

**NRES Committee South West -  
Frenchay**

**Annual Report**

**01 April 2013 – 31 March 2014**

## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	NRES Committee South West - Frenchay
<b>Type of REC:</b>	Authorised REC
<b>Type of Flag:</b>	Research Involving Adults Lacking Capacity
<b>Chair:</b>	Dr Robert Beetham until 31/01/2014 Mr Peter Jones from 31/01/2014
<b>Vice-Chair:</b>	Mr Peter Jones until 31/01/2014 Mr Stephen Draper (Acting) from 31/01/2014
<b>Alternate Vice-Chair:</b>	Mrs Kate McMahon-Parkes until 13/01/2014
<b>REC Manager:</b>	Mrs Naazneen Nathoo
<b>PRSC Manager:</b>	Mrs Naazneen Nathoo
<b>Assistant Co-ordinator:</b>	Miss Lidia Gonzalez
<b>Committee Address:</b>	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:

As my tenure of office only began on the 1<sup>st</sup> February 2014, and has involved me in Chairing just three meetings, my report will be rather brief. It will also refer to comments made by the previous Chairman in his report for the year 1<sup>st</sup> April, 2012 – 31<sup>st</sup> March, 2013

It has been pleasing to welcome three new members to the committee, and it is hoped that this will go some way towards alleviating the problem of obtaining a quorum for the meetings. The meetings in January and February relied on co-opted members from another committee, in order to be quorate; a situation, which is clearly unsatisfactory. With a number of members leaving the committee, for a variety of reasons, over the year, and others being on long term sabbaticals, it is a major issue to ensure a full complement of members, without relying on co-option. This situation will need to be closely monitored.

Arrangements for Proportionate Reviews have been further improved with the introduction of a rota system, which will involve all members of the committee. There will also be a rota for Sub – Committee work, also involving all members. The aim is to achieve an equitable distribution of work.

It has also been agreed to introduce Lead and Second Reviewers on a trial basis. Again, the aim is to achieve more involvement throughout the committee, whilst also reducing the workload on the small number of members presently involved.

The last report referred to the importance of a consistent relationship between the Chairman and the Manager for the REC. I would wholeheartedly endorse this view and stress the need for there being just one point of contact, at the Bristol Centre, for the Chairman. Obviously, there will be times when alternative arrangements have to be put in place, but this does not negate the importance of the Committee having the same Manager as much as possible. I would wish to express my sincere thanks to Mrs Naaz Nathoo for being so helpful and supportive during my introductory period as Chairman.

Finally, I feel that it is always very important to remember that our committee members are volunteers, who give up so much time to support the work of South West –Frenchay R.E.C. I'm sure that I speak for all concerned in the H.R.A when I offer my thanks to them.

## NRES Committee South West - Frenchay Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mr Paul Allen	Consultant Oral Surgeon	Expert	01/04/2011	
Dr Robert Beetham	Retired Consultant Clinical Biochemist	Lay	01/09/2006	31/01/2014
Miss Wendy Bertram	Spine Research Fellow	Lay	15/10/2010	
Dr Alison Diaper	Research Associate	Lay	21/06/2011	
Mr Alex Drake	Assistant Psychologist	Lay	15/10/2010	
Mr Stephen Draper	Retired Head teacher	Lay Plus	01/04/2011	
Miss Sarah Hirons	PhD Student	Lay Plus	01/05/2011	
Mr Peter Jones	Retired Head teacher	Lay Plus	01/03/2013	
Mrs Kerstin Kubiak	Solicitor	Lay Plus	01/07/2008	
Dr Vera Lees	Junior doctor	Expert	01/09/2009	02/04/2014
Mrs Kate McMahon-Parkes	Senior Lecturer in Adult Nursing	Expert	01/06/2003	13/01/2014
Dr Ruth Morse	Senior Lecturer in Molecular Biomedicine	Expert	01/04/2012	
Dr Sam O'Hare	Neonatal Registrar	Expert	01/04/2012	18/01/2014
Mr Jeremy Ruddock	Osteopath	Expert	28/05/2013	
Mrs Trudy Sheen	DeNDRoN Research Practitioner	Expert	01/01/2010	26/11/2013
Dr Ian Thomas	Consultant in Intensive Care Medicine	Expert	01/04/2007	

### Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Mrs Angela Clarke	Ex social worker	Lay	10/01/2014, 14/02/2014
Mr Geoffrey Jones	Retired solicitor	Lay	10/01/2014
Mr Brian Pixton	Retired Solicitor	Lay Plus	10/01/2014, 14/02/2014
Mrs Carol Richardson	Senior Nurse (Retired)	Lay	10/05/2013
Mr Roy Sinclair	Pharmacist	Expert	22/10/2013
Mr Evan Stone	Barrister	Lay Plus	22/10/2013
Ms Stephanie Ellis	Former Civil Servant	Lay Plus	22/10/2013

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

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Mr Paul Allen	None	14/02/2014
Dr Robert Beetham	None	10/01/2014
Miss Wendy Bertram	None	14/02/2014
Dr Alison Diaper	Research Associate for the University of Bristol Research Coordinator for Bioinduction Ltd	13/01/2014
Mr Alex Drake	None	01/04/2014
Mr Stephen Draper	None	10/01/2014
Miss Sarah Hirons	Director of City Road Management Co Trustee at Bristol Centre for Deaf People Volunteer at National Deaf Children's Society Researcher at University of Bristol	01/04/2013
Mr Peter Jones	None	12/01/2014
Mrs Kerstin Kubiak	None	10/01/2014
Dr Vera Lees	None	01/05/2013
Mrs Kate McMahon-Parkes	None	07/01/2013
Dr Ruth Morse	Senior Lecturer at the University of the West of England	05/02/2013
Dr Sam O'Hare	None	01/04/2013
Mr Jeremy Ruddock	None	28/4/2013
Mrs Trudy Sheen	None	18/01/2013
Dr Ian Thomas	None	28/4/2014

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

<b>Month</b>	<b>Date</b>	<b>Number of Members Present at Meeting</b>
April	12/04/2013	8
May	10/05/2013	8
June	14/06/2013	8
July	12/07/2013	9
September	13/09/2013	10
October	11/10/2013	7
October	22/10/2013	7
November	08/11/2013	10
December	13/12/2013	9
January	10/01/2014	9
February	14/02/2014	8

11 full committee meetings were held during the reporting period.

**Proportionate Review Sub Committee Meetings held during 01 April 2013 - 31 March 2014:**

<b>Month</b>	<b>Date</b>	<b>Number of Members Present at Meeting</b>
May	01/05/2013	3
June	04/06/2013	3
July	02/07/2013	3
September	02/09/2013	3
October	02/10/2013	3
October	29/10/2013	3
December	03/12/2013	3

7 proportionate review sub-committee meetings were held during the reporting period.

**Attendance of Members: 01 April 2013 – 31 March 2014:**

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Robert Beetham	10
Mr Paul Allen	9
Mr Stephen Draper	9
Mrs Kerstin Kubiak	9
Dr Vera Lees	8
Mr Peter Jones	7
Dr Alison Diaper	5
Mr Jeremy Ruddock	5
Mrs Trudy Sheen	4
Dr Ian Thomas	4
Miss Wendy Bertram	4
Mrs Kate McMahon-Parkes	3
Mr Alex Drake	2
Miss Sarah Hirons	2
Dr Ruth Morse	2

**Number of inquorate meetings held:** One: 11/10/2013 (started as quorate; then became inquorate and the final applications were ratified 22/10/2013)

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mrs Kate McMahon-Parkes	4
Mrs Trudy Sheen	2
Mr Peter Jones	2
Mr Stephen Draper	2
Dr Alison Diaper	2
Dr Robert Beetham	2
Dr Ruth Morse	2
Miss Wendy Bertram	2
Mr Alex Drake	2
Mr Paul Allen	1

**Training 01 April 2013 – 31 March 2014:**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Mrs Kerstin Kubiak	02/05/2013 - 02/05/2013	Ethical Issues of Research Involving Children, NRES
Mr Jeremy Ruddock	10/07/2013 - 10/07/2013	Induction, NRES
Dr Alison Diaper	12/08/2013 - 12/08/2013	Reading for HRA collaborative and development project, NRES
Mr Jeremy Ruddock	05/02/2014 - 05/02/2014	Researcher Training day, NRES
Dr Robert Beetham	31/01/2014 - 31/01/2014	Philosophical Res. Ethics/ethical challenges/Dec of Helsinki, (Central Bristol REC Training Day)
Mr Stephen Draper	31/01/2014 - 31/01/2014	Philosophical Research Ethics/ethical challenges/Dec of Helsinki, (Central Bristol REC Training Day)
Miss Sarah Hirons (maternity Apr-Sep14)	31/01/2014 - 31/01/2014	Philosophical Research Ethics/ethical challenges/Dec of Helsinki, (Central Bristol REC Training Day)
Mr Peter Jones	31/01/2014 - 31/01/2014	Philosophical Research Ethics/ethical challenges/Dec of Helsinki, (Central Bristol REC Training Day)
Dr Alison Diaper	31/01/2014 - 31/01/2014	Philosophical Res. Ethics/ethical challenges/Dec of Helsinki, (Central Bristol REC Training Day)
Dr Robert Beetham	28/11/2013 - 28/11/2013	NREAP Chair's Meeting, NRES
Mr Peter Jones	28/11/2013 - 28/11/2013	Equality & Diversity, 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:**

