



Health Research Authority

National Research Ethics
Service

NRES Committee Yorkshire & The Humber - South Yorkshire

Annual Report

01 April 2011 – 31 March 2012

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee Yorkshire & The Humber - South Yorkshire
Type of REC:	Authorised
Type of Flag:	Paediatric
Chair:	Ms Jo Abbott
Vice-Chair:	Mr Neil Marsden
Alternate Vice-Chair:	Ms Susan Hampshaw
Co-ordinator:	Ms Sinead Audsley
PRSC Co-ordinator:	Ms Sinead Audsley
Assistant Co-ordinator:	Mr Craig Appleby
Committee Address:	Millside Mill Pond Lane Meanwood Leeds LS6 4RA
Telephone:	0113 30 50128
Fax:	0113 85 56191
Email:	sinead.audsley@nhs.net

Chair's overview of the past year:

Another year has passed and there have been a lot of changes within the NHS including the formation of the Health Research Authority.

South Yorkshire Ethics Committee continues to review a variety of studies at their lively monthly meetings. Proportionate review commenced in January 2012 and so studies are now reviewed between meetings as well. The dedication of the committee never ceases to amaze me as all the ethics work is carried out on top of people's jobs and daily lives. I'd like to thank them all for all their hard work. I'd also like to thank the administrative staff based in Leeds who keep us on track with time lines, training, new guidance etc.

Finally I'd like to thank the researchers who put in such time and effort, often against tight deadlines and funding streams, but are dedicated to the quest of improving patient care.

NRES Committee Yorkshire & The Humber - South Yorkshire Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Ms Jo Abbott	Consultant in Public Health (Chair)	Expert	26/01/2007	
Dr A H Abdelhafiz	Consultant Physician, Elderly Medicine	Expert	07/03/2007	
Miss Stephanie Andrews	Drug & Alcohol Action Team Information Manager	Lay	04/12/2009	16/08/2011
Reverend Joan Ashton	Co-ordinator of Chaplaincy Services	Lay Plus	30/01/2007	
Ms Helen Barlow	Knowledge Service Manager	Lay Plus	30/01/2007	
Professor Nigel Beail	Consultant Clinical Psychologist & Professor of Psychology	Expert	30/01/2007	
Mr Ian Cawthorne	Chief Pharmacist	Expert	30/01/2007	
Ms Susan Hampshaw	Head of Research, Evaluation and Innovation	Lay	07/03/2007	
Mr Neil Marsden	Police Staff (Vice Chair)	Lay Plus	30/01/2007	
Dr Anton Mayer	Consultant in Paediatric Intensive Care	Expert	01/05/2008	
Mrs Andrea Porritt	Community Specialist Practitioner	Expert	01/04/2008	
Dr Ganesh Rao	Consultant Clinical Neurophysiologist	Expert	01/04/2008	05/07/2011
Mr Jaydip Ray	Consultant ENT Surgeon	Expert	01/05/2008	
Ms Stephanie Rhodes	Neonatal Sister	Expert	01/04/2008	
Dr Paul Spencer	Consultant Radiologist	Expert	07/03/2007	
Dr Jonathan Train	Consultant Anaesthetist	Expert	07/03/2007	24/05/2011

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended
Mrs Carole Taylor	Rotherham Hospital NHS Foundation Trust	Expert	28/01/2011, 26/05/2011, 30/06/2011, 25/08/2011, 29/09/2011, 26/01/2012

NRES Committee Yorkshire & The Humber - South Yorkshire: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Ms Jo Abbott	Member South Yorkshire CLARHC and CLRN Board. Member of CLARHC Inequalities Sub Group. Member of steering committee for project entitled 'Warm House, Warm Families'. R&D lead for NHS Rotherham	26/01/2012
Reverend Joan Ashton	None	12/01/2012
Ms Helen Barlow	Involved with local R&D management committee as Knowledge Service Manager. Provides support to researchers in literature reviewing, writing research proposals etc.	26/01/2012
Professor Nigel Beail	Trustee/Director of British Institute for Learning Disabilities. Occasional ad hoc peer reviews conducted for various funding bodies.	20/01/2012
Mr Ian Cawthorne	Holds shares in Associated Chemist Ltd, Sheffield. Member of local research committee.	12/01/2012
Dr A H Abdelhafiz	None	26/01/2012
Ms Susan Hampshaw	None	27/01/2012
Mr Neil Marsden	NIHR peer reviewer	26/01/2012
Dr Anton Mayer	None	16/01/2012
Mrs Andrea Porritt	None	22/02/2012
Mr Jaydip Ray	ENT Chair for South Yorkshire Comprehensive Local Research Network (CLRN). Research lead for ENT at Sheffield Teaching Hospitals NHS Foundation Trust. Member of R&D at Sheffield Teaching Hospitals.	10/01/2012
Ms Stephanie Rhodes	None	19/02/2012
Dr Paul Spencer	None	15/01/2012

Meetings for Full Ethical Review 01 April 2011 - 31 March 2012:

Month	Date	Number of Members Present at Meeting
April	28/04/2011	12
May	26/05/2011	9
June	30/06/2011	11
July	28/07/2011	10
August	25/08/2011	8
September	29/09/2011	9
October	27/10/2011	8
January	26/01/2012	9
February	23/02/2012	11
March	29/03/2012	9

10 full committee meetings were held during the reporting period.

Proportionate Review Sub Committee Meetings held during 01 April 2011 - 31 March 2012:

Month	Date	Number of Members Present at Meeting
February	17/02/2012	3
March	23/03/2012	3

2 proportionate review sub-committee meetings were held during the reporting period.

Attendance of Members: 01 April 2011 – 31 March 2012:

Name	Number of Meetings Attended
Ms Jo Abbott	9
Professor Nigel Beail	8
Reverend Joan Ashton	8
Mrs Andrea Porritt	8
Ms Helen Barlow	8
Dr A H Abdelhafiz	7
Dr Paul Spencer	7
Ms Stephanie Rhodes	7
Ms Susan Hampshaw	7
Mr Neil Marsden	6
Dr Anton Mayer	6
Mr Jaydip Ray	5
Miss Stephanie Andrews	5
Mr Ian Cawthorne	3
Dr Ganesh Rao	2

Number of inquorate meetings held: None

**Attendance of Members at proportionate review sub-committee meetings:
01 April 2011 – 31 March 2012:**

Name	Number of Meetings Attended
Dr Anton Mayer	1
Dr Paul Spencer	1
Mr Jaydip Ray	1
Mr Neil Marsden	1
Ms Jo Abbott	1
Reverend Joan Ashton	1

Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Ms Jo Abbott	20/04/2011 - 20/04/2011	Chair's meeting
Reverend Joan Ashton	25/05/2011 - 25/05/2011	Equality & Diversity
Miss Stephanie Andrews	29/06/2011 - 29/06/2011	Equality & Diversity
Ms Jo Abbott	30/09/2011 - 30/09/2011	Equality & Diversity
Ms Jo Abbott	28/04/2011 - 28/04/2011	Single Issue Debate
Ms Susan Hampshaw	28/04/2011 - 28/04/2011	Single Issue Debate
Dr A H Abdelhafiz	28/04/2011 - 28/04/2011	Single Issue Debate
Reverend Joan Ashton	28/04/2011 - 28/04/2011	Single Issue Debate
Ms Helen Barlow	28/04/2011 - 28/04/2011	Single Issue Debate
Professor Nigel Beail	28/04/2011 - 28/04/2011	Single Issue Debate
Mr Jaydip Ray	28/04/2011 - 28/04/2011	Single Issue Debate
Dr Anton Mayer	28/04/2011 - 28/04/2011	Single Issue Debate
Mrs Andrea Porritt	28/04/2011 - 28/04/2011	Single Issue Debate
Dr Paul Spencer	28/04/2011 - 28/04/2011	Single Issue Debate
Ms Jo Abbott	27/10/2011 - 27/10/2011	MCA Training DVD
Reverend Joan Ashton	27/10/2011 - 27/10/2011	MCA training DVD
Professor Nigel Beail	27/10/2011 - 27/10/2011	MCA training DVD
Mr Ian Cawthorne	27/10/2011 - 27/10/2011	MCA training DVD
Dr Paul Spencer	27/10/2011 - 27/10/2011	MCA training DVD
Mrs Andrea Porritt	27/10/2011 - 27/10/2011	MCA training DVD
Ms Stephanie Rhodes	27/10/2011 - 27/10/2011	MCA training DVD
Dr Anton Mayer	27/10/2011 - 27/10/2011	MCA training DVD
Professor Nigel Beail	28/03/2012 - 28/03/2012	National Members Training Day
Dr A H Abdelhafiz	28/03/2012 - 28/03/2012	National Members Training Day
Ms Jo Abbott	28/03/2012 - 28/03/2012	National Members Training Day
Ms Susan Hampshaw	28/03/2012 - 28/03/2012	National Members Training Day
Ms Helen Barlow	02/02/2012 - 02/02/2012	Human Tissue Act
Ms Stephanie Rhodes	28/03/2012 - 28/03/2012	National Members Training Day
Mr Neil Marsden	28/03/2012 - 28/03/2012	National Members Training Day

Part 2: REC workload and activity during the reporting period.

Table 1: Applications assigned to a full committee meeting held within the reporting period:

Applications for full ethical review – Study Type	Number	%
Clinical Trial of Investigational Medicinal Product	0	0.00
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	62	100.00
Total Applications Reviewed	62	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	1
Number of studies withdrawn prior to the meeting	4
Number of student applications reviewed	30
Number of paediatric applications reviewed	5
Number of device applications reviewed	1
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	0
Number of applications reviewed funded by the US DHHS	0

Table 3: Decisions given at meetings held within the reporting period:

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	8	12.90
Favourable Opinion with Additional Conditions	18	29.03
Unfavourable Opinion	4	6.45
Provisional Opinion	32	51.61
Invalid	0	0.00
No Opinion Pending Consultation with Referee	0	0.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Not Requiring Review by NHS REC	0	0.00
Total	62	100
Number of studies sent back to full committee meeting for final opinion	0	

Table 4: Summary of current status of applications reviewed during the reporting period:

Status of applications at date of generation of report	Number	%
Further Information Favourable Opinion with Standard Conditions	27	43.55
Further Information Favourable Opinion with Additional Conditions	4	6.45
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	8	12.90
Favourable Opinion with Additional Conditions	18	29.03
Unfavourable Opinion	4	6.45
Provisional Opinion	1	1.61
Provisional Opinion Pending Consultation with Referee	0	0.00
Invalid	0	0.00
No Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	0	0.00
Not Requiring Review by NHS REC	0	0.00
No decision entered on RED	0	0.00
Number of studies withdrawn after the meeting	0	0.00
Total	62	100

Table 5: Applications assigned to a proportionate review sub-committee within the reporting period:

Total Applications Reviewed	4
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Table 6: Decisions given at proportionate review sub-committee meetings held within the reporting period:

Decisions taken at proportionate review sub-committee meetings	Number	%
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	1	25.00
No Opinion transfer to full committee for review	1	25.00
Provisional Opinion	2	50.00
Unfavourable Opinion	0	0.00
Total	4	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	6.20
Number of applications for full ethical review over 60 days	0
Number of applications over 60 days as a % of total	0.00%
Number of days taken to final decision - average	29
Number of days taken to final decision - mode	31
Number of SSAs (non-Phase 1) reviewed	3
Number of applications for SSA review over 25 days	0
Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)	0.0%
Number of SSAs (Phase 1) reviewed	0
Number of applications for SSA review over 14 days	0
Number of applications for SSA review over 14 days as % of all Phase 1 (SSAs)	0%
Number of substantial amendments reviewed	60
Number of substantial amendments over 35 days	4
Number of substantial amendments over 35 days as a % of total substantial amendments	6.7%
Number of Section 30 applications reviewed	0
Number of Section 30 applications over 60 days	0
Number of Section 30 applications over 60 days as a % of total Section 30 applications	0%
Number of modified amendments reviewed	0
Number of modified amendments over 14 days	0
Number of modified amendments over 14 days as a % of total modified amendments	0%
Number of proportionate review applications for ethical review over 14 days*	3
Number of proportionate review applications over 14 days as a % of total	100.00%

***NB – Proportionate Review Service was in pilot phase until September 2011 and was an aim not a target**

Table 8: Breakdown of current status of all applications reviewed within the reporting period:

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/YH/0100	Is NWP more effective than normal walking in IC patients?	24
11/YH/0101	SABRE - Hypertonic Saline in Acute Bronchiolitis RCT	48
11/YH/0107	Assessing walking capacity in claudicants	33
11/YH/0108	Cartilage Tribology	40
11/YH/0123	Endothelial function in mild obstructive sleep apnoea	25
11/YH/0152	Quality of Life following Percutaneous Endoscopic Gastrostomy(PEG)	26
11/YH/0170	Impact of Physiotherapy on sexual function in women with SUI	32
11/YH/0230	Prevalence of illness behaviour in vestibular disorders	31
11/YH/0233	Human Liver Reengineering using Decellularised Donor Liver Matrix	32
11/YH/0236	Exposure and the reduction of fear of pain	33
11/YH/0239	Persistence, adherence, QoL, and treatment satisfaction Avonex® PEN	33
11/YH/0275	ADEPT WP4 Understanding the adverse effects of psychological therapies	29
11/YH/0300	GLP-2 and bone turnover in obesity	30
11/YH/0302	The stabilisation of preterm infants: investigation of practice V5	28
11/YH/0329	The Experiences of Gay Men Developing Non-Monogamous Relationships	34
11/YH/0330	MRI analysis of bone and bone marrow in children	28
11/YH/0334	Overcoming Barriers to Mainstreaming Assisted Living Technologies	28
11/YH/0356	Regulation of airway inflammation	32
11/YH/0361	Pregnancy intendedness: The potential impact of contraceptive provision	39
11/YH/0364	Microfluidic analysis of rectal cancer response to neoadjuvant therapy	38
11/YH/0371	Electronic reporting scheme in renal services	34
11/YH/0459	Pattern Glare Test in school children	44
12/YH/0032	A comparison of two colonoscopic withdrawal techniques	24
12/YH/0035	Autonomic Neuropathy and Hypoglycaemia v1.0	28
12/YH/0045	Determining the roles of neutrophil-derived IL-1 in human inflammation	21
12/YH/0080	Hypoglycaemia related sudden cardiac death in type 2 diabetes v.1	25
12/YH/0101	Lifestyle Matters	30
12/YH/0112	Effect of Head and Gaze Position on Soft Toric Lens Performance - v1	15

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock

11/YH/0158	Behavioural Activation in Depressed Adolescents - A Feasibility Study	35
11/YH/0362	Common Variable Immune Deficiency: understanding molecular mechanisms	41
12/YH/0019	Putting Life In Years (PLINY): Telephone friendship groups	36
12/YH/0164	Knowledge and awareness of long-acting reversible contraceptives.Ver.1	26

Further Information Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
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Favourable Opinion with Standard Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/YH/0171	Understanding treatment experiences of service users (V.1)	26
11/YH/0237	EORTC Oral Health Module - Phase 3 Field Testing	22
11/YH/0259	ANZAC endocrine sub study	21
11/YH/0262	Are presenting symptoms related to outcome in lung cancer? v1.1	21
11/YH/0274	ADEPT WP2-Utilising routine datasets to explore adverse effects	22
12/YH/0098	Mannose binding protein activity against staph. aureus in children	31
12/YH/0119	To determine the views of TYA regarding survivorship care plans	18
12/YH/0141	The hand held fan as a self-management strategy for breathlessness	18

