

# NRES Committee South Central - Oxford C

## Annual Report

**01 April 2011 – 31 March 2012**

## Part 1 – Committee Membership and Training

**Name of REC:** NRES Committee South Central - Oxford C

**Type of REC:** Type III

**Type of Flag:** CTIMPs in Patients  
Research Tissue Banks  
Research Databases  
Phase 1 Studies in Patients  
Adults Lacking Capacity

**Chair:** Professor Nigel Wellman

**Vice-Chair:** Mrs Sue Hallett

**Alternate Vice-Char:** Dr David Scott

**Co-ordinator:** Miss Laura Kirkbride

**Assistant Co-ordinator:** Miss Sarah Grimshaw

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## Chair's overview of the past year:

I write this overview having now completed my first full year as Chair of Oxford C. This has been another very busy year for the committee. Once again, we have lost valued and experienced members due to retirement, house moves and competing work commitments. Fortunately, we have also gained several excellent new members over the last year although maintaining an adequate complement of both lay and expert members remains challenging through the current recruitment freeze. I am delighted that we have been able to appoint Sue Hallett as Vice-Chair and Dr David Scott as Alternate Vice-Chair of the committee. Sue and David have been very active in the committee and have taken the lead in implementing proportionate review leaving the Chair free to focus on the management of the main committee and non-PR sub-committee work.

Oxford C is a very lively, friendly and conscientious committee with a committed and diligent membership who have continued to demonstrate that they are keen to support the research community through providing high quality ethical review of proposed projects. Oxford C has remained a very busy committee and our agenda slots have been well utilised by researchers although our meeting date - the last Friday of the month means that it is always impracticable for the committee to meet in December. Over the last year the committee has reviewed a wide range of research ranging from student studies through a substantial number of CTIMP studies to Research Tissue Bank and Research Database applications and a steadily growing number of studies involving adults who lack capacity. The growth in applications relating to the emergency care of critically ill and unconscious patients has been noticeable.

The sub-committee system, which was re-established last year, has continued to work well with regular sub-committees conducted by correspondence held twice per month plus additional ad hoc meeting held to review researcher responses which have been delegated to consideration by sub-committee. These sub-committees depend on the commitment of a stalwart band of members prepared to devote extra time to the review of substantial amendments and other business. Oxford C has only recently begun to hold regular proportionate review meetings and the impact of PR work on members' willingness to contribute to sub-committee business remains to be evaluated.

Oxford C has continued to be very ably co-ordinated by Ms Laura Kirkbride supported by Assistant Co-ordinator Ms Sarah Grimshaw and on behalf of the whole committee I would like to convey our thanks to Laura and Sarah for a job well done. Laura has continued to make the long trip down from Jarrow to attend our meetings. Members have greatly appreciated Laura's hard work and her application in turning many hours of discussion and ethical debate into a coherent set of minutes. Oxford C seems well-placed to continue to make a valuable contribution in protecting the public and promoting high quality research over the next 12 months and having already thanked the co-ordinators I would like to close this report by thanking members for their commitment, time and energy over the last 12 months.

## NRES Committee South Central - Oxford C Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mrs Joan Brazier	Lay Member (Retired)	Lay	01/02/2010	13/11/2011
Dr Leonard Brookes	Consultant to the Pharmaceutical Industry	Expert	30/04/2010	N/A
Dr Avinash Gupta	Clinical Research Fellow	Expert	04/02/2011	N/A
Mrs Sue Hallett	Paediatric Research Nurse	Expert	01/02/2011	N/A
Miss Kate Hicks	Clinical Trials Coordinator	Lay	01/04/2007	N/A
Dr Jane Lees-Millais	General Practitioner	Expert	01/04/2010	N/A
Mrs Susan Lousada	Lay Member	Lay	01/04/2010	N/A
Mrs Lynch Mason	Occupational Therapist	Expert	01/05/2006	N/A
Mr Barry Muir	Lay Member	Lay Plus	01/05/2006	N/A
Mrs Rachael Quinn	Nurse Member	Expert	09/03/2005	N/A
Dr David Scott	Pharmacist	Expert	10/08/2010	N/A
Dr Sabeena Sharma	Consultant Anaesthetist	Expert	23/05/2011	N/A
Mr Roy Staley	Retired Officer of the Civil Aviation Authority	Lay Plus	13/07/2011	N/A
Reverend Philip Sutton	Chaplain	Lay	01/04/2008	10/10/2011
Dr Laurence Villard	Senior Lecturer/Epidemiologist	Expert	27/09/2004	N/A
Professor Nigel Wellman	Professor of Health and Human Sciences	Expert	01/09/2010	N/A

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

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Dr Leonard Brookes	Has occasionally undertaken consultancy work for pharmaceutical companies but has not had any for over 2 years now and would in any event declare such engagement should more consultancy work become available.	07/03/2012
Dr Avinash Gupta	Clinical Research Fellow - attached to the early phase hub, Oxford Cancer and Haematology Centre Medical Monitor - R&D Department, Oxford University Hospitals NHS Trust	07/03/2012
Mrs Sue Hallett	Senior Research Nurse, employed by Thames Valley CLRN for paediatric research at Royal Berkshire NHS Foundation Trust, Reading. Responsible for day-to-day conduct of academic clinical trials within paediatric department at RBH.	07/03/2012
Miss Kate Hicks	Clinical Research Coordinator, Department of Cardiovascular Medicine, University of Oxford. This includes time funded by a couple of industry partners (GSK and Novartis) for coordination work on department-hosted CTIMPs. Clinical Trials Unit Focus Group Member (local Oxford Uni department group) OxAMI consultation panel (newly formed research group consultation panel into programme of work exploring acute setting cardiovascular research)	07/03/2012
Mrs Susan Lousada	None	N/A
Mr Barry Muir	None	N/A
Mrs Rachael Quinn	None	N/A
Dr David Scott	None	N/A
Dr Sabeena Sharma	None	N/A
Mr Roy Staley	None	N/A
Dr Laurence Villard	None	N/A
Professor Nigel Wellman	Professor of Health and Human Sciences, University of West London Senior Lecturer, Oxford Brookes University	07/03/2012

**Meetings for Full Ethical Review 01 April 2011 - 31 March 2012:**

<b>Month</b>	<b>Date</b>	<b>Number of Members Present at Meeting</b>
April	28/04/2011	10
May	27/05/2011	13
June	24/06/2011	9
July	29/07/2011	7
August	26/08/2011	12
September	30/09/2011	11
October	28/10/2011	12
November	25/11/2011	10
January	27/01/2012	9
February	24/02/2012	11
March	30/03/2012	10

11 full committee meetings were held during the reporting period.

**Attendance of Members: 01 April 2011 – 31 March 2012:**

<b>Name</b>	<b>Number of Meetings Attended</b>
Mrs Sue Hallett	11
Professor Nigel Wellman	11
Dr Laurence Villard	10
Dr David Scott	9
Dr Leonard Brookes	8
Dr Avinash Gupta	8
Mrs Susan Lousada	8
Mrs Lynch Mason	8
Mr Roy Staley	7
Mrs Joan Brazier	6
Dr Sabeena Sharma	6
Mrs Rachael Quinn	6
Reverend Philip Sutton	5
Miss Kate Hicks	5
Mr Barry Muir	5
Dr Jane Lees-Millais	1

**Number of inquorate meetings held: 0**

## Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Mrs Joan Brazier	01/07/2011	South Central Member's Training Day, South Central - Oxfordshire A REC
	28/10/2011	NRES Update Session, NRES
Dr Leonard Brookes	23/02/2012	Phase 1 CTIMP Training, NRES
Dr Avinash Gupta	01/07/2011	South Central Member's Training Day, South Central - Oxfordshire A REC
Mrs Sue Hallett	09/04/2011	International Conference on Harmonisation - Good Clinical Practice Guideline Course, Ashford & St. Peter's Hospitals NHS Trust
	17/05/2011	GCP and Regulatory Requirements for Clinical Trials, Royal Berkshire Hospital
	16/06/2011	Equality & Diversity, NHS
Miss Kate Hicks	19/10/2011	'The Structure of Good Collaboration: using governance mechanisms to your advantage', HeLEX
	30/11/2011	"From Practice to Policy: Framing Recommendations to Support Collaboration", HeLEX
Mrs Susan Lousada	01/07/2011	South Central - Oxford A Training Day, South Central Committee - Oxford A
	28/10/2011	NRES Update Session, NRES
Mrs Rachael Quinn	22/09/2011	NRES Informed Consent and Explaining Risk in Randomised Trials, NRES
Dr David Scott	28/10/2011	NRES Update Session, NRES
	27/02/2012	GCP Training - Conducting the Trial, University of Oxford
	27/02/2012	GCP Training - Protocol and Associated Documents, University of Oxford
Dr Sabeena Sharma	16/11/2011	Induction, NRES
Mr Roy Staley	26/09/2011	NRES Update Session, NRES
	27/07/2011	Ethical Review of Medicines, N/A
	06/07/2011	Research Mixed Audience, NRES
	06/10/2011	NRES Researcher Training, NRES
	07/12/2011	NRES Statistics Training, NRES
Dr Laurence Villard	29/02/2012	Personal Data in Research, HRA
Professor Nigel Wellman	28/10/2011	NRES Update Session, NRES
	01/03/2012	Adults Lacking Capacity Workshop, 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:**

<b>Applications for full ethical review – Study Type</b>	<b>Number</b>	<b>%</b>
Clinical Trial of Investigational Medicinal Product	21	27.63
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	2	2.63
Research Database	7	9.21
Others	46	60.53
<b>Total Applications Reviewed</b>	<b>76</b>	<b>100</b>

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

Number of applications made invalid by co-ordinator	0
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	19
Number of paediatric applications reviewed	4
Number of device applications reviewed	2
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:**

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	7	9.09
Favourable Opinion with Additional Conditions	5	6.49
Unfavourable Opinion	1	1.30
Provisional Opinion	63	81.82
Invalid	0	0.00
No Opinion Pending Consultation with Referee	0	0.00
Provisional Opinion Pending Consultation with Referee	1	1.30
Not Requiring Review by NHS REC	0	0.00
<b>Total</b>	<b>77</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	39	50.65
Further Information Favourable Opinion with Additional Conditions	13	16.88
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	7	9.09
Favourable Opinion with Additional Conditions	5	6.49
Unfavourable Opinion	1	1.30
Provisional Opinion	9	11.69
Provisional Opinion Pending Consultation with Referee	1	1.30
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	1.30
Number of studies withdrawn after the meeting	1	1.30
<b>Total</b>	<b>77</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	6.91
<b>Number of applications for full ethical review over 60 days</b>	0
<b>Number of applications over 60 days as a % of total</b>	0.00%
<b>Number of days taken to final decision - average</b>	34
<b>Number of days taken to final decision - mode</b>	33
<b>Number of SSAs (non-Phase 1) reviewed</b>	2
<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>	125
<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>	0.8%
<b>Number of Section 30 applications reviewed</b>	0
<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%
<b>Number of modified amendments reviewed</b>	2
<b>Number of modified amendments over 14 days</b>	0
<b>Number of modified amendments over 14 days as a % of total modified amendments</b>	0.0%

**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>
11/SC/0140	AdipoRedox Study	54
11/SC/0141	B1931008 - Aggressive NHL Study	39
11/SC/0143	Delineating affective sensation in the brain.	45
11/SC/0186	Visual testing of poorly sighted patients.	42
11/SC/0189	Investigation of the Incretin Pathway in HNF1A-MODY v1.0	43
11/SC/0197	Clostridium Difficile Asymptomatic Carriage and Acquisition Study	39
11/SC/0198	Does the severity of dental and facial problems affect quality of life	48
11/SC/0200	A Study in Type 2 Diabetes in Patients on Metformin	35
11/SC/0213	Kings Health Partners Critical Illness Biobank	29
11/SC/0243	1220.19 Phase III trial in HIV/Hepatitis patients	35
11/SC/0245	A Phase IIIB expanded access study of INC424 in myelofibrosis	37
11/SC/0253	The Psychology and Biology of new fatherhood	39
11/SC/0278	OxIGen: Oxford Imagery Generation in Depression	40
11/SC/0283	Exploring the experience of couples having a child after a stillbirth	30
11/SC/0284	Pilot- Modelling of Aneurysm Risk in Temporal Arteritis (pMARTA)	51
11/SC/0295	Memory Service Database	32
11/SC/0296	Naltrexone implants in Opioid dependence (version 1)	43
11/SC/0303	An exploration of midwives accessing and using information 1.1	38
11/SC/0305	Rectal mucus sampling to assess for Biological markers of cancer	39
11/SC/0326	UNITI 1	33
11/SC/0327	UNITI 2	33
11/SC/0329	IMUNITI	33
11/SC/0349	Registered Nurses' perceptions of Advanced Nurse Practitioners	31
11/SC/0379	Autologous Blood Study	38
11/SC/0394	The Contact-CTI study	33
11/SC/0397	OXAMI	40
11/SC/0398	The Contact-PVI Study	33
11/SC/0416	An Evaluation of the Edmonton Functional Assessment Tool 2	41
11/SC/0417	The ABLE study UK	27

11/SC/0429	The Intensive Care Study of Coagulopathy (ISOC- 2) Study	26
11/SC/0439	Adult pneumococcal kinetics study.	36
11/SC/0458	Paclitaxel +/- GSK1120212 in Melanoma	36
11/SC/0460	Helius User Validation	32
11/SC/0469	Neural effects of Naltrexone on reward.	40
11/SC/0471	PVNS	56
11/SC/0506	BEZ235 daily with weekly Trastuzumab vs Lapatinib and Capecitabine.	37
12/SC/0018	Randomised studies to reduce groin lymphocyst	29
12/SC/0019	Consequences Of Early Life Pain On Future Pain Sensitivity	37
12/SC/0029	DARLInG Database Version 1	33

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/SC/0115	An evaluation of regular community singing for people with COPD (1)	49
11/SC/0136	PM01183 in combination with Doxorubicin v 1.0 (13/12/2010)	38
11/SC/0137	PM01183 in combination with Gemcitabine (v 1.0 10/12/2010)	39
11/SC/0176	1220.7 Phase III trial in treatment-experienced Hepatitis C patients	39
11/SC/0177	1220.48 Phase III roll-over trial in TE Hepatitis C patients	37
11/SC/0237	Non-invasive urodynamics via a suprapubic catheter balloon port	28
11/SC/0254	Patients' perception of professional reputation	29
11/SC/0279	quality of life of stroke patients during and after an ESD programme v1	37
11/SC/0372	CL005_140 CCX140-B in Diabetic Nephropathy	38
11/SC/0447	Ultrasound and Dupuytren's Functional Severity V1.0 (OXF-KIR77DD)	34
11/SC/0499	A UK Phase IIIB expanded access study of INC424 in myelofibrosis	50
12/SC/0042	TMC435HPC3001(ATTAIN)	32
12/SC/0043	Safety, Tolerability & Efficacy of IV CT-011 in Metastatic Melanoma	44

#### Favourable Opinion with Standard Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/SC/0232	Improving outcomes from the treatment of back pain V1.0	19
11/SC/0236	Molecular analysis of archival tumours	19
11/SC/0285	Management of women presenting with postmenopausal vaginal bleeding.	24
11/SC/0335	Viral infection studies in foetal hepatocytes	25

11/SC/0411	Oxford Vaccine Centre Database of Healthy Volunteers Version 1.0	24
11/SC/0440	Post-Intensive Care Risk-adjusted Alerting & Monitoring (PICRAM)	24
11/SC/0482	Investigating speech motor control and learning using tDCS	25

#### **Favourable Opinion with Additional Conditions**

<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/SC/0145	How does change occur in a therapeutic community?	36
11/SC/0179	Mothers' experiences of home treatment for adolescents with anorexia	26
11/SC/0354	Patient Reported Outcomes following traumatic hip fracture	24
12/SC/0012	Assessment of female lower urinary tract symptoms	24
12/SC/0067	Oxford Faecal Biobank	17

#### **Unfavourable Opinion**

<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/SC/0325	Investigating speech motor control and learning using tDCS	25

#### **Provisional Opinion**

<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
12/SC/0062	Transfusion in Gastrointestinal Bleeding - TRIGGER	N/A
12/SC/0087	Improving the early management of neutropenic sepsis	N/A
12/SC/0090	Dual Erb B Inhibition in Oesophago-gastric Cancer	N/A
12/SC/0099	Incidence of reversible acute left ventricular dysfunction in the ICU	N/A
12/SC/0124	MR Spectroscopy in Antibody-mediated Encephalitis	N/A
12/SC/0138	Better Sleep Trial	N/A
12/SC/0141	Validating foetal ultrasound imaging using MRI	N/A
12/SC/0145	Early Cryoprecipitate for Severe Trauma Haemorrhage Trial (CRYOSTAT)	N/A
12/SC/0160	3619 Liraglutide in Islet Cell Transplants with Type I Diabetes	N/A

#### **Provisional Opinion Pending Consultation with Referee**

<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
12/SC/0153	Two different doses of IgPro20 for the treatment of CIDP	N/A

<b>Withdrawn after the meeting</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/SC/0386	Hypogonadism after cardiac surgery involving cardiopulmonary bypass	25

  

<b>Invalid Application</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

  

<b>No Opinion Pending Consultation with Referee</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

  

<b>Not Requiring Review by NHS REC</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

**Table 9: Items exceeding timelines:**

<b>Full applications for ethical review over 60 day timeline</b>			
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>	
<b>Proportionate review applications for ethical review over 14 days timeline</b>			
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>	
<b>SSAs (non Phase 1) over 25 days timeline</b>			
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>	
<b>SSAs (Phase 1) over 14 days timeline</b>			
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>	
<b>Substantial Amendments over 35 day timeline</b>			
<b>Amendment Reference</b>	<b>Application Short Title</b>	<b>Amendment Title</b>	<b>Number of Days on Clock</b>
<b>Modified Amendments over 14 day timeline</b>			
<b>Amendment Reference</b>	<b>Application Short Title</b>	<b>Amendment Title</b>	<b>Number of Days on Clock</b>
<b>Section 30 application over 60 day timeline</b>			
<b>Amendment Reference</b>	<b>Application Short Title</b>	<b>Amendment Title</b>	<b>Number of Days on Clock</b>