

London REC Centre Annual Report (Summary)  
April 2011 to March 2012

<b>Purpose</b>	To present annual reports from the Research Ethics Committee (RECs) administered from the London Centre. The reports cover the activity between April 2011 and March 2012 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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	<p>Alka Bhayani, Coordinator, NRESCommittee.London-Hampstead@nhs.net</p> <p><u>Harrow REC:</u> Libby Watson, Coordinator, Ubh-tr.HarrowREC@nhs.net (from June 2012)</p> <p><u>Kent Rec:</u> <u>Halina Pounds, Coordinator</u> NRESCommittee.SECoast-Kent@nhs.net</p> <p><u>London Bridge:</u> Stephanie Hill, Coordinator nrescommittee.london-londonbridge@nhs.net</p> <p><u>London East REC (closed):</u> Laura Keegan, Coordinator, laura.keegan@nhs,.net</p> <p><u>Queen Square</u> Audrey Adams, Coordinator NRESCommittee.London-QueenSquare@nhs.net</p> <p><u>South East</u> Janhoi MacGregor, Coordinator NRESCommittee.London-SouthEast@nhs.net</p> <p><u>Stanmore</u> Danyal Enver, Coordinator NRESCommittee.London-Stanmore@nhs.net</p> <p><u>Surrey Borders</u> Alka Bhayani, Coordinator NRESCommittee.London-SurreyBorders@nhs.net</p> <p><u>Surrey</u> Georgina Marshall, Coordinator NRESCommittee.SECoast-Surrey@nhs.net</p> <p><u>Wandsworth REC (closed):</u> Janhoi MacGregor, Coordinator, jaymcgregor@nhs.net</p> <p><u>West London</u> Georgina Marshall, Coordinator nrescommittee.london-westlondon@nhs.net</p> <p><u>Westminster</u> Laura Keegan, Coordinator nrescommittee.london-westminster@nhs.net</p>
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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 division 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;
- 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. The Appointing Authority functions were previously undertaken by the Strategic Health Authorities.

### **Update on structural change since 2010/2011 Summary of Annual Reports:**

The year 2011-2012 saw staff from small satellite offices relocated within two London REC Offices at Charing Cross Hospital and Northwick Park Hospital. Early 2012 saw the appointment of a REC Centre Manager and two Senior Coordinators (one full-time, one half-time) as well as the appointment of a large number of substantive REC Coordinators. Plans were put in place to consolidate the offices in mid 2012 on to one site at Skipton House. There was insufficient accommodation for all staff and the move saw the loss of a small number of experienced staff. The administration of a small number of London RECs was moved to NRES Offices in Jarrow, Manchester and Bristol to achieve greater parity of numbers of RECs across the large Centres. This also contributed to RECs being administered by more experienced coordinators following the significant number of new appointments made in London.

London East REC and Wandsworth REC were closed in the final quarter of 2011-2012. Post-approval work for these committees continues under Surrey and West London RECs respectively. In June 2011, GTAC formally became a NRES Committee.

### **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 by 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 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

23 Committees have submitted reports for the year 1 April 2011 to 31 March 2012:

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|--|---|
| • NRES Committee London<br>Bentham                                 | • NRES Committee London<br>Surrey Borders |
| • NRES Committee London<br>Bloomsbury                              | • NRES Committee London<br>Wandsworth     |
| • NRES Committee London Brent                                      | • NRES Committee London West<br>London    |
| • NRES Committee South East<br>Coast Brighton                      | • NRES Committee London<br>Westminster    |
| • NRES Committee London<br>Camden and Islington                    |   |
| • NRES Committee London<br>Central                                 |   |
| • NRES Committee London<br>Chelsea                                 |   |
| • NRES Committee London<br>Dulwich                                 |   |
| • NRES Committee London<br>Fulham                                  |   |
| • Gene Therapy Advisory<br>Committee 1 June 2011-31<br>March 2012) |   |
| • NRES Committee London<br>Hampstead                               |   |
| • NRES Committee London<br>Harrow                                  |   |
| • NRES Committee South East<br>Coast Kent                          |   |
| • NRES Committee London<br>London Bridge                           |   |
| • NRES Committee London East                                       |   |
| • NRES Committee London Queen<br>Square                            |   |
| • NRES Committee London South<br>East                              |   |
| • NRES Committee London<br>Stanmore                                |   |
| • NRES Committee South East<br>Coast Surrey                        |   |

## Membership as at 31 March 2012:

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 in period of annual report
Bentham	14	8	6	3 expert
Bloomsbury	15	9	6	1 expert
Brent	15	9	6	1 expert, 2 lay
Brighton and Sussex	19 (inc 2 deputies)	13 (inc 2 deputies)	6	1 expert, 1 lay
Camden & Islington	17	10	7	3 lay
Central	14	8	6	3 expert
Chelsea	14	10	4	2 expert, 1 lay
Dulwich	13	6	7	3 expert
Fulham	17	11	1	1 expert
GTAC	12	7	5	3 expert, 2 lay
Hampstead	16 (incl 1 deputy)	12 (incl 1 deputy)	4	1 expert, 3 lay
Harrow	15	7	8	1 expert, 2 lay
Kent	16	12	4	1 expert, 2 lay
London Bridge	17 (incl 1 deputy)	11 (incl 1 deputy)	6	1 expert
London East	15	6	9	1 expert
Queen Square	16	10	6	2 expert, 1 lay
South East	12	8	4	2 expert, 2 lay
Stanmore	14	9	5	2 expert
Surrey	13	9	4	1 expert
Surrey Borders	13	6	7	2 expert , 1 lay
Wandsworth	16	11	5	1 expert
West London	17	12	5	2 expert, 2 lay
Westminster	16	11	5	3 expert 1lay

*\*Annual reports signed off. Note, the data for RECs not marked \* is subject to final verification and some minor corrections may need to be made to the final version of this report.*

## Quorum:

For meetings at which ethical review is undertaken, a quorum shall consist of seven members. Of 236 scheduled meetings, 2 meetings were inquorate and managed in line with Standard Operating Procedures.

## 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 to eight studies per meeting. Of the 19 committees operating for the whole of the reporting period \*\* met the requirements in terms of numbers of meetings held.

## Summary of activity for all London Centre RECs that were operating during 2011/12

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

REC	FOSC	FOAC	UFO	PO	Invalid	NOPC	POPC	SSB	Total	SSA	PR
<b>Bentham</b>	0	18	4	33	0	0	0	0	55	19	3
<b>Bloomsbury</b>	12	11	0	40	0	0	0	0	63	1	0
<b>Brent</b>	19	21	3	26	0	0	0	0	69	36	0
<b>Brighton</b>	6	5	11	34	0	0	0	0	56	3	0
<b>Camden &amp; Islington</b>	1	10	2	44	0	0	0	1	57	2	0
<b>Central</b>	21	17	2	34	0	0	0	2	74	5	0
<b>Chelsea</b>	7	13	1	54	0	2	1	0	75	7	0
<b>Dulwich</b>	10	19	1	38	0	0	0	1	68	2	36
<b>Fulham</b>	12	12	6	33	0	0	0	0	63	7	26
<b>GTAC</b>	0	0	0	9	0	0	0	1	9	0	0
<b>Hampstead</b>	5	10	5	50	0	0	0	0	70	4	0
<b>Harrow</b>	7	12	2	44	0	0	1	1	65	3	0
<b>Kent</b>	2	5	3	31	0	0	0	0	41	1	0
<b>London Bridge</b>	9	3	4	42	0	0	0	1	58	22	0
<b>London East</b>	0	22	6	31	1	0	0	0	61	6	31
<b>Queen Sq</b>	2	0	1	49	0	0	0	0	52	1	0
<b>South East</b>	7	3	11	52	0	0	0	0	73	0	0
<b>Stanmore</b>	1	18	3	40	0	0	0	0	62	0	0
<b>Surrey</b>	3	22	1	25	0	0	0	1	51	4	0
<b>Surrey Borders</b>	5	7	1	44	0	0	0	0	57	4	32
<b>Wandsworth</b>	3	2	2	42	0	0	0	0	49	18	19
<b>West London</b>	5	7	5	48	0	0	0	0	65	17	0
<b>Westminster</b>	3	6	2	51	0	0	0	0	62	1	0

### Key

FOSC	Favourable Opinion with Standard Conditions
FOAC	Favourable Opinion with Additional Conditions
UFO	Unfavourable opinion
PO	Provisional opinion
NOPC	No Opinion Pending Consultation with Referee
POPC	Provisional Opinion Pending Consultation with Referee
SSB	Number of studies sent back to full committee meeting for final opinion
SSA	Site Specific Assessment reviewed for non NHS site
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

### Performance

1355 studies were reviewed by full Committee of which 89.1 % were given an opinion within the appropriate timescale. 147 studies were reviewed by Proportionate Review Sub-Committees of which 44.9 % were given an opinion within the appropriate timescale. Please note that the Proportionate Review Service was in pilot phase until September 2011 and the 14 day timeline was an aim not a target. Of 163 SSAs reviewed, 70.6% were given a final opinion within the appropriate timescale. Of the 1828 Substantial Amendments reviewed, 82.6% were given a final opinion within the appropriate timescale. There were no Section 30 applications reviewed during the reporting period.

REC	Number of full applications over 60 days (* 90 days for GTAC)	Number of SSAs over 25 days	Number of Substantial amendments over 35 days	Number of Section 30 applications over 60 days
Bentham	12	3	28	0
Bloomsbury	5	0	12	0
Brent	3	6	3	0
Brighton	1	0	1	0
Camden & Islington	1	1	2	0
Central	2	2	2	0
Chelsea	2	1	3	0
Dulwich	13	0	31	0
Fulham	3	3	16	0
GTAC*	7	0	11	0
Hampstead	3	0	2	0
Harrow	1	0	21	0
Kent	7	0	5	0
London Bridge	9	15	36	0
London East	8	0	4	0
Queen Square	11	0	11	0
South East	10	0	39	0
Stanmore	0	0	1	0
Surrey	5	3	4	0
Surrey Borders	15	1	26	0
Wandsworth	17	7	31	0
West London	3	1	12	0
Westminster	7	0	16	0

## Accreditation of Research Ethics Committees

Our 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.

To supplement the audit process NRES operations quality control check each committee on a six monthly basis.

### RECs Achieving Full Accreditation at first review

None
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### RECs who have received full accreditation having completed an action plan

Bloomsbury
Brent
Central
Chelsea
Fulham
Hampstead
Queen Square
South East
Stanmore

Other RECs still hold accredited status under the previous scheme.

The London East REC failed to attain accredited status and was closed during the reporting period.

### Appeals received between April 2011 and March 2012

3 appeals were received and allowed for London RECs.

### Complaints received between April 2011 and March 2012

9 complaints were received relating to London REC Centre RECs. 5 were upheld, 3 were partially upheld and 1 was not upheld.

## Conclusion and Acknowledgements

The Research Ethics Committees managed from the London REC Centre 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 Centre has achieved a varied level of performance with some RECs achieving excellent reports and others where there is a need for improvement.



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 also acknowledged and the services of our volunteer members is greatly appreciated.

Further consolidation, both in the number of committees and the location of the support to those committees, is continuing on a national basis in line with the objectives of the HRA business plan; this is to ensure that standards are improved in line with the NRES guidance.

**Jonathan Fennelly-Barnwell, Regional Manager, South  
September 2012**