

**NRES Committee South West -  
Southmead**

**Annual Report**

**01 April 2011 – 31 March 2012**

## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	NRES Committee South West - Southmead
<b>Type of REC:</b>	Authorised REC
<b>Type of Flag:</b>	None
<b>Chair:</b>	(Acting) Pam Cairns
<b>Vice-Chair:</b>	(Acting) Margrid Schindler
<b>Alternate Vice-Chair:</b>	None
<b>Co-ordinator:</b>	Naaz Nathoo
<b>PRSC Co-ordinator:</b>	Naaz Nathoo
<b>Assistant Co-ordinator:</b>	Ms. Mindy Kaur
<b>Committee Address:</b>	Whitefriars Level 3, Block B Lewin's Mead Bristol BS1 2NT
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### Chair's overview of the past year:

The Committee was suspended from full REC meetings in October 2011 and merged with the NRES South West Central Bristol REC on 31/3/12.

## NRES Committee South West - Southmead Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Miss Danielle Baker	Lab Technician	Lay	01/05/2011	
Dr Kay Barnard	Lay Member	Expert	01/04/2011	
Rev Alastair Davies	Clergy - Snr. Chaplain	Lay Plus	01/08/2010	09/03/2012
Mrs Rachel Fielding	Deputy Director of Midwifery	Expert	22/08/2006	30/03/2012
Mrs Christine Fowler	Lay member	Lay	01/08/2007	
Miss Mumtaz Goolam		Expert	20/11/2007	12/05/2011
Mr Daniel Hajioff	Consultant ENT Surgeon	Expert	01/10/2008	18/05/2011
Mr Geoffrey Jones	Lay member	Lay Plus	01/10/2003	
Dr Ruth Morse	Senior Lecturer in Molecular Biomedicine	Expert	01/04/2012	
Dr Sam O'Hare	Neonatal Registrar	Expert	01/04/2012	
Miss Sylvia Pearson	Senior trial Co-ordinator	Lay	20/10/2010	
Dr Lucy Swithinbank	Associate Specialist - Urodynamic Unit	Expert	25/04/2005	18/05/2011
Mrs Joan Wadsley	Lay member	Lay Plus	16/06/2008	19/05/2011

### Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended

### Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Cannon Ian Ainsworth-Smith	Retired Hospital Chaplain	Lay Plus	21/09/2011 and 17/08/2011
Mrs Suzanne Blowey	Clinical Nurse Specialist	Expert	21/09/2011
Dr Pamela Cairns	Consultant Neonatologist	Expert	20/07/2011
Dr Robert Beetham	Retired Consultant Clinical Biochemist	Expert	20/07/2011
Dr Mike Shere	Associate Breast Specialist.	Expert	20/04/2011 and 18/05/2011
Mr Chris Foy	Medical Statistician	Expert	20/07/2011
Dr Margrid Schindler	Consultant Senior Lecturer	Expert	17/08/2011
Katrina Glaister	Clinical Effectiveness Facilitator	Lay	20/07/2011
Mrs Angela Clarke	(Ex-social worker)	Lay Plus	17/08/2011
Mr Stephen Draper	Retired Headteacher	Lay Plus	01/04/2011
Mrs Kate McMahon-Parkes	Senior Lecturer in Adult Nursing	Expert	15/06/2011

**Member Bank**

<b>Name</b>	<b>Occupation</b>	<b>Expert or Lay</b>	<b>Meeting date attended</b>

**NRES Committee South West - Southmead: Members' Declarations of Interest:**

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Mrs Angela Clarke	NIL	18/08/2011
Dr Margrid Schindler	Nil	28/03/2012
Dr Robert Beetham	Nil	01/12/2011
Mrs Kate McMahon-Parkes	Nil	01/12/2011
Mr Stephen Draper	Nil	01/12/2011
Dr Ruth Morse	Nil	01/12/2011

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

<b>Month</b>	<b>Date</b>	<b>Number of Members Present at Meeting</b>
April	20/04/2011	8
May	18/05/2011	8
June	15/06/2011	7
July	20/07/2011	9
August	17/08/2011	9
September	21/09/2011	7

6 full committee meetings were held during the reporting period.

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

<b>Month</b>	<b>Date</b>	<b>Number of Members Present at Meeting</b>
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0 proportionate review sub-committee meetings were held during the reporting period.

