

**NRES Committee South Central -  
Southampton B**

**Annual Report**

**01 April 2011 – 31 March 2012**

## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	NRES Committee South Central - Southampton B
<b>Type of REC:</b>	Recognised to review CTIMPs in patients – Type III
<b>Type of Flag:</b>	Type III Paediatric Research Tissue Banks IRB Registered
<b>Chair:</b>	Professor Ron King
<b>Vice-Chair:</b>	N/A
<b>Alternate Vice-Char:</b>	Dr Giles Tan
<b>Co-ordinator:</b>	Libby Watson
<b>Assistant Co-ordinator:</b>	N/A
<b>Committee Address:</b>	Bristol REC Centre Level 3 Block B Whitefriars Lewins Mead Bristol BS1 2NT
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## Chair's overview of the past year:

The first part of the year was beset by problems associated with the transfer of responsibility for the Committee from the Reading to the Bristol office. However, the new oversight by the South Central Centre Manager was most welcome. Unfortunately, over the year the Committee lost through resignation its Chair and no less than six other members. The appointment of four new members went some way to ameliorate the situation, but at the year end the number of Committee members remains perilously low. It was only through the regular co-option of members that the Committee was able to achieve quoracy at all of its meetings. Despite these difficulties the Committee has carried out its business throughout the year in a conscientious and effective manner. While some target deadlines were not met, an improvement has been seen in the Committee's recent performance. This has been helped by the appointment of a new Co-ordinator whose level of support is much appreciated. Thanks are due to my predecessor as Chair, Dr Helen McCarthy, for her contributions and leadership over many years, and to the Alternate Vice-Chair, Dr Giles Tan, who in the absence of a Vice-Chair, has done more work than should reasonably have been asked of him. It is a pleasure to also acknowledge the hard work and commitment of all members of the Committee, both lay and expert volunteers, who have given so much by way of their time and energy, contributing wisely I believe to the decision making of both the Main Committee and its Sub-Committees.

## NRES Committee South Central - Southampton B Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr Catherine Angell	Midwife/Lecturer	Expert	01/12/2010	01/11/2011
Dr Steven Beaumont	RAF Officer / Nurse	Expert	27/10/2011	
Mr Brian Birch	Consultant Urological Surgeon	Expert	08/11/2007	
Mrs Janet Brember	Pharmacist	Expert	30/05/2007	
Ms Sally Callow	University Librarian	Lay Plus	27/10/2011	21/12/2011
Mr Joseph Grimshaw	Chartered Engineer	Lay Plus	01/05/2009	01/09/2011
Professor Ron King	Mathematician (Retired)	Lay	19/05/2006	
Ms Nicola Lamb	Senior Nurse	Expert	14/09/2011	
Rev Karen MacKinnon	Hospital Chaplain	Lay Plus	27/10/2011	
Dr Helen McCarthy	Haematology Consultant	Expert	20/06/2003	31/12/2011
Miss Julia Moffatt	Solicitor	Lay Plus	01/09/2008	19/09/2011
Dr Karl Nunkoosing	Principal Psychology Lecturer	Lay	13/12/2010	
Mrs Wendy Powell	Senior Lecturer	Lay	08/12/2006	04/01/2012
Dr Brian Stevenson	General Practitioner (Retired)	Expert	09/07/2002	
Dr Giles Tan	Consultant Psychiatrist	Expert	24/04/2008	
Dr Janet Walker	Health Psychologist	Expert	20/06/2003	01/12/2011
Mr Alan Smith	Barrister's Clerk (Retired)	Lay Plus	28/02/2012	

### Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended

### Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Dr Kim Cheetham	Retired Consultant Paediatrician	Expert	27/07/2011, 14/12/2011, 29/02/2012
Dr Simon Kolstoe	Academic Research Scientist	Expert	26/10/2011
Mrs Ita Berry	Retired Clinical Psychologist	Lay	25/01/2012
Dr. Mary Saunders	Senior Lecturer	Expert	25/01/2012
Dr Robert Beetham	Retired Consultant Clinical Biochemist	Expert	29/02/2012
Dr M.J. Proven	Coordinator for Quality Assurance in Research	Lay	28/03/2012
Ms Ann Quinn	Head of the School of Health and Social Care	Lay	28/03/2012

### Member Bank

Name	Occupation	Expert or Lay	Meeting date attended
Mr Harry Friedman	Retired Systems Analyst	Lay	26/10/2012

**NRES Committee South Central - Southampton B: Members' Declarations of Interest:**

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Professor Ron King	None	14/12/2011
Dr Giles Tan	None	14/12/2011
Dr Brian Stevenson	None	14/12/2011
Mrs Janet Brember	None	14/12/2011
Mr Brian Birch	None	04/01/2012
Dr Karl Nunkoosing	None	01/05/2011
Ms Nicola Lamb	None	14/12/2011
Dr Steven Beaumont	None	14/12/2011
Rev Karen MacKinnon	None	14/12/2011
Mr Alan Smith	None	19/04/2011

**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>
May	25/05/2011	7
June	29/06/2011	10
July	27/07/2011	8
August	31/08/2011	7
September	28/09/2011	7
October	26/10/2011	8
November	30/11/2011	12
December	14/12/2011	11
January	25/01/2012	9
February	29/02/2012	8
March	28/03/2012	7

11 full 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>
Professor Ron King	10
Mrs Janet Brember	9
Dr Giles Tan	9
Dr Brian Stevenson	8
Dr Karl Nunkoosing	7
Dr Janet Walker	6
Ms Nicola Lamb	5
Dr Helen McCarthy	5
Dr Steven Beaumont	5
Mr Brian Birch	4
Dr Catherine Angell	4
Rev Karen MacKinnon	4
Dr Kim Cheetham	3
Mr Joseph Grimshaw	3
Miss Julia Moffatt	2
Mrs Wendy Powell	2
Ms Ann Quinn	1
Mr Alan Smith	1
Dr. Mary Saunders	1
Mrs Ita Berry	1
Mr Harry Friedman	1
Dr M.J. Proven	1
Dr Robert Beetham	1
Dr Simon Kolstoe	1

**Number of inquorate meetings held: 0**

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

**Training 01 April 2011 – 31 March 2012:**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Mr Joseph Grimshaw	10/06/2011 - 10/06/2011	ED Equality & Diversity, NRES
Mr Joseph Grimshaw	15/09/2011 - 15/09/2011	AREC Event 'Research Involving Children', NRES
Mr Alan Smith	10/01/2012 - 10/01/2012	Induction, NRES
Mr Alan Smith	08/02/2012 - 08/02/2012	Induction, NRES
Professor Ron King	28/10/2011 - 28/10/2011	NRES Update Session, NRES
Dr Helen McCarthy	31/08/2011 - 31/08/2011	Shared Ethical Debate, NRES
Professor Ron King	31/08/2011 - 31/08/2011	Shared Ethical Debate, NRES
Dr Giles Tan	31/08/2011 - 31/08/2011	Shared Ethical debate, NRES
Dr Brian Stevenson	31/08/2011 - 31/08/2011	Shared Ethical debate, NRES
Dr Janet Walker	31/08/2011 - 31/08/2011	Shared Ethical Debate, NRES
Ms Sally Callow	20/03/2012 - 20/03/2012	Induction, NRES
Ms Nicola Lamb	20/03/2012 - 20/03/2012	Induction, NRES
Rev Karen MacKinnon	08/02/2012 - 08/02/2012	Induction, NRES
Mr Brian Birch	17/01/2012 - 17/01/2012	Adults Lacking Capacity, NRES
Professor Ron King	16/11/2011 - 16/11/2011	MCA DVD, NRES
Dr Giles Tan	16/11/2011 - 16/11/2011	MCA DVD, NRES
Dr Brian Stevenson	16/11/2011 - 16/11/2011	MCA DVD, MCA DVD
Dr Janet Walker	16/11/2011 - 16/11/2011	MCA DVD, NRES
Mrs Wendy Powell	16/11/2011 - 16/11/2011	MCA DVD, NRES
Mrs Janet Brember	16/11/2011 - 16/11/2011	MCA DVD
Mr Brian Birch	16/11/2011 - 16/11/2011	MCA DVD, NRES
Dr Karl Nunkoosing	16/11/2011 - 16/11/2011	MCA DVD, NRES
Ms Nicola Lamb	16/11/2011 - 16/11/2011	MCA DVD, NRES
Ms Sally Callow	16/11/2011 - 16/11/2011	MCA DVD, NRES
Dr Steven Beaumont	16/11/2011 - 16/11/2011	MCA DVD, NRES
Rev Karen MacKinnon	16/11/2011 - 16/11/2011	MCA DVD, NRES
Mrs Janet Brember	13/02/2012 - 13/02/2012	Institute of Clinical Research Ethics and GCP Forum Day, Institute of Clinical Research
Mrs Janet Brember	14/03/2012 - 14/03/2012	NRES Members National Training Day, NRES
Mr Brian Birch	07/12/2011 - 07/12/2011	Statistics Training for NRES members, NRES
Dr Steven Beaumont	10/01/2012 - 10/01/2012	NRES New Members Induction, NRES
Professor Ron King	17/08/2011 - 17/08/2011	South West Proportionate Review Roll Out, NRES
Professor Ron King	19/01/2012 - 19/01/2012	Shared Ethical Debate 7, 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	15	23.81
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	2	3.17
Research Database	0	0.00
Others	46	73.02
<b>Total Applications Reviewed</b>	<b>63</b>	<b>100</b>

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

Number of applications made invalid by co-ordinator	0
Number of studies withdrawn prior to the meeting	6
Number of student applications reviewed	26
Number of paediatric applications reviewed	13
Number of device applications reviewed	0
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	0
Number of applications reviewed funded by the US DHHS	1

**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	10	15.87
Favourable Opinion with Additional Conditions	3	4.76
Unfavourable Opinion	6	9.52
Provisional Opinion	44	69.84
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>63</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	33	52.38
Further Information Favourable Opinion with Additional Conditions	9	14.29
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	10	15.87
Favourable Opinion with Additional Conditions	3	4.76
Unfavourable Opinion	6	9.52
Provisional Opinion	1	1.59
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	1	1.59
Number of studies withdrawn after the meeting	0	0.00
<b>Total</b>	<b>63</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	5.73
<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>	1.59%
<b>Number of days taken to final decision - average</b>	34
<b>Number of days taken to final decision - mode</b>	27
<b>Number of SSAs (non-Phase 1) reviewed</b>	3
<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>	0.0%
<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>	105
<b>Number of substantial amendments over 35 days</b>	10
<b>Number of substantial amendments over 35 days as a % of total substantial amendments</b>	9.5%
<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>	16
<b>Number of modified amendments over 14 days</b>	7
<b>Number of modified amendments over 14 days as a % of total modified amendments</b>	43.8%

**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/SC/0173	Viral Induced Paediatric Asthma (VIPA) II Study – Intervention Phase	44
11/SC/0187	CPX Testing. A comparison study of three types of ergometers.	28
11/SC/0192	Mucociliary Clearance and PCD	34
11/SC/0209	Does a hydrotherapy/exercise programme improve BAS scores in AS?	44
11/SC/0215	ADC-PMS-GLUC-10007 Blood Glucose and Ketone Performance Test Rev 1.0	26
11/SC/0233	RCT of DreamSkin® Garments for Childhood Eczema	43
11/SC/0241	Biliary Tract Cancer QoL Validation	18
11/SC/0244	Evaluation of a patient-held record for patients with MRSA	39
11/SC/0249	Human Pain Perception: Version 1	40
11/SC/0258	Apoptosis and bicuspid aortic valve associated aortopathy. Version 3	53
11/SC/0268	Effect of Nordic Walking on AI Associated Arthralgia Version 1	36
11/SC/0275	QVA cross over study in mod to sev COPD	43
11/SC/0277	Living with Psychosis: Exploring the experience.	38
11/SC/0293	EPOC B	39
11/SC/0345	Non-invasive brain stimulation for people with stroke	33
11/SC/0346	Ranibizumab vs dexamethasone in central retinal vein occlusion	69
11/SC/0406	Study on the Effects of Extended Initial Appointments(v1)	42
11/SC/0412	Development of Symptom Based Questionnaires for patients with cancer	37
11/SC/0415	Blood pressure control mechanisms and cerebrovascular autoregulation 1	40
11/SC/0422	Periodontal and systemic inflammation and Alzheimer's disease	54
11/SC/0518	Analysis of the upper respiratory microbial community, version 1.	27
11/SC/0520	Wellmune for the prevention of URTI in a 50 to 70 year old population	30
11/SC/0529	Modelling Placental Nutrient Transport	42
11/SC/0532	VSL#3 on CV risk and liver injury in nonalcoholic fatty liver disease.	23
11/SC/0541	The Medication and Cognition Questionnaire (MCQ)	28
11/SC/0543	FOR-DMD	25
12/SC/0015	The Talking Sense communication programme for dementia family carers	30
12/SC/0119	Tralokinumab vs Placebo in moderate-severe Ulcerative Colitis - V1.0	30

**Further Information Favourable Opinion with Additional Conditions**

REC Reference	Application Short Title	Number of Days on Clock
11/SC/0382	Prophylactic Hip Positioning for Stable Hips following Breech Birth	47
11/SC/0435	Preoxygenation in the Head Up Laryngoscopy Position	56
11/SC/0449	Is impairment of ankle movement related to ankle microcirculation?	35
11/SC/0455	POWeR2	52
11/SC/0516	Diazepam and Emotional processing	40
12/SC/0010	The psychological impact of sudden arrhythmic death syndrome	33
12/SC/0068	Tissue oxygen tension and tissue impedance to study tissue oedema	35

#### 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/SC/0103	Respiratory Tissue Archive	16
11/SC/0246	CFTY720D2324 Tysabri Switch Study	29
11/SC/0256	Cardiovascular disease in a Nepali migrant population	38
11/SC/0282	XRT +/- vandetanib in CNS melanoma	23
11/SC/0286	Development and pilot evaluation of LifeCIT (Version 1)	23
11/SC/0288	Understanding difficulties in the supervisory relationship	23
11/SC/0321	A cross sectional study of the beliefs of S.U.H.T volunteers.V1.	26
11/SC/0347	Analysing steroids by LC-MSMS and establishing reference ranges	35
11/SC/0395	UK Brain Archive Information Network (BRAIN UK) (Post-Human Tissue Act	27
11/SC/0408	The SMART Trial (version 1)	27

#### Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/SC/0385	Fetal cardiac function in diabetic mothers	27
12/SC/0034	CDEB025A2306:DEB025 in protease inhibitor failure GT1 Hepatitis C	27
12/SC/0173	Saxagliptin with metformin in paediatric type 2 diabetes patients	21

#### Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/SC/0201	Is impairment of ankle movement related to ankle microcirculation?	18

11/SC/0203	Cycle analysis in women with recurrent miscarriages	30
11/SC/0281	SEXUAL FUNCTION QUESTIONNAIRE TOTAL HIP REPLACEMENT	23
11/SC/0309	Cycle analysis in women with recurrent miscarriages	26
11/SC/0323	Mechanisms and Regulation of Placental Nutrient Transport	26
11/SC/0514	Remote ischaemic preconditioning: A pilot study	21

#### Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
12/SC/0105	Remote ischaemic preconditioning: A pilot study	N/A
12/SC/0106	Stem Cell Models of Ataxia	N/A
12/SC/0152	OxCKD1 Empowering healthy lifestyle choices in chronic kidney disease.	N/A
12/SC/0168	Psychological Therapies in Homelessness Outcome Evaluation	N/A
12/SC/0175	Retreatment of recurrent Dupuytren's contractures with AA4500	N/A
12/SC/0176	Inflammation and disability progression in multiple sclerosis	N/A
12/SC/0178	Effects of the Enzira® flu vaccine; 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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**Table 9: 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/SC/0346	Ranibizumab vs dexamethasone in central retinal vein occlusion	69

<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>
09/H0504/112/AM06	Pneumococcal conjugate vaccine in acute lymphoblastic leukaemia	Substantial Amendment - 20/05/2011	45
09/H0504/104/AM14	Cardiovascular Biomedical Research Unit (RB&H NHS Foundation Trust)	Substantial Amendment RTB No.8	66
07/Q1704/19/AM06	An evaluation of the REITAN catheter pump for acute heart failure.	Amendment 5 - 16/05/2011	36
10/H0504/62/AM03	Designing a Support Protocol for People with Mild Cognitive Impairment	Amendment 3	52
07/Q1704/6/AM11	Intramuscular diamorphine versus Pethidine in labour_Version 1	Sub Amend - Change of letterhead	49
08/H0504/28/AM04	Hampshire pneumococcal infection study	Sub Amend 7.6.11	49
09/H0504/138/AM01	Case studies of experiences of cancer of unknown primary site (CUP)	Sub Amend 1 (6.7.11)	46

10/H0504/57/AM07	The safety & efficacy of AZD4547 in FGFR1 amplified breast cancer	Subs Amend 3 (24.5.11)	49
10/H0504/57/AM08	The safety & efficacy of AZD4547 in FGFR1 amplified breast cancer	Sub Amend 4 (28.6.11)	51
10/H0504/15/AM09	YM155 + Docetaxel as 1st-Line Treatment for Metastatic Breast Cancer	Sub Amend 4 (20.6.11)	49

#### Modified Amendments over 14 day timeline

Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
09/H0504/31/AM12/1	WN22018 - Use of RO5313534 as add on to donepezil in Alzheimer's	Modified Amend to Updated Safety info 8/2/11	15
10/H0504/70/AM02/1	Open Label Study Looking at Canakinumab (ACZ885) in TRAPS	Modified Substantial Amendment 2 (MAS Letter & Cha	26
09/H0504/109/AM03/1	Modelling infection and airways disease	Modified amendment 1 17 03 2011	56
09/H0504/109/AM03/2	Modelling infection and airways disease	Modified amendment 2 dated 1 June 2011	21
10/H0504/62/AM03/1	Designing a Support Protocol for People with Mild Cognitive Impairment	Modified Amendment to Sub Amend 3	28
10/H0504/2/AM06/1	IL17 in asthma	Mod Amend 3, v2 (9.9.11)	29
10/H0504/91/AM01/1	Measures in young and at risk of arterial dysfunction (MYRIAD)	Modified Amendment 1 - 21.12.11	15

#### Section 30 application over 60 day timeline

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