<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	43	100.00
<b>Total Applications Reviewed</b>	<b>43</b>	<b>100</b>

**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	5
Number of student applications reviewed	24
Number of paediatric applications reviewed	5
Number of device applications reviewed	0
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	4
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	0	0.00
Favourable Opinion with Additional Conditions	4	9.30
Unfavourable Opinion	3	6.98
Provisional Opinion	36	83.72
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>43</b>	<b>100</b>
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:**

<b>Status of applications at date of generation of report</b>	<b>Number</b>	<b>%</b>
Further Information Favourable Opinion with Standard Conditions	26	60.47
Further Information Favourable Opinion with Additional Conditions	6	13.95
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	4	9.30
Unfavourable Opinion	3	6.98
Provisional Opinion	4	9.30
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>43</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>16</b>
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**Table 6: Decisions given at proportionate review sub-committee meetings held within the reporting period:**

<b>Decisions taken at proportionate review sub-committee meetings</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	1	6.25
Favourable Opinion with Additional Conditions	2	12.50
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	12	75.00
Unfavourable Opinion	1	6.25
<b>Total</b>	<b>16</b>	<b>100</b>

**Table 7: Other Management Information for the reporting period:**

<b>Average number of applications reviewed per full meeting</b>	3.91
<b>Number of applications for full ethical review over 60 days</b>	1
<b>Number of applications over 60 days as a % of total</b>	2.33%
<b>Number of days taken to final decision - average</b>	38
<b>Number of days taken to final decision - mode</b>	42
<b>Number of SSAs (non-Phase 1) reviewed</b>	1
<b>Number of applications for SSA review over 25 days</b>	1
<b>Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)</b>	100.0%
<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>	69
<b>Number of substantial amendments over 35 days</b>	2
<b>Number of substantial amendments over 35 days as a % of total substantial amendments</b>	2.9%
<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>	7
<b>Number of modified amendments over 14 days</b>	1
<b>Number of modified amendments over 14 days as a % of total modified amendments</b>	14.3%
<b>Number of proportionate review applications for ethical review over 14 days</b>	3
<b>Number of proportionate review applications over 14 days as a % of total</b>	18.8%

**Table 8: 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>
13/SW/0076	Assessing the impact of Mandometer training on obesity using fMRI v1	45
13/SW/0084	Developing measures of empathy and reasoning	39
13/SW/0086	FIRST STEPS: Randomised Controlled Trial, Group FNP	60
13/SW/0113	FEV1 decline in irritant-induced asthma	14
13/SW/0122	ConforMIS iUni G2+ Unicompartmental Knee Resurfacing Device (v 3.0)	38
13/SW/0125	Qualitative exploration of living with and managing PDN	38
13/SW/0132	MASTER	47
13/SW/0135	Health benefits of HIT vs. walking in metabolic syndrome	44
13/SW/0151	Barriers and facilitators to insulin adjustment in type 2 diabetes	11
13/SW/0155	A Qualitative Evaluation of Feeling Well with True Colours (OXTEXT-7)	6
13/SW/0160	Continuous Wound Infiltration Catheters in Open Renal Surgery	43
13/SW/0161	Evaluation of quality of analgesia in paediatric scoliosis patients	42
13/SW/0179	MiPACT Project	31
13/SW/0195	Wrist Fracture Management - Orthopaedic Surgeon Decision Making - 1.0	16
13/SW/0196	Eye-CU: Visual Impairment Following Intensive Care Unit admission	29
13/SW/0228	Increasing standing time in non-ambulant children with cerebral palsy	34
13/SW/0229	Anterior eye shape following cataract surgery	69
13/SW/0248	Exploring the spine and lower limb kinematics of trans-tibial amputees	41
13/SW/0255	Repeat infusion of autologous bone marrow cells in multiple sclerosis	54
13/SW/0267	Effects of lowering blood glucose on T cell activation in fat tissue	42
13/SW/0273	Quality of Life in Craniofacial Patients. (Version 1)	10
13/SW/0285	The ENGAGE study	32
13/SW/0292	Validation of the myositis muscle dysfunction scale (MMDS).	42
13/SW/0298	Health benefits of a novel exercise intervention in Type 2 diabetes	37
13/SW/0316	Suicide and the Internet	26
13/SW/0319	Novel Vascular Manifestations of COPD (N.O.V.A.S.C. COPD)	42
13/SW/0321	The effect of breaking prolonged sitting on adipose tissue	34
13/SW/0329	Knowledge of cancer treatment consequences amongst survivors	12
13/SW/0330	Oral hygiene and acute diverticulitis: Is there a link?	16
14/SW/0002	Rapid Clinic Access and Rapid Diagnostics in Non-CF Bronchiectasis	48

