

**NRES Committee London - City Road  
& Hampstead**

**Annual Report**

**01 April 2011 – 31 March 2012**

## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	NRES Committee London - City Road & Hampstead
<b>Type of REC:</b>	Type ii REC not currently reviewing CTIMPS
<b>Type of Flag:</b>	No Committee flags
<b>Chair:</b>	Dr David Slovic
<b>Vice-Chair:</b>	Mr Hari Jayaram
<b>Alternate Vice-Chair:</b>	Mr Robert Goldstein
<b>Co-ordinator:</b>	Miss Tina Cavaliere
<b>PRSC Co-ordinator:</b>	Miss Tina Cavaliere
<b>Assistant Co-ordinator:</b>	Miss. Christine Hobson
<b>Committee Address:</b>	Bristol Research Ethics Centre Level 3, Block B Whitefriars Lewins Mead Bristol BS1 2NT
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### Chair's overview of the past year:

We have had a successful and fulfilling year of meetings. Our members have enjoyed vigorous discussions over the submitted papers, and feel that they have significantly improved the safety and wellbeing of participants in the reviewed studies, and received good responses from investigators.

Members have enjoyed their attendances at training events, and found them invaluable.

There have been recurrent expressions of regret that the Committee is currently prevented from reviewing Clinical Trials on Medicinal Products, but it is hoped that our joint expertise, particularly regarding pharmacy, statistics and medicines safety, may allow this activity to be resumed in the future.

The Committee has been expertly aided by the Coordinators Christine, Tina and Charlotte to whom we are most grateful for their cheerful and efficient work at all times.

David I Slovic

## NRES Committee London - City Road & Hampstead Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Miss Rita Mary Abdulahad Olivera	Clinical Project Manager	Expert	01/07/2011	10/01/2012
Dr Koula Asimakopoulou	Senior Lecturer in Health Psychology	Expert	01/07/2011	
Ms Jill Bloom	Drug Information Pharmacist	Expert	03/03/2003	
Dr Elizabeth Carrey	Former MSc Programme Director in Clinical Paediatrics	Lay	15/06/2005	12/10/2011
Mrs Stephanie Cooper	Solicitor	Lay Plus	21/05/2010	
Mrs Ros Goldfarb	Retired Immigration Judge	Lay Plus	01/08/2009	
Mr Robert Goldstein	Economist	Lay Plus	13/03/2007	
Mr Hari Jayaram	Academic Clinical Lecturer in Ophthalmology	Expert	01/07/2007	
Mr Peter Jones	Retired Head teacher	Lay Plus	12/08/2010	
Ms Sarah Kaiser	Director, Human Rights NGO	Lay	12/08/2010	13/04/2011
Dr Stella Kingett	Consultant Psychiatrist	Expert	21/03/2007	
Professor Diana Kornbrot	Professor of Mathematical Psychology	Expert	30/09/2008	
Ms. Sanaz Mehdipour	Senior Dealer Treasury Specialist	Lay Plus	01/12/2011	
Mr Israel Nartey	Associate Specialist/Lead Clinician - Ophthalmology	Expert	01/07/2011	
Ms Mary Ryan	Personnel Manager	Expert	19/12/2003	
Dr David Slovick	Consultant Physician	Expert	21/03/2007	

### Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended
N/A			

### Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
N/A			

### Member Bank

Name	Occupation	Expert or Lay	Meeting date attended
N/A			

**NRES Committee London - City Road & Hampstead: Members' Declarations of Interest:**

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Dr David Slovic	None	14/12/2011
Mr Hari Jayaram	None	01/04/2011
Mr Robert Goldstein	Shareholder in: Anaxsys Microtest Matrices Michelson Diagnostics	30/03/2012
Ms Jill Bloom	Pharmacy Section Manager which includes Pharmacy Clinical Trials, There is a Senior Clinical Trials Pharmacist which Ms Jill Bloom line manages	14/12/2011
Ms Mary Ryan	None	14/12/2011
Professor Diana Kornbrot	Funding from Cancer Research Charity	14/12/2011
Mrs Ros Goldfarb	Member Dimensions - as Non Executive Director	01/04/2011
Mrs Stephanie Cooper	Governor of Tavistock & Portman NHS Foundation Trust	30/03/2012
Mr Peter Jones	None	14/12/2011
Mr Israel Nartey	None	14/07/2011
Dr Koula Asimakopoulou	None	13/07/2011
Ms. Sanaz Mehdipour	None	23/12/2011

