



Post Specification

Post Title:	Research Assistant – CNM2 (Clinical Nurse Manager)
Post Status:	Specific Purpose Contract – 0.7 WTE
Research Group / Department / School:	Clinical Research Facility – School of Medicine
Location:	Clinical Research Facility, St. James' Hospital, Dublin 8 Ireland.
Reports to:	Assistant Director of Nursing
Salary:	HSE CNM2 PayScale Appointment will be made on Scale In line with HSE guidelines and research experience will be taken into consideration.
Hours of Work:	0.7 WTE 26.25 hrs per week, Monday to Thursday, it may be necessary to work outside these hours if the study/trial deems it necessary. Occasional weekend or night duty may be required.
Closing Date:	12 Noon (GMT), 27th February 2025

Please note that Garda vetting will be sought in respect of individuals who come under consideration for a post.

Post Summary

St. James's Hospital and Trinity College Dublin (TCD) secured funding from the Wellcome and the Health Research Board to build and operate a state-of the art clinical research facility (CRF) within St. James's Hospital. This facility opened earlier this summer.

The 1,300m² facility is located adjacent to the Centre for Advanced Medical Imaging (CAMI), the Institute of Cardiovascular Sciences and, once complete, the Centre for Successful Ageing. The CRF is jointly governed by St. James's Hospital and TCD and will function like other units and departments within the hospital. The CRF will be staffed to conduct high quality clinical research including trials of novel therapeutics, medical devices as well as investigator led academic studies involving patients and healthy volunteers.

The aim of the Wellcome – HRB Clinical Research Facility (CRF) at St. James's Hospital will be to provide the infrastructure, the physical space, facilities and expertise needed to support patient-focused research studies. Clinical Research is highly regulated and must be performed to the highest quality standard.

This cutting-edge facility provides a high quality, clinical environment, in which patients and healthy volunteers can take part in research programmes safely and effectively, according to robust and ethically approved protocols.

The post holder will have responsibility for managing all clinical research studies conducted within area of responsibility (CRF and outpatients), ensuring that studies are run to the highest standards incorporating Good Clinical Practice Guidelines. The post holder will also ensure that the highest standard of participant care is achieved within the clinical area.

The post holder will be the lead nurse responsible for clinical studies and in this role will liaise with clinical investigators to implement protocols within the clinical setting.

The post holder will deputise for the Assistant Director of Nursing where appropriate.

The post holder will undertake projects within the Clinical Research Facility as required to meet the needs of the service.

Standard Duties and Responsibilities of the Post

Clinical Management (60% of Time)

- Overseeing all research studies occurring within the unit or offsite –with particular attention to recruitment to target, informed consent process, adherence to protocol and ICH-GCP, ensuring good communication links with Principal Investigator and Sponsor, reporting of adverse events and serious adverse events.
- Troubleshooting with research nurses and PIs on studies that have low recruitment numbers, ensuring good communication links are established and maintained with the PI throughout the lifecycle of the study.
- Act as a resource and support to research nurses within the department and research teams using the CRF, advising on source documentation worksheets, recruitment strategies.
- Support research nurses throughout the study cycle from opening to closing studies.
- Active engagement with PIs on all studies in collaboration with the research nurse assigned to that study.
- Assisting with study protocol visits as required depending on service needs.
- Assisting with study set up and ensuring study timelines are met in a time efficient manner
- Assisting with study feasibilities with Principal Investigators, Sponsor and Clinical Research Co-ordination Ireland.
- Maintain effective communication with patients, carers and professionals to ensure high quality service delivery.
- Coordinate the collection of any biological samples required as part of the clinical trial/study and ensure safe and appropriate storage of specimens, in conjunction with study team members and CRF nursing teams.
- Ensure the safe administration of trial drugs, have in-depth knowledge of the legal requirements of a clinical trial sponsor regarding pharmacovigilance and of the Hospital pharmacovigilance policy. Report any adverse events and reactions in accordance with regulatory and hospital policy and the trial protocol and review events at CRF governance forum.
- At all times ensure maintenance of clear, accurate records, case report forms, study files for patient and staff records for team members.
- Implement and adhere to the principles of Good Clinical Practice (GCP) and ensure that all trials are conducted according to the Medicines for Human Use (Clinical Trial) Regulations 2004 and Amended Regulations 2006 where appropriate.
- Liaise with the relevant authorities such as ethics, HPRA to ensure approval is in place before the study commences.
- Participate in writing and updating local procedures such as Standard Operating Procedures in conjunction with ADON.
- Perform tasks requiring highly developed clinical skills including phlebotomy, cannulation, the administration of trial drugs, and other study specific interventions such as clamps and endoscopy and keep up to date with current practices.
- Oversee the routine maintenance and servicing of clinical equipment.
- Participate and oversee internal monitoring, Sponsor monitoring and regulatory audits such as the HPRA
- Participate in clinical audits such as hand hygiene, health and safety, risk assessments & inspections to maintain and improve clinical and research practice.

Educational (10% of Time)

- Ensure adequate and appropriate orientation training programs are available for all grades of staff across the unit including those required across research team members.
- Ensure CRF mandatory training and research specific training is undertaken and updated as required for all staff.
- Ensure team members are competent and have the required clinical skills to undertake studies within the portfolio, organizing additional skills training where required.
- Work on establishing key competencies for research nurses working within the CRF.
- Contribute to education and training events as appropriate.
- Work collaboratively with the hospital to ensure team has skills, knowledge and competence to deliver service excellence.
- Facilitate research/evidence based practice and support research projects.

Managerial (30% of Time)

- Act as clinical supervisor to junior research staff within the CRF and act as a role model for excellence in clinical research.
- Undertake acuity/intensity scoring of allocated studies prior to review at Operational meetings, including implications for staffing and existing service commitments, and review once study is live and at renewal.
- Report to the Nurse Manager and Operational Management Team any adverse incident/near misses in relation to research portfolio activity.
- Undertake study set up meetings with research teams for new studies ensuring approvals (HPRA, Ethics, and local applications) are in place and work with study coordinators to ensure that all study documents such as flow sheets and Standard Operating Procedures are in place before a study commences.
- Facilitate and maintain effective communication within the research clinical team and CRF staff.
- Responsibly manage the control of equipment, resources and stock through the adherence to research and local policies and clinical trials budgets.
- Work collaboratively with the Assistant Director of Nursing (ADON).
- Undertake annual performance review and appraisal of nursing team members, incorporating the Clinical Research Nurse Competency Framework.
- Manage staff performance in accordance with local policy.
- Assist ADON in the recruitment and selection of new staff.
- Deputize for ADON in their absence.
- Undertake project work as designated by ADON and provide regular feedback to CRF team through established communication forums.
- Ensure team members work to local and study specific standard operating procedures, auditing compliance as necessary.
- In conjunction with ADON, ensure effective rostering (when required), using the resources available to provide an appropriate skill mix for a safe and flexible service.
- Maintain an environment conducive to Health and Safety, undertaking and escalating outcomes from risk assessments and inspections as appropriate/delegated by ADON.
- Contributing to a pro-active, positive work culture
- Have an awareness of the strategic development plans for the CRF and work proactively to support new developments.
- Assist and develop a team approach to the day to day running of the CRF.
- Assist in attracting and developing pharmaceutical studies in the CRF.

Professional

- Be accountable for your own professional actions and be a lead specialist for portfolio acting within clearly defined policies/procedures and codes of conduct including the Nursing Scope of practice and local policies.
- Undertake a Personal Professional Development Planning (PPDP) and Objective Setting (OS) annually to identify Organisational and professional objectives and development needs.
- Keep up to date with departmental, local, national, academic and EU developments for the management of clinical research ensuring timely, effective implementation of changes.
- Maintain own competence in line with Clinical Research Nurse Competency Framework
- Attend courses as deemed relevant, including mandatory training, and to attend meetings and conferences as appropriate.
- Represent CRF as an expert research nurse in external situations such as national and international conferences, committees etc.

Funding Information

Funding for this post is from the main funder for the Wellcome – HRB Clinical HRB Clinical Research Facility at St. James’s Hospital in addition to grant funding from various grants from studies.

