

Health Research Authority

Bristol 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 Bristol 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.
Presenter	Mark Ryan-Daly Research Ethics Service Manager (England) mark.ryandaly@nhs.net
Contact RECs	<p>Research Ethics Service Manager (England): Mark Ryan-Daly Regional Manager: Tom Lucas tom.lucas@nhs.net Deputy Regional Manager: Cathy Chesham cchesham@nhs.net Deputy Regional Manager: Libby Watson libby.watson1@nhs.net</p> <p><u>London – Bromley</u> REC Manager: Maeve Ip Groot Bluemink Email: nrescommittee.london-bromley@nhs.net</p> <p><u>London – Camberwell St Giles</u> REC Manager: Aliko Sifostratoudaki Email: nrescommittee.london-camberwellstgiles@nhs.net</p> <p><u>London – Chelsea</u> REC Manager: Aliko Sifostratoudaki Email: nrescommittee.london-chelsea@nhs.net</p> <p><u>London – City and East</u> REC Manager: Rajat Khullar Email: nrescommittee.london-cityandeast@nhs.net</p> <p><u>London – City Road and Hampstead</u> REC Manager: Rajat Khullar Email: nrescommittee.london-cityroadandhampstead@nhs.net</p> <p><u>London – Harrow</u> REC Manager: Georgina Castledine Email: nrescommittee.london-harrow@nhs.net</p> <p><u>London – Riverside</u> REC Manager: Tina Cavaliere Email: nrescommittee.london-riverside@nhs.net</p>

	<p><u>South Central – Berkshire</u> REC Manager: Claudia Bywater Email: nrescommittee.southcentral-berkshire@nhs.net</p> <p><u>South Central – Berkshire B</u> REC Manager: Tina Cavaliere Email: nrescommittee.southcentral-berkshireb@nhs.net</p> <p><u>South Central – Hampshire A</u> REC Manager: Maxine Knight Email: nrescommittee.southcentral-hampshirea@nhs.net</p> <p><u>South Central – Hampshire B</u> REC Manager: Siobhan Bawn Email: nrescommittee.southcentral-hampshireb@nhs.net</p> <p><u>South Central – Oxford A</u> REC Manager: Natasha Bridgeman Email: nrescommittee.southcentral-oxforda@nhs.net</p> <p><u>South Central – Oxford B</u> REC Manager: Claudia Bywater Email: nrescommittee.southcentral-oxfordb@nhs.net</p> <p><u>South Central – Oxford C</u> REC Manager: Sadie McKeegan-Keown Email: nrescommittee.southcentral-oxfordc@nhs.net</p> <p><u>South East Coast – Surrey</u> REC Manager: Rajat Khullar Email: nrescommittee.secoast-surrey@nhs.net</p> <p><u>South West – Central Bristol</u> REC Manager: Naazneen Nathoo Email: nrescommittee.southwest-bristol@nhs.net</p> <p><u>South West – Cornwall and Plymouth</u> REC Manager: Georgina Castledine Email: nrescommittee.southwest-cornwall-plymouth@nhs.net</p> <p><u>South West – Exeter</u> REC Manager: Naazneen Nathoo Email: nrescommittee.southwest-exeter@nhs.net</p> <p><u>South West – Frenchay</u> REC Manager: Natasha Bridgeman Email: nrescommittee.southwest-frenchay@nhs.net</p>
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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

As a result of geographical reconfiguration of the committee's across the five HRA offices, administrative support for the following committee's changed during the reporting period. They continued to meet in the same locations and the transfers were achieved with minimal disruption.

- London – South East – transferred to HRA Manchester.
- London – Westminster – transferred to HRA Manchester.

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.

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

- London - Bromley
- London - Camberwell St Giles
- London - Chelsea
- London - City and East
- London - City Road and Hampstead
- London - Harrow
- London - Riverside
- South Central - Berkshire
- South Central - Berkshire B
- South Central - Hampshire A
- South Central - Hampshire B
- South Central - Oxford A
- South Central - Oxford B
- South Central - Oxford C

- South East Coast - Surrey
- South West - Central Bristol
- South West - Cornwall and Plymouth
- South West - Exeter
- South West - Frenchay

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 – Bromley	16	7	9	0	1 expert, 3 lay
London - Camberwell St Giles	16	7	9	2 expert, 2 lay	2 expert, 2 lay
London – Chelsea	18	9	9	1 lay	2 lay
London - City and East	14	7	7	3 expert, 2 lay	3 expert
London - City Road and Hampstead	11	7	4	1 expert, 1 lay	1 expert, 1 lay
London – Harrow	14	6	8	1 expert, 1 lay	4 lay
London - Riverside	13	5	8	4 expert, 1 lay	2 expert, 2 lay
South Central - Berkshire	14	5	9	1 expert,	2 lay
South Central - Berkshire B	12	4	8	1 expert	1 expert
South Central - Hampshire A	12	8	4	1 expert, 1 lay	1 expert
South Central - Hampshire B	13	7	6	1 expert, 2 lay	2 expert, 4 lay
South Central - Oxford A	15	7	8	1 expert, 3 lay	1 expert, 3 lay
South Central - Oxford B	12	5	7	1 expert, 1 lay	0
South Central - Oxford C	14	7	7	2 lay	1 expert, 2 lay
South East Coast - Surrey	14	8	6	4 expert, 2 lay	1 expert, 1 lay
South West - Central Bristol	15	8	7	2 expert	3 expert, 2 lay
South West - Cornwall and Plymouth	11	7	4	1 expert, 2 lay	2 expert
South West - Exeter	14	5	9	0	1 expert
South West - Frenchay	12	7	5	2 expert, 4 lay	2 expert, 1 lay
Total	260	126	134	51	53

Quorum

For meetings at which ethical review is undertaken, a quorum shall consist of seven members. Out of 190 meetings scheduled, only 176 went ahead as planned. A total of 14 were cancelled due to attendance issues or receiving no bookings. One meeting (London –

City Road and Hampstead) was below the quoracy limit and decisions were discussed and ratified at an additional 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. Seven committees met on ten occasions or more. A further ten committees met on nine occasions, with two committee's meeting on eight and seven occasions.
- In addition to full Committee meetings, the RECs covered in this summary held a total of 165 Sub-Committee meetings and 687 Proportionate Review Sub-Committee meetings.

Summary of activity for all RECs administered from the HRA Bristol 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 - Bromley	0	9	4	29	0	42	1
London - Camberwell St Giles	1	13	0	24	2	40	0
London - Chelsea	2	9	1	38	0	50	0
London - City and East	2	9	3	44	1	59	0
London - City Road and Hampstead	0	4	1	32	0	37	0
London - Harrow	0	4	0	42	0	46	0
London - Riverside	6	13	1	26	0	46	0
South Central - Berkshire	7	23	1	18	0	49	0
South Central - Berkshire B	0	6	0	44	0	50	0
South Central - Hampshire A	2	6	1	27	0	36	0
South Central - Hampshire B	0	6	2	38	1	47	0
South Central - Oxford A	1	7	0	36	1	45	1
South Central - Oxford B	2	7	1	40	0	50	0
South Central - Oxford C	3	17	1	37	0	58	0
South East Coast - Surrey	0	10	1	31	0	42	0
South West - Central Bristol	6	12	3	29	1	51	1
South West - Cornwall and Plymouth	3	1	3	22	0	29	0
South West - Exeter	0	5	2	28	0	35	1
South West - Frenchay	1	5	4	28	0	38	1
TOTAL	10	33	13	138	6	850	5

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 - Bromley	9	7	2	7	0	25
London - Camberwell St Giles	0	0	0	1	0	1
London - Chelsea	5	9	0	8	0	22
London - City and East	12	8	3	21	0	44
London - City Road and Hampstead	2	1	4	3	0	10
London - Harrow	4	3	2	15	0	24
London - Riverside	2	0	0	0	0	2
South Central - Berkshire	7	9	4	9	3	32
South Central - Berkshire B	10	12	0	7	0	29
South Central - Hampshire A	8	4	2	18	0	32
South Central - Hampshire B	2	4	0	8	0	14
South Central - Oxford A	0	1	0	2	0	3
South Central - Oxford B	6	2	1	4	1	14
South Central - Oxford C	12	12	0	5	1	30
South East Coast - Surrey	11	5	0	7	0	23
South West - Central Bristol	6	5	0	16	0	27
South West - Cornwall and Plymouth	15	2	1	11	0	29
South West - Exeter	0	1	0	18	0	19
South West - Frenchay	7	3	2	14	0	26
TOTAL	118	88	21	176	5	406

