

National Research Ethics  
Service

  
*Health Research Authority*

# West Midlands REC Centre Annual Report Summary

**01 April 2011 – 31 March 2012**

**West Midlands REC Centre Annual Report (Summary)  
April 2011 to March 2012**

<b>Purpose</b>	To present summary of the annual reports from Research Ethics Committees (RECs) administered from the North East Centre. The reports cover the activity between April 2011 and March 2012 and copies of the full reports are available on the HRA website.
<b>Recommendations</b>	That the annual reports be received and noted
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**INTRODUCTION:**

The Health Research Authority (HRA) is a Special Health Authority established on 1 December 2011. Its purpose is to protect and promote the interests of patients and the public in health research. The HRA does this by supporting and promoting a robust and efficient regulatory and governance framework in the UK and providing the National Research Ethics Service (NRES).

NRES as a division of the HRA has a dual mission.

- to protect the rights, safety, dignity and well-being of research participants; and
- to facilitate and promote ethical research that is of potential benefit to participants, science and society.

We do this by:

- providing robust and responsive ethical review of research by Research Ethics Committees (RECs);
- providing ethical guidance and management support to RECs;
- delivering a quality assurance framework for the research ethics service;
- delivering a training programme;
- working with colleagues across the UK to maintain a UK-wide framework for ethical review;
- The HRA is the Appointing Authority for RECs in England and is required by the Governance Arrangements for RECs (GAfREC) to receive and adopt the REC Annual Reports. The Appointing Authority functions were previously undertaken by the Strategic Health Authorities.

## **Update on structural change since 2010/2011 Summary of Annual Reports:**

The REC Centre was closed on 31 March 2012 as part of a planned closure triggered by a break in the lease for the office and the difficulties in extending the lease due to restrictions placed on SHAs and ALBs. Administrative support for 4 of the RECs was transferred to the Nottingham Centre and that for the other 2 RECs to the Manchester office. Unfortunately, 4 members of staff based in the West Midlands Centre were made redundant as a result of the closure of the office. Additional staff have been successfully recruited and trained in the Nottingham and Manchester offices and the transition has been achieved with minimal disruption to the Committees, which continued to meet at their normal venues.

Because of the office closure, proportionate review was not introduced in the Centre during the reporting period.

## **Annual Reports:**

As the Appointing Authority, the HRA is responsible for the establishment, appointment, support and training of Research Ethics Committees. The HRA also takes full legal liability for the actions of those members in the course and performance of their duties subject to compliance with terms and conditions of service.

Research Ethics Committees are required to submit Annual Reports to the Appointing Authority by no later than 30 September. Copies of the full reports are available upon request.

The Governance Arrangements for Research Committees (GAfREC, harmonised edition – DH 2011) requires annual reports include the following minimum information.

- The REC's name, address and other contact details
- The type of REC, including details of any recognition by UKECA and/or designation by the Research Ethics Service for review of certain types of research proposal
- Details of the officers and staff of the REC
- Details of the membership of the REC, including for each member and deputy member their occupation, expert/lay status, initial date of appointment, and where applicable the date on which the term of membership expired or the member resigned
- The current register of members' interests
- The attendance record of each member and deputy member during the year
- A list of full meetings held during the year and the number of members attending
- The training record of each member and deputy member
- A list of the applications reviewed during the year, including the final decision reached on each application and the time taken to complete the review (or the current status of the review)
- A report by the Chair on the REC's work during the year

6 Committees have submitted reports for the year 1 April 2011 to 31 March 2012:

- West Midlands - Coventry and Warwick
- West Midlands - Edgbaston
- West Midlands - Solihull
- West Midlands - South Birmingham
- West Midlands - Staffordshire
- West Midlands - The Black Country

### **Membership as at 31 March 2012:**

Each Research Ethics Committee may have up to 18 full members. As a minimum, one third of these should be Lay members. Deputies may also be appointed. A maximum of two members may be co-opted per meeting, from other Research Ethics Committees, where the meeting would otherwise be inquorate.

Recruitment of new members is by an open process and appropriate screening and interviewing takes place in line with GAfREC 4.2.5

<b>REC</b>	<b>Total Number</b>	<b>Expert</b>	<b>Lay</b>	<b>Resigned in period of annual report</b>
<b>Coventry &amp; Warwick</b>	13	6	7	none
<b>Edgbaston</b>	11	8	3	2 lay
<b>Solihull</b>	12	7	5	1 expert
<b>South Birmingham</b>	12*	9	3	1 expert, 1 lay
<b>Staffordshire</b>	15	9	6	1 lay
<b>The Black Country</b>	13	9	4	none

\* +2 on leave of absence, 1 expert and 1 lay

### **Quorum:**

For meetings at which ethical review is undertaken, a quorum shall consist of seven members. Out of 66 scheduled meetings, none had to be cancelled due to being inquorate.

### **Research Ethics Committees' meetings**

- To maintain competency the NRES recommends that Research Ethics Committees should meet at least ten times per year and should aim to review six to eight studies per meeting. Of the 6 committees covered by this summary, only Edgbaston REC did not meet the requirements in terms of numbers of meetings held, meeting 8 times only due to low workload and planned cancellation of meetings as part of the managed closure.

### **Summary of activity for all West Midlands Centre RECs that were operating during 2011/12**

Numerical information concerning REC workload and outcomes that is contained in the individual annual reports has been summarised below.

REC	FOSC	FOAC	UFO	PO	Invalid	POPC	SSB	Total	SSI	PR
Coventry & Warwick	13	14	4	35	0	0	0	66	3	n/a
Edgbaston	3	7	1	31	0	0	0	42	0	n/a
Solihull	5	11	1	39	0	0	0	56	4	n/a
South Birmingham	4	7	1	49	0	0	1	61	14	n/a
Staffordshire	4	0	15	37	0	0	1	56	4	n/a
The Black Country	17	10	1	28	0	0	0	56	2	n/a

**Key**

FOSC	Favourable Opinion with Standard Conditions
FOAC	Favourable Opinion with Additional Conditions
UFO	Unfavourable opinion
PO	Provisional opinion
POPC	Provisional Opinion Pending Consultation with Referee
SSB	Number of studies sent back to full committee meeting for final opinion
SSI	Site Specific Assessment reviewed
PR	Proportionate Review

**Timescales for Research Ethics Committee Decisions**

All new studies presented to the committees should be given an opinion within 60 calendar days, with Site Specific Assessments (SSAs) being carried out within 25 calendar days, Substantial Amendments within 35 calendar days and Section 30 Mental Capacity Act applications within 60 calendar days. Proportionate Review Applications should be reviewed within 14 calendar days

**Performance**

337 studies were reviewed by full Committee of which 99.7% were given an opinion within the appropriate timescale. 27 SSAs reviewed, 100% were given a final opinion within the appropriate timescale. Of the 401 Substantial Amendments reviewed, 98.5% were given a final opinion within the appropriate timescale. There were no Section 30 applications reviewed during the reporting period.

Proportionate review was not introduced in the West Midlands due to the changes because of the office closure.

REC	Number of full applications over 60 days	Number of SSAs over 25 days	Number of Substantial amendments over 35 days	Number of Section 30 applications over 60 days
Coventry & Warwick	0	0	0	0
Edgbaston	0	-	0	0
Solihull	0	-	1	0
South Birmingham	0	0	1	0
Staffordshire	1	0	4	0
The Black Country	0	0	0	0

## **Accreditation of Research Ethics Committees**

Our accreditation scheme aims to ensure that RECs are operating according to guidance set down by the Department of Health.

The Quality Assurance Department audit RECs every 3 years to check that they are interpreting procedures and standards correctly in order to maintain a consistent ethical review process across the UK. All RECs in the Centre were audited during the reporting period.

To supplement the audit process NRES operations quality control check each committee on a six monthly basis.

### **RECs Achieving Full Accreditation at first review**

REC
Coventry and Warwick

### **RECs who have received full accreditation having completed an action plan**

REC
Staffordshire

### **RECs awaiting audit during 2012/13**

REC
Edgbaston
Solihull
The Black Country

### **Appeals received between April 2011 and March 2012**

2 appeals were received for West Midlands RECs; both of these were allowed.

### **Complaints received between April 2011 and March 2012**

2 complaints were received for West Midlands RECs; 1 was upheld and 1 was not upheld.

## **Conclusion and Acknowledgements**

The Research Ethics Committees managed from the West Midlands REC Centre continued to provide valuable independent advice to researchers, sponsors and employers whilst protecting the dignity, rights, safety and wellbeing of actual and potential participants. The Centre achieved a very good level of performance and the work of the local staff is acknowledged

NRES continues to look at how best to support the Research Ethics Committees across the country and to ensure that each is able to maintain its expertise. The REC members' contribution to the performance of the RECs in the Centre is also acknowledged and the service of our volunteer members is greatly appreciated.

Further consolidation, both in the number of committees and the location of the support to those committees, is continuing on a national basis in line with the objectives of the HRA business plan; this is to ensure that standards are improved in line with the NRES guidance.

**Ann Tunley, Regional Manager, North**  
**13 September 2012**