

# NRES Committee London - Harrow

## Annual Report

**01 April 2013 – 31 March 2014**

## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	NRES Committee London - Harrow
<b>Type of REC:</b>	Type I and Type III
<b>Type of Flag:</b>	CTIMPs Phase 1 Studies Involving Healthy Volunteers Research Involving Adults Lacking Capacity
<b>Chair:</b>	Dr Jan Downer
<b>Interim Vice-Chairs:</b>	Dr John Keen (21/01/2013 – 21/07/2013) Miss Stephanie Ellis (21/01/2013 – 21/07/2013)
<b>Vice-Chair:</b>	Professor Liz Meerabeau
<b>Alternate Vice-Chair:</b>	Miss Shelly Glaister-Young
<b>REC Manager:</b>	Miss Libby Watson
<b>REC Assistant:</b>	Miss Lauren Allen (05/11/2012 – 01/10/2013) Mr Ben Manning (29/10/2013 – 08/01/2014) Miss Natasha Bridgeman (27/01/2014 – Present)
<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:

The London – Harrow REC has completed had another busy year with a large substantial amendment workload in addition to a full agenda of six applications at the REC meetings. A quarter of the studies reviewed were either CTIMPS or Phase one studies and one in ten studies involved participants who lacked capacity to provide consent for themselves. Over the year the committee were able to give 12% of applications for REC approval a favourable opinion after the first initial review, some with conditions attached, the bulk of the studies reviewed by the committee were given a provisional opinion and 8% received an unfavourable opinion. Considerable thanks must be given to all the committee members who have given their time to review the studies, and to attend REC meetings and training events. The chair has welcomed the contribution of the newly appointed officers especially as this year saw a considerable increase in the subcommittee workload. The REC wishes to thank our co-opted members and welcome two new members to the committee. I would like to express my thanks to Ms Libby Watson the REC administrator for supporting and guiding expertly through the year. Looking ahead the committee will be commencing proportionate review of studies with no material ethical issues and will continue working towards a reduction in the number of days to final decision for studies coming for full ethical review and substantial amendments.

## NRES Committee London - Harrow Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mr David Anderson-Ford	Director of Research Ethics and Governance	Lay Plus	01/03/2009	
Mrs Veronika Bernstein	Translator	Lay Plus	01/03/2009	
Mr Andrew Counce	Chief Pharmacist	Expert	01/03/2009	
Mr Kevin Coughlan	Retired	Lay	01/03/2009	
Dr Jan Downer	Consultant Anaesthetist (Chair)	Expert	01/03/2009	
Dr Annette Gilmore	Research Nurse	Expert	11/11/2011	
Miss Shelly Glaister-Young	Barrister (Alternate Vice-Chair)	Lay Plus	01/03/2009	
Dr Sanober Haq	Doctor of Medicine	Expert	23/10/2011	
Dr Mary Leung	Clinical Psychologist	Expert	01/06/2010	
Ms Ann Malkin	Consultant Psychologist	Expert	01/03/2009	
Reverend Catherine McBride	Vicar	Lay	01/02/2014	
Professor Liz Meerabeau	University Professor (Vice-Chair)	Expert	14/05/2013	
Mrs Helen Turner	Clinical Study Manager	Lay	01/01/2014	
Mr Jim Wood	Retired IT Consultant	Lay Plus	01/03/2009	
Miss Stephanie Ellis	Former Civil Servant	Lay Plus	21/01/2013	21/07/2013
Dr John Keen	GP	Expert	21/01/2013	21/07/2013
Dr Goher Rahbour	Clinical Research Fellow	Expert	13/12/2011	07/10/2013

### Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Mr Roy Sinclair	Pharmacist	Expert	10 September 2013

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

Name	Declaration of Interest	Date
Professor Liz Meerabeau	Visiting professor at Kingston/St George's	02/01/2014
Mrs Helen Turner	Clinical Study Manager at Cancer Research UK	21/12/2013
Mrs Veronika Bernstein	None	30/12/2013
Mr Andrew Counce	None	31/12/2013
Dr Mary Leung	None	06/01/2014
Miss Shelly Glaister-Young	None	13/01/2014
Mr Jim Wood	Shareholdings in organisations involved in or possibly seeking to be involved in the conduct of research, Glaxo Smith Kline, Astra Zeneca	27/01/2014
Reverend Catherine McBride	Ordinary Shares in GSK	08/01/2014
Ms Ann Malkin	British Psychotherapy Foundation - Chair of Professional Standards and Ethics Committee, British Psychoanalytical Council - Member of the Professional Standards Committee and Ethics Committee, Communicare Counselling Service - Trustee	14/01/2014
Mr Kevin Coughlan	None	08/01/2014
Dr Jan Downer	None, other than on the periphery if a colleague is running a research project - an irregular occurrence	14/01/2014
Dr John Keen	Member of NREAP (HRA Advisory Panel)	06/02/2014
Miss Stephanie Ellis	No declarations of interest.	17/01/2014
Dr Annette Gilmore	None	11/02/2014
Mr David Anderson-Ford	Director, Research Ethics and Governance – Brunel University. Chair, University Research Ethics Committee – Brunel University. Association of Research Ethics Committees – Past Chairman. .Brunel University employee	25/02/2014

**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	09/04/2013	9
May	14/05/2013	8
June	11/06/2013	8
August	13/08/2013	10
September	10/09/2013	7
October	08/10/2013	11
November	12/11/2013	7
December	10/12/2013	8
January	14/01/2014	9
February	11/02/2014	11
March	11/03/2014	9

11 full 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>
Dr Jan Downer	11
Ms Ann Malkin	10
Professor Liz Meerabeau	10
Mr Kevin Coughlan	9
Dr Annette Gilmore	8
Mrs Veronika Bernstein	8
Dr Mary Leung	7
Mr Andrew Counce	7
Mr David Anderson-Ford	7
Mr Jim Wood	6
Miss Shelly Glaister-Young	4
Mrs Helen Turner	3
Reverend Catherine McBride	2
Miss Stephanie Ellis	2
Dr Sanober Haq (Break in Service – 01/06/2013 – 31/07/2014)	1
Dr John Keen	1
Dr Goher Rahbour (Break in Service – 17/10/2012 – 07/10/2013)	0

**Number of inquorate meetings held: 0**

## Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Dr Jan Downer	17/04/2013 - 17/04/2013	Ethical review of Mental Health and Psychiatric Research , HRA
Dr Jan Downer	11/12/2013 - 11/12/2013	Chair's Training Day, NRES
Professor Liz Meerabeau	06/06/2013 - 06/06/2013	Chairing Skills, HRA
Professor Liz Meerabeau	02/05/2013 - 02/05/2013	Training - Ethical Issues of Research Involving Children, Great Ormond Street Hospital / HRA
Professor Liz Meerabeau	11/12/2013 - 11/12/2013	Chair's Training Day, NRES
Professor Liz Meerabeau	27/09/2013 - 27/09/2013	Meeting to present findings from the patient and public engagement project , HRA
Miss Shelly Glaister-Young	04/09/2013 - 04/09/2013	Training - Research Involving Adults Who Lack Capacity (including research in emergency situations), HRA
Miss Shelly Glaister-Young	18/06/2013 - 18/06/2013	Equality & Diversity, HRA
Dr Mary Leung	24/09/2013 - 24/09/2013	Quantitative research methods and statistics, HRA
Dr Mary Leung	02/10/2013 - 02/10/2013	Researcher Training Day, HRA
Mr Andrew Counce	15/08/2013 - 15/08/2013	NRES CTIMP e-learning module, NRES
Mr Andrew Counce	20/11/2013 - 20/11/2013	National Member's Training Day, NRES
Mr Kevin Coughlan	04/09/2013 - 04/09/2013	Adults Lacking Capacity Training, NRES
Mr Kevin Coughlan	25/03/2014 - 25/03/2014	Training - Research Involving the Disadvantaged and Vulnerable, HRA
Dr Annette Gilmore	11/09/2013 - 11/09/2013	Effective Information Governance in Health, Understanding ModernGov
Dr Annette Gilmore	22/01/2014 - 22/01/2014	Equality & Diversity, North West London Hospitals NHS Trust
Mr Jim Wood	05/11/2013 - 05/11/2013	Training - Human Tissue Act (Advanced Training in the use of Tissues in Research), HRA
Mr David Anderson-Ford	05/11/2013 - 05/11/2013	Training - Human Tissue Act (Advanced Training in the use of Tissues in Research), HRA
Mrs Veronika Bernstein	20/11/2013 - 20/11/2013	National Members' Training Day, NRES
Ms Ann Malkin	24/09/2013 - 24/09/2013	Quantitative Research Training Day, NRES
Mrs Helen Turner	03/03/2014 – 03/03/2014	NRES REC Member Induction, NRES
Dr Sanobar Haq	01/07/2013 - 01/07/2013	Equality & Diversity, NRES
Reverend Catherine McBride	25/01/2014 - 25/01/2014	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	11	17.46
Phase 1	6	9.52
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	46	73.02
<b>Total Applications Reviewed</b>	<b>63</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	6
Number of student applications reviewed	17
Number of paediatric applications reviewed	3
Number of device applications reviewed	3
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	7
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	1	1.59
Favourable Opinion with Additional Conditions	7	11.11
Unfavourable Opinion	5	7.94
Provisional Opinion	50	79.37
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>63</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	18	28.57
Further Information Favourable Opinion with Additional Conditions	26	41.27
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	1.59
Favourable Opinion with Additional Conditions	7	11.11
Unfavourable Opinion	5	7.94
Provisional Opinion	4	6.35
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	1.59
Number of studies withdrawn after the meeting	1	1.59
<b>Total</b>	<b>63</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	5.73
<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>	35
<b>Number of days taken to final decision - mode</b>	32
<b>Number of SSAs (non-Phase 1) reviewed</b>	13
<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>	163
<b>Number of substantial amendments over 35 days</b>	1
<b>Number of substantial amendments over 35 days as a % of total substantial amendments</b>	0.6%
<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>	8
<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>	12.5%
<b>Number of proportionate review applications for ethical review over 14 days</b>	0
<b>Number of proportionate review applications over 14 days as a % of total</b>	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>
13/LO/0365	LeoPARDS	26
13/LO/0435	An RCT of triclosan coated sutures in primary hip and knee replacement	41
13/LO/0800	Post-meal anxiety and cognitive processes in eating disorders V1.0	27
13/LO/0821	0112 -Phase 3 open-label study in HIV-1 patients with renal impairment	50
13/LO/1163	Reasons for Non-Participation in Physical Activity Interventions	47
13/LO/1264	Olaparib maintenance monotherapy in PSR ovarian cancer	28
13/LO/1268	fMRI scan study to find out how nalmefene works (ver 1)	22
13/LO/1293	The experience of receiving a diagnosis of an eating disorder.	46
13/LO/1440	Evaluation of mechanisms and innovations in biventricular pacing	29
13/LO/1541	Inflammation resolution in inflammatory bowel disease	35
13/LO/1647	Intermittent fasting in refractory epilepsy	20
13/LO/1670	Autologous Stem Cells in Achilles Tendinopathy	32
13/LO/1863	Stocking Outflow Performance in Venous and Lymphatic Disease v1	34
13/LO/1899	Nasal Challenge with Microbial Constituents and Allergen	25
14/LO/0114	Promoting recovery in mental health	33
14/LO/0189	ASIST: version 1	48
14/LO/0224	Feasibility of Teen BodyWise in Adolescents with Anorexia Nervosa	42
14/LO/0244	Comparison of 20 mg vortioxetine tablet and capsules;version 1	26

<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>
13/LO/0457	The DISCOVER I Study	31
13/LO/0503	Asfotase Alfa in infants and children ( $\leq$ 5 Years of Age) with HPP	30
13/LO/0580	Regional lung mechanics in mechanically ventilated adults	31
13/LO/0595	Social style, motivations & reasoning ability of people with OCD	40
13/LO/0653	The SCI-POEM Study (v1.0)	34
13/LO/0747	Retrograde leak point pressures in incontinent men Version 1	32
13/LO/0796	Pattern of proteinuria in Type 1 Diabetes- Version 1 (02/04/2013)	38
13/LO/1020	309: XL184 vs placebo in subjects with hepatocellular carcinoma	38
13/LO/1114	Persisting blood propofol in the critically ill and levels of sedation	38
13/LO/1122	Componential analysis of verbal fluency in HIV-infection. (V1)	32

13/LO/1125	Observational follow up study of MIDAS participants	49
13/LO/1280	P50 suppression and cognition in schizophrenia	42
13/LO/1282	The oral health of people living with Epidermolysis bullosa(EB)V1	28
13/LO/1356	The impact of acupuncture on the success of IVF treatments - a RCT	52
13/LO/1420	Sexual and Reproductive Health in psychiatric patients	26
13/LO/1469	Dental Anxiety in Adult Individuals with Learning Disabilities	49
13/LO/1585	EORTC Quality of Life Module for patients with vulva cancer	60
13/LO/1653	Predicting disease remission in sight threatening uveitis	52
13/LO/1758	A Safety and Efficacy Study of MK8931 for Prodromal AD v.019-00	44
13/LO/1891	MORE-CRT MPP	51
14/LO/0034	Agitation and quality of life in care homes version 1	41
14/LO/0041	Clariti™ 1Day Multifocal Contact Lenses Clinical Evaluation	58
14/LO/0063	Postprandial effects of genetic variation on carbohydrate digestion	43
14/LO/0138	Effect of citrate on the coagulation system in patients receiving CRRT	33
14/LO/0184	An innovative approach to harm reduction	39
14/LO/0185	PROXIMUS - PRotective role of OXcabazepine In MULTiple Sclerosis	33

#### 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/1275	Comparing the abortion rates in Britain and France	32

#### Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/LO/0455	Pilot Study: Retinal Embolisation in TAVI	23
13/LO/0808	Comparing Lu AE58054 in Japanese and Caucasian volunteers; version 1	27
13/LO/1663	Safety, blood levels & effects of DS-1040b taken with aspirin;version1	10
13/LO/1729	Test And Detect Antibodies in HPV Vaccinated Women Study	22
13/LO/1861	Cariprazine: comparison of slow- and immediate-release forms, ver A	17
14/LO/0082	A bioequivalence trial of Liquid 7 and NovoSeven in healthy volunteers	38
14/LO/0201	Evaluating optimal dosing conditions of GLP-1analogue in healthy males	35

#### Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
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13/LO/0414	The Veteran Athlete's Heart	22
13/LO/0646	Changes in risk factors during treatment in anorexia nervosa	27
13/LO/0659	Test And Detect Antibodies in HPV Vaccinated Women Study	41
13/LO/1534	'Black ethnic minority' men and Primary mental health engagement 1	31
13/LO/1550	Anal Cytology screening and High Resolution Anoscopy in the UK	24

#### Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
14/LO/0302	International Ovarian Tumour Analysis (IOTA) Phase 5: UK Study	N/A
14/LO/0313	GE-122-016: Prognostic Usefulness of AdreView	N/A
14/LO/0314	Risk of Seizure Among Subjects with mCRPC	N/A
14/LO/0392	Randomised study of ABT-494 in subjects with Rheumatoid Arthritis	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
13/LO/1130	Sensory gating deficits after audio presentation.	29

#### 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 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>	
<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>
12/LO/0827/AM05	Study of Asunaprevir + Daclatasvir in subjects with HCV G1b Infection	Substantial Amendment 05- 3rd July 2013	45
<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>
11/LO/0330/AM01/1	Investigation of rheumatic disease in teenagers and adults : v1.0	Modified Amendment v1.3; 22 December 2013	16
<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>