



Health Research Authority

Nottingham REC Office Annual Report Summary April 2015 to March 2016

Purpose	To present a summary of the annual reports from Research Ethics Committees (RECs) managed from the Nottingham 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.
Recommendations	That the annual reports be received and noted
Presenter	Ann Tunley Research Ethics Service Manager Ann.tunley@nhs.net
Contact RECs	<p>Research Ethics Service Manager (England): Ann Tunley</p> <p>Regional Manager – Linda Ellis linda.ellis12@nhs.net</p> <p>East of England – Cambridge Central, REC Manager - Rebecca Morledge, nrescommittee.eastofengland-cambridgecentral@nhs.net</p> <p>East of England – Cambridge East, REC Manager - Carolyn Halliwell, nrescommittee.eastofengland-cambridgeeast@nhs.net</p> <p>East of England – Cambridge South, REC Manager - Ellen Swainston, nrescommittee.eastofengland-cambridgesouth@nhs.net</p> <p>East of England – Cambridgeshire & Hertfordshire, REC Manager - Georgia Copeland nrescommittee.eastofengland-cambsandherts@nhs.net</p> <p>East of England – Essex, REC Manager - Helen Poole, nrescommittee.eastofengland-cambridgeeast@nhs.net</p> <p>East Midlands – Derby, REC Manager - Vic Strutt nrescommittee.eastmidlands-derby@nhs.net</p> <p>East Midlands – Leicester Central, REC Manager - Ellen Swainston, nrescommittee.eastmidlands-leicestercentral@nhs.net</p> <p>East Midlands – Leicester South, REC Manager - Rebecca Morledge, nrescommittee.eastmidlands-leicestersouth@nhs.net</p>

	<p>East Midlands – Nottingham 1, REC Manager - Rachel Nelson, nrescommittee.eastmidlands-nottingham1@nhs.net</p> <p>East Midlands – Nottingham 2, REC Manager - Carolyn Halliwell, nrescommittee.eastmidlands-nottingham2@nhs.net</p> <p>London – West London & GTAC, REC Manager - Andrea Graham, nrescommittee.london-westlondon@nhs.net</p> <p>West Midlands – Coventry and Warwick, REC Manager – Rachel Nelson, nrescommittee.westmidlands-coventryandwarwick@nhs.net</p> <p>West Midlands – Edgbaston, REC Manager - Helen Poole, nrescommittee.westmidlands-edgbaston@nhs.net</p> <p>West Midlands – Solihull, REC Manager - Vic Strutt, nrescommittee.westmidlands-solihull@nhs.net</p> <p>West Midlands – South Birmingham, REC Manager - Penelope Gregory, nrescommittee.westmidlands-southbirmingham@nhs.net</p> <p>West Midlands – The Black Country, REC Manager - Georgia Copeland, nrescommittee.westmidlands-blackcountry@nhs.net</p>
--	---

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 Research Ethics Service (RES).

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 West Midlands – South Birmingham and West Midlands – The Black Country transferred from the Manchester Centre to the Nottingham Centre and that for East of England – Cambridgeshire & Hertfordshire transferred from the Jarrow Centre to the Nottingham. The Committees continued to meet in the same locations and the transfers were achieved with minimal disruption.

The meeting venue for East of England - Northampton moved to Leicester and as a result of this the REC was renamed East Midlands – Leicester South and East Midlands – Leicester was renamed East Midlands – Leicester Central.

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:

- East of England - Cambridge Central
- East of England - Cambridge East
- East of England - Cambridge South
- East of England – Cambridgeshire & Hertfordshire
- East of England - Essex
- East Midlands - Derby
- East Midlands – Leicester Central
- East Midlands – Leicester South
- East Midlands - Nottingham 1
- East Midlands - Nottingham 2
- London - West London & GTAC
- West Midlands - Coventry and Warwick
- West Midlands - Edgbaston
- West Midlands – Solihull
- West Midlands – South Birmingham
- West Midlands – The Black Country

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
East of England - Cambridge Central	14	8	6	4 expert, 1 lay	2 expert, 1 lay
East of England - Cambridge East	13	7	6	2 expert, 2 lay	2 expert, 1 lay
East of England - Cambridge South	15 +1 deputy	6 +1 deputy	9	1 expert + 1 expert deputy	3 lay, 1 expert deputy
East of England – Cambs & Hertfordshire	11	7	4	2 expert, 1 lay	2 expert, 1 lay
East of England - Essex	10 +1 break in service	6	4 +1 break in service	1 expert, 2 lay	3 expert
East Midlands - Derby	14	5	9	1 expert, 2 lay	2 expert, 3 lay
East Midlands – Leicester Central	10	5	5	1 expert, 3 lay	1 expert, 2 lay
East Midlands – Leicester South	11	6	5	None	1 expert
East Midlands - Nottingham 1	13	7	6	1 lay	3 expert, 2 lay

East Midlands - Nottingham 2	13	5	8	3 expert, 1 lay	2 lay
London - West London & GTAC	12	6	6	2 expert, 2 lay	2 expert, 3 lay
West Midlands - Coventry and Warwick	12	6	6	2 lay	1 expert, 2 lay
West Midlands - Edgbaston	13	8	5	1 expert	2 expert, 1 lay
West Midlands - Solihull	9	6	3	1 expert, 1 lay	none
West Midlands – South Birmingham	14	9	5	None	1 expert
West Midlands – The Black Country	12	8	4	None	1 expert, 1 lay

Quorum:

For meetings at which ethical review is undertaken, a quorum shall consist of seven members. Out of 160 scheduled meetings, 2 had to be cancelled; 1 due to quoracy issues and 1 due to low workload.

