

NRES Committee South Central - Hampshire B

Annual Report

01 April 2013 – 31 March 2014

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee South Central - Hampshire B
Type of REC:	Type III
Type of Flag:	CTIMPs Research Tissue Banks IRB Registered
Chair:	Professor Ron King
Vice-Chair:	Dr Giles Tan
Alternate Vice-Chair:	Dr Chris Markham
REC Manager:	Miss Libby Watson
REC Assistant:	Miss Lauren Allen (05/11/2012 – 01/10/2013) Mr Ben Manning (29/10/2013 – 08/01/2014) Miss Natasha Bridgeman (27/01/2014 – Present)
Committee Address:	Bristol REC Centre Level 3 Block B Whitefriars Lewins Mead Bristol BS1 2NT
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Chair's overview of the past year:

This has been the inaugural year of the Hampshire B REC, following the merger of the Southampton B and Portsmouth RECs. Happily the majority of members of both pre-existing committees were able to join the new committee. However the timing and venue for meetings led to some resignations, most notably that of Jayne Tyler who had contributed so much over many years on the Portsmouth Committee, first as a member and then as Vice-Chair. During the year we have also lost Nicola Lamb, Karen MacKinnon and Ian McAndrew as a result of the pressure of their other duties. They should be thanked for their valuable input into discussions and decision making on both the main committee and its sub-committees, including some for proportionate review. Despite these losses the merged committee has dealt well and efficiently with all the application that have come its way.

The REC Manager, Libby Watson, is to be particularly thanked and indeed congratulated for ensuring that all deadlines were met. This could only be accomplished through clear decisions and conditions being made, recorded, minuted and then issued to the applicants. It has been encouraging to receive positive feedback from a number of these applicants.

From a personal point of view I would like to thank my fellow officers, Giles Tan and Chris Markham for their work, not only for the main committee, but also for the sub-committees, where their role in dealing with substantial amendments and proportionate reviews has been particularly helpful. Of course, on merging the committees there have been a number of ethical issues on which views have differed rather more widely than usual, and that have therefore generated healthy debate. I see this as a positive development and look forward to the coming year in which no doubt there will be further debates as we deal with the rich variety of applications that come our way.

NRES Committee South Central - Hampshire B Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mrs Ita Berry	Clinical Psychologist (Retired)	Lay	01/04/2013	
Mr Brian Birch	Consultant Urological Surgeon	Expert	01/04/2013	
Mrs Alison Bowser	Patient and Public Involvement Officer	Lay Plus	01/04/2013	
Mrs Janet Brember	Pharmacist	Expert	01/04/2013	
Dr Diane Carpenter	Lecturer, Mental Health Studies	Expert	01/04/2013	
Mr Mark Cassidy	Lecturer in Radiography	Expert	01/04/2013	
Mrs Angela Iveson	Oncology Research Nurse	Expert	01/04/2013	
Professor Ron King (Chair)	Mathematician (Retired)	Lay Plus	01/04/2013	
Ms Nicola Lamb	Senior Nurse	Expert	01/04/2013	09/08/2013
Mr Geoff Lowndes	Chartered Engineer (Retired)	Lay Plus	01/04/2013	
Rev Karen MacKinnon	Healthcare Chaplaincy	Lay Plus	01/04/2013	31/05/2013
Dr Chris Markham (Alternate Vice-Chair)	Principal Lecturer - Public Health, Social Care and Research Design Lead	Expert	01/04/2013	
Dr Ian McAndrew	Independent EU Consultant/Lecturer	Lay Plus	01/04/2013	22/01/2014
Dr Karl Nunkoosing	Principal Psychology Lecturer	Lay	01/04/2013	
Dr Andrew Scott	Course Leader, M.Sc. Clinical Exercise Science	Expert	01/04/2013	
Mr Alan Smith	Barrister's Clerk (Retired)	Lay Plus	01/04/2013	
Dr Giles Tan (Vice-Chair)	Consultant Psychiatrist	Expert	01/04/2013	
Mrs Jayne Tyler	Local Authority Project Officer	Lay Plus	01/04/2013	31/05/2013

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Mr Trevor Olding	Clinical Coordinator	Lay	27 November 2013

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

Name	Declaration of Interest	Date
Dr Karl Nunkoosing	None	03/05/2013
Dr Giles Tan (Vice-Chair)	Member of BMA, MRCPsych	08/04/2013
Dr Andrew Scott	None	08/04/2013
Mrs Angela Iveson	Employed as an oncology research nurse by Salisbury NHS Foundation Trust.	04/04/2013
Mr Brian Birch	Paid advisor (ad hoc) for Astellas Received honoraria to speak at, chair and attend meetings or liaised/received educational material from representatives of the following companies: Astellas, Pfizer, Ipsen, Glaxo Smith Kline, Sanofi, Lilly, Bayer, Amgen, Ferring, Takeda, AstraZeneca Janssen-Cilag	15/05/2013
Dr Diane Carpenter	None	09/04/2013
Mrs Janet Brember	None	24/04/2013
Mr Geoff Lowndes	None	04/10/2013
Mrs Ita Berry	None	29/05/2013
Mr Alan Smith	None	29/05/2013
Ms Nicola Lamb	Currently studying masters degree in clinical research at the University of Southampton. Employed by NIHR CLRN as research nurse for portfolio studies in clinical care, primarily involving data collection.	29/05/2013
Dr Ian McAndrew	None	29/05/2013
Mr Mark Cassidy	Supervision of BSc student projects. Membership of Nationwide Building Society.	05/06/2013
Dr Chris Markham (Alternate Vice-Chair)	Works with a University collaborate in Health Service Research.	26/06/2013
Mrs Alison Bowser	Lay commissioner on the Commission on Human Medicines (Advisory Scientific Committee to MHRA).	26/06/2013
Professor Ron King (Chair)	Shareholdings in organisations involved in or possibly seeking to be involved in the conduct of research. None other than investments in certain managed funds	02/01/2014

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

Month	Date	Number of Members Present at Meeting
May	29/05/2013	14
June	26/06/2013	11
July	31/07/2013	11
August	28/08/2013	8
September	25/09/2013	9
October	30/10/2013	11
November	27/11/2013	7
December	11/12/2013	12
January	29/01/2014	11
February	26/02/2014	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
July	05/07/2013	3
August	14/08/2013	3
September	11/09/2013	3
October	09/10/2013	3
November	14/11/2013	3
December	10/12/2013	3
January	13/01/2014	3
February	12/02/2014	3
March	13/03/2014	3

9 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
Dr Andrew Scott	8
Mr Brian Birch	8
Mrs Ita Berry	8
Mrs Janet Brember	8
Professor Ron King (Chair)	8
Mr Alan Smith	8
Mrs Angela Iveson	7
Mr Geoff Lowndes	7
Mr Mark Cassidy	7
Dr Diane Carpenter	7
Dr Giles Tan (Vice-Chair)	7
Mrs Alison Bowser	6
Dr Chris Markham (Alternate Vice-Chair)	5
Dr Karl Nunkoosing	5
Ms Nicola Lamb	2
Rev Karen MacKinnon	1
Dr Ian McAndrew	1
Mrs Jayne Tyler	1

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
Dr Chris Markham (Alternate Vice-Chair)	5
Mrs Angela Iveson	3
Dr Giles Tan (Vice-Chair)	3
Dr Ian McAndrew	3
Professor Ron King (Chair)	3
Mrs Janet Brember	2
Dr Karl Nunkoosing	2
Dr Diane Carpenter	2
Mrs Ita Berry	1
Mr Alan Smith	1
Mr Mark Cassidy	1
Dr Andrew Scott	1

Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Mrs Ita Berry	26/03/2014 - 26/03/2014	Hampshire B Local Training Day, REC Manager
Mr Brian Birch	20/11/2013 - 20/11/2013	National Members Training Day, HRA
Mr Brian Birch	04/12/2013 - 04/12/2013	Human Tissue Act (Use of Human Samples in Research) - An Introductory Level, HRA
Mr Brian Birch	02/02/2014 - 02/02/2014	Equality & Diversity, HRA
Mr Brian Birch	05/02/2014 - 05/02/2014	Researcher Training Day, HRA
Mr Brian Birch	26/03/2014 - 26/03/2014	Hampshire B Local Training Day, REC Manager
Mrs Alison Bowser	04/09/2013 - 04/09/2013	Research Involving Adults Who Lack Capacity (including research in emergency situations, HRA
Mrs Alison Bowser	03/02/2014 - 03/02/2014	Equality & Diversity, HRA
Mrs Alison Bowser	05/02/2014 - 05/02/2014	Researcher Training Day, HRA
Mrs Alison Bowser	26/03/2014 - 26/03/2014	Hampshire B Local Training Day, REC Manager
Mrs Janet Brember	20/11/2013 - 20/11/2013	National Member's Training, NRES
Mrs Janet Brember	13/01/2014 - 13/01/2014	Equality & Diversity, HRA
Mrs Janet Brember	26/03/2014 - 26/03/2014	Hampshire B Local Training Day, REC Manager
Dr Diane Carpenter	17/10/2013 - 17/10/2013	Equality & Diversity, HRA
Dr Diane Carpenter	26/03/2014 - 26/03/2014	Hampshire B Local Training Day, REC Manager
Mr Mark Cassidy	07/11/2013 - 07/11/2013	Public involvement in health research - where, why and how?, South Central Informal PPI Network
Mr Mark Cassidy	01/04/2013 - 08/01/2014	Self-Directed Learning, Annotated reading of 'A review of ethical frameworks for the disclosure of individual research results in population-based genetic and genomic research'; <i>Research Ethics</i> (2012) Vol.8 (1); and development of one-hour lecture to introduce concepts and applications of research ethics to Year 2 undergraduates.
Mr Mark Cassidy	10/01/2014 - 10/01/2014	Equality & Diversity, HRA
Mr Mark Cassidy	26/03/2014 - 26/03/2014	Hampshire B Local Training Day, REC Manager
Mrs Angela Iveson	26/03/2014 - 26/03/2014	Hampshire B Local Training Day, REC Manager
Professor Ron King	10/06/2013 - 10/06/2013	NREAP Chairs meeting - South Central, NREAP
Professor Ron King	10/12/2013 - 10/12/2013	Quantitative Methods and Statistics , NRES
Professor Ron King	18/02/2014 - 18/02/2014	Equality & Diversity, HRA
Professor Ron King	26/03/2014 - 26/03/2014	Hampshire B Local Training Day, REC Manager
Mr Geoff Lowndes	19/02/2014 - 19/02/2014	Reviewing CTIMPs, HRA
Mr Geoff Lowndes	26/03/2014 - 26/03/2014	Hampshire B Local Training Day, REC

		Manager
Dr Chris Markham	13/11/2013 - 13/11/2013	South Central NREAP/REC Chairs Network Meeting, NREAP
Dr Chris Markham	26/03/2014 - 26/03/2014	Hampshire B Local Training Day, REC Manager
Dr Andrew Scott	20/08/2013 - 20/08/2013	Berkshire Training Day, Berkshire REC
Mr Alan Smith	20/08/2013 - 20/08/2013	Berkshire Training Day, Berkshire B REC
Mr Alan Smith	20/11/2013 - 20/11/2013	National Members' Training Day, NRES
Dr Giles Tan	11/12/2013 - 11/12/2013	National Chair's Training Day, HRA
Dr Giles Tan	13/11/2013 - 13/11/2013	South Central NREAP/REC Chairs Network Meeting, NREAP
Dr Giles Tan	01/01/2014 - 01/01/2014	Equality & Diversity, HRA
Dr Giles Tan	26/03/2014 - 26/03/2014	Hampshire B Local Training Day, REC Manager

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	13	23.64
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	3	5.45
Research Database	0	0.00
Others	39	70.91
Total Applications Reviewed	55	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	6
Number of studies withdrawn prior to the meeting	6
Number of student applications reviewed	17
Number of paediatric applications reviewed	9
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	1

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	0	0.00
Favourable Opinion with Additional Conditions	15	27.27
Unfavourable Opinion	1	1.82
Provisional Opinion	39	70.91
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	55	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	18	32.73
Further Information Favourable Opinion with Additional Conditions	19	34.55
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	15	27.27
Unfavourable Opinion	1	1.82
Provisional Opinion	2	3.64
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	55	100

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

Total Applications Reviewed	16
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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	4	25.00
Favourable Opinion with Additional Conditions	9	56.25
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	3	18.75
Unfavourable Opinion	0	0.00
Total	16	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.50
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	30
Number of days taken to final decision - mode	29
Number of SSAs (non-Phase 1) reviewed	4
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	136
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	8
Number of modified amendments over 14 days	0
Number of modified amendments over 14 days as a % of total modified amendments	0.0%
Number of proportionate review applications for ethical review over 14 days	0
Number of proportionate review applications over 14 days as a % of total	0.0%

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/SC/0258	Characterisation of immune/T cell responses in contact sensitisation.	36
13/SC/0272	Yogic breathing techniques in generalized anxiety disorder	35
13/SC/0282	Intermittent catheterisation research programme: Module 1	37
13/SC/0287	Development of a HRQOL questionnaire module for anal cancer patients	27
13/SC/0391	Social-emotional Under 4's Screening and Intervention. Version 1.1	40
13/SC/0393	A clinical study of a shingles vaccine in people aged 50 and over (V1)	47
13/SC/0435	ABICUS Trial: Version 2	21
13/SC/0480	SER100 in ISH	32
13/SC/0551	Oocyte deVelopment and matUrity in reproductive woMen (OVUM)	40
13/SC/0559	Telotristat Etiprate for Carcinoid Syndrome Therapy – TELECAST	36
13/SC/0587	PLATFORM Trial	35
13/SC/0592	Barts Pancreas Tissue Bank	29
13/SC/0593	PCRF National Pancreatic Registry & Tissue Bank V1	29
13/SC/0598	Neural effects of Naltrexone on reward in women with Bulimia Nervosa	32
13/SC/0601	Inspiratory Muscle Training in Adult Fontan Population	8
13/SC/0611	Chronic pain, Childhood trauma and Emotional Dysregulation	26
14/SC/0020	The impact of attention on behavioural difficulties during adolescence	27
14/SC/0090	CBT in FMS Patients	11
14/SC/0099	Adolescents with Liver Disease: Impact of Culture & Faith v1.0	10
14/SC/0101	Physical Inactivity in COPD (Chronic Obstructive Pulmonary Disease) V1	27
14/SC/0102	Neural responses to reward and aversion in depressed adolescents	32

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
13/SC/0260	Stroke Early Supported Discharge - treatment burdens on carers	43
13/SC/0263	Brain pulse project - Chiari Pilot version 1	35
13/SC/0268	Ease of use of TIP compared to TIS and colistimethate in P. aeruginosa	25
13/SC/0279	Phase 3 study of TAF-containing combination STR in HIV-1 subjects	29
13/SC/0323	PCI-32765DBL3001	25
13/SC/0378	Lixisenatide - effects on glucose and TG metabolism in type 2 diabetes	24

13/SC/0384	Tremilimumab in pleural or peritoneal malignant mesothelioma	41
13/SC/0394	METRIC(MR Enterography or uLTRasound In Crohn's disease)	38
13/SC/0423	K-877 In Patients With Abnormal Lipid Levels	23
13/SC/0443	Analysis of genetic contributors to infertility	49
13/SC/0447	Oxygenation during gaseous induction of anaesthesia in children	23
13/SC/0478	LGX818, MEK162 and LGX818 vs vemurafenib in melanoma patients.	23
13/SC/0531	It Slipped my Mind! Enhancing Prospective Remembering through Enactment	36
13/SC/0538	PDSAFE Stage 1 Pilot Trial	29
13/SC/0540	The experience of intimate partner violence amongst HIV patients	34
13/SC/0613	Development of haematological analysis techniques	26
13/SC/0643	Prevalence of cardiac ATTR amyloidosis in the elderly	29
13/SC/0644	UNBLOCS: UriNary oBstruction relieved by Laser Or Conventional Surgery	22
14/SC/0098	UK Brain Archive Information Network (BRAIN UK)	27

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/SC/0543	Breathlessness and presentation to the ED	2
13/SC/0647	Acellular allogeneic bone-tendon-bone. Version 2	7
13/SC/0648	Perinatal Maternal Well-being: An Exploratory Study V 1.0	7
14/SC/0050	Development of a diagnostic assay for a TNF-inhibitor	10

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/SC/0320	Identifying the prevalence of chronic wounds & chronic wound infection	32
13/SC/0389	Factors influencing adherence to pelvic floor exercises	2
13/SC/0392	AtherOx1 V1.00	28
13/SC/0409	SPRING Southampton Pregnancy Intervention for the Next Generation	20
13/SC/0425	Mass Casualty Decontamination: clothing and hydrodynamics	39
13/SC/0427	Rescuer safety during implanted defibrillator discharge	29
13/SC/0446	Self-Harm pts' experience of mental health services in acute hospital	20

13/SC/0449	Constipation Risk in an Outpatient Chemotherapy Population	5
13/SC/0464	Duck egg allergy in children allergic to hen's egg (Pilot Quack Study)	20
13/SC/0495	Study to evaluate biology of keloids after different treatments v1.0	27
13/SC/0499	Adipose stem cells in reconstructive surgery	5
13/SC/0605	Compassion-focused expressive writing: carers of people with dementia	7
13/SC/0626	Brain stimulation in aphasia (version 1.0)	28
13/SC/0630	STAARS UK	24
13/SC/0645	PHOENIX Study - Final Version 1	20
13/SC/0649	Parents' stories of adjustment to their child's chronic illness	7
14/SC/0039	PDSAFE trial	28
14/SC/0040	Reducing Distress from Somatic Symptoms (REDRESS)	34
14/SC/0047	Patient, GP and pharmacist views on the information on medicine labels	4
14/SC/0051	Frailty in older adults living with HIV - version 1.0	26
14/SC/0094	Comorbidity Cohort in Heart Failure (2C-HF) study.	7
14/SC/0104	AZD1722 for phosphate lowering in dialysis patients	26
14/SC/0158	Patient Record Access	8
14/SC/0159	CMV and cancer reactive gamma delta T cells for immunotherapy	7

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
14/SC/0052	The effect of depression on counterfactual thinking	23

Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
14/SC/0066	EDICT - Exercise inDuced changes In Colorectal Cancer Tissues	N/A
14/SC/0070	The role of CFTR in mechanisms of perception of bladder fullness	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
Invalid Application		
REC Reference	Application Short Title	Number of Days on Clock
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
Proportionate review applications for ethical review over 14 days timeline			
REC Reference	Application Short Title		Number of Days on Clock
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