**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	13/04/2011	9
May	11/05/2011	7
June	15/06/2011	11
July	13/07/2011	9
September	14/09/2011	10
October	12/10/2011	12
November	16/11/2011	9
December	14/12/2011	11
January	11/01/2012	12
February	08/02/2012	10
March	14/03/2012	11

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>
Mr Robert Goldstein	11
Ms Jill Bloom	11
Professor Diana Kornbrot	9
Mr Hari Jayaram	9
Mr Peter Jones	9
Dr David Slovick	9
Mrs Ros Goldfarb	8
Mrs Stephanie Cooper	8
Dr Stella Kingett	7
Mr Israel Nartey	6
Miss Rita Mary Abdulahad Olivera	5
Dr Elizabeth Carrey	4
Dr Koula Asimakopoulou	4
Ms Mary Ryan	4
Ms. Sanaz Mehdipour	3
Miss Tobie Patterson	3
Ms Sarah Kaiser	1

**Training 01 April 2011 – 31 March 2012:**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Mr Robert Goldstein	07/12/2011 - 07/12/2011	NRES Statistics for NRES REC Members, NRES
Mr Hari Jayaram	01/11/2011 - 01/11/2011	NRES Reviewing Clinical Trials of Investigational Medicinal Products, NRES
Mr Hari Jayaram	28/09/2011 - 28/09/2011	NRES Phase 1 training, NRES
Mrs Stephanie Cooper	07/12/2011 - 07/12/2011	NRES Statistics Training, NRES
Miss Rita Mary Abdulahad Olivera	10/01/2012 - 10/01/2012	Induction, NRES
Mrs Stephanie Cooper	01/03/2012 - 01/03/2012	Adults Lacking Capacity, NRES
Dr Elizabeth Carrey	01/09/2011 - 01/09/2011	Equality & Diversity, NRES
Ms Jill Bloom	15/06/2011 - 15/06/2011	Shared Ethical Debate Exercise, NRES
Dr Elizabeth Carrey	15/06/2011 - 15/06/2011	Shared Ethical Debate Exercise , NRES
Mrs Stephanie Cooper	15/06/2011 - 15/06/2011	Shared Ethical Debate Exercise, NRES
Mrs Ros Goldfarb	15/06/2011 - 15/06/2011	Shared Ethical Debate Exercise, NRES
Mr Robert Goldstein	15/06/2011 - 15/06/2011	Shared Ethical Debate Exercise, NRES
Mr Hari Jayaram	15/06/2011 - 15/06/2011	Shared Ethical Debate Exercise, NRES
Mr Peter Jones	15/06/2011 - 15/06/2011	Shared Ethical Debate Exercise, NRES
Dr Stella Kingett	15/06/2011 - 15/06/2011	Shared Ethical Debate Exercise, NRES
Professor Diana Kornbrot	15/06/2011 - 15/06/2011	Shared Ethical Debate Exercise, NRES
Ms Mary Ryan	15/06/2011 - 15/06/2011	Shared Ethical Debate Exercise, NRES
Dr David Slovic	15/06/2011 - 15/06/2011	Shared Ethical Debate Exercise, NRES
Professor Diana Kornbrot	28/09/2011 - 28/09/2011	NRES Phase 1 training
Dr Elizabeth Carrey	26/09/2011 - 26/09/2011	NRES Business Update, NRES
Mr Israel Nartey	05/09/2011 - 05/09/2011	Induction DVD - 2 hours, NRES
Dr Koula Asimakopoulou	05/09/2011 - 05/09/2011	Induction DVD - 2 hours, NRES
Miss Rita Mary Abdulahad Olivera	05/09/2011 - 05/09/2011	Induction DVD - 2 hours, NRES
Mr Israel Nartey	08/02/2012 - 08/02/2012	Induction, NRES
Mr Hari Jayaram	26/09/2011 - 26/09/2011	NRES Buisness Update (half day), NRES
Professor Diana Kornbrot	26/09/2011 - 26/09/2011	NRES Buisness Update (half day), NRES
Mrs Ros Goldfarb	19/01/2012 - 19/01/2012	Shared Ethical Debate - Children's Clinical Trials in CTIMPs, NRES
Mr Robert Goldstein	07/12/2011 - 07/12/2011	NRES Statistics training, NRES

Miss Tobie Patterson	05/01/2012 - 05/01/2012	Induction DVD - 2 hours, NRES
Ms. Sanaz Mehdipour	05/01/2012 - 05/01/2012	Induction DVD - 2 hours, NRES
Mr Peter Jones	13/02/2012 - 13/02/2012	ICR GCP Forum Training Day
Dr David Slovick	11/01/2012 - 11/01/2012	Induction DVD - 2 hours, NRES
Mr Hari Jayaram	11/01/2012 - 11/01/2012	Induction DVD - 2 hours, NRES
Mr Robert Goldstein	11/01/2012 - 11/01/2012	Induction DVD - 2 hours, NRES
Ms Jill Bloom	11/01/2012 - 11/01/2012	Induction DVD - 2 hours, NRES
Ms Mary Ryan	11/01/2012 - 11/01/2012	Induction DVD - 2 hours, NRES
Dr Stella Kingett	11/01/2012 - 11/01/2012	Induction DVD - 2 hours, NRES
Professor Diana Kornbrot	11/01/2012 - 11/01/2012	Induction DVD - 2 hours, NRES
Mrs Ros Goldfarb	11/01/2012 - 11/01/2012	Induction DVD - 2 hours, NRES
Mrs Stephanie Cooper	11/01/2012 - 11/01/2012	Induction DVD - 2 hours, NRES
Mr Peter Jones	11/01/2012 - 11/01/2012	Induction DVD - 2 hours, NRES
Miss Tobie Patterson	26/04/2012 – 26/04/2012	Induction, NRES
Dr Stella Kingett	14/03/2012 - 14/03/2012	NRES Members National Training Day, NRES
Mr Peter Jones	29/02/2012 - 29/02/2012	Personal data in research: a workshop for members of Research Ethics Committees, NRES
Ms Jill Bloom	06/12/2011 - 06/12/2011	GCP for the non commercial sector, PharmExcel



**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	0	0.00
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	66	100.00
<b>Total Applications Reviewed</b>	<b>66</b>	<b>100</b>

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

Number of applications made invalid by co-ordinator	1
Number of studies withdrawn prior to the meeting	7
Number of student applications reviewed	28
Number of paediatric applications reviewed	4
Number of device applications reviewed	3
Number of prisoner applications reviewed	2
Number of applications involving adults unable consent reviewed	1
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	0	0.00
Favourable Opinion with Additional Conditions	24	36.36
Unfavourable Opinion	2	3.03
Provisional Opinion	40	60.61
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>66</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	32	44.48
Further Information Favourable Opinion with Additional Conditions	7	10.61
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	24	36.36
Unfavourable Opinion	2	3.03
Provisional Opinion	1	1.52
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>66</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	6.00
<b>Number of applications for full ethical review over 60 days</b>	3
<b>Number of applications over 60 days as a % of total</b>	4.55%
<b>Number of days taken to final decision - average</b>	45
<b>Number of days taken to final decision - mode</b>	57
<b>Number of SSAs (non-Phase 1) reviewed</b>	1
<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>	30
<b>Number of substantial amendments over 35 days</b>	7
<b>Number of substantial amendments over 35 days as a % of total substantial amendments</b>	23.3%
<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>	4
<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 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/0347	Addressing low treatment rates of chronic HCV in injecting drug users	57
11/LO/0368	The Family Partnership Model in Routine Practice - Version 1	36
11/LO/0477	The psychosocial effect of congenital ptosis and the role of surgery	38
11/LO/0552	Real-Time Elastography for Noninvasive Assessment of Liver Fibrosis	55
11/LO/0559	Nurses perceptions of support needed to deal with stressful working	60
11/LO/0678	Novel MRI markers in dementia: pilot study	39
11/LO/0802	Factors affecting the diagnostic accuracy of mammography	55
11/LO/0813	Stretching exercise and hamstring muscle adaptation (V1)	57
11/LO/0819	The role of patient expertise inside and outside the health system	32
11/LO/1030	Investigating the neuromusculature and specialised cells of human gut.	60
11/LO/1044	A Clinical Placement Scheme: Matching needs and resources	65
11/LO/1045	HIV / TST Study, Version 1	58
11/LO/1484	Scar Geometry in Post-Infarction Ventricular Arrhythmias (Version 1)	58
11/LO/1836	GammaTrack GAM 10-06	45
11/LO/1859	Feasibility of use of gynaecological cancers leaflet in a GP practice	54
11/LO/1876	Measuring Rehabilitation Outcome in Trauma	53
11/LO/1882	Narrative therapy groups for stroke (version 1)	59
11/LO/1994	Infra-red light imaging of the eye: OCT imaging	57
11/LO/2038	Investigation of influence of gender on cardiovascular inflammation	44
11/LO/2039	Biomedical markers of response to intravesical BCG treatment	59
11/LO/2040	Feasibility study using facial analysis software on newborn infants	41
11/LO/2044	Autobiographical memories in children exposed to trauma	47
11/LO/2054	Cat-Info Tool	69
12/LO/0021	Patients' Views of Doctors' Training - Version 1	52
12/LO/0038	Gait Assessment during Rehabilitation after Knee Surgery	43
12/LO/0042	Clinical Study to Evaluate Femtosecond Laser Assisted Lens Surgery	26
12/LO/0063	Continuous recording of short time fluctuations in IOP	50
12/LO/0185	Characterisation of mucosally transmitted HIV-1 founder viruses	53
12/LO/0209	Enabling Recovery in a structured Hope Programme	54
12/LO/0392	The effects of music on spatial neglect V1.0	57
12/LO/0409	An investigation into Social Anhedonia in Eating Disorders	65

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/LO/0545	Blood sampling from AMD patients and controls for immunogenicity study	55
11/LO/0571	The validation of two inpatient adult nutrition screening tools	47
11/LO/0816	Eryptosis in Renal Failure	60
11/LO/0817	Comorbid disorders on smoking cessation treatment outcomes	52
11/LO/1040	NV22688 Long-term Monitoring Study in Hepatitis C	59
11/LO/1048	Dynamic effects of pulsatile GnRH on circulating AMH concentrations.	59
11/LO/1880	ALMASED Multicentre Diabetes Intervention Trial (AMDIT) v.1.	37

<b>Further Information Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<b>Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<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/0344	Genetic markers and liver disease in HIV patients	37
11/LO/0352	Psychiatrists' views of antipsychotic use for BPSD	36
11/LO/0362	Trabecular meshwork in angle closure glaucoma. v1.0	42
11/LO/0450	Counselling Psychologists' stress & resource experiences in NHS CAMHS	35
11/LO/0570	First episode psychosis: Exploring the experiences of partners	27
11/LO/0572	Pedometer use in Pulmonary Rehabilitation programmes	32
11/LO/0814	Lived experience of surviving prostate cancer after the age of 65	29
11/LO/0985	JTC, impulsivity & cognitive function in opioid-dependent subjects	44
11/LO/0989	Treatment for insomnia in IAPT services v1.0	43
11/LO/1386	Seasonal variations and the incidence of diabetic foot complications	50
11/LO/1433	Immune regulation in autoimmune rheumatic disease	29
11/LO/1496	Attentional expectancies and cholinergic neurotransmission - part II	33
11/LO/1621	Clinical Cohorts in Coronary disease Collaboration (4C) Version 1.0	33
11/LO/1656	Invasive Evaluation of Echocardiographic Parameters in HCM	29
11/LO/1657	PICTURE-Imaging for significant prostate cancer risk evaluation	33

11/LO/1844	Cognitive function and pain management in patients with chronic pain	32
11/LO/2045	Phenomenology and treatment of nightmares in psychosis - version 1	23
12/LO/0061	Prospective study of impact of indacaterol on patient's health & lives	27
12/LO/0187	Cardiac and vascular changes with kidney transplantation	26
12/LO/0218	Testing for Cytomegalovirus infection in HIV-infected individuals (V1)	28
12/LO/0357	Compassionate Mind Training in Psychosis: Client & Clinician Views	49
12/LO/0358	Accelerometry monitoring of exercise therapy for people who fall.V2	53
12/LO/0359	Parenting and Borderline Personality Disorder V1	41
12/LO/0376	IL-17 in periodontitis	34

#### Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/LO/0478	Quality of life in congenital ptosis- child and parent concerns	37
11/LO/1494	Improving Sperm Cryopreservation	34

#### Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/LO/1653	Protocol to Collect Volunteer Blood Samples for T-cell Research	N/A

#### 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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<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>
11/LO/1044	A Clinical Placement Scheme: Matching needs and resources	65
11/LO/2054	Cat-Info Tool	69
12/LO/0409	An investigation into Social Anhedonia in Eating Disorders	65

<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>
10/H0721/66/AM01	UBIOPRED Understanding severe asthma in Adults	Substantial Amendment 1 25/03/2011	52
09/H0721/6/AM02	Induction of corneal endothelial cell replication	Substantial Amendment 1 28/07/2011	38
08/H0721/56/AM03	Role of PS20, A Novel innate immune effector protein, in HIV	Substantial Amendment 3 12.10.2011	36
11/LO/0212/AM01	Developing interventions for carers of chemotherapy patients	Substantial Amendment 1 27/10/2011	38
11/LO/1045/AM01	HIV / TST Study, Version 1	Substantial Amendment 1 28.11.2011	37
09/H0721/54/AM03	Autoantigen and genetic phenotyping of mucous membrane pemphigoid	Substantial Amendment 3 11.11.11	41
10/H0721/11/AM01	Postural stability in patients with visual impairment	Substantial Amendment 1 13.01.2012	38



<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>