Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

Post Specification

Post Title:	Research Assistant – CNM (Clinical Nurse Manager) 2 Clinical Trial Start-up Specialist
Post Status:	Specific Purpose Contract – Full-time
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:	37.5 Hours per week
Closing Date:	12 Noon GMT, 15th November 2024.

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

Post Summary

The post-holder will manage and support the start- up of all clinical trials and research studies conducted by the Clinical Research Facility (CRF). This will involve working as part of a multi-disciplinary team of doctors, research nurses, data managers and pharmacists.

Standard Duties and Responsibilities of the Post

The post holder will be responsible for clinical trial identification and the set-up activities for all clinical trials and research studies. They will be tasked with ensuring that the CRF has a complete portfolio of clinical trials in keeping with the patient cohorts treated at St James's Hospital and PI needs. They will be responsible for opening clinical trials within a set time period and identifying issues that prevent this timely opening and addressing them accordingly.

This role combines functions of trial setup, business development, "horizon scanning" and marketing.

The post holder will be:

- Be the First point-of contact both for Investigator led and Clinical trials. At the initial point of contact the post holder will be responsible for arranging sign off on Confidentiality Disclosure Agreements (CDA) for all new clinical trials and research studies by the Principal Investigator/ Research and Innovation office and return of same to trial/study sponsors. They will be responsible for keeping a log of same and following up on progress, obtaining protocols and following up with Principal Investigator (PI).
- Initiate investigator site activities, including collection and submission of regulatory documents, customization, and negotiation of informed consent documents, serve as the point of contact for the site's Ethics Committee and Competent Authority (where applicable), review ethics submissions and advise on changes as required, track and ensure site compliance to required training, and effectively drive timelines aligned with CRF priorities.
- Conduct appropriate evidence-based feasibility to establish the operational viability of proposed projects, through the verification of data relating to

    - i) previous study performance metrics, performed in similar indication/patient population
    - ii) previous feasibility data and
    - iii) development of external feasibility studies and consultation with internal/external experts and the wider Investigator community.
- Work with PIs in advance of study to ensure recruitment targets can be achieved.
- Follow-up and tracking of CDA progression by liaising with colleagues in the National Clinical Trials Office and the study/trial Sponsors.
- Completion of site feasibility questionnaires for all new clinical trials and research studies in collaboration with the Principal Investigator and ADON and return of same to trial/study sponsors.

- Assist with the development of worksheets for studies as required.
- Ensure country specific regulatory and data privacy requirements are incorporated into submission documents and any other documents/systems.
- Scheduling and attending site selection visits; to include giving Sponsors a tour of the facilities and the collaborating departments. Assist in the resolution of queries arising from such visits.
- Understand and comply with procurements, legal and financial requirements, and procedures.
- Register all new clinical trials and research studies undertaken by the CRF with the Research & Innovation Office of the hospital.
- Liaise with sponsors to ensure that Ethics and Regulatory submissions are on course.
- Preparation of documents for site approval, including ethics applications and DPIAs, agreement letters and risk assessments.
- Manage the collection of all site set-up paperwork and return of same to the sponsor (e.g. financial disclosures, personal data consent forms, CVs, protocol and IB signature etc)
- Manage the sign-off process for the Contract, Indemnity and other relevant documents by the Deputy CEO and return of same to trial sponsor.
- Assist in scheduling the site initiation visit and attendance of same.

- Manage local set up of studies – study set-up checklist, completion of CRF manager form etc.
- Set Key Performance Indicators as regards set up timelines, analyse and collate metrics to make sure processes are in place that drive efficiency and reduction of timelines across start up and contracts negotiation. Issue KPI reports on a quarterly basis.
- Co-operate with the relevant departments (e.g. Radiology, Pharmacy, laboratory etc) to further improve clinical trial set-up.
- Develop a working relationship with potential sponsors, encouraging them to contact the CRF should they have any suitable trials.
- Attend monthly operational meetings and present on the pipeline, delays, gaps in the portfolio and other key issues.
- Liaise with CNM2s regarding study start up timelines and handover study for implementation phase.

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

- Master's degree in science or health related
- Be registered in the Appropriate Division of the Register of Nurses & Midwives maintained by the Nursing & Midwifery Board of Ireland (NMBI).
- Bachelor's degree preferably in a scientific or health related field such as nursing with two years clinical research experience or relevant experience preferred.
- Experience in clinical trials, in an industry or clinical setting.

- Ability to learn and comply with financial and legal guidelines and policies (budget and contract).

Knowledge & Experience (Essential)

- Excellent communication, written and oral. The candidate must be able to produce reports to a high standard and review the quality.
- Fluency in English is essential.
- Good Clinical Practice certification.
- Knowledge of GDPR/HRR.
- Requires effective organizational and time management skills.
- Able to multi-task under limited direction and on own initiative.
- Strong communication and inter-personal skills.
- Highly responsive and proactive, a team player.
- Proficiency with Microsoft Office Products – Word, Excel, PowerPoint, SharePoint.
- Direct experience in clinical trials.

Knowledge & Experience (Desirable)

Previous Start-Up unit experience, preferred.

Application Procedure

Applicants should submit a full Curriculum Vitae to include the names and contact details of 2 referees (including email addresses), to:

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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Applicants should submit a full Curriculum Vitae, with cover note outlining relevant experience two contact details of 2 referees (including work email addresses & phone number), before the deadline list above to:

Mr. Seán Hall – Administrative Officer 3,

Wellcome – HRB Clinical Research Facility at St. James Hospital

Email Address: Hallse@tcd.ie