

National Research Ethics  
Service

  
*Health Research Authority*

# NRES Committee London - Surrey Borders

## Annual Report

**01 April 2013 – 31 March 2014**

## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	NRES Committee London - Surrey Borders
<b>Type of REC:</b>	Recognised
<b>Type of Flag:</b>	Type I, Type III
<b>Chair:</b>	Canon Chris Vallins
<b>Vice-Chair:</b>	Mr Derek Cock
<b>Alternate Vice-Chair:</b>	Wendy Brooks
<b>REC Manager:</b>	Mrs Alka Bhayani
<b>PRSC Co-ordinator:</b>	Mrs Alka Bhayani
<b>REC Assistant:</b>	Amy Spruce
<b>Committee Address:</b>	HRA Research Ethics Committee (REC) London Centre Ground Floor Skipton House 80 London Road London SE1 6LH
<b>Telephone:</b>	020 7972 2554
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### Chair's overview of the past year:

The London Surrey borders REC continues to be served by a dedicated group of people. Attendance at meetings is very high as is the attendance of members at training. We believe that our role is of vital importance in the delivery of good research.

Our chief concern in the past year has been the difficulty we have in recruiting clinicians. Local Trusts are often unwilling to give their clinicians the necessary time to prepare for and attend meetings; whilst the clinicians themselves find that they are overburdened with heavy workloads. This is a serious problem for us and we often struggle, but I trust succeed, to give the required rigorous scrutiny to some studies.

My thanks to our coordinator for her work in the past year and to all the members of the committee who have served us so well.

## NRES Committee London - Surrey Borders Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mrs Wendy Brooks	Stroke Nurse Consultant	Expert	01/01/2004	30/01/2014
Mr Derek Cock	Chief Pharmacist	Expert	03/02/2005	
Dr Jeff Corne	Retired Pharmacologist	Lay	12/02/2008	14/06/2013
Mrs Anne Davies	Chief Pharmacist	Expert	01/04/2004	09/01/2014
Mr Eddy Digman	Retired Local Government & Personnel Consultant	Lay Plus	01/01/2004	22/07/2013
Mr Dominic Fairclough	Solicitor	Lay Plus	01/04/2009	
Mrs Anne Laurie	Lecturer in Clinical Communications	Lay	01/06/2007	
Dr Rosemary O'Neil	Senior Lecturer (Statistics and Mathematics)	Lay Plus	01/12/2008	
Mrs Rebecca Quayle	Solicitor	Lay Plus	01/03/2008	
Dr Nazira Sumar	Clinical Scientist in Immunology	Expert	01/02/2010	
Mr Graham Tate	Tissue Bank Manager	Expert	03/06/2013	
Canon Christopher Vallins	Regional Chaplaincy Adviser	Lay Plus	01/01/2007	
Mrs Jana Wanli	MSc Neuroscience Student	Lay Plus	18/06/2013	
Dr Mark Weeks	Senior Research Associate	Expert	03/06/2013	

## NRES Committee London - Surrey Borders: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Dr Mark Weeks	Currently employed as senior research scientist in paediatric cancer research at UCL ICH.	14/01/2014
Mrs Anne Davies	Chief Pharmacist - responsible for managing the pharmacy service and their input into the clinical trial drug supplies/R&D Committee at the Trust.	08/01/2014
Mr Graham Tate	Designated individual at Barts Health NHS Trust (Tissue Bank Manager)	14/01/2014
Canon Christopher Vallins	No declared interests.	05/02/2014
Mrs Wendy Brooks	No declared interests.	05/02/2014
Mr Derek Cock	Occasional consultancies on behalf of 3rd party Pharmaceutical company.	05/02/2014
Mrs Anne Laurie	Small number of shares in SmithKline. Member and Chair of local women's groups that often fundraise for health and social care, these are the Ladies Circle, tangent club and inner wheel clubs of Wallington & Carshalton in Surrey.	05/02/2014
Mr Dominic Fairclough	No declared interests.	05/02/2014
Dr Nazira Sumar	No declared interests.	05/02/2014
Dr Rosemary O'Neil	Occasional statistical advice to researchers on an ad-hoc basis.	05/02/2014
Mrs Jana Wanli	No declared interests.	05/02/2014
Mrs Rebecca Quayle	No declared interests.	05/02/2014

**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>
April	10/04/2013	9
May	08/05/2013	8
June	12/06/2013	11
July	10/07/2013	11
August	14/08/2013	8
September	11/09/2013	10
October	09/10/2013	10
November	13/11/2013	7
December	11/12/2013	9
January	08/01/2014	9
March	12/03/2014	9

11 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>
June	12/06/2013	3
July	10/07/2013	3
August	14/08/2013	3
September	11/09/2013	3
October	09/10/2013	3
December	11/12/2013	3
January	08/01/2014	3
March	12/03/2014	3

8 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>
Mrs Rebecca Quayle	11
Canon Christopher Vallins	10
Dr Nazira Sumar	10
Mr Derek Cock	8
Mr Graham Tate	8
Mrs Wendy Brooks	8
Mrs Anne Davies	8
Mr Dominic Fairclough	8
Mrs Anne Laurie	7
Dr Rosemary O'Neil	7
Dr Mark Weeks ( <b>appointed June 2013</b> )	6
Mrs Jana Wanli ( <b>appointed June 2013</b> )	5
Dr Jeff Corne ( <b>Resigned June 2013</b> )	3
Mr Eddy Digman ( <b>Resigned July 2013</b> )	2

**Number of inquorate meetings held: None**

**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 Derek Cock	7
Mrs Anne Laurie	7
Mrs Rebecca Quayle	7
Canon Christopher Vallins	1
Dr Nazira Sumar	1

## Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Mr Derek Cock	06/06/2013 - 06/06/2013	Training day for new REC Chairs, HRA
Mrs Anne Laurie	13/11/2013 - 13/11/2013	Training - Personal Data in Research - A Workshop, HRA
Dr Mark Weeks	24/09/2013 - 24/09/2013	Equality & Diversity, HRA
Dr Nazira Sumar	20/11/2013 - 20/11/2013	National Members Training Day, HRA
Dr Mark Weeks	20/11/2013 - 20/11/2013	National Members Training Day, HRA
Canon Christopher Vallins	02/09/2013 - 02/09/2013	NREAP - Chair's Meeting
Mrs Anne Laurie	13/02/2014 - 13/02/2014	Training - Assessing the Consequences (benefits and harms) of Research: a Health Research Authority , HRA
Mrs Jana Wanli	03/03/2014 - 03/03/2014	Induction, HRA
Mr Derek Cock	11/12/2013 - 11/12/2013	Local REC training day – human tissue act training, HRA
Dr Mark Weeks	11/12/2013 - 11/12/2013	Local REC training day – human tissue act training, HRA
Mr Graham Tate	11/12/2013 - 11/12/2013	Local REC training day – human tissue act training, HRA
Mr Graham Tate	31/07/2013 – 31/07/2013	Equality & Diversity , Barts Health NHS Trust
Mrs Jana Wanli	11/12/2013 - 11/12/2013	Local REC training day – human tissue act training, HRA
Dr Nazira Sumar	11/12/2013 - 11/12/2013	Local REC training day – human tissue act training, HRA
Mrs Wendy Brooks	11/12/2013 - 11/12/2013	Local REC training day – human tissue act training, HRA
Mrs Anne Davies	11/12/2013 - 11/12/2013	Local REC training day – human tissue act training, HRA
Mrs Rebecca Quayle	11/12/2013 - 11/12/2013	Local REC training day – human tissue act training, HRA
Canon Christopher Vallins	11/12/2013 - 11/12/2013	Local REC training day – human tissue act training, 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	19	33.93
Phase 1	3	5.36
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	1	1.79
Others	33	58.92
<b>Total Applications Reviewed</b>	<b>56</b>	<b>100</b>

**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	2
Number of student applications reviewed	6
Number of paediatric applications reviewed	3
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	0

**Table 3: Decisions given at meetings held within the reporting period:**

3.57

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	2	3.57
Favourable Opinion with Additional Conditions	11	19.64
Unfavourable Opinion	2	3.57
Provisional Opinion	41	73.21
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>56</b>	<b>100</b>
Number of studies sent back to full committee meeting for final opinion	2	



**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	35	62.5
Further Information Favourable Opinion with Additional Conditions	4	7.14
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	3.57
Favourable Opinion with Additional Conditions	11	19.64
Unfavourable Opinion	2	3.57
Provisional Opinion	1	1.78
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	1.78
Number of studies withdrawn after the meeting	0	0.00
<b>Total</b>	<b>56</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>16</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	4	25.00
Favourable Opinion with Additional Conditions	2	12.50
No Opinion transfer to full committee for review	1	6.25
Provisional Opinion	9	56.25
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>16</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	5.00
<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>	41
<b>Number of days taken to final decision - mode</b>	37
<b>Number of SSAs (non-Phase 1) reviewed</b>	4
<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>	106
<b>Number of substantial amendments over 35 days</b>	0
<b>Number of substantial amendments over 35 days as a % of total substantial amendments</b>	0.0%
<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%
<b>Number of proportionate review applications for ethical review over 14 days</b>	9
<b>Number of proportionate review applications over 14 days as a % of total</b>	60.0%

**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>
13/LO/0483	OKCSIB versus convention in stroke physiotherapy: Pilot RCT	47
13/LO/0486	Reward and Dopamine Interactions in Spatial Neglect, Version 1.0	45
13/LO/0552	SinuSys Patency of Maxillary Sinus Ostia Study	36
13/LO/0556	PDE-10A expression in Huntington's disease gene carriers	41
13/LO/0596	Blood donation	35
13/LO/0644	MicroRNAs as potential Biomarkers for Coronary Artery Calcification	54
13/LO/0654	Diagnostic accuracy of a novel assay for the detection of MRSA	55
13/LO/0665	Study with secukinumab in palmoplantar psoriasis	48
13/LO/0666	A clinical study to evaluate secukinumab in Nail Psoriasis	56
13/LO/0826	C diffense	55
13/LO/0863	The role of PDE-10A in Parkinson's disease L-dopa-induced dyskinesias.	46
13/LO/0988	To assess safety/tolerability and PK/PD AZD8848 in MAD.	56
13/LO/1010	The eMESH I Feasibility Study	52
13/LO/1049	Exploring the school experiences of adolescents who have self-harmed.	44
13/LO/1081	PROSPER:MDV3100-14 Phase 3,Enzalutamide,non-metastatic CRPC patients	38
13/LO/1083	C32001 MLN0128 + MLN1117 in advanced non-haematologic malignancies	21
13/LO/1102	The Value of Experience-Led Interventions at Self Help Services	18
13/LO/1109	Evaluating SALT needs in Older Community Mental Health Service Users	37
13/LO/1137	Tumour Genome sequencing in patients with salivary gland cancers	56
13/LO/1138	The Role of Diabetic Stimuli on kidney resident cells	53
13/LO/1288	Prevalence of OSAS in a Medical Admissions Unit	19
13/LO/1303	InfeCtion respONse through vIrus genomiCs (ICONIC)	14
13/LO/1320	Study of FAI insert in subjects with chronic non-infectious uveitis	45
13/LO/1357	Impact of rectal GC and CT on HIV infectiousness and transmission risk	48
13/LO/1451	GSK2647544 RD, DDI study in healthy young and elderly volunteers	48
13/LO/1459	Predictive Biomarkers for Drugs Targeting ALK/p53 in Neuroblastoma	51
13/LO/1474	Using nasal High Flow from birth in premature infants - a pilot study	46
13/LO/1478	Mechanisms to support compliance to iron chelation	41
13/LO/1613	Central fatigue in Parkinson's disease	14

13/LO/1616	Phase 1 study of MEDI4736 in Subjects With Advanced Solid Tumors	37
13/LO/1633	H03_02TP Phase 1 Clinical Study with Shigella sonnei vaccine 1790GAHB	28
13/LO/1665	OPUS study-version 1	48
13/LO/1684	Direct Flow Medical DISCOVER Registry	50
13/LO/1696	Method Evaluation of Nova Biomedical Statsensor Creatinine	59
13/LO/1850	Phase 1 advanced cancer study of VS-5584	37
14/LO/0049	PRiMe: Cognitive Outcome Following Major Burns	38
14/LO/0058	Salivary factors affecting enamel pellicles version 1	39
14/LO/0080	Luster PCI32765FLR3001	57
14/LO/0354	015 - extension study of CL-503012 in patients with AA Amyloidosis	33
14/LO/0483	Boosting uptake of NHS Health Checks in Bromley Using Heart Age	25

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/LO/0528	Rivaroxaban vs. Vitamin K antagonist in AF patients undergoing a PCI	37
13/LO/1279	The MyAction LifeNote study	15
13/LO/1464	Care pathways:children with neurodisability and feeding difficulties	16
13/LO/1506	A Low FODMAP diet for diarrhoea predominant FGID in NET patients	59
13/LO/1597	Midwifery Practices during the Second Stage of labour	53
13/LO/1957	Liver Cirrhosis in Chronic Pancreatitis	31
14/LO/0045	Value of PFS to patients: longitudinal study	41

#### 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/LO/1113	Effect of deposit build up on prosthetic eyes	29
13/LO/1926	Normothermic Machine Perfusion of Marginal Donor Livers	14
13/LO/1959	ALAS1 gene analysis in patients with acute intermittent porphyria	25
13/LO/1961	Pre-Operative Lung Function Assessment	25
14/LO/0489	Proteomic analysis of myeloproliferative neoplasms and leukaemias	13
05/Q0806/34+5	Neonatal Infection Surveillance Database	24

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
13/LO/0867	1199.93 - Nintedanib in mesothelioma	23
13/LO/0872	Text messaging reminders for influenza vaccine in primary care (v1)	30
13/LO/0935	A Phase I trial of ONX-0801	44
13/LO/0983	GO28625 - Phase II study of MPDL3280A for non-small cell lung cancer	22
13/LO/1065	Metal detector and flexible sigmoidoscopy completion rates	23
13/LO/1106	Patients as active partners in safety	16
13/LO/1350	HYBRID	26
13/LO/1352	GO28753 Anti-PDL1 in NSCLC	27
13/LO/1365	MRI scan to investigate micro bleeds in thrombocytopenic patients	35
13/LO/1482	MDV3100-10 TBP, Phase 4, Enzalutamide, metastatic CRPC patients	21
13/LO/1924	CD88 and CD64 as markers of sepsis in critical care patients	13
14/LO/0057	Pre-PARE Study	22
14/LO/0259	RE-AKT	21

<b>Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
13/LO/0649	Age-related differences in coronary wall MRI in adults	42
14/LO/0079	Lung HeXeRT	39

<b>Provisional Opinion</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
14/LO/0478	What factors influence couple's decisions about infant feeding	N/A
14/LO/0481	Lung HeXeRT	N/A

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

<b>Further information response not complete</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<b>Withdrawn after the meeting</b>		
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<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
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<b>Invalid Application</b>		
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<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
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<b>No Opinion Pending Consultation with Referee</b>		
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<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
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<b>Not Requiring Review by NHS REC</b>		
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<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
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**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>
13/LO/1106	Patients as active partners in safety	16
13/LO/1102	The Value of Experience-Led Interventions at Self Help Services	18
13/LO/1279	The MyAction LifeNote study	15
13/LO/1288	Prevalence of OSAS in a Medical Admissions Unit	19
13/LO/1464	Care pathways:children with neurodisability and feeding difficulties	16
13/LO/1957	Liver Cirrhosis in Chronic Pancreatitis	31
13/LO/1961	Pre-Operative Lung Function Assessment	25
13/LO/1959	ALAS1 gene analysis in patients with acute intermittent porphyria	25
14/LO/0483	Boosting uptake of NHS Health Checks in Bromley Using Heart Age	25

<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>

**Section 30 application over 60 day timeline**



Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
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