



Post Specification – Comp: 033510

Post Title:	Administrative Officer Quality and Regulatory Affairs (sponsorship)
Post Status:	Fixed Term one year
Research Group / Department / School:	Clinical Research Facility, Trinity College Dublin, the University of Dublin
Location:	Clinical Research Facility (at St James’s Hospital), Trinity College Dublin, the University of Dublin College Green, Dublin 2, Ireland
Reports to:	CRF Director
Salary:	Appointment will be made on the Administrative 2 at a point in line with Government Pay Policy € 48,153 – €56,581, appointment will be made no higher than point 5
Hours of Work:	8am – 4pm (Monday – Friday)
Closing Date:	12 Noon (Irish Standard Time), Monday January 14th 2019

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

Post Summary

Administrative Officer Quality and Regulatory Affairs (sponsorship) will be based in the Wellcome-HRB Clinical Research Facility at St James's Hospital (CRF) and will be responsible for implementing operational procedures and a quality management system for clinical trial sponsorship services (IMP and Medical Device) within the CRF. The CRF is a collaboration between St James's Hospital (SJH) and Trinity College Dublin (TCD) and has been providing investigator services for clinical trials since 2013. TCD has recently been approved to act as a clinical trial (IMP and medical device) sponsor and the CRF will be the operational support for this. The Sponsorship Project Manager will form part of the CRF operational staff team and will report to the CRF Director.

Standard Duties and Responsibilities of the Post

Administrative Officer Quality and Regulatory Affairs (sponsorship) will be responsible establishing and managing trial sponsorship services in the CRF and will:

- Take the lead on continued development of standard operating procedures (SOPs) for sponsorship services for IMP and medical device trials (including application process, risk-based management, project set-up, pharmacovigilance, quality assurance, data management and reporting).
- Implement and maintain a risk-based quality management system (QMS) for sponsorship in the CRF to ensure compliance with International Conference on Harmonisation Good Clinical Practice Guidelines (ICH-GCP), ISO 14155 and all applicable legislation and standards.
- Establish processes for risk-based monitoring of CRF supported trials (this includes developing a risk-based monitoring plan).
- Implement procedures for protocol deviation management and escalation of breaches to sponsor oversight office.
- Assist in site selection reviews and provide site initiation training.
- Take a lead on interpreting complex legislation as it relates to trial sponsorship, identifying the implications for the CRF and initiating necessary changes to practice to ensure continued compliance with ICH GCP, ISO 14155 and all applicable regulations.

- Implement and maintain a regulatory and ethics tracker for CRF supported trials to manage reporting requirements.
- Communicate on behalf of the CRF with competent authorities and ethics committees in relation to CRF sponsorship services.
- Maintain the sponsor trial master file (TMF).
- Manage pharmacovigilance services for the CRF.
- Perform vendor audits and selection for sub-contracted sponsorship services on behalf of the CRF.
- Implement and manage a quality assurance system for CRF sponsorship services.
- Develop linkages with colleagues in similar posts nationally and internationally.

Administrative Officer Quality and Regulatory Affairs (sponsorship) will provide project set-up assistance to investigators on approved TCD sponsored trials, and as part of this will:

- Work with Trinity's Head of Clinical Sponsorship Oversight (HCSO) to establish an application, review and risk assessment procedure for investigators to submit requests for TCD sponsorship.
- Provide an initial assessment of feasibility for CRF supported studies.
- Prepare budget proposals for CRF sponsorship support.
- Provide professional advice to investigators in relation to regulation, management and conduct of trials.
- Assist in preparation and coordination of submission documentation (including protocols, patient information leaflets, informed consent forms, annual safety reports, investigator's brochures, etc.) for regulatory and ethical review of CRF supported trials.
- Work with the Head of Clinical Sponsorship Oversight (HCSO) and relevant departments in TCD to promote sponsorship services to TCD investigators.
- Perform additional tasks (on mutual agreement) that arise to fulfil the aims of this role.

