

**NRES Committee South West -
Cornwall & Plymouth**

Annual Report

01 April 2013 – 31 March 2014

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee South West - Cornwall & Plymouth
Type of REC:	Authorised REC
Type of Flag:	Research Involving Children Qualitative Research
Chair:	Canon Ian Ainsworth-Smith
Vice-Chair:	Suzanne Blowey (until 1/10/2013) Mrs Sheila Bullard (from 4/11/2013)
Alternate Vice-Chair:	Mrs Sheila Bullard (until 4/11/2013)
REC Manager:	Mrs Kirsten Peck
PRSC Manager:	Miss Georgina Castledine
REC Assistant:	Miss Georgina Castledine
Committee Address:	Bristol Research Ethics Committee Centre Level 3 Block B Whitefriars Lewins Mead Bristol BS1 2NT
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Chair's overview of the past year:

The Committee continues to review a wide variety of studies and is becoming accustomed to offering Proportionate Reviews. I always find our meetings enjoyable and stimulating. I am extremely grateful, as always, for the enthusiastic support of our members and the administrative back up which the Bristol REC Centre continues to give us.

NRES Committee South West - Cornwall & Plymouth Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Canon Ian Ainsworth-Smith	Retired Hospital Chaplain	Lay Plus	01/02/2009	
Mrs Suzanne Lesley Blowey	Clinical Nurse Specialist (Pain)	Expert	01/04/2009	01/10/2013
Mrs Sheila Bullard	Clinical Research Project Manager	Expert	30/04/2009	
Mr Rich Crowe	Retired Planning Manager	Lay Plus	01/12/2011	30/04/2014
Dr Sheila Dziobon	Retired Lecturer in Law	Lay Plus	01/10/2013	
Dr Veronica Maynard	Senior Lecturer Postgraduate Clinical Education	Expert	01/04/2011	
Mr Louis Pobereskin	Consultant Neurosurgeon	Expert	01/04/2011	
Mr Rory Rickard	Consultant Burns & Plastic Surgeon	Expert	31/05/2009	
Dr Hilary Sanders	Retired Senior Lecturer in Statistics	Expert	01/01/2006	
Mrs Sue Smith	Manager, Mustard Tree Centre, PHNT	Lay	01/01/2003	01/01/2014
Miss Rosalyn Squire	Research Nurse	Expert	01/04/2011	
Mrs Caroline Theyer	Solicitor and Board Member of Tamar Housing Society	Lay Plus	01/04/2011	
Mr Roger Watkins	Retired Consultant Surgeon	Expert	01/04/2011	
Mr Christopher Winfield	Programme Manager	Lay Plus	01/09/2009	
Mr Robert Wosley	Research & Quality Manager	Lay	01/04/2011	

NRES Committee South West - Cornwall & Plymouth: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Mr Roger Watkins	Trustee/Director: Operation Hernia	19/02/2014
Canon Ian Ainsworth-Smith	None	21/02/2014
Dr Hilary Sanders	None	27/01/2014
Mrs Caroline Theyer	None	19/02/2014
Miss Rosalyn Squire	None	19/02/2014
Mr Louis Pobereskin	None	19/02/2014
Mrs Sheila Bullard	Owner of holistic measures - will be commencing some research using complementary therapy in conjunction with standard chemotherapy.	19/02/2014
Dr Sheila Dziobon	Member of Benenden Health	19/02/2014
Dr Veronica Maynard	3 Year NICE Fellowship awarded 2014-17	26/02/2014
Mr Robert Wosley	Member of European Blood and Marrow Transplantation Group (EBMT) and British Society for Bone Marrow Transplants (BSBMT). Member of Research Quality Association (RQA). Person Designate for Haematology under HTA Licence 11093, Plymouth Hospitals NHS Trust. Governance Manager; Clinical Haematology, Immunology and Oncology Services, Plymouth Hospitals NHS Trust. (Overseeing research activity from a Quality Assurance perspective).	01/03/2014

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

Month	Date	Number of Members Present at Meeting
April	16/04/2013	9
May	21/05/2013	10
June	18/06/2013	9
July	16/07/2013	10
August	20/08/2013	11
October	15/10/2013	8
November	19/11/2013	11
January	21/01/2014	11
February	18/02/2014	7
March	18/03/2014	9

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
April	08/04/2013	3
May	13/05/2013	3
June	10/06/2013	3
July	08/07/2013	3
August	12/08/2013	3
October	07/10/2013	3
November	11/11/2013	3
December	30/12/2013	3
January	27/01/2014	3
February	24/02/2014	3
March	24/03/2014	3

11 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
Canon Ian Ainsworth-Smith	10
Miss Rosalyn Squire	9
Mrs Sheila Bullard	9
Mr Robert Wosley	8
Mr Rich Crowe	8
Mr Christopher Winfield	8
Dr Hilary Sanders	7
Dr Veronica Maynard	6
Mr Louis Pobereskin	6
Mr Roger Watkins	6
Mrs Caroline Theyer	6
Mr Rory Rickard	4
Dr Sheila Dziobon	4
Mrs Suzanne Lesley Blowey	3
Mrs Sue Smith	1

Number of inquorate meetings held:

**Attendance of Members at proportionate review sub-committee meetings:
01 April 2013 – 31 March 2014:**

Name	Number of Meetings Attended
Canon Ian Ainsworth-Smith	8
Mrs Sheila Bullard	7
Miss Rosalyn Squire	4
Mrs Caroline Theyer	4
Mr Robert Wosley	3
Mr Roger Watkins	2
Dr Hilary Sanders	2
Mr Roger Watkins	1
Dr Sheila Dziobon	1
Mrs Suzanne Lesley Blowey	1

Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Mrs Sheila Bullard	06/06/2013 - 06/06/2013	Training Day for new REC Chairs, HRA
Dr Veronica Maynard	24/09/2013 - 24/09/2013	Quantitative Research and Statistics, Health Research Authority
Mr Robert Wosley	04/09/2013 - 04/09/2013	Research Involving Adults Who Lack Capacity (including research in emergency situations), Health Research Authority
Mr Louis Pobereskin	13/11/2013 - 13/11/2013	Personal Data in Research, Health Research Authority
Canon Ian Ainsworth-Smith	19/11/2013 - 19/11/2013	Philosophical research Ethics, HRA
Canon Ian Ainsworth-Smith	21/01/2014 - 21/01/2014	REC Decision Making, HRA
Mrs Sheila Bullard	19/11/2013 - 19/11/2013	Philosophical Research Ethics, HRA
Mrs Sheila Bullard	21/01/2014 - 21/01/2014	REC Decision Making, HRA
Dr Hilary Sanders	21/01/2014 - 21/01/2014	REC Decision Making, HRA
Dr Hilary Sanders	19/11/2013 - 19/11/2013	Philosophical Research Ethics, HRA
Mr Rory Rickard	21/01/2014 - 21/01/2014	REC Decision Making, HRA
Mr Christopher Winfield	19/11/2013 - 19/11/2013	Philosophical Research Ethics, HRA
Mr Christopher Winfield	21/01/2014 - 21/01/2014	REC Decision Making, HRA
Canon Ian Ainsworth-Smith	28/11/2013 - 28/11/2013	NREAP Chair's Meeting, HRA
Mrs Sheila Bullard	28/11/2013 - 28/11/2013	NREAP Chair's Meeting, HRA

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	46	100.00
Total Applications Reviewed	46	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	5
Number of studies withdrawn prior to the meeting	10
Number of student applications reviewed	14
Number of paediatric applications reviewed	2
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	1	2.17
Favourable Opinion with Additional Conditions	13	28.26
Unfavourable Opinion	9	19.57
Provisional Opinion	23	50.00
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	46	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	22	47.83
Further Information Favourable Opinion with Additional Conditions	1	2.17
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	2.17
Favourable Opinion with Additional Conditions	13	28.26
Unfavourable Opinion	9	19.57
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
Total	46	100

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

Total Applications Reviewed	26
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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	19.23
Favourable Opinion with Additional Conditions	7	26.92
No Opinion transfer to full committee for review	2	7.69
Provisional Opinion	12	46.15
Unfavourable Opinion	0	0.00
Total	26	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	4.60
Number of applications for full ethical review over 60 days	0
Number of applications over 60 days as a % of total	0.00%
Number of days taken to final decision - average	26
Number of days taken to final decision - mode	22
Number of SSAs (non-Phase 1) reviewed	1
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	52
Number of substantial amendments over 35 days	0
Number of substantial amendments over 35 days as a % of total substantial amendments	0.0%
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	0
Number of modified amendments over 14 days	0
Number of modified amendments over 14 days as a % of total modified amendments	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	4.3%

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/0089	Do Patients Perceptions of Health Change Along the Amputation Pathway?	8
13/SW/0092	The experience of older people self-managing cancer pain - Version 1.1	8
13/SW/0093	White cell azathioprine metabolites for patients on thiopurines	10
13/SW/0097	Clinical Evaluation of two Daily Disposable Contact Lenses v1	25
13/SW/0099	Emotion processing in individuals with a history of depression	19
13/SW/0103	STOPCUTS	50
13/SW/0126	Genetics of Diabetes Associated Hormones(GENDAH)	33
13/SW/0133	Virtual environments for offenders with intellectual disabilities	24
13/SW/0149	TeenTEXT: A feasibility study (v.1)	25
13/SW/0158	Accuracy Trial of MBIR Technique in CT in Lung Nodule Surveillance	27
13/SW/0167	Mindfulness and OCD	10
13/SW/0177	Measuring post-operative oxygen delivery and consumption v1.2.1	22
13/SW/0201	Chemotherapy induced cognitive changes in colorectal cancer patients	25
13/SW/0206	Focus group sleep problems	8
13/SW/0225	Markers in inflammation	40
13/SW/0227	Measurement of Inorganic Nitrate Synthesis in Haemodialysis Patients	27
13/SW/0233	How People Who Have Troubling Fears Think About Themselves (Version 1)	23
13/SW/0235	TGM6 related genetic ataxia(vers. 1)	14
13/SW/0240	Blood Collection (Adaptimmune)	24
13/SW/0276	Experience of psychiatric admission for relatives of those admitted	44
13/SW/0278	What are the early symptoms of bone tumours around the knee joint?V6.0	11
13/SW/0287	Methodology for the Early Detection of Neurodegenerative Disorders	27
13/SW/0309	Developing a falls intervention for people with Multiple Sclerosis	41
13/SW/0315	Novel proteins in colorectal carcinoma	7
13/SW/0334	The effect of insole features on balance in people with diabetes	22
13/SW/0335	Guided Relaxation and Daily Diary in Non-REM Parasomnia	13
13/SW/0337	Managing Intolerance of Uncertainty in ASD	18
14/SW/0009	Interpersonal styles and effectiveness of Cognitive Behaviour Therapy	24
14/SW/0020	Salivary and subgingival plaque lipid-A profile – periodontitis	24

14/SW/0042	Mesenchymal stem cells from perinatal tissues for cellular therapy	14
14/SW/0048	MBCT for people with vascular disorders version 1.0	24
14/SW/0055	Effects of self-compassion on post-traumatic stress symptoms	35
14/SW/0056	PrEvENT: Prostate Cancer Evidence of Exercise and Nutrition Trial V1.0	32

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/SW/0202	Undiagnosed Hyperparathyroidism and Recurrent Miscarriage Version 1.0	40

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/0259	The use of Rotational Thromboelastometry (ROTEM®) in Pre-eclampsia	21
14/SW/0024	HomeR	7
14/SW/0043	PRDM9 in childhood leukaemia	7
14/SW/0045	Mast cells in Barrett's oesophagus. Version 1.0	5
14/SW/0078	SHOES	8
14/SW/0083	Patient experience of MI and taking part in a research study	8

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/SW/0111	Is MRI better than CT for diagnosis of occult wrist fractures V 3.0	29
13/SW/0123	Research into female reproductive tract disorders_v.1	8
13/SW/0128	Evaluating immunity in mesothelioma	22
13/SW/0129	Physical activity promotion in cystic fibrosis patients	7
13/SW/0131	Making sense of Dementia in Couples	22
13/SW/0146	Efficacy of platinum segment implants in upper eyelid loading	32
13/SW/0157	Exploring how families and therapists view key moments in therapy	26
13/SW/0217	Health resource use after knee replacement: a feasibility study	47
13/SW/0226	ASPIRE (V1)	39
13/SW/0234	Validating the Tinnitus Functional Index (TFI) for use in the UK	11

13/SW/0236	Post-authorisation safety study of Esbriet (PASSPORT)	10
13/SW/0272	Links between perio score and Alzheimers	29
13/SW/0280	Influenza and pneumococcal vaccinations in ANCA Associated Vasculitis	5
13/SW/0310	Instant insole enhancement for ulcer prevention: a feasibility trial	22
13/SW/0338	Can length of stay be predicted by a simple bedside tool? Version 1.0	11
13/SW/0339	iNeo: Outcomes of Very Low Birth Weight and Very Preterm Neonates	14
14/SW/0022	Screening in Pregnancy	21
14/SW/0035	Skype on Wheels to give families better contact with patients	22
14/SW/0049	The Optimal Collection Method for Measuring Albumin in Urine.	29
14/SW/0052	Impact of arterio-venous fistula flow on cardio-respiratory fitness	28

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/SW/0090	Evaluating immunity in mesothelioma	21
13/SW/0094	TV Box	20
13/SW/0095	Efficacy of platinum segment implants in upper eyelid loading	20
13/SW/0145	Cognitive impairment in emergency general surgery. Version 1	26
13/SW/0203	Cultured Chondrocytes Vs. Cultured BMAC	14
13/SW/0204	PRP vs HA intra-articular knee injections for cartilage defects	14
13/SW/0205	ACIC Vs MCIC	14
13/SW/0264	Understanding and Experiencing Screening and Diagnosis in Pregnancy.	21
14/SW/0032	Exercise and bone health in adolescents engaged in different sports	22

Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
14/SW/0023	ESWL for Ureteric Calculi: Predictors of Success	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		
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REC Reference	Application Short Title	Number of Days on Clock
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Invalid Application		
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REC Reference	Application Short Title	Number of Days on Clock
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No Opinion Pending Consultation with Referee		
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REC Reference	Application Short Title	Number of Days on Clock
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Not Requiring Review by NHS REC		
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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	
Proportionate review applications for ethical review over 14 days timeline			
REC Reference	Application Short Title	Number of Days on Clock	
13/SW/0337	Managing Intolerance of Uncertainty in ASD	18	
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
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