

NRES Committee London - Stanmore

Annual Report

01 April 2011 – 31 March 2012

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee London - Stanmore
Type of REC:	Authorised
Type of Flag:	Devices
Chair:	Mrs Rosemary Hill
Vice-Chair:	Mr Stephen Humphreys
Alternate Vice-Char:	n/a
Co-ordinator:	Uzma Chaudhry (Danyal Enver since July 2012)
PRSC Co-ordinator:	n/a
Assistant Co-ordinator:	Reema Ved
Committee Address:	Skipton House Ground Floor NRES/HRA 80 London Road London SE1 6LH
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Chair's overview of the past year:

The Committee were delighted to receive full Accreditation in June 2012. It is a measure of the quality of the committee as a whole and of the Co-ordinator Uzma Chaudhry.

During the year both the Chair and the Co-ordinator received a large number of requests for advice on possible applications. The Chair is grateful for the help and advice that Uzma Chaudhry gave to others as well as to the very efficient way she managed the concerns of the committee. Alison O'Kane became our new co-ordinator in March 2012 after Uzma Chaudhry was promoted. The committee welcomed Alison, she is well known to some of them.

The committee are enthusiastic and very willing. There are specialists in a wide variety of fields, as well as enthusiastic lay members. Quite a few members have conducted research themselves and have been in a position to help and advise applicants on their research.

NRES Committee London - Stanmore Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Ms Margaret Byers	Senior biomedical scientist	Expert	18/06/2009	06/05/2011
Mr Gordon Coleman	Retired	Lay Plus	26/06/2009	
Mrs Marion Cumbers	Retired	Lay Plus	16/06/2009	
Dr Geraldine Edge	Consultant Anaesthetist	Expert	16/06/2009	
Dr Anthony Gilbert	Medical Doctor	Expert	21/06/2009	
Dr Mike Hetreed	Consultant Anaesthetist	Expert	17/06/2009	
Mrs Rosemary Hill	Statistician	Expert	18/06/2009	
Mr Stephen Humphreys	Practice Manager	Lay	19/06/2009	
Mrs Cara Lovell	Occupational Therapist	Expert	22/06/2009	14/04/2011
Mrs Elayne Nasr	Retired	Lay	17/06/2009	
Dr Carol Pellowe	Senior Lecturer - Infection Control	Expert	17/06/2009	
Mrs Susan Ruben	Pharmacist / Pharmacy Manager	Expert	09/12/2011	
Ms Gill Thurlow	Consultant Nurse - Rehabilitation and Pain Management Programmes	Expert	17/06/2009	
Mr George Verghese	Orthopaedic Surgeon	Expert	01/07/2011	
Mrs Marina Wells	Midwife/Matron	Expert	16/06/2009	
Mrs Shirley Williams	Retired	Lay	17/06/2009	

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 - Stanmore: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Mr George Verghese	No declared interests.	01/12/2011
Mrs Marina Wells	No declared interests.	23/12/2011
Mrs Rosemary Hill	No declared interests.	01/12/2011
Dr Anthony Gilbert	Medical Director - Retroscreen Virology Ltd.	01/04/2011
Mrs Susan Ruben	Employee of Lloyds pharmacy PLC as a pharmacist.	29/12/2011
Mr Stephen Humphreys	Practice Manager of a general practitioner's surgery where research might be conducted. Director of the addociation of Research Ethics Committees. 1000 shares in Asterand plc. Trustee of the Association of Research Ethics Committees.	01/12/2011
Dr Mike Hetreed	No delcared interests.	01/12/2011
Mrs Marion Cumbers	Member of RNOH Patient Group (successor to PPI forum) - Not likely to be involved in research. Consumer representative (lay member) NIHR Medicines for Children Research network, Neonatal clinical studies group. Lay revirewer for for NIHR-CCF/Involve. Lay member of group applying for a grant for advice surgery research.	01/12/2011
Mr Gordon Coleman	No declared interests.	01/12/2011
Ms Gill Thurlow	No declared interests.	01/12/2011
Dr Geraldine Edge	Consultant Anaesthetists and Clinical Director for Clinical Governance - Royal National Orthopaedic Hospital.	01/12/2011
Dr Carol Pellowe	Vernacare Advisory Board member (paper maceration). Active researcher, just awarded contract from DH on patient experience of MRSA screening.	01/12/2011
Mrs Elayne Nasr	No declared interests.	01/12/2011

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

Month	Date	Number of Members Present at Meeting
April	07/04/2011	10
May	05/05/2011	11
June	02/06/2011	10
July	07/07/2011	10
September	01/09/2011	11
October	06/10/2011	10
November	03/11/2011	11
December	01/12/2011	10
January	05/01/2012	11
February	02/02/2012	11
March	01/03/2012	8

11 full committee meetings were held during the reporting period.

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

Name	Number of Meetings Attended
Mrs Rosemary Hill	11
Dr Mike Hetreed	10
Mr Gordon Coleman	9
Mr Stephen Humphreys	9
Mrs Shirley Williams	9
Ms Gill Thurlow	8
Mrs Marion Cumbers	8
Mrs Elayne Nasr	8
Dr Carol Pellowe	8
Dr Anthony Gilbert	8
Dr Geraldine Edge	8
Mrs Marina Wells	6
Mr George Verghese	5
Mrs Susan Ruben	3
Ms Margaret Byers	1

Number of inquorate meetings held: None

**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 Rosemary Hill	08/11/2011 - 08/11/2011	Chairing Skills, NRES
Mr Stephen Humphreys	26/07/2011 - 26/07/2011	NRES medical devices training, NRES
Mrs Marina Wells	12/04/2011 - 12/04/2011	Equality & Diversity, NRES
Mrs Marina Wells	19/05/2011 - 19/05/2011	NRES: Ethical issues arising from research involving adolescents, NRES
Dr Anthony Gilbert	08/04/2011 - 08/04/2011	GCP Incorporating UK, Retroscreen virology (self directed training)
Dr Geraldine Edge	01/06/2011 - 01/06/2011	MCA, NRES MCA DVD
Ms Gill Thurlow	10/06/2011 - 10/06/2011	MCA DVD, NRES
Dr Geraldine Edge	17/06/2011 - 17/06/2011	ED Equality & Diversity, Core Learning Unit
Mrs Elayne Nasr	20/07/2011 - 20/07/2011	MCA DVD 2011-06-10, NRES
Mr Stephen Humphreys	11/07/2011 - 11/07/2011	MCA DVD 200-06-10, NRES
Mr George Verghese		East of Scotland Research Ethics Service Annual Training Day, East of Scotland Research Ethics Service
Mr Stephen Humphreys	26/09/2011 - 26/09/2011	NRES Update Session, NRES
Mrs Susan Ruben	30/12/2011 - 30/12/2011	New Member Induction DVD, NRES
Mrs Susan Ruben	30/12/2011 - 30/12/2011	MCA DVD, NRES
Mr Stephen Humphreys	17/11/2011 - 18/11/2011	AREC AGM, AREC
Mrs Marion Cumbers	09/11/2011 - 09/11/2011	Delivering Neonatal Studies on the NIHR Portfolio, NIHR and MCRN
Mrs Marion Cumbers	05/01/2012 - 05/01/2012	Designing Trials, Rosemary Hill / Uzma Chaudhry
Dr Geraldine Edge	05/01/2012 - 05/01/2012	Designing Trials, Rosemary Hill / Uzma Chaudhry
Dr Mike Hetreed	05/01/2012 - 05/01/2012	Designing Trials, Rosemary Hill / Uzma Chaudhry
Mrs Rosemary Hill	05/01/2012 - 05/01/2012	Designing Trials, Rosemary Hill / Uzma Chaudhry
Mr Stephen Humphreys	05/01/2012 - 05/01/2012	Designing Trials, Rosemary Hill / Uzma Chaudhry
Dr Carol Pellowe	05/01/2012 - 05/01/2012	Designing Trials, Rosemary Hill / Uzma Chaudhry
Mrs Susan Ruben	05/01/2012 - 05/01/2012	Designing Trials, Rosemary Hill / Uzma Chaudhry
Ms Gill Thurlow	05/01/2012 - 05/01/2012	Designing Trials, Rosemary Hill / Uzma Chaudhry
Mr George Verghese	05/01/2012 - 05/01/2012	Designing Trials, Rosemary Hill / Uzma Chaudhry

Mrs Shirley Williams	05/01/2012 - 05/01/2012	Designing Trials, Rosemary Hill / Uzma Chaudhry
Mr Gordon Coleman	05/01/2012 - 05/01/2012	Designing Trials, Rosemary Hill / Uzma Chaudhry
Mrs Rosemary Hill	18/10/2011 - 18/10/2011	Chair's Network Meeting, NRES
Mr Stephen Humphreys	29/02/2012 - 29/02/2012	NRES Personal Data in Research, NRES
Mr George Verghese	26/01/2012 - 26/01/2012	NRES Medical Devices, NRES
Mrs Susan Ruben	29/03/2012 - 29/02/2012	NRES Members Induction Training, NRES
Mrs Susan Ruben	13/02/2012 - 13/02/2012	Health Research Authority ICR GCP Forum , 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	62	100.00
Total Applications Reviewed	62	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	2
Number of studies withdrawn prior to the meeting	4
Number of student applications reviewed	21
Number of paediatric applications reviewed	3
Number of device applications reviewed	18
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	1	1.61
Favourable Opinion with Additional Conditions	18	29.03
Unfavourable Opinion	3	4.84
Provisional Opinion	40	64.52
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	62	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	27	43.55
Further Information Favourable Opinion with Additional Conditions	13	20.97
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	1.61
Favourable Opinion with Additional Conditions	18	29.03
Unfavourable Opinion	3	4.84
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	62	100

Table 5: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.64
Number of applications for full ethical review over 60 days	0
Number of applications over 60 days as a % of total	0.00%
Number of days taken to final decision - average	32
Number of days taken to final decision - mode	26
Number of SSAs (non-Phase 1) reviewed	0
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%
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	38
Number of substantial amendments over 35 days	1
Number of substantial amendments over 35 days as a % of total substantial amendments	2.6%
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	3
Number of modified amendments over 14 days	1
Number of modified amendments over 14 days as a % of total modified amendments	33.3%

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/0306	Powerwheel Feasibility Study	59
11/LO/0441	Empathic and moral processing in personality disordered patients - V.1	39
11/LO/0490	Pilot testing a software algorithm to analyse the character of a pulse	26
11/LO/0498	Understanding Carer Experiences in Psychosis	38
11/LO/0499	Women with dual diagnosis and offending behaviour:A qualitative study	43
11/LO/0501	General Practitioners (GPs) Attitudes to Health & Work Issues V1	40
11/LO/0529	Coherex FlatStent EF PFO Migraine Registry (Rev. C)	42
11/LO/0618	MRgFUS Compared with Myomectomy for the Treatment of Uterine Fibroids	23
11/LO/0922	OVATION Post Market Study	30
11/LO/0966	Molecular Genetic Analysis of Hidradenitis Suppurativa	42
11/LO/1347	2gBT compared with LMA for pressure ventilation and intubation.	42
11/LO/1493	v1 Strategies to Improve Life Quality in dementia(feasibility study)	38
11/LO/1554	efficacy and safety of the wearable ultrafiltration device	29
11/LO/1556	2RT pilot study for DMO	31
11/LO/1580	Genesis Feasibility Study BEP 4409-2010 Version 1	39
11/LO/1613	Genetic progression of pre-malignant gastrointestinal disease	42
11/LO/1632	Patient preferences towards surgery for oesophagogastric cancer	42
11/LO/1754	Optimising the use of MRI in the management of Crohn's Fistula-in-Ano	42
11/LO/1866	Savile Row	52
11/LO/1879	RADI-CRT Randomised Controlled Trial	26
11/LO/1912	Adjustment in men whose female partners have an acquired brain injury	34
11/LO/1937	Ductal flow pattern and need for treatment in premature neonate	29
12/LO/0084	Study to validate optical coherence tomography in patients with MS	23
12/LO/0152	Nurse involvement in decision support for patients with IBD	25
12/LO/0160	Neuropathy Assessment in Chemotherapy-treated Patients	29
12/LO/0162	Cardiac CT/MR role in optimising resynchronisation therapy response	31
12/LO/0297	New Haemostatic Interventions in Haemophilia	23

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/LO/0248	Improving cognition in schizophrenia using brain stimulation.	35
11/LO/0294	Functional outcomes following segmental colectomy	34
11/LO/0485	Evaluation of the IncoStress device. Version 1	35
11/LO/0505	Feasibility and effect of extended Haemodialysis treatment time	30
11/LO/0621	Coherex WaveCrest Left Atrial Appendage Occlusion Study	38
11/LO/0714	Creating a patient reported experience measure for COPD	33
11/LO/0721	Exploration of the psychological needs of physically ill older people	43
11/LO/0730	Central and peripheral adenosine-induced maximal coronary hyperaemia	56
11/LO/0963	Amyloidosis PET study, version 1	51
11/LO/1014	Sodium loss and insulin resistance following colonic resection	35
11/LO/1134	SX ELLA Oesophageal Degradable BD Stent System (DESTINY)	39
11/LO/1548	Oesophageal doppler guided fluid therapy in major head & neck surgery	26
12/LO/0194	REVOLUTION (WFCC-133)	26

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/1924	Analysis of cardiac tissue from patients with pulmonary regurgitation	19

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/LO/0252	CP214OC River 1	22
11/LO/0707	Z7821320 A Study Investigating the Level of Dentine Tubule Occlusion	15
11/LO/0715	Effect of dietary nitrate ingestion in hypercholesteroleemics.	32
11/LO/0728	In vivo fluorescence lifetime endoscopy - version 1.2	21
11/LO/0873	Woundcare for Epidermolysis Bullosa (Version 2)	18
11/LO/0964	Sexual Well-Being and Sexually Transmitted Infections version 1	35
11/LO/0965	European Community Respiratory Health Survey III	32
11/LO/1011	Advancing the assessment of sensory neuropathy	26
11/LO/1323	A study of friction between nonwoven fabrics and human skin	25
11/LO/1324	Friction between skin and nonwoven fabrics.	25

11/LO/1410	ISIS	21
11/LO/1633	Evaluation of the Transmedics Lung Organ Care System	27
11/LO/1641	Venous lactate in acute on chronic respiratory illness	24
11/LO/1766	Working in a reconfigured major trauma system: the nurse experience	27
11/LO/1810	DEFLECT I trial	19
12/LO/0125	Information and knowledge about cognition in mental health problems	29
12/LO/0290	Interactions between burs, dental tissues and adhesives	31
12/LO/0369	AQUACEL® Extra™ in Venous Leg Ulcers (CW-0209-11-U361)	20

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/LO/0416	Boosting cognitive reserve to improve recovery after psychosis onset-1	27
11/LO/1635	A qualitative study of mental disorder in sexual offending.	26
11/LO/1768	(duplicate) (duplicate) Women's decision making process regarding amni	30

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 7: Items exceeding timelines:

Full applications for ethical review over 60 day timeline			
REC Reference	Application Short Title	Number of Days on Clock	
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/LO/0485/AM01	Evaluation of the IncoStress device. Version 1	Amendment 1, 24/01/2012	80
Modified Amendments over 14 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
11/H0724/6/AM01/1	Psychosocial and clinical outcomes of surgery for Thyroid Eye Disease	Version 3, 06.01.2012	22
Section 30 application over 60 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock