

National Research Ethics
Service


Health Research Authority

**NRES Committee South West -
Central Bristol**

Annual Report

01 April 2013 – 31 March 2014

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:	IRB Registered, Research Tissue Banks, Research Databases, Research Involving Children
Chair:	Dr Pamela Cairns
Vice-Chair:	Dr Margrid Schindler
Alternate Vice-Chair:	Mr Trevor Beswick
REC Manager:	Mrs Naazneen Nathoo
PRSC Manager:	Ms Georgina Castledine
REC Assistant:	Ms Lidia Gonzalez
Committee Address:	Bristol Research Ethics Committee Centre Whitefriars Level 3, Block B Lewin's Mead Bristol BS1 2NT
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Chair's overview of the past year:

The Central Bristol REC remains busy, dealing with full and PR applications. All sub-committee work is now handled via email.

A very useful training day for the membership was held in January 2014, which was also attended by members from the neighbouring Frenchay REC.

We bade farewell to a long-serving member who will be transferring to another REC, and gained a member from the Frenchay REC.

We look forward to welcoming additional new members to enhance our expertise.

NRES Committee South West - Central Bristol Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr Kay Barnard	Ex-research scientist	Lay	01/04/2012	
Dr Robert Beetham	Retired Consultant Clinical Biochemist	Lay	21/01/2014	31/01/2014
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	10/06/2004	
Dr Simon Crosson	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	
Mr Geoffrey Jones	Retired Solicitor	Lay	04/04/2012	28/04/2014
Dr Adrian Kendrick	Clinical Scientist	Expert	15/01/2013	
Mr Paul Lewis	Patient Involvement Coordinator	Lay	01/05/2011	
Miss Sylvia Pearson	Senior Clinical Trials Coordinator	Lay	01/04/2012	10/12/2013
Mr Brian Pixton	Retired solicitor	Lay Plus	11/03/2013	
Dr Colette Reid	Consultant in Palliative Care	Expert	01/08/2013	
Dr Margrid Schindler	Consultant Senior Lecturer	Expert	06/03/2007	

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended
Mr Stephen Brown	Pharmacist	Expert	None

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

Name	Declaration of Interest	Date
Dr Kay Barnard	None	31/03/2014
Dr Margrid Schindler	None	31/03/2014
Mrs Angela Clarke	None	31/03/2014
Dr Robert Beetham	Shareholding in Smith & Nephew plc	27/02/2014
Mr Trevor Beswick	None	28/03/2014
Dr Pamela Cairns	Occasional peer review grants and research papers	13 /12/ 2012
Dr Simon Croxson	Consultant to several pharmaceutical companies	31/03/2014
Dr Ian Davies	None	28/03/2014
Dr Michael Halliwell	None	21/03/2014
Mr Geoffrey Jones	Lay member on UoB Faculty of Medicine & Dentistry Ethics Committee	28/03/2014
Dr Adrian Kendrick	Member of Assoc. of Respiratory Technology & Research Committee. Reviewer of NIHR/I4I research applications (as requested), Wellcome Grants and BLF.	31/03/2014
Mr Paul Lewis	None	31/03/2014
Miss Sylvia Pearson	None	
Mr Brian Pixton	None	31/03/2014
Dr Colette Reid	None	28/03/2014

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

Month	Date	Number of Members Present at Meeting
April	26/04/2013	12
May	31/05/2013	10
June	28/06/2013	12
July	26/07/2013	10
September	20/09/2013	9
October	18/10/2013	9
November	15/11/2013	10
December	13/12/2013	11
February	28/02/2014	10
March	28/03/2014	11

10 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	18/06/2013	3
July	15/07/2013	3
October	04/10/2013	3
November	04/11/2013	3
December	02/12/2013	3
January	20/01/2014	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
Mr Brian Pixton	10
Mrs Angela Clarke	10
Dr Adrian Kendrick	9
Dr Kay Barnard	9
Dr Simon Crosson	8
Mr Paul Lewis	8
Mr Trevor Beswick	7
Mr Geoffrey Jones	7
Dr Pamela Cairns	7
Dr Margrid Schindler	7
Dr Michael Halliwell	6
Dr Ian Davies	6
Miss Sylvia Pearson	5
Dr Colette Reid	3
Dr Robert Beetham	2

