

NRES Committee South Central - Hampshire A

Annual Report

01 April 2013 – 31 March 2014

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee South Central - Hampshire A
Type of REC:	RECs recognised to review CTIMPS in patients - type iii
Type of Flag:	Research Involving Adults Lacking Capacity Research Involving Children
Chair:	Dr Iain MacIntosh
Vice-Chair:	Dr Simon Kolstoe
Alternate Vice-Chair:	Dr Ronja Bahadori
REC Manager:	Mrs Maxine Knight until 01/11/13 Mrs Vicky Canfield-Duthie from 01/11/13
PRSC Co-ordinator:	Mrs Maxine Knight until 01/11/13 Mrs Vicky Canfield-Duthie from 01/11/13
REC Assistant:	Mrs Vicky Canfield-Duthie until 01/11/13
Committee Address:	Bristol Research Ethics Committee Centre Level 3, Block B Whitefriars Lewins Mead Bristol BS1 2NT
Telephone:	0117 342 1381
Email:	nrescommittee.southcentral-hampshirea@nhs.net

Chair's overview of the past year:

In the last year we reviewed almost exactly the same number of applications as the year before. I note that we have improved in our time to completion of applications for full ethical review, SSAs and substantial amendments. This is undoubtedly because of the hard work of the co-ordinator. The number of provisional opinions remains high, in keeping with the committee's desire to do all it can to get applications into a position to approve them. There was a substantial rise in the unfavourable opinions from 1 to 6, which is unusual for this committee. Although this may reflect the submissions received in that year the committee will need to give this some consideration, particularly with the increasing emphasis on consistency. I have stepped down as chair this year and Dr Kolstoe will take over. Simon has chaired on several occasions, comes from a strong academic background and also enjoys the light-hearted side of the committee. We have appointed physicians to ensure that there are enough medical professionals to help him as well as some other lay appointments to ensure that the committee has adequate numbers

NRES Committee South Central - Hampshire A Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr Clifford Allen	Corporate Development and Learning	Lay	14/10/2011	
Mr Richard Andoh	Pharmacist	Expert	01/12/2009	
Dr Catherine Angell	Midwife/Lecturer	Expert	01/12/2010	
Mrs Lisa Frances Armstrong	Senior Lecturer Social Work	Lay Plus	14/10/2011	
Dr Ronja Bahadori	Clinical Trial Coordinator	Expert	01/06/2011	
Ms Sonia Baryschpolec	Research Nurse	Expert	01/01/2014	
Dr Stewart Bruce-Low	Laboratory Director & Senior Lecturer	Lay Plus	01/11/2010	
Mr David Hutchings	Retired	Lay Plus	21/11/2013	
Dr Simon Kolstoe	Academic Research Scientist/Vice-Chair	Expert	01/07/2009	
Dr Mary Lanyon	Retired Veterinarian	Lay Plus	01/01/2010	
Dr Iain MacIntosh	Consultant Paediatric Intensive Care	Expert	15/07/2007	
Mr Trevor Olding	Clinical Coordinator	Lay	11/03/2013	
Dr Kesava Ananth Ramakrishnan	Consultant, Paediatric Intensive Care Unit (PICU)	Expert	01/01/2014	
Ms Fran Richards	PA	Lay Plus	01/01/2014	
Dr Ramya Ramanujachar	Paediatric Oncology Consultant	Expert	01/03/2014	
Mr John Roskilly	Healthcare Support Worker	Lay	06/09/2011	25/05/2013
Mr Jack Steer	Student	Lay Plus	14/10/2011	09/10/2013
Mrs Margaret Stephens	Senior Specialist, Speech & Language Therapist (Adult Neurology & Elderly Care)	Expert	10/07/2008	

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Mrs Ita Berry	Retired Clinical Psychologist	Lay	08 October 2013
Ms Stephanie Ellis	Former Civil Servant	Lay Plus	23 September 2013 (PRS)

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

Name	Declaration of Interest	Date
Dr Ronja Bahadori	No declarations of interest	17/06/2013
Mrs Margaret Stephens	No declarations of interest	17/06/2013
Mr Jack Steer	No declarations of interest	17/06/2013
Dr Stewart Bruce-Low	No declarations of interest	17/06/2013
Dr Simon Kolstoe	Consultancy_Glaxo Smith KlineConsultancy_Wolfson Drug Design Unit. Employed by Uni of Portsmouth Member of MOD research ethics committee	17/06/2013
Dr Clifford Allen	Member of HCC pension fund	17/06/2013
Mr Trevor Olding	No declarations of interest	17/06/2013
Dr Mary Lanyon	No declarations of interest	17/06/2013
Dr Iain MacIntosh	No declarations of interest	11/07/2013
Mrs Lisa Frances Armstrong	No declarations of interest	11/07/2013
Dr Catherine Angell	Ethical review for school of health and social care - Bournemouth University	11/07/2013
Ms Sonia Baryschpolec	No declarations of interest	27/02/2014
Mr David Hutchings	Director of TinTack Solutions	27/02/2014
Dr Kesava Ananth Ramakrishnan	Currently involved in research conducted in PICU at Southampton. Pursuing a PhD with University of Southampton	27/02/2014
Ms Fran Richards	PA and administrator at RDS South Central which is funded by NIHR	25/03/2014
Mr Richard Andoh	No declarations of interest	31/03/2014

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

Month	Date	Number of Members Present at Meeting
April	09/04/2013	9
May	14/05/2013	10
June	11/06/2013	9
July	09/07/2013	9
August	13/08/2013	7
October	08/10/2013	9
November	12/11/2013	9
December	10/12/2013	8
January	14/01/2014	13
February	11/02/2014	11
March	11/03/2014	10

11 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	23/04/2013	3
May	28/05/2013	3
June	24/06/2013	3
August	27/08/2013	3
September	23/09/2013	3
October	28/10/2013	3
November	25/11/2013	3
December	18/12/2013	3
January	21/01/2014	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
Mr Trevor Olding	11
Dr Mary Lanyon	10
Dr Simon Kolstoe	10
Dr Clifford Allen	9
Dr Iain MacIntosh	9
Mr Richard Andoh	9
Dr Ronja Bahadori	8
Mrs Margaret Stephens	7
Dr Stewart Bruce-Low	6
Dr Catherine Angell	5
Mrs Lisa Frances Armstrong	5
Mr Jack Steer	4
Mr David Hutchings	3
Ms Sonia Baryschpolec	3
Ms Fran Richards	2
Dr Kesava Ananth Ramakrishnan	2

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
Dr Ronja Bahadori	7
Dr Simon Kolstoe	5
Mrs Margaret Stephens	3
Dr Mary Lanyon	3
Mr Richard Andoh	2
Mrs Lisa Frances Armstrong	2
Dr Stewart Bruce-Low	2
Mr John Roskilly	1
Mr Trevor Olding	1

Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Dr Stewart Bruce-Low	30/05/2013 - 30/05/2013	ethics workshop, University of Surrey
Dr Ronja Bahadori	02/05/2013 - 02/05/2013	Ethical Issues of Research Involving Children
	04/12/2013 - 04/12/2013	Human Tissue Act (Use of Human Samples in Research) - An Introductory Level, HRA
	11/12/2013 - 11/12/2013	Chairs Training Day, HRA
	04/09/2013 - 04/09/2013	Training - Research Involving Adults Who Lack Capacity (including research in emergency situations), HRA
	10/03/2014 - 10/03/2014	Equality & Diversity, HRA Online
	10/03/2014 - 10/03/2014	Improving Informed Consent & Participant Information Sheets, HRA
Dr Clifford Allen	04/07/2013 - 04/07/2013	Induction
	04/07/2013 - 04/07/2013	Equality & Diversity
Mr Trevor Olding	10/07/2013 - 10/07/2013	Induction, HRA
	13/03/2014 - 13/03/2014	Equality & Diversity
Mrs Lisa Frances Armstrong	10/07/2013 - 10/07/2013	Induction, HRA
Dr Mary Lanyon	11/03/2014 - 11/03/2014	Medical Devices Training Day, HRA
Ms Sonia Baryschpolec	12/03/2014 - 12/03/2014	Equality & Diversity
	26/03/2014 - 26/03/2014	Hampshire B Training Day
Mr Richard Andoh	28/03/2014 - 28/03/2014	Clinical trials learning@ lunch (2014), CPPE
Dr Simon Kolstoe	11/12/2013 - 11/12/2013	National NRES Chairs Training Day, HRA
	10/06/2013 - 13/11/2013	NREAP hosted chairs meeting x 2: 10th June 2013 and 13th November 2013.
	29/10/2013 - 29/10/2013	Equality & Diversity, University of Portsmouth
Mr David Hutchings	17/03/2014 - 17/03/2014	Equality & Diversity
Mrs Margaret Stephens	25/03/2014 - 25/03/2014	Research Involving the Disadvantaged and Vulnerable, HRA
Ms Fran Richards	26/03/2014 - 26/03/2014	Hampshire B Training Day
Dr Iain MacIntosh	11/12/2013 - 11/12/2013	Chair's Training Day, HRA
	13/11/2013 - 13/11/2013	NREAP Chairs meeting - training - 2 hours
	27/03/2014 - 27/03/2014	Equality & Diversity, HRA
Dr Catherine Angell	10/03/2014 - 10/03/2014	Improving Informed Consent and Participant Information Sheets, HRA
	26/03/2014 - 26/03/2014	Member Training Day

	28/03/2014 - 28/03/2014	Equality & Diversity
--	-------------------------	----------------------

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	15	28.85
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	37	71.15
Total Applications Reviewed	52	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	7
Number of studies withdrawn prior to the meeting	15
Number of student applications reviewed	16
Number of paediatric applications reviewed	8
Number of device applications reviewed	3
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	7
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	1.92
Favourable Opinion with Additional Conditions	8	15.38
Unfavourable Opinion	6	11.54
Provisional Opinion	36	69.23
Invalid	0	0.00
No Opinion Pending Consultation with Referee	0	0.00
Provisional Opinion Pending Consultation with Referee	1	1.92
Not Requiring Review by NHS REC	0	0.00
Total	52	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	32	61.54
Further Information Favourable Opinion with Additional Conditions	4	7.69
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	1.92
Favourable Opinion with Additional Conditions	8	15.38
Unfavourable Opinion	6	11.54
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	1	1.92
Number of studies withdrawn after the meeting	0	0.00
Total	52	100

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

Total Applications Reviewed	19
------------------------------------	-----------

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	21.05
Favourable Opinion with Additional Conditions	1	5.26
No Opinion transfer to full committee for review	2	10.53
Provisional Opinion	12	63.16
Unfavourable Opinion	0	0.00
Total	19	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	4.73
Number of applications for full ethical review over 60 days	1
Number of applications over 60 days as a % of total	1.92%
Number of days taken to final decision - average	36
Number of days taken to final decision - mode	29

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	164
Number of substantial amendments over 35 days	4
Number of substantial amendments over 35 days as a % of total substantial amendments	2.4%

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	21
Number of modified amendments over 14 days	1
Number of modified amendments over 14 days as a % of total modified amendments	4.8%

Number of proportionate review applications for ethical review over 14 days	3
Number of proportionate review applications over 14 days as a % of total	17.6%

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/0174	Phase IIb, GS-6624 in subjects with primary sclerosing cholangitis	46
13/SC/0179	Stem cells for drug discovery	38
13/SC/0182	GORD in Asthma	44
13/SC/0197	Can you get sutures wet?	29
13/SC/0202	SUPPORT BACK Study	54
13/SC/0215	Characterisation of bacterial colonisation in ascitic fluid	31
13/SC/0225	Behaviour in children of CF parents	19
13/SC/0237	A Trial of LMTM in Patients with Mild AD (TRx-237-005)	25
13/SC/0249	A phase IIb study of GS-6624 in subjects with compensated cirrhosis	35
13/SC/0259	Idelalisib + Bendamustine + Rituximab for Previously Treated iNHL	57
13/SC/0265	Measuring long-term outcomes in people with dementia in care homes	50
13/SC/0285	Extension Study of Oral ELND005 in Patients with Alzheimer's Disease	37
13/SC/0299	Perfectionism and psychosocial adaptation to spinal cord injury (v1)	12
13/SC/0367	RECAPTURE 04: Phase 3 study of CAZ-AVI vs Doripenum in Complicated UTI	60
13/SC/0369	Advanced endoscopic imaging strategies for colitis surveillance.	29
13/SC/0386	M13-765 Extension Study for M10-855	30
13/SC/0416	Leukocytes: Inflammation Model Systems (LIMS)	40
13/SC/0469	The impact of formulation letter on the therapeutic alliance	14
13/SC/0471	PHIEBI: Investigating comorbid urinary incontinence & vascular disease	10
13/SC/0472	Stereotactic radiotherapy vs proton beam therapy	14
13/SC/0490	Lebrikizumab in adolescent patients with uncontrolled asthma	38
13/SC/0507	Impact of inflammation on age related hearing loss.	48
13/SC/0513	Improving the transfer of care study-001	11
13/SC/0514	EPICure@19 v1	47
13/SC/0556	Maps follow up.	55
13/SC/0574	Evaluating the pathogenicity of novel germline RET sequence variants	14
13/SC/0576	A study of the interaction between BCG And MenC immunisation: BAM	38
13/SC/0577	Humanly Sensitive Care: Improving older people's hospital experiences	36
13/SC/0582	Immune, molecular & genetic mechanisms of disease in patients with RCC	43

13/SC/0619	Group B streptococcus Immunisation Attitudes	41
13/SC/0621	People with Learning Disabilities as Interviewers	15
13/SC/0623	Haemodynamic Changes during Laparoscopy with Deep Neuromuscular Block	27
13/SC/0658	Ethnicity, patterns of substance misuse and associated comorbidity	6
14/SC/0014	CHaPPP v1.0	25
14/SC/0017	SET Trial (protocol version 9)	35
14/SC/0029	A Study of GLPG0634 in Patients With Active Crohn's Disease	62
14/SC/0048	A new intervention for social skills following brain injury Version 1	22
14/SC/0056	EBV Biomarkers	9
14/SC/0061	Assessing the Effects of Pregnancy on the Face of the Pubic Symphysis	29
14/SC/0068	MRS Predictors of Response to Lamotrigine	33
14/SC/0078	3WINTERS-IPS	22
14/SC/0130	Emergency decontamination in clinical treatments at scene	27

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/SC/0159	Emotional and executive sequelae of paediatric brain injury	41
13/SC/0177	Late preterm infant lung function version 1	42
13/SC/0324	Evaluating the role of lymphatic tissue in health and disease	26
13/SC/0332	Takeda TOMM40 301 Alzheimer's Disease study	55
13/SC/0656	Investigating patient recruitment to Radiotherapy Clinical Trials	19

Further Information Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
---------------	-------------------------	-------------------------

Favourable Opinion with Standard Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/SC/0301	A Retrospective Analysis in Patients with Acute Lymphoblastic Leukemia	12
13/SC/0419	Living with Cystic Fibrosis: Relationship to self and with others. v1.	36
13/SC/0475	Patient experiences of heart failure diagnosis	7
13/SC/0512	Exploring tissue repair in inflamed dental pulp	9
13/SC/0570	A Review of Shoulder Dystocia Management at North Bristol NHS Trust	14

Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
13/SC/0218	Lower Limb Blood Flow Geko vs IPC	37
13/SC/0248	NICEVIS Version 1.0	23
13/SC/0280	SB2-G31-RA: Phase 3 SB2 compared to Remicade in Rheumatoid Arthritis	29
13/SC/0506	Feasibility Study of a Coping Intervention for Recurrent Miscarriage	35
13/SC/0511	An exploration of home haemodialysis schedules	13
13/SC/0616	COPD Exacerbation Vaccine Study	21
14/SC/0002	Liver Disease Early Detection Study	45
14/SC/0016	Establishing normal oximetry values in infants using Masimo technology	18
14/SC/0111	Maintaining patency of fine-bore nasogastric feeding tubes in adults	26

Unfavourable Opinion		
REC Reference	Application Short Title	Number of Days on Clock
13/SC/0228	FREE-FLOW	29
13/SC/0355	MILEPOST	24
13/SC/0404	Patient experience of being nursed in a single-bedded room	50
13/SC/0505	Chronic pain, Childhood trauma and Emotional Dysregulation	24
13/SC/0522	Pregabalin Open Label Follow up study of A0081105	31
13/SC/0615	Making Safeguarding Personal	14

Provisional Opinion		
REC Reference	Application Short Title	Number of Days on Clock

Provisional Opinion Pending Consultation with Referee		
REC Reference	Application Short Title	Number of Days on Clock

Further information response not complete		
REC Reference	Application Short Title	Number of Days on Clock

Withdrawn after the meeting		
REC Reference	Application Short Title	Number of Days on Clock
13/SC/0353	Maternal and fetal physiology in pregnancy	8

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	
14/SC/0029	A Study of GLPG0634 in Patients With Active Crohn’s Disease	62	
Proportionate review applications for ethical review over 14 days timeline			
REC Reference	Application Short Title	Number of Days on Clock	
13/SC/0225	Behaviour in children of CF parents	19	
13/SC/0621	People with Learning Disabilities as Interviewers	15	
13/SC/0656	Investigating patient recruitment to Radiotherapy Clinical Trials	19	
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
08/H0502/5/AM06	Long term safety and efficacy of Omnitrope	Changes to Protocol for EP00-501	38
08/H0502/5/AM07	Long term safety and efficacy of Omnitrope	EP00-502 Version 3	38
07/H0502/113/AM25	MAVIDOS	Amendment 2.2 03/10/13	43
13/SC/0386/AM01	M13-765 Extension Study for M10-855	Amendment 1	36
Modified Amendments over 14 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock

13/SC/0182/AM01/1	GORD in Asthma	Amendment no.2.1	18
-------------------	----------------	------------------	----

Section 30 application over 60 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock