

**NRES Committee South Central -
Portsmouth**

Annual Report

01 April 2011 – 31 March 2012

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee South Central - Portsmouth
Type of REC:	Authorised REC
Type of Flag:	Research involving Children
Chair:	Dr Chris Markham
Vice-Chair:	Mrs Jayne Tyler
Alternate Vice-Chair:	n/a
Co-ordinator:	Mrs Ruth Avery
PRSC Co-ordinator:	Mrs Ruth Avery
Assistant Co-ordinator:	Mr Thomas Fairman
Committee Address:	Bristol Research Ethics Centre Level 3, Block B Whitefriars Lewins Mead Bristol BS1 2NT
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Chair's overview of the past year:

Having joined the committee in August 2011, it has been very rewarding and gratifying to work with.

During this time the committee increased its membership, welcoming a number of pleasant, competent and professional individuals to help support our work. Also, we have seen the introduction of Proportionate Review (PR) and the changes to GafREC. These have brought with them new challenges and learning opportunities, which the committee has responded to admirably and we hope has facilitated the research reviewed in the new ways.

We have also said goodbye to both members and staff supporting us from NRES and wish them very well in the future. Of course, the staff departures have led to new team members within the office, in particular Tom Fairman who has been extremely helpful and supportive and we look forward to working with him and other colleagues over the next year.

This report of the committee's activity demonstrates the commitment, hard work and effectiveness of the committee. It is encouraging to see good attendance at meetings, 5 PRs and a commitment to personal development and training. We look forward to continuing to develop as a committee and supporting the work of NRES and research in Health and Social Care.

NRES Committee South Central - Portsmouth Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mr Paul Andersen	Broadcaster	Lay Plus	01/03/2004	
Dr Ronja Bahadori	Clinical Trial Coordinator	Expert	01/06/2011	15/12/2011
Mrs Ita Berry	Retired Clinical Psychologist	Lay	01/03/2011	
Mrs. Alison Bowser	Patient and Public Involvement Officer	Lay	01/09/2011	
Mr David Carpenter	Social Scientist	Expert	22/09/2000	01/09/2011
Dr Diane Carpenter	Academic Group Lead (Mental Health)	Expert	01/09/2011	
Mr. Mark Cassidy	Lecturer in Radiography	Expert	01/09/2011	
Dr Fiona Cowdell	Research Fellow and Practice Development Consultant	Expert	01/04/2011	20/05/2011
Mrs Angela Iveson	Oncology Research Nurse	Expert	28/02/2010	
Mr Geoff Lowndes	Chartered Engineer - Retired	Lay Plus	01/02/2010	
Dr Chris Markham	Senior Lecturer - Speech and Language Therapy	Expert	24/08/2011	
Dr. Ian McAndrew	Independent EU Consultant/Lecturer	Lay	01/08/2011	
Dr Pradeep Moonot	SpR Trauma & Orthopaedics	Expert	02/03/2009	23/08/2011
Dr Lynne Oldman	SpR Child & Adolescent Psychiatry	Expert	13/03/2008	23/08/2011
Dr Arumugam Ravindrane	Consultant Physician	Expert	01/06/2005	19/08/2011
Mr. Steve Rose	Senior Staff Nurse/Research Nurse	Expert	01/09/2011	
Dr. Mary Saunders	Senior Lecturer	Expert	01/08/2011	
Dr. Andrew Scott	Course Leader, M.Sc. Clinical Exercise Science	Expert	01/08/2011	
Mrs Jayne Tyler	Senior Fire Control Operator	Lay Plus	01/03/2004	
Dr Marcus White	Lecturer	Lay	01/06/2003	23/08/2011

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Dr Simon Kolstoe	Academic Research Scientist/Vice-Chair	Expert	01/07/2011

Member Bank

Name	Occupation	Expert or Lay	Meeting date attended

NRES Committee South Central - Portsmouth: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Dr Chris Markham	Health Service Researcher	20/01/2012
Mrs Jayne Tyler	None	24/01/2012
Mr Paul Andersen	None	10/01/2012
Mrs Angela Iveson	Oncology Research Nurse for Salisbury NHS Foundation Trust	16/01/2012
Mr Geoff Lowndes	None	19/01/2012
Mrs Ita Berry	None	15/01/2012
Dr. Ian McAndrew	None	08/08/2011
Dr. Mary Saunders	None	15/01/2012
Dr. Andrew Scott	None	18/01/2012
Dr Diane Carpenter	None	06/09/2011
Mr. Mark Cassidy	University of Portsmouth School of Health Sciences and Social work Research Ethics Committee	13/02/2012
Mr. Steve Rose	None	04/02/2012
Mrs. Alison Bowser	None	07/09/2011

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

Month	Date	Number of Members Present at Meeting
May	20/05/2011	8
July	22/07/2011	8
August	19/08/2011	9
September	23/09/2011	12
November	18/11/2011	9
January	20/01/2012	13
February	24/02/2012	10
March	23/03/2012	9

8 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
October	10/10/2011	3
November	14/11/2011	3
February	02/02/2012	3
March	05/03/2012	3
March	16/03/2012	3

