

National Research Ethics  
Service

  
*Health Research Authority*

**NRES Committee London - Stanmore**

**Annual Report**

**01 April 2013 – 31 March 2014**

## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	NRES Committee London - Stanmore
<b>Type of REC:</b>	Authorised
<b>Type of Flag:</b>	Medical devices
<b>Chair:</b>	Mrs Rosemary Hill
<b>Vice-Chair:</b>	Dr Stephen Humphreys
<b>Alternate Vice-Char:</b>	Dr Anthony Gilbert
<b>REC Manager:</b>	Ms Julie Kidd
<b>PRSC Co-ordinator:</b>	Julie Kidd/Hayley Fraser
<b>REC Assistant:</b>	Miss Hayley Fraser
<b>Committee Address:</b>	Skipton House Ground Floor NRES/HRA 80 London Road London SE1 6LH
<b>Telephone:</b>	020 7972 2552
<b>Email:</b>	<a href="mailto:NRESCommittee.London-Stanmore@nhs.net">NRESCommittee.London-Stanmore@nhs.net</a>

### Chair's overview of the past year:

The Committee members 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.

The Committee is flagged for reviewing medical devices trials and for qualitative research. We have had many applications of these types to look at. The Committee has an in-depth knowledge of medical device research including that with specially built equipment and equipment used in a novel way. We also have experts in qualitative research.

The members' skills have enabled the committee to respond to these applications in a helpful and knowledgeable way.

Training is important to the Committee and every year we have a training session for the Committee led by an expert member of the committee. We have found this an excellent way of sharing our skills.

## NRES Committee London - Stanmore Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
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	Lay	18/06/2009	
Dr Stephen Humphreys	Practice Manager	Lay Plus	19/06/2009	
Dr Anthony Kaiser	Consultant Neonatologist	Expert	01/12/2013	
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

**NRES Committee London - Stanmore: Members' Declarations of Interest:**

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Mr Gordon Coleman	N/A	21/05/2013
Dr Geraldine Edge	Clinical Director for clinical quality & governance, also is the designated individual for the HTA at RNOH & therefore responsible for ensuring that R & D applications involving human tissue comply with HTA licencing regulation	11/12/2013
Mr George Verghese	None	11/12/2013
Dr Anthony Kaiser	None	11/12/2013
Mrs Elayne Nasr	Director of Larchmoor park Management Co Ltd	11/12/2013
Ms Gill Thurlow	None	11/12/2013
Mrs Rosemary Hill	Astra Zenica - A few inherited shares.	03/01/2014
Dr Stephen Humphreys	External member of Cranfield University's Science and Engineering Research Ethics Committee. Continuing academic interest in Research Ethics and publish on this and allied topics (researcher id; 6983-2013)	10/02/2014
Dr Carol Pellowe	Honorary Senior Lecturer - Guy's & St Thomas Trust. Consultant Star Syringesconsultant	10/02/2014
Mrs Shirley Williams	No declared interests.	10/02/2014
Mrs Marina Wells	None	04/07/2013
Mrs Marion Cumbers	NIHR Medicines for children research network, lay member neonatal studies group. Occasional reviewer of grant applications.	02/05/2013
Dr Mike Hetreed	None	13/06/2013
Mrs Susan Ruben	None	02/05/2013
Dr Anthony Gilbert	None	06/06/2013

**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	04/04/2013	10
May	02/05/2013	12
June	06/06/2013	11
July	04/07/2013	9
September	05/09/2013	9
October	03/10/2013	11
November	07/11/2013	9
December	05/12/2013	12
February	06/02/2014	11
March	06/03/2014	12

10 full committee meetings were held during the reporting period.

**Proportionate Review Sub Committee Meetings held during 01 April 2013 - 31 March 2014:**

<b>Month</b>	<b>Date</b>	<b>Number of Members Present at Meeting</b>
May	15/05/2013	4
November	18/11/2013	3
November	26/11/2013	3
December	16/12/2013	3
January	20/01/2014	3
February	14/02/2014	3
March	20/03/2014	3

7 proportionate review sub-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>
Mrs Rosemary Hill	10
Dr Stephen Humphreys	9
Mr Gordon Coleman	8
Mrs Elayne Nasr	8
Dr Anthony Gilbert	8
Mrs Susan Ruben	8
Ms Gill Thurlow	7
Mrs Shirley Williams	7
Dr Carol Pellowe	7
Dr Geraldine Edge	7
Mr George Verghese	7
Dr Mike Hetreed	6
Mrs Marion Cumbers	6
Mrs Marina Wells	5
Dr Anthony Kaiser	3

**Number of inquorate meetings held: None**

**Attendance of Members at proportionate review sub-committee meetings:  
01 April 2013 – 31 March 2014:**

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Stephen Humphreys	7
Mrs Rosemary Hill	7
Mr George Verghese	2
Mrs Elayne Nasr	1
Dr Carol Pellowe	1
Dr Anthony Gilbert	1
Dr Anthony Kaiser	1
Dr Geraldine Edge	1
Dr Mike Hetreed	1

**Training 01 April 2013 – 31 March 2014:**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr Stephen Humphreys	01/04/2013 - 01/04/2013	Equality & Diversity, HRA/NRES
Mr George Verghese	09/09/2013 - 09/09/2013	Induction, HRA/NRES
Mr Gordon Coleman	22/05/2013 - 22/05/2013	Attended Central London Committee to get experience of clinical trials
Dr Stephen Humphreys	20/11/2013 - 20/11/2013	National Members Training Day, HRA
Mrs Marion Cumbers	11/03/2014-11/03/2014	Medical Devices Training Day, HRA
Dr Anthony Kaiser	07/11/2013 - 07/11/2011	NRES Statistics, NRES
Dr Anthony Gilbert	09/12/2013 - 09/12/2013	Equality & Diversity, NHS HRA
Dr Stephen Humphreys	02/09/2013 - 02/09/2013	NREAP, HRA
Mrs Shirley Williams	11/03/2014 - 11/03/2014	Medical Devices Training Day, HRA/
Mrs Rosemary Hill	09/01/2014 - 09/01/2014	Human Viral Challenge, Dr Anthony Gilbert
Dr Stephen Humphreys	09/01/2014 - 09/01/2014	Human Viral Challenge, Dr Anthony Gilbert
Dr Anthony Gilbert	09/01/2014 - 09/01/2014	Anti Viral Challenge, Dr Anthony Gilbert
Dr Mike Hetreed	09/01/2014 - 09/01/2014	Anti Viral Challenge, Dr Anthony Gilbert
Mrs Rosemary Hill	25/03/2014 - 25/03/2014	Research Involving the disadvantaged and vulnerable, HRA

## 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
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	50	100.00
<b>Total Applications Reviewed</b>	<b>50</b>	<b>100</b>

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

Number of applications made invalid by co-ordinator	3
Number of studies withdrawn prior to the meeting	7
Number of student applications reviewed	15
Number of paediatric applications reviewed	4
Number of device applications reviewed	11
Number of prisoner applications reviewed	1
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:**

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	2	4.00
Favourable Opinion with Additional Conditions	15	30.00
Unfavourable Opinion	2	4.00
Provisional Opinion	31	62.00
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>50</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	25	50.00
Further Information Favourable Opinion with Additional Conditions	4	8.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	4.00
Favourable Opinion with Additional Conditions	15	30.00
Unfavourable Opinion	2	4.00
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	2	4.00
<b>Total</b>	<b>50</b>	<b>100</b>

**Table 5: Applications assigned to a proportionate review sub-committee within the reporting period:**

<b>Total Applications Reviewed</b>	<b>11</b>
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**Table 6: Decisions given at proportionate review sub-committee meetings held within the reporting period:**

<b>Decisions taken at proportionate review sub-committee meetings</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	4	36.36
Favourable Opinion with Additional Conditions	4	36.36
No Opinion transfer to full committee for review	1	9.09
Provisional Opinion	2	18.18
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>11</b>	<b>100</b>

**Table 7: Other Management Information for the reporting period:**

<b>Average number of applications reviewed per full meeting</b>	5.00
<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>	2.00%
<b>Number of days taken to final decision - average</b>	33
<b>Number of days taken to final decision - mode</b>	22
<b>Number of SSAs (non-Phase 1) reviewed</b>	2
<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>	45
<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>	2.2%
<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>	0
<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%
<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>	0.0%

**Table 8: 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/0430	An exploration of uncertainty in parents.	55
13/LO/0432	Exploring the Role of Trauma in Mentally Disordered Offenders	47
13/LO/0571	Real time patient pain feedback study	33
13/LO/0584	The POPPY St. Mary's MRI Sub-study	44
13/LO/0775	A GT study to elicit why women who initiate BF do not access local PS	14
13/LO/0792	Exploring therapy processes with people experiencing psychosis	51
13/LO/0849	Clinical Assessment of a Novel Microprobe Continuous Glucose Monitor	22
13/LO/0969	Visual processing and working memory deficits in schizophrenia	39
13/LO/0975	International Ovarian Tumour Analysis (IOTA) Phase 5	23
13/LO/1000	JetTouch Injection System to deliver saline into bladder wall-healthy.	28
13/LO/1021	Optical Imaging of Oral Mucosal lesions	21
13/LO/1255	Clinical and neurophysiological assessments of DBS frequency in PD	15
13/LO/1385	STEP-UP	32
13/LO/1431	Inter-observer variability in the assessment of diabetic foot ulcers	56
13/LO/1433	Young People's Use of the Internet for Emotional Wellbeing	32
13/LO/1634	195263-007 Meibomian Gland Dysfunction	39
13/LO/1643	Transgenerational aspects of PCOS	43
13/LO/1645	Understanding how we treat the Achilles tendon	40
13/LO/1661	Preliminary Safety Evaluation of RPC Pure-Collagen	40
13/LO/1741	Micra Transcatheter Pacing Study. Version 1. 19th June 2013.	32
13/LO/1828	Salivary Acetaldehyde in Various Foods and Drinks (v1)	11
13/LO/1832	Safety and efficacy evaluation of Hairstetics' hair implant	31
13/LO/1837	Radiocyst 01	44
14/LO/0005	Graded Motor Imagery for Phantom Limb Pain	57
14/LO/0119	Overcoming Self-Critical Attitudes in Virtual Reality	54
14/LO/0290	Genetic variation and cough	29
14/LO/0387	FOAM study	29

**Further Information Favourable Opinion with Additional Conditions**

<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
13/LO/0788	Alcohol screening tools for people with cognitive impairment	33
13/LO/0793	Investigation of balance strategies following postural perturbation	64
14/LO/0328	VMET 2	32
14/LO/0374	GG-007	53

#### **Further Information Unfavourable Opinion**

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

<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
13/LO/0686	MIRACLE EF	28
13/LO/0769	Evaluation of burden of illness among adults with psoriasis in the UK	7
13/LO/1233	MAGNABLATE I	26
13/LO/1826	Cells as a model system to study Neuromuscular Disorders	4
14/LO/0180	Retrospective study of surgical factors' impact on reoperation in BCS	3
14/LO/0564	Multigene analysis in carcinogenesis of Colorectal Cancer.	3

#### **Favourable Opinion with Additional Conditions**

<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
13/LO/0451	The UK TAVI Trial (version 1.0)	22
13/LO/0576	Evaluating an automated diabetic retinopathy screening tool.	31
13/LO/0765	The implant journey (ver-1)	2
13/LO/0781	Parent expectations following treatment of paediatric medulloblastoma	22
13/LO/0973	The RESHAPE-HF Trial (MitraClip)	22
13/LO/1254	EVERREST: Developing a therapy for Fetal Growth Restriction	26
13/LO/1273	Anticoagulation in Haemodialysis	40
13/LO/1274	FOrMAT	41
13/LO/1367	Blood Flow in the Deep Veins of the Leg	25
13/LO/1438	User Assessment of the NovaLife One-Piece Flat Skin Barrier	25
13/LO/1639	Correction of Angular Deformities in Knee Arthrosis	25
13/LO/1818	Pnh clones detection in MDS patients using flow cytometry	8
13/LO/1847	Multi-centre Sunshine Heart C-Pulse Study	13

13/LO/1932	Carers' experiences of end of life care for people with H.F. V.1.	6
14/LO/0160	Intensive weight management in obese women planning a pregnancy.	25
14/LO/0183	REDIT-CT: Randomised Evaluation Study of DIT compared to CBT	29
14/LO/0361	3D Transoesophageal Echocardiographic Assessment of the Mitral Valve	24
14/LO/0376	CLN0016	22
14/LO/0557	SCOPE-ME PREM development	6

#### Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/LO/0993	Migration and Health: Latin American men selling sex in London	28
13/LO/1432	Impact of traumatic brain injury on perception of self and behaviour	22

#### 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
13/LO/0484	LITE Study - L.E.D. in Intra-abdominal Tissue Evaluation.(v1 3/3/2013)	27
13/LO/0581	Diagnosing fractures in children - is ultrasound safe and sound?	37

#### 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 9: 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>
13/LO/0793	Investigation of balance strategies following postural perturbation	64

<b>Proportionate review applications for ethical review over 14 days 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>
13/LO/0291/AM01	Accu-Chek® Insight Insulin Pump EU Study; Study Protocol RD001514	Substantial Amendment 1	40

<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>