14/SW/0007	An expressive writing study for breast cancer patients	34
14/SW/0011	The 3D Study: Improving care for multimorbidity patients v1.0	35
14/SW/0028	Improving diagnosis with endocervical curettage and P16 staining.	42
14/SW/0029	Metformin and colorectal cancer.	19

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/SW/0112	Post-Traumatic Growth following a Subarachnoid Haemorrhage.	14
13/SW/0117	Serosurveillance for hantavirus exposure in people exposed to rats	33
13/SW/0140	STEPS - the development and evaluation of stepped care	52
13/SW/0152	Exploring the influence of handovers on patients' experience of care	11
13/SW/0237	Anxiety profile of adolescents with and without chronic pain	59
13/SW/0256	MRI in Acute Stroke	34
13/SW/0291	Pituitary adrenal activity in patients undergoing pituitary surgery	44
13/SW/0318	RCT of follow-up after cataract extraction	50

#### 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/0303	Biological Implications of Polyomavirus Genomic Diversity	10

#### Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/SW/0082	Myocardial Oedema in ST segment elevation myocardial infarction	28
13/SW/0138	Identity and Meaning Making in the Post-Treatment Phase of Cancer	28
13/SW/0180	Animal-Assisted Therapy in a Challenging Behaviour Team	31
13/SW/0231	Oral SCC in Cervical SCC pts	20
13/SW/0251	Wound care in boys undergoing hypospadias surgery; version 1	9
13/SW/0253	Patient experiences of telehealth	11

#### Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
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13/SW/0121	Music therapy for stroke rehabilitation	24
13/SW/0275	Research on medication administration on a paediatric ward.	32
13/SW/0275	Anonymous club-drugs survey in patients attending a GUM clinic.	7
13/SW/0323	A mixed method study of inequality in health in the South West	27

#### Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/SW/0154	Do Vascular Risk Factors cause Alzheimer's Disease?	N/A
13/SW/0241	Service users' experiences of a memory clinic	N/A
13/SW/0274	Determination of normal gallbladder function using volume ultrasound	N/A
13/SW/0294	Analysing the cost of treating patients born with cleft lip and palate	N/A
14/SW/0004	The experience of elderly carers of a person who has dementia.	N/A
14/SW/0010	timelines in early interventions version 1	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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### Full applications for ethical review over 60 day timeline

REC Reference	Application Short Title	Number of Days on Clock
13/SW/0229	Anterior eye shape following cataract surgery	69

### Proportionate review applications for ethical review over 14 days timeline

REC Reference	Application Short Title	Number of Days on Clock
13/SW/0196	Eye-CU: Visual Impairment Following Intensive Care Unit admission	29
13/SW/0195	Wrist Fracture Management - Orthopaedic Surgeon Decision Making - 1.0	16
13/SW/0330	Oral hygiene and acute diverticulitis: Is there a link?	16

### SSAs (non Phase 1) over 25 days timeline

REC Reference	Application Short Title	Number of Days on Clock
13/SW/0189	CT327 Phase IIb Atopic Dermatitis Study	27

### SSAs (Phase 1) over 14 days timeline

REC Reference	Application Short Title	Number of Days on Clock
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### Substantial Amendments over 35 day timeline

Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
12/SW/0212/AM06	PRISM	2, 25 September 2013	42
12/SW/0012/AM01	Clinical Outcomes of Zenith Total Ankle Replacement	N1, 16/07/2013	40

### Modified Amendments over 14 day timeline

Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
11/SW/0248/AM07/1	BY-BAND	3 03/03/2014	20

### Section 30 application over 60 day timeline

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