

NRES Committee South Central - Oxford A

Annual Report

01 April 2013 – 31 March 2014

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee South Central - Oxford A
Type of REC:	Recognised Type I, Type III
Type of Flag:	Phase 1 in Health Volunteers, Phase 1 Studies in Patients Transfers from GTAC, Paediatric, IRB registered
Chair:	Dr Karen Melham
Vice-Chair:	Dr Cynthia Graham
Alternate Vice-Chair:	Ms Alison Eden
REC Manager:	Miss Stephanie Macpherson
PRSC Manager:	Miss Stephanie Macpherson
REC Assistant:	Miss Gemma Oakes
Committee Address:	Bristol Research Ethics Committee Centre Whitefriars Level 3 Block B Lewins Mead Bristol BS1 2NT
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Chair's overview of the past year:

The committee has continued to review a very wide range of research proposals at full meetings and through proportionate review. This range increased this year when we gained the additional flag, 'Gene Therapy or Stem Cell Clinical Trials.'

Committee members remain consistent in their outstanding commitment to the work, providing robust review and constructive advice for researchers. They function very well as a group, complementing one another and together acting as a forum for ethical reflection and deliberation, and as a repository of institutional memory and good practice.

We welcomed back Stephanie Macpherson as our manager following her secondment to R&D, and were pleased that her cover, Thomas Fairman, has gone on to be a committee manager in his own right. Stephanie is ably assisted by Gemma Oakes, and together they manage administrative procedures and interactions with both researchers and committee members with efficiency, clarity, and good grace.

NRES Committee South Central - Oxford A Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Ms Raj Bains	Pharmacovigilance Business Consultant	Lay Plus	29/05/2008	
Ms Jane Cheeseman	Research Nurse	Expert	20/05/2013	
Mr Stuart Cole	Head of Communications	Lay Plus	01/06/2011	
Ms Alison Eden	Publisher	Lay Plus	01/01/2008	
Mrs Marion Fiddes	Consultant Project Manager	Lay Plus	13/02/2006	
Dr Cynthia Graham	Senior Lecturer in Psychology	Expert	12/12/2005	
Mrs Lyndsay Hills	Retired Registered Nurse	Lay	01/04/2010	
Tayo Jaiyesimi	Clinical Trials Pharmacist	Expert	01/09/2011	06/05/2013
Mrs Alison Kealy	Legal Assistant – Wills and Probate	Lay Plus	28/05/2013	
Mrs Doreen Laity	Retired Pharmacist	Lay	05/08/2013	
Dr Karen Melham	Ethicist (Chair)	Lay Plus	15/12/2005	
Dr Mike Murphy	Epidemiologist	Expert	01/08/2003	01/08/2013
Dr Mohit Sharma	Consultant in Public Health	Expert	29/05/2013	
Mr Martin Usherwood	Retired Gynaecologist	Expert	05/09/2011	
Dr Sian Warriner	Consultant Midwife	Expert	12/01/2004	12/01/2014

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Canon Ian Ainsworth-Smith	Retired Hospital Chaplain	Lay Plus	05 April 2013
Dr Robert Beetham	Retired Consultant Clinical Biochemist	Lay	05 April 2013
Mrs Ita Berry	Clinical Psychologist (Retired)	Lay	05 April 2013
Dr Richard Philip Craven	Senior lecturer in physiology	Lay	06 December 2013
Miss Stephanie Ellis	Former Civil Servant	Lay	05 April 2013
Mr Brian Pixton	Retired solicitor	Lay Plus	05 April 2013
Professor David Scott	Pharmacist	Expert	06 December 2013
Mr Barry Muir	Retired NHS Management Consultant	Lay	PR Meeting 18 December 2013

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

Name	Declaration of Interest	Date
Ms Jane Cheeseman	No Declarations of interest.	06/12/2013
Mr Stuart Cole	No Declarations of interest.	06/12/2013
Mrs Alison Kealy	Shareholding in GlaxosmithKline	06/12/2013
Mrs Marion Fiddes	No Declarations of interest.	06/12/2013
Dr Mohit Sharma	No Declarations of interest.	06/12/2013
Dr Cynthia Graham	Editor in Chief of a Taylor & Francis Scientific Journal	06/12/2013
Mrs Lyndsay Hills	No Declarations of Interest.	17/02/2014
Mrs Doreen Laity	No Declarations of interest.	07/02/2014
Ms Alison Eden	100% owner of Alison Brand - sometimes writes patient information/interviews sites, advises on recruitment/retention strategy.	17/02/2014
Mr Martin Usherwood	No Declarations of interest.	07/03/2014
Ms Raj Bains	No Declarations of interest	07/03/2014
Dr Karen Melham	Provides advice at R&D drop in sessions.	07/03/2014

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

Month	Date	Number of Members Present at Meeting
April	05/04/2013	9
May	03/05/2013	10
June	07/06/2013	9
July	05/07/2013	11
August	02/08/2013	10
September	06/09/2013	9
October	04/10/2013	7
November	01/11/2013	10
December	06/12/2013	9
February	07/02/2014	11
March	07/03/2014	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	22/04/2013	3
May	20/05/2013	3
June	24/06/2013	3
September	23/09/2013	3
October	21/10/2013	3
November	18/11/2013	3
December	17/12/2013	3
January	27/01/2014	3
February	24/02/2014	3
March	24/03/2014	3

10 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 Karen Melham	10
Dr Mohit Sharma	9
Dr Cynthia Graham	9
Mr Martin Usherwood	8
Mrs Alison Kealy	8
Mrs Lyndsay Hills	8
Mrs Marion Fiddes	8
Ms Jane Cheeseman	8
Ms Alison Eden	7
Mr Stuart Cole	7
Mrs Doreen Laity	5
Ms Raj Bains	4
Dr Sian Warriner	3
Dr Mike Murphy	3
Tayo Jaiyesimi	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 Karen Melham	4
Mr Stuart Cole	4
Mrs Lyndsay Hills	3
Dr Cynthia Graham	3
Mr Martin Usherwood	3
Ms Raj Bains	3
Mrs Marion Fiddes	2
Ms Alison Eden	2
Dr Sian Warriner	2
Dr Mohit Sharma	1
Ms Jane Cheeseman	1

Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Mrs Alison Kealy	28/05/2013 - 28/05/2013	Equality & Diversity, HRA
Dr Karen Melham	19/04/2013 - 19/04/2013	British Society for Gene and Cell Therapy Conference (Attendance and Presentation), British Society for Gene and Cell Therapy
Dr Karen Melham	06/09/2013 - 06/09/2013	Oxford REC A Training Day, HRA
Dr Cynthia Graham	06/09/2013 - 06/09/2013	Oxford A REC Training Day, HRA
Ms Alison Eden	06/09/2013 - 06/09/2013	Oxford A Training Day, HRA
Ms Raj Bains	06/09/2013 - 06/09/2013	Oxford A Training Day, HRA
Mrs Lyndsay Hills	06/09/2013 - 06/09/2013	Oxford A Training Day, HRA
Mr Stuart Cole	06/09/2013 - 06/09/2013	Oxford A Training Day, HRA
Mrs Marion Fiddes	06/09/2013 - 06/09/2013	Oxford A Training Day, HRA
Mr Martin Usherwood	06/09/2013 - 06/09/2013	Oxford A Training Day, HRA
Ms Jane Cheeseman	10/07/2013 - 10/07/2013	Induction, HRA
Ms Jane Cheeseman	06/09/2013 - 06/09/2013	Oxford A REC Training Day, HRA
Dr Mohit Sharma	06/09/2013 - 06/09/2013	Oxford A Joint Training Day, HRA
Mrs Doreen Laity	06/09/2013 - 06/09/2013	Oxford A Joint Training Day, HRA
Ms Alison Eden	11/08/2013 - 11/08/2013	Equality & Diversity, HRA
Ms Jane Cheeseman	12/08/2013 - 12/08/2013	Equality & Diversity, University of Oxford
Ms Raj Bains	22/08/2013 - 22/08/2013	Equality & Diversity, HRA
Ms Alison Eden	24/09/2013 - 24/09/2013	Quantitative Research Methods and Statistics, HRA
Ms Alison Eden	02/10/2013 - 02/10/2013	Researcher Training Day, HRA
Mrs Alison Kealy	10/07/2013 - 10/07/2013	Induction, NRES
Dr Karen Melham	11/12/2013 - 11/12/2013	Chairing Skills, HRA
Ms Jane Cheeseman	11/03/2014 - 11/03/2014	Training - Medical Devices Training Day, 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	12	21.43
Phase 1	7	12.50
Gene Therapy	5	8.93
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	32	57.14
Total Applications Reviewed	56	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	7
Number of student applications reviewed	11
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	2

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	10	17.86
Unfavourable Opinion	2	3.57
Provisional Opinion	42	75.00
Invalid	0	0.00
No Opinion Pending Consultation with Referee	0	0.00
Provisional Opinion Pending Consultation with Referee	2	3.57
Not Requiring Review by NHS REC	0	0.00
Total	56	100
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:

Status of applications at date of generation of report	Number	%
Further Information Favourable Opinion with Standard Conditions	34	60.71
Further Information Favourable Opinion with Additional Conditions	9	16.07
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	10	17.86
Unfavourable Opinion	2	3.57
Provisional Opinion	1	1.79
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	56	100

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

Total Applications Reviewed	22
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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	3	13.64
Favourable Opinion with Additional Conditions	0	0.00
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	16	72.73
Unfavourable Opinion	3	13.64
Total	22	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.09
Number of applications for full ethical review over 60 days	1
Number of applications over 60 days as a % of total	1.79%
Number of days taken to final decision - average	32
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	2
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)	0.0%

Number of substantial amendments reviewed	138
Number of substantial amendments over 35 days	1
Number of substantial amendments over 35 days as a % of total substantial amendments	0.7%

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	6
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	3
Number of proportionate review applications over 14 days as a % of total	13.6%

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/0144	The effect of cycloserine and hydrocortisone on learning	46
13/SC/0153	Computerised analysis of labour fetal heart rate traces II	45
13/SC/0156	Chingford 1000 Women Study	27
13/SC/0163	Sensorimotor plasticity and brain stimulation	36
13/SC/0173	Phase III Study in Metastatic Castration Resistant Prostate Cancer	40
13/SC/0186	LV CONCEPT study	29
13/SC/0200	Stem Cell Research in Early-Onset Psychosis	37
13/SC/0220	Breaking Free Online- Qualitative Interview Study with Inpatients	13
13/SC/0223	Scottish Book Trust Antenatal Pilot 2	14
13/SC/0226	Development of novel treatments based on T cell receptors	39
13/SC/0227	(duplicate) Development of novel treatments based on T cell receptors	39
13/SC/0245	Relationship between BP variability, aortic and cerebral haemodynamics	31
13/SC/0267	Pilot Study of Deep Brain Stimulation for Severe Anorexia nervosa	41
13/SC/0276	Men's attitudes to breast symptoms	14
13/SC/0283	Ovarian Cancer Biomarkers: A Preliminary Study	14
13/SC/0291	GO28053 Ph1 Vemurafenib in BRAF V600 mutation positive cancer patients	35
13/SC/0305	INIRA	34
13/SC/0307	Romantic relationships in young adults with burn scarring (V1)	56
13/SC/0317	IELSG 37	59
13/SC/0322	Immunotherapy with CD25/71 Allodepleted T-cells (ICAT)	34
13/SC/0326	HIV treatment satisfaction v1	45
13/SC/0329	TB035: MVA85A- Homologous boosting by heterologous route	30
13/SC/0349	A Retrospective Study: Smoking in Pregnancy	13
13/SC/0352	Identify & Explore Barriers to Exercise in patients with Pre-Diabetes	12
13/SC/0358	Towards a randomised primary chemoprevention trial of curcumin in FAP	13
13/SC/0365	ALPPS versus PVO (USZ-ZH-VIS-ALPPS)	31
13/SC/0375	Complement 2: Blood donations to develop vaccines against infection	43
13/SC/0383	MK-8237-009 House Dust Mite Biomarker Study	29
13/SC/0421	Phase 1 dose escalation - recombinant viral vector coding HIV antibody	41

13/SC/0456	Having a parent with a learning disability	27
13/SC/0509	Investigating brain tumours using next-generation sequencing	19
13/SC/0510	RADAR ICU	20
13/SC/0537	Vaccinia Isolated PERfusion	23
13/SC/0544	PREPARE - Preconceptional diet and embryo quality: an RCT.	22
13/SC/0548	CAM2038, PK, bioavailability and safety in healthy volunteers	29
13/SC/0549	Anthem 1	20
13/SC/0558	Secukinumab in treatment of chronic palmoplantar pustular psoriasis	42
13/SC/0560	Women and indoor air pollution study - WINAP (Pilot study)v1	10
13/SC/0561	Neurostructural assessment of spasticity with advanced MR tools	7
13/SC/0596	VAC054: Safety, immunogenicity and efficacy of FMP2.1 in AS01B	41
13/SC/0604	Treg Liver Trial	23
13/SC/0654	Full thickness laparo-endoscopic excision for benign colonic polyps	14
14/SC/0004	Understanding Paratyphoid Infection	26
14/SC/0025	Biomarker and immune function prediction in Rheumatoid arthritis	29
14/SC/0077	Investigating the immune response to 4CMenB in infants(EUCLIDS)2+1	30
14/SC/0084	ULCERS	20
14/SC/0112	RUTIS - A Study of Sexual Function in Women with Recurrent UTI's	16
14/SC/0119	The IMPACT Study (Pulse Wave Velocity follow-up study)	13

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
13/SC/0199	Protection against Pneumococcal infection in children with T1DM	45
13/SC/0372	Effect of Omeprazole on Baricitinib PK in Healthy subjects	56
13/SC/0374	Phase I, AZD8186 in Patients with CRPC, sqNSCLC, TNBc, PTEN malignancy	66
13/SC/0387	Treatment trial of chronic central serous chorioretinopathy	40
13/SC/0470	Platelet-Oriented Inhibition in New TIA and Minor Ischemic stroke	23
13/SC/0492	B7.1/IL-2 Leukaemia Cell Vaccine forNon-Transplant AML	25
13/SC/0562	Understanding Medication Adherence in Parkinsons Disease	8
13/SC/0599	Parental Responses to Child Experiences of Trauma: PROTECT Study v.1	28
13/SC/0609	Measuring synaptic function using EEG and MEG	28
14/SC/0065	28431754DIA4003 (CANVAS-R)	34

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/0222	Comparison between the Oesophageal Doppler and a Suprasternal Doppler	12
13/SC/0607	Calcification of digital arteries and impact on current PAD guidelines	7
13/SC/0610	Retrospective analysis of radiotherapy treatment outcomes Version 1	7

Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
13/SC/0207	Phase 1 trial:MVA85A-IMX313 compared with MVA85A	26
13/SC/0208	A Safety and Efficacy Study of ChAd63/MVA ME-TRAP + RTS,S	26
13/SC/0376	Cardiac MRI at higher magnetic field strength to assess heart function	28
13/SC/0395	Multimodal imaging of Neural Networks and Reward in Anorexia Nervosa	38
13/SC/0479	Acesulfame K as an Exogenous Marker of Glomerular Filtration Rate	24
13/SC/0568	The ONE Study Cell Therapy Trial	20
13/SC/0578	Understanding Pneumococcal Carriage and Disease	16
13/SC/0597	Vital Sign Monitoring of Premature Infants - Pilot Study (v 5.0)	21
14/SC/0103	Autoantibodies in cardiac arrhythmias v1.0	24
14/SC/0120	A Study to Assess New Malaria Vaccines ChAd63 RH5 and MVA RH5 (VAC057)	21

Unfavourable Opinion		
REC Reference	Application Short Title	Number of Days on Clock
13/SC/0515	Dejour Test validity study & its use in respiratory failure.	11
13/SC/0606	Full thickness laparo-endoscopic excision for benign colonic polyps	8
14/SC/0024	Experiences of women attending a preterm birth clinic	25
14/SC/0063	Safe use of medicines	11
14/SC/0110	Long-term safety study of Z-338 in patients with functional dyspepsia	19

Provisional Opinion		
REC Reference	Application Short Title	Number of Days on Clock
14/SC/0096	Whole body vibration and plasma FGF23 concentrations	N/A

14/SC/0175	The Awareness and Knowledge of Medicines Sick Day Rules Cards (V1.0)	N/A
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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:

Full applications for ethical review over 60 day timeline			
REC Reference	Application Short Title	Number of Days on Clock	
13/SC/0374	Phase I, AZD8186 in Patients with CRPC, sqNSCLC, TNBc, PTEN malignancy	66	
Proportionate review applications for ethical review over 14 days timeline			
REC Reference	Application Short Title	Number of Days on Clock	
13/SC/0509	Investigating brain tumours using next-generation sequencing	19	
13/SC/0510	RADAR ICU	20	
14/SC/0112	RUTIS - A Study of Sexual Function in Women with Recurrent UTI's	16	
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
12/SC/0566/AM02	Rivaroxaban in Antiphospholipid Syndrome (RAPS)	Substantial Amendment 1	37
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