

National Research Ethics
Service


Health Research Authority

North East (Jarrow) REC Centre Annual Report Summary

01 April 2011 – 31 March 2012

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

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|------------------------|---|
| 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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| Contact | Centre Manager – Leigh Pollard, leigh.pollard@nhs.net North East - County Durham & Tees Valley REC – Hayley Jeffries – Co-ordinator, hayley.jeffries@nhs.net North East - Newcastle & North Tyneside 1 REC – Laura Kirkbride – Co-ordinator, laura.kirkbride@sotw.nhs.uk North East - Newcastle & North Tyneside 2 REC – Gillian Mayer – Co-ordinator, gillian.mayer@sotw.nhs.uk North East - Northern & Yorkshire REC – Hayley Jeffries – Co-ordinator, hayley.jeffries@nhs.net North East - Sunderland REC – Helen Wilson – Co-ordinator, helen.wilson@sotw.nhs.uk South Central - Oxford C REC – Laura Kirkbride – Co-ordinator, laura.kirkbride@sotw.nhs.uk |

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 provides high quality administrative support to the RECs managed from the centre. All RECs and the REC centre itself have achieved full accreditation during the reporting period; this was the first centre to attain this achievement.

The pilot for the proportionate review process for the review of studies where the applicant considers their research to present no material ethical issues had been introduced into this Centre last year and the 5 North East RECs continued to participate in the pilot until the service was rolled out nationally.

This Centre will be taking part in the Ethics Officer pilot.

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

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

- North East - County Durham & Tees Valley (CDTV)
- North East - Newcastle & North Tyneside 1 (NNT1)
- North East - Newcastle & North Tyneside 2 (NNT2)
- North East - Northern & Yorkshire (N&Y)
- North East - Sunderland
- South Central - Oxford C

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 |
|---------------------------------|---------------------|---------------|------------|--|
| North East - CDTV | 15 | 9 | 6 | 2 expert |
| North East - NNT1 | 16 | 9 | 7 | 2 lay |
| North East - NNT2 | 15 +1 deputy | 9 +1 | 6 | none |
| North East - N & Y | 12 | 8 | 4 | 2 expert |
| North East - Sunderland | 15 | 9 | 6 | 2 expert, 2 lay |
| South Central - Oxford C | 14 | 10 | 4 | 2 lay |

Quorum:

For meetings at which ethical review is undertaken, a quorum shall consist of seven members. Out of 66 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 6 committees covered by this summary, only County Durham and Tees Valley REC did not meet the requirements in terms of numbers of meetings held, meeting 8 times only due to low workload.

Summary of activity for all RECs administered from the North East 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 | POPC | SSB | Total | SSA | PR |
|--------------------------------|------|------|-----|----|---------|------|-----|-------|-----|----|
| North East -CDTV | 0 | 1 | 1 | 32 | 0 | 0 | 1 | 34 | 1 | 28 |
| North East -NNT1 | 1 | 6 | 2 | 37 | 0 | 0 | 0 | 46 | 1 | 33 |
| North East -NNT2 | 1 | 16 | 6 | 22 | 0 | 0 | 0 | 45 | 0 | 37 |
| North East - N & Y | 2 | 11 | 5 | 28 | 0 | 0 | 0 | 46 | 9 | 21 |
| North East - Sunderland | 10 | 4 | 5 | 40 | 0 | 0 | 0 | 59 | 0 | 35 |
| South Central - Oxford C | 7 | 5 | 1 | 63 | 0 | 1 | 0 | 77 | 2 | 0 |

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 |
| SSA | Site Specific Assessments 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

307 studies were reviewed by full Committee of which 100% were given an opinion within the appropriate timescale. 154 studies were reviewed by Proportionate Review Sub-Committees of which 93.5% 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. 13 SSAs reviewed, 100% were given a final opinion within the appropriate timescale. Of the 433 Substantial Amendments reviewed, 97.2% 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 |
|--------------------------|--|-----------------------------|---|--|
| North East - CDTV | 0 | 0 | 0 | 0 |
| North East - NNT1 | 0 | 0 | 3 | 0 |
| North East - NNT2 | 0 | 0 | 1 | 0 |
| North East - N & Y | 0 | 0 | 4 | 0 |
| North East - Sunderland | 0 | 0 | 3 | 0 |
| South Central - Oxford C | 0 | 0 | 1 | 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. All RECs in the Centre were audited during the reporting period.

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

RECs Achieving Full Accreditation at first review

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|--------------------------------|
| REC |
| Newcastle and North Tyneside 1 |
| Oxford C |
| County Durham & Tees Valley |
| Newcastle & North Tyneside 2 |

RECs who have received full accreditation having completed an action plan

| |
|----------------------|
| REC |
| Northern & Yorkshire |
| Sunderland |

The North East REC Centre achieved full accreditation for the REC Centre management and administrative activities following the completion of an action plan.

Appeals received between April 2011 and March 2012

No appeals were received for RECs administered from the North East Centre

Complaints received between April 2011 and March 2012

2 complaints were received for REC administered from the North East Centre; 1 was not upheld and the other has been actioned and closed.

Conclusion and Acknowledgements

The Research Ethics Committees managed from the North East 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 an exceptional 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**