



Post Specification 034621

Post Title:	Research Assistant (Clinical Research Quality Officer)
Post Status:	Specific Purpose Contract – Approximately 1 year
Research Group / Department / School:	Wellcome-HRB Clinical Research Facility, School of Medicine, Trinity College Dublin, the University of Dublin
Location:	Wellcome-HRB Clinical Research Facility at St James's Hospital, Dublin 8
Reports to:	Quality and Regulatory Affairs Manager (QRAM)
Salary:	Appointment will be made on the Research Assistant Salary Scale at a point in line with Government Pay Policy IUA Research Assistant Point 12 – Point 15 €31,701-€33,967 Depending on experience.
Hours of Work:	38 Hours 8am – 4pm
Closing Date:	12 Noon (GMT) 25 th September 2020

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

Post Summary

The Clinical Research Quality Officer's role is to support the CRF quality staff in maintaining a quality management system and knowledge management for clinical research conduct in compliance with good clinical practice guidelines and applicable legislation. The Clinical Research Quality Officer will also be involved in the operational aspects of clinical trial set up and conduct.

Standard Duties and Responsibilities of the Post

- GCP Quality system document change control
- Writing and reviewing Standard Operating Procedures
- Assist in quality control audits of clinical study documentation (e.g. Main Study Files, CRF Files, Monitoring Files, etc.)
- Assist with the coordination and tracking of study team training
- Preparation of quality metrics reports for the CRF
- Introduce process and quality improvements
- Preparation of documents for site approval, including ethics applications and DPIAs.
- Support the Sponsor office in Clinical trial monitoring and Pharmacovigilance
- Contribution to the development and setup of appropriate clinical trial co-ordination processes, SOPs and associated templates to guide the successful delivery of clinical trials
- Responsible for the correct filing and archiving of clinical trial documents, and the maintenance of study site files.
- Maintaining current knowledge of relevant standards and participating in continuous professional development activities
- Assisting with site readiness for sponsor audits or inspections
- Attend project team meetings and generate meeting minutes
- Managing staff permissions for CRF IT systems
- Other duties as assigned

Funding Information

Health Research Board

Person Specification

Qualifications

- Degree in health care, life sciences or related fields
- Desirable: MSc in Clinical Research or equivalent (or willing to undertake this)

Knowledge & Experience (Essential & Desirable)

- Basic knowledge of clinical trial processes and ICH/GCP guidelines.
- Proficient in MS Office including Access and Excel for data manipulation

- Desirable: 2 years' experience in a clinical research role in commercial or academic setting

Skills & Competencies

- Strong general administration skills and experience
- An interest in clinical trial conduct and quality improvement
- Good people and collaboration skills are essential in this role
- An individual with initiative, capable of problem solving and working independently
- Excellent time management skills and ability to work to deadlines
- Excellent communication and report writing skills
- Ability to be flexible, to prioritise and manage workload
- Confidence and ability to understand and navigate new IT systems quickly

Application Procedure

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

Geraldine Quinn, Senior Executive Officer
gquinn@tcd.ie

Further Information for Applicants

URL Link to Area	www.sjh/crf
URL Link to Human Resources	https://www.tcd.ie/hr/

GARDA CLEARANCE:

Police vetting 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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Name: Ms. Geraldine Quinn

Email Address: gquinn@tcd.ie



**UNIVERSITY
VACANCIES IRELAND**
universityvacancies.com

