

# NRES Committee South Central - Oxford B

## Annual Report

**01 April 2013 – 31 March 2014**

## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	NRES Committee South Central - Oxford B
<b>Type of REC:</b>	Recognised REC (CTIMPs in patients, phase 3)
<b>Type of Flag:</b>	Phase one studies in patients IRB registered
<b>Chair:</b>	Until 01/04/13 – Prof Margaret Rees From 14/05/13 - Mr Chris Foy
<b>Vice-Chair:</b>	Until 13/01/14 – Mr Robert King From 13.01.14 - Dr Kim Cheetham
<b>Alternate Vice-Chair:</b>	Until 13/01/14 – Dr Kim Cheetham From 13/03/14 - Dr Liesl Osman
<b>REC Manager:</b>	Until 01/11/14 – Mrs Siobhan Bawn From 01/11/14 - Mr Thomas Fairman
<b>PRSC Manager:</b>	Until 01/11/14 – Mrs Siobhan Bawn From 01/11/14 - Mr Thomas Fairman
<b>Assistant REC Manager:</b>	Until 31/07/13 – Ms Jitka Kotelenska From 21/10/13 - Miss Elizabeth Hearn
<b>Committee Address:</b>	Bristol Research Ethics Committee Centre Whitefriars Level 3, Block B Lewin's Mead Bristol BS1 2NT
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### Chair's overview of the past year:

This is my second spell of chairing an NRES committee. I was appointed, to succeed Prof Margaret Rees, on the day of the May 2013 meeting, but the notice was too short to attend that day, so I first appeared in June. I was at once impressed with the commitment of members to the review task, and with the high level of ethical debate.

I pay particular tribute to Robert King, who fulfilled the duties of Vice Chair admirably until his ten years of membership meant he had to retire in January 2014. Robert, I gathered, had given over 20 years of service to research ethics committees, including the old Broadmoor ethics committee. He will be greatly missed.

For the rest of the membership, it has been a period of stability. Dr Richard Craven joined at the same time as I did, and brings welcome physiological expertise. I am especially pleased that the offices of Vice Chair and Alternate Vice Chair have been filled by existing members, Drs Kim Cheetham and Liesl Osman. All the members are happy to introduce the discussion of a study.

Sub-committees, for proportionate review of studies and for considering amendments, are held in correspondence. I had previously been used to face-to-face or telephone sub-committee meetings, but correspondence works well. In the coming year, we aim to give members more opportunities to take part in sub-committee work.

The Committee has been very fortunate in being managed by highly competent and hard-working staff from the Bristol office, especially Siobhan Bawn until her maternity leave, and since then Tom Fairman, together with their assistants. It has been a pleasure to work with them. It is largely thanks to the staff that the Committee was awarded full accreditation following a periodic audit by the Quality Assurance team in October 2013.

Chris Foy  
April 2014

### NRES Committee South Central - Oxford B Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mr Peter Brown	Lay Plus Member	Lay Plus	01/09/2011	
Dr Kim Cheetham	Retired Consultant Paediatrician	Expert	01/09/2010	
Dr Richard Philip Craven	Senior lecturer in physiology	Lay	28/05/2013	
Mr Chris Foy	Medical Statistician	Expert	14/05/2013	
Mr Robert King	Retired University Lecturer (Philosophy)	Lay Plus	12/01/2004	12/01/14
Dr Wilhelm Kuker	Consultant Neuroradiologist	Expert	01/12/2010	
Dr Pamela Laurie	Retired Consultant Anaesthetist	Expert	05/06/2006	
Mr Ian MacKenzie	Retired Consultant / Reader Emeritus in Obstetrics and Gynaecology	Expert	09/11/2010	
Dr Liesl Osman	Retired Research Advisor	Lay	10/10/2009	
Rev Emma Percy	Lay Plus Member	Lay Plus	01/09/2011	
Dr Iveta Simera	Head of Programme Development, EQUATOR Network, Centre for Statistics in Medicine	Lay	21/09/2011	
Mrs Kate Thompson	Retired In patient and day hospice manager	Lay	10/03/2009	
Ms Rose Wharton	Medical Statistician	Expert	27/09/2012	
Mr Paul Windscheif	Pharmacist	Expert	07/12/2006	
Dr Zenobia Zaiwalla	Consultant in Paediatric Neurophysiology	Expert	13/12/2010	04/06/2013

### Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Mrs Susan Lousada	Company Director (Property) & Non-legal member of first-tier tax tribunal	Lay	10/09/14

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

Name	Declaration of Interest	Date
Dr Richard Philip Craven	None	28/01/2014
Rev Emma Percy	None	28/01/2014
Mrs Kate Thompson	None	28/01/2014
Dr Kim Cheetham	None	28/01/2014
Mr Peter Brown	None	28/01/2014
Mr Ian MacKenzie	Director, Elliott Smith Vasectomy Clinic	28/01/2014
Mr Paul Windscheif	Minor number of shares in Procter & Gamble due to past employment. Member of more than 20 scientific (mainly chemistry) pharmaceutical and medical organisations, societies and associations (national UK & Germany & US, and international (incl. European), but no direct interests with any companies who may sponsor conferences, a congress, training, annual meetings of these organisations.	28/01/2014
Dr Iveta Simera	None	28/01/2014
Dr Pamela Laurie	Volunteer at the Anaesthesia Heritage Museum, London.	17/02/2014
Mr Chris Foy	Father has a substantial holding of shares in GSK and Chris has lasting power of attorney for him. Chris is employed by NIHR to provide advice to grant applicants in the NHS in South-West England. He is a member of 2GETHER NHS Foundation Trust's R&D Committee.	17/02/2014
Dr Liesl Osman	£5000 in Glaxo Smith Kline shares Sub-consultancy employment on assessment of QOL benefits of Greenspace, work carried out for Forestry Scotland.	17/02/2014
Dr Wilhelm Kuker	None	31/03/2014
Dr Zenobia Zaiwalla	No fixed position. Invited to review research grant applications and papers.	31/03/2014
Ms Rose Wharton	None	31/03/2014

**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>
May	14/05/2013	10
June	11/06/2013	13
July	09/07/2013	10
September	10/09/2013	8
October	08/10/2013	10
November	12/11/2013	12
December	10/12/2013	12
January	14/01/2014	12
February	11/02/2014	11
March	11/03/2014	9

10 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	27/05/2013	3
July	22/07/2013	3
November	27/11/2013	5
January	29/01/2014	3
March	25/03/2014	6

5 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 Kim Cheetham	10
Mr Paul Windscheif	9
Ms Rose Wharton	8
Dr Liesl Osman	8
Dr Pamela Laurie	8
Mr Chris Foy	8
Mr Ian MacKenzie	8
Dr Iveta Simera	7
Dr Richard Philip Craven	7
Mr Peter Brown	7
Mrs Kate Thompson	7
Rev Emma Percy	6
Mr Robert King	6
Dr Wilhelm Kuker	6
Dr Zenobia Zaiwalla	1

**Number of inquorate meetings held: 0**

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr Chris Foy	4
Dr Kim Cheetham	4
Dr Pamela Laurie	3
Rev Emma Percy	3
Dr Richard Philip Craven	1
Mr Robert King	1
Mr Ian MacKenzie	1
Mr Paul Windscheif	1
Mr Peter Brown	1
Mrs Kate Thompson	1

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

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr Richard Philip Craven	18/09/2013 - 18/09/2013	Induction, HRA
Mr Peter Brown	06/09/2013 - 06/09/2013	Joint Oxford REC Training Day
Mr Robert King	02/10/2013 - 02/10/2013	Researcher Training Day, HRA
Mr Robert King	05/02/2014 - 05/02/2014	Researcher Training Day, HRA
Dr Iveta Simera	17/04/2013 - 17/04/2013	Ethical Review of Mental Health / Psychiatric Research, HRA
Dr Pamela Laurie	06/09/2013 - 06/09/2013	Joint Oxford REC Training Day
Mrs Kate Thompson	06/09/2013 - 06/09/2013	Joint Oxford REC Training Day
Dr Liesl Osman	06/09/2013 - 06/09/2013	Joint Oxford REC Training Day
Mr Peter Brown	12/09/2013 - 12/09/2013	Equality & Diversity, HRA
Rev Emma Percy	12/09/2013 - 12/09/2013	Equality & Diversity, HRA
Rev Emma Percy	20/11/2013 - 20/11/2013	National Training Day for Members, HRA
Mr Robert King	12/09/2013 - 12/09/2013	Equality & Diversity, NRES
Dr Iveta Simera	18/09/2013 - 18/09/2013	Equality & Diversity, Online
Dr Iveta Simera	04/12/2013 - 04/12/2013	Human Tissue Act (Use of Human Samples in Research) - An Introductory Level
Dr Iveta Simera	11/03/2014 - 11/03/2014	Training - Medical Devices Training Day
Dr Iveta Simera	04/11/2013 - 04/11/2013	HRA Meeting - Ethics & GCP Forum. Adapting to structural and regulatory changes.
Mr Ian MacKenzie	20/05/2013 - 23/05/2013	Reviewed the manuscript submitted for publication in Obstetrics & Gynaecology: "Breastfeeding after delivery: a systematic review and reviewed literature on the importance of the presentation of clear study objectives and the need to explore other published literature to justify conducting a research study
Mr Chris Foy	11/12/2013	National Training Day for NRES Committee Chairs
Mr Chris Foy	16/01/2014	Research Involving Adults Who Lack Capacity



## 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	20	38.46
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	32	61.54
<b>Total Applications Reviewed</b>	<b>52</b>	<b>100</b>

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

Number of applications made invalid by co-ordinator	2
Number of studies withdrawn prior to the meeting	7
Number of student applications reviewed	6
Number of paediatric applications reviewed	3
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	2

**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	1	1.92
Favourable Opinion with Additional Conditions	5	9.62
Unfavourable Opinion	1	1.92
Provisional Opinion	45	86.54
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>52</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	29	55.77
Further Information Favourable Opinion with Additional Conditions	14	26.92
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	1.92
Favourable Opinion with Additional Conditions	5	9.62
Unfavourable Opinion	1	1.92
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	1	1.92
<b>Total</b>	<b>52</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>10</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	10.00
Favourable Opinion with Additional Conditions	0	0.00
No Opinion transfer to full committee for review	1	10.00
Provisional Opinion	8	80.00
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>10</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	5.20
<b>Number of applications for full ethical review over 60 days</b>	2
<b>Number of applications over 60 days as a % of total</b>	3.85%
<b>Number of days taken to final decision - average</b>	36
<b>Number of days taken to final decision - mode</b>	25
<b>Number of SSAs (non-Phase 1) reviewed</b>	8
<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>	111
<b>Number of substantial amendments over 35 days</b>	1
<b>Number of substantial amendments over 35 days as a % of total substantial amendments</b>	0.9%
<b>Number of Section 30 applications reviewed</b>	1
<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>	0.0%
<b>Number of modified amendments reviewed</b>	9
<b>Number of modified amendments over 14 days</b>	2
<b>Number of modified amendments over 14 days as a % of total modified amendments</b>	22.2%
<b>Number of proportionate review applications for ethical review over 14 days</b>	1
<b>Number of proportionate review applications over 14 days as a % of total</b>	11.1%

**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/SC/0152	Use of an in vitro model to study novel influenza vaccines	81
13/SC/0204	The Pleural Infection Longitudinal Outcome Study (PILOT)	54
13/SC/0210	Inositol and slow wave sleep	53
13/SC/0217	Guided self-help for binge eating	75
13/SC/0270	The impact of regular respite on parental relationships	56
13/SC/0294	Novel Applications for Measuring T Wave Alternans	7
13/SC/0328	Depression and proton MRS at 7T	44
13/SC/0348	LY2875358 plus Erlotinib and LY2875358 Monotherapy in NSCLC (JTBC)	38
13/SC/0406	Sensory Sensitivity, Play & Repetitive Behaviour in Children with ASD	12
13/SC/0410	The PELICAN Study	16
13/SC/0420	Development of a 3D lung model to investigate fibrotic lung disease	25
13/SC/0437	Connectivity in memory disorders	29
13/SC/0439	Iron status and human metabolism	31
13/SC/0467	Phase I, dose escalation of LTX-315 in transdermally accessible tumours	25
13/SC/0502	Neural Mechanisms underlying tactile perceptual learning	22
13/SC/0503	B2151002: Phase 1b of PF-05212384 in combination.	21
13/SC/0519	Phase I study of oral PQR309 in Patients with Advanced Solid Tumours	25
13/SC/0523	The impact of AZD4017 on bone turnover in post-menopausal osteopaenia	25
13/SC/0554	4064 NNC0109-0012 (anti-IL-20 mAb) Mechanism of Action Study	38
13/SC/0555	A cross cultural exploration into the experience of pregnancy loss	46
13/SC/0572	IBSA Study 13EU/FSH01	35
13/SC/0581	VIOLA (Version 1.0 15-Oct-2013)	27
13/SC/0617	Neuroimaging in painful diabetic neuropathy v1.0	40
13/SC/0628	Effect of AFQ056 in OCD patients resistant to SSRI therapy	34
13/SC/0629	EORTC 90091-10093	30
13/SC/0638	HIPvac Trial	39
14/SC/0003	Amyloid and cognition after TIA and stroke	59
14/SC/0005	Understanding pathological pathways in atypical parkinsonian disorders	60
14/SC/0021	Effects of darapladib on experimental skin blisters in type 2 diabetes	44
14/SC/0032	Pfizer B1481022 - Phase 3 PF-04950615 in Reducing Major CV Events	33

14/SC/0033	Pfizer B1481038 - Phase 3 PF-04950615 in Reducing Major CV Events	33
14/SC/0085	Evolution, 07-13 version AA	29
14/SC/0179	Understanding and Supporting children's difficulties with ADL	14
14/SC/0182	QFM - reliability in children with hyperkinetic movement disorders	13

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/SC/0269	The impact of social anxiety on Facebook use	59
13/SC/0275	Mid-term outcomes of highly cross-linked polyethylene hip replacements	58
13/SC/0300	Clinical Effects of Two Dose Regimens of Aes-103 in Sickle cell	49
13/SC/0302	Anterior Cingulate Cortex: pain and empathy	24
13/SC/0319	Thoracic Ultrasound Assessment of Lung Water and Respiratory Failure	49
13/SC/0368	OPTIMISE	25
13/SC/0455	Effects of ivabradine on plaque progression in coronary artery disease	33
13/SC/0622	Evaluating noise reduction algorithms	10
13/SC/0635	AZ D081DC00008 Metastatic Castrate-Resistant Prostate Cancer	38
14/SC/0030	Circadian Rhythms and Personality Disorders	26
14/SC/0036	TB031 BCG Challenge Study	20
14/SC/0041	Methods of ovarian tissue culturing for fertility preservation	26
14/SC/0075	Pfizer B3461028 Study for patients with TTR-CM	39
14/SC/0082	RMT and COPD	25
14/SC/0147	Red cell membrane cholesterol: a marker of unstable carotid plaque?	25

#### 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/0618	Evolution, 07-13 version AA	35
14/SC/0180	Is there a relationship between trauma, substance use and offending	10

#### Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
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13/SC/0517	FORM -2C v0.1	26
13/SC/0553	Predicting functional outcomes after brain surgery using MRI	47
14/SC/0012	Blood donation from volunteers for anthrax immunoglobulin development	26
14/SC/0087	Pediatric vasculitis initiative (PedVas Study)	22
14/SC/0107	Cognitive therapy for fears about other people	31

#### Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/SC/0533	Tangent versus bowl perimetry: an exploratory study (version 1.0)	19

#### Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/SC/0625	Pilot study of self-reported wellness as a reliable prognostic tool v3	N/A
14/SC/0076	The Breast-Q LD Module	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
13/SC/0493	A phase 1b study of BGJ398 in combination with BYL719 in solid tumours	20

#### 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/0152	Use of an in vitro model to study novel influenza vaccines	81	
13/SC/0217	Guided self-help for binge eating	75	
Proportionate review applications for ethical review over 14 days timeline			
REC Reference	Application Short Title	Number of Days on Clock	
13/SC/0410	The PELICAN Study	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
10/H0605/59/AM24	WN25203 - Proof of Efficacy of RO4909832 in prodromal alzheimer's	Substantial Amendment 13	36
Modified Amendments over 14 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
10/H0605/59/AM21/1	WN25203 - Proof of Efficacy of RO4909832 in prodromal alzheimer's	Modified Sub Amen 12; 15 May 2013	16
12/SC/0682/AM02/1	Measuring heart and lung function in anaesthetised patients	Modified Substantial Amendment 1, 07/07/2013	22



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