

<p>Yorkshire and the Humber Strategic Health Authority</p> <p>BOARD MEETING</p>	 <p>Yorkshire and the Humber</p>
<p>Date: 3 November 2009</p>	<p>Report Author: Professor Sue Proctor, Director of Patient Care and Partnerships</p>
<p>Title of paper: Local Research Ethics Committees – Summary of Annual Reports 2008-9</p>	
<p>Actions Requested:</p> <ol style="list-style-type: none"> 1) To note the summary report of the Local research Ethics Committees and 2) To formally accept the full Annual Reports of the Local Research Ethics Committees (previously circulated and available on the SHA website) 	
<p>Governance Requirements</p>	
<p>SHA Objectives supported by this paper:</p> <p>Objective 1 : Ensure the three elements of quality, patient safety, patient experience and effectiveness of service are routinely measured and adopted across NHS regions;</p> <p>Objective 13: Ensure the integrity and development of systems which safeguard the wellbeing of the public throughout the NHS and in collaboration with other relevant agencies.</p>	
<p>Risk Management:</p>	
<p>Board Assurances:</p> <ul style="list-style-type: none"> • The attached paper and the full Annual Reports of the LRECs (previously circulated), provide assurance to the Board that the LRECs are being managed according to the Governance Arrangements for Research Ethics Committees (GAfREC), the national standards for LRECs. Any variation from these standards will be reported to the Board as necessary. 	
<ul style="list-style-type: none"> • Risk Assessment: The SHA appoints and indemnifies the volunteer members of the Research Ethics Committees and shares any risk arising from this activity with the National Research Ethics Service (NRES), which is part of the National Patient Safety Agency. No significant risks to the SHA have been identified in this arrangement. 	
<p>Legal Implications:</p> <p>There are no significant legal implications for the SHA in the publication of the overarching report or the LREC specific annual reports</p>	
<p>Equality and Diversity:</p> <p>Any patient in any location may be asked to become part of a research project – sometimes involving experimental systems. A rigorous system of Local research Ethics Committees ensures that only quality ethical research is conducted within the NHS, so safeguarding all patients including the most vulnerable.</p>	

Yorkshire and the Humber Strategic Health Authority

3 November 2009

Local Research Ethics Committees – Summary of Annual Reports 2008-9

Purpose

To advise the Strategic Health Authority (SHA) of the activity of the Local Research Ethics Committees (LRECs) in Yorkshire and the Humber between 1 April 2008 and 31 March 2009.

Introduction

Local Research Committees have been set up across the country to consider applications to conduct health related research, both in the NHS and in private industry, involving patients, the public and their data. Their role is specifically to look at the ethics of the research proposal and provide independent, competent and a timely review of the ethics of the study. The aim is to ensure that patients and the public are protected from unethical and poor research and that best research practice is used at all times.

The SHA is responsible for the establishment, appointment, support and training of the LRECs within its boundary. The SHA indemnifies the members of the LRECs for their actions as committee members except when those involve bad faith, wilful default or gross negligence.

LRECs are supported managerially by the National Research Ethics Service (NRES) which is part of the National Patient Safety agency (NPSA).

All members of the LRECs are volunteers. The majority are “expert” members – either as clinicians or with specialist qualifications in research or statistics, but a minimum of one third should be lay members.

Annual Reports

The LRECs are required to submit Annual Reports to the Appointing Authority for approval and publication every year.

Attached is an overarching report provided by the Acting Senior Research Ethics Service Manager for Yorkshire and the Humber which pulls together key information provided in the individual Annual Reports from the Local Research Ethics Committees across the region.

The annual reports of the nine committees have been circulated independently under cover of a letter from the Director of Patient Care and Partnerships. These have also been made available on the SHA’s website.

The nine committees currently operating in Yorkshire and the Humber are : Bradford; Hull and East Yorkshire; Leeds Central; Leeds east; Leeds West; Sheffield; South Humber; South Yorkshire; York. These currently operate from six sites across the region.

