

**NRES Committee South West -
Central Bristol**

Annual Report

01 April 2011 – 31 March 2012

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee South West - Central Bristol
Type of REC:	RECs recognised to review CTIMPS in patients - type iii
Type of Flag:	Establishing Research Tissue Banks Establishing Research Databases IRB Registered Research Involving Children
Chair:	Dr Pamela Cairns
Vice-Chair:	Dr Margrid Schindler
Alternate Vice-Char:	Mr Trevor Beswick (from 16 Dec 2011)
Co-ordinator:	Mrs Naazneen Nathoo
PRSC Co-ordinator:	Miss Mindy Kaur
Assistant Co-ordinator:	Miss Mindy Kaur
Committee Address:	Whitefriars Level 3, Block B Lewin's Mead Bristol BS1 2NT Email: ubh-tr.SouthWest3@nhs.net
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Chair's overview of the past year:

This was a busy year for the South West Central Bristol Committee. Three members resigned from the Committee due to other commitments after a number of years of valuable service. We were fortunate to have four new members join us and their skills have enhanced the Committee. We have successfully introduced proportionate review, absorbed on-going work from adjacent Committees which have closed and we were happy to gain full accreditation. We look forward to the next year with more new members transferring from other Committees.

NRES Committee South West - Central Bristol Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mr Trevor Beswick	Director - SW Medicines, Information & Training	Expert	20/02/2009	
Dr Pamela Cairns	Consultant Neonatologist	Expert	01/12/2006	
Mrs Angela Clarke	(Ex-social worker)	Lay Plus	01/03/2003	
Dr Simon Croxson	Consultant Physician	Expert	11/02/2008	
Dr Ian Davies	Consultant in Cardiac Anaesthesia & Intensive Care	Expert	01/05/2011	
Dr Michael Halliwell	Medical Physicist (retired)	Lay	01/01/2006	
Ms Patsy Hudson	Coach/Mentor	Lay Plus	03/08/2009	
Mr John Judges	Lay Member (Insurance/audit)	Lay Plus	17/02/2003	
Rev Veronica Lee	Chaplain - Lay Member	Lay Plus	14/11/2007	31/12/2011
Mr Paul Lewis	Patient Involvement Coordinator	Lay	01/05/2011	
Dr Jane Meyrick	Snr. Lecturer in Health Psychology	Expert	27/07/2005	12/04/2011
Mr Andrew Monk	Assistant Director of Charity	Lay	03/08/2009	21/06/2011
Dr Pauline Primrose	General Practitioner	Expert	01/06/2004	
Mr Russell Richards	Ex-school governor	Lay Plus	01/05/2011	
Dr Margrid Schindler	Consultant Senior Lecturer	Expert	06/03/2007	
Dr Robert Tulloh	Consultant Paediatric Cardiologist	Expert	16/06/2011	

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended
Mr Stephen Brown	Director of Pharmacy	Expert	06/05/2004

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended

Member Bank

Name	Occupation	Expert or Lay	Meeting date attended

NRES Committee South West - Central Bristol: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Mr John Judges	NIL	18/08/2011
Dr Robert Tulloh	RECEIVED EDUCATIONAL GRANTS FROM ABBOTT, MEDIMMUNE, PFIZER, GSK, ENCYSINE.	18/08/2011
Mr Russell Richards	NIL	18/08/2011
Dr Ian Davies	NIL	18/08/2011
Mr Paul Lewis	Work in Patient & Public involvement regularly brings him into contact with clinical staff who may also be researchers. Would declare this at full REC meeting if applicable.	23/03/2012
Mrs Angela Clarke	NIL	18/08/2011
Dr Pamela Cairns	NIL	18/08/2011
Mr Stephen Brown	NIL	18/08/2011
Dr Michael Halliwell	NIL	18/08/2011
Dr Margrid Schindler	NIL	28/03/2012
Dr Pauline Primrose	NIL	28/03/2012
Dr Simon Croxson	Has been a Committee member on British Geriatrics Society; Diabetes UK; Institute of Diabetes of Older People. "Probably been employed by or received research funding from every single drug company which has diabetes drugs. Full list available from Trust documentation"	28/03/2012
Mr Trevor Beswick	NIL	28/03/2012
Ms Patsy Hudson	NIL	28/03/2012

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

Month	Date	Number of Members Present at Meeting
May	27/05/2011	10
June	24/06/2011	12
July	22/07/2011	10
September	23/09/2011	12
October	21/10/2011	12
November	25/11/2011	11
December	16/12/2011	10
January	27/01/2012	11
February	24/02/2012	10
March	30/03/2012	8

10 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	13/01/2012	3
February	13/02/2012	3
March	19/03/2012	3

3 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
Mr John Judges	10
Mr Paul Lewis	9
Mr Russell Richards	9
Mrs Angela Clarke	9
Dr Margrid Schindler	8
Dr Michael Halliwell	7
Dr Pamela Cairns	7
Dr Pauline Primrose	7
Ms Patsy Hudson	7
Dr Simon Croxson	7
Mr Trevor Beswick	7
Rev Veronica Lee	6
Dr Ian Davies	5
Dr Robert Tulloh	5
Mr Stephen Brown	2
Dr Jane Meyrick	1

Number of inquorate meetings held: NIL

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

Name	Number of Meetings Attended
Dr Pamela Cairns	2
Dr Robert Tulloh	1
Mr John Judges	1
Mr Paul Lewis	1
Mr Russell Richards	1
Mr Trevor Beswick	1
Mrs Angela Clarke	1
Dr Ian Davies	1

Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Dr Robert Tulloh	04/10/2011 - 04/10/2011	Induction, NRES
Mr Paul Lewis	04/10/2011 - 04/10/2011	Induction, NRES
Dr Pauline Primrose		'Diabetes Study Day, Bristol GP education
Mr John Judges	12/06/2011 - 12/06/2011	Equality & Diversity, Core Learning Unit
Mr Russell Richards	05/05/2011 - 05/05/2011	Equality & Diversity, NHS Core Learning Unit
Mr Trevor Beswick	06/05/2011 - 06/05/2011	In house training, SW - Central Bristol REC
Rev Veronica Lee	22/11/2011 - 22/11/2011	Adults Lacking Capacity (including research in emergency situations) workshop for RECs, NRES
Dr Margrid Schindler	06/05/2011 - 06/05/2011	In house training, Central Bristol REC
Mr Russell Richards	06/05/2011 - 06/05/2011	In house training, Central Bristol REC
Dr Pauline Primrose	06/05/2011 - 06/05/2011	In house training, Central Bristol REC
Mr Paul Lewis	06/05/2011 - 06/05/2011	In house training, Central Bristol REC
Ms Patsy Hudson	06/05/2011 - 06/05/2011	In house training, Central Bristol REC
Mrs Angela Clarke	06/05/2011 - 06/05/2011	in house training, Central Bristol REC
Dr Pamela Cairns	06/05/2011 - 06/05/2011	In house training, Central Bristol REC
Rev Veronica Lee	03/04/2011 - 03/04/2011	Equality & Diversity
Mr Russell Richards	27/09/2011 - 27/09/2011	Members and Mixed Audience Training - New Training Registration, NRES
Dr Pauline Primrose	27/09/2011 - 27/09/2011	Update session by Janet Wisely, NRES
Mr Paul Lewis		A research ethics syllabus for REC members CD/DVD
Dr Robert Tulloh		A research ethics syllabus for REC members CD/DVD
Mr Russell Richards		A research ethics syllabus for REC members CD/DVD
Mr Russell Richards	27/09/2011 - 27/09/2011	Update session by Janet Wisely
Mr Russell Richards	20/03/2012 - 20/03/2012	Induction, NRES
Dr Ian Davies	05/09/2011 - 05/09/2011	Equality & Diversity
Dr Pauline Primrose	24/01/2012 - 24/01/2012	Adult/Child/Infant Basic Life Support + Defibrillation Training
Mr Trevor Beswick	29/02/2012 - 29/02/2012	NRES Personal Data in Research, NRES

Dr Simon Croxson	15/11/2011 - 15/11/2011	Introduction to information governance, Dept of Health
Dr Simon Croxson	27/06/2011 - 27/06/2011	Educational Supervision, Severn Deanery
Dr Margrid Schindler	22/03/2012 - 22/03/2012	Good Clinical Practice, On-line
Dr Margrid Schindler	25/10/2011 - 25/10/2011	Ethical issues of Paediatric Organ donation
Dr Margrid Schindler	20/01/2012 - 20/01/2012	Child protection update
Dr Margrid Schindler	11/07/2011 - 11/07/2011	Equality & Diversity, On-line
Dr Pamela Cairns	16/12/2011 - 16/12/2011	MCA DVD, 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	18.03
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	1	1.64
Research Database	5	8.20
Others	44	72.13
Total Applications Reviewed	61	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	1
Number of studies withdrawn prior to the meeting	8
Number of student applications reviewed	20
Number of paediatric applications reviewed	11
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	10	16.39
Favourable Opinion with Additional Conditions	13	21.31
Unfavourable Opinion	4	6.56
Provisional Opinion	33	54.10
Invalid	1	1.64
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	61	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	25	40.98
Further Information Favourable Opinion with Additional Conditions	1	1.64
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	10	16.39
Favourable Opinion with Additional Conditions	13	21.31
Unfavourable Opinion	4	6.56
Provisional Opinion	6	9.84
Provisional Opinion Pending Consultation with Referee	0	0.00
Invalid	1	1.64
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	1	1.64
Total	61	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	2	16.67
Provisional Opinion	3	25.00
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	6.10
Number of applications for full ethical review over 60 days	1
Number of applications over 60 days as a % of total	1.64%
Number of days taken to final decision - average	33
Number of days taken to final decision - mode	27
Number of SSAs (non-Phase 1) reviewed	13
Number of applications for SSA review over 25 days	2
Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)	15.4%
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	83
Number of substantial amendments over 35 days	1
Number of substantial amendments over 35 days as a % of total substantial amendments	1.2%
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	10.00%

***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/SW/0106	GLIDE: Gastric band and Liraglutide Intervention in Diabetes Evolution	39
11/SW/0112	What is Revalidation in Practice? [version 1]	59
11/SW/0113	Fathers' beliefs about emotional support to child's self-harm. Version1	40
11/SW/0136	Sleep Disturbance and Learning in BECCTS	39
11/SW/0153	LLR Childhood Leukaemia Cell Bank	37
11/SW/0160	UK Multiple Sclerosis Register	56
11/SW/0178	Investigating a role for IGF-II in adipocyte regulation	46
11/SW/0209	Collaborative Neonatal Dataset (CONED) v1	43
11/SW/0249	Does a follow-up appointment help parents of children on PICU?	29
11/SW/0262	Liraglutide after Acute Stroke Trial (LAST).	30
11/SW/0269	Pilot Study - markers of reno-vascular ageing in COPD patients	30
11/SW/0273	Database of scarring in children following burns and scalds	60
11/SW/0276	Optimisation of GALT activity analysis by UPLC-MS/MS	51
11/SW/0302	Understanding immune and genetic factors in hepatitis C protection 1.0	45
11/SW/0304	Antibiotic prophylaxis timing in total knee replacement	43
11/SW/0318	MMR uptake in Somerset following the 2009 catch-up campaign	47
11/SW/0328	A new vaccine for babies which adds protection against hepatitis B	52
11/SW/0345	Bristol Bladder Trial	61
12/SW/0004	Role of hormone and genetic polymorphisms in prostate cancer	36
12/SW/0010	CoolXenon2 study	23
12/SW/0014	Pelvic girdle pain during pregnancy	49
12/SW/0018	Predicting individual health benefits to a novel exercise intervention	33
12/SW/0022	Does TOPAZ improves outcome after arthroscopic shoulder surgery ?	35
12/SW/0039	An investigation into enterocyte substrate utilization	7
12/SW/0043	Investigation of patients' perceptions of haemodialysis services	12
12/SW/0055	COCO90s Version 1.0	41
12/SW/0056	MEG and GABA receptor function in healthy volunteers	33

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock

11/SW/0139	Is it necessary to dilate the vagina after radiotherapy	39
12/SW/0041	Short term clinical outcomes in babies with cord pH \leq 7.10	37

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/0075	Multi-centre cardiac surgery and transfusion audit database	27
11/SW/0108	SUMO - surveillance of moderate dyskaryosis	21
11/SW/0132	Surveillance of Acute Pancreatitis in Children	28
11/SW/0143	STRATEGIES TO ATTENUATE RED CELL TRANSFUSION MEDIATED ORGAN INJURY	28
11/SW/0144	Patient perspectives of clinical trials v1.0 26/05/2011	28
11/SW/0179	Improving the Management of Stroke in Childhood (Parent Delphi)	34
11/SW/0224	Molecular Characterisation of AmpC Beta-lactamase Enzymes in E.coli	19
11/SW/0242	Evaluation of the BacT/ALERT System for the Culture of Tissue Samples	36
11/SW/0305	Development of a core outcome set for reconstructive breast surgery.	29
11/SW/0327	Learning about feet in rheumatoid arthritis	17
12/SW/0042	Paediatric phenotypes of Neurofibromatosis 2 - a surveillance study	6
12/SW/0063	Resilience After Stroke (1)	12
12/SW/0064	Breast cancer patients experiences of neo-adjuvant chemotherapy	12
12/SW/0098	Patient Experience of MRSA Screening and Decolonisation	8
12/SW/0101	Care giver experience in Huntington's disease – A feasibility study	8

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/SW/0110	ALSPAC Focus on Mothers 2 & 3. Version 1	23
11/SW/0138	Jun: InterferonSVR v1	28
11/SW/0140	Experiences of mental health service users in relation to stigma.v1	27
11/SW/0234	ReSPonD Study - Rivastigmine to Stabilise gait in Parkinson's Disease	27
11/SW/0241	Use of MBIR CT technique in oncological surveillance	27
11/SW/0245	What prevents young women attending for cervical screening	33
11/SW/0270	The experiences of patients undergoing blood transfusions in a hospice	25

11/SW/0278	OPERA study	23
11/SW/0309	EQUAL Pilot Study	29
11/SW/0313	Living with a Husband or Partner who has a Life-Limiting Illness	22
11/SW/0315	Improving the responses of health services to domestic violence part 2	25
12/SW/0015	VEGF165b and Infertility	21
12/SW/0065	Chronic back pain patients' beliefs and pain management methods v1	9
12/SW/0066	In vitro measurements of tooth wear using low abrasivity dentifrices.	12
12/SW/0087	Evaluation of a computer application for measuring body perception	28

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/SW/0175	Pilot Study - markers of reno-vascular ageing in COPD patients	27
11/SW/0239	A0081256-Chronic neuropathic low back pain-PINPOINT Study	25
11/SW/0240	Qualitative investigation of disinvestment from NHS procedures (v 1.0)	29
12/SW/0006	The prognostic significance of biomarkers in anaplastic glioma.	21

Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
12/SW/0047	Intermittent Bilateral GDNF for Parkinson's Disease	N/A
12/SW/0079	Hypothalamic-Pituitary-Adrenal Axis Ultradian Rhythm in Depression	N/A
12/SW/0084	Study of Intravitreal LFG316 in patients with multifocal choroiditis	N/A
12/SW/0096	GP Randomised Extended Action Triptorelin (GREAT study)- v1.0 11/01/12	N/A
12/SW/0102	In-vivo measurement of distal radio-ulnar joint translation	N/A
12/SW/0105	EQUIP v1	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
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Withdrawn after the meeting

REC Reference	Application Short Title	Number of Days on Clock
11/SW/0150	(duplicate) Radio frequency imaging of breast tissues	26

Invalid Application		
REC Reference	Application Short Title	Number of Days on Clock
11/SW/0111	Pilot Study Biological markers of reno-vascular aging in COPD patients	20

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	
11/SW/0345	Bristol Bladder Trial	61	

Proportionate review applications for ethical review over 14 days timeline		
REC Reference	Application Short Title	Number of Days on Clock
12/SW/0041	Short term clinical outcomes in babies with cord pH \leq 7.10	37

SSAs (non Phase 1) over 25 days timeline		
REC Reference	Application Short Title	Number of Days on Clock
11/SW/0314	Varenicline and Cognitive Bias Modification on Smoking Cue Response	29
12/SW/0027	Healthlines Study Randomised Controlled Trial	31

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
05/Q2001/5/AM03	Early ACTID Version 1	P/A 5 dated 21 July 2011	36

Modified Amendments over 14 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
11/SW/0043/AM01/1	The effects of rumination in mother-infant interactions	P/A 1 - modified	21

Section 30 application over 60 day timeline			
Amendment Referene	Application Short Title	Amendment Title	Number of Days on Clock