

NRES Committee London - Queen
Square

Annual Report

01 April 2011 – 31 March 2012

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee London - Queen Square
Type of REC:	Authorised
Type of Flag:	Adults Lacking Capacity
Chair:	Dr Yogi Amin
Vice-Chair:	Dr Gella Richards
Alternate Vice-Chair:	Dr Lorraine Ludman
Co-ordinator:	Mrs Audrey Adams Ms Adriana Fanigliulo (up to December 2011)
PRSC Co-ordinator:	None
Assistant Co-ordinator:	Mr Thomas McQuillan
Committee Address:	Health Research Authority Ground Floor, Skipton House 80 London Road London SE1 6LH
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Chair's overview of the past year:

It gives me great pleasure to introduce the NRES Committee Queen Square Annual Report. I have been Chair since the beginning of 2010. I would like to welcome Ciaran, Elias, and Eamonn to the committee, and thank Chris, Lois, Martin and Elias, who have left the committee for all their hard work and contribution to the committee's excellent work. Finally I would like to thank Mrs Lorraine Ludman for her help and support as alternate vice chair, from which she has now stepped down.

We continue to be grateful to Miss Audrey Adams, REC Administrator, for her calm efficiency, and conscientiousness, during these ever-changing times that we find ourselves in.

As a flagged 'mental capacity act' committee we receive applications involving adults with incapacity. Several members of the committee have undergone additional training to support our important role in protecting vulnerable adults whilst ensuring they are not denied the benefits of medical research.

This has been a difficult year, with me on sick leave at the start of the year and all the changes that have taken place nationally and locally, with this in mind, I would like to thank all the members for their generous time, support and commitment, it is much appreciated. I am always grateful that we have corate meetings, and work so well together.

NRES Committee London - Queen Square Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr Yogi Amin	Consultant in Neuroanaesthesia & Neurocritical Care	Expert	28/07/2006	
Dr Mark Barrett	GP	Expert	19/04/2005	
Mrs Philippa Mary Cumberland	Medical Statistician	Expert		
Mr Francis Curtiss	Accountant	Lay Plus	19/01/2004	
Dr Simon Eaton	Senior Lecturer in Paediatric Surgery and Metabolic Biochemistry	Expert	11/09/2006	
Mr Chris Frost	Medical Statistician	Expert	01/09/2004	30/06/2011
Mr Robin Hay	Barrister	Lay Plus	18/04/2002	
Mr Ciaran Scott Hill	Neurosurgery Speciality Registrar	Expert	08/03/2011	
Mrs Jenny Johnson	Raising Family	Lay Plus	18/03/2008	
Dr Lois Kim	Statistician	Expert	04/12/2008	21/06/2011
Professor Martin Koltzenburg	Head of Neural Plasticity Unit, Neuroscience Theme Leader	Expert	21/07/2007	
Dr Lorraine Ludman	Chartered Psychologist	Lay	18/05/2006	
Dr Gella Richards	Psychologist	Expert	20/01/2005	
Mrs Ann Rosenthal	Literary Consultant (retired)	Lay Plus	09/05/2003	
Miss Sheetal Sumaria	Pharmacist	Expert	12/05/2009	
Dr Elias Tsakanikos	Senior Lecturer in Psychology	Lay	19/04/2011	30/10/2011
Dr Eamonn Walsh	Postdoctoral Researcher	Expert	19/04/2011	
Ms Mary Watkinson	Teacher	Lay Plus	24/08/2008	
Mr Ludvic Zrinzo	Consultant in Neurosurgery	Expert	30/03/2008	

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 - Queen Square: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Mr Ludvic Zrinzo	Provides peer review to grant applicants, scientific publications & bodies such as NICE.	31/03/2012
Professor Martin Koltzenburg	Consultant for Pfizer, Merels and GSK. Position in The European Federation of IASP chapters. Membership to EFIC, IASP, British Pain Society, ABN.	31/03/2012

Meetings for Full Ethical Review 01 April 2011 - 31 March 2012:

Month	Date	Number of Members Present at Meeting
April	21/04/2011	11
May	19/05/2011	10
June	16/06/2011	9
July	21/07/2011	10
August	18/08/2011	16
September	15/09/2011	8
October	20/10/2011	15
November	17/11/2011	15
January	19/01/2012	13
February	16/02/2012	10
March	15/03/2012	13

11 full committee meetings were held during the reporting period, one for training purposes.

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

Month	Date	Number of Members Present at Meeting
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No proportionate review sub-committee meetings were held during the reporting period.

Attendance of Members: 01 April 2011 – 31 March 2012:

Name	Number of Meetings Attended
Dr Eamonn Walsh	11
Miss Sheetal Sumaria	10
Mrs Ann Rosenthal	10
Mrs Jenny Johnson	10
Mrs Philippa Mary Cumberland	10
Mr Francis Curtiss	9
Dr Gella Richards	8
Ms Mary Watkinson	8
Dr Simon Eaton	8
Dr Lorraine Ludman	7
Dr Mark Barrett	7
Dr Yogi Amin	7
Mr Ciaran Scott Hill	6
Mr Ludvic Zrinzo	5
Mr Robin Hay	5
Professor Martin Koltzenburg	5
Dr Elias Tsakanikos	4

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:

Name of Member	Date	Event(s) attended
Mrs Philippa Mary Cumberland	26/06/2011 - 26/06/2011	Equality & Diversity, NRES
Dr Gella Richards	19/05/2011 - 19/05/2011	REC Training meeting (MCA), REC Training meeting
Mrs Jenny Johnson	19/05/2011 - 19/05/2011	REC Training meeting (MCA), REC Training meeting
Dr Simon Eaton	19/05/2011 - 19/05/2011	REC Training meeting (MCA), REC Training meeting
Miss Sheetal Sumaria	19/05/2011 - 19/05/2011	REC Training meeting (MCA), REC Training meeting
Mrs Ann Rosenthal	19/05/2011 - 19/05/2011	REC Training meeting (MCA), REC Training
Mr Francis Curtiss	19/05/2011 - 19/05/2011	REC Training meeting (MCA), REC Training meeting
Mr Ciaran Scott Hill	19/05/2011 - 19/05/2011	REC Training meeting (MCA), REC Training meeting
Mrs Philippa Mary Cumberland	19/05/2011 - 19/05/2011	REC Training meeting (MCA), REC Training meeting
Dr Elias Tsakanikos	19/05/2011 - 19/05/2011	REC Training meeting (MCA), REC Training meeting
Dr Eamonn Walsh	19/05/2011 - 19/05/2011	REC Training meeting (MCA), REC Training meeting
Mrs Ann Rosenthal	27/06/2011 - 27/06/2011	Equality & Diversity, NRES
Dr Simon Eaton	11/07/2011 - 11/07/2011	Equality & Diversity, NRES
Dr Eamonn Walsh	11/10/2011 - 11/10/2011	Induction, NRES
Mrs Philippa Mary Cumberland	11/10/2011 - 11/10/2011	Induction, NRES
Ms Mary Watkinson	03/07/2011 - 03/07/2011	Equality & Diversity, NRES
Ms Mary Watkinson	07/12/2011 - 07/12/2011	NRES Statistics , NRES
Ms Mary Watkinson	14/03/2012 - 14/03/2012	NRES Members' National Training Day , NRES
Mr Ciaran Scott Hill	10/01/2012 - 10/01/2012	Induction, 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:

Applications for full ethical review – Study Type	Number	%
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	52	100.00
Total Applications Reviewed	52	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	6
Number of studies withdrawn prior to the meeting	7
Number of student applications reviewed	18
Number of paediatric applications reviewed	4
Number of device applications reviewed	1
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:

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	2	3.85
Favourable Opinion with Additional Conditions	0	0.00
Unfavourable Opinion	1	1.92
Provisional Opinion	49	94.23
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	52	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	41	78.85
Further Information Favourable Opinion with Additional Conditions	4	7.69
Further Information Unfavourable Opinion	1	1.92
Favourable Opinion with Standard Conditions	2	3.85
Favourable Opinion with Additional Conditions	0	0.00
Unfavourable Opinion	1	1.92
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	3	5.77
Total	52	100

Table 5: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	4.73
Number of applications for full ethical review over 60 days	11
Number of applications over 60 days as a % of total	21.15%
Number of days taken to final decision - average	51
Number of days taken to final decision - mode	47
Number of SSAs (non-Phase 1) reviewed	1
Number of applications for SSA review over 25 days	0
Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)	0.0%
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	65
Number of substantial amendments over 35 days	11
Number of substantial amendments over 35 days as a % of total substantial amendments	16.9%
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	2
Number of modified amendments over 14 days as a % of total modified amendments	50.0%

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
11/LO/0339	Psychological predictors of weight loss after gastric band surgery	105
11/LO/0395	Biochemical and genetic studies in pulmonary vascular disease	51
11/LO/0396	The Metabolic Profile in Obstetric Cholestasis	87
11/LO/0481	Observational study: Switching patients from Fabrazyme to Replagal.	55
11/LO/0753	Longitudinal Research into Alzheimer's Disease and other Dementias	47
11/LO/0803	Treatment outcomes of men worried by the size of their genitalia	27
11/LO/0809	Attitudes to Opiate Substitution Treatment amongst opiate users	64
11/LO/0810	Cerebral hypoxia in multiple sclerosis	48
11/LO/0823	Tuberculosis immunity study (version 1)	57
11/LO/1087	WELLFOCUS - Developing a model of well-being for people with psychosis	59
11/LO/1097	Overfeeding in preterm adults	43
11/LO/1100	(AUG) Relationship between hormones and psychological aspects of PCOS	56
11/LO/1102	Systemic inflammation and apoptosis markers in HIV	48
11/LO/1119	Focus groups to develop experiences of music therapy questionnaires	44
11/LO/1143	predictive validity of the RAPID in adults with LD.	48
11/LO/1153	Role of Complement in Acute Disease States	34
11/LO/1233	Optimised therapies in low awareness states -version 9	55
11/LO/1242	Optimizing memory function in temporal lobe epilepsy	53
11/LO/1258	Health seeking in Psoriasis v1.0	71
11/LO/1263	Activity of anti-HIV agents in genital secretions v1	30
11/LO/1288	Modelling the variability in shape of human lower limb anatomy	32
11/LO/1326	A pilot trial for Think Effectively About Mood Swings (TEAMS)	43
11/LO/1423	Falls in people with Inclusion Body Myositis v1.0	46
11/LO/1425	MRI in Motor Neuropathies V1	69
11/LO/1429	EndoFLIP: A new diagnostic modality for measuring Anal Canal Pressure	33
11/LO/1448	Pharmacy Alcohol Study	61
11/LO/1452	Hip wound closure - Clips vs subcuticular monocryl	52
11/LO/1471	Children after adoption: defining their psychological needs. Version 1	47
11/LO/1499	Can Art Therapy Improve Emotional Awareness in Adults with Autism?	35

11/LO/1675	Hearing Evaluation And Rehabilitation after Stroke-HEARS	52
11/LO/1702	PTNS Intensity of Treatment study	39
11/LO/1703	Anal Gatekeeper Study for Faecal Incontinence	35
11/LO/1800	MRI in hypokalaemic periodic paralysis	58
11/LO/1845	Genes involved in liposarcomas	47
11/LO/2051	Randomised comparison of ablation therapies in treating persistent AF	75
12/LO/0074	Model of arterial and brain tissue oxygenation relationship	47
12/LO/0088	Deep phenotyping in COPD	43
12/LO/0176	Does Biventricular Pacing Represent True Cardiac Resynchronisation?	62
12/LO/0237	Protein biomarkers for assessing IBD treatment efficiency	40
12/LO/0419	Mapping Brain Changes in Cluster Headaches	54
12/LO/0433	A study of gastrointestinal symptoms and motility in PD Version 1.1	76

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/LO/1774	The Study of Altered Sensory Responses in Bladder Dysfunction	53
11/LO/1846	The Effects of Ageing on the Cutaneous Immune System, Version 1	88
12/LO/0238	Ultrasound elastography of lower leg muscle compartment	60
12/LO/0377	Novel multimodality imaging for epilepsy surgery	57

Further Information Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/LO/1872	Measuring patients engagement using the Electronic Patient Record	100

Favourable Opinion with Standard Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/LO/0862	Evaluation of a local financial incentive scheme (QOF+) V2	34
12/LO/0300	Outcomes of mother and child in maternal vitamin D deficiency	29

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
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Unfavourable Opinion		
REC Reference	Application Short Title	Number of Days on Clock
11/LO/1678	Stressbusters: RCT of computerised CBT package for adolescents	23

Provisional Opinion		
REC Reference	Application Short Title	Number of Days on Clock

Provisional Opinion Pending Consultation with Referee		
REC Reference	Application Short Title	Number of Days on Clock

Further information response not complete		
REC Reference	Application Short Title	Number of Days on Clock

Withdrawn after the meeting		
REC Reference	Application Short Title	Number of Days on Clock
11/LO/0821	The impact of a conversation partner on health related quality of life	38
11/LO/1074	(duplicate) Clinical use of nasal Nitric Oxide in children with allerg	27
12/LO/0034	MSA-postural instability and gait disability v. 1.1	28

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

No Opinion Pending Consultation with Referee		
REC Reference	Application Short Title	Number of Days on Clock

Not Requiring Review by NHS REC		
REC Reference	Application Short Title	Number of Days on Clock

Table 7: Items exceeding timelines:

Full applications for ethical review over 60 day timeline			
REC Reference	Application Short Title	Number of Days on Clock	
11/LO/0396	The Metabolic Profile in Obstetric Cholestasis	87	
11/LO/0339	Psychological predictors of weight loss after gastric band surgery	105	
11/LO/0809	Attitudes to Opiate Substitution Treatment amongst opiate users	64	
11/LO/1258	Health seeking in Psoriasis v1.0	71	
11/LO/1425	MRI in Motor Neuropathies V1	69	
11/LO/1448	Pharmacy Alcohol Study	61	
11/LO/1846	The Effects of Ageing on the Cutaneous Immune System, Version 1	88	
11/LO/1872	Measuring patients engagement using the Electronic Patient Record	100	
11/LO/2051	Randomised comparison of ablation therapies in treating persistent AF	75	
12/LO/0176	Does Biventricular Pacing Represent True Cardiac Resynchronisation?	62	
12/LO/0433	A study of gastrointestinal symptoms and motility in PD Version 1.1	76	

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

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
11/H0716/6/AM01	PDM cbd urban exposure. version 2	Amendment 1	44
08/H0716/47/AM02	Development of the LDS (England and Wales application)	Amendment 2	45

09/H0716/7/AM11	Life Opportunities Survey	Amendment 11	45
09/H0716/74/AM04	PROBE	Amendment 4	40
08/H0716/55/AM12	Open, Safety and Efficacy of Levodopa-Carbidopa in Advanced Parkinsons	Substantial Amendment - Protocol Amend 7, 16/08/11	62
11/LO/1471/AM01	Children after adoption: defining their psychological needs. Version 1	Substantial Amendment 1 - 09/01/2012	45
10/H0716/64/AM04	Clinical Relevance Of Microbleeds In Stroke -Intracerebral Haemorrhage	Substantial Amendment 04 – 27/01/2012	36
10/H0716/51/AM02	European Friedreich's Ataxia Consortium for Translational Studies v1	Substantial Amendment 02 – 31/01/2012	60
10/H0716/41/AM01	Longitudinal changes in motor system connectivity after stroke.	Substantial Amendment 01 – 31/01/2012	36
10/H0716/70/AM02	Motor system connectivity after stroke: an MEG study	Substantial Amendment 02 – 02/02/2012	36
09/H0716/71/AM05	Optimisation of the management of stroke and TIA	Substantial Amendment 5 – 12/01/2012	66

Modified Amendments over 14 day timeline

Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
06/Q0512/81/AM04/1	Neuropsychology of posterior cortical atrophy (Version 1)	Amendment 4a	15
11/H0716/9/AM01/1	Neutrophil Gelatinase-associated Lipocalin in Acute Kidney Injury	Changes to protocol and PIS	15

Section 30 application over 60 day timeline

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