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
Mr Brian Pixton	5
Dr Pamela Cairns	3
Miss Sylvia Pearson	2
Dr Kay Barnard	2
Mr Paul Lewis	2
Mr Trevor Beswick	1
Mrs Angela Clarke	1
Dr Margrid Schindler	1
Dr Michael Halliwell	1
Dr Adrian Kendrick	1
Dr Colette Reid	1
Mr Geoffrey Jones	1

Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Dr Adrian Kendrick	04/07/2013 - 04/07/2013	NRES Committee Members Induction, NRES
Dr Michael Halliwell	20/08/2013 - 20/08/2013	Berkshire REC training day, Berkshire REC, NRES
Mr Brian Pixton	23/04/2013 - 23/04/2013	Induction, NRES
Mr Brian Pixton	20/06/2013 - 20/06/2013	Equality & Diversity, NRES
Dr Ian Davies	19/02/2014 - 19/02/2014	Reviewing CTIMPs, HRA
Dr Pamela Cairns (Chair)	31/01/2014 - 31/01/2014	Philosophical Research Ethics/ethical challenges/Declaration of Helsinki, (Central Bristol REC Training Day, NRES)
Dr Margrid Schindler (V-C)	31/01/2014 - 31/01/2014	Philosophical Research Ethics/ethical challenges/Declaration of Helsinki, (Central Bristol REC Training Day, NRES)
Mrs Angela Clarke	31/01/2014 - 31/01/2014	Philosophical Research Ethics/ethical challenges/Declaration of Helsinki, (Central Bristol REC Training Day, NRES)
Dr Michael Halliwell	31/01/2014 - 31/01/2014	Philosophical Research Ethics/ethical challenges/Declaration of Helsinki(Central Bristol REC Training Day, NRES)
Dr Simon Croxson	31/01/2014 - 31/01/2014	Philosophical Research Ethics/ethical challenges/Declaration of Helsinki, (Central Bristol REC Training Day, NRES)
Mr Geoffrey Jones	31/01/2014 - 31/01/2014	Philosophical Research Ethics/ethical challenges/Declaration of Helsinki, (Central Bristol REC Training Day, NRES)
Mr Paul Lewis	31/01/2014 - 31/01/2014	Philosophical Research Ethics/ethical challenges/Declaration of Helsinki(Central Bristol REC Training Day, NRES)
Dr Ian Davies	31/01/2014 - 31/01/2014	Philosophical Research Ethics/ethical challenges/Declaration of Helsinki, (Central Bristol REC Training Day, NRES)
Dr Kay Barnard	31/01/2014 - 31/01/2014	Philosophical Research

		Ethics/ethical challenges/Declaration of Helsinki, (Central Bristol REC Training Day, NRES)
Mr Brian Pixton	31/01/2014 - 31/01/2014	Philosophical Research Ethics/ethical challenges/Declaration of Helsinki, (Central Bristol REC Training Day, NRES)
Dr Colette Reid	31/01/2014 - 31/01/2014	Philosophical Research.Ethics/ethical challenges/Declaration of Helsinki, (Central Bristol REC Training Day, NRES)
Dr Kay Barnard	13/02/2014 - 13/02/2014	Assessing the Consequences (benefits and harms) of Research: a Health Research Authority workshop, NRES
Dr Pamela Cairns (Chair)	28/11/2013 - 28/11/2013	NREAP Chairs Meeting, NRES
Dr Pamela Cairns (Chair)	06/06/2013 - 06/06/2013	NREAP Chairs Meeting, 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	8	15.1
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	5	9.4
Research Database	5	9.4
Others	35	66.0
Total Applications Reviewed	53	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	7
Number of student applications reviewed	10
Number of paediatric applications reviewed	17
Number of device applications reviewed	2
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	0
Number of applications reviewed funded by the US DHHS	3

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	1.9
Favourable Opinion with Additional Conditions	18	33.9
Unfavourable Opinion	7	13.2
Provisional Opinion	27	50.9
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	53	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	24	45.3
Further Information Favourable Opinion with Additional Conditions	2	3.8
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	1.9
Favourable Opinion with Additional Conditions	18	33.9
Unfavourable Opinion	7	13.2
Provisional Opinion	1	1.9
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
Total	53	100

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

Total Applications Reviewed	15
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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	6.7
Favourable Opinion with Additional Conditions	4	26.7
No Opinion transfer to full committee for review	1	6.7
Provisional Opinion	8	53.3
Unfavourable Opinion	1	6.7
Total	15	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.3
Number of applications for full ethical review over 60 days	1
Number of applications over 60 days as a % of total	1.96%
Number of days taken to final decision - average	30
Number of days taken to final decision - mode	28
Number of SSAs (non-Phase 1) reviewed	7
Number of applications for SSA review over 25 days	1
Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)	14.3%
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	113
Number of substantial amendments over 35 days	7
Number of substantial amendments over 35 days as a % of total substantial amendments	6.2%
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	5
Number of modified amendments over 14 days	2
Number of modified amendments over 14 days as a % of total modified amendments	40.0%
Number of proportionate review applications for ethical review over 14 days	2
Number of proportionate review applications over 14 days as a % of total	14.3%

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
13/SW/0073	Pilot study: intraoperative clonidine and postoperative behaviour	43
13/SW/0075	DVT natural history, recurrence and PTS	25
13/SW/0078	Assessment of RV Function in CHD using Exercise Echocardiography	33
13/SW/0096	The Bath Spondyloarthritis (SpA) Biobank	46
13/SW/0110	Evaluating the benefits of four weeks of Cognitive Stimulation Therapy	41
13/SW/0163	The Veteran Athlete's Heart (Version 2)	44
13/SW/0171	Phase 1/2 Oxabact OC5 study, Protocol OC5-DB-01, version 3, Am 1	26
13/SW/0172	Qualitative study exploring older adults' experiences of living alone	13
13/SW/0210	Patients' experience of fat transfer to breast: A qualitative study	9
13/SW/0211	Feeling Better with Film: The Benefits of attending a MediCinema	15
13/SW/0214	The patients experience of nurse led melanoma self management workshop	19
13/SW/0224	Using 'Evernote' to support memory for children with ABI	58
13/SW/0230	Changes in Taste Perception and Preference Following ENT Surgery	40
13/SW/0238	IDA Study	25
13/SW/0239	Post-exercise nutrition and endurance training adaptations	53
13/SW/0245	Biota BTA51-350-201 - Symptomatic Influenza	51
13/SW/0269	Carers' efforts to help loved ones cope psychologically with psychosis	36
13/SW/0270	Sequana 2013-AAR-008	44
13/SW/0277	PLEX-ID BAL study v1.3	6
13/SW/0279	Patient & Health Professionals Perspectives of Clozapine Information	6
13/SW/0284	AFAST:Follow-Up of Offspring-Version 1.0	59
13/SW/0290	Which point of Rectal Measurement best reflects Abdominal Pressure?	42
13/SW/0300	CoolXenon3	39
13/SW/0312	T1D, Immunology, Genetics, Endogenous Insulin Production (TIGI) vs 1	58
13/SW/0317	TrialNet Dried Blood Spot Substudy	34
13/SW/0326	The use of Eclipse bordered dressing in the treatment of wounds	10
13/SW/0331	Sleep disturbance and inflammatory bowel disease. Version 1.	41
14/SW/0030	Feeding and Autoimmunity in Down's syndrome Evaluation Study (FADES)	50
14/SW/0031	Investigating the use of photo-making in hospice.	44

14/SW/0036	Establishing a database of potential otology research volunteers	28
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Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/SW/0148	New methods for identifying genetic conditions in unborn baby	49
13/SW/0173	Perceptions of SC medications & adherence behaviours of adult smokers	11
13/SW/0265	Advanced Ocular Imaging Program Bank	64

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
13/SW/0168	Impact of overweight on prognosis of diabetes mellitus	24
14/SW/0018	V1.0: Diagnosing urine infection in kidney transplant patients	7