5 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
Mrs Ita Berry	8
Mrs Jayne Tyler	8
Mr Geoff Lowndes	7
Dr. Mary Saunders	6
Dr Chris Markham	6
Mrs Angela Iveson	6
Mr Paul Andersen	5
Mr. Mark Cassidy	5
Mr. Steve Rose	4
Mrs. Alison Bowser	4
Dr. Andrew Scott	4
Dr. Ian McAndrew	4
Dr Diane Carpenter	3
Mr David Carpenter	3
Dr Arumugam Ravindrane	2
Dr Fiona Cowdell	1
Dr Ronja Bahadori	1
Dr Simon Kolstoe	1

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 Chris Markham	5
Mrs Jayne Tyler	4
Ms Diane Carpenter	2
Dr. Ian McAndrew	1
Mr Geoff Lowndes	1
Mrs Angela Iveson	1
Mrs Ita Berry	1

Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Mrs Jayne Tyler	06/12/2011 - 06/12/2011	NRES Chairs National Training Day, NRES
Dr. Ian McAndrew	01/09/2011 - 01/09/2011	Induction DVD, NRES
Dr. Mary Saunders	01/09/2011 - 01/09/2011	Induction CD, NRES
Dr. Andrew Scott	01/09/2011 - 01/09/2011	Induction CD, NRES
Dr Diane Carpenter	01/09/2011 - 01/09/2011	Induction CD, NRES
Mr. Mark Cassidy	01/09/2011 - 01/09/2011	Induction CD, NRES
Mr. Steve Rose	01/09/2011 - 01/09/2011	Induction CD, NRES
Mrs. Alison Bowser	01/09/2011 - 01/09/2011	Induction CD, NRES
Mrs Angela Iveson	17/10/2011 - 17/10/2011	Good Clinical Practice (GCP) Refresher, NIHR
Mrs Angela Iveson	20/09/2011 - 20/09/2011	Equality & Diversity, NHS
Dr. Mary Saunders	14/03/2012 - 14/03/2012	Members national training day, NRES
Mr. Steve Rose	20/03/2012 - 20/03/2012	Induction, NRES
Mrs Ita Berry	14/03/2012 - 14/03/2012	Members national Training Day, NRES
Dr Diane Carpenter	10/01/2012 - 10/01/2012	Induction, NRES
Dr Chris Markham	08/02/2012 – 08/02/2012	Feasibility Studies Away Day
Dr Chris Markham	01/05/2011 – 01/05/2011	Patient and Public Involvement in Research Study Day
Dr Chris Markham	25/01/2012 – 25/01/2012	University of Portsmouth Research Conference
Dr Chris Markham	09/08/2011 – 10/08/2011	MCA DVD
Mrs Jayne Tyler	20/01/2012 - 20/01/2012	Shared Ethical Debate, NRES
Mr. Mark Cassidy	20/01/2012 - 20/01/2012	Shared Ethical Debate, NRES
Mr. Steve Rose	20/01/2012 - 20/01/2012	Shared Ethical Debate, NRES
Mrs. Alison Bowser	20/01/2012 - 20/01/2012	Shared Ethical Debate, NRES
Mr Paul Andersen	20/01/2012 - 20/01/2012	Shared Ethical Debate, NRES
Mr Geoff Lowndes	20/01/2012 - 20/01/2012	Shared Ethical Debate, NRES
Mrs Angela Iveson	20/01/2012 - 20/01/2012	Shared Ethical Debate, NRES
Mrs Ita Berry	20/01/2012 - 20/01/2012	Shared Ethical Debate, NRES
Dr. Ian McAndrew	20/01/2012 - 20/01/2012	Shared Ethical Debate, NRES
Dr. Mary Saunders	20/01/2012 - 20/01/2012	Shared Ethical Debate, NRES
Dr Diane Carpenter	20/01/2012 - 20/01/2012	Shared Ethical Debate, NRES
Dr. Andrew Scott	20/01/2012 - 20/01/2012	Shared Ethical Debate, 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	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	43	100.00
Total Applications Reviewed	43	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	4
Number of studies withdrawn prior to the meeting	8
Number of student applications reviewed	19
Number of paediatric applications reviewed	3
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	4	9.30
Favourable Opinion with Additional Conditions	3	6.98
Unfavourable Opinion	1	2.33
Provisional Opinion	35	81.40
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	43	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	62.79
Further Information Favourable Opinion with Additional Conditions	4	9.30
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	4	9.30
Favourable Opinion with Additional Conditions	3	6.98
Unfavourable Opinion	1	2.33
Provisional Opinion	3	6.98
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	1	2.33
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	43	100

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

Total Applications Reviewed	12
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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	5	41.67
Favourable Opinion with Additional Conditions	2	16.67
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	5	41.67
Unfavourable Opinion	0	0.00
Total	12	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.38
Number of applications for full ethical review over 60 days	1
Number of applications over 60 days as a % of total	2.33%
Number of days taken to final decision - average	37
Number of days taken to final decision - mode	40
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	28
Number of substantial amendments over 35 days	1
Number of substantial amendments over 35 days as a % of total substantial amendments	3.6%
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	1
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*	3
Number of proportionate review applications over 14 days as a % of total	25.00%

***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/SC/0188	How young type 1 diabetics engage with technology to influence QOL v1	31
11/SC/0193	Women's experiences of student midwife caseloading (1)	32
11/SC/0194	WEIGHTED Study version 2.1	42
11/SC/0196	Measurement of epidural pressures in parturients - version 1.0	26
11/SC/0199	Rolling versus non-rolling of patients during CT urography	56
11/SC/0248	Inflammatory response after sclerotherapy and radiofrequency	48
11/SC/0280	Factors contributing to non concordance of young people on dialysis	31
11/SC/0287	Analysis of adipose tissue DNA methylation profiles in Breast Ca	47
11/SC/0291	Towards a New Clinical Protocol for Tuning Cochlear Implants v2.0	51
11/SC/0316	E-learning for structured Type 1 diabetes education	34
11/SC/0317	Head and neck skin malignancy	25
11/SC/0333	Daily hassles and cortisol in Multiple Sclerosis (Version 1)	48
11/SC/0337	The scarring process in patients on peritoneal dialysis	64
11/SC/0338	Experience and needs of families during end of life care	56
11/SC/0343	Incidental Findings (IFs) from genetic tests	49
11/SC/0344	What are the Interprofessional Skills required for team working	50
11/SC/0391	Comparison of Preschool Parenting Interventions (COPPI) Trial (V1)	35
11/SC/0401	Using tDCS in children with numerical difficulties	41
11/SC/0405	Trial of WiiTM in STroke - TWIST	42
11/SC/0407	Psycho education in Forensic Setting (version 1) A qualitative enquiry	43
11/SC/0465	Exploring the lived experience of phantom bladder syndrome (PBS)	31
11/SC/0501	Low desire-Couples'distinct views on Hypoactive sexual desire disorder	33
11/SC/0502	Young mothers' views of breastfeeding support from professionals	26
12/SC/0041	The effectiveness of methylprednisolone in the treatment of MN - V3	39
12/SC/0057	Adaptation and validation of CNQ-YP for use in children	40
12/SC/0083	Qualitative interviews with NMIBC patients: v1.0	13
12/SC/0088	Built environment in acute care for older people - Version 02	14
12/SC/0112	Frequent HbA1c study	38
12/SC/0115	ICoS (Inflammation, Cogntion, and Stress) Version 1.0	40
12/SC/0117	Human biomarkers of nausea and Version 6.0	35

12/SC/0157	The Rasch analysis of the BRIEF Questionnaire	20
12/SC/0159	Joint specialty renal genetic clinic	20

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/SC/0484	Neuroimmunological and Cognitive Factors in Anxiety (Version 1)	38
11/SC/0490	Early Fluid Resuscitation in Acute Pancreatitis (EFRA)	40
12/SC/0048	Effects on health following collapse during marathon running	16
12/SC/0107	EAST: Early treatment of AF for Stroke prevention Trial: 09-Dec-2011	49

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/SC/0144	To Sit or to Stand? Ultrasound and Needle Placement - 2011	27
11/SC/0202	Extended follow-up of three occupational cohorts	40
11/SC/0276	A user evaluation of Unifine Pentips diabetes pen needles	28
11/SC/0396	Molecular markers of prognosis in endocrine cancers	28
11/SC/0456	PR: Community Stroke Reviews (v.1)	10
11/SC/0457	PR: Group Intervention for Trauma Related Nightmares	7
11/SC/0500	3D Surface Imaging in Maxillofacial Prosthodontics v1	8
12/SC/0080	Orofacial Clefts and Associated Malformations	6
12/SC/0161	The relationship between femoral head strength and shaft strength	13

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/SC/0301	Patients' Perspectives of Insomnia	21
11/SC/0314	What do GPs think and feel about DNACPR decisions for dying patients?	23
11/SC/0504	Exploring the health information needs of sarcoma patients	11
12/SC/0113	Norovirus Longitudinal Pilot Study to study evolution	27
12/SC/0158	Retrospective Lung Resection Translational Study	13

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/SC/0129	Exploring the lived experience of phantom bladder syndrome (PBS)	19

Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
12/SC/0148	Post-operative satisfaction following elective amputation	N/A
12/SC/0166	Preoperative pancreatic enzyme supplementation in Whipple's procedure	N/A
12/SC/0167	Experiencing Breech Diagnosis:women's perception of choice and support	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
12/SC/0147	Non-contact sensors to detect the human fetal electrocardiogram	N/A

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
11/SC/0337	The scarring process in patients on peritoneal dialysis	64

Proportionate review applications for ethical review over 14 days timeline		
REC Reference	Application Short Title	Number of Days on Clock
11/SC/0502	Young mothers' views of breastfeeding support from professionals	26
12/SC/0157	The Rasch analysis of the BRIEF Questionnaire	20
12/SC/0159	Joint specialty renal genetic clinic	20

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
8/2/1394/AM03	Casemix adjusted predictive models of adverse clinical outcomes	Amendment 3, 22 December 2011	57

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