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 - Bromley	42	1	0	0	21	0	0	33	13	1
London - Camberwell St Giles	76	2	0	0	53	0	5	80	10	8
London - Chelsea	178	2	2	58	87	106	1	55	0	16
London - City and East	199	5	0	56	32	21	0	70	5	10
London - City Road and Hampstead	51	3	0	0	30	0	0	18	19	4
London - Harrow	117	7	0	17	100	20	0	98	1	12
London - Riverside	129	9	2	43	105	231	0	59	15	8
South Central - Berkshire	134	9	9	24	104	21	1	68	10	15
South Central - Berkshire B	110	6	1	12	100	17	1	12	10	25
South Central - Hampshire A	122	5	1	17	50	31	22	42	9	6
South Central - Hampshire B	119	5	1	17	71	80	6	239	81	8
South Central - Oxford A	160	4	0	36	76	86	3	76	12	21
South Central - Oxford B	139	6	3	62	87	43	1	90	17	18
South Central - Oxford C	174	0	0	54	65	49	2	82	33	3
South East Coast - Surrey	51	0	0	0	42	0	2	25	9	1
South West - Central Bristol	112	1	0	20	15	31	0	43	6	8
South West - Cornwall and Plymouth	51	0	0	0	37	1	0	56	1	7
South West - Exeter	59	6	0	12	19	5	1	20	1	7
South West - Frenchay	63	2	0	0	6	0	6	33	14	4
TOTAL	2086	73	19	428	1100	742	51	1199	266	182

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

850 studies were reviewed by full Committee of which 100% were given an opinion within the 60 day timeline, and 87% within the 40 day timeline. 406 studies were reviewed by Proportionate Review Sub-Committees of which 93% were given an opinion within the 14 day timeline. Of the 2086 Substantial Amendments reviewed, 99% were given a final opinion within the 35 day timeline and 93% within the 28 day timeline. There were 44 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 - Bromley	100%	95%	100%	100%	96%
London - Camberwell St Giles	100%	97%	100%	99%	100%
London - Chelsea	100%	92%	100%	99%	95%
London - City and East	100%	87%	99%	86%	100%
London - City Road and Hampstead	95%	49%	100%	90%	100%
London - Harrow	100%	87%	100%	87%	95%
London - Riverside	98%	91%	100%	96%	100%
South Central - Berkshire	100%	94%	100%	99%	96%
South Central - Berkshire B	100%	96%	100%	99%	100%
South Central - Hampshire A	100%	86%	100%	86%	80%
South Central - Hampshire B	100%	91%	99%	94%	100%
South Central - Oxford A	100%	87%	99%	96%	100%
South Central - Oxford B	100%	98%	100%	96%	92%
South Central - Oxford C	100%	97%	100%	99%	97%
South East Coast - Surrey	100%	95%	100%	100%	100%
South West - Central	98%	63%	95%	67%	92%

Bristol					
South West - Cornwall and Plymouth	100%	93%	100%	94%	96%
South West - Exeter	100%	71%	95%	81%	58%
South West - Frenchay	100%	89%	100%	92%	75%
Average for Centre	100%	87%	99%	93%	93%

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 Bristol 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
South Central – Hampshire B
South West – Frenchay

RECs who have received full accreditation having completed an action plan

REC
South West – Cornwall and Plymouth

Appeals received between April 2015 and March 2016

Two for full applications (revised applications resubmitted to the RECs and favourable opinions given).

Three for substantial amendments (one did not proceed and two resubmitted as modified amendments).