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Kay Barnard	6
Mrs Rachel Fielding	5
Rev Alastair Davies	4
Dr Ruth Morse	4
Dr Sam O'Hare	4
Miss Danielle Baker	4
Miss Sylvia Pearson	3
Dr Mike Shere	2
Mrs Joan Wadsley	2
Cannon Ian Ainsworth-Smith	2
Mrs Kate McMahon-Parkes	1
Dr Pamela Cairns	1
Dr Robert Beetham	1
Dr Lucy Swithinbank	1
Dr Margrid Schindler	1
Katrina Glaister	1
Mr Chris Foy	1
Mr Daniel Hajioff	1
Mr Geoffrey Jones	1
Mr Stephen Draper	1
Mrs Angela Clarke	1
Mrs Suzanne Blowey	1

**Number of inquorate meetings held: 0**

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

<b>Name</b>	<b>Number of Meetings Attended</b>
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**Training 01 April 2011 – 31 March 2012:**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Miss Danielle Baker	04/10/2011 - 04/01/2011	Induction, NRES
Mr Geoffrey Jones	07/07/2011 - 07/07/2011	Equality & Diversity, Core Learning Unit
Miss Sylvia Pearson	04/10/2011 - 04/10/2011	Induction, NRES
Dr Ruth Morse	04/10/2011 - 04/10/2011	Induction, NRES
Mr Geoffrey Jones	22/11/2011 - 22/11/2011	ALC/research in emergency situations, NRES
Miss Danielle Baker	18/10/2011 - 18/10/2011	A research ethics syllabus for REC members CD/DVD, NRES
Dr Ruth Morse	18/10/2011 - 18/10/2011	A research ethics syllabus for REC members CD/DVD, NRES
Dr Kay Barnard	18/10/2011 - 18/10/2011	A research ethics syllabus for REC members CD/DVD, NRES
Miss Sylvia Pearson	18/10/2011 - 18/10/2011	A research ethics syllabus for REC members CD/DVD, NRES
Dr Sam O'Hare	18/10/2011 - 18/10/2011	A research ethics syllabus for REC members CD/DVD, NRES
Dr Ruth Morse	15/09/2011 - 15/09/2011	Human tissue Act, NRES
Dr Kay Barnard	10/01/2012 - 10/01/2012	Induction, 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:**

<b>Applications for full ethical review – Study Type</b>	<b>Number</b>	<b>%</b>
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	42	100.00
<b>Total Applications Reviewed</b>	<b>42</b>	<b>100</b>

**Table 2: Other REC activity during the reporting period:**

Number of applications made invalid by co-ordinator	2
Number of studies withdrawn prior to the meeting	7
Number of student applications reviewed	16
Number of paediatric applications reviewed	6
Number of device applications reviewed	0
Number of prisoner applications reviewed	1
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:**

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	6	14.29
Favourable Opinion with Additional Conditions	1	2.38
Unfavourable Opinion	1	2.38
Provisional Opinion	34	80.95
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
<b>Total</b>	<b>42</b>	<b>100</b>
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:**

<b>Status of applications at date of generation of report</b>	<b>Number</b>	<b>%</b>
Further Information Favourable Opinion with Standard Conditions	34	80.95
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	6	14.29
Favourable Opinion with Additional Conditions	1	2.38
Unfavourable Opinion	1	2.38
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	0	0.00
Number of studies withdrawn after the meeting	0	0.00
<b>Total</b>	<b>42</b>	<b>100</b>

**Table 5: Other Management Information for the reporting period:**

<b>Average number of applications reviewed per full meeting</b>	7.00
<b>Number of applications for full ethical review over 60 days</b>	3
<b>Number of applications over 60 days as a % of total</b>	7.14%
<b>Number of days taken to final decision - average</b>	41
<b>Number of days taken to final decision - mode</b>	58
<b>Number of SSAs (non-Phase 1) reviewed</b>	0
<b>Number of applications for SSA review over 25 days</b>	0
<b>Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)</b>	0%
<b>Number of SSAs (Phase 1) reviewed</b>	0
<b>Number of applications for SSA review over 14 days</b>	0
<b>Number of applications for SSA review over 14 days as % of all Phase 1 (SSAs)</b>	0%
<b>Number of substantial amendments reviewed</b>	59
<b>Number of substantial amendments over 35 days</b>	0
<b>Number of substantial amendments over 35 days as a % of total substantial amendments</b>	0.0%
<b>Number of Section 30 applications reviewed</b>	0
<b>Number of Section 30 applications over 60 days</b>	0
<b>Number of Section 30 applications over 60 days as a % of total Section 30 applications</b>	0%
<b>Number of modified amendments reviewed</b>	2
<b>Number of modified amendments over 14 days</b>	0
<b>Number of modified amendments over 14 days as a % of total modified amendments</b>	0.0%
<b>Number of proportionate review applications for ethical review over 14 days*</b>	0
<b>Number of proportionate review applications over 14 days as a % of total</b>	0%

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

**Table 6: Breakdown of current status of all applications reviewed within the reporting period:**

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/SW/0053	Facilitating Activity and Self-management in Arthritis	85
11/SW/0055	PIVOT	27
11/SW/0056	Spiral study	34
11/SW/0064	The patients' experience of a bowel cancer diagnosis through the BCSP	35
11/SW/0067	Exploring the experiences of the patient tutor	53
11/SW/0068	Characterising pain in medical inpatients (V.16)	21
11/SW/0078	Intravenous and subcutaneous microdialysis of free cortisol	57
11/SW/0080	Experience of Cancer Professionals as they care for family with Cancer	54
11/SW/0081	Experience of the relationship between family & staff after suicide	43
11/SW/0087	Tongue Tie and Frenotomy a feasibility RCT	28
11/SW/0097	Mothers who experience physical assault by their children 1	35
11/SW/0101	VOC profile during anaesthesia	24
11/SW/0105	Staff Perspectives of Teenage Brain Injury Behaviour at the RNHRD	32
11/SW/0109	A DISEASE SPECIFIC QUALITY OF LIFE MEASURE FOR CHILDREN WITH UVEITIS	22
11/SW/0122	THERMIC-2: Normothermic v Hypothermic Perfusion in Paediatric CPB v1.0	47
11/SW/0126	Reducing stress and improving restorative opportunities for ED staff	52
11/SW/0129	Assessing and Improving the Quality of CPR using feedback device	39
11/SW/0157	Saline Brisement - treatment for Achilles tendinopathy	40
11/SW/0169	Emotion processing from faces following childhood brain injury.	37
11/SW/0170	WHEN CAN I GO BACK TO DRIVING DOCTOR (version number: 1.1.4.2011	34
11/SW/0176	Nurses' exploration of existential concerns with cancer patients	47
11/SW/0181	Qualitative evaluation of how ward managers are developed as leaders	44
11/SW/0182	Assessment of cutaneous sensory loss after knee arthroplasty	33
11/SW/0186	The first BCVC nasal flu vaccine study. Version 2.6	70
11/SW/0192	CIAT in an outpatient service version 1	58
11/SW/0193	Metabolic and immune system responses to a mixed meal	33
11/SW/0197	Chest Pain feasibility study V2	56
11/SW/0201	Ubuntu and its influence on leadership style.	46

11/SW/0202	Pulsed glucocorticoid replacement therapy (1)	57
11/SW/0207	Hypertension, brain blood flow and nerve activity	58
11/SW/0226	A study investigating four colour-coded risk identification system	59
11/SW/0227	UKOSS: Pregnancy in women with a gastric band	58
11/SW/0228	Child Talk - What Works (Phase 1)	54
11/SW/0236	Stool specimens: Finding out how to make collection easier	62

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
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#### 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/SW/0057	Cytological features associated with CIN2+ in BC/HPV+ LBC samples.	20
11/SW/0127	Biomarkers in breast cancer.	31
11/SW/0174	Cognitive testing in dementia and mild cognitive impairment	19
11/SW/0180	Survey of Obstetricians Mode of Delivery Preferences in the South West	19
11/SW/0230	Vascular endothelial cell growth factor (VEGF) in lung disease	50
11/SW/0235	ESBL producing coliforms in bowel cancer screening cards - Pilot study	28

#### Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/SW/0203	Pharmaceutical Services in Pharmacies and Dispensing Doctor Practices	30

#### Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/SW/0131	Cushings mechanism and sympathetic activity in human hypertension V1	29

#### Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
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#### 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 7: Items exceeding timelines:**

<b>Full applications for ethical review over 60 day timeline</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/SW/0053	Facilitating Activity and Self-management in Arthritis	85
11/SW/0186	The first BCVC nasal flu vaccine study. Version 2.6	70
11/SW/0236	Stool specimens: Finding out how to make collection easier	62

<b>Proportionate review applications for ethical review over 14 days timeline</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

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

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

<b>Substantial Amendments over 35 day timeline</b>			
<b>Amendment Reference</b>	<b>Application Short Title</b>	<b>Amendment Title</b>	<b>Number of Days on Clock</b>

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

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