

## **Information for potential Research Ethics Service Committee members**

### **What is a REC?**

A REC is a Research Ethics Committee, which is an independent committee of the Health Research Authority, whose task it is to consider the ethics of proposed research projects which will involve human participants and which will take place, generally, within the NHS. Healthcare research cannot proceed without the approval of the REC. The key duty of a REC is to protect the interests of 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.

Each REC consists of:

- A minimum of seven and a maximum of 15 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 and others).

The definition of lay and expert members is defined in the UK Clinical Trials Regulations.

There are approximately 100 RECs in the UK based in England, Scotland, Wales and Northern Ireland.

### **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 asked.

An extremely important part of this is ensuring that patients or other potential 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 undertake to take part in the study (i.e. informed consent). Members undertake ethical review in line with Research Ethics Service (RES) Standard Operating Procedures (<http://www.hra.nhs.uk/resources/research-legislation-and-governance/standard-operating-procedures/>) 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 healthcare research, but in addition some have special responsibilities:

- Type 1 REC – reviews applications for phase 1 trials in healthy volunteers within the UK.
- Type 3 REC – reviews applications for Clinical Trials of Investigational Medicinal Products (CTIMPs) within the UK.

- 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, 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 Research Ethics Committees.

## **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, Research administrators at pharmaceutical companies or other clinical research bodies, Lawyers, Hospital Chaplains, administrative staff.

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

The definition of an 'expert member' is defined under the Medicines for Human Use (Clinical Trials) Regulations 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 health care professional, but has been a registered medical practitioner or a registered dentist.

*"Health care 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 provides for registration of the following:
  - arts therapists
  - chiropodists
  - clinical scientists
  - dieticians
  - medical laboratory technicians
  - occupational therapists
  - orthoptists
  - paramedics
  - physiotherapists
  - practising psychologists

- prosthetists and orthotists
- radiographers
- speech and language therapists.

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

To help you decide if you wish apply for appointment for the role of member, 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.

### **Essential**

You should:

- have a strong personal commitment to the interests of patients who take part (or are asked to) in healthcare research;
- have a strong personal commitment to ensuring the highest standards for healthcare 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.
- understand the requirement for confidentiality in issues faced by a REC;
- be willing to undertake initial induction training and then at least 5 hours training per year to equip you to carry out your role.
- be IT literate and have access to a computer or tablet to allow some REC work to be carried out via email and via the Member Portal.

### **Desirable**

You might:

- Live in, or close to, the geographical area served by the REC
- Have access to the internet to be able to review applications using the Member Portal.

## **Some questions you may have**

### **For lay members**

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

You would have a very real interest in protecting the interests of individuals but also in supporting healthcare research. You would be able to take a balanced view of the likely harms and benefits of a research project from a lay perspective. Someone who can say “this is all very well, but what about the participant?”, you will need to be confident about expressing and supporting your own opinions. You will need the ability to understand the sometimes complex issues involved in reaching ethical decisions. You will require no specific qualifications for this role, but you will need flexibility, excellent communication skills and a desire to “make a difference”.

#### **Who would I be representing as a lay member?**

Members of a REC are not there to represent any particular interest group. Members are drawn from a variety of groups to give as wide a perspective as possible. However your voice will be one of a small number drawn from outside the healthcare professions and your viewpoint will be important in supporting the interests of the research participant. It is hoped that the lay member 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 any decisions might appear or feel to an outsider or to 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.

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

Lay members come from all walks of life and bring differing experience to committees. It is not necessary to have been involved in committee work before, however you may have some understanding of how organisations work and in particular of how meetings are run through experience gained through involvement with community groups, schools’ representative bodies, voluntary organisations and charities, business, or industry.

#### **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 proposals. Prior to the meeting you would be expected to read the agenda papers. 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.

#### **Will I be able to continue with my current job?**

This will clearly depend upon your current employer’s policy on such appointments (e.g. for employees who are also JPs or who serve on parole boards and school governors). You must bear in mind that a majority of the meetings are held during the working day but we do have some meetings in the evening.

If you are self-employed you might be eligible for payment of loss of earnings. You will need to get prior approval from your REC Manager 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 only cover provided in the UK will be covered.

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. The HRA 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.

### **For expert members**

#### **Will my organisation support my attendance at the meetings?**

There will be a number of RECs within the local area which will meet at different times of the day. Some meet during the evening. Some employers may allow you time to attend the meetings but you should check this with your line manager or HR department. Most organisations appreciate the valuable work of the committees, without which, research in the NHS could not be carried out. REC membership is often recognised in Consultant Job Plans.

If you are self-employed you might be eligible for payment of loss of earnings. For example locum fees are payable to GP upon submission of receipts from a locum agency or other valid locum provider.

### **For lay and expert members**

Please note: this is a voluntary position and as such does not accrue employment rights under employment legislation.

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

Approximately four to five hours per month at the meeting, plus four to six hours preparatory reading. It is difficult to be precise as the workload of one committee may be different from another. After six months as a member you would be expected to participate in the review of Proportionate Review applications as part of a Sub-Committee. Proportionate Review applications are lower risk studies containing fewer ethical issues. Proportionate Review meetings may be held electronically, face-to-face or by telephone. 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.

#### **Who else is on a Research Ethics Committee?**

The RECs draw their membership from:

- General practitioners
- Hospital medical staff
- Nursing 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 meetings be held?**

Please indicate the committees you wish to be considered for on your application form. A list of meeting dates is available on the HRA website: <http://www.hra.nhs.uk/research-ethics-committees-meeting-dates/>

### **What is my legal position?**

Any member acting responsibly within the committee is 'indemnified' by the Health Research Authority. That is, the Health Research Authority will protect members against civil action that might arise from the business of the committee. This is with the provisos that the member informs the Health Research Authority and co-operates with them in respect of any claim made against them, and has not acted in bad faith, wilfully defaulted on their responsibilities or been grossly negligent.

### **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, so you could be a member for up to a maximum of 10 years.

### **Will training be provided?**

The Health Research Authority holds a number of training events for REC members to attend. You would be expected to attend an initial induction event and then at least one training event per year. The HRA also provides E-Learning training courses.

### **Will I be able to claim expenses?**

Any travel costs or other agreed expenses, such as childcare, incurred undertaking REC duties will be reimbursed. All payments are made by BACS and in line with the HRA Members' Expenses Policy.

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

If you would like further information please contact Sharon Melbourne, Operations Coordinator, Email: [Sharon.melbourne@nhs.net](mailto:Sharon.melbourne@nhs.net) and she can arrange for you to speak to a member of staff.

Prospective applicants often find it helpful to attend a REC meeting as an observer in order to gain a greater understanding of the work of Research Ethics Committees before submitting an application form. This can also be arranged by contacting Sharon Melbourne.

### **How do I apply?**

You will need to complete an application form, which is published on the HRA website.

**Further information about the Health Research Authority and the Research Ethics Service can be found on our website: [www.hra.nhs.uk](http://www.hra.nhs.uk)**

