Health Research Authority

Manchester REC Centre Annual Report Summary
April 2012 to March 2013

Purpose	To present a summary of the annual reports from Research Ethics Committees (RECs) managed from the Manchester REC Centre. The reports cover the activity between April 2012 and March 2013 and copies of the full reports are available on the HRA website.
Recommendations	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 directorate 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;
- working with colleagues in the wider regulatory environment to streamline the processes for approving research; and
- working with colleagues to promote transparency in research

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.

Update on change since 2011/2012 Summary of Annual Reports:

The REC Centre continues to be well managed and provides high quality administrative support to the RECs managed from the Centre.

An options appraisal was carried out in respect of the RECs in the North West region in November 2012 and the recommendation was made to close North West – Cheshire and North West – GM North. The RECs were disestablished at the end of the reporting period. 12 members transferred to other RECs; 15 members left the service from North West RECs.

An options appraisal was carried out in respect of the RECs in the West Midlands region in January 2013 and the recommendation was made to close West Midlands – Staffordshire. The REC was disestablished in April 2013 and 14 members left the service from this REC.

The Leeds Centre closed at the end of the reporting period and administrative support for 2 of the RECs was transferred to the Manchester Centre (the annual reports for these RECs are reported separately). The workload was absorbed within the existing staffing establishment due to the closure of 2 RECs from the North West region as part of the options appraisal. The transition has been achieved with minimal disruption to the Committees which continue to meet in the same venues.

The proportionate review process for the review of studies (PR) where the applicant considers their research to present no material ethical issues was extended to the 2 RECs from the West Midlands region.

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 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 to 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

15 Committees have submitted reports for the year 1 April 2012 to 31 March 2013:

London – Bloomsbury
London – Fulham
North West – Cheshire
North West – GM Central
North West – GM East
North West – GM North
North West – GM South
North West – GM West
North West – Haydock
North West – Lancaster
North West – Liverpool Central
North West – Liverpool East
North West – Preston
West Midlands – Staffordshire
West Midlands – The Black Country

Membership as at 31 March 2013:

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

REC	Total Number	Expert	Lay	Resigned/left in period of annual report
London - Bloomsbury	14	9	5	3 expert, 2 lay
London - Fulham	16	10	6	1 expert
North West - Cheshire	14	8	6	1 expert (also 4 expert & 4 lay left the service)
North West – GM Central	12	8	4	2 expert, 1 lay
North West – GM East	12	8	4	1 expert, 1 lay
North West – GM North	13	9	4	1 expert (also 5 expert & 2 lay left the service)
North West – GM South	13 +1 deputy	8 +1 deputy	5	4 expert
North West – GM West	11	5	6	1 lay
North West - Haydock	11	8	3	1 expert, 1 lay
North West - Lancaster	13	9	4	none
North West Liverpool Central	14	8	6	none
North West – Liverpool East	13	8	5	2 lay
North West – Preston	12	8	4	1 lay
West Midlands - Staffordshire	14	8	6	1 expert (also 8 expert & 1 lay left the service)
West Midlands – The Black Country	12	8	4	none

Quorum:

For meetings at which ethical review is undertaken, a quorum shall consist of seven members. Out of 165 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 studies at main per meeting. Of the 15 committees covered by this summary, 3 did not meet the meeting requirements: GM East which met 8 times, GM North which met 9 times and GM West which met 9 times. This was as a result of meeting cancellations due to low workload.

Summary of activity for all RECs administered from the Manchester Centre operating during 2012/13

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

REC	FOSC	FOAC	UFO	PO	Invalid	POPC	Total	SSB	SSA	PR
London - Bloomsbury	4	18	6	33	0	0	61	3	0	18
London - Fulham	4	9	3	46	0	0	62	0	3	22
North West – Cheshire	3	11	5	19	0	0	38	0	4	10
North West – GM Central	4	5	2	46	0	0	57	0	44	0
North West – GM East	1	8	2	20	0	0	31	0	1	19
North West – GM North	1	9	2	18	0	0	30	0	1	15
North West – GM South	0	7	0	45	0	0	52	1	41	11
North West – GM West	0	10	3	17	0	0	30	0	0	17
North West – Haydock	6	4	4	36	0	0	50	1	0	13
North West - Lancaster	4	16	1	15	0	0	36	0	4	31
North West – Liverpool Central	7	7	1	38	0	0	53	0	14	14
North West – Liverpool East	2	7	3	36	0	0	48	0	0	16
North West – Preston	7	15	1	18	0	0	41	0	13	27
West Midlands - Staffordshire	2	5	4	29	0	0	40	2	6	10
West Midlands – Black Country	9	12	3	19	0	0	43	0	0	12

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
SSA	Site Specific Assessments reviewed for non-NHS sites
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.

The NRES is also working towards achieving the following KPIs (Key Performance Indicators), 95% of applications to full committee to receive a final decision within 40 calendar days, 95% of amendments to receive a decision within 28 calendar days.

Performance

672 studies were reviewed by full Committee of which 99.7% were given an opinion within the appropriate timescale. 235 studies were reviewed by Proportionate Review Sub-Committees of which 97.9% were given an opinion within the appropriate timescale. 131 SSAs reviewed, 100% were given a final opinion within the appropriate timescale. Of the 1172 Substantial Amendments reviewed, 97.6% were given a final opinion within the appropriate timescale. There was 1 Section 30 application reviewed during the reporting period; this was within the appropriate timescale.

REC	Number of full applications over 60 days	Number of SSAs over 25 days	Number of Substantial amendments over 35 days	Number of PR applications over 14 days
London - Bloomsbury	**2**	**0**	**18***	**0**
London - Fulham	**0**	**0**	**11****	**2**
North West – Cheshire	**0**	**0**	**0**	**1**
North West – GM Central	**0**	**0**	**0**	**0**
North West – GM East	**0**	**0**	**0**	**0**
North West – GM North	**0**	**0**	**0**	**1**
North West – GM South	**0**	**0**	**0**	**0**
North West – GM West	**0**	**0**	**0**	**0**
North West – Haydock	**0**	**0**	**0**	**0**
North West – Lancaster	**0**	**0**	**0**	**0**
North West – Liverpool Central	**0**	**0**	**0**	**0**
North West – Liverpool East	**0**	**0**	**1**	**2**
North West – Preston	**0**	**0**	**0**	**0**
West Midlands - Staffordshire	**0**	**0**	**0**	**0**
West Midlands – The Black Country	**0**	**0**	**1**	**1**

*****13 of these amendments were processed when the REC was managed in the London Centre or during the transfer period.

**all of the amendments were processed when the REC was managed in London Centre or during the transfer period.

Accreditation of Research Ethics Committees

The HRA 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. 2 RECs in the Centre were audited during the reporting period.

To supplement the audit process NRES operations undertake quality control checks on each committee every six months.

RECs Achieving Full Accreditation at first review

REC
North West - GM South
North West - Preston

RECs who have received full accreditation having completed an action plan

REC

The Manchester REC Centre achieved full accreditation for the REC Centre management and administrative activities in November 2012. Accreditation status lasts for 3 years.

Appeals received between April 2012 and March 2013

2 appeals for full applications were received for RECs managed from the Manchester Centre; both were allowed. 4 appeals for substantial amendments were received, I was progressed and 3 were not progressed.

Complaints received between April 2012 and March 2013

3 complaints were received for RECs managed from the Manchester Centre; 2 were upheld and 1 was partly upheld. The 2 complaints which were upheld related to the period when the REC was managed from the London Centre.

Conclusion and Acknowledgements

The Research Ethics Committees managed from the Manchester 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 has achieved an exceptional level of performance and the work of the local management and 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 acknowledged and the services of our volunteer members is greatly appreciated.

Consolidation, both in the number of committees and the location of the support to those committees, has taken place during and at the end of this reporting period on a national basis in line with the objectives of the HRA business plan. The Centre has now taken on the administration of 2 RECs from the Yorkshire and the Humber region since the closure of the Leeds Centre. Administration of 1 REC from the West Midlands region has transferred from the Nottingham Centre as a result of the transfer of 5 RECs from the East of England region to the Nottingham Centre following the closure of the Cambridge Centre.

Ann Tunley, Regional Manager – North, 15 August 2013

Appendix A

% Opinion rates for each REC

Operational managers are investigating where a REC's decision making significantly varies from the national average.

REC	FOSC %	FOAC %	UFO %	PO %	Invalid no.	POPC no.	Total no.	SSB no.	SSA no.	PR no.
London - Bloomsbury	6.6	29.5	9.8	54.1	0	0	61	3	0	18
London - Fulham	6.5	14.5	4.8	74.2	0	0	62	0	3	22
North West – Cheshire	7.9	28.9	13.2	50.0	0	0	38	0	4	10
North West – GM Central	7.0	8.8	3.5	80.7	0	0	57	0	44	0
North West – GM East	3.2	25.8	6.5	64.5	0	0	31	0	1	19
North West – GM North	3.3	30.0	6.7	60.0	0	0	30	0	1	15
North West – GM South	0.0	13.5	0.0	86.5	0	0	52	1	41	11
North West – GM West	0.0	33.3	10.0	56.7	0	0	30	0	0	17
North West – Haydock	12.0	8.0	8.0	72.0	0	0	50	1	0	13
North West – Lancaster	11.1	44.4	2.8	41.7	0	0	36	0	4	31
North West – Liverpool Central	13.2	13.2	1.9	71.7	0	0	53	0	14	14
North West – Liverpool East	4.2	14.6	6.3	75.0	0	0	48	0	0	16
North West – Preston	17.1	36.6	2.4	43.9	0	0	41	0	13	27
West Midlands – Staffordshire	5.0	12.5	10.0	72.5	0	0	40	2	6	10
North West – The Black Country	20.9	27.9	7.0	44.2	0	0	43	0	0	12

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