Person Specification

Qualifications Knowledge & Experience

The successful candidate would be required to have the following essential requirements:

- Registered General Nurse through Nursing and Midwifery Board of Ireland (NMBI).
- 4 years post-registration experience in the acute hospital setting within the last 7 years
- 2 years’ experience of working in a research setting including working directly on clinical trials
- Proven clinical skills
- Excellent oral and written communication skills
- Good IT Skills (e.g. Microsoft Office – Word, PowerPoint, Excel, Outlook etc)
- Good organisational and analytical/problem solving skills
- Experience in personal and professional development of staff
- Knowledge of Risk Management
- Management Experience

It would be desirable that the successful candidate would have:

- Postgraduate Course

Application Procedure

Applicants should submit a Cover Letter, Curriculum Vitae to include the names and contact details of 2 referees (including email addresses), to: Sean Hall – Administrative Officer 3 – Email: crfsjh@tcd.ie

Informal enquires for the post can be directed to Ms. Derval Reidy – Assistant Director of Nursing and Operations Manager – Wellcome – HRB Clinical Research Facility at St James Hospital Email: reidyde@tcd.ie

Further Information for Applicants

URL Link to Area	www.tcd.ie
URL Link to Human Resources	https://www.tcd.ie/hr/
URL Wellcome – HRB Clinical Research Facility at St. James Hospital	https://www.sjhcrf.ie/

Gardaí Vetting Clearance

Gardaí Vetting Clearance will be sought in respect of individuals who come under consideration for a post.

PLEASE NOTE: Applicants will be required to complete and return a Garda vetting form should they come under consideration for appointment. In some cases, they may be requested to complete the form on the day of interview. This form will be forwarded to An Garda Síochána (Irish Police) for security checks on all Irish addresses at which they have resided. An Garda Síochána will make enquiries with the Police Service of Northern Ireland with respect to addresses in Northern Ireland. If an applicant is not successful in obtaining the post for whatever reason, this information will be destroyed. If an applicant, therefore, subsequently comes under consideration for another position, they will be required to supply this information again.

While applicants must complete information in relation to all addresses at which they have resided, the vetting is only done on addresses on the island of Ireland.

If an applicant has resided / studied in countries outside of Ireland for a period of 6 months or more, it is mandatory for them to furnish a Police Criminal Records Check/ Police Certificate from those countries stating that they have no convictions recorded against them while residing there. Applicants will need to provide a separate Police Criminal Records Check/ Police Certificate for each country in which they have resided. The Police Criminal Records Check/ Police Certificate must be dated after the date the applicant left the relevant country. Applicants should provide documentation in the English and/or Irish language. Translations must be provided by a registered translation company/institute in the Republic of Ireland; all costs will be borne by the applicant. Only original version documents will be accepted.

Applicants should be aware that any information obtained in the Garda Vetting process can be made available to the employing area.

It is the responsibility of the applicant to seek security clearances in a timely fashion as they can take some time. No applicant will be appointed without this information being provided and being in order.

The following websites may be of assistance in this regard:

www.disclosurescotland.co.uk

www.psni.police.uk

This website provides information on obtaining a national police clearance certificate for Australia.

www.afp.gov.au

This website provides information on obtaining police clearance in New Zealand.

www.courts.govt.nz

For other countries not listed above applicants may find it helpful to contact the relevant embassies who could provide information on seeking Police Clearance. Original Police Clearance documentation should be forwarded to Human Resources where it will be copied, and the original returned to the applicant by post. **Any cost incurred in this process will be borne by the Applicant.**

Trinity College Dublin, the University of Dublin

Trinity is Ireland's leading university and is ranked 108th in the world (QS World University Rankings 2020). Founded in 1592, the University is steeped in history with a reputation for excellence in education, research, and innovation.

Located on an iconic campus in the heart of Dublin's city centre, Trinity has 18,000 undergraduate and postgraduate students across our three faculties – Arts, Humanities, and Social Sciences; Engineering, Mathematics and Science; and Health Sciences.

Trinity is ranked as the 17th most international university in the world (Times Higher Education Rankings 2020) and has students and staff from over 120 countries.

The pursuit of excellence through research and scholarship is at the heart of a Trinity education, and our researchers have an outstanding publication record and strong record of grant success. Trinity has developed 19 broad-based multidisciplinary research themes that cut across disciplines and facilitate world-leading research and collaboration within the University and with colleagues around the world. Trinity is also home to 5 leading flagship research institutes:

- Trinity Biomedical Sciences Institute (TBSI)
- Trinity College Institute of Neuroscience (TCIN)
- Trinity Translational Medical Institute (TTMI)
- Trinity Long Room Hub Arts and Humanities Research Institute (TLRH)
- Centre for Research on Adaptive Nanostructures and Nanodevices (CRANN)

Trinity is the top-ranked European university for producing entrepreneurs for the past five successive years and Europe's only representative in the world's top-50 universities. (Pitchbook Universities Report).

Trinity is home to the famous Old Library and to the historic Book of Kells as well as other internationally significant holdings in manuscripts, maps and early printed material. The Trinity Library is a legal deposit library, granting the University the right to claim a copy of every book published in Ireland and the UK. At present, the library's holdings span approximately 6.5 million printed items, 400,000 e-books and 150,000 e-journals.

With over 120,000 alumni, Trinity's tradition of independent intellectual inquiry has produced some of the world's finest, most original minds including the writers Oscar Wilde and Samuel Beckett (Nobel laureates), the mathematician William Rowan Hamilton and the physicist Ernest Walton (Nobel laureate), the political thinker Edmund Burke, and the former President of Ireland Mary Robinson. This tradition finds expression today in a campus culture of scholarship, innovation, creativity, entrepreneurship, and dedication to societal reform.

Rankings

Trinity is the top ranked university in Ireland and ranked 108th in the world (QS World University Rankings 2020). Trinity ranks in the top 50 in the world on 6 subjects and in the top 100 in 20 subjects (QS World University Rankings by Subject 2019). Full details are available at: www.tcd.ie/research/about/rankings.

The Selection Process in Trinity

The Selection Committee (Interview Panel) may include members of the Academic and Administrative community together with External Assessor(s) who are expert in the area. Applications will be acknowledged by email. If you do not receive confirmation of receipt within 1 day of submitting your application online, please contact the named Recruitment Partner on the job specification immediately and prior to the closing date/time.

Given the degree of co-ordination and planning to have a Selection Committee available on the specified date, the University regrets that it may not be in a position to offer alternate selection dates. Where candidates are unavailable, reserves may be drawn from a shortlist. Outcomes of interviews are notified in writing to candidates and are issued no later than 5 working days following the selection day.

In some instances, the Selection Committee may avail of telephone or video conferencing. The University's selection methods may consist of any or all of the following: Interviews, Presentations, Psychometric Testing, References and Situational Exercises.

It is the policy of the University to conduct pre-employment medical screening/full pre-employment medicals. Information supplied by candidates in their application (Cover Letter and CV) will be used to shortlist for interview.

Applications from non-EEA citizens are welcomed. However, eligibility is determined by the Department of Business, Enterprise and Innovation and further information on the Highly Skills Eligible Occupations List is set out in Schedule 3 of the Regulations <https://dbei.gov.ie/en/What-We-Do/Workplace-and-Skills/Employment-Permits/Employment-Permit-Eligibility/Highly-Skilled-Eligible-Occupations-List/> and the Ineligible Categories of Employment are set out in Schedule 4 of the Regulations <https://dbei.gov.ie/en/What-We-Do/Workplace-and-Skills/Employment-Permits/Employment-Permit-Eligibility/Ineligible-Categories-of-Employment/>. Non-EEA candidates should note that the onus is on them to secure a visa to travel to Ireland prior to interview. Non-EEA candidates should also be aware that even if successful at interview, an appointment to the post is contingent on the securing of an employment permit.

Equal Opportunities Policy

Trinity is an equal opportunities employer and is committed to employment policies, procedures and practices which do not discriminate on grounds such as gender, civil status, family status, age, disability, race, religious belief, sexual orientation, or membership of the travelling community. On that basis we encourage and welcome talented people from all backgrounds to join our staff community. Trinity's Diversity Statement can be viewed in full at <https://www.tcd.ie/diversity-inclusion/diversity-statement>.

Pension Entitlements

This is a pensionable position, and the provisions of the Public Service Superannuation (Miscellaneous Provisions) Act 2004 will apply in relation to retirement age for pension purposes. Details of the relevant Pension Scheme will be provided to the successful applicant.

Applicants should note that they will be required to complete a Pre-Employment Declaration to confirm whether or not they have previously availed of an Irish Public Service Scheme of incentivised early retirement or enhanced redundancy payment. Applicants will also be required to declare any entitlements to a Public Service pension benefit (in payment or preserved) from any other Irish Public Service employment.

Applicants formerly employed by the Irish Public Service that may previously have availed of an Irish Public Service Scheme of Incentivised early retirement or enhanced redundancy payment should ensure that they are not precluded from re-engagement in the Irish Public Service under the terms of such Schemes. Such queries should be directed to an applicant's former Irish Public Service Employer in the first instance.

Application Procedure

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