Complaints received between April 2015 and March 2016

One complaint received and upheld

Conclusion and Acknowledgements

The Research Ethics Committees managed from HRA Bristol 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 - Bromley	0.00%	21.43%	9.52%	69.05%	0.00%	100.00%
London - Camberwell St Giles	2.50%	32.50%	0.00%	60.00%	5.00%	100.00%
London - Chelsea	4.00%	18.00%	2.00%	76.00%	0.00%	100.00%
London - City and East	3.39%	15.25%	5.09%	74.58%	1.69%	100.00%
London - City Road and Hampstead	0.00%	10.81%	2.70%	86.49%	0.00%	100.00%
London - Harrow	0.00%	8.70%	0.00%	91.30%	0.00%	100.00%
London - Riverside	13.04%	28.26%	2.17%	56.53%	0.00%	100.00%
South Central - Berkshire	14.29%	46.94%	2.04%	36.73%	0.00%	100.00%
South Central - Berkshire B	0.00%	12.00%	0.00%	88.00%	0.00%	100.00%
South Central - Hampshire A	5.56%	16.66%	2.78%	75.00%	0.00%	100.00%
South Central - Hampshire B	0.00%	12.76%	4.26%	80.85%	2.13%	100.00%
South Central - Oxford A	2.22%	15.56%	0.00%	80.00%	2.22%	100.00%
South Central - Oxford B	4.00%	14.00%	2.00%	80.00%	0.00%	100.00%
South Central - Oxford C	5.17%	29.31%	1.73%	63.79%	0.00%	100.00%
South East Coast - Surrey	0.00%	23.81%	2.38%	73.81%	0.00%	100.00%
South West - Central Bristol	11.66%	25.53%	4.99%	55.86%	1.96%	100.00%
South West - Cornwall and Plymouth	10.34%	3.46%	10.34%	75.86%	0.00%	100.00%
South West - Exeter	0.00%	14.29%	5.71%	80.00%	0.00%	100.00%
South West - Frenchay	2.63%	13.16%	10.53%	73.68%	0.00%	100.00%
Average for Centre	4.14%	19.08%	3.59%	72.50%	0.68%	100.00%

Key

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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 - Bromley	36.00%	28.00%	8.00%	28.00%	0.00%	100.00%
London - Camberwell St Giles	0.00%	0.00%	0.00%	100.00%	0.00%	100.00%
London - Chelsea	22.73%	40.91%	0.00%	36.36%	0.00%	100.00%
London - City and East	27.27%	18.18%	6.82%	47.73%	0.00%	100.00%
London - City Road and Hampstead	20.00%	10.00%	40.00%	30.00%	0.00%	100.00%
London - Harrow	16.67%	12.50%	8.33%	62.50%	0.00%	100.00%
London - Riverside	100.00%	0.00%	0.00%	0.00%	0.00%	100.00%
South Central - Berkshire	21.88%	28.13%	12.50%	28.11%	9.38%	100.00%
South Central - Berkshire B	34.48%	41.38%	0.00%	24.14%	0.00%	100.00%
South Central - Hampshire A	25.00%	12.50%	6.25%	56.25%	0.00%	100.00%
South Central - Hampshire B	14.29%	28.57%	0.00%	57.14%	0.00%	100.00%
South Central - Oxford A	0.00%	33.33%	0.00%	66.67%	0.00%	100.00%
South Central - Oxford B	42.86%	14.29%	7.24%	28.47%	7.24%	100.00%
South Central - Oxford C	40.00%	40.00%	0.00%	16.67%	3.33%	100.00%
South East Coast - Surrey	47.83%	21.74%	0.00%	30.43%	0.00%	100.00%
South West - Central Bristol	22.22%	18.52%	0.00%	59.26%	0.00%	100.00%
South West - Cornwall and Plymouth	51.72%	6.90%	3.45%	37.93%	0.00%	100.00%
South West - Exeter	0.00%	5.26%	0.00%	94.74%	0.00%	100.00%
South West - Frenchay	26.92%	11.54%	7.69%	53.85%	0.00%	100.00%
Average for Centre	28.94%	19.57%	5.27%	45.17%	1.05%	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