IRISH RESEARCH NURSES NETWORK

CLINICAL RESEARCH NURSE COMPETENCY PACK

November 2015

Research Nurse Competency Pack

Version 1

November 2015

Launched at the 8th Annual Conference of the

Irish Research Nurses Network

12th November 2015

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1.0 Introduction

Clinical research activity in Ireland is increasing, and in parallel the number of research nurses[1] with varying levels of experience is also growing. The Irish Research Nurses Network (IRNN) identified the need to develop a competency framework as a tool to aid learning and development for clinical research nurses as part of its commitment to support the educational and professional needs of clinical research nurses (CRNs) in Ireland. It is anticipated that this document will support research nurses in achieving the optimum level of competence to function safely and confidently in their role. Although currently there is no recognised career progression for research nurses and grading of appointments are on a case by case/unit basis, the IRNN would expect that standardisation of competencies across all clinical research facilities/centres in Ireland will place individual nurses in a stronger position to justify career promotion dependent on level of competency achieved.

We would like to acknowledge the UK Clinical Research Facility (UKCRF) Network who kindly allowed us to adapt sections from their competency framework documents for inclusion in this folder, for which we are most grateful.

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For more information about the Irish Research Nurses Network see : http://irnn.ie

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[1] The terms 'nurses', 'research nurse' or 'clinical research nurse' used throughout this document refers to both research nurses and/or research midwives

1.1 What is a competency?

For the purposes of this framework 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 role. This involves problem solving and being sufficiently flexible to meet changing demands."[1]

The purpose of this competency framework document is to enable a nurse working in the area of clinical research to:

- Understand more clearly what is expected of them in their role
- Identify personal development needs
- Provide evidence of achievements to support career development and progression.
- Employ a tool to improve and develop performance

Competencies are described as the building blocks that shape nursing in all clinical and practice settings. As nurses acquire skills, knowledge, understanding and confidence in their area of practice they are able to demonstrate how they meet the increasing levels of competence, from novice to advanced practitioner.

1.2 Using the IRNN Competency Framework

The competencies incorporated in this framework indicate the expected progression for the development of the individual as a clinical research nurse. It provides the opportunity for the research nurse to document their progress and provide evidence of achievement as well as the opportunity to reflect on how they apply their theoretical knowledge to practice. The framework helps to develop the research nurse from novice to advanced practitioner in individual topics allowing the nurse to plan their progression through the different levels. The framework should be adaptable to reflect the existing skills of the individual nurse and is not aimed primarily at those new to the role. It should also be used by more experienced nurses to identify gaps in their knowledge and skills and to assist in the progression towards achieving the level of expert practitioner. The framework is not exhaustive and can be revised to meet changes in research legislation and practice and for the addition of practical study specific competencies. It should also be noted that the competencies presented in this document focus on the core knowledge and skills unique to the role of CRNs. Clinical

skills assessment strategies may be developed using the UKCRF competency assessment tools for single or multiple assessments (Appendix 1).

The Competency Framework has been developed to assist research nurses in developing their knowledge and skills and to aid progression through the career pathways, and to assist line managers in identifying when individuals have sufficient knowledge and skills to enable career progression to a more senior role. Therefore, each competency begins at novice level and progresses to the competency expected of an advanced practitioner (Table 1). The IRNN suggest aligning these competencies to nursing grades as detailed in Table 1.

Table 1: Categorisation

Level	Category	Definition	Job grade
N	Novice	Requires induction Limited knowledge and experience Requires theoretical knowledge Requires training, observation and supervision	Staff nurse
S	Supported	Possesses knowledge and experience Able to perform in area but requires guidance	Staff nurse
C	Competent	Knowledgeable and experienced within the role Able to assess situations identifying where additional support is required	Senior staff nurse/CNM1
E	Expert	Expert practitioner uses knowledge, skills and experience to provide optimal service	CNM 2 or CNS
AP	Advanced Practitioner	Leader in the field with advanced level knowledge and skills	CNM 3 / ADON/ Operations Manager

1.3 Assessment

The assessment of competency should be performed in partnership with an assigned mentor. Each research nurse is expected to assess their own performance by evaluating their knowledge, skills and experience in each of the key competencies. Additionally, the mentor will be responsible for confirming the level of competency attained and sign off at

each level. As they progress through the competency framework the research nurse and the mentor will rank attainment according to the categories outlined in Table 1. There are a variety of ways which the nurse may provide evidence of achieving competence; these are detailed in Table 2.

Table 2: Demonstrating Competence

Evidence	Example
Direct Observation	Observing/shadowing other research nurses at competent, expert or advanced practitioner level
Simulation	Practical sessions providing the opportunity for individuals to practice competency demonstration in controlled supervised environment, e.g. CRF Workshops, emergency scenario training
Testimony of others	Verbal or written feedback from colleagues, investigators research participants and research sponsors
Discussion	Questioning competent, experts or advanced practitioners, Agendas and Minutes of meetings,
Reflection	Personal Professional Portfolio, Case Studies
Project Management	Project plans, pro-forma development, SOP writing, monitoring reports, data query response timelines, recruitment targets, site file, protocol review, ethical approval submissions, HPRA submissions
Documentation	Letters, email management, notes work books working files
Teaching	Copies of presentations given and evaluation of sessions
Assignments	Evidence from formal academic programmes
Education	Training log, objectives of courses study days attended, literature review, internet search
Work Product	Implementing change, Action following policy or legislative review, risk management, Producing SOPs, QA Tools
Presentations / publication	National / international presentation / publication Presentations to PI on research progress

1.4 Expectation

It is not the expectation that all research nurses will achieve the same level of competency in all of the research competencies identified in the framework; however it is expected that competency is achieved in all competencies that are relevant to their individual role.

SECTION 2 Research Nurse Competencies

Research Nurse Key Competencies Skill Level Summary

Key competency skill level should be assessed by the individual and line manager.

Level attained should be signed and dated by both individual and Line Manager

Record to be kept as part of Portfolio

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

Skills and behaviours	Knowledge and understanding
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 the Irish healthcare setting.	History of ethics related to clinical research [2-12]. Development of research ethics and governance [13-16]. Methodological developments in clinical research [17-20]. Political and strategic developments in clinical research [21,22].

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

	Evidence of achievement	Date
Novice; Requires induction Limited knowledge and experience Requires theoretical knowledge Requires training, observation and supervision	Mentor (Print & Sign name):	
Supported; Possesses knowledge and experience Able to perform in area but requires guidance	Mentor (Print & Sign name):	
Competent; Knowledgeable and experienced within the role Able to assess situations identifying where additional support is required	Mentor (Print & Sign name):	
Expert; Expert practitioner uses knowledge, skills and experience to provide optimal service	Mentor (Print & Sign name):	
Advanced practitioner; Leader in the field with advanced level knowledge and skills	Mentor (Print & Sign name):	

Competence 2: To work within the regulation framework

2.1 Understands the role and remit of research ethics committees

Skills and behaviours	Knowledge and understanding
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]. Undertakes completion of ethics submissions	Structure and policy for the regulation of research [23, 24]. Roles and responsibilities of RECs [14, 24]. Structure and organisation of RECs and their membership [14, 22-25]. Processes for the submission of applications and their review [14,22, 26]. Local policies and procedures related to ethical review and research governance [22, 24]. Local and national policy developments [25]. Roles and responsibilities of investigators and other members of the research team [22,26]. Knowledge of procedures when breaches of protocol are identified or when fraud and misconduct is suspected [22, 27-29]. Actions required when processes to protect participant confidentiality are not followed [30, 31].

Assessment of Competence 2.1: Understands the role and remit of research ethics committees

	Evidence of achievement	Date
Novice; Requires induction Limited knowledge and experience Requires theoretical knowledge Requires training, observation and supervision	Mentor (Print & Sign name):	
Supported; Possesses knowledge and experience Able to perform in area but requires guidance	Mentor (Print & Sign name):	
Competent; Knowledgeable and experienced within the role Able to assess situations identifying where additional support is required	Mentor (Print & Sign name):	
Expert; Expert practitioner uses knowledge, skills and experience to provide optimal service	Mentor (Print & Sign name):	
Advanced practitioner; Leader in the field with advanced level knowledge and skills	Mentor (Print & Sign name):	

2.2 Contributes to the preparation of submissions for regulatory reviews

Skills and behaviours	Knowledge and understanding
Demonstrates awareness of the application processes for competent authority approval e.g. Health products Regulatory Authority (HPRA) and requirements for document management. Leads or contributes to the preparation of paperwork and submission of applications. Leads on trial registration on a public registry e.g. clinicaltrials.gov Maintains accuracy of information on registry and updates in a timely manner.	REC and R&D application processes [14, 31]. Other centralised permissions [21]. Key documentation required to support REC and R&D submissions. Protocol development Local review and reporting of research studies. Clinical Research Agreements, Risk assessment and feasibility. Local and national policy developments. Research sponsorship and researcher roles [10]. Professional responsibilities and potential for conflict with research role [31-33].

Assessment of 2.2: Contributes to the preparation of submissions for regulatory reviews

	Evidence of achievement	Date
Novice; Requires induction Limited knowledge and experience Requires theoretical knowledge Requires training, observation and supervision Mentor (Print & Sign name):		
Supported; Possesses knowledge and experience Able to perform in area but requires guidance Mentor (Print & Sign name):		
Competent; Knowledgeable and experienced within the role Able to assess situations identifying where additional support is required Mentor (Print & Sign name):		
Expert; Expert practitioner uses knowledge, skills and experience to provide optimal service Mentor (Print & Sign name):		
Advanced practitioner; Leader in the field with advanced level knowledge and skills Mentor (Print & Sign name):		

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

Skills and behaviours	Knowledge and understanding
Assures the provision of an environment conducive to obtaining valid informed consent.	Principles of informed consent for participation in research [35-38].
Delivers informed consent process in clinical environment	Roles of researchers, including CI and PI, in gaining and maintaining informed consent [10].
Demonstrates awareness of rationale for re-consent	Role of research nurses [39-42].
Demonstrates knowledge of the timelines for re-consent to occur	Role of the REC [14, 24, 43, 44].
Demonstrates awareness of consent process for vulnerable groups	Key information required in Patient Information sheets and informed consent forms [10, 22, 38, 45-48].
Demonstrate knowledge of key elements that should be discussed with the subject during the consent process	Ongoing nature of informed consent.
Contributes to policy and practice development.	Legal requirements related to gaining and maintaining valid informed consent, especially when participants lack capacity [10].
Demonstrates awareness of and is responsive to factors contributing to decision making during the consent process.	Local policies and procedures relating to gaining and maintaining valid informed consent [38].
Assures patient safety by proactively managing any breaches of the informed consent process.	

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

	Evidence of achievement	Date
Novice; Requires induction Limited knowledge and experience Requires theoretical knowledge Requires training, observation and supervision	Mentor (Print & Sign name):	
Supported; Possesses knowledge and experience Able to perform in area but requires guidance	Mentor (Print & Sign name):	
Competent; Knowledgeable and experienced within the role Able to assess situations identifying where additional support is required	Mentor (Print & Sign name):	
Expert; Expert practitioner uses knowledge, skills and experience to provide optimal service	Mentor (Print & Sign name):	
Advanced practitioner; Leader in the field with advanced level knowledge and skills	Mentor (Print & Sign name):	

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
Demonstrates an understanding of the research designs and methodologies used in clinical research.	The need for Quality Assurance [48, 49].
	Phases of clinical research [50, 51].
Plays a central role in the design and logistic planning of internal and or collaborative research studies/projects	Different research study designs: including protocol design and development; sample size and power; inclusion and exclusion criteria; randomisation; blinding and unblinding [28, 52, 53].
Demonstrates an understanding of the implications for practice of the regulatory and legal frameworks related to the planning, delivery and closure of clinical research studies.	Recruitment strategies [52-57]
Demonstrates a comprehensive knowledge and understanding of the regulatory and legal frameworks related to the planning, undertaking and closure of clinical research studies.	Translational research [58, 59].
	Multi-centre studies.
Encourages, appreciates and values the contribution of study participants in all areas of research activity.	Management processes, from feasibility to closure [28].
Conducts or partakes in aspects of clinical research activity with the clinical investigator	Pharmacovigilance [60, 61].
	Local, national and international dissemination of clinical research findings [62-65].
Conducts independent research project	Relevant Irish legislation [66].
Prepares and presents results from clinical research studies at relevant national/international conferences	Professional codes of practice [33].
Writes or contributes to the write up of articles for publication	Roles of licensing authorities and the licensing of investigational products. Local requirements, policies and procedures.

Assessment of Competence 4.1: Contribute to the development and facilitation of clinical research

	Evidence of achievement	Date
Novice; Requires induction Limited knowledge and experience Requires theoretical knowledge Requires training, observation and supervision	Mentor (Print & Sign name):	
Supported; Possesses knowledge and experience Able to perform in area but requires guidance	Mentor (Print & Sign name):	
Competent; Knowledgeable and experienced within the role Able to assess situations identifying where additional support is required	Mentor (Print & Sign name):	
Expert; Expert practitioner uses knowledge, skills and experience to provide optimal service	Mentor (Print & Sign name):	
Advanced practitioner; Leader in the field with advanced level knowledge and skills	Mentor (Print & Sign name):	

4.2 Contribute to effective and efficient use of resources

Skills and behaviours	Knowledge and understanding
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. Plans and/or maps out project logistic map for clinical research project (involves realistic considerations regarding points of access for target populations, recruitment numbers versus time (recruitment window), visit duration/frequency, implications of longitudinal data capture, resource utilisation (personnel/equipment) & realistic access to these over time, on-site versus remote assessment etc...) Plans and/or prepares budget for clinical research project	Funding of research studies [67]. Financial agreements [68]. Financial management during the course of a clinical research study [68]. Identification of costs. Role of the research funder. National and local research costing models. Local employment policies and models of working.

Assessment of Competence 4.2: Contribute to effective and efficient use of resources

	Evidence of achievement	Date
Novice; Requires induction Limited knowledge and experience Requires theoretical knowledge Requires training, observation and supervision	Mentor (Print & Sign name):	
Supported; Possesses knowledge and experience Able to perform in area but requires guidance	Mentor (Print & Sign name):	
Competent; Knowledgeable and experienced within the role Able to assess situations identifying where additional support is required	Mentor (Print & Sign name):	
Expert; Expert practitioner uses knowledge, skills and experience to provide optimal service	Mentor (Print & Sign name):	
Advanced practitioner; Leader in the field with advanced level knowledge and skills	Mentor (Print & Sign name):	

4.3 Facilitate the delivery of clinical research

Skills and behaviours	Knowledge and understanding
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.

Understand the rationale behind adherence to HPRA guidelines.

Adhere to data protection regulations.

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 [48].

Standard Operating Procedures (SOPs) [69].

Relevant clinical skills in line with local procedures and national occupational standards.

Knowledge of research study protocol.

Knowledge of data protection regulations.

Processes for participant recruitment.

Risk Management.

Public involvement in research [52, 70].

Local organisational policies and procedures. |

Assessment of Competence 4.3: Facilitate the delivery of clinical research

	Evidence of achievement	Date
Novice; Requires induction Limited knowledge and experience Requires theoretical knowledge Requires training, observation and supervision	Mentor (Print & Sign name):	
Supported; Possesses knowledge and experience Able to perform in area but requires guidance	Mentor (Print & Sign name):	
Competent; Knowledgeable and experienced within the role Able to assess situations identifying where additional support is required	Mentor (Print & Sign name):	
Expert; Expert practitioner uses knowledge, skills and experience to provide optimal service	Mentor (Print & Sign name):	
Advanced practitioner; Leader in the field with advanced level knowledge and skills	Mentor (Print & Sign name):	

4.4 Contribute to effective study care co-ordination

Skills and behaviours	Knowledge and understanding
Facilitates the education of the interdisciplinary team on protocol directed study requirements. Collaborates with the research and interdisciplinary team to plan study conduct that allows for safe and effective collection of clinical research data Coordinates research participant study visits Co-ordinates the scheduling of study related tests Fulfils all delegated study responsibilities effectively and efficiently Demonstrates nursing leadership within the interdisciplinary team Coordinates referrals to appropriate interdisciplinary services outside the immediate research team Coordinates interdisciplinary study related meetings and activities. Communicates the impact of study procedures on the research participants Provides nursing expertise to health care personnel not directly involved in the study but involved in the care of study participants Identifies and addresses research participant inquiries and concerns	Understand the importance of coordinating research study activities while meeting individual clinical needs Knowledge of research study protocol. Comprehensive understanding of the roles and responsibilities of key personnel within the clinical research environment. Awareness of the clinical environment and research personnel interactions with the wider clinical setting. Importance of managing linkage with interdisciplinary referring and primary care providers. Knowledge of data protection regulations. Processes for participant recruitment.

Assessment of Competence 4.4: Contribute to effective study care co-ordination

	Evidence of achievement	Date
Novice; Requires induction Limited knowledge and experience Requires theoretical knowledge Requires training, observation and supervision Mentor (Print & Sign name):		
Supported; Possesses knowledge and experience Able to perform in area but requires guidance Mentor (Print & Sign name):		
Competent; Knowledgeable and experienced within the role Able to assess situations identifying where additional support is required Mentor (Print & Sign name):		
Expert; Expert practitioner uses knowledge, skills and experience to provide optimal service Mentor (Print & Sign name):		
Advanced practitioner; Leader in the field with advanced level knowledge and skills Mentor (Print & Sign name):		

4.5 Study management

Skills and behaviours	Knowledge and understanding
Participate in research participant recruitment	Knowledge of effective recruitment strategies
Participate in screening potential research participants for eligibility	Quality assurance
Develop study specific materials for research participant education	Understanding timeframes surrounding participant study related visits.
Contribute to the development of case report forms	Understanding the importance of maintaining site files
Perform quality assurance activities to assure data integrity	Development of study specific standard operating procedures (SOP's)
Demonstrates effective accurate communication among research team and research sites	
Participates in the set-up of a study specific database	
Facilitate scheduling and coordination of study procedures.	
Ensure completion of study procedures in the right order and in a timely manner	
Oversee human resources (people) related to research process	
Record and store data on approved study documents	
Identify clinical care implications during study development (Example: staff competencies and resources, equipment, etc.	

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Assessment of Competence 4.5: Study management

	Evidence of achievement	Date
Novice; Requires induction Limited knowledge and experience Requires theoretical knowledge Requires training, observation and supervision	Mentor (Print & Sign name):	
Supported; Possesses knowledge and experience Able to perform in area but requires guidance	Mentor (Print & Sign name):	
Competent; Knowledgeable and experienced within the role Able to assess situations identifying where additional support is required	Mentor (Print & Sign name):	
Expert; Expert practitioner uses knowledge, skills and experience to provide optimal service	Mentor (Print & Sign name):	
Advanced practitioner; Leader in the field with advanced level knowledge and skills	Mentor (Print & Sign name):	

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

Skills and behaviours	Knowledge and understanding
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. Demonstrates a knowledge and understanding of source data Undertakes data query completion Understands the role of the study monitor and organises and facilitates their visit to monitor research studies. Undertakes responding to data monitoring visit letters and reports Demonstrates knowledge on the appropriate procedures for entering and correcting written data Ensures the safe and secure storage of data. Participates in the preparation of reports for appropriate regulatory and monitoring bodies/boards Facilitating the monitoring process. Ensures participant's confidentiality. Abide by Data Protection Regulations	Roles of those involved in all aspects of research [38, 40]. Data insertion techniques, including the use of electronic data entry. Audio and other media as means of data. Source document verification. Fraud and misconduct [71]. Audit and monitoring of data [72]. The process of inspections [61]. Local and national policies and procedures relating to data collection and safe transfer [30, 72]. Actions required when processes to protect confidentiality are not adhered to [30].

Assessment of Competence 4.6: Contribute to the safe collection and storage of data and accurate completion of study documentation

	Evidence of achievement	Date
Novice; Requires induction Limited knowledge and experience Requires theoretical knowledge Requires training, observation and supervision	 Mentor (Print & Sign name):	
Supported; Possesses knowledge and experience Able to perform in area but requires guidance	 Mentor (Print & Sign name):	
Competent; Knowledgeable and experienced within the role Able to assess situations identifying where additional support is required	 Mentor (Print & Sign name):	
Expert; Expert practitioner uses knowledge, skills and experience to provide optimal service	 Mentor (Print & Sign name):	
Advanced practitioner; Leader in the field with advanced level knowledge and skills	 Mentor (Print & Sign name):	

4.7 Management and handling of biological specimens

Skills and behaviours	Knowledge and understanding

Coordinate and facilitate the collection of research specimens
 	
Undertakes/demonstrates training in handling of hazardous material and sample management
 	
Undertakes training in phlebotomy and demonstrates ability in phlebotomy
 	
Demonstrates ability to set-up, and maintain a working relationship with relevant laboratories who will process research specimens taking into account:
1.   Nature of trial (trial team blind to the results)
2.   Time to process samples (for example one day turnaround)
3.   Where and how results should be sent to identified individual
 	
Demonstrates ability to process specimens
    1. Knowledge of and access to procedure manual
    2. Demonstrate ability to centrifuge specimens
    3. Demonstrate ability to complete laboratory requisition forms
 	
Demonstrates understanding and process of
    1. sample storage in appropriate temperature
    2. completion of appropriate sample tracking logs
 	
Demonstrate the ability to ship biological materials.
    1. Contact courier
    2. Use appropriate account number
    3. Package specimen according to requirement
    4. Use correct shipping labels, airways bills and invoices.
	Individual Study requirements
	
	Local laboratory standard operating procedures
	
	Appropriate personal protective clothing when
	    1. handling biological specimens
	    2. storing in -80 freezer conditions
	    3. when preparing for shipment
	
	Handling of hazardous biological materials.

Assessment of Competence 4.7: Management and handling of biological specimens

	Evidence of achievement	Date
Novice; Requires induction Limited knowledge and experience Requires theoretical knowledge Requires training, observation and supervision	Mentor (Print & Sign name):	
Supported; Possesses knowledge and experience Able to perform in area but requires guidance	Mentor (Print & Sign name):	
Competent; Knowledgeable and experienced within the role Able to assess situations identifying where additional support is required	Mentor (Print & Sign name):	
Expert; Expert practitioner uses knowledge, skills and experience to provide optimal service	Mentor (Print & Sign name):	
Advanced practitioner; Leader in the field with advanced level knowledge and skills	Mentor (Print & Sign name):	

4.8 Safety reporting

Skills and behaviours	Knowledge and understanding
Demonstrates knowledge of definitions of serious adverse events During patient assessment demonstrates ability to identify potential serious adverse events and initiates investigator evaluation of these in a timely manner Ensures serious adverse events are reported within the required time lines to the appropriate authority Compiles clinical information from all applicable sources to provide accurate data when reporting serious adverse events Demonstrates evidence of completion of serious adverse events report forms Demonstrates evidence of following up serious adverse events to closure as per protocol requirements Completes all associated documentation (e.g. concomitant medication records)	Knowledge and understanding of responsibilities of investigator in managing Serious Adverse Events. Knowledge and understanding of definition of serious adverse events Knowledge and understanding of the times lines for SAE reporting Knowledge and understanding of location and completion of serious adverse event forms and follow up query forms Knowledge and understanding of using the fax machine or other electronic reporting systems (dependent on research study) to report serious adverse events

Assessment of Competence 4.8: Safety reporting

	Evidence of achievement	Date
Novice; Requires induction Limited knowledge and experience Requires theoretical knowledge Requires training, observation and supervision	Mentor (Print & Sign name):	
Supported; Possesses knowledge and experience Able to perform in area but requires guidance	Mentor (Print & Sign name):	
Competent; Knowledgeable and experienced within the role Able to assess situations identifying where additional support is required	Mentor (Print & Sign name):	
Expert; Expert practitioner uses knowledge, skills and experience to provide optimal service	Mentor (Print & Sign name):	
Advanced practitioner; Leader in the field with advanced level knowledge and skills	Mentor (Print & Sign name):	

REFERENCES:

1. **UK CRF Competency Framework Working Group. Competency framework for clinical research nurses 2011** http://www.crn.nihr.ac.uk/wpcontent/uploads/Learning%20and%20development/Research%20Nurse%20Competency%20Framework-Oct2011.pdf
2. **Spitz V. (2005)** *Doctors from hell: the horrific account of Nazi experiments on humans*. **Colorado, Sentient Publications.**
3. *Nuremberg Code.* **Available at:** www.cirp.org/library/ethics/neuremburg/
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 reappraisal.** *Journal of American Medical Association*. **276(20), 1662-1666.**
6. **Kious BM. (2001) The Nuremberg Code: its history and implications.** *Princeton Journal of Bioethics*. **4, 7-19.**
7. **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.**
8. **Tadd W. (2000) The Declaration of Helsinki: why all the fuss?** *Nursing Ethics*. **7(5), 439-450.**
9. **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.**
10. *International Conference on Harmonisation Good Clinical Practice.* **Available at:** http://ichgcp.net/
11. **Goliszek A. (2003)** *In the name of science: a history of secret programs, medical research, and human experimentation*. **New York, St Martin's Press.**
12. **Barth KL. (2005)** *Human medical trials*. **Greenhaven Press.**
13. *Declaration of Helsinki.* **Available at:** www.wma.net/en/20activities/10ethics/10helsinki/
14. **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.**
15. *History of research ethics.* **Available at:** http://research.unlv.edu/ORI-HSR/historyethics.htm
16. **Jenkins J and Hubbard S. (1991) History of clinical trials.** *Seminars in Oncology Nursing*. **7(4), 228-234.**
17. **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.**
18. *The Evolution of the Clinical Trials Process – A Brief History Lesson.* **Available at:** http://www.psoriasiscouncil.org/chapter_pdfs/chapter_01.pdf.
19. *A brief history of clinical trials.* **Available at:** http://genome.wellcome.ac.uk/doc_WTD020948.html.
20. **Hoey R. (2007) The EU Clinical Trial Directive: 3 years on.** *The Lancet*. **369, 1777-1778.**
21. **Health Products Regulatory Authority, Ireland.** http://www.hpra.ie/
22. *Directive 2001/20/EC of the European Parliament and of the Council 4 April 2001.* **Available at:** http://www.irishstatutebook.ie/2004/en/si/0109.html
23. **The Academy of Medical Sciences. (2011)** *A new pathway for the regulation and governance of health research*. **London, The Academy of Medical Sciences.**
24. **Review of Research Ethics Committees & Processes in the Republic of Ireland. HSE Research Ethics Committees Review Group, 2008** http://www.hse.ie/eng/services/Publications/corporate/etr/Review_of_Research_Ethics.pdf
25. **Irish Universities Association. National policy statement on Ensuring Research Integrity in Ireland. 2014** http://www.iua.ie/wp-content/uploads/2014/06/National-Policy-Statement-on-Ensuring-Research-Integrity-in-Ireland-2014.pdf
26. **European Commission. (2006)** *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. Available at: http://ec.europa.eu/health/files/eudralex/vol-10/12-ec-guideline-20060216-en.po4

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

28. 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.

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

30. Data Protection (Amendment) Act 2003 http://www.irishstatutebook.ie/2003/en/act/pub/0006/index.html

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

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

33. Nursing and Midwifery Board of Ireland (NMBI). The Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives 2014. http://www.nursingboard.ie/en/code/new-code.aspx

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

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

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

37. 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.

38. Health Service Executive (HSE). National Consent Policy QPSD-D-026-1.1. V.1.1. 2013 http://www.hse.ie/eng/about/Who/qualityandpatientsafety/National_Consent_Policy/consenttrainerresource/trainerfiles/NationalConsentPolicyM2014.pdf

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

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

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

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

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

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

45. *Language Awareness Infrastructure Support Services.* Available at: http://www.llais.org/.

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

47. National Adult Literacy Agency. Policy brief; Use of plain English in written communications 2009. https://www.nala.ie/sites/default/files/publications/NALA%20policy%20paper%20on%20plain%20English_1.pdf

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

49. 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.

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

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

52. *INVOLVE.* Available at: www.invo.org.uk.

53. *Medical Research Council - Translational Research.* Available at: http://www.mrc.ac.uk/Ourresearch/ResearchInitiatives/Translationalresearch/index.htm.

54. **Adams M, Caffrey L, McKevitt C. (2015** *Barriers and opportunities for enhancing patient recruitment and retention in clinical research: findings from an interview study in an NHS academic health science centre*. **Health Res Policy Syst. Mar 12;13(1):8**

55. **Newington L, Metcalfe A. (2014).** *Factors influencing recruitment to research: qualitative study of the experiences and perceptions of research teams.* **BMC Med Res Methodol. Jan 23;14:10**

56. **Bower P, Brueton V, Gamble C, Treweek S, Smith CT, Young B, Williamson P. (2014).** *Interventions to improve recruitment and retention in clinical trials: a survey and workshop to assess current practice and future priorities.* **Trials. Oct 16;15:399**

57. **Luzurier Q, Damm C, Lion F, Daniel C, Pellerin L, Tavolacci MP. (2015).** *Strategy for recruitment and factors associated with motivation and satisfaction in a randomized trial with 210 healthy volunteers without financial compensation.* **BMC Med Res Methodol. Jan 5;15:2**

58. *Wellcome Trust - what is translational research?* **Available at: http://www.wellcome.ac.uk/Funding/Technology-transfer/WTD027704.htm.**

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

60. *Pharmacovigilance and drug safety.* **Available at: http://www.pharmacovigilance.org.uk/.**

61. **Health Products Regulatory Authority, Ireland http://www.hpra.ie/homepage/medicines/special-topics/new-eu-pharmacovigilance-legislation**

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

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

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

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

66. **Clinical Trials on Medicinal Products for Human Use Regulations 2004 http://www.irishstatutebook.ie/2004/en/si/0190.html**

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

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

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

70. **Irish Platform for Patients' Organisations, Science & Industry (IPPOSI) at http://www.ipposi.ie/**

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

72. **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.**

Appendix 1

**UKCRF Competency
Assessment Templates**

**Word versions of these
templates are available on
request via the IRNN website**

Insert Hospital Name/ Logo

Single Competency Assessment for
Insert title of competency here

Staff Group(s):	
Version Number & Date:	**Review Date:**
Related to SOP:	

Author of Template: **Designation:**	**Signature:**	**Date:**
Expert Authorisation: **Designation:**	**Signature:**	**Date:**
Name of Assessee: **Designation:**		**This is a Single Competency Assessment**

Assessment

Assessor Name:

Designation:

Signature:

Initials:

Date of Assessment:

Title of Competency Assessment: *Insert title*

Name of Assessee: *Insert name*

K/S/B[1]	Competency Statement Components of the overall competency i.e. knowledge, skills and behaviour required	Assessment Criteria Evidence required	Assessment	
			Achieved Y / N	**Initials of Assessor**
			Y / N: Assessor's comments:	Initials:
			Y / N: Assessor's comments:	Initials:
			Y / N: Assessor's comments:	Initials:
			Y / N: Assessor's comments	Initials:
			Y / N: Assessor's comments:	Initials:

[1]K=Knowledge, S=Skills, B=Behaviour

Title of Competency Assessment: *Insert title*

Name of Assessee: *Insert name*

K/S/B[1]	Competency Statement Components of the overall competency i.e. knowledge, skills and behaviour required	Assessment Criteria Evidence required	Assessment	
			Achieved Y / N	Initials of Assessor
			Y / N:	Initials:
			Assessor's comments:	
			Y / N:	Initials:
			Assessor's comments:	
			Y / N:	Initials:
			Assessor's comment	

[1]K=Knowledge, S=Skills, B=Behaviour

Add further lines as required for the competency you wish to populate.

Multiple Competency Assessment for
Insert title of competency here

Staff Group(s):	

Version Number & Date:		**Review Date:**
Related to SOP:		

Author of Template: **Designation:**	**Signature:**	**Date:**
Expert Authorisation: **Designation:**	**Signature:**	**Date:**

Name of Assessee **Designation:**	**Number of achieved competency assessments required in order to be signed off as competent:**

Assessment 1	**Assessment 2**	**Assessment 3**
Assessor Name: Designation: Signature: Initials: Date of Assessment:	Assessor Name: Designation: Signature: Initials: Date of Assessment:	Assessor Name: Designation: Signature: Initials: Date of Assessment:

Title of Competency Assessment: *Insert title*

Name of Assessee: *Insert name*

K/S/B[1]	Competency Statement	Assessment Criteria	Assessment 1		Assessment 2		Assessment 3	
	Components of the overall competency i.e. knowledge, skills and behaviour required	Evidence required	Achieved Y / N	Initials of Assessor	Achieved Y / N	Initials of Assessor	Achieved Y / N	Initials of Assessor
			Y / N:	Initials:	Y / N:	Initials:	Y / N:	Initials:
			Assessor's comments		Assessor's comments:		Assessor's comments	
			Y / N:	Initials:	Y / N:	Initials:	Y / N:	Initials:
			Assessor's comments:		Assessor's comments:		Assessor's comments:	

[1]K=Knowledge, S=Skills, B=Behaviour

Add further lines as required for the competency you wish to populate.

Competency Assessment Record

(requiring multiple competency assessment in order to be signed off as competent)

Insert title of competency here

Assessor – Assessment 1	
Date of Competency Assessment:	Attempt Number:
Have all the components of the competency assessment been achieved: Yes / No *(delete as appropriate)*	
The assessee named below has been assessed as having / not having (delete as appropriate) the appropriate knowledge, skills & behaviours for the above competency at this assessment: **Assessor** Name: Comments*: Designation: Signature: Date: *Where further assessments are required, please specify and consider giving time frame. Where multiple assessments have been attempted and competency has not been achieved, consider review with line manager as appropriate	

Assessee – Assessment 1
Assessee Name: Comments: Designation: Signature: Date:

Competency Assessment Record

(requiring multiple competency assessment in order to be signed off as competent)

Insert title of competency here

Assessor – Assessment 2	
Date of Competency Assessment:	Attempt Number:
Have all the components of the competency assessment been achieved: Yes / No *(delete as appropriate)*	
The assessee named below has been assessed as having / not having (delete as appropriate) the appropriate knowledge, skills & behaviours for the above competency at this assessment: **Assessor** Name: Comments:* Designation: Signature: Date: *Where further assessments are required, please specify and consider giving time frame. Where multiple assessments have been attempted and competency has not been achieved, consider review with line manager as appropriate	

Assessee – Assessment 2
Assessee Name: Comments: Designation: Signature: Date:

Competency Assessment Record

(requiring multiple competency assessment in order to be signed off as competent)

Insert title of competency here

Assessor – Assessment 3	
Date of Competency Assessment:	Attempt Number:
Have all the components of the competency assessment been achieved: Yes / No *(delete as appropriate)*	
The assessee named below has been assessed as having / not having (delete as appropriate) the appropriate knowledge, skills & behaviours for the above competency at this assessment:	
Assessor Name: Comments*:	
Designation: Signature: Date:	
*Where further assessments are required, please specify and consider giving time frame. Where multiple assessments have been attempted and competency has not been achieved, consider review with line manager as appropriate	

Assessee – Assessment 3	
Assessee Name: Comments:	
Designation: Signature: Date:	

Competency Assessment Record

Insert title of competency here

Assessor Statement – final sign off
All the components of the competency assessment have been achieved on *(insert number here)* occasions.
The assessee named below has been assessed as having / not having (delete as appropriate) the appropriate knowledge, skills & behaviours for the above competency: **Assessor** Name: Comments*: Designation: Signature: Date: *Where further assessments are required, please specify and consider giving time frame. Where multiple assessments have been attempted and competency has not been achieved, consider review with line manager as appropriate
Assessee Statement – final sign off
I agree with the outcome of the competency assessment and I accept responsibility for being competent to undertake the task/s detailed above and for my ongoing maintenance of knowledge, skills and behaviours: **Assessee** Name: Comments: Designation: Signature: Date:

Reassessment period (if applicable), *e.g. every 2 years*	Reassessment date (for the candidate):

IRNN
Irish Research Nurses Network

CLINICAL RESEARCH NURSE COMPETENCY FRAMEWORK
Version 1 November 2015
IRISH RESEARCH NURSES NETWORK

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