

Call for Expressions of Interest for Membership of Ireland's

NATIONAL RESEARCH ETHICS COMMITTEES

Your opportunity to strengthen Irish health research



Expressions of Interest should be completed by answering the questions on pages 7-14 of this form. Submissions should be made to <u>membership@nrec.ie</u> prior to midday **Monday 11th January 2021**. Please include 'NREC Member Eol' in the subject line.

'Being a Member of an NREC is an opportunity to work collaboratively with a diversity of people towards a shared national goal – to strengthen Irish research'

Prof. Mary Horgan Chair, NREC COVID-19 President, Royal College of Physicians of Ireland



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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 new national system of ethics review for health research will be implemented in Ireland and Expressions of Interest are sought for Membership of the first 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 decisions on the ethics underpinning Irish health research are informed by the diversity of skills, experience, interests and backgrounds reflective of Irish society.

The Government approved drafting of the National Research Ethics Committees Bill in July 2019, which is the basis for a new national approach to research ethics review. This bespoke system will improve the national infrastructure for health research and ensure Ireland represents a favourable environment for the conduct of clinical trials to derive the benefits of health research for society and the economy. The newly established National Office for Research Ethics Committees will establish National Research Ethics Committees (NRECs) in select areas of health research* at the request of the Minister for Health, the initial priorities being for clinical trials of medicinal products for human use and clinical investigations of medical devices.

The NRECs will work alongside local research ethics committees to support the spectrum of health research in Ireland through rigorous independent review in a timely and transparent manner. The NRECs will make decisions on applications for ethics approval submitted to them through the National Office and will be supported by National Office staff. Importantly, NRECs will be mandated to return a 'single national opinion' on applications for ethics approval meaning that NREC decisions will be respected nationally.

The National Office for Research Ethics Committees is seeking Expressions of Interest for NREC Membership to make a selection for consideration for appointment by the Minister for Health. This may include clinicians, pharmacists, nurses, other healthcare workers, legal practitioners, research scientists, social scientists, patients and other members of the public. Interest from those with expertise in, but not limited to, clinical trials, ethics and philosophy, diagnostics, epidemiology, genetics, general practice medicine, health psychology, medical devices, medicolegal practice, paediatric medicine, public health, radiology, and statistics is welcome. Individuals with prior research ethics committee experience are welcome to apply, although experience is not essential. Experiential knowledge, in addition to professional knowledge, valuably informs the process of research ethics review. Expressions of Interest are therefore particularly invited from those who may be, or have been, patients, parents, carers or involved in patient organisations or feel they have an informed life experience or perspective to bring to bear for health research in Ireland.

The National Office for Research Ethics Committees is an equal opportunity organisation 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.

* Health research as defined by the Health Research Regulations 2018

This is an exciting and rare opportunity to enable Irish research, to gain insight into forefront health developments and to ensure that Irish research is strengthened by the highest ethics standards. Appointed Members will receive training, access to the electronic tools necessary to conduct Committee work, and administrative support from the National Office team.

Reasons to join a National Research Ethics Committee

- Contribute to protecting the safety, dignity and well-being of research participants
- Make a difference at a national level
- Gain insight into forefront research
- Enhance your professional & personal development

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. By modelling and sharing best practice, NRECs will have the opportunity to improve the quality of ethics decision-making across the spectrum of research in Ireland.

Members will be appointed by the Minister for Health, and NRECs as a whole will report to the Minister. The purpose, structure, and scope of the NRECs will be defined by their Terms of Reference, which will be provided at appointment.

It is expected that three NRECs will be appointed in the first instance - two for clinical trials of medicinal products for human use (NREC-CT), and one for clinical investigations of medical devices (NREC-MD). Decisions made by NRECs on applications for research ethics approval will be entirely independent. The decision-making process of the national ethics review system will engender and sustain the trust of the research community and wider public. An important component of the new national system of research ethics review will be an independent mechanism to appeal a decision of an NREC. NREC meetings will require a quorum for decisions and detailed minutes of meetings will be made publicly available.

Membership of an NREC is an important public role requiring commitment. Details of appointed Members will be listed on the National Office website. Committee meetings will be convened monthly, mostly virtually and occasionally in person. Meetings will be 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.

You will be expected to:

- Adhere to the Terms of Reference for the NREC and the standard operating procedures provided by the National Office;
- Observe the specific role requirements provided, where you are appointed as Chairperson / Deputy Chairperson;
- Actively participate in a minimum of nine monthly NREC meetings per year, confirming attendance and any foreseen absences in advance;
- Prepare ahead of NREC meetings including review of applications, and documentation of your preliminary comments;
- 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 staff 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 conflicts of interest;
- 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 will be managed by the National Office for Research Ethics Committees with a view to making a selection for consideration for appointment by the Minister for Health. The National Office will review Expressions of Interest in consultation with an assessment panel. 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 team, 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. Additionally, applicants interested in the roles of Chair or Deputy Chair should evidence relevant experience at an appropriately senior level and knowledge of the Irish health research environment as it relates to the remit of the NREC.

Member selection will be proposed based on the diversity of skills, qualifications, interests and backgrounds required to make decisions on applications likely to be made to the NREC. Selection will also be informed by appropriate representation of both 'expert' and 'lay' Members as provided for in the NREC Bill. A maximum of 21 Members will be appointed to each NREC, including one quarter lay Members eg Patient & Public Involvement (PPI). Where in the view of the National Office there is likely to be a particular gap in expertise or representation, prospective Members may be approached to invite an Expression of Interest.

Chairpersons and Deputy Chairpersons may serve for four years, and other Members for three years, unless their tenure is terminated earlier. Members will be eligible for reappointment for one additional consecutive term. 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 a voluntary role in public service. Given the extent of the commitment required for the roles of Chairperson and Deputy Chairperson, annual fees will be paid of €10K and €5K to these appointees respectively. Acknowledging that Committee work may not be professionally recognised or may clearly fall outside of typical responsibilities for some, PPI Members will be offered an annual fee of €2.5K. Other NREC Members will not be paid. 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 work will be reimbursed to all Members (eg travel to meetings where necessary, stationery).

Members will receive use of an iPad, in addition to access to the electronic tools necessary to conduct NREC work.

NREC MEMBERSHIP

What NREC role are you interested in?

Chairperson	Committee Member
Deputy Chairperson	Any

Which Committee are you interested in?

NREC for Clinical Trials of Medicinal Products Either

NREC for Clinical Investigations of Medical Devices

If not appointed on this occasion, are you happy for your details to be retained for contact about future opportunities including the NREC Expert Group?

Yes No

Personal Details

Title:	Ms	Mrs	Mr	Dr	Prof
Surname:					
Forename:					
Address:					
Email:					
Phone:					
Current position:	Employed	I	Unemployed		Student
	Retiree	l	Home-maker		

If employed, please state your role and employer

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

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 interested in the roles of Chair or Deputy Chair should include their experience acting in a relevant similar role (eg Chairperson or leadership of other committees). 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).

Expertise by Experience

Please provide 5 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

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

- Artificial Intelligence (Healthcare) Assisted Human Reproduction Clinical Trials Ethics / Philosophy Epidemiology Data Protection Diagnostics Disability / Accessibility General Practice Medicine Genetics General Public Health Psychology Ionising Radiation
- Medical Practitioner (registered) Other Healthcare Professional Medical Devices Medical Sciences Medico-legal Practice Nursing Paediatric Medicine Patient / Patient Organisation Pharmacy Public Health Social Sciences Statistics

Character References

Please provide the contact details (name, address, phone and email) of two individuals unrelated to you but who know you well and will be happy to be contacted to speak to your character. Applicants may draw from both their professional and personal networks, which may not necessarily represent employers or managers.

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. 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) (Thompson DF et al. 1993), independent judgement of the Member may be compromised. NREC 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 Regulation and the Data Protection Act 2018.

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. The National Office will act as the Data Controller and will retain this personal information for up to five years.

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 third parties. We will also use the information you have provided to generate 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

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declare that the

information I have provided is true and correct.

Date:

Diversity & Inclusion Information

The National Office for Research Ethics Committees is an equal opportunity organisation. 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?

Female Male Prefer to self-describe as:

Prefer not to say

Please indicate your age:

18-24	45-54	75-84
25-34	55-64	85 and over
35-44	65-74	Prefer not to say

What is your ethnic or cultural background?

Asian or Asian Irish

Chinese

Any other Asian background

Black or Black Irish

African

Any other Black background

White

Irish

Irish Traveller

Any other White background

Other, including mixed background

Other, please describe

Prefer not to say

Diversity & Inclusion Information (continued)

Please select the option that best describes your sexuality:

Bisexual Gay Heterosexual Lesbian Prefer to self-describe as:

Prefer not to say

Please select the option that best describes your religion or beliefs:

Atheism Buddhism Christianity Islam Other:

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