

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

Purpose	To present annual reports from the Research Ethics Committee (RECs) administered from the Bristol Centre. The reports cover the activity between April 2011 and March 2012 and copies of the full reports are available on the HRA website
Recommendations	That the annual reports be received and noted
Presenter	Jonathan Fennelly-Barnwell, Regional Manager (South) – j.fennelly-barnwell@nhs.net
Contact	<p>Centre Manager – Tom Lucas, tom.lucas@nhs.net</p> <p>Senior Coordinators: Cathy Chesham cchesham@nhs.net Charlotte Allen Ubh-tr.SouthWest1@nhs.net</p> <p>Cornwall and Plymouth REC : Charlotte Allen, Coordinator, Ubh-tr.SouthWest1@nhs.net</p> <p>Exeter REC: Kirsten Peck, Coordinator Ubh-tr.SouthWest2@nhs.net</p> <p>Bristol Central: Naaz Nathoo, Coordinator Ubh-tr.SouthWest3@nhs.net</p> <p>Frenchay REC: Ruth Avery, Coordinator Ubh-tr.SouthWest5@nhs.net</p> <p>Southmead REC Naaz Nathoo, Coordinator Ubh-tr.SouthWest3@nhs.net</p> <p>Oxford A REC: Stephanie Macpherson, Coordinator, scsha.OxfordRECA@nhs.net</p> <p>Oxford B REC: Siobhan McDonagh, Coordinator, scsha.OxfordRECB@nhs.net</p> <p>Southampton A REC: Maxine Knight, Coordinator scsha.SWHRECA@nhs.net</p> <p>Southampton B REC: Libby Watson, Coordinator scsha.swhrecb@nhs.net</p> <p>Portsmouth REC: Ruth Avery, Coordinator scsha.sehrec@nhs.net</p> <p>Berkshire B REC: Naaz Nathoo, Coordinator ubh-tr.BerkshireB@nhs.net</p> <p>Berkshire REC: Rae Granville, Coordinator scsha.berksREC@nhs.net</p> <p>London City Road and Hampstead REC: Tina Cavaliere, Coordinator, ubh-tr.CityRoadHampsteadREC@nhs.net</p>

	London City and East REC: Raj Khullar, Coordinator, Ubh-tr.CityandEastREC@nhs.net London Bromley: Stephanie Mcpherson, Coordinator Ubh-tr.BromleyREC@nhs.net London Riverside Tina Cavaliere, Coordinator, Ubh-tr.RiversideREC@nhs.net
--	---

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 REC Centre continues to be well managed and provide high quality administrative support to the RECs in the South Central and South West areas, as well as to a number of London RECs. 2011-2012 saw a phased move of South Central Region RECs to the Bristol Centre from the now-closed Reading Office. This includes the former Berkshire Independent REC which became a NRES Committee and now operates as NRES Committee Berkshire B.

As the number of RECs managed in the Centre has increased, additional staff have been successfully recruited and trained and the transition has been achieved with minimal disruption to the Committees. In December 2011 and January 2012, two Senior Coordinators (one full-time, one half-time) were appointed.

Southmead REC was suspended from full REC meetings in October 2011 and merged with the NRES South West Central Bristol REC on 31/3/12.

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

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

- Plymouth and Cornwall
- Exeter
- Central Bristol
- Frenchay
- Southmead
- Oxford A
- Oxford B
- Southampton A
- Southampton B
- Portsmouth
- Berkshire
- Berkshire B (1 June 2011 to 31 March 2012)
- London Bromley
- London City and East
- London City road and Hampstead
- London Riverside

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
Cornwall and Plymouth	16	9	2	2 expert
Exeter	17	10	7	none
Central Bristol	13	7	6	1 expert, 2 lay
Frenchay	16	7	9	1 expert, 2 lay
Southmead	7	3	4	4 expert, 2 lay
Oxford A	16	9	7	3 expert
Oxford B	15	10	5	2 lay
Berkshire	14	8	6	3 expert, 2 lay
Berkshire B	10	6	4	3 lay
Portsmouth	13	7	6	5 expert
Southampton A	13	7	6	4 expert, 1 lay
Southampton B	10	6	4	3 expert, 4 lay
London City and East	19 (inc 1 deputy)	13 (inc 1 deputy)	6	1 lay
London City Rd and Hampstead	13	7	6	1 expert, 2 lay
London Bromley	12	5	7	2 expert
London Riverside	14	10	4	1 expert, 1 lay

Quorum:

For meetings at which ethical review is undertaken, a quorum shall consist of seven members. Out of 159 scheduled meetings, one meeting of Southmead REC had to be cancelled and rescheduled by telecom due to being inquorate.

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 14 committees operating for the whole of the reporting period 12 met the requirements in terms of numbers of meetings held. Bromley held 8 full REC meetings as did Portsmouth.

Summary of activity for all Bristol 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	SSI	PR
Cornwall and Plymouth	7	6	11	33	0	1	0	0	58	2	14
Exeter	0	0	7	58	0	0	0	3	65	1	21
Central Bristol	10	13	4	33	1		0	1	61	13	12
Frenchay	5	3	1	53	0	0	0	0	62	3	16
Southmead	6	1	1	34	0	0	0	0	42	0	0
Oxford A	0	4	3	61	0	0	0	0	68	13	8
Oxford B	1	3	4	50	0	2	0	0	60	5	11
Berkshire	1	9	16	38	0	0	0	0	64	14	9
Berkshire B	1	12	1	22	0	0	0	0	36	0	3
Portsmouth	4	3	1	35	0	0	0	0	43	0	12
Southampton A	8	9	0	49	0	0	0	0	66	5	3
Southampton B	10	3	6	44	0	0	0	0	63	3	0
London City and East	7	7	6	32	0	1	0	1	53	28	11
London City Rd and Hampstead	0	24	2	40	0	0	0	0	66	1	0
London Bromley	8	14	4	19	0	0	1	0	46	2	8
London Riverside	4	8	3	46	0	3	0	0	64	2	2

Key

FOSC	Favourable Opinion with Standard Conditions
FOAC	Favourable Opinion with Additional Conditions
UFO	Unfavourable opinion
NOPC	No Opinion Pending Consultation with Referee
PO	Provisional opinion
POPC	Provisional Opinion Pending Consultation with Referee
NRR	Not Requiring Review by NHS REC
SSB	Number of studies sent back to full committee meeting for final opinion
SSI	Site Specific Assessment reviewed
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

917 studies were reviewed by full Committee of which 96.5 % were given an opinion within the appropriate timescale. 130 studies were reviewed by Proportionate Review Sub-Committees of which 72.3% 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 92 SSAs reviewed, 85.8% were given a final opinion within the appropriate timescale. Of the 1431 Substantial Amendments reviewed, 92.7% 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	Number of SSAs over 25 days	Number of Substantial amendments over 35 days	Number of Section 30 applications over 60 days
Cornwall and Plymouth	0	0	0	0
Exeter	3	0	6	0
Central Bristol	1	2	1	0
Frenchay	0	2	1	0
Southmead	3	0	0	0
Oxford A	0	1	0	0
Oxford B	4	1	31	0
Berkshire	1	0	8	0
Berkshire B	0	0	0	0
Portsmouth	1	0	1	0
Southampton A	7	3	19	0
Southampton B	1	0	10	0
London City and East	5	4	9	0
London City Rd and Hampstead	3	0	7	0
London Bromley	2	0	1	0
London Riverside	1	0	11	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

REC
Plymouth and Cornwall

RECs who have received full accreditation having completed an action plan

REC
Exeter
Oxford A
Oxford B
Southampton A
Southampton B
London Bromley
London City and East
London Riverside

Appeals received between April 2011 and March 2012

4 appeals were received for Bristol RECs, including one Substantial Amendment. 3 appeals were allowed, including that for the Substantial Amendment.

Complaints received between April 2011 and March 2012

3 complaints were received relating to Bristol REC Centre RECs, one of which related to four studies. This and one other were partially upheld, and one complaint upheld.

Conclusion and Acknowledgements

The Research Ethics Committees managed from the Bristol 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 good level of performance and the work of the local management and staff is acknowledged by members, applicants and stakeholders.

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
4 September 2012**