

Yorkshire & the Humber REC Centre Annual Report (Summary) April 2011 to March 2012

Purpose	To present annual reports from the Yorkshire & the Humber Research Ethics Committees. The reports cover the activity between April 2011 and March 2012.
Recommendations	That the annual reports be received and noted
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INTRODUCTION:

NRES is one of the divisions of the Health Research Authority 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.

Establishment of Health Research Authority and transfer of Appointing Authority functions

The Government announced in the Plan for Growth the intention to establish a Health Research Authority (HRA), initially as a Special Health Authority with NRES at its core. The HRA was established on 1 December 2011, the NRES transferred to it and the HRA took on all ethics functions including the Appointing Authority functions from

SHAs. There was a phased transfer of staff to the HRA, NPSA NRES staff transferred in on 1 December 2011 with the remaining hosted staff transferring during 2012, transfers are expected to be completed by September 2012. Contracts transferred from SHAs to the HRA during 2011/12.

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

Proportionate review was introduced into the Centre from January 2012 with 6 RECs taking part: Humber Bridge, Leeds Central, Leeds East, Leeds West, Sheffield and South Yorkshire RECs.

Leigh Pollard became Centre Manager for the Yorkshire & the Humber and the North East REC Centres.

Annual Reports:

As the appointing authority, the Health Research Authority is responsible for the establishment, appointment, support and training of Research Ethics Committees within its boundary. The Health Research Authority also takes full legal liability for the actions of those members in the course and performance of their duties.

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

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

- Bradford REC
- Humber Bridge REC
- Leeds Central REC
- Leeds East REC
- Leeds West REC
- Sheffield REC
- South Yorkshire

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 5.3

REC	Total Number	Expert	Lay	Resigned in period of annual report
Bradford	11	10	1	3 expert, 2 lay
Humber Bridge	11	7	4	2 expert, 1 lay
Leeds Central	10	7	3	1 expert
Leeds East	13	9	4	1 expert, 1 lay
Leeds West	13	9	4	1 expert, 1 lay
Sheffield	17	12	5	1 lay
South Yorkshire	13	9	4	2 expert, 1 lay

Quorum:

For meetings at which ethical review is undertaken, a quorum shall consist of seven members. Out of 77 scheduled meetings, 3 had to be cancelled due to quoracy issues.

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 7 committees covered by this summary, only Leeds Central REC did not meet the requirements in terms of numbers of meetings held, meeting 8 times with 2 meetings cancelled due to low workload and 1 due to quoracy issues.

Summary of activity for all Yorkshire & the Humber 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	POPC	NRR	Total	SSB	SSI	PR
Bradford	2	15	4	28	0	0	0	49	0	3	n/a
Humber Bridge	2	11	5	32	0	0	0	50	0	3	6
Leeds Central	3	13	5	21	0	0	0	42	0	1	6
Leeds East	3	11	0	46	0	0	0	60	0	0	2
Leeds West	6	9	4	51	0	0	0	70	1	31	5
Sheffield	1	7	6	60	0	0	0	74	1	18	4
South Yorkshire	8	18	4	32	0	0	0	62	0	3	4

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
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 days, with Site Specific Assessments (SSAs) being carried out within 25 days, Substantial Amendments within 35 days and Section 30 Applications within 60 days. There were 407 studies reviewed by full Committee across the region of which 99.0% were given an opinion within the appropriate timescale. There were 27 studies reviewed by Proportionate Review Sub-Committees of which 70.4% 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 the 59 SSAs reviewed, 98.3% were given a final opinion within the appropriate timescale. Of the 550 Substantial Amendments reviewed, 96.2% 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
Bradford	1	0	2	0
Humber Bridge	0	0	1	0
Leeds Central	2	1	2	0
Leeds East	0	0	8	0
Leeds West	0	0	3	0
Sheffield	1	0	1	0
South Yorkshire	0	0	4	0

Accreditation of Research Ethics Committees

Through our accreditation scheme, our Quality Assurance (QA) team aims to ensure that Research Ethics Committees (RECs) are operating according to guidance set down by the Department of Health.

QA check that they are interpreting procedures and standards correctly in order to maintain a consistent ethical review process across the UK.

RECs Achieving Full Accreditation at first review

REC
Humber Bridge

RECs who have received full accreditation having completed an action plan

REC
Leeds West
Sheffield
Leeds East

RECs awaiting audit during 2012/13

REC
Leeds Central
South Yorkshire
Bradford

Appeals received April 2011 to March 2012

No appeals were received for Yorkshire & the Humber RECs

Complaints received April 2011 to March 2012

3 complaints were received for the Yorkshire & the Humber RECs; 2 were upheld and 1 was partly upheld.

Conclusion and Acknowledgements

The Research Ethics Committees managed from the Yorkshire & the Humber 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 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.

Ann Tunley, Regional Manager, North
23 August 2012

Appendix A

% opinion rates for each REC

REC	FOSC %	FOAC %	UFO %	PO %	Invalid	POPC	NRR	Total	SSB	SSI	PR
Bradford	4.1	30.6	8.2	57.1	0	0	0	49	0	3	n/a
Humber Bridge	4.0	22.0	10.0	64.0	0	0	0	50	0	3	6
Leeds Central	7.1	31.0	11.9	50.0	0	0	0	42	0	1	6
Leeds East	5.0	18.3	0.0	76.7	0	0	0	60	0	0	2
Leeds West	8.6	12.9	5.7	72.9	0	0	0	70	1	31	5
Sheffield	1.4	9.5	8.1	81.1	0	0	0	74	1	18	4
South Yorkshire	12.9	29.0	6.5	51.6	0	0	0	62	0	3	4

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