

Expression of Interest for membership of Ireland's

NATIONAL RESEARCH ETHICS COMMITTEES

Your opportunity to support Irish health research and embed best ethical research practices



Expressions of Interest should be completed by answering the questions on pages 8-14 of this form. Submissions should be made to membership@nrec.ie Please include 'NREC Member Eol' in the subject line.





Please only use Adobe Reader 10 or higher to complete this form.

You can download a free copy of Adobe Reader <u>here</u>. Adobe Reader is available for Windows, Mac and Android Devices

An Oifig Náisiúnta do Choistí um Eitic Thaighde

Teach Grattan, 67-72 Sráid an Mhóta Íochtarach, Baile Átha Cliath 2, D02 H638, Éire National Office for Research Ethics Committees

Grattan House, 67-72 Lower Mount Street, Dublin 2, D02 H638, Ireland

Call for Expressions of Interest for National Research Ethics Committee Membership

A national system of ethics review for health research¹ has been successfully implemented in Ireland and Expressions of Interest are sought to further bolster the membership of the National Research Ethics Committees for clinical trials and medical devices. Ethics review is an essential component of regulating health research to ensure that the safety, dignity and well-being of research participants is protected. It is important that national ethics opinions underpinning Irish health research are informed by the diversity of skills, experience, interests and backgrounds reflective of Irish society.

The National Office for Research Ethics Committees is responsible for establishing National Research Ethics Committees (NRECs) in specific areas of health research as requested by the Minister of Health. The NRECs strengthen the national research infrastructure to protect patients and the public, while creating a more conducive environment for clinical trials for investigational medical products, clinical investigations of medical devices and performance studies of *in vitro* diagnostic medical devices.

The NRECs deliver opinions on health research applications for ethical assessment submitted to them through the National Office and are supported by National Office staff. Importantly, NRECs are mandated to return a 'single national opinion' on research applications for ethics assessment, meaning that NREC decisions will be respected nationally. The National Office wishes to expand its membership of the existing NRECs for Clinical Trials of Investigational Medicinal Products (NREC-CT) and Clinical Investigations of Medical Devices and Performance Studies of *In Vitro* Diagnostic Medical Devices (NREC-MD) to supplement committee expertise and representations, and to enable Ireland to meet its regulatory requirements under existing EU regulations, namely the Clinical Trial Regulation (EU No 536/2014), Medical Device Regulation (EU No 2017/745) and In-Vitro Diagnostic Device Regulation (EU No 2017/746).

The National Office for Research Ethics Committees facilitates equal opportunity membership and welcomes Expressions of Interest from applicants inclusive of race, religion, ethnicity, gender, sexual orientation, responsibilities for dependents, age, disability, civil status, membership of the Traveller community, and geographic location.

Membership of the NRECs provides an exciting and rare opportunity to support Irish research, to gain insight into forefront health developments and new legislative regulatory frameworks, and to ensure that Irish research is underpinned by the highest standards of ethical research practice.

Reasons to join a National Research Ethics Committee

- Contribute to protecting the safety, dignity, and well-being of research participants
- Contribute to health research at a national level
- Gain insight into emerging European regulatory changes and best practice in research ethics
- Gain insight into forefront research and emerging areas
- Enhance your professional & personal development through the benefit of the 'Lunch & Learn' speaker series

What does it mean to be a member of a National Research Ethics Committee?

NRECs are the essential component of the new national system of research ethics review in Ireland, for regulated areas of research. By modelling and sharing best practice, NREC members have the opportunity to deliver quality and best practice ethical opinions through a robust and transparent decision-making process across the spectrum of research in Ireland.

Members are appointed by the Minister for Health, and NRECs as a whole will report to the Minister. The purpose, structure, and scope of the NRECs are defined by their Terms of Reference, which will be provided at appointment. The Terms of Reference are informed by the legislation that prescribe how the NRECs are constituted and operate.²³⁴

Members are appointed for three years and may be eligible for reappointment for another term.

Opinions delivered by NRECs on applications for research ethics assessment are independent and consensus-based.

NREC meetings require a quorum for decisions and detailed minutes of meetings and opinions delivered, are made publicly available.⁵ The transparency of the decision-making process aims to engender the trust of the research community and wider public.

Membership of an NREC is an important and valued public service role requiring commitment.

The National Office acknowledges and appreciates the time committed by each committee member.

Details of appointed members, with permission, are listed on the National Office website.⁶

² https://www.irishstatutebook.ie/eli/2022/si/41/made/en/pdf

³ https://www.irishstatutebook.ie/eli/2021/si/260/made/en/pdf

⁴ https://www.irishstatutebook.ie/eli/2022/si/257/made/en/pdf

⁵ https://www.nrecoffice.ie/committees/decisions/

⁶ https://www.nrecoffice.ie/committees/nrec-ct/nrec-ct-a-members/, https://www.nrecoffice.ie/committees/nrec-ct/nrec-ct-b-members/, https://www.nrecoffice.ie/committees/nrec-md/nrec-md/nrec-md-members/

Terms of membership

- Adhere to the Terms of Reference for the NREC provided by the National Office;
- Actively participate in the majority of NREC monthly meetings each year, confirming attendance and any foreseen absences in advance;
- Prepare ahead of NREC meetings including review of applications, completion of an ethics assessment report and assist with reviewing applicant responses to ethical considerations raised;
- Commit to a consensus-based approach to decision-making under the direction of the Chairperson, contributing your opinion in line with your capacity and comfort;

- Respect the opinions of all fellow NREC Members, the diversity of which enrich the NREC process;
- Work collaboratively with the Chairperson, fellow NREC Members and National Office team to ensure the highest standards of ethics review and efficiency in the process;
- Maintain the strictest confidentiality on proprietary information;
- Declare all affiliations and any interests, actual conflicts or potential;
- Attend and complete the requisite training provided;
- Be comfortable using the basic IT tools that facilitate NREC work;
- Uphold the National Office's values of trust and transparency in NREC work.

Selection Process

Expressions of Interest are managed by the National Office for Research Ethics Committees with a view to making a recommendation for consideration for appointment by the Minister for Health.

The National Office will review Expressions of Interest in consultation with an assessment panel, which may include the Chairpersons, and/or Deputy Chairpersons and/or external experts as required. Applicants may be invited to meet the assessment panel to discuss their Expression of Interest further.

Expressions of Interest will be evaluated for demonstration of the skills and attributes necessary for effective NREC participation. This will include an ability to work as part of a committee, to understand complex issues to the extent required to form and voice an opinion, and to be objective in considering issues and weighing-up conflicting opinions.

Committee constitution

Member selection will be proposed based on the diversity of skills, qualifications, subject matter expertise, interests and backgrounds required to deliver opinions on applications made to the NRECs. Selection is also informed by appropriate representation of both 'expert' and 'lay' Members as provided for in Irish legislation.

Where the National Office determines there is likely to be a specific gap in expertise or

representation, prospective Members may be invited to submit an Expression of Interest.

Given the breadth of expertise and perspectives required and the anticipated expansion of the scope of NRECs over time, where applicants are not appointed on this occasion, they may be invited to be included on an NREC Expert Group list. In this case, individuals may be approached from time to time to contribute to NREC deliberations based on their expertise, experience or perspective.

Payment & Expenses

NREC membership is broadly considered a voluntary role in public service. The NREC review system is entirely dependent on this voluntary commitment, availability, expertise and experience of professionals, patients and public representatives.

All members appointed are considered expert ethical assessors. In recognition of the technical, scientific, experiential, or other subject matter expertise required of members to deliver expert ethical assessments on ethics applications, remuneration for this service, conducted outside of normal employment, will be provided.

Members are required to participate at NREC meetings to deliberate and consider the expert ethical assessments and deliver a national ethics opinion. This role will be carried out during business hours and is unremunerated.

Training for and participation in NREC meetings may be eligible for recognition for Continuing Professional Development (CPD) points. The National Office team can provide confirmation of attendance and other evidence to support CPD applications.

Reasonable out-of-pocket and receipted expenses directly associated with NREC business will be reimbursed to all Members (e.g. travel to meetings where necessary, stationery).

Time commitment

Committee meetings (main meetings and sub-committee meetings) are convened monthly, mostly virtually/remotely and may occasionally be convened in person. Generally NREC main meetings are scheduled to meet 10 - 11 times a year, with schedules set in Q3 of the calendar year, for the forthcoming year. Additional sub-committee meetings may also convened on a rotational basis, typically of 1 hour duration.

NREC meetings are scheduled within business hours on a recurring day scheduled in advance and will typically be 2 - 3 hours in duration. The meeting schedule for the year will be provided at appointment by the National Office.

Additional NREC related work, such as preparation for the meetings, completion of written expert ethical assessment reports, reviewing of applicant responses to considerations raised by the NRECs, can amount to at least 2 - 4 hours per month.

On average, it is anticipated that NREC membership and associated work can range from 4 - 8 hours a month.

National Office team and supports

Appointed Members will receive training, access to the electronic tools necessary to conduct Committee work, and operational and technical expert support from the dedicated National Office team.

The National Office comprises 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.

Each NREC has a dedicated Programme Manager and is supported by Project Officers. The NREC-CT has additional support for the Clinical Trial Regulations requirements and submissions via the Clinical Trial Information System (CTIS).⁷

⁷ https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-information-system

NREC Membership

What Committee are you interested in?

NREC for Clinical Trials of Medicinal Products⁸

NREC for Clinical Investigations of Medical Devices9

Either

Personal Details

TITIE:	MS	Mrs	Mr	MX	Dr	Prof	Otner
Surname:							
Forename:							
Address:							
Email:							
Phone:							
Current position:	Employed		Unemplo	yed	Student		
	Retiree		Home-ma	aker	Other		

If employed, please state your role and employer (to determine any potential conflict of interest).

⁸ Assessing ethics applications for medicinal products for human use

⁹ Assessing ethics applications for clinical investigations for medical devices and performance studies for vitro diagnostic medical devices

Expertise by Experience

Please provide five keywords to describe the expertise or experience you can bring to a National Research Ethics Committee (eg carer, clinical trialist, community health, health economics, healthcare policy, legal practitioner, parent, patient, scientific researcher, social work, student). Applicants may draw from experiential knowledge and life experiences in addition to professional knowledge.

Areas of Expertise

Under the current call, the National Office particularly welcomes Expressions of Interest from individuals with expertise in the following areas.

Please select areas of expertise relevant to you (you may select more than one):

Bioengineering / Clinical Engineering Orthopaedics

Cardiology Paediatrics and Neonatology

Clinical Genetics Pathology / Histopathology Microbiology

Clinical Pharmacology Patient / Carer / Patient Organisation

Clinical Research Nursing and Midwifery Psychiatry and Health Psychology

Emergency medicine Rare Diseases

In vitro diagnostics Regulatory Affairs

Neurology Research Ethics

Obstetrics and Gynaecology Respiratory Medicine

Oncology Software / Electronics

Ophthalmology Statistics

CV / Career or Work Summary

Please attach or provide below a CV or summary (two-page maximum) of your career and work experience to date. Applicants may describe the chronology of their work experience in any capacity including work inside and outside the home (eg volunteering, community work).

Attached to email with this expression of interest form

Committee, Advisory & Other Relevant Experience

Please describe your experience that is relevant to the role of a National Research Ethics Committee Member (250-500 words maximum). This could include working on committees or boards, or previous experience acting in an advisory capacity. Applicants may draw from both their professional and personal life experiences, which may not necessarily represent formal appointments.

Statement of Motivation

Please describe your individual motivations to be a Member of a National Research Ethics Committee (250-500 words maximum).

Conflicts of Interest

It is acknowledged that NREC Members may have competing interests spanning their work inside and outside of the Committee. Most competing interests will simply need to be acknowledged and managed appropriately to minimise their impact. The National Office manages material interests in accordance with Schedule 5 of the respective Statutory Instruments that provide the legislative framework for the respective NRECs. Where a competing interest is sufficiently serious to constitute a conflict of interest, namely where a primary interest (such as objective ethics review of a research study or research area) tends to be unduly influenced by a secondary interest (such as financial gain), independent judgement of the Member may be compromised. In accordance with the legislation underpinning the work of the NRECs, Members will be invited to declare any competing interests, including conflicts of interest, in relation to the applications for review in advance of the Committee discussion.

Do you have any potential conflicts of interest or legal impediment that would likely interfere with your ability to play a full and proper role on an NREC?

Yes	No
If Yes, please describe	

Data Protection & Privacy Statement

The National Office for Research Ethics Committees fully respects your right to privacy. Any personal information that you provide to us will be treated with the highest standards of security and confidentiality, strictly in accordance with the General Data Protection Regulations and the Data Protection Act 2018. The National Office are an independent unit hosted by the Health Research Board and as such are the Data Controllers of personal data being processed by the National Office.

The National Office for Research Ethics Committees has a statutory role to establish National Research Ethics Committees (NRECs) at the request of the Minister for Health. This includes publicly inviting, managing and evaluating Expressions of Interest for NREC membership. We may collect, use and disclose personal data provided in the Expression of Interest submission, or in connection with the submission, for the processing of the submission and its evaluation for Committee membership, including sharing the information securely with select third parties involved in the evaluation of the submission and the appointment of Members.

With a view to ensuring that NREC decisions are informed by the diversity of skills, experience, interests and backgrounds reflective of Irish society, the National Office invites applicants to complete the Diversity & Inclusion information overleaf. If you choose to provide this personal information, it will be used to help the National Office evaluate its progress towards achieving diverse and inclusive NREC membership. This personal information will not be sent to any third parties. We will also use the information you have provided to generate deidentified summary information and general statistics to describe and evaluate NREC membership.

Further details regarding the National Office's collection, use and disclosure of personal data, and the rights of individuals with respect to any personal data held by the National Office, are available in our <u>Privacy Policy</u> and <u>Data Retention Policy</u>.

Declaration

I	declare that the
information I have provided is true and correct.	
Date:	

Diversity & Inclusion Information (Optional)

The National Office for Research Ethics Committees provides equal opportunity for membership of the NRECs. Your answers to the following questions will help us to evaluate our progress towards achieving diverse and inclusive NREC Membership.

How would you describe your gender?

Woman

Man

Prefer to self-describe as:

Prefer not to say

Please indicate your age:

18-24	45-54	75-84
18-24	45-54	75-84

25-34 55-64 85 and over

35-44 Prefer not to say

Do you consider yourself to have a disability?

Yes No Prefer not to say

Please describe any accessibility requirements you may have for Committee participation