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/SW/0120	Dietary advice in diabetes	9
13/SW/0124	Performance Evaluation of urinary Mcm5 test for prostate cancer	7
13/SW/0130	RSV Observational Study 2	9
13/SW/0159	NN304-4016 Diabetes Pregnancy Registry	24
13/SW/0170	Behavioural and neurophysiological effects of schizophrenia risk genes	28
13/SW/0181	Extension Study of Intermittent Bilateral GDNF for Parkinsons Disease	28
13/SW/0187	Sedentary time and metabolic health in people with type 2 diabetes	28
13/SW/0199	EVRA (Early Venous Reflux Ablation) Ulcer trial Version 1.0	28
13/SW/0207	Measuring Vitamin D3 in Bone Healing After Total Hip Arthroplasty	28
13/SW/0247	Buparlisib or placebo, plus paclitaxel, in head and neck carcinoma	25
13/SW/0249	The Peninsula Pre/Perinatal Twins Research Bank (PTRB)	25
13/SW/0266	Ulnar Fracture Study	25
13/SW/0297	COMET	28
13/SW/0308	The development of a prognostic risk score for a diabetic foot ulcer.	5
13/SW/0311	Change in dentine occlusion after use of an occluding toothpaste	20

14/SW/0021	Prevention and Risk Identification of SUDEP Mortality-PRISM v1.0	35
14/SW/0027	Impact of Prostate Swelling on HDR Brachytherapy Dosimetry v1.2	20
14/SW/0033	V1: Development of a PRO Measure in Haematological Practice	22
14/SW/0050	Identification of factors associated with speech disorder-cleft palate	21
14/SW/0053	Therapist Supported ONline CBT for depression – the TONIC Study	21
08/H0106/132+5	Immunity and Infection Research Tissue Bank (IIRTB)	21
08/H0106/28+5	South West Dementia Brain Bank	22

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/SW/0077	Behavioural and neurophysiological effects of schizophrenia risk genes	21
13/SW/0116	Using 'Evernote' to support memory for children with ABI	21
13/SW/0127	Clinician decision making for non-life threatening respiratory illness	21
13/SW/0197	The Peninsula Pre/Perinatal Twins Research Bank (PTRB)	28
13/SW/0271	Needs of people with learning disabilities and drugs and alcohol V1.0	28
13/SW/0301	Professional views of cause for concern with medication in paediatrics	35
13/SW/0325	NASH and cryptogenic cirrhosis liver transplantation.15years follow-up	8
14/SW/0062	EORTC 1211	27

Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
14/SW/0051	Chelsea and Westminster Hospital Pelvic Floor Database	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
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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
13/SW/0265	Advanced Ocular Imaging Program Bank	64

Proportionate review applications for ethical review over 14 days timeline		
REC Reference	Application Short Title	Number of Days on Clock
13/SW/0211	Feeling Better with Film: The Benefits of attending a MediCinema	15
13/SW/0214	The patients experience of nurse led melanoma self management workshop	19

SSAs (non Phase 1) over 25 days timeline		
REC Reference	Application Short Title	Number of Days on Clock
13/SW/0288	Furlong Evolution® Hip Trial	33

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/SW/0195/AM02	Perceptions of RA and decisions to seek help in the general public	SA2 dated 15/3/2013	42
11/SW/0174/AM02	Cognitive testing in dementia and mild cognitive impairment	Sub. amend. dated 19.3.2013	51
09/H0102/32/AM06	Monitoring hospital attendance due to self-harm	SA6 dated 10/10/2012	49
08/H0106/132/AM05	Immunity and infection	SA4 dated 28/03/2013	51
12/SW/0318/AM02	Vildagliptin+metformin vs gliclazide+metformin in Type 2 Diabetes, V1	Change of CI	48
11/SW/0078/AM02	Intravenous and subcutaneous	Sub. Amend 2 dated 26/08/2013	36

	microdialysis of free cortisol		
11/SW/0269/AM01	Pilot Study - markers of reno-vascular ageing in COPD patients	Sub. Amend 3 dated 9.8.2013	36

Modified Amendments over 14 day timeline

Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
11/SW/0081/AM02/1	Experience of the relationship between family & staff after suicide	Sub. amend 3 dated 04 Oct 2013	23
11/SW/0262/AM02/1	Liraglutide after Acute Stroke Trial (LAST).	Modified Amendment 1, 17/12/2013	16

Section 30 application over 60 day timeline

Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
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