

National Research Ethics
Service


Health Research Authority

**East of England (Cambridge)
REC Centre Annual Report
Summary**

01 April 2011 – 31 March 2012

**East of England REC Centre Annual Report (Summary)
April 2011 to March 2012**

Purpose	To present summary of the annual reports from Research Ethics Committees (RECs) administered from the North East 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
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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:

As a result of the introduction of the new harmonised governance arrangements for research ethics committees (GAfREC) and the consultation with the Independent Ethics Committees appointed by AAPEC, Welwyn Clinical Pharmaceutical Ethics Committee agreed to continue as a functioning committee for the review of Phase I CTIMPs in healthy volunteers. In January 2012, as part of a managed transition to the NRES under the newly formed HRA, this committee became an NRES Committee and was renamed East of England – Welwyn and the administrative support transferred to the East of England Centre.

The administrative support for Camberwell St Giles REC transferred from the London Centre to the East of England Centre in May 2011; meetings continued to be held at the Institute of Psychiatry, King's College London as usual.

Proportionate review was rolled out to 5 of the RECs administered from the East of England Centre with effect from July 2011.

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

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

- East of England – Cambridge Central
- East of England – Cambridge East
- East of England – Cambridge South
- East of England – Essex
- East of England – Hertfordshire
- East of England – Norfolk
- East of England – Welwyn
- London – Camberwell St Giles

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
East of England – Cambridge Central	14	8	6	3 expert, 1 lay
East of England – Cambridge East	12	7	5	none
East of England – Cambridge South	15	9	6	none
East of England – Essex	13	6	7	1 lay
East of England – Hertfordshire	11	6	5	1 expert, 1 lay
East of England – Norfolk	12	8	4	2 lay
East of England – Welwyn	9	4	5	3 expert, 4 lay
London – Camberwell St Giles	13	4	9	2 expert, 4 lay

Please note that the high number of resignations for Welwyn REC was as a result of the restructuring of Independent Ethics Committees in January 2012 with several members taking the opportunity to end their membership at that time.

Quorum:

For meetings at which research ethical review is undertaken, a quorum shall consist of seven members. Out of 86 scheduled meetings, none had to be cancelled 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 8 committees covered by this summary, Hertfordshire and Welwyn RECs did not meet the requirements in terms of numbers of meetings held, both meeting 9 times. Hertfordshire met only 9 times due to low workload and Welwyn did not meet from January to March 2012 due to restructuring.

Summary of activity for all RECs administered from the East of England Centre 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	SSB	Total	SSA	PR
East of England - Cambridge Central	4	6	2	59	0	0	1	71	17	24
East of England – Cambridge East	1	3	3	54	0	0	0	61	6	-
East of England – Cambridge South	3	3	7	50	0	1	0	64	6	16
East of England - Essex	1	1	3	47	0	0	1	52	1	14
East of England - Hertfordshire	1	6	4	41	0	0	1	52	10	19
East of England - Norfolk	1	7	2	40	0	0	0	50	2	19
East of England – Welwyn	2	2	0	14	0	1	0	19	15	-
London – Camberwell St Giles	2	4	2	44	0	0	0	52	11	-

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
NRR	Not Requiring Review by NHS REC
SSB	Number of studies sent back to full committee meeting for final opinion
SSA	Site Specific Assessment reviewed for non-NHS sites
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

421 studies were reviewed by full Committee of which 94.5% were given an opinion within the appropriate timescale. 92 studies were reviewed by Proportionate Review Sub-Committees of which 65.2% 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. 68 SSAs reviewed, 88.2% were given a final opinion within the appropriate timescale. Of the 703 Substantial Amendments reviewed, 97.3% 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
East of England – Cambridge Central	0	1	1	0
East of England – Cambridge East	2	0	1	-
East of England – Cambridge South	2	0	1	0
East of England - Cambridge Essex	7	1	8	0
East of England - Hertfordshire	4	0	0	0
East of England - Norfolk	2	0	2	0
East of England – Welwyn	3	0	1	0
London – Camberwell St Giles	3	6	5	-

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.

No audits were conducted in the reporting period due to a series of closures/mergers which took place as part of an options appraisal; this resulted in a restructuring of the East of England RECs with effect from 1 April 2011. The programme of audits was resumed in April 2012 with all of the RECs administered from the Centre scheduled for audit between June 2012 and June 2013.

Appeals received between April 2011 and March 2012

3 appeals were received for RECs administered from the East of England Centre; 1 of these was not allowed. Of the 2 which were allowed, the appeal RECs gave favourable opinions following the provision of further information by the applicants and 1 of these also had additional conditions attached.

Complaints received between April 2011 and March 2012

No complaints were received for RECs administered from the East of England Centre.

Conclusion and Acknowledgements

The Research Ethics Committees managed from the East of England REC Centre 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 has achieved a good level of performance and the work of the local management and staff is acknowledged

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 service 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.

Ann Tunley, Regional Manager, North
29 August 2012