



Health Research Authority

London HRA 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 London HRA 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.
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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 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

On 1 April 2015, responsibility for the National Social Care REC transferred to the HRA. The committee continues to meet as normal and was transferred with minimal disruption. No further changes have taken place to the committee's managed from HRA London.

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.

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

- London – Brent
- London – Dulwich
- London – London Bridge
- London – Stanmore
- London – Surrey Borders
- National Social Care
- South East Coast – Brighton and Sussex

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 – Brent	17	11	6	1 expert	1 expert, 1 lay
London – Dulwich	16	7	9	2 expert, 2 lay	1 expert, 1 lay
London – London Bridge	16	10	6	1 expert, 1 lay	1 expert, 1 lay
London – Stanmore	13	8	5	1 expert	0
London – Surrey Borders	15	9	6	1 expert, 1 lay	2 expert
National Social Care	18	6	12	1 expert, 2 lay	1lay
South East Coast – Brighton & Sussex	16	10	6	0	2 expert, 1 lay
Total	111	61	50	7 expert, 6 lay	12

Quorum

For meetings at which ethical review is undertaken, a quorum shall consist of seven members. Out of 70 meetings scheduled, none had to be cancelled. One additional meeting for London – Brent was arranged to ratify decisions due to it being below the quorum on the day of meeting.

Research Ethics Committees' meetings

- To maintain competency, the HRA recommends that Research Ethics Committees should meet at least ten times per year and should aim to review six studies at main per meeting. All seven committees covered by this summary met on 10 occasions.
- In addition to full Committee meetings, the RECs covered in this summary held a total of 202 Sub-Committee meetings and 45 Proportionate Review Sub-Committee meetings. It should be noted that London – Dulwich and London – London Bridge do not take part in Proportionate Review at the time of this summary.

Summary of activity for all RECs administered from the HRA London 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
London – Brent	5	13	1	22	1	42	6
London – Dulwich	0	7	1	47	1	56	0
London – London Bridge	0	2	2	46	0	50	0
London – Stanmore	0	8	5	27	0	40	0
London – Surrey Borders	1	14	7	30	0	52	0
National Social Care	0	13	5	34	0	52	0
South East Coast – Brighton & Sussex	0	10	10	28	0	48	0
TOTAL	6	67	31	234	2	340	6

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 – Brent	8	4	1	8	0	21
London – Dulwich	0	0	0	0	0	0
London – London Bridge	0	0	0	0	0	0
London – Stanmore	4	6	3	8	0	21
London – Surrey Borders	3	3	0	8	0	14
National Social Care	0	3	0	0	0	3
South East Coast – Brighton & Sussex	5	5	5	9	1	25
TOTAL	20	21	9	33	1	84

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
London – Brent	125	2	0	23	73	34	2	65	28	20
London – Dulwich	98	1	1	15	69	22	10	117	39	5
London – London Bridge	114	3	0	31	82	56	2	0	47	9
London – Stanmore	48	1	0	0	28	0	5	41	7	1
London – Surrey Borders	114	5	1	33	89	50	11	60	24	10
National Social Care	15	4	0	0	13	0	0	38	29	0
South East Coast – Brighton & Sussex	72	6	1	16	59	29	1	47	21	1
TOTAL	586	22	3	118	413	191	31	368	195	46

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

340 studies were reviewed by full Committee of which 100% were given an opinion within the 60 day timeline, and 74% within the 40 day timeline. 84 studies were reviewed by Proportionate Review Sub-Committees of which 85% were given an opinion within the 14 day timeline. Of the 586 Substantial Amendments reviewed, 98% were given a final opinion within the 35 day timeline and 90% within the 28 day timeline. There were 16 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
London – Brent	100%	88%	100%	89%	90%
London – Dulwich	100%	89%	95%	92%	N/A
London – London Bridge	100%	66%	99%	94%	N/A
London – Stanmore	100%	72.5	92%	77%	78%
London – Surrey Borders	100%	77%	99%	96%	79%
National Social Care	100%	90%	100%	100%	100%
South East Coast – Brighton & Sussex	100%	88%	100%	79%	80%
Average for Centre	100%	81.5%	98%	90%	85%

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. One REC in HRA London was 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
National Social Care (with conditions)
London – Dulwich (provisional)

RECs who have received full accreditation having completed an action plan

REC
South East Coast – Brighton and Sussex

Appeals received between April 2015 and March 2016

One for full application (not progressed, revised application resubmitted to the same REC, favourable opinion given). One for substantial amendment (modified amendment submitted to the REC).

Complaints received between April 2015 and March 2016

No complaints were received for the period covered.

Conclusion and Acknowledgements

The Research Ethics Committees managed from HRA London continue to provide valuable independent advice to researchers, sponsors and employers whilst protecting the dignity, rights, safety and wellbeing of actual and potential participants. The office achieved a 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 services of our volunteer members is greatly appreciated.

Mark Ryan-Daly
Research Ethics Service Manager (England)
17 September 2016

Appendix A

% Opinion rates for each REC

Applications reviewed at Full Committee meetings

REC	FOSC	FOAC	UFO	PO	POPC	Total
London – Brent	12.20%	31.15%	2.00%	52.65%	2.00%	100.00%
London – Dulwich	0.00%	12.50%	1.78%	83.93%	1.79%	100.00%
London – London Bridge	0.00%	4.00%	4.00%	92.00%	0.00%	100.00%
London – Stanmore	0.00%	20.00%	12.50%	67.50%	0.00%	100.00%
London – Surrey Borders	1.92%	26.92%	13.47%	57.69%	0.00%	100.00%
National Social Care	0.00%	25.00%	9.62%	65.38%	0.00%	100.00%
South East Coast – Brighton & Sussex	0.00%	20.83%	20.83%	58.34%	0.00%	100.00%
Average for Centre	2.02%	20.06%	9.17%	68.21	0.54%	100.00%

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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 – Brent	38.10%	19.05%	4.76%	38.10%	0.00%	100.00%
London – Dulwich	N/A	N/A	N/A	N/A	N/A	N/A
London – London Bridge	N/A	N/A	N/A	N/A	N/A	N/A
London – Stanmore	19.05%	28.56%	14.29%	38.10%	0.00%	100.00%
London – Surrey Borders	21.43%	21.43%	0.00%	57.14%	0.00%	100.00%
National Social Care	0.00%	100.00%	0.00%	0.00%	0.00%	100.00%
South East Coast – Brighton & Sussex	20.00%	20.00%	20.00%	36.00%	4.00%	100.00%
Average for Centre	19.72%	37.81%	7.81%	33.87%	0.80%	100.00%

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