

Guidance for Applicants attending a Full REC meeting

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1. Purpose of document

This document provides guidance and advice for applicants who have submitted an application for Research Ethics Committee (REC) review and will therefore be attending a REC meeting in the near future. This guidance applies to full REC meetings. This document provides you with a greater insight into the process of attending a REC meeting in the UK and is designed to ensure you are more familiar with the procedure of ethical review.

2. Scope

This document is for chief investigators, students, academic supervisors, research sponsors, observers and anyone else involved in the research who may be attending a REC meeting for the review of an application. This document applies to RECs within the UK Health Departments' Research Ethics Service.

3. Composition of a REC

A REC is comprised of 7 – 18 members (the optimum maximum membership is 15 members), and at least seven of these will be present at the meeting. Each REC is made up of expert and lay members. Expert members could include hospital consultants, nurses, academics, health care professionals, clinical trial statisticians, and pharmacists, whilst lay members are often people with no affiliation with the National Health Service, such as solicitors, members of the clergy and teachers. The opinion letter from the REC will advise you of the names and designation of those members in attendance at the meeting for the review of your application.

Whereas every effort is made to ensure that each REC has a broad range of expertise, it is not possible for RECs to be specialists in all research topic areas, nor is this necessary. However, RECs have the option to request expert advice from a specialist referee (either a member of a different Committee or an external referee), if the members feel that they would benefit from additional guidance. If advice from a referee was sought before or after the meeting, this will be communicated to you in the decision letter.

4. Is attendance required?

Whilst attendance at a REC meeting is not compulsory, it is strongly recommended. If you are unable to attend the meeting in person, it is possible for you to request to be contacted by telephone. If attending the meeting by telephone, you should ensure that you are in a quiet environment with a good quality phone line, and that you have a copy of the application documents with you. Where possible, a land line number rather than a mobile number should be provided. If you are unable to attend either in person or over the telephone, the REC will make its decision based on the information in the application form and supporting documentation. Any queries which arise will be dealt with via further correspondence. You are recommended to attend the meeting however; as some issues the REC may identify with the application could be resolved if you are present to provide an explanation.

If you or another person attending the meeting has a disability, please contact the REC Manager prior to the meeting to allow appropriate arrangements to be made. The contact details for the REC Manager will be detailed on your meeting invitation letter.

5. Who should attend?

The chief investigator should attend; whilst any other key investigators or a representative of the sponsor are also welcome to attend. Any representative who does attend the meeting should have a good understanding of the proposed research in order to be able to answer any questions. For student applications, it is strongly recommended that the academic supervisor attends the meeting with the student for undergraduate and postgraduate level courses. The academic supervisor is also recommended to attend the meeting with the student for doctorate level studies. You do not need to bring anything specific to the meeting although it is useful to have a copy of your application to refer to. You will not be able to give a formal presentation however, if you would like to bring any software or demonstration models to the meeting, please check with the REC Manager in advance and we will try and accommodate this.

6. Time and venue

REC meetings are usually held monthly in the same venue at the same time. Directions to the meeting venue and the time of the review will be detailed in the invitation letter which will be emailed to you once a valid application has been received. Please check the venue details carefully, to ensure that you arrive at the correct place. You will be given a specific time for the discussion of the application however, whilst RECs do try to keep to time, this can be difficult dependent upon the discussions required for individual applications. You should be prepared to wait beyond the allocated time if necessary but the REC will try and keep this to a minimum and keep you informed of any delays.

7. Arrival at the venue

You should check the meeting venue and follow the instructions detailed on the formal invitation letter from the REC as meeting venues and arrangements differ across the country. You should wait outside the meeting room in the waiting area provided and not enter the meeting room until a member of the REC or the REC Manager invites you into the meeting.

8. Consideration of an application

The REC will discuss any ethical issues in the application prior to inviting you into the meeting.

Once the REC has conducted this initial review, you will be invited into the meeting to answer any questions which may have been raised. You will be asked to introduce yourself, and the Chair will introduce him/herself. All members will have name plates and any member who wishes to ask a question should introduce themselves. The Chair may also explain that the REC uses a lead reviewer system which involves allocating one or two members to review the application in particular detail. If you have requested to attend the meeting by telephone, you will receive a telephone call from the Chair however; your answers will be heard by all of the members who are present at the meeting.

You may be asked to give a brief overview of the project but formal presentations are not required. You should be prepared to answer questions from the REC including questions regarding the science/methodology of the study. Any questions the REC has could be

directed from the Chair alone, a member who has led the review of the study or anyone else on the Committee. This varies by REC. The REC may not be able to ask you all of their questions at the meeting therefore, further information may be requested as part of the ethical opinion letter.

The length of time you can expect to be in the meeting will vary depending on the type of study and any questions the REC may have, however, you can expect to be present in the meeting usually for anywhere between 5 and 20 minutes.

Once all the REC's main queries have been answered, you will be thanked for attending and shown out of the room. The REC will then discuss the application further, taking into account the answers that you provided. At the end of the discussion the REC will make a decision and a formal letter containing that decision will be e-mailed to the chief investigator (copying in the sponsor) within a maximum of 10 working days of the meeting (although the aim is to provide the letter within 7 days). On occasions, the REC may find all aspects of the project completely satisfactory and there may be no need to ask you any questions. However, if you have attended the meeting the REC will still, out of courtesy, invite you into the meeting in case you have any questions. If you had stated that you would be available to be contacted by telephone, the REC will telephone you to state that there are no questions to be asked and to thank you for being available. You may contact the REC Manager after the meeting to be informed of the decision however; you will need to wait for the decision letter in order to receive the details of any ethical considerations or further information required.

9. User feedback

The HRA website offers you the opportunity to provide feedback on the service received when making an application for ethical review. Any comments received will help to inform the operational system and improve the service the HRA provides. Compliments, concerns or suggestions are shared with the Regional Manager for the Centre and the REC Manager. The information is collated and analysed by the HRA Quality Assurance department. The name of the REC, for which the feedback was provided, is shared with the Research Ethics Service Senior Operational team, but not the study number or name of the person providing feedback.

The feedback form is available at: <http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>

In addition to feedback provided by you post review, the HRA Quality Assurance Department may also approach you to provide feedback on the service you have received;

The HRA has a complaints policy if you request that any aspect of the processing and review of the application is investigated on a more formal basis.

10. Observers

REC meetings are occasionally attended by observers, who will have no vested interest in the applications under review and will take no part in the discussion. All observers are required to sign a confidentiality agreement. You will be advised if any observer is in attendance at the meeting and will be offered the opportunity to ask the observer to leave. This does not apply to HRA staff who may be in attendance to observe the meeting.

Document Control

Change Record

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V1.1 final	30.01.2011	Final Version
V 1.2	03.10.2013	Annual Review
V 1.3	23.10.13	UKREDG
V 1.4	13/12/2013	Additional comments received at UKREDG
V1.5 Draft	10/11/2015	Annual Review
V1.5 Draft	16/12/2015	Additional comments received at UKREDG
V1.5 Final	04/01/2016	Out of session comments received from UKREDG

Reviewers

Name (name of reviewer and/or management group reviewing)	Date Reviewed	Version Reviewed
Joan Kirkbride	Head of Ops	V1.0 draft
Charlotte Allen	10/11/2015	V1.4
UKREDG	December 2015	V1.5 draft

Distribution of Approved Versions

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HRA Website	January 2014	V1.4
HRA Website	January 2016	V1.5