



# Health Research Authority

## Manchester REC Office Annual Report Summary April 2015 to March 2016

<b>Purpose</b>	To present a summary of the annual reports from Research Ethics Committees (RECs) managed from the Manchester REC Office. The reports cover the activity between April 2015 and March 2016 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 Non Departmental Public Body, established initially as a Special Health Authority 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.

The Research Ethics Service in England is part of the Operations Directorate within the HRA and 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 changes since 2014/2015 Summary of Annual Reports:**

As a result of a geographical reconfiguration of RECs across the five Centres, administrative support for London – South East and London – Westminster transferred from the Bristol Centre to the Manchester Centre, that for Yorkshire and Humber – Sheffield transferred from Manchester to the Jarrow Centre and that for West Midlands – South Birmingham and West Midlands – The Black Country transferred from Manchester to the Nottingham Centre. The Committees continued to meet in the same locations and the transfers were achieved with minimal disruption.

## **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

16 Committees have submitted reports for the year 1 April 2015 to 31 March 2016:

- London – Bloomsbury
- London – Central
- London – Fulham
- London – Hampstead
- London – Queen Square
- London – South East

- London – Westminster
- North West – GM Central
- North West – GM East
- 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

### Membership as at 31 March 2016:

Each Research Ethics Committee may have up to 15 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 in period	Appointed in period
London - Bloomsbury	13+1 break in service	6+1 break	7	2 expert	2 lay, 2 expert
London – Central	12	7	5	1 expert, 1 lay	2 lay, 2 expert
London – Fulham	13	6	7	4 expert	3 lay, 1 expert
London – Hampstead	16+1 deputy	12+1 deputy	4	none	none
London – Queen Square	16	9	7	2 expert	1 lay, 2 expert
London – South East	15	8	7	none	1 lay, 2 expert
London - Westminster	13	7	6	1 expert	2 lay
North West – GM Central	16	10	6	1 lay	2 expert
North West – GM East	14	6	8	1 expert	1 lay
North West – GM South	12	8	4	2 lay	1 lay, 1 expert
North West – GM West	10	6	4	none	1 expert
North West - Haydock	12	9	3	1 expert, 1 lay	2 expert
North West - Lancaster	13	7	6	1 lay	2 lay
North West – Liverpool Central	11	6	5	1 expert, 2 lay	None
North West – Liverpool East	13	8	5	1 expert	1 lay, 3 expert
North West - Preston	12	7	5	2 expert	1 lay

**Quorum:**

For meetings at which ethical review is undertaken, a quorum shall consist of seven members. Out of 161 scheduled meetings, 1 had to be cancelled due to being inquorate and 1 was cancelled due to low workload.

**Research Ethics Committees' meetings**

- To maintain competency the RES 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 16 committees covered by this summary, 14 RECs held 10 meetings, 1 REC held 11 meetings and 2 RECs held 9 meetings.
- In addition to full Committee meetings, the RECs covered in this summary held a total of 471 Sub-Committee meetings and 139 Proportionate Review Sub-Committee meetings

**Summary of activity for all RECs administered from the Manchester Office operating during 2015/16**

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

**Applications for review at full Committee meetings**

<b>REC</b>	<b>FOSC</b>	<b>FOAC</b>	<b>UFO</b>	<b>PO</b>	<b>POPC</b>	<b>Total</b>	<b>SSB</b>
London - Bloomsbury	5	9	1	37	0	52	0
London – Central	2	11	1	41	0	55	0
London – Fulham	3	6	3	36	0	48	0
London – Hampstead	8	12	0	35	1	56	0
London – Queen Square	2	13	1	37	0	53	1
London - South East	5	6	7	37	1	56	0
London - Westminster	0	11	3	41	1	56	0
North West – GM Central	2	9	1	45	0	57	0
North West – GM East	2	21	0	29	0	52	0
North West – GM South	2	1	0	52	0	55	0
North West – GM West	3	18	2	26	0	49	0
North West - Haydock	6	19	1	25	0	51	0
North West - Lancaster	0	13	1	30	0	44	0
North West – Liverpool Central	2	14	0	40	1	57	0
North West – Liverpool East	5	7	0	28	0	40	0
North West - Preston	3	10	2	34	0	49	0
<b>TOTAL</b>	<b>50</b>	<b>180</b>	<b>23</b>	<b>573</b>	<b>4</b>	<b>830</b>	<b>1</b>

**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

### Applications reviewed at Proportionate Review Sub-Committee meetings

REC	FOSC	FOAC	NOT	PO	UFO	Total
London - Bloomsbury	6	4	0	7	7	17
London – Central	0	1	1	2	2	4
London – Fulham	6	4	0	5	5	15
London – Hampstead	15	2	5	13	13	36
London – Queen Square	5	11	1	1	1	18
London – South East	14	3	2	5	5	24
London - Westminster	5	8	6	8	8	27
North West – GM Central*	0	0	0	0	0	0
North West – GM East	10	5	3	2	2	21
North West – GM South	9	6	1	14	14	30
North West – GM West	8	10	6	6	6	31
North West - Haydock	18	3	0	2	2	23
North West - Lancaster	16	6	1	9	9	32
North West – Liverpool Central	17	7	1	6	6	31
North West – Liverpool East	7	3	3	8	8	21
North West - Preston	10	13	2	6	6	31
<b>TOTAL</b>	<b>146</b>	<b>86</b>	<b>32</b>	<b>94</b>	<b>94</b>	<b>361</b>

\* This REC did not take part in proportionate review during the reporting period

#### Key

FOSC	Favourable Opinion with Standard Conditions
FOAC	Favourable Opinion with Additional Conditions
NOT	No Opinion, transfer to Full Committee for review
PO	Provisional Opinion
UFO	Unfavourable Opinion

**Summary of workload after REC favourable opinion**

<b>REC</b>	<b>NOSA</b>	<b>MOD</b>	<b>INFO</b>	<b>PI</b>	<b>MIN</b>	<b>SR</b>	<b>SAE</b>	<b>APR</b>	<b>FR</b>	<b>SSA</b>
London - Bloomsbury	145	10	0	43	92	32	17	105	25	6
London – Central	134	3	0	52	55	37	0	15	9	7
London – Fulham	131	2	0	39	66	32	3	126	37	5
London – Hampstead	136	2	0	41	100	15	1	85	31	5
London – Queen Sq.	100	4	0	0	56	0	0	44	5	3
London – South East	86	0	0	48	83	29	1	140	33	6
London - Westminster	128	1	0	29	66	42	3	119	5	5
North West – GM Central	128	6	1	68	90	93	0	96	29	32
North West – GM East	55	6	0	0	45	0	0	52	31	2
North West – GM South	147	4	0	32	95	36	18	102	39	34
North West – GM West	76	4	0	0	71	0	0	114	45	0
North West - Haydock	167	2	0	63	84	60	1	138	31	12
North West - Lancaster	87	1	0	0	27	0	0	31	14	6
North West – Liverpool Central	149	9	4	66	71	34	0	120	35	14
North West – Liverpool East	96	2	0	32	65	41	6	91	26	1
North West - Preston	58	2	0	0	29	0	2	56	37	5
<b>TOTAL</b>	<b>1823</b>	<b>58</b>	<b>5</b>	<b>513</b>	<b>1095</b>	<b>451</b>	<b>52</b>	<b>1434</b>	<b>432</b>	<b>143</b>

**Key**

NOSA	Notice of Substantial Amendment
MOD	Modified Amendment
INFO	Substantial Amendment received for information only
PI	Substantial Amendment received for new sites/PIs
MIN	Minor Amendment
SR	Safety Report
SAE	Serious Adverse Event
APR	Annual Progress Report
FR	Final Study Report
SSA	Site Specific Assessment

**Timescales for Research Ethics Committee Decisions**

All new studies presented to the committees should be given an opinion within 60 calendar days, Substantial Amendments within 35 calendar days, and Proportionate Review Applications should be reviewed within 14 calendar days. Site Specific Assessments (SSAs) are now being carried out by the main REC.

The RES is 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 proportionate review applications to receive a final decision in 14 days and 95% of amendments to receive a decision within 28 calendar days.

## Performance

830 studies were reviewed by full Committee of which 99.39 % were given an opinion within the 60 day timeline, and 92.20% within the 40 day timeline. 329 studies were reviewed by Proportionate Review Sub-Committees of which 93.92% were given an opinion within the 14 day timeline. Of the 1823 Substantial Amendments reviewed, 98.57 % were given a final opinion within the 35 day timeline and 91.62% within the 28 day timeline. 1 Section 30 application was reviewed during the reporting period.

REC	% of full applications reviewed within 60 days	% reviewed meeting the 40 day KPI	% of Substantial amendments reviewed within 35 days	% reviewed meeting the 28 day KPI	% of PR applications reviewed within 14 days
London - Bloomsbury	98.08	80.77	95.17	74.48	70.59
London – Central	100.00	98.18	97.76	94.03	100.00
London – Fulham	100.00	93.75	98.47	84.73	93.33
London – Hampstead	100.00	92.86	97.79	96.32	87.10
London – Queen Square	100.00	88.68	98.0	93.00	94.12
London – South East	100.00	89.29	98.84	86.05	90.91
London - Westminster	98.21	76.79	93.75	78.12	95.24
North West – GM Central	100.00	96.49	100.00	90.62	n/a
North West – GM East	96.15	90.38	100.00	100.00	94.44*
North West – GM South	100.00	96.36	100.00	97.28	100.00
North West – GM West	100.00	95.92	100.00	96.05	96.00
North West - Haydock	98.04	84.31	100.00	94.01	100.00*
North West - Lancaster	100.00	100.00	100.00	98.85	100.00
North West – Liverpool Central	100.00	100.00	100.00	99.33	100.00
North West – Liverpool East	100.00	95.00	100.00	94.79	77.78
North West - Preston	100.00	100.00	100.00	100.00	100.00
<b>Average for Centre</b>	<b>99.39</b>	<b>92.20</b>	<b>98.57</b>	<b>91.62</b>	<b>93.92*</b>

*\*Please note that some applications were reviewed by these RECs as part of the Proportionate Review Pilot which has been set up to test whether allowing REC staff*

*increased time to work with applicants to ensure that the study documentation is clear, accurate and complete, as well as allowing a minimum number of days for REC members to undertake the ethical review is preferable against set evaluation criteria. One of the objectives of the pilot is to assess the impact of extending the length of review to 21 calendar days rather than 14 calendar days. These figures exclude any applications which were part of the Proportionate Review pilot.*

## **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. 4 RECs in the Centre were audited during the reporting period.

To supplement the audit process RES Operations undertakes quality control checks of each committee every six months.

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

<b>REC</b>
GM – East (with conditions)
North West - Preston

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

<b>REC</b>
London – Queen Square
GM - South

### **Appeals received between April 2015 and March 2016**

3 appeals for full applications were received for RECs managed from the Manchester Centre; these were allowed. 2 of these received a further unfavourable opinion and 1 received a favourable opinion after a request for further information.

### **Complaints received between April 2015 and March 2016**

There were no complaints relating to RECs managed from the Manchester Centre.

## **Conclusion and Acknowledgements**

The Research Ethics Committees managed from the Manchester REC Office 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 high level of performance and the work of the local management and staff is acknowledged.

The Research Ethics Service 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 service of our volunteer members is greatly appreciated.

Ann Tunley  
RES Manager  
25 October 2016

## Appendix A - % Opinion rates for each REC

### Applications reviewed at Full Committee meetings

REC	FOSC	FOAC	UFO	PO	POPC	Total
London - Bloomsbury	9.62	17.31	1.92	71.15	0.0	100
London – Central	3.64	20.00	1.82	74.55	0.0	100
London – Fulham	6.25	12.50	6.25	75.00	0.0	100
London – Hampstead	14.29	21.43	0.00	62.50	1.79	100
London – Queen Square	3.77	24.53	1.89	69.81	0.00	100
London – South East	8.93	10.71	12.50	66.07	1.79	100
London - Westminster	0.0	19.64	5.36	73.21	1.79	100
North West – GM Central	3.51	15.79	1.75	78.95	0.0	100
North West – GM East	3.85	40.38	0.00	55.77	0.00	100
North West – GM South	3.64	1.82	0.00	94.55	0.0	100
North West – GM West	6.12	36.73	4.08	53.06	0.0	100
North West - Haydock	11.76	37.25	1.96	49.02	0.0	100
North West - Lancaster	0.0	29.55	2.27	68.18	0.0	100
North West – Liverpool Central	3.51	24.56	0.0	70.18	1.75	100
North West – Liverpool East	12.50	17.50	0.00	70.00	0.00	100
North West - Preston	6.12	20.41	4.08	69.39	0.0	100
<b>Average for Centre</b>	<b>6.02</b>	<b>21.69</b>	<b>2.77</b>	<b>69.04</b>	<b>0.48</b>	<b>100</b>

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PO	Provisional opinion
POPC	Provisional Opinion Pending Consultation with Referee

### Applications reviewed at Proportionate Review Sub-Committee meetings

REC	FOSC	FOAC	NOT	PO	UFO	Total
London - Bloomsbury	35.29	23.53	0.00	41.18	0.0	100
London – Central	0.00	25.00	25.00	50.0	0.0	100
London – Fulham	40.00	26.67	0.00	33.33	0.0	100
London – Hampstead	41.67	5.56	13.89	36.11	2.78	100
London – Queen Square	27.78	61.11	5.56	5.56	0.00	100
London – South East	58.33	12.50	8.33	20.83	0.00	100
London - Westminster	18.52	29.63	22.22	29.63	0.0	100
North West – GM Central*	n/a	n/a	n/a	n/a	n/a	n/a
North West – GM East	47.62	23.81	14.29	9.52	4.76	100
North West – GM South	30.00	20.00	3.33	46.67	0.0	100
North West – GM West	25.81	32.26	19.35	19.35	3.23	100
North West - Haydock	78.26	13.04	0.00	8.7	0	100
North West - Lancaster	50.00	18.75	3.13	28.13	0.0	100
North West – Liverpool Central	54.84	22.58	3.23	19.35	0.0	100
North West – Liverpool East	33.33	14.29	14.29	38.10	0.00	100
North West - Preston	32.26	41.94	6.45	19.35	0.0	100
<b>Average for Centre</b>	<b>40.44</b>	<b>23.82</b>	<b>8.86</b>	<b>26.05</b>	<b>0.83</b>	<b>100</b>

\* This REC did not take part in PR during the reporting period

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