

Role profile – Project Officer (2 posts)

National Office for NREC's

HRB Grade VI Job Family (consisting of R&I III, Services III & Researcher II grades).

Background

The Health Research Board (HRB) is a statutory agency under the aegis of the Department of Health. As the lead agency in Ireland responsible for supporting and funding health research, generating health information and promoting the use of evidence in policy and practice, we are motivated and inspired by our vision – for better health through excellent research, data and evidence. The HRB's mission is to support research that improves people's health, promotes evidence-informed care and creates solutions to societal challenges. An overview of the HRB's objectives and activities may be found in The *HRB Strategy 2021-2025, Health research - making an impact*, (<https://www.hrb.ie/strategy-2025/>).

The National Office for Research Ethics Committees is an independent office with a statutory function in the regulation of health research (www.nrecoffice.ie), established in 2020 as a key component of the reform of the research ethics committee framework in Ireland led by the Department of Health. The National Office is an independent unit within the Health Research Board (HRB) and works under the auspices of the Department of Health.

The primary function of the National Office is to support a robust and transparent system of National Research Ethics Committees (NRECs), which provides competent and timely ethics assessment of regulated research, to protect the safety, dignity and wellbeing of research participants.

The NRECs are mandated under legislation, or by ministerial instruction, to deliver ethics opinions for regulated research studies that are respected nationally ('single national ethics opinion') and specifically to meet Ireland's requirements under the Medical Devices Regulation (MDR: EU No 2017/745)¹, the *In Vitro* Diagnostic Medical Devices Regulation (IVDR: EU No 2017/746)² and Clinical Trial Regulations (CTR: EU No 536/2014).³

¹ MDR: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745&from=EN>

² IVDR: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0746&from=EN>

³ CTR: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0536&from=EN>

The National Office supports the:

- National Research Ethics Committee for Medical Devices (NREC-MD) for clinical investigations of medical devices (under the **MDR**) and performance studies of *in vitro* diagnostic medical devices (under the **IVDR**),
- National Research Ethics Committee for Clinical Trials (NREC-CT; A, B, C, D) for Medicinal Products (under the **CTR**),
- National Irish COVID-19 Biobank Research Ethics Committee (NICB-REC) for the National Irish COVID-19 Biobank, and standing NREC-COVID-19 subcommittee for COVID19 research studies with a previous national opinion.

The National Office receives applications for ethics approval on behalf of the NRECs, and operationally supports the Committees' independent review processes. Sponsors of clinical trials conducted under the Clinical Trials Regulations, must submit ethics applications for assessment, through the pan-European online portal Clinical Trial Information System (CTIS), which the National Office interfaces with.

NRECs adhere to international best practice and the highest standards in research ethics review to protect the safety, dignity and well-being of research participants

Key responsibilities of the Project Officer (2 post)

The HRB is now seeking to recruit two Project Officers to support the processes and procedures underpinning a high-performing system for NRECs in Ireland:

1. A permanent full-time position
2. A fixed term, two-year contract

These roles offer an exciting opportunity for suitably qualified candidates to join a vibrant team of dynamic and dedicated high-performing professionals whose core values of integrity, knowledge, collegiality and transparency drive their work of delivering an agile and trusted office in national public service.

The National Office team comprises Programme Managers, a Programme Officer, Project Officers, Project Administrator, Administrative Assistant, including a Finance and Communications Officer.

The Project Officers will play a central role in supporting the four NRECs for Clinical Trials on Medicinal Products (NREC-CTs) in their independent reviewing of and decision-making for research ethics applications.

Duties will include, but are not limited to:

The Project Officer roles will play a key part in providing operational support to the Programme Managers, Programme Officers, Head of Office, and committee members. They will be expected to support the overall work of the National Office including the technical and organisational requirements of the NRECs and may from time to time be assigned other duties depending on business needs. The posts will be assigned to support the Clinical Trials team within the National Office, with potential for assignment across other areas of the National Office also.

Project Officers should be able to multi-task and manage a varied workload, including but not limited to the following:

Operational support of NREC applications

The Project Officer roles will provide operational support throughout the lifecycle of an ethics review application, from validation and pre-review to post-review and NREC decision-making stage, to ensure timely and robust ethics review, and in particular, will be responsible for the following actions / activities:

- Provide guidance and respond to queries from prospective applicants
- Champion a continuous improvement mindset and approach to processes within NREC-CT operations, to facilitate NREC members review and efficient application submission, including update of relevant application forms, checklists, FAQs etc
- Organise NREC meetings, including liaising with members, meeting pack preparation and dissemination, and responding to member queries
- Coordinate the preparation of agenda papers and review documentation for NREC meetings
- Work closely with NREC members to finalise outcomes for initial clinical trial applications and substantial modifications submitted under the CTR and CTD
- Develop excellent working relationships with NREC members and Chairpersons
- Attend NREC meetings and record accurate minutes of proceedings and decisions, and conveying NREC decisions and other feedback
- Maintain a working proficiency with the Clinical Trial Information System (CTIS)
- Work closely with the other Programme Officer and Project Officers to manage and track clinical trial applications submitted through the EU portal - Clinical Trial Information System (CTIS), completing 'CTIS' tasks and subtasks daily within legislative timelines

- Support the administration and management of substantial modifications applications submitted to the National Office, including applications for studies that are transitioning to the CTR
- Assist with managing Expressions of Interest for NREC membership
- Implement processes to track applications from submission to post-approval to ensure both legal and best-practice requirements are met in relation to research ethics, including safety and annual reporting.

Operational support of NREC applications

The Project Officer roles will provide administrative support to developing and refining processes, policies and standard operating procedures (SOPs) to ensure that the National Office adopts best-practice in all elements of its activities, both applicant- and NREC-interfacing; the Project Officer roles will have particular responsibilities for the following actions / activities:

- Develop and implement standardised internal processes for management of NREC applications where required
- Work closely with the National Office Finance Officer to accurately monitor NREC application fees to ensure seamless application processing
- Contribute to development and implementation of National Office policies as required
- Develop an expertise on the administration of ethics review as it relates to regulated health research and the role of the NRECs
- Contribute to and conduct literature- and legislative-based searches as required to inform the processes and procedures of the National Office
- Actively contribute to Clinical Trial team meetings as a forum for informed solutions to pertinent issues in applications and processes
- Develop a working knowledge of the Clinical Trials Regulations, Health Research Regulations and other applicable legislative frameworks, including keeping abreast of EU and international developments as they pertain to the work of the National Office.

Operational support of NREC applications

The Project Officer roles will contribute to effective engagement and communication with key stakeholders including the health research community, European collaborators, Department of Health and HPRA to ensure the roles of the National Office and the NRECS are understood and that the associated processes are robust and transparent; the Project Officer roles will have particular responsibilities for the following actions / activities:

- Be a central contact point and helpdesk function for applicant queries
- Maintain accurate and timely content on the National Office website

- Provide information and data on the collective of National Office activities for key stakeholders as requested, including by the Department of Health
- Present at external meetings to foster understanding and visibility of the roles of the National Office and the NRECs
- Liaise with other bodies involved in the regulation of health research as required including the Health Research Consent Declaration Committee (HRCDC), the HPRA, European and National clinical trial-related working groups
- Organise webinars and other information events to support the work of the National Office including education and outreach.

Essential knowledge and experience

Formal requirements include:

Ideally, the successful candidates will be PhD qualified but must, at a minimum, have a NFQ Level 9 qualification (Masters / Post Graduate Diploma) in a relevant field with a minimum of three years' relevant experience post-degree,

or

At a minimum, have a NFQ Level 8 Qualification (Honours Bachelor's degree) in a relevant field with a minimum of five years' relevant

NOTE: A relevant field includes the biomedical sciences, the healthcare professions, law, and ethics.

Desirable criteria

Project Officers interact closely with the academic and healthcare research community and should therefore have a strong interest in and good understanding of these environments.

The ideal candidate will have:

- A legal or / ethics qualification as a distinct advantage
- Experience in ethics administration or similar research administration environment as a distinct advantage
- A high degree of computer literacy, including knowledge and experience of using Microsoft Word, Excel, Outlook and experience of databases
- An understanding of the requirements of project management objectives

Competencies

Competencies incorporated into this role profile reflect the competency framework issued in conjunction with the Civil Service Competency Framework which has been adopted by the HRB. The complete list of core competencies for this post is in Appendix A.

Key competencies include the following:

- Excellent planning and organising abilities with a strong attention to detail
- Be result-oriented and possess excellent organisational/administrative skills
- A demonstrable ability to multitask, prioritise, meet deadlines and manage competing and changing priorities
- Have excellent collaboration skills with an ability to work well in a team and on own initiative
- Strong problem analysis and resolution skills
- Excellent communication and interpersonal skills
- A high degree of motivation and professional integrity
- An ability to exercise confidentiality and discretion

Reporting relationship

Project Officers report to a Programme Manager, National Office for NREC's

Salary scale

Salary Range for Project Officer – National Office (Grade VI) €55,093 - € 67,308

Appointment will be made in accordance with the Department of Health guidelines. New entrants to the public service will be appointed at the first point of the scale.

How to apply

To apply, please submit a cover letter and curriculum vitae by email to recruitment@hrb.ie

Note: There are two post available, please indicate which you wish to apply for or whether you wish to apply for both posts. In the e-mail subject line.

- **Permanent Full-time Project Officer post**
- **Two -year fixed term Project Officer post.**

Closing date for applications is **12.00 Noon on 29 August 2024**

Interviews for this position are expected to take place between **9 and 12 September 2024**.

Please note, the interviews will be conducted in person at our HRB offices.

The HRB reserves the right to form a panel from this interview process which may remain in place for a maximum period of 12 months from the date of interview and may be used to fill posts at the same grade that arise applicable to this recruitment campaign based on order of merit.

Placement on a panel is not a guarantee of appointment to a position.

If you require further information, please contact Karen O'Donnell, HR Officer at recruitment@hrb.ie or refer to the recruitment page on the HRB website at <http://www.hrb.ie/about/recruitment/> for full details on this campaign.

The Health Research Board is an equal opportunities employer and welcomes applications from all sections of the community. We do not discriminate based on gender, age, race, religion, marital status, sexual orientation, disability, membership of the Travelling community or family status. If you have a disability and require accommodations to be made during the recruitment process, please contact HR in advance and we would be happy to assist.

Appendix A: Core competencies - Project Officer (National Office)

Leadership Potential

- Is flexible and willing to adapt, positively contributing to the implementation of change.
- Contributes to the development of policies in own area and the broader Department/ Organisation.
- Seeks to understand the implications of taking a particular position on issues and how interdependencies need to be addressed in a logical and consistent way.
- Maximises the contribution of the team, encouraging ownership, providing support and working effectively with others.
- Formulates a perspective on issues considered important and actively contributes across a range of settings.

Analysis & Decision Making

- Is skilled in policy analysis and development, challenging the established wisdom and adopting an open-minded approach.
- Quickly gets up to speed in a complex situation, rapidly absorbing all relevant information/data (written and oral).
- Uses numerical data skilfully to understand and evaluate business issues.
- Identifies key themes and patterns in and across different sources of information, drawing sound and balanced conclusions.
- Is resourceful and creative, generating original approaches when solving problems and making decisions.

Delivery of Results

- Assumes personal responsibility for and delivers on agreed objectives/ goals.
- Manages and progresses multiple projects and work activities successfully.
- Accurately estimates time parameters for projects and manages own time efficiently, anticipating obstacles and making contingencies for overcoming these.
- Maintains a strong focus on meeting the needs of customers at all times.
- Ensures all outputs are delivered to a high standard and in an efficient manner.
- Use resources effectively, at all times challenging processes to improve efficiencies.

Interpersonal & Communication Skills

- Communicates in a fluent, logical, clear and convincing manner verbally and in writing.
- Is able to listen effectively and develop a two-way dialogue quickly.
- Maintains a strong focus on meeting the needs of internal and external customers.
- Effectively influences others to take action.
- Works to establish mutual understanding to allow for collaborative working.
- Works effectively with a broad range of stakeholders to achieve objectives.

Drive and Commitment

- Consistently strives to perform at a high level
- Maintains consistent effort under pressure and is resilient to criticism or setbacks at work
- Demonstrates high levels of initiative, taking ownership of projects and demonstrating high levels of self sufficiency
- Is personally trustworthy and can be relied upon
- Places the citizen at the heart of all process and systems
- Upholds the highest standards of honesty, ethics and integrity.

Specialist Knowledge, Expertise and Self Development

- Clearly understands the role, objectives and targets and how they fit into the work of the unit and Department
- Develops the expertise necessary to carry out the role to a high standard and shares this with others
- Is proactive in keeping up to date on issues and key developments that may impact on own area, the Department and/ or wider public service
- Consistently reviews own performance and sets self-challenging goals and targets
- Has significant expertise in his/her field that is recognised and utilised by colleagues.