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 16 committees covered by this summary, 1 REC held 11 meetings (an additional meeting was held to review a section 30 application), 13 RECs held 10 meetings and 2 RECs held 9 meetings.
- In addition to full Committee meetings, the RECs covered in this summary held a total of 419 Sub-Committee meetings and 154 Proportionate Review Sub-Committee meetings

Summary of activity for all RECs administered from the Nottingham 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

REC	FOSC	FOAC	UFO	PO	POPC	Total	SSB
East of England - Cambridge Central	1	4	2	47	0	54	0
East of England - Cambridge East	0	3	6	35	0	44	0
East of England - Cambridge South	1	2	5	49	0	57	0
East of England – Cambridgeshire & Hertfordshire	2	2	2	38	0	44	0
East of England - Essex	2	1	2	43	0	48	0
East Midlands - Derby	5	6	4	42	0	57	0
East Midlands – Leicester Central	2	4	2	33	0	41	0
East Midlands – Leicester South	0	1	7	43	0	51	0

East Midlands - Nottingham 1	0	6	0	42	0	48	0
East Midlands - Nottingham 2	3	9	3	38	0	53	0
London - West London & GTAC	1	6	6	45	0	58	0
West Midlands - Coventry and Warwick	5	7	2	35	0	49	0
West Midlands - Edgbaston	0	3	0	51	0	54	0
West Midlands - Solihull	1	7	3	38	0	49	0
West Midlands – South Birmingham	2	6	1	42	0	51	0
West Midlands – The Black Country	4	10	2	32	0	48	0
TOTAL	29	77	47	653	0	806	0

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
East of England - Cambridge Central	5	3	5	14	0	27
East of England - Cambridge East	0	0	0	7	0	7
East of England - Cambridge South	3	0	2	29	2	36
East of England – Cambs & Hertfordshire	2	1	2	15	0	20
East of England - Essex	4	2	0	8	1	15
East Midlands - Derby	5	1	1	21	3	31
East Midlands – Leicester Central	11	6	3	21	2	43
East Midlands – Leicester South	6	4	0	17	1	28
East Midlands - Nottingham 1	10	9	0	16	1	36
East Midlands - Nottingham 2	9	9	3	19	2	42
London - West London & GTAC	0	2	0	3	2	7
West Midlands - Coventry and Warwick	6	5	3	21	0	35
West Midlands - Edgbaston	7	6	3	13	1	30
West Midlands - Solihull	7	3	4	15	1	30
West Midlands – South Birmingham	5	15	1	10	1	32
West Midlands – The Black Country	7	5	3	8	1	24
TOTAL	87	71	30	237	18	443

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

REC	NOSA	MOD	INFO	PI	MIN	SR	SAE	APR	FR	SSA
East of England - Cambridge Central	137	8	0	7	108	21	8	157	19	13
East of England - Cambridge East	85	3	0	16	54	26	1	85	19	3
East of England - Cambridge South	146	7	0	36	125	73	0	140	24	14
East of England – Cambridgeshire & Herts	127	2	0	14	120	24	5	142	46	8
East of England - Essex	74	5	0	25	68	24	6	70	16	4
East Midlands - Derby	150	1	0	19	114	49	61	126	27	4
East Midlands – Leicester Central	169	4	0	32	141	68	1	122	34	5
East Midlands – Leicester South	119	1	0	22	89	55	2	109	13	13
East Midlands - Nottingham 1	89	2	0	0	83	0	0	82	14	2
East Midlands - Nottingham 2	127	4	0	37	108	53	0	96	30	3
London - West London & GTAC	162	17	1	24	123	86	0	147	26	3
West Midlands - Coventry and Warwick	127	2	2	37	153	45	0	94	10	9
West Midlands - Edgbaston	145	10	1	53	142	57	2	116	23	7
West Midlands - Solihull	64	6	0	0	46	0	9	57	18	2
West Midlands – South Birmingham	67	0	0	0	55	2	2	104	47	0
West Midlands – The Black Country	51	0	0	0	26	3	0	55	32	0
TOTAL	1839	72	4	322	1555	586	97	1702	398	90

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

806 studies were reviewed by full Committee of which 99.75% were given an opinion within the 60 day timeline, and 91.71% within the 40 day timeline. 443 studies were reviewed by Proportionate Review Sub-Committees of which 97.57* were given an opinion within the 14 day timeline. Of the 1839 Substantial Amendments reviewed, 99.89% were given a final opinion within the 35 day timeline and 96.63% within the 28 day timeline. There were 4 Section 30 applications 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
East of England - Cambridge Central	98.15	53.70	100.00	91.97	100.00
East of England - Cambridge East	100.00	97.73	98.82	96.47	57.14
East of England - Cambridge South	100.00	85.96	100.00	99.32	85.29
East of England – Cambs. & Herts.	97.73	97.73	100.00	97.64	100.00
East of England - Essex	100.00	89.58	100.00	97.30	100.00
East Midlands - Derby	100.00	87.72	100.00	93.33	100.00
East Midlands – Leicester Central	100.00	97.56	100.00	95.27	100.00
East Midlands – Leicester South	100.00	100.00	100.00	99.16	100.00
East Midlands - Nottingham 1	100.00	91.67	100.00	95.51	100.00
East Midlands - Nottingham 2	100.00	94.34	100.00	95.28	100.00
London - West London & GTAC	100.00	87.93	100.00	99.38	100.00
West Midlands - Coventry and Warwick	100.00	97.96	100.00	95.28	100.00
West Midlands - Edgbaston	100.00	96.80	100.00	100.00	100.00*
West Midlands - Solihull	100.00	97.96	98.44	93.75	92.31
West Midlands – South Birmingham	100.00	100.00	100.00	98.51	100.00
West Midlands – The Black Country	100.00	100.00	100.00	98.04	100.00
Average for Centre	99.75	91.71	99.89	96.63	97.57*

**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. 6 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

REC
West Midlands – Edgbaston
East of England – Essex
East of England – Cambridge South
West Midlands - Solihull

RECs who have received full accreditation having completed an action plan

REC
West Midlands – South Birmingham
West Midlands – Coventry & Warwick

Appeals received between April 2015 and March 2016

There was 1 appeal against a decision given as part of a full review by a REC from the Nottingham Centre; this was not progressed, a revised application was re-submitted to another REC for review and was given a favourable opinion.

There were 3 appeals related to substantial amendments; these were not progressed, modified amendments were submitted to the REC for review and were given a favourable opinion.

Complaints received between April 2015 and March 2016

There was 1 complaint in relation to a REC managed from the Nottingham Centre; this was upheld.

Conclusion and Acknowledgements

The Research Ethics Committees managed from the Nottingham 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
East of England - Cambridge Central	1.85	7.41	3.70	87.04	0.00	100
East of England - Cambridge East	0.00	6.82	13.64	79.55	0.00	100
East of England - Cambridge South	1.75	3.51	8.77	85.96	0.00	100
East of England – Cambridgeshire & Hertfordshire	4.55	4.55	4.55	86.36	0.00	100
East of England - Essex	4.17	2.08	4.17	89.58	0.00	100
East Midlands - Derby	8.77	10.53	7.02	73.68	0.00	100
East Midlands – Leicester Central	4.88	9.76	4.88	80.49	0.00	100
East Midlands – Leicester South	0.00	1.96	13.73	84.31	0.00	100
East Midlands - Nottingham 1	0.00	12.50	0.00	87.50	0.00	100
East Midlands - Nottingham 2	5.66	16.98	5.66	71.70	0.00	100
London - West London & GTAC	1.72	10.34	10.34	77.59	0.00	100
West Midlands - Coventry and Warwick	10.20	14.29	4.08	71.43	0.00	100
West Midlands - Edgbaston	0.00	5.56	0.00	94.44	0.00	100
West Midlands - Solihull	2.04	14.29	6.12	77.55	0.00	100
West Midlands – South Birmingham	3.92	11.76	1.96	82.35	0.00	100
West Midlands – The Black Country	8.33	20.83	4.17	66.67	0.00	100
Average for Centre	3.60	9.55	5.83	81.02	0.00	

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
East of England - Cambridge Central	18.52	11.11	18.52	51.85	0.00	100
East of England - Cambridge East	0.00	0.00	0.00	100	0.00	100
East of England - Cambridge South	8.33	0.00	5.56	80.56	5.56	100
East of England – Cambridgeshire and Hertfordshire	10.00	5.00	10.00	75.00	0.00	100
East of England - Essex	26.67	13.33	0.00	53.33	6.67	100
East Midlands - Derby	16.13	3.23	3.23	67.74	9.68	100
East Midlands – Leicester Central	25.58	13.95	6.98	48.84	4.65	100
East Midlands – Leicester South	21.43	14.29	0.00	60.71	3.57	100
East Midlands - Nottingham 1	27.78	25.00	0.00	44.44	2.78	100
East Midlands - Nottingham 2	21.43	21.43	7.14	45.24	4.76	100
London - West London & GTAC	0.00	28.57	0.00	42.86	28.57	100
West Midlands - Coventry and Warwick	17.14	14.29	8.57	60.00	0.00	100
West Midlands - Edgbaston	23.33	20.00	10.00	43.33	3.33	100
West Midlands - Solihull	23.33	10.00	13.33	50.00	3.33	100
West Midlands – South Birmingham	15.63	46.88	3.13	31.25	3.13	100
West Midlands – The Black Country	29.17	20.83	12.50	33.33	4.17	100
Average for Centre	19.64	16.03	6.77	53.50	4.06	

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