

**NRES Committee Yorkshire & The
Humber - Sheffield**

Annual Report

01 April 2013 – 31 March 2014

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee Yorkshire & The Humber - Sheffield
Type of REC:	Type 3
Type of Flag:	Medical Devices, RTB, Paediatric, IRB registered
Chair:	Professor Basil Sharrack
Vice-Chair:	Dr Ruth Stirton
Alternate Vice-Chair:	Dr Nana Theodorou
REC Manager:	Miss Helen Penistone
REC Assistant:	Ms Rachel Katzenellenbogen
Committee Address:	HRA NRES Centre Manchester Barlow House 3rd Floor 4 Minshull Street Manchester M1 3DZ
Telephone:	0161 625 7832
Fax:	0161 625 7299
Email:	nrescommittee.yorkandhumber-sheffield@nhs.net

Chair's overview of the past year:

I am delighted that the committee were able to offer an excellent service despite the on-going challenges.

We were sad to say goodbye to a number of excellent members but delighted to welcome equally excellent new ones.

I am particularly grateful to Helen and Rachel for the excellent support that they provided the committee with.

NRES Committee Yorkshire & The Humber - Sheffield Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr Paul Bacon	Lead Clinical Scientist in Audiological Science, Medical Physics	Expert	01/06/2011	
Dr Mary Cooke	Lecturer/Researcher - Nursing and Midwifery	Expert	24/04/2006	13/09/2013
Dr Helena Davies	Senior Lecturer in Late Effects/Medical Education	Expert	16/05/2011	21/10/2013
Mrs Jacqui Gath	Retired Senior Systems Analyst	Lay Plus	15/06/2011	
Professor Frank Jones	Lay Member	Lay	31/01/2014	
Mr Pete Laud	Statistical Consultant	Expert	01/04/2011	
Dr Marie Marron	Lay Member	Lay	01/03/2014	
Mrs Jennifer Martin	Pharmacist	Expert	07/05/2010	
Dr Amaka Offiah	HEFCE Clinical Senior Lecturer & Honorary Consultant Radiologist	Expert	16/05/2011	
Professor Basil Sharrack	Consultant Neurologist	Expert	29/06/2006	
Dr Soon Song	Consultant Diabetologist	Expert	25/08/2006	
Mrs Yvonne Stephenson	Lead Technician in the Department of Infection and Immunity	Expert	16/05/2011	
Dr Ruth Stirton	Lecturer in Law	Lay Plus	04/10/2010	
Mr Neil Sykes	Retired Engineer/Scientist	Lay Plus	01/04/2003	
Mrs Helen Teasdale	University Executive Assistance	Lay Plus	01/05/2011	
Dr Nana Theodorou	Specialist Orthoptist	Expert	01/10/2011	
Dr Steven Thomas	Consultant Vascular and Cardiac Radiologist	Expert	18/05/2006	

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended
Mr Richard Lindley	Consultant Paediatric Surgeon	Expert	08/04/2013 02/09/2013 02/12/2013 03/02/2014

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Mr James Burns	Lay Plus Member	Lay	02/12/2013

Mr Chris Houston	Lay Plus Member	Lay	02/12/2013
Mrs Gillian Rimington	Lay Member	Lay	07/10/2013

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

Name	Declaration of Interest	Date
Dr Soon Song	None	06/12/2013
Mrs Jennifer Martin	None	06/12/2013
Dr Nana Theodorou	Research Coordinator at Sheffield Teaching Hospitals NHS Trust Guest Lecturer at University of Manchester Guest Lecturer at University of Sheffield Specialist Orthopist at Sheffield Teaching Hospitals NHS Trust Peer reviewer for: Research Department at STH, Nursing Standard, Eye News, Member of the evidence based council at STH. No involvement in study authorisation and signing off at STH R&D but support investigators with their research proposals pre-award and post-award such as coordinating study costings, liaise with support services (pharmacy and radiology) and finance.	05/12/2013
Mrs Yvonne Stephenson	I work in the Department of Infection and Immunity in Sheffield University Medical School and as such sometimes take part in research by processing samples.	05/12/2013
Mr Pete Laud	Shares in pharmaceutical companies, held within an investment fund. Employed part-time by AstraZeneca as a contract statistician. Part of a team of consultants providing statistical advice to Sheffield Teaching Hospitals Clinical Research Office. Both contracts are paid to employer (University of Sheffield).	06/01/2014
Professor Basil Sharrack	I am an active researcher and will declare involvement in any research projects discussed by the committee.	12/12/2013
Mrs Helen Teasdale	None	06/12/2013
Dr Amaka Offiah	Consultancy: HTA Group of Hospitals Chairperson; Skeletal Dysplasia Group for Teaching and Research European Society of Paediatric Radiologists; Child Abuse Taskforce Member; International Consortium for Vertebral Anomalies and Scoliosis; MPSIVA Guidelines Advisory Board Peer Reviewer for radiology and general medical journals; Member: Sheffield Children's Hospital Research and Innovation Committee; Sheffield Children's Hospital Scientific Advisory Committee; NICE Standing Committee for Guideline Updates; Sheffield Children's NHS Foundation Trust Board of Governors; Journal Editor: Paediatric Radiology	15/01/2014
Mrs Jacqui Gath	As lay advocate: administrator of NTCRN Consumer Research Panel, Member of independent Cancer Patient's Voice. Membership of trial steering groups e.g. AVALPROFS, SPECIAL	14/01/2014

Dr Paul Bacon	Employed as Lead Clinical Scientist, Dept. of Medical Physics, STH NHS Trust. No directorships to declare. External clinical examiner to trainees on behalf of British Academy of Audiology (BAA) higher training scheme (HTS), but I am not involved in any grants/awards/ research activities they may find/conduct. As a Lead Clinical Scientist I support R&D activities with the Audiological Science section of MIMP (medical Imaging and Medical Physics) and Audiology (ENT Directorate) of Sheffield Teaching Hospitals NHS Trust.	27/01/2014
Dr Marie Marron	None	03/03/2014
Dr Steven Thomas	Sheffield Teaching Hospitals Research Committee and NICE Diagnostics Advisory Committee	03/03/2014
Professor Frank R Jones	Emeritus Professor in Materials Science with University but not health related research.	03/03/2014

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

Month	Date	Number of Members Present at Meeting
April	08/04/2013	12
May	13/05/2013	11
June	03/06/2013	9
July	01/07/2013	11
September	02/09/2013	11
October	07/10/2013	9
November	04/11/2013	9
December	02/12/2013	9
January	06/01/2014	11
February	03/02/2014	9
March	03/03/2014	14

11 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	13/05/2013	3
June	03/06/2013	3
July	01/07/2013	3
September	02/09/2013	3
October	07/10/2013	3
November	04/11/2013	3
March	26/03/2014	3

7 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
Professor Basil Sharrack	11
Mr Pete Laud	10
Dr Nana Theodorou	10
Mrs Jacqui Gath	9
Mrs Yvonne Stephenson	9
Mrs Jennifer Martin	8
Mrs Helen Teasdale	8
Dr Paul Bacon	8
Dr Amaka Offiah	8
Dr Soon Song	8
Mr Neil Sykes	7
Dr Steven Thomas	4
Dr Helena Davies	4
Dr Mary Cooke	3
Professor Frank Jones	1
Dr Marie Marron	1
Dr Ruth Stirton	1

Number of inquorate meetings held: 0

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

Name	Number of Meetings Attended
Professor Basil Sharrack	7
Mrs Helen Teasdale	3
Mrs Jacqui Gath	2
Mr Neil Sykes	2
Mr Pete Laud	1
Mr Richard Lindley	1
Mrs Yvonne Stephenson	1
Dr Helena Davies	1
Dr Soon Song	1
Dr Steven Thomas	1

Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Dr Nana Theodorou	19/09/2013 - 19/09/2013	Medical Devices Training Day, NRES
Mrs Yvonne Stephenson	30/07/2013 - 30/07/2013	Human Tissue Act Training, HRA
Dr Nana Theodorou	12/11/2013 - 12/11/2013	Researcher Training Day, HRA
Mrs Jennifer Martin	10/12/2013 - 10/12/2013	Quantative Research Methods and Statistics, HRA
Dr Soon Song	10/12/2013 - 10/12/2013	Quantative research methods and statistics , HRA
Dr Paul Bacon	16/01/2014 - 16/01/2014	SDL: Workshop on Writing for Publication, Irene Mabbott
Mrs Helen Teasdale	12/03/2014 - 12/03/2014	Improving Informed Consent and Participant Information Sheets – A Collaborative HRA, NIHR and MRC Workshop, HRA
Professor Basil Sharrack	11/03/2014 - 11/03/2014	Medical Devices, HRA
Dr Steven Thomas	01/01/2014 - 01/01/2014	Informed consent in CTIMP, Self-Directed Learning
Dr Steven Thomas	01/02/2014 - 01/02/2014	MRC Human tissue legislation, Self-Directed Learning
Dr Steven Thomas	18/02/2014 - 18/02/2014	Research and human tissue, MRC Regulatory Support Centre

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	17	32.69
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	2	3.84
Research Database	0	0.00
Others	33	63.46
Total Applications Reviewed	52	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	9
Number of studies withdrawn prior to the meeting	9
Number of student applications reviewed	10
Number of paediatric applications reviewed	12
Number of device applications reviewed	7
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	0
Number of applications reviewed funded by the US DHHS	1

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	2	3.84
Favourable Opinion with Additional Conditions	9	17.30
Unfavourable Opinion	3	5.76
Provisional Opinion	38	73.07
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	52	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	31	59.61
Further Information Favourable Opinion with Additional Conditions	5	9.61
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	3.84
Favourable Opinion with Additional Conditions	9	17.30
Unfavourable Opinion	3	5.76
Provisional Opinion	0	0.00
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	1	1.92
Number of studies withdrawn after the meeting	1	1.92
Total	52	100

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

Total Applications Reviewed	14
------------------------------------	-----------

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	6	42.86
Favourable Opinion with Additional Conditions	2	14.29
No Opinion transfer to full committee for review	3	21.43
Provisional Opinion	3	21.43
Unfavourable Opinion	0	0.00
Total	14	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	4.72
Number of applications for full ethical review over 60 days	1
Number of applications over 60 days as a % of total	1.92%
Number of days taken to final decision - average	33
Number of days taken to final decision - mode	23
Number of SSAs (non-Phase 1) reviewed	6
Number of applications for SSA review over 25 days	4
Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)	66.7%
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	80
Number of substantial amendments over 35 days	1
Number of substantial amendments over 35 days as a % of total substantial amendments	1.3%
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	9
Number of modified amendments over 14 days	0
Number of modified amendments over 14 days as a % of total modified amendments	0.0%
Number of proportionate review applications for ethical review over 14 days	2
Number of proportionate review applications over 14 days as a % of total	18.2%

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
08/H1308/193+5	STH-ObS (renewal)	66
13/YH/0100	Electrical muscle stimulation programme for swallowing post stroke V.1	31
13/YH/0123	Chemotherapy-induced peripheral neuropathy and neurotrophins	24
13/YH/0142	Decision aids in paediatric dental sedation	58
13/YH/0152	FIGARO	33
13/YH/0164	Lifestyle Matters for Depression	30
13/YH/0166	Decision aid for orthodontic treatment. Protocol version 1	29
13/YH/0167	Cervical Electrical Impedance Measurement for Predicting Preterm Birth	30
13/YH/0172	Coloplast CP242 Version 1.0	44
13/YH/0184	Development and piloting of a low intensity CAT-informed intervention	30
13/YH/0192	Coping responses in clinical depression	14
13/YH/0204	Bariatric surgery and colorectal cancer	32
13/YH/0255	Blinatumomab (MT103) in patients aged <18 years with B-Precursor ALL	38
13/YH/0263	SarCaBon: Saracatinib versus placebo for cancer-induced bone pain	52
13/YH/0273	Using MRI to investigate energy metabolism in MND	33
13/YH/0275	Revitive for the treatment of Venous Insufficiency	50
13/YH/0308	Sheffield Cancer Biobank	48
13/YH/0321	Oral Laquinimod Compared to Interferon β -1a for Multiple Sclerosis	37
13/YH/0361	Improved discrimination of central and obstructive apnoeas	40
13/YH/0362	Metabolic endotoxaemia, dietary manipulation and prior exercise	31
13/YH/0364	Clinical study to evaluate the efficacy of a mouth wash	23
13/YH/0389	Pfizer B1481021 - Phase 3 PF-04950615 LDL-C lowering in HeFH	43
13/YH/0391	MUNIX in MND	38
13/YH/0393	Pfizer B1481020 - Phase 3 PF-04950615 for Hyperlipidemia	43
13/YH/0397	ADAPT	34
13/YH/0419	Improving bone marrow stem cells performance	31
14/YH/0002	IPI-145 vs Ofatumumab in CLL or SLL	31
14/YH/0003	Extension study of IPI-145 and Ofatumumab in Patients with CLL/SLL	31
14/YH/0005	IMPERIUM (IOQL)	33

14/YH/0012	BASIC Study: Bone Age Study in Children (version 1)	37
14/YH/0023	AQUACEL Ag+ Extra in burns (U373) Version 5	29
14/YH/0047	Intraoperative Real Time Diagnosis of Human Brain Tumours	27

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/YH/0086	STUDY LT4020-PIII-12/11 - Application Form updated on the 29/01/2013	43
13/YH/0140	Ivabradine in heart failure with preserved ejection fraction	30
13/YH/0289	Impact of feedback on adherence and clinical outcomes in asthma	33
13/YH/0374	Understanding the support needs of disabled children and families	16
14/YH/0042	Orientation discrimination in Autism	26
14/YH/0050	Haemodynamic changes during spinal anaesthesia for elective caesarean	38

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/0161	Exploration of women's knowledge and expectations of early labour care	7
13/YH/0189	A comparison of two sensitive sensory tests in carpal tunnel syndrome	14
13/YH/0193	Groupwork engagement outcomes for forensic patients	7
13/YH/0228	Evaluation of a new cognitive measure in children who have had cancer	9
13/YH/0307	Contributing clinical MRI scans to multi-centre collaboration	8
13/YH/0339	Arthroscopic Hindfoot Fusion - A Biomechanical Study	9
13/YH/0415	Pilot study of behavioural Intervention for Nutrition in CF	28
14/YH/0046	HELP trial (systemic therapy for vulval Erosive Lichen Planus)	23

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/YH/0082	074: Phase 3 study of Solifenacin in Children age 2-5 with NDO	23
13/YH/0154	Getting used to hearing aids	15
13/YH/0157	Diabetes Mellitus and Erectile Dysfunction v.1	22
13/YH/0160	Studies of pepsin in respiratory disease	13
13/YH/0162	HABSelect – Hyaluronic Acid Binding Sperm selection_V1.0	22

13/YH/0312	IMT in people with COPD who decline pulmonary rehabilitation	28
13/YH/0320	28689 Phase III Study of Lebrikizumab in Uncontrolled Asthma Patients	28
13/YH/0332	Optical imaging with 3-D reconstruction of torso topography in common	28
13/YH/0403	OHQoL with removable partial dentures; a pilot study	28
14/YH/0020	ABP 501 Extension Study	22
14/YH/0052	ALV003 in patients with Celiac disease	24

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/YH/0073	Optical imaging with 3-D reconstruction of torso topography in common	23
13/YH/0131	Plasma Rich Protein vs Dry Needling for Achilles Tendonopathy	23
13/YH/0132	MICA vs Open Scarf/Akin; A Prospective Randomised Control Tial	23

Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
14/YH/0103	Assessment of pelvic floor dysfunction symptoms at 6 weeks postpartum	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
13/YH/0215	ZS-003	24

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
08/H1308/193+5	STH-ObS (renewal)	66

Proportionate review applications for ethical review over 14 days timeline		
REC Reference	Application Short Title	Number of Days on Clock
13/YH/0154	Getting used to hearing aids	15
13/YH/0374	Understanding the support needs of disabled children and families	16

SSAs (non Phase 1) over 25 days timeline		
REC Reference	Application Short Title	Number of Days on Clock
13/YH/0165	Education and rehabilitation in intermittent claudication	141
13/YH/0384	Clinical study to evaluate the efficacy of a mouth wash	27
13/YH/0385	Clinical study to evaluate the efficacy of a mouth wash	27
13/YH/0386	Clinical study to evaluate the efficacy of a mouth wash	27

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
12/YH/0087/AM04	077: Phase 3 Extension Study of Solifenacin in Children with OAB	Substantial Amendment #3	36

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
--	--	--	--------------