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/YH/0096	Census of care in hospitals - final focus groups	21
11/YH/0119	Melanoma: Experience and support needs	31
11/YH/0155	ECLIPS: Evaluating CLAHRCs impact & process	25
11/YH/0164	Nutritional Rehabilitation in Stable COPD - Pilot Project (v 1.8)	41
11/YH/0217	Macrophage apoptosis during spn infection: influence of HIV.v2	36
11/YH/0228	Smoothies and enamel erosion	31
11/YH/0256	Psychotic-like experiences in pregnant and postpartum women	38
11/YH/0269	Adult attachment;childbirth memory processing and perception of pain 1	34
11/YH/0271	Systematic Techniques for Assisting Recruitment to Trials (START)	31
11/YH/0288	Communication Skills Feasibility Study.V 1	24
11/YH/0297	Trial of management of fractures of fifth metatarsal bone	22
11/YH/0320	Delivering shared decision-making (version 1)	60
11/YH/0331	The feasibility and acceptability of GP Commissioning	22
11/YH/0332	Improving medicines adherence and informed choice	22

11/YH/0370	Malignant ascitic fluid: cell isolation and tissue factor expression.	28
11/YH/0392	IQuESTS Work Package 3 - Service improvements for self-management	20
11/YH/0396	Information given to patients about their medicines in secondary care	21
12/YH/0078	Non-attendance at drug service hepatitis C outreach clinics. (v1)	21
12/YH/0161	Measurement of social isolation in chronic non-malignant pain	21

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/YH/0120	Moral reasoning style following traumatic brain injury	31
11/YH/0232	The stabilisation of preterm infants: investigation of practice V5	31
11/YH/0369	RCT of Open Stabilisation versus TPS	36
12/YH/0025	Burden of illness in painful diabetic neuropathy	26

Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
12/YH/0159	Health and Homelessness Study for North Lincolnshire	N/A
12/YH/0163	Pilot comparison study of patients who fall versus patients who don't	N/A

Provisional Opinion Pending Consultation with Referee

REC Reference	Application Short Title	Number of Days on Clock
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Further information response not complete

REC Reference	Application Short Title	Number of Days on Clock
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Withdrawn after the meeting

REC Reference	Application Short Title	Number of Days on Clock
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Invalid Application

REC Reference	Application Short Title	Number of Days on Clock
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No Opinion Pending Consultation with Referee

REC Reference	Application Short Title	Number of Days on Clock
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Not Requiring Review by NHS REC

REC Reference	Application Short Title	Number of Days on Clock
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Table 9: Items exceeding timelines:

Full applications for ethical review over 60 day timeline		
REC Reference	Application Short Title	Number of Days on Clock

Proportionate review applications for ethical review over 14 days timeline		
REC Reference	Application Short Title	Number of Days on Clock
12/YH/0112	Effect of Head and Gaze Position on Soft Toric Lens Performance - v1	15
12/YH/0161	Measurement of social isolation in chronic non-malignant pain	21
12/YH/0163	Pilot comparison study of patients who fall versus patients who don't	31

SSAs (non Phase 1) over 25 days timeline		
REC Reference	Application Short Title	Number of Days on Clock

SSAs (Phase 1) over 14 days timeline		
REC Reference	Application Short Title	Number of Days on Clock

Substantial Amendments over 35 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
10/H1310/45/AM01	Sheffield Physical Activity Booster Trial Evaluation Subprotocol	Substantial Amendment 1	40
09/H1310/62/AM05	Metal Ions Study	Substantial Amendment	39
10/H1310/70/AM01	ADHD outcomes in a city wide cohort - a pilot study	Substantial amendment 1 31 March 2011	38
11/YH/0101/AM01	SABRE - Hypertonic Saline in Acute Bronchiolitis RCT	Substantial Amendment	39

Modified Amendments over 14 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock

Section 30 application over 60 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock