

Expression of Interest:

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 7-13 of this form.
Submissions should be made to membership@nrec.ie

Please include '**NREC Member EoI**' in the subject line.



**Please only use Adobe Reader 10 or higher
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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

Background

National Research Ethics Committees (NRECs) are responsible for reviewing research proposals in prescribed areas of health research, and to deliver a single national ethics opinion. They play a key role to ensure the safety, dignity and well-being of health research participants.

In 2021, the National Office for Research Ethics Committees established National Research Ethics Committees (NRECs) in specific areas of health research as requested by the Minister for Health to enable Ireland to meet its regulatory requirements under existing EU regulations; 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).

These NRECs established have a specific remit to assess the ethical aspects of health research studies in the following areas:

- Clinical trials for investigational medicinal products for human use (NREC-CT A, B, C & D)
- Clinical investigations for medical devices (NREC-MD)
- Performance studies for *in vitro* diagnostic devices (NREC-MD)

As the national system of ethics review is an integral infrastructure within the Irish health research ecosystem, it is critical that the National Office ensures the NRECs are constituted with a diverse membership with skills, lived experience, interests and backgrounds reflective of Irish society to deliver robust ethics opinions.

From time to time, the National Office may seek additional members to fill any vacancies that might arise and to assist the NRECs as subject matter experts throughout the year. To that end, the National Office now accepts Expressions of Interest applications for membership of the National Research Ethics Committees on a rolling basis.

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.

The National Office 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 and geographic location.

Reasons to join a National Research Ethics Committee

- Contribute to safeguarding of safety, dignity and well-being of research participants
- Contribute to health research at a national and international level
- Gain insight into emerging European regulatory changes and best practice in research ethics
- Gain insight into forefront research and emerging areas of healthcare and treatments
- Enhance your professional & personal development through your membership on a NREC and the benefit of continuous member training opportunities, such as '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 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 ethics 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 report to the Minister. The purpose, structure, and scope of the NRECs are defined by their Terms of Reference, which are provided at appointment and are informed by the legislation that prescribe how the NRECs are constituted and operate.^{1 2 3}

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.⁴ The transparency of the decision-making process aims to engender the trust of the research community and wider public.

All NRECs have a Chairperson and two Deputy Chairpersons, whose tenure is four years.

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 are listed on the National Office website.⁵

¹ [S.I. No. 41 of 2022, European Union \(Clinical Trials on Medicinal Products for Human Use\) \(National Research Ethics Committees\) Regulations 2022](#)

² [S.I. No. 671 of 2023 European Union](#)

³ [\(National Research Ethics Committees for Clinical Investigations of Medical Devices\) Regulations 2023](#)

⁴ [S.I. No. 257 of 2022 European Union \(National Research Ethics Committees for Performance Studies of In Vitro Diagnostic Medical Devices\) Regulations 2022](#)

⁵ [NREC Decisions](#)

⁵ [NREC-CT Members, NREC-MD Members](#)

Terms of membership

- Observe the Terms of Reference for the NREC provided by the National Office;
- Actively participate in the majority of NREC monthly meetings, 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 ethics considerations raised;
- Commit to a consensus-based approach to decision-making under the direction of the Chairperson;
- 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 for the NREC are managed by the National Office for Research Ethics Committees. All Expression of Interest are acknowledged by the National Office on receipt. As opportunities for membership on a NREC arise, the National Office reviews Expressions of Interest in consultation with the Chairpersons, and/or Deputy Chairpersons and/or external experts as required, for appropriate expertise.

Applicants may be invited to meet the assessment panel to discuss their Expression of Interest further.

Expressions of Interest are evaluated for demonstration of the skills, lived experiences and attributes necessary for effective NREC participation.

Member selection is 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 prospective members are deemed suitable for selection, the National Office will put forward to the Minister for Health for recommendation for appointment to a NREC.

Where no vacancy is immediately available on a NREC, suitable applicants, with their permission will be placed on a reserve panel, with a view to being contacted as future opportunities for membership arise. Given the breadth of expertise and perspectives required and the anticipated expansion of the scope of NRECs over time, individuals on this panel may also be approached from time to time to contribute to NREC deliberations based on their expertise and experience.

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 ethics assessors. In recognition of the technical, scientific, experiential, or other subject matter expertise required of members to deliver expert assessments on ethic applications, remuneration for this service conducted outside of normal business hours will be provided.

Members are required to participate at NREC meetings to deliberate and consider the expert ethics 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 (eg travel to meetings where necessary, stationery).

Time commitment

Committee meetings are convened monthly, mostly virtually/remotely and may occasionally be convened in person. The meeting schedule for the year will be provided at appointment by the National Office.

NREC meetings are scheduled within business hours on a recurring day scheduled in advance and will typically be 2 - 3 hours in duration.

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

Generally NRECs meet 10-12 times per year, and 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 other team members within the National Office.

Expression of Interest Form

What Committee are you interested in?

NREC for Clinical Trials of Medicinal Products for Human Use

NREC for Clinical Investigations of Medical Devices and Performance Studies
of *In Vitro* Diagnostic Medical Devices

Either

Personal Details

Title: Ms Mrs Mr Mx Dr Prof Other

Forename:

Surname:

Address:

Email:

Phone:

Current employment status

Employed

Retired from employment

Unemployed

Looking after family or home

Student

Other

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

Expertise and Experience

Please provide up to 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

The National Office welcomes Expressions of Interest from individuals with diverse expertise.

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

| | |
|---|--|
| Artificial Intelligence (Healthcare) | Member of Public |
| Assisted Human Reproduction | Microbiology |
| Biomedical Science | Molecular Diagnostics |
| Cardiology | Nursing |
| Clinical Genetics | Obstetrics and Gynaecology |
| Clinical Trials | Oncology |
| Data Protection | Paediatric Medicine |
| Diagnostics | Pathology/ Histopathology |
| Disability / Accessibility | Patient / Carer |
| Epidemiology | Patient Organisation / Advocacy Group / Non-governmental Organisation / Community Organisation |
| Ethics / Philosophy | Pharmacology/ Pharmaceutical Medicine |
| Gene Therapy | Public Health Medicine |
| General Practice Medicine | Radiology/ Radiation Oncology/ Radiation Therapy/ Medical Physic |
| Haematology | Respiratory Medicine |
| Infectious Disease Medicine | Social Sciences |
| Medical Devices | Statistics |
| Medical Engineering / Software Development | Other: |
| Medical Practitioner (registered) | |
| Medical Software Development | |
| Medico-legal Practice | |

Do you have a prior experience as member of a Research Ethics Committee?

No

Yes – please list committee and role

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 the respective Statutory Instruments that provide the legislative framework for the respective NRECs. 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 is 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.

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 Privacy Policy and Data Retention Policy.

Declaration

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

Date: