



## *Health Research Authority*

# Procedure for inviting Applicants to attend REC meetings

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**Owner:** Director of Operations  
**Scope of Document:** REC Staff (UK wide)

## 1. Purpose of document

This document provides guidance to all Research Ethics Committee (REC) staff, REC Chairs and REC members regarding the attendance of applicants at a REC meeting. This includes the procedures REC staff should follow prior to a meeting and guidance for REC staff and REC members to follow at a meeting.

## 2. Scope

This document is for all REC staff involved in inviting applicants to REC meetings and all REC members and REC staff who attend a REC meeting in the UK. This document applies to RECs in the UK Health Departments' Research Ethics Service.

## 3. Reference Documents

- Research Ethics Service (RES) Standard Operating Procedures
- Guidance for applicants attending a REC meeting
- Operational Management Guidance: 'Process for Supporting and Managing REC Members and Officers in their role on a Research Ethics Committee'

## 4. Responsibilities

### REC Manager/Co-ordinator

- Emailing a copy of the meeting invitation letter to the applicant when the application has been validated.
- Informing applicants of the meeting details including the venue and their appointment time.
- Recording who will be attending to discuss each application and ensuring that this information is available to be referred to at the meeting (including telephone numbers if applicable).
- Ensuring that arrangements are made at the meeting venue for those attending with disabilities.
- Providing observers with a confidentiality agreement (and link to feedback questionnaire where applicable) and ensuring that a signed copy is uploaded to HARP.
- Ensuring that appropriate signs are in place at the venue to inform applicants where they should wait and ensuring that the waiting area is a suitable distance from the meeting room in order that the discussions cannot be overheard.
- Ensuring that a name plate for each member is displayed at the meeting, and that the name plates are clearly visible to the researchers.
- Assisting the Chair to help ensure that the meeting runs to time and informing applicants who are attending in person or on the phone if the meeting is running late.
- Feeding back to the Regional Manager or RES Operational Manager where the meeting runs continually over time.
- Ensuring that applicants are dealt with in a courteous and polite manner raising any areas of concern regarding the conduct of members with the Chair or Regional Manager.
- Ensuring that the Chair makes researchers in attendance aware if an observer is present at the meeting (including if a Regional or RES Operational manager is in attendance for meeting observation purposes).

### Regional Manager

- Raising issues regarding the conduct of a member with the member in question (in consultation with the Chair where appropriate).

- Undertaking a meeting observation for the REC on at least an annual basis.
- Investigating reasons for meetings running over time.

### REC Chair

- Contacting applicants who are attending the meeting by telephone.
- Informing applicants if an observer is present, and notifying them that they can ask the observer to leave if they would prefer (with the exception of official observers).
- Summarising the discussion and agreeing the questions which need to be asked to the applicant prior to them being invited into the meeting, including establishing which member/s will ask the questions.
- Providing applicants with an overview of what will happen during the meeting.
- Ensuring that the meeting runs to time.
- Ensuring that members conduct themselves in a polite and respectful manner.
- Raising issues regarding the conduct of a member with the member in question (in consultation with the Regional Manager where appropriate).
- Notifying the applicant what will happen after the meeting.

### REC Members

- Introducing themselves to each applicant before asking a question. If appropriate, advising researchers of their background when asking the question.
- Asking questions in a polite and respectful manner.

## **5. Breakdown of Activities covered by the Procedure**

### **• Pre-meeting**

- 5.1 Politeness and courtesy should be the guiding principle in all interactions with applicants.
- 5.2 Invitations should be emailed to applicants to attend REC meetings when a valid application is received by the REC Manager. The sponsor, academic supervisor, and student should be copied into the invitation letter (where applicable)
- 5.3 Appointment times should be scheduled at appropriately spaced intervals in order to allow for sufficient discussion and to ensure that the meeting runs to time.
- 5.4 The REC Manager should check that appropriate arrangements can be made at the meeting venue to ensure that applicants with disabilities are able to attend the meeting.
- 5.5 The offer of appointment times should be made with plenty of notice to allow sufficient time for discussion and negotiation of times.
- 5.6 Agreed appointment times should be confirmed in writing together with details of the meeting venue. Applicants should be asked to confirm who will be attending and the REC Manager should keep a record of this.
- 5.7 It should be made clear that the invitation to attend is not an invitation to present the research in entirety. If an applicant requests to bring in software or a model to demonstrate part of the study, this should be accommodated where possible. It should be emphasised that committee members may or may not wish to raise specific questions in relation to the study being reviewed.
- 5.8 Applicants may attend the meeting by telephone if they are not able to attend in person. The REC Manager is responsible for obtaining the relevant contact number from the applicant and for ensuring that suitable teleconferencing facilities will be available at the meeting venue.

5.9 The meeting may be attended by observers. This should be agreed in advance and the observers will be asked to sign a confidentiality agreement at the meeting.

- **Conduct at the meeting**

5.10 The venue should have an appropriate waiting area for applicants to sit while waiting to be seen.

5.11 Where appropriate, inform the venue reception of the names of expected visitors and make clear arrangements for the collection of applicants from reception. Where no reception service is available, clear instructions should be given to applicants of what to expect on arrival at the venue.

5.12 Signs for the doors and/or where appropriate, directions to the meeting room and waiting area should also be clearly marked.

5.13 Applicants attending the meeting should always be called into the meeting room regardless of whether specific questions are required by the REC. If an applicant has arranged to attend the meeting by telephone, they should always receive a courtesy phone call even if there are no specific questions to be asked by the Committee. Applicants who are waiting should be informed if the meeting is running late. If an applicant is expecting to be contacted by telephone and the meeting is running more than 20 minutes late, the REC Manager should contact the applicant to let them know that the discussion will be later than planned.

5.14 Nameplates carrying the title and full name of the member should be placed in front of Committee members who are present at the meeting, and should be clearly visible to the researchers.

5.15 Prior to the applicant being invited into the room, it is considered good practice for the Chair to summarise with the committee members the areas of clarification identified during the review. The Chair has the discretion to decide to conduct the interview with the applicant but may nominate Committee members to lead on the questioning. It is strongly advised that a structure is agreed before the applicant is invited into the room. It is not good practice for numerous members to ask questions.

5.16 The Chair should introduce themselves, thank the applicant for attending the meeting and make a short statement about the purpose of the discussion, i.e. to ask the applicant to respond to specific questions in clarification of the submission being reviewed. It should be made clear at the outset that there are time limits and questioning should be concentrated on the main ethical issues. It is not necessary to introduce all members.

5.17 The Chair should ask the applicant(s) to introduce themselves to the REC.

5.18 The Chair should inform the applicant if there are any observers present at the meeting and should check that the applicant is happy for the observer to remain in the meeting (with the exception of official observers e.g. RES operational managers, Scientific Officers).

5.19 Any member posing a question to an applicant should introduce themselves. It is the responsibility of the Chair to ensure the discourse with the applicant is maintained with a purposeful and relevant focus during the time the applicant is present to answer questions. The Chair should ensure that the questioning is appropriate and is not prolonged or confrontational.

5.20 The purpose of the invitation is to facilitate the review of the application, not to interrogate the applicant.

- 5.21 The applicant should be offered the opportunity to ask questions of the REC in relation to the review process.
- 5.22 Applicants should be given a verbal summary of the procedure they can expect to happen following the meeting and should be shown from the room in a courteous manner.
- 5.23 The final opinion of the REC must not be given at this point; there must be opportunity for members to make final points and/or clarifications. It is acceptable for the decision to be conveyed to the applicant by asking them to return to the room. The applicant may also telephone the REC Manager after the meeting and prior to the decision letter being issued to find out the ethical opinion.
- 5.24 Applicant(s) should always be complimented when a well put-together application containing high quality participant documentation is provided.

## **6. Monitoring of Activities Covered by the Process**

- 6.1. If a REC Manager/Co-ordinator has concerns regarding the conduct of a member at the meeting they should raise the issue with the Chair and their manager. The Chair should then arrange to have a discussion with the member. If the issue is not resolved after the discussion, the REC Manager should escalate their concern to the Regional Manager.
- 6.2. If a REC Manager/Co-ordinator has a concern about the conduct of the Chair at the meeting, the issue should be raised with the Regional Manager who should investigate the concern and arrange to discuss the issue with the Chair.
- 6.3. A meeting observation forms part of the Quality Control process and is conducted annually by the Regional or Deputy Regional Manager to check the conduct of the meeting. The Regional or Deputy Regional Manager conducting the meeting observation should follow-up both positive and negative feedback with the Chair. The observer should make arrangements to provide feedback to the Chair. Feedback can be provided immediately after the meeting or at a later date which suits both parties.
- 6.4. Applicants are provided the opportunity to comment on their experience of attending the REC meeting by completing the feedback form available on the HRA website. The results of the feedback received from applicants are published in the User Satisfaction Report which is available on the HRA website.

## **7. Supporting Documents/Forms**

- Observer Confidentiality Agreement
- Validation Letter

## **8. Dissemination and publication of the document**

This document will be published on the intranet: <https://intranet.hra.nhs.uk/policies-and-procedures>

### 9. Screening Questions - HRA Equality Analysis and Privacy Impact Assessment

EQUALITY AND PRIVACY SCREENING QUESTIONS			
FOR EVERY HRA POLICY ( <i>defined by the Equality and Human Rights Commission (EHRC) as a function, strategy, procedure, practice, project, or decision</i> ) PLEASE ANSWER THE QUESTIONS BELOW TO DETERMINE WHETHER FURTHER ANALYSIS IS REQUIRED.		<b>YES / NO</b>	If yes, please complete as required the HRA Initial Equality Analysis and / or Initial Privacy Impact Assessment Template and copy and paste the completed assessment (s) below. This one document can be found on the Intranet.
<b>Equality</b>	With due regard to our Equality Duty, could this policy have the potential to have a detrimental impact on anyone with a protected characteristic?	No	
<b>Privacy</b>	With due regard to the Data Protection Act, does this policy involve the use of Personal Information?	No	

## Document Control

### Change Record

Version Number & Status	Date of Change	Reason for Change
2.0	28/01/2011	Update to Version 1
2.0	30/01/2011	Update to Version 2
2.1	30/01/2011	Update to Version 2
2.2	02/10/2013	Annual Review
2.3	23/10/2013	UKREDG
2.4	13/12/2013	Additional comments received at UKREDG
2.5 Draft	10/11/2015	Annual Update
2.5 Draft	16/12/2015	Additional comments received at UKREDG
2.5 Final	04/01/2016	Out of session comments received from UKREDG

### Reviewers

Name	Date Reviewed	Version Reviewed
Joan Kirkbride	Head of Ops	V2
Charlotte Allen	10/11/2015	V2.4
UKREDG	01/12/2015	V2.5

### Distribution of Approved Versions

Platform	Date of Publication	Version Released
HRA Intranet	January 2015	V2.4
HRA Intranet	08/01/2016	V2.5 Final