

NRES Committee South Central - Oxford C

Annual Report

01 April 2013 – 31 March 2014

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee South Central - Oxford C
Type of REC:	Type III
Type of Flag:	Research Tissue Banks, Research Databases, Phase 1 Studies in Patients, Qualitative Research, Research Involving Adults Lacking Capacity
Chair:	Professor Nigel Wellman
Vice-Chair:	Professor David Scott
Alternate Vice-Chair:	Mrs Susan Lousada
REC Manager:	Lauren Allen (1 st October 2013- Present) Rae Granville
PRSC Co-ordinator:	Naaz Nathoo
REC Assistant:	Sarah Payne (28 th October 2013-Present) Lidia Gonzalez
Committee Address:	Bristol REC Centre Level 3, Block B Whitefriars Building Lewins Mead Bristol BS1 2NT
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Chair's overview of the past year:

Oxford C has continued to deliver sound and timely decisions on a wide-range of research projects, meeting all of its timelines for both full-committee and PR applications over the last year. This has been a year of considerable change for the committee with the departure of our long-standing coordinator Laura Kirkbride to greater and better things and her replacement initially by Rae Granville and latterly by Lauren Allen. Lauren Allen now titled 'REC Manager' rather than coordinator is doing a splendid job for the committee, ably assisted by Sarah Payne. On behalf of the committee I would like to offer our thanks to Laura and Rae and their assistants Sarah Grimshaw and Lidia Gonzalez as well as to Lauren and Sarah Payne for their hard work on our behalf. We have also lost a number of members over the year including the departure of our longest serving member - Dr Laurence Villard and also Dr Yael Vinciguerra, Mrs Kate Hicks and the vice-chair Mrs Sue Hallett who stepped down after 13 years of service on the West Berkshire, Berkshire and Oxford C RECS and I would like to convey our thanks to Laurence, Yael, Kate & Sue for their commitment to the committee, good-humour and sound advice.

Professor David Scott has replaced Sue Hallett as Vice-Chair and Mrs Susan Lousada has replaced David as the Alternate Vice-Chair and we have maintained the division of labour whereby the chair runs the business of the main committee and associated sub-committees and the vice-chairs manage the proportionate review work. Although old friends and colleagues have moved on, we have welcomed a number of new members who have quickly settled in and begun doing excellent work on the committee and we hope to recruit further new members over the coming year. The committee has welcomed a number of observers from the research, clinical and academic communities to our meetings and it is now rare for us not to have observers present at full-committee. Gratifyingly, the committee has received positive feedback from observers and from a number of applicants and I think that the committee continues to work very well and seems well-placed to continue to provide a first-class, prompt and courteous service to the research community.

NRES Committee South Central - Oxford C Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr Leonard Brookes	Consultant to the Pharmaceutical Industry	Lay	30/04/2010	
Miss Gemma Davison	Solicitor	Lay Plus	04/02/2014	
Dr Avinash Gupta	Clinical Research Fellow	Expert	14/02/2011	
Mrs Sue Hallett	Paediatric Research Nurse	Expert	11/02/2011	30/09/2013
Miss Katherine Hicks	Researcher	Lay Plus	01/04/2007	31/01/2014
Mrs Rebekah Howe	Farmer	Lay Plus	30/11/2012	
Mrs Vivienne Laurie	Barrister	Lay Plus	15/11/2012	
Mrs Susan Lousada	Company Director (Property) & Non-legal member of first-tier tax tribunal	Lay	01/04/2010	
Mr Barry Muir	Retired NHS Management Consultant	Lay	01/05/2006	
Mrs Rachael Quinn	Nurse Member	Expert	09/03/2005	
Professor David Scott	Pharmacist	Expert	10/08/2010	
Dr Sabeena Sharma	Consultant Anaesthetist	Expert	23/05/2011	
Dr Surjeet Singh	Clinical Trials Coordinator	Expert	17/01/2013	
Dr Laurence Villard	Senior Lecturer/Epidemiologist	Expert	27/09/2004	31/12/2013
Mrs Yael Vinciguerra	Independent Freelances	Lay	01/11/2012	27/06/2013
Professor Nigel Wellman	Professor of Health and Human Sciences	Expert	01/09/2010	

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

Name	Declaration of Interest	Date
Mrs Yael Vinciguerra	None	09/04/2013
Miss Gemma Davison	None	04/02/2014
Professor David Scott	None	11/02/2014
Dr Surjeet Singh	Share options with previous company (Glide Pharma) which has conducted Phase I Research. Involved in reviewing research applications within the department he worked in (NDORMS University of Oxford) as part Senior Clinical Project Manager role.	11/02/2014
Dr Leonard Brookes	None	12/02/2014
Mr Barry Muir	None	10/03/2014
Mrs Susan Lousada	None	10/03/2014
Mrs Rebekah Howe	None	10/03/2014
Mrs Rachael Quinn	None	10/03/2014
Dr Avinash Gupta	Clinical research Fellow- Department of Oncology, University of Oxford and Oxford University Hospitals NHS Trust. Medical Monitor for the Oxford Joint Research office.	10/03/2014
Professor Nigel Wellman	Owner and Director of Wellman Research & Consulting. Associate Professor University of West London. Course Leader Masters in Mental health Nursing Oxford Brookes University.	11/03/2014
Dr Sabeena Sharma	None	24/03/2014
Mrs Vivienne Laurie	Health watch Oxfordshire	24/03/2014

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

Month	Date	Number of Members Present at Meeting
April	26/04/2013	10
May	31/05/2013	9
June	28/06/2013	11
July	26/07/2013	9
August	30/08/2013	11
September	27/09/2013	10
October	25/10/2013	9
November	29/11/2013	9
January	31/01/2014	9
February	28/02/2014	9
March	28/03/2014	12

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	24/04/2013	3
May	23/05/2013	3
June	24/06/2013	3
July	24/07/2013	3
August	19/08/2013	3
October	23/10/2013	3
November	27/11/2013	3
December	18/12/2013	3
January	15/01/2014	3
February	12/02/2014	3
March	12/03/2014	3

11 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 Leonard Brookes	11
Professor Nigel Wellman	11
Mr Barry Muir	10
Dr Surjeet Singh	8
Professor David Scott	8
Mrs Rebekah Howe	8
Mrs Susan Lousada	8
Mrs Rachael Quinn	7
Dr Sabeena Sharma	7
Dr Avinash Gupta	6
Mrs Vivienne Laurie	6
Miss Katherine Hicks	6
Mrs Sue Hallett	5
Dr Laurence Villard	5
Miss Gemma Davison	2

Number of inquorate meetings held: None

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

Name	Number of Meetings Attended
Mrs Susan Lousada	6
Dr Leonard Brookes	5
Professor David Scott	5
Mrs Rachael Quinn	4
Mrs Sue Hallett	3
Mr Barry Muir	3
Dr Avinash Gupta	3
Mrs Chrissie Lawson	1
Miss Katherine Hicks	1
Ms Alison Eden	1
Ms Susan Tonks	1

Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Mrs Susan Lousada	13/11/2013 - 13/11/2013	Training - Personal Data in Research - A Workshop, NRES
Mrs Rachael Quinn	06/09/2013 - 06/09/2013	Joint Oxford Training Day
Mr Barry Muir	06/09/2013 - 06/09/2013	Joint Oxford Training Day
Dr Laurence Villard	06/09/2013 - 06/09/2013	Joint Oxford Training Day
Professor David Scott	06/09/2013 - 06/09/2013	Joint Oxford Training Day
Miss Katherine Hicks	06/09/2013 - 06/09/2013	Joint Oxford Training Day
Mrs Susan Lousada	06/09/2013 - 06/09/2013	Joint Oxford Training Day
Dr Sabeena Sharma	06/09/2013 - 06/09/2013	Joint Oxford Training Day
Mrs Vivienne Laurie	06/09/2013 - 06/09/2013	Joint Oxford Training Day
Mrs Rebekah Howe	06/09/2013 - 06/09/2013	Joint Oxford Training Day
Dr Surjeet Singh	06/09/2013 - 06/09/2013	Joint Oxford Training Day
Dr Avinash Gupta	06/09/2013 - 06/09/2013	Joint Oxford Training Day
Dr Surjeet Singh	15/10/2013 - 15/10/2013	Equality & Diversity, HRA
Professor Nigel Wellman	25/03/2014 - 25/03/2014	Research Involving the Disadvantaged and Vulnerable: A workshop for researchers and reviewers
Professor Nigel Wellman	10/06/2013 - 10/06/2013	NREAP Chair's Training Meeting, HRA
Professor Nigel Wellman	13/11/2013 - 13/11/2013	NREAP Chair's Training Meeting, HRA
Miss Gemma Davison	03/03/2014 - 03/03/2014	Induction, HRA
Mrs Susan Lousada	23/02/2014 - 23/03/2014	Equality & Diversity, HRA
Dr Leonard Brookes	11/03/2014 - 11/03/2014	Medical Devices Training Day, HRA
Mrs Rachael Quinn	25/03/2014 - 25/03/2014	Research Involving the Disadvantaged and Vulnerable, 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	18	31.5
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	6	10.5
Research Database	4	7.0
Others	29	50.7
Total Applications Reviewed	57	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	4
Number of studies withdrawn prior to the meeting	10
Number of student applications reviewed	13
Number of paediatric applications reviewed	2
Number of device applications reviewed	0
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	9
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	7	12.2
Favourable Opinion with Additional Conditions	10	18.52
Unfavourable Opinion	1	1.85
Provisional Opinion	39	68.42
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	57	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	56.14
Further Information Favourable Opinion with Additional Conditions	5	9.26
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	7	12.28
Favourable Opinion with Additional Conditions	10	18.52
Unfavourable Opinion	1	1.85
Provisional Opinion	2	3.51
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	57	100

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

Total Applications Reviewed	26
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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	9	34.62
Favourable Opinion with Additional Conditions	6	23.08
No Opinion transfer to full committee for review	3	11.54
Provisional Opinion	8	30.77
Unfavourable Opinion	0	0.00
Total	26	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.18
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	22
Number of days taken to final decision - mode	19
Number of SSAs (non-Phase 1) reviewed	8
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	188
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	2
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/0145	SMS to monitor challenging behaviour in a Learning Disabled population	25
13/SC/0184	212082PCR3011	25
13/SC/0213	Protocol CDX110-04	29
13/SC/0266	Early Prediction of Severe Sepsis (ExPRES-Sepsis) study (England)	33
13/SC/0273	Phase I of MK-3475 in Pts with non small cell lung cancer	35
13/SC/0309	ELASTIC	39
13/SC/0325	Individualized prophylaxis with Human cl rhFVIII in haemophilia A	27
13/SC/0330	LINES: Eurosarc Trial of Linsitinib in advanced Ewing Sarcoma	32
13/SC/0331	Barts Upper GI Tissue Bank	40
13/SC/0343	Experiences of parenting a child receiving dexamethasone for ALL	32
13/SC/0354	PankoMab-GEX™ in recurrent ovarian cancer GEXMab 25201 v1.0 12Mar13	41
13/SC/0357	Screening blood donated from NSCLC cancer patients and controls	9
13/SC/0363	The Cardiopulmonary Resuscitation Debriefing study (CODE study)	30
13/SC/0417	Patient perception of major trauma recovery and rehabilitation v1.2	14
13/SC/0436	Adjuvant Steroids in Adults with Pandemic Influenza	32
13/SC/0440	Living Well with Dementia Groups in Primary Care (IAPT)	33
13/SC/0441	Oral and respiratory health in adults with a neuro-disability	37
13/SC/0457	Pain in spinal cord injuries: investigating associated factors (1)	41
13/SC/0461	The impact of tooth agenesis on oral health-related quality of life	13
13/SC/0486	A Nitric Oxide (NOx) generating solution for prevention of VAP	27
13/SC/0491	UKAEA & AWE Epidemiology Studies in the SHIELD database	36
13/SC/0516	Blood BioBank of the Brains for Dementia Research cohort	23
13/SC/0541	Nivolumab Monotherapy vs Nivolumab combined therapy in Solid Tumors	31
13/SC/0594	An enhanced clinical heart failure service (Research database)	38
13/SC/0608	Explore informal carers' experiences using self-management programme	29
13/SC/0631	Donation of Saliva for pH profile studies of toothpaste in saliva,V1.0	7
14/SC/0001	Brain Imaging of Opioid Therapy	21
14/SC/0008	NIHR BioResource-Adult Infectious Disease	22
14/SC/0010	The neurological effects of pancreatectomy in chronic pancreatitis v1	21

14/SC/0031	Reliability of measuring joint ranges for adults with complex postures	21
14/SC/0037	A Study of Gantenerumab in Patients with Mild Alzheimer Disease	23
14/SC/0038	PET Imaging Substudy to WN28745	48
14/SC/0088	RIFSYS	19
14/SC/0091	The Germinal Centre Reaction in Alloantibody Formation	11
14/SC/0097	Diabetes prevention in primary care (version 1)	9
14/SC/0100	Assessment of Patients Treated With JETREA® for Vitreomacular Traction	20
14/SC/0122	Prostatic artery embolisation	22
08/H0606/107+5	Oxford BioBank	30
08/H0606/87+5	Saliva Bank	31

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/SC/0271	Effect of Heart Failure on Infarct Volume in Acute Stroke	35
13/SC/0298	The cerebral signature for pain perception and modulation version 1	32
13/SC/0534	Efficacy of Methylene Blue for screening/surveillance colonoscopy	19
13/SC/0547	Effects of Health Anxiety in recently diagnosed Multiple Sclerosis	29
13/SC/0565	Mindfulness interventions + breast cancer (MABCan)	13

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/0169	The Epidemiology of Ocular Surface Squamous Neoplasia in the UK	21
13/SC/0231	Pilot study to assess dynamic PET for imaging hepatic inflammation	8
13/SC/0292	Psychological determinants of successful weight loss	7
13/SC/0341	Parental adherence to Speech Language Therapy treatments in children	8
13/SC/0351	Do statins have an effect on colonic tissue at the molecular level?	8
13/SC/0361	Out of Hospital Cardiac Arrest Outcomes Project	25
13/SC/0362	AMICI study Version 1.0	24
13/SC/0399	Retrospective analysis of reversible myocardial dysfunction in ICU	25
13/SC/0414	Bristol-based study of the protective effect of breastfeeding	12

13/SC/0458	HER-2 Status on primary breast cancer and concurrent LN metastasis	11
13/SC/0564	Coreceptor control of T cell cross-reactivity	12
13/SC/0657	Fathers' influence on women's decision making during labour and birth	8
14/SC/0093	PreDiCT-TB: Model-based preclinical dev. of TB drug combinations v1	19
14/SC/0155	CDX1, CDX2 and A33 as markers for metastatic colorectal adenocarcinoma	7
14/SC/0163	Prehospital Recognition of Sepsis by Ambulance Clinicians (PRoSAiC)	19
08/H0606/71+5	South London and Maudsley Biomedical Research Centre Case Register	20

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/SC/0211	Adjunctive Clindamycin For Cellulitis Clinical Trial (C4C)	21
13/SC/0243	NICOLA V1.0	45
13/SC/0250	Oxford Abdominal Aortic Aneurysm Study - OxAAA	35
13/SC/0281	Improving Well-being and Health for People with Dementia.	20
13/SC/0289	Stromal - epithelial interactions in prostate cancer	7
13/SC/0415	ADHD 'One Stop Shop'	8
13/SC/0418	An exploration of strategies to enhance PA in people with RA	6
13/SC/0442	Experiences of young adult women who have Cystic Fibrosis	26
13/SC/0460	TransCal Study	10
13/SC/0528	End of life, carers at a distance and ehealth: a mixed-methods study.	19
13/SC/0660	ASD - children's and parents' views of health services	4
14/SC/0044	Inattentive and impulsive brain. Version 1.0	44
14/SC/0106	Role of cellular immune responses in inflammation of the skin v1.0	19
14/SC/0134	BP28920 Phase I study of RO6895882 in solid tumours	19
14/SC/0156	Resources for sleep treatment using community pharmacists (REST-UP)	8
14/SC/0162	South Coast CLL and Lymphoproliferative Disorders (LPD)Tissue Bank	19

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/SC/0536	1237.25 - Tiotropium/olodaterol vs tiotropium and placebo in COPD	19

Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
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14/SC/0152	OxAMI: Consent	N/A
14/SC/0157	PARAMEDIC 2: The Adrenaline Trial	N/A

Provisional Opinion Pending Consultation with Referee
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REC Reference	Application Short Title	Number of Days on Clock
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Further information response not complete
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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
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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
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