



Health Research Authority

Closure or Merger of Research Ethics Committees – Management of Change

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Approved By: OMG

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Owner: Director of Operations

Scope of Document:

This document will apply within:

Country	Applicability	Comment
England	Yes / No	
Northern Ireland	Yes/No	
Scotland	Yes/No	
Wales	Yes/No	

Background

The Health Research Authority (HRA) is the Appointing Authority for Research Ethics Committees in England, with responsibility for establishing RECs and appointing members, and officers. The HRA will undertake a regular review of REC capacity and make formal recommendations to the HRA Board on any proposed reduction of RECs.

The REC system in England is managed by the HRA and over recent years has rationalised from an original 200+ RECs to 67 (April 2016). Decisions to merge or close committees have been made on the basis of workload, local capacity requirements, areas of special interest, membership and support staff in place. In all cases the Appointing Authority has been consulted and decisions ratified before action is taken to rationalise RECs. Historically, mergers have been preferred, since this enables a smooth transition for the management of studies approved by the original RECs, and also, with careful management, can ensure that membership from the original RECs can be retained within the REC service. In some cases it has been necessary to close individual RECs, for example, where there is very low workload, no support staff in place or membership below quorum requirements. Here good practice has been to suspend RECs for review of new applications whilst managing the closure, and also inviting members to join other committees.

Policy

The (HRA) values the essential contribution of volunteer Research Ethics Committee (REC) members and officers to its service and is committed to ensuring that any changes resulting from proposed closures or mergers of RECs are undertaken in a transparent and supportive way.

This policy and procedure focuses primarily on changes affecting Members and officers, issues relating to the employment of HRA staff are covered in separate guidance, in all cases HRA policy on change management will be followed.

This policy and procedure has been developed with consideration to the HRA's six core values: Inspiring Leadership, Integrity, Trusted, Transparent, Collaborative and Empowering.

Procedure

1. Purpose

This procedure sets out the steps to follow when it is necessary to either close or merge a Research Ethics Committee (REC) in England. It focuses primarily on changes affecting Members and Chairs, issues relating to the employment of HRA staff are covered in separate guidance - in all cases HRA policy on change management will be followed.

The Operations Directorate will undertake a regular review of REC capacity and make formal recommendations to the Board on any proposed reduction of RECs.

This procedure has been developed to be used by HRA operational managers to enable them to support the closure and merger of RECs

2. Scope

This policy and procedure applies to all RECs in England (including REC staff, Chairs, Vice Chairs and Members) which may be affected by Closure or Merger.

3. Reference Documents

Policy and procedure for the Appointment of Chair and Vice Chairs
Policy and Procedure for the Recruitment and Selection of REC Members
Procedure for the Suspension of RECs
Procedure for Closures/Mergers of RECs on HARP

4. Responsibilities

The Director of Operations owns this policy and is responsible for its development and implementation, and for ensuring it is reviewed regularly to ensure that it remains appropriate and up to date.

The Head of Corporate Governance is the Appointing Authority Lead and is responsible for agreeing proposals to take forward options appraisals for the closure and merger of RECs.

The Head of Research Ethics Service is responsible for undertaking or commissioning options appraisals as required or as directed by the Director of Operations.

Responsibilities of other HRA staff are defined within the body of this procedure

5. Breakdown of activities covered by the procedure

5.1 – Initial Discussions

REC and Regional Managers continually monitor committees and review requirements on a regular basis. As soon as a manager feels that it may be necessary to close or merge one or more committees, they should discuss this with the Research Ethics Service (RES) Manager. The RES Manager should discuss their proposals with the Head RES and Director of Operations.

The Director of Operations will discuss the potential options with the Appointing Authority Lead and seek initial agreement, and also consider discussion with the REC community about the proposal to reduce the number of committees where this is appropriate.

Where there is a clear case for the closure of one committee, or a merger of committees a recommendation will be made to the Appointing Authority Lead under delegated authority from the Board. The consultation process with the REC/RECs concerned should follow that detailed in 5.2 as appropriate.

Where more than one option is possible, the RES Manager or Head of RES may meet with REC Chairs and Manager to seek their views on the potential future reconfiguration of RECs within the REC Office or Geographical location. The outcome of these discussions will help inform the development of a formal Options Appraisal if this is required.

5. 2 – Options Appraisal

A detailed analysis of the RECs within the Centre or Region should be undertaken. This should include consideration of issues such as applications per committee, anticipated changes in demand, membership issues and geographical issues that are relevant e.g. investigator base. Other issues which will be considered are the performance of the RECs in relation to meeting timelines, the commitment of the RECs to taking forward new HRA initiatives; and accreditation status. Additionally, staff resources within the HRA Office, and other budgetary measures will also be taken into consideration.

An Options Appraisal will be written which recommends the proposed future configuration in the area, together with recommendations of which RECs should close or merge. The Options Appraisal document should be submitted to the EMT for approval. The Options Appraisal will be discussed with the Appointing Authority Lead prior to any formal sharing of the appraisal with the REC community - likely objections from the committee(s) should also be discussed.

The Options Appraisal document should be shared initially with the Chair(s), Vice Chair(s), and REC Managers and Assistants of the affected committee(s) and the RES and Regional Managers. The Head of RES or RES Manager should then attend a meeting of the affected committee(s) to discuss the proposals. A 30 day consultation period will be held for REC members to submit comments on the proposals. A copy of the Options Appraisal document should also be sent to local R&D Lead for information purposes.

Where there is potential impact on the employment of REC staff, as the first step, they should be given the document on a one to one basis and their line manager and HR department should be informed in advance. They should also be given advanced notice of meetings to discuss the Options Appraisal and it should be explained that some options may affect their role and that, once decisions are made, there will be meetings to discuss the impact on their role and the management of change, and that they would be invited to bring a representative to those meetings. It would be preferable to hold an initial joint meeting with all affected staff, however, where circumstances may directly affect staff on an individual basis then one-to-one meetings should be held in the first instance.

At any stage during the consultation process other factors or proposals, not previously considered or consulted on, may emerge. Where these factors or proposals are deemed to potentially have a significant effect on the success of the proposed closure or merger, a second Options Appraisal should be developed and made available to the parties to the original circulation. A further 14 day consultation period will apply during which written comments may be submitted.

At the end of the consultation period a Recommendation Report will be developed outlining the proposed option and will be submitted to the Director of Operations and the Appointing Authority Lead for approval. With the agreement of the Director of Operations, the Recommendation Report should be shared with REC Chairs, Vice Chairs, and relevant REC staff and Managers. Following approval of the recommendation, the decision should be shared with the affected RECs - a 14 day review period will apply during which time comments may be submitted to the Appointing Authority Lead.

The HRA Board will make a final decision about whether to close or merge committees - this responsibility can be delegated to the Appointing Authority Lead. The Head of RES will commence/instigate discussions at the earliest opportunity with the any affected REC staff using the relevant HRA HR guidance and policy. REC staff should be notified of potential closure or merger that may affect their employment in a face to face meeting.

The Appointing Authority Lead, in consultation with the Director of Operations, may also if required prepare a draft press release in anticipation of any party affected by the OA contacting the press.

5.3 – Development of Project Plan

Once decisions have been made on specific mergers or closures, the RES Manager will need to develop a project plan for each closure or merger. Project plans will be developed in consultation with the Regional Manager and the affected RECs to detail planning for each merger or closure, for example, the timing of final REC meetings, a venue for merged REC meetings, other practical issues including arrangements for review of ongoing work and an overall timescale. Aspects of the project planning may be 'Management in Confidence' and Managers may consider developing summary plans for wider circulation in these circumstances. Business plans will also require sign-off by the Director of Operations prior to implementation.

In preparing the project plan, it is important to note that an application must be made to UKECA for recognition status for any new REC which will review new applications or will be required to progress ongoing work from merged committees. Closure and merger of RECs will be notified to the Four Nations meeting.

A separate guidance note exists for the actions required to manage the closure or the merger of a REC on HARP.

5.4 – Informing Committees and Individuals of Closure / Merger

The HRA will write to members of the affected committees individually, notifying them that their membership will cease on the date that the committee closes, asking whether they wish to serve on another committee and thanking them for their contribution to the REC service. Example letters in Appendix A and B.

5.5 – Retaining Members from Closing / Merging Committees

Wherever possible, the HRA wishes to retain the skills and expertise of members of committees within the system. Where a committee closes, members should be given the option, if possible, of applying to serve on a different committee. Details of other committees should be included in the letter sent at 5.4, and members asked to indicate if they would like to serve on another committee. This should include opportunities with RECs managed from a different office if this is appropriate. Where members have been through a formal appointment process previously, and suitable vacancies exist, members may be transferred to the new REC without a further formal interview, but subject to meeting terms and conditions of membership. If there are no vacancies, a list of interested members from the closed committee should be maintained by the relevant Regional Manager. Normally new recruitment to a merged or newly established committee will take place only after all other affected members have been offered places.

When committees merge, all members from those committees should be asked to indicate if they wish to be considered to serve on the new committee. If more than the required number of members in any of the categories wishes to continue then there should be a selection exercise. The selection exercise will seek to select the appropriate number of committee members with the appropriate skills and qualifications required for the committee to function. If more members wish to serve than there are posts, consideration should be given to employ criteria such as performance, length of remaining service, meeting attendance and completion of training when selecting for the new committee. In choosing criteria, it must be possible to demonstrate that information can be collected in an objective and transparent way, and that reasons for non-selection could be made available to unsuccessful candidates. If necessary, a selection interview process will take place. Un-appointed members may transfer to other committees or be placed on a waiting

list as detailed in the above paragraph. There may also be opportunities for appointment as deputy members.

5.6 – Appointing the Chair and Vice-Chair to the new/merged Committee

The Chair and Vice-Chair will be appointed from the list of members who have been interviewed and placed on the Chairs' Appointment Waiting List. All members of the affected RECs will be given an opportunity to apply for the vacant roles if they have previously not expressed an interest.

The process of appointing the Chair and Vice-Chair will be consistent with the principles set out in Policy and Procedure for Appointment of Chairs and Vice-Chairs.

6. Monitoring of activities covered by the procedure

It is expected that this procedure will be used only infrequently. Those using the procedure should, on the completion of any activity related to this procedure satisfy themselves that the procedure has been correctly followed and reporting where appropriate any non-compliance with this procedure to the Director of Operations.

Internal audits will be undertaken to monitor the activities covered in this procedure.

7. How lessons are learnt and incorporated into the procedure

Those using this procedure may submit any comments on their experience of the application of this procedure and related documents to the Head of RES to highlight any issues which may arise or suggestions for improvement. Findings from internal audit will be incorporated into this process.

Feedback from REC Members and officers and the REC Community will also be taken into consideration to further improve this policy and procedure.

8. Management of Documents and Records

Records produced as part of this procedure will be retained in a folder on the shared drive.

9. Supporting paperwork/forms

Template letter and supporting form.

10. Dissemination and publication of the document

This policy and procedure is held on the HRA Intranet

11. 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.		YES / NO	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.
Equality	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	
Privacy	With due regard to the Data Protection Act, does this policy involve the use of Personal Information?	Yes	

INITIAL EQUALITY ANALYSIS

An Equality Analysis is an examination of a proposed function, strategy, procedure, practice, project, or decision to see if it could adversely affect those with protected characteristics.

Aims and outcomes	Description / Details
Give a brief summary of the aims, purpose and outcomes of the policy / procedure in relation to equality and diversity.	<p>This document details the policy and procedure for the closure and merger of RECs and includes possible implications for REC members and staff. It ensures REC members and staff are treated transparently, fairly and reasonably and that staff have a support and framework to follow.</p> <p>The HRA recognises and actively promotes the benefits of a diverse workforce and are committed to treating all volunteers with dignity and respect regardless of race, gender, disability, age, sexual orientation, religion or belief.</p>

Questions for you to answer in the analysis process	YES	NO
1. Will or does the policy / procedure directly or indirectly affect our workforce (including volunteers), stakeholders or the public?	x	
2. Could the policy / procedure involve or have an adverse impact upon the Public Sector Equality Duties to:		
• eliminate unlawful discrimination		x
• promote equality of opportunity		x
• foster good relations between people who share a protected characteristic and those who do not		x
3. If you have answered YES to any of the questions in 2. above, please explain the impact you have identified. N/A		

4. Could the policy / procedure have an adverse impact on some of our workforce (including volunteers), stakeholders or the public because they have one or more of the protected equality characteristics:	YES	NO
Race (race, colour and nationality (including citizenship), ethnic or national origins)		x
People with disabilities (including mental, physical, sensory, long term health, learning disabilities)		x
Gender (male, female)		x
Age (young and old)		x
Religion or belief (incl. non-believers)		x
Sexual orientation (lesbian, gay, bisexual)		x
Gender reassignment (the process of transitioning from one gender to another)		x
Pregnancy/ maternity		x
Marital/ Civil Partnership status		x
5. If you have answered yes to any of the protected characteristics above in question 4 please give further information about the potential adverse impact N/A		
6. Based on the responses above, please describe any actions that will be or have been taken to mitigate or minimise any negative impact for our workforce (including volunteers), stakeholders or the public. N/A		
7. Where appropriate give details of any consultation carried out related to the policy or procedure N/A		
8. Give details of any changes to be made to the policy or procedure as a result of the analysis. N/A		

If you have answered YES to any of the questions in 2 and 4 above and the answers to question 6, 7 and 8 do not mitigate and adequately address the adverse impact, you may need to complete a full Equality Analysis. Please consult the Corporate Secretary.

Document Control

Change Record

Version Number & Status	Date of Change	Reason for Change
v3.0	09/02/2010	Annual revision of document – initial proposals for alterations in main document and in embedded documents
v3.1	18/02/2010	Alterations agreed by JK
v4.0	2010.05.01	Final version agreed
v4.1 → v4.2	08.11.2010 → 14.12.2010	Additional paragraphs proposed @ Step 2 – second consultation + referral to SHA / managers identified / Appendix A+B - alterations
v4.3	31.12.2010	Minor corrections via UKRDG
V5.0	November 2011 & April 2012	Change of Appointing Authority/annual review, removal of embedded documents, and inclusion of references to other OMGs
V5.1	August 2012	Minor changes to include case for merger as well as closure. Staff title changes and additional changes reflecting staff transfer to the HRA.
V6.0	April 2016	Planned revision, changes in job titles and responsibilities including delegated responsibility to the Appointing Authority lead.

Reviewers

Name (name of reviewer and/or management group reviewing)	Date Reviewed	Version Reviewed
Joan Kirkbride	Head of Operations - England	v3.0 & v4.0
Joan Kirkbride/Sheila Oliver	Head/Deputy Head of Ops	v4.1 draft
	UKRDG (17.12.2010)	v4.2 draft
Joan Kirkbride/Sheila Oliver/Len Key	Head/Deputy Head of Ops and UKRDG	V 5.0 draft
OMG and Head of Corporate Governance	April and May 2016	V6.0 draft then final

Distribution of Approved Versions

Platform (e.g. HRA intranet or website)	Date of Publication	Version Released
HRA Intranet	August 2016	V6.0