) Writing for publication: a practical guide. *Nursing Standard*. 22(28), 35-40.

95. Happell B. (2008) Conference presentations: a guide to writing the abstracts. *Nurse Researcher*. 15(4), 79-87.

96. Happell B. (2008) From conference presentation to journal publication: a guide. *Nurse Researcher*. 15(2), 40-48.

97. Keen A. (2007) Writing for publication: pressures, barriers and support strategies. *Nurse Education Today*. 27(5), 382-388.

98. *Medicines for Human Use (Clinical Trials) Regulations 2004.* Available at: www.opsi.gov.uk/si/si2004/20041031.htm. Last accessed: 11 July 2011.

99. *Adults With Incapacity (Scotland) Act 2000.* Available at: www.opsi.gov.uk/legislation/scotland/acts2000/asp_20000004_en_1. Last accessed: 11 July 2011.

100. *Human Rights Act 2004.* Available at: www.opsi.gov.uk/si/si2004/draft/20049193.htm. Last accessed:

101. *Human Tissue (Scotland) Act 2006.* Available at: www.opsi.gov.uk/legislation/scotland/acts2006/asp_20060004_en_1. Last accessed: 11 July 2011.

102. *Human Tissue Act 2004.* Available at: www.opsi.gov.uk/ACTS/acts2004/ukpga_20040030_en_1. Last accessed: 11 July 2011.

103. *The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) Regulations 2008.* Available at: www.opsi.gov.uk/si/si2008/uksi_20080941_en_1. Last accessed: 11 July 2011.

104. Horowitz A. (2001) Role of the FDA, NIH and other bodies in the United States. In: Lock S, Wells F and Farthing M. (Editors). *Fraud and misconduct in biomedical research*. 3rd Edition. London, BMJ Books.

105. *US Food and Drug Administration.* Available at: www.fda.gov. Last accessed: 11 July 2011.

106. Watts G. (2008) Getting the best from research funding. *British Medical Journal*. 336(7636), 120-122.

107. *UK Clinical Research Network Costing Template.* Available at: www.ukcrn.org.uk/index/industry/costing.html. Last accessed:

108. *Medical Research Council Experimental Medicine Tool Kit.* Available at: www.em-toolkit.ac.uk. Last accessed: 11 July 2011.

109. Medical Research Council. (1998) *Guidelines for good clinical practice in clinical trials*. London, MRC.

110. *Good Clinical Practice.* Available at: www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodClinicalPractice. Last accessed: 11 July 2011.

111. Redsell SA and Cheater FM. (2001) The Data Protection Act (1998): implications for health researchers. *Journal of Advanced Nursing*. 35(4), 508-513.

112. Wells F and Farthing M. (2008) *Fraud and misconduct in biomedical research*. 4th Edition. London, Royal Society of Medicine Press.

113. *Medicines and Healthcare Products Regulatory Agency - Audit.* Available at: www.mhra.gov.uk/Howweregulate. Last accessed: 11 July 2011.

114. *Medical Research Council Data and Tissues Tool Kit.* Available at: www.dt-toolkit.ac.uk. Last accessed: 11 July 2011.

115. Medical Research Council. (2000) *Personal information in medical research*. London, MRC.

116. *Data Protection Act 1998.* Available at: www.opsi.gov.uk/Acts/Acts1998/ukpga_19980029_en_1. Last accessed: 11 July 2011.

117. Boyd P. (2003) The requirements of the Data Protection Act 1998 for the processing of medical data. *Journal of Medical Ethics*. 29(1), 34-35.

118. *National Information Governance Board (NIGB).* Available at: http://www.nigb.nhs.uk/. Last accessed: 11 July 2011.

119. Medical Research Council. (2001) *Human tissue and biological samples for use in research: operational and ethical guidelines*. London, MRC.

120. Medical research Council. (2001) *Human tissue and biological samples for use in research*. London, MRC.

121. Department of Health. (1997) *The Caldicott Committee: Report of the Review of Patient-Identifiable Information*. London, Department of Health.

Appendix: Competency Working Group for second edition

The following were members of the Working Group involved in the revision and preparation of the second edition of the Competency Framework:

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