There have been no closures of LRECs in this region during the financial year to 31 March 2009.

The National Research Ethics Service (NRES) which provides support for the LRECs has introduced a programme of audit for all committees. These audits look at the quality of the work of the co-ordinators and also includes committee observations so that the quality of the decision making of the committee can be assessed.

Recommendation

- The Board is asked to formally receive the Annual Reports of the Local Research Ethics Committees

Professor Sue Proctor
Director of Patient Care and Partnerships
3 November 2009

Yorkshire and the Humber Annual Report (Summary)
April 2008 to March 2009

PURPOSE	To present annual reports from the Research Ethics Committees to Yorkshire and the Humber Strategic Health Authority. Yorkshire and the Humber Strategic Health Authority being the appointing authority for the Research Ethics Committees. The reports cover the activity for the period April 2008 to March 2009.
Recommendations	That the annual reports be received and noted
Presenter	Ann Tunley, Acting Senior Research Ethics Service Manager, Yorkshire and the Humber, ann.tunley@leedsth.nhs.uk
Contact	<p>Bradford REC – Susan Jude – Susan.Jude@bradfordhospitals.nhs.uk</p> <p>Hull and East Riding REC – Louise Hunn – Louise.Hunn@humber.nhs.uk</p> <p>Leeds (Central) REC – Rachel Bell - rachelt.bell@leedsth.nhs.uk</p> <p>Leeds East REC – Ann Tunley (as above)</p> <p>Leeds (West) REC – Elaine Hazell – Elaine.hazell@leedsth.nhs.uk</p> <p>Sheffield REC – Sue Rose – sue.rose@sth.nhs.uk</p> <p>South Humber REC – Karen Waltham – Karen.Waltham@humber.nhs.uk</p> <p>South Yorkshire REC – Joan Brown - joan.brown@sth.nhs.uk</p> <p>York REC – Joanne Holmes – joanne.holmes@york.nhs.uk</p>

Introduction:

The National Research Ethics Service is one of the divisions of the National Patient Safety Agency 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.

Annual Reports:

As the appointing authority, the Strategic Health Authority is responsible for the establishment, appointment, support and training of the Research Ethics Committees within its boundary. The Strategic Health 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 – DH 2001) requires annual reports include the following minimum information:

- The names, affiliations and occupations of committee members and deputies
- Number and dates of meetings held
- Attendance of members
- A list of proposals considered and the decisions reached on each
- The time taken from acceptance of application to final decision on each proposal
- A list of projects completed or terminated during the year
- The training undertaken by the committee and by its members

Nine Committees have submitted reports for the year 1 April 2008 to 31 March 2009:

- Bradford REC
- Hull and East Riding REC
- Leeds (Central) REC
- Leeds (East) REC
- Leeds (West) REC
- Sheffield REC
- South Humber REC
- South Yorkshire REC
- York REC

Update on structural change since 2007/2008 Summary of Annual Reports:

In October 2008 NRES published the first research summaries on the NRES website which the public and researchers can access.

In January 2009 NRES launched the Integrated Research Application System (IRAS). IRAS is a single system for applying for the permissions and approvals for health and social care/community research in the UK. NRES is an IRAS partner and delivers IRAS for the partnership.

Membership as at 31 March 2009:

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	15	11	4	1 expert
Hull & East Riding	16	10	6	1 lay, 4 expert
Leeds (Central)	13	9	4	2 expert
Leeds (East)	17	11	6	1 expert
Leeds (West)	16	10	6	1 expert
Sheffield	17 + 3 deputy members	11 + 3 deputies	6	1 lay, 1 expert
South Humber	14	9	5	6 expert, 1 lay
South Yorkshire	17	12	5	3 expert, 1 lay
York	13	10	3	2 expert, 2 lay

Quorum

For meetings at which research ethical review is undertaken, a quorum shall consist of seven members. Out of 95 scheduled meetings, none had to be cancelled due to being in quorate.

Research Ethics Committees – Ex-Member Bank

The amendments to the UK Clinical Trials Regulations (1 May 2008) allowed for the creation of an ex member bank. Members resigning from, or reaching the end of their tenure with, a Research Ethics Committee, may upon recommendation of the Chair be appointed to serve on the Ex member bank. Consideration is given to a member's attendance and training record and to their contribution to the ethical debate at meetings.

- Bank members appointed to the Yorkshire and the Humber Research Ethics Committees may serve on any committee appointed by the Yorkshire and the Humber Strategic Health Authority.
- Bank members are appointed for a period of two years and this term is renewable for a further two years.
- Bank members are required to attend two REC meetings in each year, but should not attend more than six meetings of any one committee in a twelve month period.
- Bank members are expected to take part in either one REC training session or provide evidence of keeping up to date with ethical issues as detailed in the NRES guidance on self directed learning.

Research Ethics Committees' meetings

- In order 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 9 committees covered by this summary, 7 met the requirements in terms of numbers of meetings held. Bradford and York RECs held 9 meetings during the reporting period. Bradford REC cancelled a scheduled meeting as only one study was booked for review; this was transferred to another REC to avoid any inconvenience to the researchers. York REC held a training meeting in October 2008 and the months when scheduled meetings were not held in 2008 and 2009 unusually both fell within the reporting period.

Summary of activity for all RECs that were operating within the Yorkshire and the Humber SHA during 2008/9

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	NRR	Total	SSB	SSI
Bradford	13	3	2	32	1	0	7	58	0	62
Hull & East Riding	15	10	4	22	0	0	5	56	2	88
Leeds Central	8	0	7	54	0	0	0	69	1	21
Leeds East	11	1	4	53	0	2	0	71	3	110
Leeds West	5	0	16	58	0	0	1	80	0	61
Sheffield	9	11	3	50	0	0	0	73	0	207
South Humber	5	11	10	19	0	0	5	50	0	45
South Yorkshire	5	18	3	31	0	0	1	58	0	58
York	9	0	0	35	0	0	4	48	0	90

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
SSI	Site Specific Assessment reviewed

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 562 studies reviewed across the region of which 99.8% were given an opinion within the appropriate timescale. Of the 742 SSAs reviewed, 98% were given a final opinion within the appropriate timescale, of the 407 Substantial Amendments reviewed 96.3% were given a final opinion within the appropriate timescale, of the 29 Section 30 Applications reviewed, 100% were given a final opinion within the appropriate timescale.

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	0	0	0	0
Hull and East Riding	0	0	0	0
Leeds (Central)	0	0	1	0
Leeds (East)	0	8	2	0
Leeds (West)	1	6	10	0
Sheffield	0	1	2	0
South Humber	0	0	0	0
South Yorkshire	0	0	0	0
York	0	3	0	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

REC
Sheffield

RECs Achieving Preliminary Accreditation

REC
None

RECs who have received full accreditation having completed an action plan

REC
Leeds (East)
Leeds (West)

Action plans outstanding

REC
None

Failure to address audit findings

REC
none

RECs awaiting audit (all scheduled for 2009/10)

REC
Bradford
Hull and East Riding
Leeds (Central)
South Humber
South Yorkshire
York

Appeals April 2008 to March 2009

Yorkshire and the Humber RECs received 1 appeal

Complaints April 2008 to March 2009

Yorkshire and the Humber RECs received 1 complaint

Conclusion

The Research Ethics Committees across the Yorkshire and the Humber Strategic Health Authority continued to provide valuable independent advice to researchers, sponsors and employers whilst protecting the dignity rights, safety and wellbeing of actual and potential participants.

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.

Further consolidation, both in the number of committees and the location of the support to those committees, is continuing; this is to ensure that standards are improved in line with the NRES guidance.