

# NRES Committee London - Harrow

## Annual Report

**01 April 2011 – 31 March 2012**

## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	NRES Committee London - Harrow
<b>Type of REC:</b>	REC recognised to review CTIMPS in healthy volunteers - type i REC recognised to review CTIMPS in patients - type iii
<b>Type of Flag:</b>	Phase 1 Studies in Healthy Volunteers Research Involving Adults Lacking Capacity
<b>Chair:</b>	Dr Jan Downer
<b>Vice-Chair:</b>	Mrs Doreen West
<b>Alternate Vice-Chair:</b>	N/a
<b>Co-ordinator:</b>	Libby Watson
<b>PRSC Co-ordinator:</b>	Libby Watson
<b>Assistant Co-ordinator:</b>	Barbara Shannon
<b>Committee Address:</b>	Bristol Research Ethics Committee Centre Level 3, Block B Whitefriars Lewins Mead Bristol BS1 2NT
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### Chair's overview of the past year:

A busy year, the committee has seen a wide range of studies and seen an average of one CTIMP per meeting. The committee has also welcomed some new members and taken a variety of training courses. The committee has been fortunate in that most of the researchers have attended their relevant meeting and the subsequent dialogue has been very helpful. For the subsequent year the committee was expecting changes to NRES.

## NRES Committee London - Harrow Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mr David Anderson-Ford	Senior Lecturer	Lay	24/03/2009	
Mrs Veronika Bernstein	Translator	Lay	24/03/2009	
Mr Andrew Caunce	Chief Pharmacist	Expert	24/03/2009	
Mr Kevin Coughlan	Retired	Lay	24/03/2009	
Dr Jan Downer	Consultant Anaesthetist	Expert	09/09/2009	
Dr. Annette Gilmore	Research Nurse	Expert	11/11/2011	
Miss Shelly Glaister-Young	Barrister	Lay	24/03/2009	
Dr Sanober Haq	Doctor of Medicine	Expert	23/10/2011	
Dr Richard Kaczmariski	Consultant Haematologist	Expert	23/07/2008	13/12/2011
Mr Peter Laszlo	Retired Financial Services Compliance Officer	Lay Plus	24/03/2009	10/08/2011
Dr Mary Leung	Clinical Psychologist	Lay	01/06/2010	
Ms Ann Malkin	Consultant Psychologist	Expert	24/03/2009	
Ms Fatima Nathoo	Administrator	Lay Plus	24/03/2009	15/11/2011
Miss Maggie Otter	Chief Pharmacist	Expert	24/03/2009	
Dr. Goher Rahbour	Clinical Research Fellow	Expert	23/11/2011	
Jean Silkoff	Retired Nurse	Lay	11/11/2011	
Mrs Doreen West	Lecturer	Lay	24/03/2009	
Mr Jim Wood	Retired IT Consultant	Lay Plus	24/03/2009	

### Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended

### Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended

### Member Bank

Name	Occupation	Expert or Lay	Meeting date attended

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

Name	Declaration of Interest	Date
Mrs Doreen West	None	13/12/2011
Mr David Anderson-Ford	Immediate Past Chairman, Association of Research Ethics Committee.Chairman - University Research Ethics Committee, Brunel University	13/12/2011
Mrs Veronika Bernstein	None	13/12/2011
Mr Andrew Counce	Review of pharmaceutical aspect of proposed studies as part of the local R&D.	31/03/2012
Ms Ann Malkin	Trustee - Lincoln Centre for psychotherapy.Governor - Communicare Counselling Service. (Both Charities).PCT representative on R&D steering group of Hillingdon Hospital.	31/03/2012
Miss Shelly Glaister-Young	None	31/03/2012
Dr Mary Leung	NHS employee	31/03/2012
Jim Wood	Glaxo Smith-Kline & Astra Zeneca - small share holdings, less than 1000 shares.Lay (external) member of Brunel University Research Ethics Committee.	13/12/2011
Dr Sanober Haq	None	10/01/2012
Dr. Annette Gilmore	None	13/12/2011
Jean Silkoff	None	13/12/2011

## 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	12/04/2011	8
May	10/05/2011	11
June	14/06/2011	9
August	09/08/2011	9
September	13/09/2011	9
October	11/10/2011	7
November	08/11/2011	7
December	13/12/2011	11
January	10/01/2012	9
February	14/02/2012	13
March	13/03/2012	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>
Dr Jan Downer	11
Mrs Doreen West	11
Miss Maggie Otter	9
Jim Wood	8
Mrs Veronika Bernstein	8
Ms Ann Malkin	8
Mr Kevin Coughlan	8
Mr Andrew Counce	6
Mr David Anderson-Ford	6
Dr Richard Kaczmarski	5
Miss Shelly Glaister-Young	4
Dr Sanober Haq	4
Jean Silkoff	4
Dr. Goher Rahbour	3
Dr. Annette Gilmore	3
Mr Peter Laszlo	3
Ms Fatima Nathoo	2

**Number of inquorate meetings held: 0**

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

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

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Mrs Doreen West	26/09/2011 - 26/09/2011	NRES update session (London), NRES
Dr Jan Downer	18/10/2011 - 18/10/2011	Chair's Meeting NREAP
Dr Jan Downer		Phase 1 Advisory Group - Wednesday 16th November 2011 -
Dr. Annette Gilmore	29/02/2012 - 29/02/2012	Personal Data in Research, NRES
Dr. Annette Gilmore	01/03/2012 - 01/03/2012	Adults Lacking Capacity (including research in emergency situations), NRES
Dr. Annette Gilmore	08/02/2012 - 08/02/2012	Induction training for new NRES committee members, 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	11	16.92
Phase 1	2	3.08
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	52	80.00
<b>Total Applications Reviewed</b>	<b>65</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	7
Number of student applications reviewed	16
Number of paediatric applications reviewed	4
Number of device applications reviewed	3
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	10.61
Favourable Opinion with Additional Conditions	12	18.18
Unfavourable Opinion	2	3.03
Provisional Opinion	44	66.67
Invalid	0	0.00
No Opinion Pending Consultation with Referee	0	0.00
Provisional Opinion Pending Consultation with Referee	1	1.52
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	1	



**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	43	65.15
Further Information Favourable Opinion with Additional Conditions	1	1.52
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	7	10.61
Favourable Opinion with Additional Conditions	12	18.18
Unfavourable Opinion	2	3.03
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	1	1.52
Number of studies withdrawn after the meeting	0	0.00
<b>Total</b>	<b>66</b>	<b>100</b>

**Table 6: Decisions given at proportionate review sub-committee meetings held within the reporting period:**

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

<b>Average number of applications reviewed per full meeting</b>	<b>6.00</b>
<b>Number of applications for full ethical review over 60 days</b>	1
<b>Number of applications over 60 days as a % of total</b>	1.54%
<b>Number of days taken to final decision - average</b>	35
<b>Number of days taken to final decision - mode</b>	35
<b>Number of SSAs (non-Phase 1) reviewed</b>	3
<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>	72
<b>Number of substantial amendments over 35 days</b>	21
<b>Number of substantial amendments over 35 days as a % of total substantial amendments</b>	29.2%
<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>	1
<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/0274	Defining Antibiotic Levels in ICU Patients	35
11/LO/0299	3D ultrasound for the evaluation of carotid plaque disease	42
11/LO/0342	Assessing the prevalence of nicotine dependence and IRAS Version 3.1	29
11/LO/0355	OASIS: Talactoferrin for treatment of Severe Sepsis	38
11/LO/0458	BP treatment in SVD	59
11/LO/0522	Medial temporal lobes and memory 1	37
11/LO/0523	Teenagers and Young Adults with Bone Sarcomas version 1	60
11/LO/0553	Late sodium current inhibition in aortic stenosis	47
11/LO/0558	Saccadometry Trial	14
11/LO/0737	ATHENE	38
11/LO/0754	Extracorporeal Devices in Lung Failure - 1	46
11/LO/0765	Effectiveness of ICM support for people with anxiety or depression	25
11/LO/0780	SNPs in genes involved in acute toxicity from chemo-radiation	29
11/LO/0793	Neuroinflammation in alcohol dependence	43
11/LO/0795	Mechanisms of treatment failure in hepatitis C infection	38
11/LO/1197	"Are oxidized steroids markers of liver damage?"	39
11/LO/1208	Version 2: Therapeutic Interventions on Acute Psychiatric Wards	53
11/LO/1210	Do adolescents evaluate orthodontic treatment differently to adults?	31
11/LO/1211	Group Psychotherapy for young adults with IBD (version 1)	43
11/LO/1213	Impact of Hospital Environment on Dignity, Satisfaction & Safety.	38
11/LO/1219	Study of U3-1287 in Subjects with Lung Cancer	42
11/LO/1400	Tulip vs Guedel; Randomized,Controlled,Cross-Over Trial with BLS Users	44
11/LO/1418	Developing a Therapeutic Environment	39
11/LO/1432	Prevalence of Heterotopic Ossification in Spinal Cord injured patients	54
11/LO/1436	ART	39
11/LO/1447	Proof of Concept study for GSK249320 versus placebo in Stroke patients	35
11/LO/1474	Efficacy And Safety Study Of CYCLOKAT® In Dry Eye Disease Patients	67
11/LO/1525	Communication difficulties & self-esteem in adults with Down syndrome	27
11/LO/1628	Development of new therapeutic agents for multiple myeloma	51
11/LO/1631	Does pointing affect performance on the RBMT-3 route subtest?	27

11/LO/1636	Fibre specific signalling in the locomotor myopathy of COPD	45
11/LO/1645	Effects of different appliances on the lives of patients with a stoma	36
11/LO/1773	Investigation into the efficacy of MEK162 in Noonan syndrome V1	56
11/LO/1953	Safety, blood levels and effects of RO5186582; version 1	51
11/LO/2068	Motor timing in patients with cerebellar degeneration	35
12/LO/0019	A RCT of a new ORS in intestinal failure	30
12/LO/0024	Prothrombotic biomarkers in venous insufficiency (v 1.0)	35
12/LO/0167	Monocyte and macrophage phenotype and function in liver failure	39
12/LO/0199	Pre IVF pipelle biopsy following a previous unsuccessful IVF cycle	30
12/LO/0363	MAPLE - Version 1	40
12/LO/0383	The experience of hearing voices that tell you what to do - version 1	39
12/LO/0405	HIV-1 viral reservoir following chemotherapy V1	52
12/LO/0410	BEYOND Study	29

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
12/LO/0250	MATISSE STUDY	48

#### 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
11/LO/0314	Validation of the Victim Empathy Rating Assessment	21
11/LO/0794	Metabolic syndrome, fatty acids synthesis and prostate cancer	32
11/LO/0796	Umbilical Cord Bilirubin and Neonatal Jaundice	36
11/LO/1435	Comparing M5161 tablets in Japanese and Caucasian men; version 1	24
11/LO/1802	European Mortality and Length of ICU Stay Evaluation V1	21
12/LO/0207	Antibiotics in the severely demented	25
12/LO/0382	Factors affecting treatment outcome for Personality Disorder.Version 9	25

#### Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/LO/0345	Customising Stockings in Post Thrombotic Syndrome (v1.0)	23

11/LO/0526	Partners' experiences of trauma and posttraumatic stress	35
11/LO/1217	Functional correlations in Thrombocytopaenia	29
11/LO/1218	A Pilot study of a composite called smart dentine replacement	27
11/LO/1434	Blood levels of Z160; version 1	21
11/LO/1825	SERAPHIN Open Label	23
11/LO/1916	Informing VZV vaccination policy: validity of chickenpox history v1	36
11/LO/1977	Safety & blood levels of single & repeated doses of ONO-4053; ver 1	22
11/LO/1986	DUAL 2	22
11/LO/2029	Recording retinal responses in health and disease	23
12/LO/0184	Comparison of 5 mg & 20 mg Lu AA21004 tablets	20
12/LO/0197	In-house evaluation an experimental mouthwash on oral bacteria (V1.0)	31

#### Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/LO/0597	Coronary artery disease and physical activity levels	31
12/LO/0027	Intravenous Sildenafil in Cardiac Intensive Care	35

#### 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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<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/1474	Efficacy And Safety Study Of CYCLOKAT® In Dry Eye Disease Patients	67

<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/H0709/21/AM01	Quality of life in patients with different levels of tooth wear.	Amendment 1, 10th February 2011	39
10/H0710/4/AM01	New Transcatheter Aortic Valve Implantation Guidewire	Amendment 1 Product Design Change February 2011	39
09/H0710/46/AM01	Reasoning and Rehabilitation in ADHD adults	Amendment 1.1; 23.02.2011	42
09/H0710/35/AM02	Financial incentives to improve adherence to medication	Version 3: 13.05.2011	45
10/H0709/84/AM01	Tailoring varenicline to individual needs (TVIN)	Amendment 1, dated 11/07/2011	42
10/H0709/77/AM01	Mechanisms of monocyte priming and tolerance	Amendment 1 August 2011	42
09/H0710/70/AM01	An evaluation of the Reasoning and Rehabilitation 2 programme.	Amendment1, 25th July 2011	45
09/H0709/42/AM08	Monoclonal antibodies in recurrent B cell ALL (MARALL)	Amendment 5, version 6, 25th July 2011	41
10/H0709/60/AM06	ALX-0681-2.1/10 Protocol Version 2.0	change to PIS and Consent Form	39

11/LO/0355/AM02	OASIS: Talactoferrin for treatment of Severe Sepsis	Protocol Version 2.00 (20Sep11); ICF version 2.1 (	40
10/H0709/60/AM07	ALX-0681-2.1/10 Protocol Version 2.0	Amendment to Protocol, PIS and ICF	48
05/Q0405/112/AM05	Pudendal Nerve Stimulation for Bowel Dysfunction	Amendment 2 24th November 2011	36
10/H0709/52/AM02	Effects of Yakult on preventing AAD in elective orthopaedic surgery	change to protocol	36
07/Q0407/6/AM03	The convergence of hypoxia and cytokines in colorectal cancer	Change to CI and additional investigator	36
09/H0710/10/AM02	The association between AMD and Alzheimer's disease	Version 5.1, 30th November 2011	37
10/H0709/38/AM04	Acceptance and Commitment Therapy (ACT) for Psychosis in the Community	Amendment 4, 17/01/2012	41
11/LO/1636/AM01	Fibre specific signalling in the locomotor myopathy of COPD	Amendments to Patient Information Sheet	38
11/LO/1219/AM05	Study of U3-1287 in Subjects with Lung Cancer	updated PIS and Consent Form	38
10/H0710/4/AM04	New Transcatheter Aortic Valve Implantation Guidewire	Extension of the trial - Amendments to protocol	38
11/LO/1525/AM01	Communication difficulties & self-esteem in adults with Down syndrome	Addition of transcriber	36
09/H0709/63/AM14	Alogliptin in patients with Type2 Diabetes and Acute Coronary Syndrome	Updated IB	41

#### 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



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