

National Research Ethics  
Service

  
*Health Research Authority*

**NRES Committee London - Chelsea**

**Annual Report**

**01 April 2011 – 31 March 2012**

## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	NRES Committee London - Chelsea
<b>Type of REC:</b>	Type 3
<b>Type of Flag:</b>	None
<b>Chair:</b>	Dr Shelley Dolan
<b>Vice-Chair:</b>	Mrs Patricia Pank
<b>Alternate Vice-Chair:</b>	n/a
<b>Co-ordinator:</b>	Audrey Adams Lara Callaghan (up to July 2012) Rosalind Cooke (up to March 2012)
<b>PRSC Co-ordinator:</b>	n/a
<b>Assistant Co-ordinator:</b>	Thomas McQuillan
<b>Committee Address:</b>	Health Research Authority Research Ethics Committee (REC) London Centre Ground Floor 80 Skipton House London Road London SE1 6LH
<b>Telephone:</b>	020 797 22584
<b>Fax:</b>	020 797 22592
<b>Email:</b>	nrescommittee.london-chelsea@nhs.net

### Chair's overview of the past year:

Not received at time of publication

## NRES Committee London - Chelsea Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mr Roger Ahern	Medical Statistician	Expert	14/06/2010	
Dr. Sonya Babu-Narayan	Cardiologist Specialist Registrar	Expert	14/06/2010	
Mr Jeremy Butler	Former NHS Non Executive Director	Lay Plus	14/06/2010	
Dr Robin Chung	Academic Medicine Trainee doctor and Engineer	Expert	14/06/2010	20/09/2011
Dr Shelley Dolan	Chief Nurse	Expert	14/06/2010	
Mr Christopher Exeter	Executive Director	Lay Plus	18/05/2011	12/09/2011
Dr Adam Jacobs	Medical Statistician	Expert	14/06/2010	
Mr Philip Kimberley	Clinical Governance Information Manager	Lay	14/06/2010	
Professor Elizabeth Meerabeau	University professor	Expert	01/12/2011	
Mrs Patricia Pank	Retired University Lecturer	Lay Plus	14/06/2010	
Dr Nazima Pathan	Consultant PICU	Expert	14/06/2010	20/06/2011
Mrs Paula Rogers	Research Nurse Manager	Expert	14/06/2010	
Mrs Laura Royde	School Governor	Lay Plus	14/12/2010	
Ms Cate Savidge	CT Scanning Superintendent	Expert	14/06/2010	
Dr Michael Schachter	Clinical Pharmacologist	Expert	01/12/2010	
Dr Elliot Shinebourne	Consultant Paediatric Cardiologist	Expert	14/06/2010	
Dr Mary Taj	Consultant Paediatric in Oncologist	Expert	14/06/2010	

### Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended

### Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Miss Stephanie Ellis	Former Civil Servant	Lay	13/06/2011

### Member Bank

Name	Occupation	Expert or Lay	Meeting date attended

## NRES Committee London - Chelsea: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Dr Shelley Dolan	Board member at MHRA. Board member at the Royal Marsden NHS Foundation Trust.	18/10/2012
Mrs Patricia Pank	Trustee, clinical advisor the Helen Bamber foundation for survivors of torture. Trustee baobab centre for young survivors in exile	12/12/2011
Mrs Paula Rogers	None.	08/04/2011
Mr Jeremy Butler	Through a stockbroker and from time to time hold shares in pharmaceutical companies I currently have an investment in GSK. Member of Small Mental Health Research Forum to help allocate small funds for mental health research.	12/01/2012
Dr Mary Taj	None.	12/12/2011
Mr Philip Kimberley	As part of my role as clinical development manager at Royal Brompton and Harefield NHS Foundation Trust. I may build databases for research projects, some of which may come to the committee for approval.	06/07/2011
Mr Roger Ahern	Employed by Institute of cancer research, Sutton Surrey. Statistician at clinical trials and statistics unit, ICR. ICR has a commercial intervention of some drugs Member of several Independent Data Monitoring Committees.	01/12/2011
Dr Elliot Shinebourne	None.	13/12/2011
Dr. Sonya Babu-Narayan	None.	18/10/2012
Dr Michael Schachter	None.	18/01/2011
Mrs Laura Royde	None.	12/12/2011
Dr Adam Jacobs	Director of Dianthus Medical Limited, a privately owned company providing consultancy services to researchers. Owner of Dianthus Medical Limited. 100% share ownership of Dianthus Medical Limited. Own shares in other research-based companies via pension fund, but not aware of the names of these companies.	13/04/2010
Ms Cate Savidge	None.	09/07/2012
Professor Elizabeth Meerabeau	Reviewer for SDO. Supervision of PhD students, University of Greenwich	12/12/2011

**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	11/04/2011	11
May	09/05/2011	12
June	13/06/2011	10
July	11/07/2011	11
August	08/08/2011	11
September	12/09/2011	10
October	10/10/2011	7
November	14/11/2011	12
December	12/12/2011	11
January	09/01/2012	13
February	13/02/2012	12
March	12/03/2012	13

12 full committee meetings were held during the reporting period.

**Proportionate Review Sub Committee Meetings held during 01 April 2011 - 31 March 2012:**

No proportionate review sub-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>
Mr Roger Ahern	12
Mrs Patricia Pank	12
Mr Jeremy Butler	11
Mr Philip Kimberley	10
Dr Mary Taj	10
Dr Elliot Shinebourne	10
Mrs Paula Rogers	10
Mrs Laura Royde	9
Dr Adam Jacobs	9
Dr Michael Schachter	9
Dr Shelley Dolan	9
Dr. Sonya Babu-Narayan	9
Dr Robin Chung	5
Professor Elizabeth Meerabeau	4
Dr Nazima Pathan	2
Miss Stephanie Ellis	1
Ms Cate Savidge	1

**Number of inquorate meetings held: 0**

**Attendance of Members at proportionate review sub-committee meetings:  
01 April 2011 – 31 March 2012:**

No proportionate review sub-committee meetings were held during the reporting period.

## Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Dr Michael Schachter	04/04/2011 - 04/04/2011	Equality & Diversity, on line
Dr Adam Jacobs	26/07/2011 - 26/07/2011	NRES Medical Devices training, NRES
Mrs Paula Rogers	15/09/2011 - 15/09/2011	NRES Human Tissue Act training (Code PO5001), NRES
Dr Elliot Shinebourne	15/09/2011 - 15/09/2011	NRES Human Tissue Act training Code PO5001, NRES
Mrs Patricia Pank	01/11/2011 - 01/11/2011	NRES Reviewing Clinical Trials of Investigational Medicinal Products (code - PO1101, NRES
Mrs Paula Rogers	12/04/2011 - 11/04/2012	Equality & Diversity, NHS
Dr. Sonya Babu-Narayan	26/07/2011 - 26/07/2011	NRES Medical Devices training , NRES
Dr Mary Taj	19/05/2011 - 19/05/2011	Adults Lacking Capacity, NHS
Dr. Sonya Babu-Narayan	22/05/2011 - 22/05/2011	Equality & Diversity, NHS
Mrs Patricia Pank	23/05/2011 - 23/05/2011	Equality & Diversity, NRES
Dr Michael Schachter	02/11/2011 - 02/11/2011	NRES -'The Nuts and Bolts of running a REC' (code OP1202, NRES
Mr Christopher Exeter	11/10/2011 - 11/10/2011	Induction, NRES
Dr Michael Schachter	11/10/2011 - 11/10/2011	Induction, NRES
Mrs Patricia Pank	11/10/2011 - 11/10/2011	Induction, NRES
Dr Adam Jacobs	01/10/2011 - 01/10/2011	Ethics in real life, Open University
Dr Adam Jacobs	17/06/2011 - 17/06/2011	Research and Human Tissue legislation, Medical Research Council
Mr Jeremy Butler	16/06/2011 - 16/06/2011	Equality & Diversity, NRES
Dr Robin Chung	05/07/2011 - 05/07/2011	Equality & Diversity, e-learning for health.org Stage 1
Dr Robin Chung	26/07/2011 - 26/07/2011	Medical Devices, NRES
Dr Robin Chung	07/12/2011 - 07/12/2011	NRES Statistics Training for NRES REC Members , NRES
Mrs Patricia Pank	08/11/2011 - 08/11/2011	Chairing Skills, NRES
Mr Jeremy Butler	28/09/2011 - 28/09/2011	Phase I, NRES
Mr Roger Ahern	10/10/2011 - 10/10/2011	shared Ethical Debate, NRES
Mrs Patricia Pank	10/10/2011 - 10/10/2011	Shared Ethical Debate, NRES
Mrs Patricia Pank	18/10/2011 - 18/10/2011	Chair's Meeting, NRES
Dr. Sonya Babu-Narayan	10/10/2011 - 10/10/2011	Shared Ethical Debate, NRES
Mrs Paula Rogers	10/10/2011 - 10/10/2011	Shared Ethical Debate, NRES
Mr Jeremy Butler	10/10/2011 - 10/10/2011	Shared Ethical Debate, NRES
Mr Philip Kimberley	10/10/2011 - 10/10/2011	Shared Ethical Debate, NRES
Dr Michael Schachter	10/10/2011 - 10/10/2011	Shared Ethical Debate, NRES
Mr Philip Kimberley	05/07/2011 - 05/07/2011	Equality & Diversity, NHS
Mr Philip Kimberley	28/09/2011 - 28/09/2011	NRES Phase 1 training, NRES
Mr Jeremy Butler	16/11/2011 - 16/11/2011	MCA video, NRES
Mrs Laura Royde	29/11/2011 - 29/11/2011	Equality & Diversity, NRES

**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	25	33.33
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	50	66.67
<b>Total Applications Reviewed</b>	<b>75</b>	<b>100</b>

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

Number of applications made invalid by co-ordinator	3
Number of studies withdrawn prior to the meeting	17
Number of student applications reviewed	18
Number of paediatric applications reviewed	2
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:**

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	7	8.97
Favourable Opinion with Additional Conditions	13	16.67
Unfavourable Opinion	1	1.28
Provisional Opinion	54	69.23
Invalid	0	0.00
No Opinion Pending Consultation with Referee	2	2.56
Provisional Opinion Pending Consultation with Referee	1	1.28
Not Requiring Review by NHS REC	0	0.00
<b>Total</b>	<b>78</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	55	72.37
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	7	9.21
Favourable Opinion with Additional Conditions	13	17.11
Unfavourable Opinion	1	1.32
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	0	0.00
Number of studies withdrawn after the meeting	0	0.00
<b>Total</b>	<b>76</b>	<b>100</b>

**Table 5: Other Management Information for the reporting period:**

<b>Average number of applications reviewed per full meeting</b>	6.25
<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>	2.67%
<b>Number of days taken to final decision - average</b>	30
<b>Number of days taken to final decision - mode</b>	21
<b>Number of SSAs (non-Phase 1) reviewed</b>	7
<b>Number of applications for SSA review over 25 days</b>	1
<b>Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)</b>	14.3%
<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>	116
<b>Number of substantial amendments over 35 days</b>	3
<b>Number of substantial amendments over 35 days as a % of total substantial amendments</b>	2.6%
<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>	7
<b>Number of modified amendments over 14 days</b>	1
<b>Number of modified amendments over 14 days as a % of total modified amendments</b>	14.3%

**Table 6: 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/LO/0309	Responsibility and thought-action fusion in command hallucinations	46
11/LO/0357	Safety Culture across Intensive Care units V1.0	30
11/LO/0359	A phase II study of BEZ235 in patients with endometrial carcinoma.	21
11/LO/0372	IPF Drug Deposition Study	36
11/LO/0447	Sensory modulation and motor skills in children with ASD. V.1	25
11/LO/0504	Physio and Speech Therapy management of chronic cough	23
11/LO/0519	MRI of the testis in complete androgen insensitivity syndrome version1	53
11/LO/0550	STEFFI	19
11/LO/0551	Phase I study of a FAK inhibitor in subjects with solid tumours	18
11/LO/0665	[GLORIA] DUODOPA Registry	23
11/LO/0762	1200.89: Afatinib in Inflammatory Breast Cancer	18
11/LO/0783	Cardiopulmonary exercise testing in sickle cell disease	36
11/LO/0791	Using HIV-1 resistance tests to predict superinfection	33
11/LO/0792	Comprehension of Health Information in Relapsing Remitting MS	28
11/LO/0836	VRS-317 11VR1.1 Version 3	20
11/LO/0957	DC Vax-Brain Phase II trial for GBM	17
11/LO/0971	Investigation of the maternal immune system	36
11/LO/0972	Hindgut Sensorimotor Function post Rectal Resection	33
11/LO/0999	H2H PIF-ILD study	23
11/LO/1198	Safety and imaging of Florbetapir in individuals with MCI	21
11/LO/1204	Serum S100B measurement in minor traumatic brain injury	24
11/LO/1205	Utility of Sleep-Minder monitoring of respiratory patterns in HF	29
11/LO/1206	Ultrasound Lead treatment in Rheumatoid Arthritis	30
11/LO/1207	Evaluation of the Allergenic Potential of Air Structuring Protein	41
11/LO/1209	LOCUS v1	26
11/LO/1216	MESO-02	30
11/LO/1332	S133 Home delivery Pemetrexed post induction therapy in advanced NSCLC	26
11/LO/1362	MUK three	35
11/LO/1392	Study of Pleural effusions for pulmonary and pleural malignancies	27

11/LO/1416	Developing new patient reported outcome measures in aortic surgery	32
11/LO/1420	Routine carbon monoxide testing of pregnant women	36
11/LO/1442	SSAT 044 HBR study	22
11/LO/1549	CyberKnife for Hepatic Metastases from Colorectal Cancer	24
11/LO/1594	Image Quality of Cone Beam CT	35
11/LO/1598	Diffusion-weighted Imaging Study in Cancer of the Ovary(DISCOVAR) V1	35
11/LO/1644	Predictive model of therapy outcomes in Breast Cancer patients	25
11/LO/1765	FIH study of AKN-028 in Patients with Acute Myelogenous Leukemia	30
11/LO/1775	Analysis of Tumour Specimens for Biomarkers in Gynae Cancers	29
11/LO/1795	IV Ferric Carboxymaltose in Iron Deficiency in Chronic Heart Failure 1	42
11/LO/1915	Phase III prostate cancer trial: surgery, radiotherapy, Cyberknife	37
11/LO/1917	Non invasive measurement of filtration fraction in diabetic patients	43
11/LO/2064	Insulin resistance and metabolism in Bardet-Biedl syndrome version 1.1	49
12/LO/0018	Primary Laryngeal Reinnervation	51
12/LO/0023	Effect of sampling method on contamination of blood cultures	61
12/LO/0051	LenD (Lenalidomide in CLL)	43
12/LO/0103	Cabazitaxel/XRP6258 - Phase 1/2 TCD12128	36
12/LO/0131	Effects of S44121 vs placebo on cardiac arrhythmia in CPVT patients	52
12/LO/0229	Effect of the electronic cigarette on withdrawal symptoms (ECIG24)	72
12/LO/0240	Analysis of the human stool microbiome in health and disease	39
12/LO/0334	Follow-up study of breast health outcomes and selected biomarkers.	60
12/LO/0360	Computer-Delivered Cognitive Behaviour Therapy for Cancer Patients	30
12/LO/0394	Genetic and Urinary Biomarkers of Incontinence	30
12/LO/0397	Straight leg raise; responses in patients with referred leg pain	26
12/LO/0402	PCIA202-10 Phase 2 Amphinex-based PCI of Bleomycin	33

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
---------------	-------------------------	-------------------------

#### Further Information Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
---------------	-------------------------	-------------------------

<b>Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/LO/0305	Investigating regulatory T-cells in HIV/HCV coinfection	20
11/LO/0557	Targeting SHIP-1 in COPD	16
11/LO/0785	A4001098 - Maraviroc Study in HIV-1 coinfectd pts	50
11/LO/0787	A database of echo studies to develop technology to help new operators	21
11/LO/0790	FloriNASH	22
11/LO/1003	Why non medical practitioners have not taken up the RC role.	27
12/LO/0183	A Narrative longitudinal study with young adults with cancer	33

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/LO/0304	Predicting Hepatitis C treatment responses	20
11/LO/0510	DELINEATE v1.1	16
11/LO/0954	1200.131 LUX-Head & Neck 2; Afatinib in Squamous Cell Carcinoma	22
11/LO/1201	An exploration of future perceptions of QoL in adults with anorexia.	28
11/LO/1563	Viamet Phase I/II Study VMT-VT-464-CL-001	17
11/LO/1619	Comparing safety & efficacy of AI/lapatinib/trastuzumab in HR+HER2 MBC	17
11/LO/1777	Ventilator monitoring in early exacerbation detection	22
11/LO/1779	EPOS S1: Patient and Key Worker Feedback on DIALOG	22
11/LO/1830	Time and Motion Study of Subcutaneous and Intravenous Trastuzumab	22
11/LO/1973	GABA-B receptor function in healthy volunteers	21
11/LO/1974	Extension Study with AMG 145 in Subjects With Hypercholesterolemia	21
11/LO/1989	Vitamin D and Longevity (VIDAL) Trial: randomised feasibility study v1	21
12/LO/0094	QAB versus Seretide 26 week study	26

<b>Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/LO/1018	Seeking help for alcohol problems in the Turkish-Kurdish community	14

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

<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>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
<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 7: 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>
12/LO/0023	Effect of sampling method on contamination of blood cultures	61
12/LO/0229	Effect of the electronic cigarette on withdrawal symptoms (ECIG24	74

<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>
12/LO/0226	CyberKnife for Hepatic Metastases from Colorectal Cancer	54

<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>
11/LO/0954/AM03	1200.131 LUX-Head & Neck 2; Afatinib in Squamous Cell Carcinoma	Substantial Amendment 3, 8/02/2012	60
09/H0801/93/AM09	MK2206 + AZD6244 in Patients With Advanced or Metastatic Tumours (010)	PIS/consent form Version 9 16/02/2012	55
12/LO/0023/AM01	Effect of sampling method on contamination of blood cultures	1.0	37

<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>
08/H0801/98/AM12/1	MK-4827 in BRCA Ovarian Cancer and Other Advanced Solid Tumours	SA09	17

<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>