

NRES Committee Yorkshire & The Humber - Sheffield

Annual Report

01 April 2011 – 31 March 2012

Part 1 – Committee Membership and Training

Name of REC: NRES Committee Yorkshire & The Humber - Sheffield

Type of REC: Recognised, Type III

Type of Flag: Establishing Research Tissue Banks
IRB Registered
Medical Device Study
Research Involving Children

Chair: Dr Basil Sharrack

Vice-Chair: Mr Neil Sykes

Alternate Vice-Chair: Mrs Ruth Stirton

Co-ordinator: Mr John Robinson until 17 January 2012
Mrs Anne Ward (Acting)

PRSC Co-ordinator: Mrs Anne Ward

Assistant Co-ordinator: Mrs Anne Ward until 17 January 2012
Miss Lucy Andersson from 7 February 2012

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Chair's overview of the past year:

The Sheffield Research Ethics Committee has had a very successful period during the last 12 months which followed a rather turbulent year.

The Committee was very fortunate to attract new members of an extremely high calibre which restored it to full membership numbers. We were also fortunate to have Mrs Anne Ward acting as a Coordinator for the last few months which helped the Committee conduct its business very efficiently despite a significant increase in the volume of the work which reflected the increasing number of Sub Committee meetings. Despite that, the Committee was able to adhere to the time line targets in almost all the studies which were assessed over the last 12 months.

I would like to thank Coordinator Mr John Robinson, who left during the year, for his hard work and excellent contribution.

In the next few months, the Committee would need to adapt to the new changes which are being introduced by NRES whilst striving to provide an excellent service to the public at large and the research community.

NRES Committee Yorkshire & The Humber - Sheffield Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Miss Golanna Ashtari	Student	Lay Plus	01/06/2011	
Dr Paul Bacon	Lead Clinical Scientist in Audiological Science, Medical Physics	Expert	01/06/2011	
Dr Mary Cooke	Lecturer in Midwifery and Nursing	Expert	24/04/2006	
Dr Helena Davies	Retired Senior Lecturer/Honorary Consultant	Expert	16/05/2011	
Mrs Jacqui Gath	Retired Senior Systems Analyst	Lay Plus	15/06/2011	
Miss Pamela Kingman	Retired Care Home Deputy Manager	Lay Plus	22/02/2006	03/10/2011
Mr Pete Laud	Statistical Consultant	Expert	01/04/2011	
Mrs Jennifer Martin	Pharmacist	Expert	07/05/2010	
Dr Amaka Offiah	HEFCE Clinical Senior Lecturer	Expert	16/05/2011	
Mr Ian Potter	Senior Operating Department Practitioner	Expert	01/03/2008	
Dr Basil Sharrack	Chair of REC and Consultant Neurologist	Expert	29/06/2006	
Dr Soon Song	Consultant Diabetologist	Expert	25/08/2006	
Mrs Yvonne Stephenson	Lead Technician	Expert	16/05/2011	
Dr Ruth Stirton	Lecturer in Law	Lay Plus	01/10/2010	
Mr Neil Sykes	Retired	Lay Plus	01/04/2008	
Mrs Helen Teasdale	Executive Assistant	Lay Plus	01/05/2011	
Dr Nana Theodorou	Research Lead 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
Dr Nigel Hoggard (Resigned 19/01/2012)	Consultant Neuro-Radiologist	Expert	04/04/2011 09/05/2011 07/11/2011 09/01/2012 06/02/2012
Dr Angela Tod (Resigned 02/06/2011)	Reader in Health and Social Care Research	Expert	n/a

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Dr Rhona Bratt	Retired Multimedia Project Manager	Lay Plus	04/04/2011

Member Bank

Name	Occupation	Expert or Lay	Meeting date attended

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

Name	Declaration of Interest	Date
Dr Basil Sharrack	None	05/12/2011
Mr Neil Sykes	GMC Fitness to Practice Panel. On occasion will chair panel involving researchers who are accused of 'research fraud'. Similarly with the Nursing and Midwifery Council.	05/12/2011
Dr Mary Cooke	Shareholdings in Glaxo Smith Klein. Member of NICE panel.	08/12/2011
Dr Steven Thomas	None	31/03/2012
Dr Soon Song	None	05/12/2011
Mrs Jennifer Martin	Occasional honorarium from pharma for lectures etc	12/12/2011
Mr Pete Laud	Work as a paid consultant for AstraZeneca biostatistics department. Part of a team providing statistical advice on a commercial basis to Sheffield Teaching Hospitals NHS Trust Research Office.	05/12/2011
Mrs Yvonne Stephenson	Works within the Department of Infection and Immunity in labs in the Sheffield University Medical School, so may be involved in research projects.	05/12/2011
Miss Golanna Ashtari	None	06/12/2011
Dr Paul Bacon	Local R&D activities with audiological Science section of Medical Physics, Royal Hallamshire Hospital	05/12/2011
Dr Nana Theodorou	Reviewer for R&D, Sheffield Teaching Hospitals Directorate of Ophthalmology, Nursing Standard	05/12/2011
Mrs Helen Teasdale	None	06/12/2011
Mrs Jacqui Gath	Committee membership of Sheffield ECMC, Experimental Cancer Medicines Centre, Clinical Trials Executive	05/12/2011
Dr Helena Davies	None	31/03/2012
Dr Amaka Offiah	Member of Skeletal Dysplasia Group for Teaching and Research. Member of ICVAS - International Consortium for Vertebral Anomalies and Scoliosis	05/12/2011
Mr Ian Potter	None	05/12/2011
Dr Ruth Stirton	None	21/12/2011

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

Month	Date	Number of Members Present at Meeting
April	04/04/2011	9
May	09/05/2011	7
June	06/06/2011	10
July	04/07/2011	13
September	05/09/2011	13
October	03/10/2011	15
November	07/11/2011	13
December	05/12/2011	14
January	09/01/2012	16
February	06/02/2012	14
March	05/03/2012	10

11 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
January	27/01/2012	3
March	16/03/2012	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
Dr Basil Sharrack	11
Mr Pete Laud	10
Mr Neil Sykes	9
Mrs Yvonne Stephenson	8
Mrs Helen Teasdale	8
Dr Ruth Stirton	8
Dr Paul Bacon	8
Dr Amaka Offiah	7
Dr Helena Davies	7
Dr Soon Song	7
Miss Golanna Ashtari	7
Mrs Jacqui Gath	7
Mrs Jennifer Martin	7
Mr Ian Potter	7
Miss Pamela Kingman	5
Dr Mary Cooke	5
Dr Nigel Hoggard	5
Dr Steven Thomas	4
Dr Nana Theodorou	3

Number of inquorate meetings held: 0

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

Name	Number of Meetings Attended
Dr Basil Sharrack	2
Dr Ruth Stirton	1
Dr Soon Song	1
Mrs Helen Teasdale	1
Mrs Jacqui Gath	1

Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Dr Basil Sharrack	20/04/2011 - 20/04/2011	Yorkshire and the Humber Chairs Meeting, NRES
Dr Basil Sharrack	01/09/2011 - 30/06/2012	MA in Research Ethics, University of Keele
Mr Pete Laud	07/07/2011 - 07/07/2011	Induction, NRES
Mrs Helen Teasdale	13/10/2011 - 13/10/2011	Induction, NRES
Mrs Helen Teasdale	13/05/2011 - 13/05/2011	Equality & Diversity, University of Sheffield
Dr Ruth Stirton	13/05/2011 - 13/05/2011	Equality & Diversity, NRES
Mr Ian Potter	28/06/2011 - 28/06/2011	Statistics Training for NRES REC Members, NRES
Mrs Yvonne Stephenson	07/07/2011 - 07/07/2011	Induction, NRES
Dr Amaka Offiah	22/02/2012 - 22/02/2012	Induction, NRES
Mr Pete Laud	27/06/2011 - 27/06/2011	Equality & Diversity, NRES
Mr Ian Potter	27/06/2011 - 27/06/2011	Equality & Diversity, NRES
Dr Soon Song	27/06/2011 - 27/06/2011	Equality & Diversity, NRES
Mrs Jacqui Gath	02/02/2012 - 02/02/2012	NRES Human Tissue Act training, NRES
Dr Amaka Offiah	18/07/2011 - 18/07/2011	Equality & Diversity, NRES
Dr Amaka Offiah	08/09/2011 - 08/09/2011	Qualitative Research for NRES Committee members NRES
Mr Neil Sykes	06/09/2011 - 06/09/2011	Equality & Diversity, NRES
Miss Golanna Ashtari	21/09/2011 - 21/09/2011	Induction, NRES
Mrs Jennifer Martin	28/06/2011 - 28/06/2011	Equality & Diversity, NRES
Mrs Jacqui Gath	07/07/2011 - 07/07/2011	Induction, NRES
Dr Helena Davies	29/03/2012 - 29/03/2012	Induction, NRES
Dr Paul Bacon	29/03/2012 - 29/03/2012	Induction, NRES
Dr Helena Davies	14/10/2011 - 14/10/2011	Equality & Diversity, NRES
Dr Amaka Offiah	28/03/2012 - 28/03/2012	NRES Members National Training Day - Leeds, NRES

Mrs Jennifer Martin	23/02/2012 - 23/02/2012	Reviewing Clinical Trials of Investigational Medicinal Products; NRES
Dr Nana Theodorou	29/03/2012 - 29/03/2012	Induction
Mr Ian Potter	23/02/2012 - 23/02/2012	Reviewing Clinical Trials of Investigational Medicinal Products, NRES
Mrs Jacqui Gath	28/03/2012 - 28/03/2012	NRES Members National Training Day - Leeds, NRES
Mrs Yvonne Stephenson	12/11/2011 - 12/11/2011	Equality and Diversity, NRES

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	11	14.86
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	63	85.14
Total Applications Reviewed	74	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	3
Number of studies withdrawn prior to the meeting	6
Number of student applications reviewed	30
Number of paediatric applications reviewed	14
Number of device applications reviewed	18
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	1	1.35
Favourable Opinion with Additional Conditions	7	9.46
Unfavourable Opinion	6	8.11
Provisional Opinion	60	81.08
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	74	100
Number of studies sent back to full committee meeting for final opinion	1	

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	47	63.51
Further Information Favourable Opinion with Additional Conditions	2	2.70
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	1.35
Favourable Opinion with Additional Conditions	7	9.46
Unfavourable Opinion	6	8.11
Provisional Opinion	8	10.81
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	2	2.70
Number of studies withdrawn after the meeting	1	1.35
Total	74	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	1	25.00
Favourable Opinion with Additional Conditions	0	0.00
No Opinion transfer to full committee for review	3	75.00
Provisional Opinion	0	0.00
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	6.73
Number of applications for full ethical review over 60 days	1
Number of applications over 60 days as a % of total	1.35%
Number of days taken to final decision - average	33
Number of days taken to final decision - mode	29

Number of SSAs (non-Phase 1) reviewed	18
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	68
Number of substantial amendments over 35 days	1
Number of substantial amendments over 35 days as a % of total substantial amendments	1.5%

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	17
Number of modified amendments over 14 days	1
Number of modified amendments over 14 days as a % of total modified amendments	5.9%

Number of proportionate review applications for ethical review over 14 days*	0
Number of proportionate review applications over 14 days as a % of total	0.00%

***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/0042	Detection of autophagy in colorectal cancer specimens	43
11/YH/0062	REM-HF	30
11/YH/0072	The LEONIDAS-2 study	43
11/YH/0075	Qualitative exploration of diabetes outcomes post-structured education	27
11/YH/0076	(duplicate) Negative Pressure Wound Therapy Quality of Life study	36
11/YH/0078	CODIFI: Concordance in Diabetic Foot Infection	41
11/YH/0079	SiRE	34
11/YH/0081	Vascular remodelling in human wound repair - Version 1	44
11/YH/0116	Efficacy and Safety of Pentrox™ (Methoxyflurane)	57
11/YH/0118	The HeartCycle Heart Failure Trials Programme	26
11/YH/0121	LDE225 in patients with basal cell carcinoma	38
11/YH/0124	After treatment: Acknowledging the importance of returning to work	43
11/YH/0130	Closing the loop in adolescents during non-compliance behaviours	37
11/YH/0132	Can Physiotherapy Treat Patients with Sciatica? A Preliminary RCT	45
11/YH/0136	The feasibility and practicalities of prehospital clinical trials	39
11/YH/0137	Patient expectations of minor injury care	39
11/YH/0140	Luminous	42
11/YH/0166	IRay System To Treat Age-Related Macular Degeneration CLH005	29
11/YH/0188	Mechanisms and impact of bacterial colonisation in COPD	37
11/YH/0193	Occupational Therapy, Asperger's Syndrome and Employment	32
11/YH/0194	Bangladeshi Pathways project v 1.0	39
11/YH/0216	Palonosetron in CINV prevention paediatric patients PALO-10-20 v3.0	25
11/YH/0238	Theory of Mind and Attributional Style in Grandiose Delusions	28
11/YH/0242	Retrospective expectations of quality of life after hip surgery	36
11/YH/0244	Postnatal Sleep and its Impact on First-Time Mothers (Version 1)	38
11/YH/0250	Peristomal Skin Irritation: Evaluation of the CASTLE Barrier Prototype	40
11/YH/0321	EXPLANT	43
11/YH/0323	effect (CIP Version 1.2)	48
11/YH/0339	The safety of twice daily Oxycodone HCl CR tablets - Extension Study	20
11/YH/0341	Group Psychology and outcomes of Multidisciplinary child assessment	33
11/YH/0342	Attitudes of older women to treatment choices in breast cancer	36

11/YH/0345	First person accounts of grandiose beliefs - Version 1	33
11/YH/0349	LoFric ABC-0005, version 1.0	27
11/YH/0400	preventable unplanned admission rates	32
11/YH/0403	A Study of the Vascular Effects of Phosphate Intake; Version 1.0	39
11/YH/0406	Access to antenatal care and maternal health and psychosocial indices	29
11/YH/0408	Performance of an Implanted Glucose Sensor	26
11/YH/0417	Effects of OSA and its treatment on vascular endothelial function V1	53
11/YH/0422	Non-invasive assessment of dysfunctional breathing in children	56
11/YH/0423	LEONIDAS-1	26
11/YH/0460	Making sense of depressive symptoms associated with stroke	23
12/YH/0001	Effects of cancer treatments on quality of life (ECT-QoL)	33
12/YH/0004	Phase I Study of Intraoperative Fluorescent Imaging in neck surgery	37
12/YH/0005	Subjects' satisfaction on pan facial aesthetic enhancement	65
12/YH/0006	Chlamydia Isolates Study	33
12/YH/0009	effect of growth hormone treatment on Body volume Index	32
12/YH/0090	Tendril MRI	25

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/YH/0328	Human palatal characterisation	19
11/YH/0357	Hep Zero Trial	19

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/0179	Defining, modelling and mapping frequent use of Paediatric ED	35
12/YH/0152	16s Validation	14

Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/YH/0182	Social marketing campaign on stroke awareness: a qualitative study v1	36
11/YH/0221	Performance Evaluation of POC INR Monitor	37
11/YH/0243	HIV partner testing by oral fluid home sampling	31
11/YH/0304	Wellbeing Intervention Study	23
11/YH/0335	Musculoskeletal profiling of peripheral arterial disease	23
11/YH/0387	The effect of morphine on prasugrel absorption in STEMI patients	24
11/YH/0434	Measuring outcomes in depression (MOD)	28

Unfavourable Opinion		
REC Reference	Application Short Title	Number of Days on Clock
11/YH/0372	Access to antenatal care and maternal health and psychosocial indices	24
11/YH/0377	Non-invasive microbiology sampling of the lower airways	23
11/YH/0378	Non-invasive assessment of dysfunctional breathing in children	22
11/YH/0407	ZM99 Supplementary prescribing utilising NICE guidelines Version:4	29
11/YH/0410	Making sense of depressive symptoms associated with stroke	27
11/YH/0411	Subjects' satisfaction on pan facial aesthetic enhancement	28

Provisional Opinion		
REC Reference	Application Short Title	Number of Days on Clock
12/YH/0003	Compulsory patient registration with community pharmacy	N/A
12/YH/0081	Finding out more about nonepileptic attacks	N/A
12/YH/0085	Non-invasive microbiology sampling of the lower airways	N/A
12/YH/0087	077: Phase 3 Extension Study of Solifenacin in Children with OAB	N/A
12/YH/0088	047: Phase 3 Study of Solifenacin in children with NDO	N/A
12/YH/0089	076: Phase 3 Study of Solifenacin vs Placebo in Children with OAB	N/A
12/YH/0116	Effectiveness of self-help augmented with II for people with MUS	N/A
12/YH/0127	Sutured trephine annular reinforcement technique (START)	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
11/YH/0435	Testosterone and glycaemic control in hypogonadal men. Version 1	22
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	
12/YH/0005	Subjects' satisfaction on pan facial aesthetic enhancement	65	
Proportionate review applications for ethical review over 14 days timeline			
REC Reference	Application Short Title	Number of Days on Clock	
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
09/H1308/117/AM01	The Prevalence of Long QT Syndrome Gene Variants in SIDS	Substantial Amendment 1	36
Modified Amendments over 14 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
09/H1308/21/AM04/1	Validation of ePAQ-HM: An electronic Personal Assessment Questionnaire	Modified 29 March 2011	15
Section 30 application over 60 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock