

National Research Ethics
Service


Health Research Authority

NRES Committee London - Chelsea

Annual Report

01 April 2013 – 31 March 2014

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee London - Chelsea
Type of REC:	Type I and III
Type of Flag:	Phase I in Healthy Volunteers and Phase I Studies in Patients
Chair:	Dr Shelley Dolan
Vice-Chair:	Mrs Patricia Pank
Alternate Vice-Chair:	Dr Michael Schachter
REC Manager:	Mr Danyal Enver
PRSC Co-ordinator:	Mr Danyal Enver
REC Assistant:	Mr Thomas McQuillan
Committee Address:	HRA Ground Floor, Skipton House 80 London Road London SE1 LH
Telephone:	020 7972 2536
Fax:	
Email:	Nres.committee.london-chelsea@nhs.net

Chair's overview of the past year:

The Chair's overview was unavailable at the time of publication

NRES Committee London - Chelsea Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mr Roger A'Hern	Medical Statistician	Expert	01/06/2010	
Dr Judy Allfrey	Retired Nurse	Lay	01/06/2013	
Dr. Sonya Babu-Narayan	Clinical Senior Lecturer and Consultant Cardiologist	Expert	01/06/2010	
Mr Jeremy Butler	Former NHS Non Executive Director	Lay Plus	01/06/2010	
Dr Shelley Dolan	Chief Nurse	Expert	01/06/2010	
Dr Adam Jacobs	Medical Statistician	Expert	01/06/2010	
Mr Philip Kimberley	Clinical Governance Information Manager	Lay	14/06/2010	
Professor Elizabeth Meerabeau	University Professor	Expert	01/12/2011	08/07/2013
Mr Serge Miodragovic	Ophthalmology Clinical Research Coordinator	Expert	22/05/2013	
Mrs Patricia Pank	Retired University Lecturer	Lay	01/06/2010	
Mrs Paula Rogers	Cardiology Research Nurse	Expert	01/06/2010	
Mrs Laura Royde	School Governor	Lay Plus	14/12/2010	07/05/2013
Ms Cate Savidge	CT Scanning Superintendent	Expert	01/06/2010	
Dr Michael Schachter	Clinical Pharmacologist	Expert	01/12/2010	
Dr Elliot Shinebourne	Consultant Paediatric Cardiologist	Expert	01/06/2010	
Dr Mary Taj	Consultant Paediatric in Oncologist	Expert	01/06/2010	
Miss Isobel Vass	Magistrate	Lay	19/06/2013	

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Jenny Johnson	Charity Trustee	Lay	17/03/2013

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

Name	Declaration of Interest	Date
Miss Isobel Vass	No interests to declare	27/06/2013
Mr Serge Miodragovic	None.	31/03/2014
Dr Shelley Dolan	Board Member at the Royal Marsden NHS Foundation Trust; Board Member at MHRA until May 2013.	31/03/2014
Dr Adam Jacobs	Director of Dianthus Medical Limited. Owner of Dianthus Medical Limited.	31/03/2014
Mr Roger A'Hern	None.	31/03/2014
Mrs Paula Rogers	None.	31/03/2014
Dr Elliot Shinebourne	None.	31/03/2014
Dr Mary Taj	Paediatric at Oncologist at Royal Marsden Hospital. Member of Paediatric NCRI B-NHL Group. Chair of CCCG Lymphoma (NHL) Interest Group. Chair of CCLG PODC Group	31/03/2014
Dr Judy Allfrey	Lay member on Kings College London Research Ethics Sub-Committee.	31/03/2014
Mrs Patricia Pank	Trustee for Helen Bamber Foundation. Trustee for Baobab Trust and Lay member of clinical governance committee UCLH Emergency Services Com.	31/03/2014
Dr. Sonya Babu-Narayan	None	31/03/2014
Dr Michael Schachter	None	31/03/2014

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

Month	Date	Number of Members Present at Meeting
April	08/04/2013	11
May	13/05/2013	11
June	10/06/2013	11
July	08/07/2013	13
September	09/09/2013	12
October	14/10/2013	11
November	11/11/2013	12
December	09/12/2013	13
January	13/01/2014	15
February	17/02/2014	8
March	17/03/2014	9

11 full committee meetings were held during the reporting period.

Attendance of Members: 01 April 2013 – 31 March 2014:

Name	Number of Meetings Attended
Mr Roger A'Hern	11
Mrs Patricia Pank	10
Mrs Paula Rogers	9
Dr Judy Allfrey	9
Dr Michael Schachter	9
Dr Shelley Dolan	9
Dr Mary Taj	8
Mr Jeremy Butler	8
Dr Adam Jacobs	8
Mr Serge Miodragovic	8
Ms Cate Savidge	7
Mr Philip Kimberley	7
Dr Elliot Shinebourne	7
Dr. Sonya Babu-Narayan	6
Miss Isobel Vass	5
Professor Elizabeth Meerabeau	4

Number of inquorate meetings held: 0

Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Mr Serge Miodragovic	02/05/2013 - 02/05/2013	Training - Ethical Issues of Research Involving Children, HRA
Mr Serge Miodragovic	23/04/2013 - 23/04/2013	NRES Committee Members Induction, HRA
Mrs Paula Rogers	02/10/2013 - 02/10/2013	Researcher Training Day, HRA
Mr Jeremy Butler	17/04/2013 - 17/04/2013	Ethical Review of Mental Health / Psychiatric Research, HRA
Dr Elliot Shinebourne	08/07/2013 - 08/07/2013	Training - Qualitative Research and Ethical Review, HRA
Mr Roger A'Hern	24/04/2013 - 24/04/2013	Good Clinical Practice and Regulatory Requirements for Clinical Trials: A Refresher Session, T Symons Associates Ltd
Mr Serge Miodragovic	19/09/2013 - 19/09/2013	Training - Medical Devices Training Day, HRA
Miss Isobel Vass	18/09/2013 - 18/09/2013	Induction, HRA
Dr Michael Schachter	31/10/2013 - 31/10/2013	Qualitative Research and Ethical Review, HRA
Mrs Paula Rogers	26/07/2013 - 26/07/2013	Good Clinical Practice (GCP) Refresher, NIHR
Mrs Patricia Pank	20/11/2013 - 20/11/2013	Training - National Members Training Day, HRA
Ms Cate Savidge	20/11/2013 - 20/11/2013	National Members Training Day, HRA
Dr Judy Allfrey	03/03/2014 - 03/03/2014	Induction, HRA
Mrs Patricia Pank	13/02/2014 - 13/02/2014	Assessing the Consequences (benefits and harms) of Research: a Health Research Authority workshop, HRA
Miss Isobel Vass	13/02/2014 - 13/02/2014	Assessing the Consequences (benefits and harms) of Research: a Health Research Authority 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:

Applications for full ethical review – Study Type	Number	%
Clinical Trial of Investigational Medicinal Product	18	30.00
Phase 1	1	1.67
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	41	68.33
Total Applications Reviewed	60	100

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	2
Number of student applications reviewed	19
Number of paediatric applications reviewed	8
Number of device applications reviewed	2
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:

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	3	5.00
Favourable Opinion with Additional Conditions	14	23.33
Unfavourable Opinion	3	5.00
Provisional Opinion	40	66.67
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	60	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	39	65.00
Further Information Favourable Opinion with Additional Conditions	1	1.67
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	3	5.00
Favourable Opinion with Additional Conditions	14	23.33
Unfavourable Opinion	3	5.00
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
Total	60	100

Table 5: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.45
Number of applications for full ethical review over 60 days	12
Number of applications over 60 days as a % of total	20.00%
Number of days taken to final decision - average	45
Number of days taken to final decision - mode	36
Number of SSAs (non-Phase 1) reviewed	2
Number of applications for SSA review over 25 days	1
Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)	50.0%
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	119
Number of substantial amendments over 35 days	5
Number of substantial amendments over 35 days as a % of total substantial amendments	4.2%
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	4
Number of modified amendments over 14 days	0
Number of modified amendments over 14 days as a % of total modified amendments	0.0%

Table 6: 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/LO/0433	DILSTENT-2:	61
13/LO/0434	In-vivo Studies of Chronic Lymphocytic Leukaemia Kinetics V.I	61
13/LO/0491	CATCH-AMI	57
13/LO/0501	Phase 2 study in Maribavir vs Valganciclovir in CMV infections	47
13/LO/0628	Imaging Hypoxia in Head & Neck Cancer - A pilot study	31
13/LO/0629	Investigating recovery amongst MDO's living in the Community	31
13/LO/0702	EVP-6124 as a treatment to improve mental function in Schizophrenia	42
13/LO/0762	Perception of altered salivary flow in patients on antipsychotics	40
13/LO/0807	Phase 2a study of JNJ-38618168 in asthmatics	61
13/LO/0883	Histological correlation of textural features of PET & ceCT in NSCLC	40
13/LO/0944	A cross-sectional study of young-onset diabetes in 2 UK ethnic groups	59
13/LO/0954	Study to detect coronary biomarker gradients in arteries using the LBS	47
13/LO/1146	Improving Patient Understanding of Hypodontia	51
13/LO/1248	Immunopathogenesis and Molecularbiology in Breast Cancer Subtypes	51
13/LO/1256	How do your teeth make you feel?	63
13/LO/1430	Families' experiences: Patients on Phase I trials	60
13/LO/1436	My Baby and Me	71
13/LO/1477	Clinical validation of a CT generated dynamic shoulder model	26
13/LO/1579	SPOT Trial v 1.0 (13th June 2013)	83
13/LO/1581	DNIB0600A in patients with Platinum-Resistant Ovarian Cancer	49
13/LO/1646	Myocardial regeneration using shockwave, DPP4 inhibitor and PTH. V1	28
13/LO/1648	Safety and performance of Orbix breast lifting system	35
13/LO/1649	An exploratory study of the psychological impact of a VAD	74
13/LO/1730	Voices over time	57
13/LO/1797	EORTC 40091/ BOS-2	65
13/LO/1805	A Phase 2 Study of the Pharmacokinetics and Pharmacodynamics of galete	49
14/LO/0002	Outcome of MCL reconstruction using LARS ligament	51
14/LO/0031	ASP8477 in Peripheral Neuropathic Pain (MOBILE)	83
14/LO/0032	Prophylactic Elective Clipping of Colonic Diverticula	31

14/LO/0060	The effect of Dexamethasone on glucose profiles in Diabetes. v1.0	67
14/LO/0070	Needs of children, young people & families following childhood stroke	57
14/LO/0200	Safety and Efficacy of AA4500 in men with Peyronie's Disease	69
14/LO/0232	Genetics of Multiple Cancers Study (GeMCaS)	33
14/LO/0240	Using the AQ-10 with adults who have a learning disability	46
14/LO/0247	EMR 63325-021 Phase 3 Trial of Tecemotide in NSCLC	48
14/LO/0298	Single Arm Study of Enzalutamide in Patients with Prostate Cancer	38
14/LO/0301	Study of induction of cell cycle arrest following chemotherapy	63
14/LO/0372	Vertex VX13-970-002	36
14/LO/0406	Needle Placements in Patients with Subacromial Impingement Syndrome V1	36

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/LO/0424	Saliency processing in schizophrenia	53

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/1250	Biomolecular analysis of prostate cancer tissue	36
13/LO/1819	The anatomical approach to mitral device implantation	35
14/LO/0231	Patients with axial spondyloarthritis: Five year observation study	40

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/LO/0565	Non-Invasive Ventilation For Airway Clearance in Adult Cystic Fibrosis	30
13/LO/0668	Onyx: Study of Carfilzomib in Newly Diagnosed Multiple Myeloma Patients	30
13/LO/0693	Defining the intestinal microbiota in premature neonates: Follow-up	36
13/LO/0758	WB-EQ-MRI assessment of treatment response in cancer	36
13/LO/0965	Brain stimulation to improve motor learning after stroke (V1)	46
13/LO/1252	The MILO Study (MEK Inhibitor in Low-grade Serous Ovarian Cancer)	43
13/LO/1265	First in Human, Dose-Escalating Study of HuMaX®-TF-ADC in solid Tumour	43

13/LO/1270	CMVVASC	36
13/LO/1417	FINESSE	24
13/LO/1827	AZD5363 Formulation Comparison, Effect of Food, Safety & Tolerability	6
13/LO/1848	Enhanced Early Supported Discharge Project	35
14/LO/0054	White blood cell collection for development of Adoptive Immunotherapies	30
14/LO/0209	Breast Radiotherapy: Invisible Tattoos for External References(BRITER)	28
14/LO/0292	ABC-BIO: Biological Sample Collection Protocol	36

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/LO/0934	Adolescents' perception of pain management in sickle cell disease	25
13/LO/1487	AZD5363 Formulation Comparison, Effect of Food, Safety & Tolerability	24
14/LO/0415	Prospective Outcome Evaluation of Trauma (POET)	33

Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
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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
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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

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/LO/0434	In-vivo Studies of Chronic Lymphocytic Leukaemia Kinetics V.I	61
13/LO/0433	DILSTENT-2:	61
13/LO/0807	Phase 2a study of JNJ-38618168 in asthmatics	61
13/LO/1256	How do your teeth make you feel?	63
13/LO/1436	My Baby and Me	71
13/LO/1579	SPOT Trial v 1.0 (13th June 2013)	83
13/LO/1649	An exploratory study of the psychological impact of a VAD	74
13/LO/1797	EORTC 40091/ BOS-2	65
14/LO/0031	ASP8477 in Peripheral Neuropathic Pain (MOBILE)	83
14/LO/0060	The effect of Dexamethasone on glucose profiles in Diabetes. v1.0	67
14/LO/0200	Safety and Efficacy of AA4500 in men with Peyronie's Disease	69
14/LO/0301	Study of induction of cell cycle arrest following chemotherapy	63

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
14/LO/0198	The MILO Study (MEK Inhibitor in Low-grade Serous Ovarian Cancer)	28

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
09/H0801/93/AM13	MK2206 + AZD6244 in Patients With Advanced or Metastatic Tumours	SA15	43

	(010)		
11/LO/0954/AM08	1200.131 LUX-Head & Neck 2; Afatinib in Squamous Cell Carcinoma	Substantial Amendment 6, 5th March 2013	48
12/LO/0131/AM09	Effects of S44121 vs placebo on cardiac arrhythmia in CPVT patients	Addendum no.2 to IB no.4 (final version 04/02/2013)	43
12/LO/0402/AM03	PCIA202-10 Phase 2 Amphinex- based PCI of Bleomycin	PCI 202/10-UK003	43
09/H0708/74/AM10	ADVANCE-ON	5, dated 25.11.13	42

Modified Amendments over 14 day timeline

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

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