

NRES Committee Yorkshire & The Humber - South Yorkshire

Annual Report

01 April 2013 – 31 March 2014

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:	Dr Ian Woollands
Vice-Chair:	Mr Neil Marsden
Alternate Vice-Chair:	Ms Susan Hampshaw
Co-ordinator:	Mrs Joan Brown (October 2013 – March 2014) Miss Sarah Grimshaw (March 2013 – September 2013)
PRSC Co-ordinator:	Mrs Joan Brown
Assistant Co-ordinator:	Miss Kerry Dunbar
Committee Address:	North East REC Centre Unit 002 Jarrow Business Centre Rolling Mill Road Jarrow Tyne and Wear NE32 3DT
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Chair's overview of the past year:

As the newly appointed Chair of the South Yorkshire Committee I have the pleasure and privilege of writing the "Chairs Overview of the Past Year".

During the year the Committee has been ably supported initially by the REC Manager Miss Sarah Grimshaw and then from October 2013 by Mrs Joan Brown and REC Assistant Mrs Kerry Dunbar and I wish to acknowledge their hard work which has ensured the smooth running of the Committee and provided an efficient service for researchers.

The National Research Ethics Service reorganized its regional administration offices and the South Yorkshire Committee is now serviced from the Regional REC Office at Jarrow.

There have been a number of resignations from the South Yorkshire REC since April 2013 due to changes in their employment or personal circumstances which meant they were unable to continue as a member of the Committee. Particular thanks go to Jo Abbot who was Chair of the South Yorkshire REC for 7 years.

On behalf of the Committee, I wish to record our thanks and appreciation for their contributions and support in the work of the Committee during their tenures.

The Committee has met the NRES targets for processing research applications and successfully implemented the Proportional Review process. This is further detailed in the body of the Annual Report below.

Finally, I wish to record the continuing commitment and support from all members who have given freely of their time and expertise to ensure the Committee meets its duties to safeguard the rights, safety, dignity and well-being of people participating in research in the National Health Service.

NRES Committee Yorkshire & The Humber - South Yorkshire Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Ms Jo Abbott	Consultant in Public Health	Expert	26/01/2007	31/01/2014
Dr Ahmed H Abdelhafiz	Consultant Physician, Elderly Medicine	Expert	07/03/2007	
Dr Peter Allmark	Principal Nursing Lecturer	Expert	01/10/2013	
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	
Dr Rhona Bratt	Retired Multimedia Project Manager	Lay Plus	01/03/2013	31/12/2013
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	Lay Plus	30/01/2007	
Dr Duane Mellor	Lecturer in Dietetics	Expert	26/09/2013	
Mrs Andrea Porritt	Community Specialist Practitioner/District Nurse	Expert	01/04/2008	
Ms Stephanie Rhodes	Neonatal Sister	Expert	01/04/2008	31/01/2014
Dr Paul Spencer	Consultant Radiologist	Expert	07/03/2007	30/09/2013
Dr Ian Woollands	Retired Clinical Director Occupational Health	Expert	17/02/2014	

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended
Mrs Carole Taylor	Deputy Chief Pharmacist	Expert	25/04/2013 27/06/2013 25/07/2013 28/11/2013 30/01/2014 27/03/2014

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Mr James Burns (Co-opted from NRES Committee)	Retired	Lay	25/07/2013
Professor Anne Topping (Co-opted from North West – GM East)	Director Centre for Health & Social Care Research	Expert	25/07/2013

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

Name	Declaration of Interest	Date
Reverend Joan Ashton	None	14/01/2014
Dr Duane Mellor	Volunteer Diabetes UK peer reviewer for NIHR. Lecturer at University of Nottingham.	14/01/2014
Mr Ian Cawthorne	As Chief Pharmacist of an NHS Trust he has regular and routine dealings with pharmaceutical companies wishing to promote their drugs as part of post. He also has infrequent meetings with Research Companies that are setting up trials within the Trust to ensure that all parties are acting within Good Clinical Trials procedures. The Trust and the pharmacy take payment for managing these trials on behalf of the industry to cover administration costs. No personal gain is made either financially, through hospitality or any other means from any of these transactions.	13/01/2014
Dr Peter Allmark	Chair of Sheffield Hallam University Faculty (HWB) Research Ethics Committee Lay Member of Sheffield University REC. Member Labour Party	17/01/2014
Professor Nigel Beail	British Institute for Learning Disabilities (Trustee) Institute for Psychotherapy and Disability (Director/Trustee) South West Yorkshire Partnership NHS Foundation Trust. Member of Research Trust Action Group. Review projects for R&D Department and peer review for various funding bodies on an ad-hoc basis.	05/02/2014
Mrs Carole Taylor	Involved with dispensing of medications as part of clinical trials which have a medication aspect.	05/02/2014
Dr Ian Woollands	None	13/02/2014
Ms Susan Hampshaw	None noted. Part of DMBC RG. Process Member of AHSN (South York Rep) Post match into Public Health & Inequalities Theme - CLAHRC YH	31/03/2014
Dr Ahmed H Abdelhafiz	Consultant Physician. None noted for the rest.	31/03/2014
Ms Helen Barlow	None noted but is a Library and Knowledge Service Manager for TRFT.	31/03/2014
Mrs Andrea Porritt	None	06/06/2014

Meetings for Full Ethical Review 01 April 2013 - 31 March 2014:

Month	Date	Number of Members Present at Meeting
April	25/04/2013	9
May	30/05/2013	8
June	27/06/2013	7
July	25/07/2013	7
October	31/10/2013	10
November	28/11/2013	9
January	30/01/2014	9
March	27/03/2014	8

8 full committee meetings were held during the reporting period.

Proportionate Review Sub Committee Meetings held during 01 April 2013 - 31 March 2014:

Month	Date	Number of Members Present at Meeting
May	02/05/2013	3
June	13/06/2013	3
July	17/07/2013	3
July	25/07/2013	3
August	14/08/2013	3
August	28/08/2013	3
September	05/09/2013	3
October	17/10/2013	3
November	28/11/2013	3
January	28/01/2014	3
February	25/02/2014	3
March	24/03/2014	3

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

Attendance of Members: 01 April 2013 – 31 March 2014:

Name	Number of Meetings Attended
Dr Ahmed H Abdelhafiz	7
Ms Helen Barlow	7
Ms Jo Abbott	7
Reverend Joan Ashton	6
Mrs Carole Taylor	6
Professor Nigel Beail	5
Mr Neil Marsden	4
Ms Susan Hampshaw	4
Mrs Andrea Porritt	4
Dr Rhona Bratt	4
Dr Peter Allmark	3
Ms Stephanie Rhodes	3
Mr Ian Cawthorne	2
Dr Duane Mellor	2
Dr Ian Woollands	1
Mr James Burns	1
Professor Anne Topping	1

Number of inquorate meetings held: None

**Attendance of Members at proportionate review sub-committee meetings:
01 April 2013 – 31 March 2014:**

Name	Number of Meetings Attended
Ms Jo Abbott	6
Dr Rhona Bratt	5
Mr Neil Marsden	5
Reverend Joan Ashton	4
Ms Susan Hampshaw	3
Professor Nigel Beail	3
Mr Ian Cawthorne	3
Mrs Carole Taylor	2
Mrs Andrea Porritt	2
Ms Helen Barlow	1
Dr Ahmed H Abdelhafiz	1
Dr Duane Mellor	1

Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Mr Ian Cawthorne	30/07/2013 - 30/07/2013	Human Tissue Act (Use of Tissue in Research)
Dr Ian Woollands	20/11/2013 - 20/11/2013	National Training Members Day, HRA
Reverend Joan Ashton	10/09/2013 - 10/09/2013	Equality & Diversity, HRA
Dr Rhona Bratt	22/06/2013 - 22/06/2013	Equality & Diversity
Dr Ahmed H Abdelhafiz	10/09/2013 - 10/09/2013	Equality & Diversity
Ms Susan Hampshaw	18/09/2013 - 18/09/2013	Equality & Diversity
Reverend Joan Ashton	27/11/2013 - 27/11/2013	National Members Training Day, HRA
Dr Duane Mellor	05/08/2013 - 04/04/2014	SDL completed: Interview discussion with A. Hunn re the role of NHS ethics in student research – 2 hours Meeting of University of Chester Research Ethics Advisory Board – 3 hours Peer review for a number of journals – 40 hours Training of colleagues at the University of Chester re ethics – 3 hours Reading of material linked to the ethics of pharmaceutical practice and evidence based medicine – 36 hours
Ms Susan Hampshaw	12/03/2014 – 12/03/2014	Improving Informed Consent & Participant Information Sheets – a Collaborative HRA, NIHR and MRC Workshop
Professor Nigel Beail	22/10/2013 - 22/10/2013	Equality & Diversity, South West Yorkshire Partnership NHS Foundation Trust
Mrs Andrea Porritt	09/09/2013 - 18/03/2014	SDL completed: Safe and effective record keeping – 3 hours Legal record keeping – 7 hours Information governance – 2 hours Scenario based workshop on safe use of syringe drivers – 2 hours CRITICAL APPRAISAL WORKSHOP Read clinical papers with confidence – 7 hours
Dr Ahmed H Abdelhafiz	01/10/2013 - 01/02/2014	SDL completed: Online equality and diversity training – 3 hours Writing a paper on hypoglycaemic

		drug withdrawal in frail elderly with diabetes to avoid hypoglycaemic complications – <i>6 hours</i>
Professor Nigel Beail	01/04/2013 - 17/12/2013	SDL completed: The Mental Capacity Act, DOLS and Advanced decisions Update – <i>4 hours</i> Reading and reviewing of research and research methods papers concerning the use of qualitative research methods. Examination of how this research can be applied usefully and ethically in studies with people who have intellectual disabilities – <i>40+ hours</i>
Ms Helen Barlow	20/03/2014 - 20/03/2014	SDL Completed: Attended a day-long critical appraisal skills workshop – <i>5 hours</i> Equality and Diversity E-learning package – <i>1 hour</i>
Mrs Carole Taylor	12/03/2014 - 12/03/2014	Patient Consent & Participant Information Sheets, HRA

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	33	100.00
Total Applications Reviewed	33	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	10
Number of studies withdrawn prior to the meeting	4
Number of student applications reviewed	17
Number of paediatric applications reviewed	4
Number of device applications reviewed	2
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	5	15.15
Favourable Opinion with Additional Conditions	6	18.18
Unfavourable Opinion	0	0.00
Provisional Opinion	22	66.67
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	33	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	18	54.55
Further Information Favourable Opinion with Additional Conditions	1	3.03
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	5	15.15
Favourable Opinion with Additional Conditions	6	18.18
Unfavourable Opinion	0	0.00
Provisional Opinion	3	9.09
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	33	100

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

Total Applications Reviewed	17
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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	9	52.94
Favourable Opinion with Additional Conditions	3	17.65
No Opinion transfer to full committee for review	1	5.88
Provisional Opinion	4	23.53
Unfavourable Opinion	0	0.00
Total	17	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	4.13
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	25
Number of days taken to final decision - mode	18

Number of SSAs (non-Phase 1) reviewed	0
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%

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	70
Number of substantial amendments over 35 days	0
Number of substantial amendments over 35 days as a % of total substantial amendments	0.0%

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	2
Number of modified amendments over 14 days	1
Number of modified amendments over 14 days as a % of total modified amendments	50.0%

Number of proportionate review applications for ethical review over 14 days*	1
Number of proportionate review applications over 14 days as a % of total	6.3%

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
13/YH/0107	The effects of Listening on Balance Control	23
13/YH/0146	Club drug users' problems and motivation to access a club drug clinic	18
13/YH/0150	Eating Disorder Transitions	28
13/YH/0151	Version 1. PTSD and appearance concern following burn injury	29
13/YH/0208	Geo-spatial and demographic features of Barrett's Oesophagus	14
13/YH/0209	1 Effectiveness, feasibility & acceptability of working memory training	37
13/YH/0220	Exploring the relationship between stress and seizures	51
13/YH/0225	Lower limb alignment after unicompartmental knee replacement using PSI	28
13/YH/0243	Journey through services: Adults with a Learning Disability	29
13/YH/0311	Evaluating Simulation Based Training in Cardiology	8
13/YH/0350	A Narrative Analysis of the Construction of ADHD: A Case Study.	25
13/YH/0351	Construction of dementia	29
13/YH/0352	Be Here Now: Evaluating Mindfulness for ABI patients	14
13/YH/0353	Stigma and Pakistani patients on treatment for Hepatitis C	32
13/YH/0354	Exercise Training During Chemotherapy in Advanced Lung Cancer Patients	36
13/YH/0357	Gait Biomechanics six months post ACL Reconstruction	8
13/YH/0358	Can steerable capsule endoscopy enhance gastric emptying?	28
13/YH/0378	Memory functioning in type 1 diabetes	45
13/YH/0379	The Impact of Amblyopia (v 1)	28
13/YH/0398	Role of CRT on PR interval in patients with LV dysfunction.	20
14/YH/0018	Continuous vs. intermittent energy restriction and weight loss v1	24

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
13/YH/0186	Factors affecting cascade genetic screening and counselling	26
13/YH/0261	How does the loss of exostosin gene function induce tumour formation?	15

Further Information Unfavourable Opinion		
REC Reference	Application Short Title	Number of Days on Clock

Favourable Opinion with Standard Conditions		
REC Reference	Application Short Title	Number of Days on Clock
13/YH/0094	TYGACIL PASS, Final Protocol Amendment 2 dated 08 Nov 12	22
13/YH/0206	Sense of self and anorexia nervosa	11
13/YH/0212	UNITI (Version 2.1)	18
13/YH/0237	Vitamin D & Immunity Study. Version 1.1	24
13/YH/0256	Developing HIV services: the patient's perspective	11
13/YH/0291	Feasibility of a cluster trial for identifying OA	2
13/YH/0304	Seroprevalence of Chlamydia trachomatis and herpes simplex virus	6
13/YH/0370	Dementia, enjoyable activities & touch-screen computers 122714	20
13/YH/0409	ACST-2 QRI	8
14/YH/0019	STructured lifestyle Education for People Wlth SchizophrEnia V1.0	19
14/YH/0026	DVA test, version 1	8
14/YH/0062	GEM (EORTC 08114)	11
14/YH/0064	IMPAQTS V1	11
14/YH/0066	Inherited renal disease: attitudes to prenatal diagnosis and PGD	7

Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
13/YH/0109	PAIRS COPD	22
13/YH/0114	A Pilot Study of Biomarkers in Patients with Periodontal Disease	22
13/YH/0143	Adherence to prophylaxis among young people with haemophilia	11
13/YH/0145	Advanced fetal MRI	18
13/YH/0181	A feasibility adherence study in adults with cystic fibrosis	18
13/YH/0191	Lung HeXeRT	18
13/YH/0242	Exploring factors of engagement in weight management patients.	11
14/YH/0001	Counselling for Depression: The PRaCTICED Trial	19
14/YH/0095	Effect of phosphate reduction on novel biomarkers & QOL Version 1.0	7

Unfavourable Opinion		
REC Reference	Application Short Title	Number of Days on Clock
Provisional Opinion		
REC Reference	Application Short Title	Number of Days on Clock
14/YH/0082	Evaluation of MSIMT & Videotherapy for Young Children with SSD v.1	N/A
14/YH/0087	Collection of joint mesenchymal stem cells (MSCs)	N/A
Provisional Opinion Pending Consultation with Referee		
REC Reference	Application Short Title	Number of Days on Clock
Further information response not complete		
REC Reference	Application Short Title	Number of Days on Clock
Withdrawn after the meeting		
REC Reference	Application Short Title	Number of Days on Clock
Invalid Application		
REC Reference	Application Short Title	Number of Days on Clock
No Opinion Pending Consultation with Referee		
REC Reference	Application Short Title	Number of Days on Clock
Not Requiring Review by NHS REC		
REC Reference	Application Short Title	Number of Days on Clock

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	
13/YH/0261	How does the loss of exostosin gene function induce tumour formation?	15	
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
Modified Amendments over 14 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
13/YH/0181/AM01/2	A feasibility adherence study in adults with cystic fibrosis	Amendment 3, 07/10/13	19
Section 30 application over 60 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock