

## **Supporting Information pack for potential Research Ethics Committee Members**

### **What is a Research Ethics Committee (REC)?**

A Research Ethics Committee (REC) is an independent committee that considers the ethics of applications to conduct health or social care research in the UK. The applications will involve human participants, and most will take place within the NHS or HSC. The research proposal cannot proceed without the approval of the REC. The key duty of a REC is to protect the interests of the research participants whilst at the same time facilitating ethical research. The committee reviews research applications and gives an opinion on whether the research is ethical.

REC members receive training in ethical review and have opportunities to debate challenging issues.

The Business Services Organisation (BSO) is the appointing authority for the 2 HSC RECs in Northern Ireland. The Office for Research Ethics Committees Northern Ireland (ORECNI) services the HSC RECs, and has a Head of Service and a team of committee managers who provide assistance and advice to researchers who are in the process of submitting their proposals for ethical review by the HSC RECs.

Each REC consists of:

- A minimum of seven and a maximum of 18 volunteers;
- Lay members (a term used to describe people who are not registered healthcare professionals and whose primary professional interest is not in clinical research). At least one third of members must be lay;
- Expert members (a range of specialists including doctors, other healthcare professionals, statisticians with expertise in clinical research and others).

The definition of lay and expert members is defined in the UK Clinical Trials Regulations. Although there are different classifications (i.e. expert and lay), everyone's role on the committee is the same.

### **The process of ethical review**

This process involves ensuring that any research project should fairly balance the likely benefits to the participant, or society at large, against the burdens involved and any risk of harm or actual harm to those taking part. It also means ensuring that the research proposal itself is necessary, properly designed, supervised and conducted and that the outcome will answer the research question.

An extremely important part of this is ensuring that patients or other participants are not unfairly pressured into taking part and that they are fully informed about the project and what it will mean for them. Central to this is the requirement to ensure that participants have appropriate information before they agree to take part in the study (i.e. informed consent).

Members undertake ethical review in line with the Standard Operating Procedures for Research Ethics Committees and other national and international legislation and guidance, such as the Clinical Trials Regulations, Mental Capacity Act and the Human Tissue Act.

There are three categories of RECs in the UK. All RECs review a wide range of different types of health and social care research, but in addition some have special responsibilities:

- Type 1 REC – reviews applications for phase 1 trials in healthy volunteers within the UK (i.e. a clinical trial to study the effect of a new medicine when administered to humans for the first time).
- Type 3 REC – reviews applications for Clinical Trials of Investigation Medicinal Products (CTIMPs) within the UK (i.e. a clinical trial of a new medicine or an existing medicine being used outside of its licence).
- Authorised REC – is not permitted to review CTIMPs but reviews other types of research.

Some RECs may also be flagged to review research in special areas, such as medical devices, research tissue banks / databases, research involving children, social care, prisons and participants assessed under the Mental Capacity Act as being unable to consent for themselves.

REC meetings are not held in public, although meetings may be attended by observers with an interest in the work of RECs.

### **What is a lay member?**

A lay member means someone who is not currently professionally qualified in healthcare. Our lay members come from a wide range of professional backgrounds. For example, teachers / lecturers, students, research administrators at pharmaceutical companies or other clinical research bodies, medical ethicists, solicitors, barristers and administrative staff.

### **What is an expert member?**

The definition of an 'expert member' is defined under the Medicines for Human Use (Clinical Trials) Regulation 2004. Under the Regulations, an expert member means a member who:

- a) Is a 'healthcare professional' (see below) \*
- b) Has professional qualifications or experience relating to the conduct of, or use of statistics in clinical research, unless those professional qualifications or experience relate only to the ethics of clinical research or medical treatment.
- c) Is not a healthcare professional but has been a registered medical practitioner or a registered dentist.

\*Healthcare professional is defined in the Regulations and includes the following:

- A doctor
- A dentist
- A nurse or midwife
- A pharmacist
- An ophthalmic optician registered under section 7 of the Opticians Act 1989
- A registered osteopath as defined by section 41 of the Osteopaths Act 1993
- A registered chiropractor as defined by section 43 of the Chiropractors Act 1994
- A person registered by the Health Professions Council under the Health Professions Order 2001, which includes the following:
  - Art therapists
  - Chiropodists
  - Clinical scientists
  - Dieticians
  - Medical laboratory technicians
  - Occupational therapists
  - Orthoptists
  - Paramedics
  - Physiotherapists
  - Practicing psychologists
  - Prosthetists and orthotists
  - Radiographers
  - Social workers in England
  - Speech and language therapists

### **Qualities required for the role of lay and expert members**

To help you decide if you wish to apply for REC membership, we have listed below the criteria that will be applied when assessing candidates. To be considered, you must be able to demonstrate that you have the qualities, skills and experience to meet the criteria.

You should:

- Have a strong personal commitment to the interests of patients who take part (or are asked to) in health and social care research;
- Have a strong personal commitment to ensuring the highest standards for health and social care research;
- Be able to read, understand and analyse complex issues from research proposals and weigh up conflicting opinions;
- Be able to take an objective stance, looking at a situation from several perspectives;
- Be a good communicator with a practical approach and confidence to voice your opinions;
- Be able to discuss issues with people who may not agree with you, including being able to influence others from a range of backgrounds;
- Be committed to the public service values of accountability, probity, openness and equality of opportunity;
- Be able to demonstrate an ability to contribute to the work of the REC;
- Be available monthly (approximately 10 meetings per year) with a commitment to attend at least 6 of the meetings;
- Be available to undertake the review of Proportionate Review applications and substantial

- amendments electronically on a rota basis (approximately 2 to 3 meetings a year)
- Understand the requirement for confidentiality in issues faced by a REC;
- Be willing to undertake initial induction training and Equality and Diversity training in the first year of membership and then complete at least 5 hours training per year to equip you to carry out your role;
- Be IT literate and comfortable reviewing documents electronically. Access to a computer or tablet is desirable but if not, we can loan you a netbook to enable you to undertake REC work to be carried out via email and the Member Portal.

### **Some questions you may have:**

#### **What kind of person would make a good REC member?**

You would have a very real interest in protecting interests of individuals but also in supporting health and social care research. You would be able to take a balanced view of the likely harms and benefits of a research project. You will need to be confident about expressing and supporting your own opinions, whilst also taking into consideration the opinions of your colleagues on the committee. You will need the ability to understand the sometimes-complex issues involved in reaching ethical decisions. You will need to be flexible, have excellent communication skills and possess a desire to “make a difference”.

#### **Who would I be representing?**

Members of a REC are not there to represent any interest group. Members are drawn from a variety of groups to give as wide a perspective as possible. Lay members will bring their own valuable perspective to the committee’s deliberations through a variety of experiences, contacts and networks, and be able to reflect current public views and concerns. You might like to think about the lay member role as the person who consciously considers how decisions might appear or would feel to an outsider or a participant. This is clearly not the sole prerogative of the lay member because other people within the ethics committee will undoubtedly have their own sensitivities and perceptions. Expert members will also bring to the discussion their knowledge and experience of working within the healthcare system and / or conducting research.

#### **What experience should I have?**

REC members come from all walks of life and bring differing experiences to the committees. It is not necessary to have been involved in committee work before, however, you may have some understanding of how organisations work and, how meetings are run through experience gained via involvement in business, industry, community groups, school representative bodies, voluntary organisations and charities. We will provide you with training to undertake the role.

#### **What would I be expected to do?**

You would work with the rest of the committee using your skills and personal experience to reach decisions about research applications. Prior to the meeting you would be expected to read the meeting papers electronically via our Member Portal. At the meetings, the proposals

will be discussed, and it may be possible to ask questions directly to the researchers themselves, before a decision is taken by the committee. As the meeting papers are reviewed electronically, it is important that you are comfortable using a computer or a tablet to review the documents. If you would like to see what our Member Portal looks like, why not have a look at our demonstration video by clicking [here](#).

### **How much time is involved?**

Approximately four hours per month at the REC meeting, plus at least four hours preparatory reading. After six months as a member, you would be expected to participate in the review of Proportional Review (PR) applications as part of a sub-committee. PR applications are lower risk studies containing fewer ethical issues. You would also be expected to take part in sub-committees to review amendments to studies, which have already received a favourable ethical opinion on a rota basis. Both types of meetings will be held electronically via our Member Portal. You will be asked to participate in approximately 2 to 3 sub-committee meetings a year, each requiring about 2 hours reading.

### **Will I be able to carry out the role of a REC member alongside my current job?**

This will clearly depend on your current employer's policy regarding voluntary appointments. Some employers may allow you time to attend the REC meetings, recognising the activity as professional development or via a corporate social responsibility policy. However, you will need to check this with your line manager or HR department. Most organisations appreciate the valuable work of committees, without which, research in the NHS or HSC could not be carried out. We can also send a letter to your employer asking them to support your application to join a REC, should you feel this would be helpful.

For healthcare professionals, REC membership is recognised as Continuing Professional Development (CPD) and can count towards Clinical Excellence Awards.

If you are not a healthcare professional, it is important to acknowledge the work you undertake and the skills you have developed as a result of being a REC member during your work appraisal.

### **Will I get paid for being a REC member?**

This is a voluntary position and as such, does not accrue employment rights under employment legislation. You will not be paid for this role but the BSO will reimburse any travel costs or other agreed expenses, such as childcare, incurred whilst undertaking REC duties.

If you are self-employed, you might be eligible for payment of loss of earnings e.g. if you are a GP and need to arrange for a GP locum to cover your clinic. You will need to get prior approval from ORECNI and then submit receipts to show that you arranged for someone to cover your work whilst you were engaged on REC business. There is a maximum amount that can be claimed, and this arrangement only applies to cover provided in the UK.

If you are in receipt of certain state benefits you may wish to obtain independent advice about

whether your planned involvement in our work affects your continued entitlement. ORECNI wishes to ensure that people who must keep within benefit conditions that may apply to paid or voluntary participation are not prevented from participating in our work. We may be able to adjust our offer to you, to comply with your benefit conditions if requested.

### **Who else is on a REC?**

The RECs draw their membership from:

- General practitioners
- Hospital medical staff
- Lay persons
- Other health service professionals
- Research professionals
- Academics

Our membership is taken from people in all walks of life who are representative of the community and general population, whether employed, unemployed or retired.

### **Where will REC meetings be held?**

ORECNI currently supports the 2 HSC RECs in Northern Ireland (REC A and REC B). Both REC A and REC B meeting dates and times are available on the Health Research Authority (HRA) website: [Search Research Ethics Committee Directory - Health Research Authority \(hra.nhs.uk\)](https://www.hra.nhs.uk/research-ethics-committee-directory). All meetings are currently held via videoconferencing.

### **What is the legal position of a REC member?**

Any member acting responsibly within the HSC committee is 'indemnified' by the Department of Health in Northern Ireland. The Department of Health will take full responsibility for all actions of an HSC REC member in the course of his/her performance of duties other than those involving bad faith, wilful default or gross negligence. Members should, however, notify the ORECNI if any action or claim is threatened or made, and in such an event be ready to assist the Department of Health as required.

### **How long would I serve?**

A term of office is generally five years. Terms of appointment may be renewed, but normally not more than two terms of office are served consecutively. You may resign at any point during your membership, but members can, and many do, stay on for a maximum of 10 years.

### **Who can I discuss this with in greater detail?**

If you would like further information about REC membership, please contact Karen Beattie or Fiona McNally at [info.orecni@hscni.net](mailto:info.orecni@hscni.net)

**Please note that the ORECNI website is currently under construction, and does not contain up-to-date information.**

## How do I apply?

You will need to complete the application form accompanying this Information pack. We also ask that you complete a REC Members Equal Opportunities Monitoring form. The BSO is committed to the principles of appointments based on merit with independent assessment, openness and transparency of process. It is also committed to equality of opportunity and welcomes application forms from all suitably qualified applicants irrespective of religious belief, gender, race, political opinion, age, disability, marital status, sexual orientation, or whether or not they have dependants.

In order to improve diversity on its HSC Research Ethics Committees, BSO wants to encourage more young people, ethnic minorities and people with disabilities to apply for appointments. Applications from these groups would be particularly welcome.

Applicants shortlisted are invited to complete a short assessment and attend an interview. **Interviews will be held on 28<sup>th</sup> February and 1<sup>st</sup> March 2023, via teleconference.**

Further information about the Research Ethics Committee Service can be found at [www.hra.nhs.uk](http://www.hra.nhs.uk)