Person Specification

Qualifications

Third level qualification in scientific discipline or life sciences related discipline

Knowledge & Experience (Essential & Desirable)

- A minimum of 3 years' experience in quality assurance of clinical research (or closely related field)
- Prior experience working on investigator-led or clinical trial research
- Knowledge of Sponsor responsibilities as defined by Good Clinical Practice guidelines
- Knowledge/familiarity of non-interventional research
- Proven project management skills
- Prior experience in conducting site audits/monitoring
- Prior experience as clinical trials coordinator or clinical project manager for regulated clinical trials
- Experience of quality management systems
- Competent with Microsoft Office (including Word, Excel, Outlook and Powerpoint)

Desirable:

- Familiar with clinical trial management software and Pharmacovigilance systems
- Prior experience in managing medical device clinical investigations
- Experience of working with regulatory bodies (e.g. HPRA, EMA, FDA, MHRA)
- Experience in pharmacovigilance reporting

Skills & Competencies

- Highly organised, with good time management skills
- Effective communication skills (oral, written, presentations)
- Proven ability to work as part of a team
- Self-motivated, showing strong leadership and initiative
- Ability to work independently and make decisions

Further Information for Applicants

URL Link to Area	www.tcd.ie
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.psnipolice.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 premier university, with a proud tradition of excellence stretching back to its foundation in 1592. The oldest university in Ireland, and one of the oldest in Europe, today Trinity sits at the intersection of the past and the future, and is ideally positioned as a major university in the European Union. Our 47-acre campus is located in the heart of Dublin city centre and is home to historic buildings dating from the University's establishment, as well as some of the most cutting-edge teaching and research facilities in Ireland. Students at Trinity benefit from a unique educational experience across a range of disciplines in our three faculties – Arts, Humanities, and Social Sciences; Engineering, Mathematics and Science; and Health Sciences. 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 [18 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. These internationally recognised themes include such diverse areas as Cancer, Immunology, Telecoms, Identities in Transformation, Nanoscience, Neuroscience, and Making Ireland. Researchers from across the University work together in innovative ways to develop new and exciting approaches to their research and explore the frontiers of knowledge in the 21st century. In creating these dedicated research themes, Trinity's researchers are able to become a more powerful force on the global stage, successfully competing for large-scale grants and attracting top students and faculty to the University. Trinity is home to Ireland's first purpose-built Nanoscience research institute, CRANN, which opened in January 2008. This state-of-the-art facility houses 150 scientists, technicians, and graduate students in specialised laboratories, fostering creative innovations that have seen Trinity's researchers make significant breakthroughs.

The Trinity Long Room Hub for Arts and Humanities Research Institute is the University's flagship institute for research in the Arts and Humanities, providing a world-class environment for cross-disciplinary collaborative projects. The Long Room Hub provides a central location through which the University's internationally respected Arts and Humanities research can become more visible, demonstrating its relevance for contemporary and future societies.

Researchers from across the University regularly participate in debates on topical issues facing the world today. As well as operating an International Visiting Research Fellowship programme, the Long Room Hub also hosts major EU-funded Digital Humanities projects.

One of the most instantly recognised parts of Trinity's campus is the famous Old Library, home to the historic Book of Kells as well as other internationally significant holdings in manuscripts, maps, and early printed material. Trinity's Library is the largest research library in Ireland and is an invaluable resource to Trinity's students and research community. Built up over the four centuries of the University's existence, the Library's collections have benefitted from its status as a Legal Deposit library for the past 200 years, granting Trinity the right to claim a copy of every book published in Ireland and the UK. At present, the Library's holdings span approximately 4.25 million books, 22,000 printed periodical titles, and access to 60,000 e-journals and 250,000 e-books.

Trinity attracts top students from Ireland and abroad and prides itself on the consistently high standard of student admitted to the University every year. These students are drawn to Trinity for the excellence of our research-led teaching and for the quality and prestige a degree from this University confers. Trinity has also pioneered accessibility to education in Ireland, becoming the first university in the country to reserve 15% of its undergraduate places for students from non-traditional learning groups. Trinity is the top-ranked European university for student entrepreneurship and Europe's only representative in the world's top-50 universities.

Our alumni have gone on to shape the history of Ireland and of Western Europe in a wide range of fields. These include such notable figures as Jonathan Swift, Oscar Wilde, William Rowan Hamilton, Edmund Burke, William Stokes, Denis Burkitt, Louise Richardson, Lenny Abrahamson, and Anne Enright. Three of Trinity's graduates have been awarded Nobel prizes: Ernest Walton for Physics in 1951; Samuel Beckett for Literature in 1968; and William Campbell for Physiology / Medicine in 2015. Trinity also counts the first female President of Ireland among its alumni in Mary Robinson, as well as other notable former Presidents Douglas Hyde and Mary McAleese. At Trinity we are justifiably proud of our tradition, and we strive to uphold this excellence as we face the demands of the 21st century.

Ranking Facts

Trinity is the top ranked university in Ireland. Using the QS methodology, the University is ranked 104th in the world and using the Times Higher Education World University Rankings methodology Trinity is 117th in the world.



Overall

- Trinity is Ireland's No.1 University in the QS World University Ranking, THE World University Ranking and the Academic Ranking of World Universities (Shanghai).
- Trinity is ranked 104th in the World, and 36th in Europe, in the 2018/2019 QS World University Ranking.
- Trinity is ranked in the Top 120 for Graduate Employability in the QS 2018 Rankings.
- Trinity is in the Top 50 most innovative universities in Europe according to Reuters.¹
- Between 2010 and 2015, Trinity was ranked the top university in Europe for entrepreneurship according to Pitchbook's independent analysis.²

¹ <http://www.reuters.com/article/us-innovative-stories-europe-idUSKCN0Z00CT>

² <http://pitchbook.com/news/reports/2015-2016-pitchbook-universities-report>

Internationalisation

- Trinity is ranked 52nd in the world in the THE World University Ranking for international outlook.

Research Performance

- Of the 981 institutions included in the THE World University Rankings for 2017, Trinity is in the top 15% internationally for research performance.
- Trinity is ranked in the top 15% internationally by QS for citations.

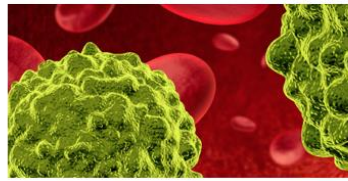
In the QS World University Subject Rankings:

- Trinity is ranked in the top 50 worldwide in four subject areas according to the QS World University Subject Rankings 2018. The University is ranked in the top 100 globally for 20 subjects overall.
- Trinity's Top 50 subjects include Nursing (25th), Classics (28th), English (28th) and Politics (43rd).
- Trinity is ranked in the top 100 for each of the following 16 subjects: History, Languages, Philosophy, Theology, Computer Science, Biology, Medicine, Pharmacy, Chemistry, Geography, Materials Science, Education, Law, Social Policy, Sociology and Sport.
- The University is ranked in the top 100 for three broad subject areas: Arts & Humanities (57th), Life Sciences & Medicine (87th), and Engineering & Technology (89th).

Research Themes



Ageing



Cancer



Creative Arts Practice



Creative Technologies



Digital Engagement



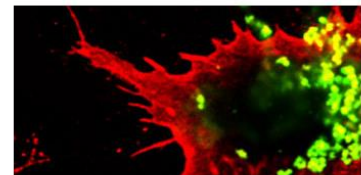
Digital Humanities



Genes & Society



Identities in Transformation



Immunology, Inflammation & Infection



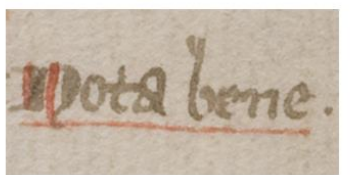
International Development



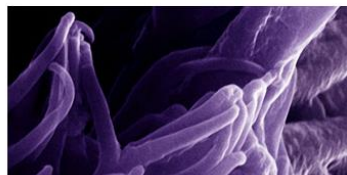
International Integration



Making Ireland



Manuscript, Book and Print Cultures



Nanoscience



Neuroscience



Telecommunications



Smart Sustainable Planet



Next Generation Medical Devices

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 Jobs, Enterprise and Innovation and further information on the Highly Skills Eligible Occupations List is set out in Schedule 3 of the Regulations <https://www.djei.ie/en/What-We-Do/Jobs-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://www.djei.ie/en/What-We-Do/Jobs-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 to include the names and contact details of 3 referees (including email addresses), together with a cover letter (1x A4 page), a Teaching Statement and Research Plan as outlined in the Application Process above.

APPLICATIONS WILL ONLY BE ACCEPTED BY E-RECRUITMENT:

<http://jobs.tcd.ie>

If you have any application queries, please contact:

Siobhan Keane

Human Resources, House No. 4,

Trinity College Dublin, the University of Dublin

Tel: +353 1 896 1030

Email: skeane5@tcd.ie

