

National Research Ethics
Service


Health Research Authority

NRES Committee London - Central

Annual Report

01 April 2013 – 31 March 2014

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee London - Central
Type of REC:	Type III
Type of Flag:	Research involving children & Phase I in patients
Chair:	Dr Andrew Hilson
Vice-Chair:	Sir Adrian Baillie
Alternate Vice-Chair:	Mr Clive Carsley
REC Manager:	Ms Audrey Adams
PRSC Co-ordinator:	Ms Hayley Fraser
REC Assistant:	Ms Hayley Fraser
Committee Address:	Health Research Authority, Ground Floor, Skipton House 80 London Road London SE1 6LH
Telephone:	0207 972 2584
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Chair's overview of the past year:

The committee continues to function well, reviewing a wide range of applications. We remain popular with researchers for our position as well as for the quality of our reviews.

There has been some change in membership over the year, but the committee members continue to have excellent internal working relationships.

We have had some administrative hiccups, but look forward with interest and hope to our new relationship with Manchester - although we will still be using Skipton House for sub-committees.

NRES Committee London - Central Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Sir Adrian Baillie	Financial Investment Advisor	Lay Plus	22/12/2006	31/03/2014
Mr Clive Carsley	Retired Lawyer	Lay Plus	01/01/2013	
Ms Sally Davis	Lawyer/PhD Student	Lay Plus	01/01/2013	
Dr Beverley Donaldson	Academic Research Midwife	Expert	11/02/2014	
Dr Olivia Festy	Clinical Trials Administrator	Lay	14/04/2006	
Mrs Sophie Forsyth	Lawyer	Lay Plus	01/04/2011	
Dr Frances Goodhart	Consultant Clinical Psychologist	Expert	01/04/2011	
Dr Andrew Hilson	Consultant in Nuclear Medicine	Expert	01/02/2012	
Dr Leslie Huson	Consultant Medical Statistician	Expert	14/09/2007	
Mr Roy Sinclair	Former Pharmacist	Expert	12/12/2012	
Professor Lewis Spitz	Emeritus Nuffield Professor of Paediatric Surgery	Expert	29/11/2007	
Mr Benjamin Stanfield-Davies	University Lecturer	Expert	23/05/2012	
Dr Gareth Tudor-Williams	Consultant in Paediatric Infectious Diseases	Expert	02/02/2011	
Miss Zalika Xavier	Market Researcher	Lay Plus	01/01/2013	

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Dr John Keen	GP	Expert	PR Meeting 16/07/2013
Dr Daniel Bradford	Pharmacologist	Expert	24/04/2013

NRES Committee London - Central: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Dr Leslie Huson	Director of GNB Limited, numerous consultancies with pharmaceutical and biotechnology companies, consultant at Imperial College/Welcome Trust Clinical Trials Facility, Hammersmith Hospital. Owner of GNB Limited. Membership of the Protocol Review Board at Imperial College/Welcome Trust Clinical Research Facility, Hammersmith Hospital.	30/05/2013
Mr Benjamin Stanfield-Davies	Senior Lecturer at London Southbank University	06/06/2013
Dr Olivia Festy	Currently working in business development at Queen Mary University where own research is carried out at associated Barts Health and Medical school.	29/05/2013
Mrs Sophie Forsyth	None	03/06/2013
Dr Beverley Donaldson	Currently an academic research midwife employed by Imperial College London. .Holds a licence to attend Imperial College NHS Trust. Actively involved in undertaking research in the Women and Children's division. .An academic supervisor and mentor.	31/03/2014
Mr Clive Carsley	None	31/03/2014
Dr Frances Goodhart	None	31/03/2014
Mr Roy Sinclair	None	31/03/2014
Mrs Sophie Forsyth	None	31/03/2014
Dr Gareth Tudor-Williams	Member, Scientific Steering Committee, Paediatric European Network for Treatment of AIDS (PENTA).Chair, Data Monitoring Committees for: Pfizer - 13 valent pneumococcal conjugate vaccine trial using mult-dose trials in the Gambia. BMS - Prince I and II studies of atazanavir in HIV children. GSK - Fofamprenavir studies in HIV children	31/03/2014
Ms Sally Davis	A few shares (540) in GSK currently. These are managed on my behalf. .I am researching a M/Phil/DPhil PhD in public policy and the moral status of animals at King's College London. This covers a wide range of subjects and themes related to the role of animals in our lives generally but is not directly involved in the conduct of any practical research. The emphasis is philosophical.	31/03/2014
Professor Lewis Spitz	None	31/03/2014

Meetings for Full Ethical Review 01 April 2013 - 31 March 2014:

Month	Date	Number of Members Present at Meeting
April	24/04/2013	11
May	22/05/2013	12
June	26/06/2013	8
July	31/07/2013	9
August	28/08/2013	9
September	25/09/2013	9
October	30/10/2013	11
November	27/11/2013	11
January	29/01/2014	9
February	26/02/2014	11
March	26/03/2014	10

11 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
April	22/04/2013	3
May	27/05/2013	3
June	24/06/2013	3
June	27/06/2013	4
July	31/07/2013	3
August	13/08/2013	3
August	26/08/2013	3
September	30/09/2013	3
October	28/10/2013	3
November	25/11/2013	4
February	10/02/2014	3
March	05/03/2014	3

12 proportionate review sub-committee meetings were held during the reporting period.

Attendance of Members: 01 April 2013 – 31 March 2014:

Name	Number of Meetings Attended
Dr Andrew Hilson	10
Dr Frances Goodhart	10
Mr Clive Carsley	10
Mrs Sophie Forsyth	10
Professor Lewis Spitz	10
Sir Adrian Baillie	10
Mr Roy Sinclair	9
Miss Zalika Xavier	9
Ms Sally Davis	8
Dr Gareth Tudor-Williams	7
Dr Olivia Festy	6
Mr Benjamin Stanfield-Davies	4
Dr Leslie Huson	3
Dr Beverley Donaldson	2

Number of inquorate meetings held: None

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

Name	Number of Meetings Attended
Dr Andrew Hilson	12
Sir Adrian Baillie	9
Mr Clive Carsley	7
Roy Sinclair	3
Dr Frances Goodhart	3
Dr Leslie Huson	1
Roy Sinclair	1
Professor Lewis Spitz	1

Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Sir Adrian Baillie	06/06/2013 - 06/06/2013	New REC Chairs Training, NRES/HRA
Dr Frances Goodhart	08/07/2013 - 08/07/2013	Qualitative Research & Ethical Review, Health Research Authority
Dr Andrew Hilson	26/04/2013 - 26/04/2013	Clinical Research now and in the future, The Royal Society of Medicine
Professor Lewis Spitz	26/04/2013 - 26/04/2013	Clinical Research now and in the future, The Royal Society of Medicine
Ms Sally Davis	15/06/2013 - 15/06/2013	A One Day Medical Ethics Symposium, Worshipful Society of Apothecaries of London
Miss Zalika Xavier	04/07/2013 - 04/07/2013	Induction, NRES
Sir Adrian Baillie	06/06/2013 - 06/06/2013	Chairing Skills, London REC
Dr Andrew Hilson	10/08/2013 - 10/08/2013	Equality & Diversity
Dr Andrew Hilson	02/09/2013 - 02/09/2013	Chair's Training, NRES/HRA
Mr Roy Sinclair	21/11/2013 - 21/11/2013	Prison Visit - Elmley Prison - HMP Rochester, David Caplin
Mr Roy Sinclair	28/01/2014 - 28/01/2014	Equality & Diversity, NRES
Mr Roy Sinclair	11/12/2013 - 11/02/2014	Read NRES Training Material on: Human Tissue Act 2004 Training - Adults Lacking Capacity in CTIMPs, 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	15	24.19
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	1	1.61
Research Database	0	0.00
Others	46	74.19
Total Applications Reviewed	62	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	4
Number of studies withdrawn prior to the meeting	7
Number of student applications reviewed	14
Number of paediatric applications reviewed	14
Number of device applications reviewed	1
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	9	14.52
Favourable Opinion with Additional Conditions	21	33.87
Unfavourable Opinion	2	3.23
Provisional Opinion	30	48.39
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	26	41.94
Further Information Favourable Opinion with Additional Conditions	3	4.84
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	9	14.52
Favourable Opinion with Additional Conditions	20	32.26
Unfavourable Opinion	2	3.23
Provisional Opinion	2	3.23
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: Applications assigned to a proportionate review sub-committee within the reporting period:

Total Applications Reviewed	30
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Table 6: Decisions given at proportionate review sub-committee meetings held within the reporting period:

Decisions taken at proportionate review sub-committee meetings	Number	%
Favourable Opinion with Standard Conditions	11	36.67
Favourable Opinion with Additional Conditions	2	6.67
No Opinion transfer to full committee for review	8	26.67
Provisional Opinion	8	26.67
Unfavourable Opinion	1	3.33
Total	30	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.55
Number of applications for full ethical review over 60 days	2
Number of applications over 60 days as a % of total	3.28%
Number of days taken to final decision - average	33
Number of days taken to final decision - mode	23
Number of SSAs (non-Phase 1) reviewed	26
Number of applications for SSA review over 25 days	7
Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)	26.9%
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	126
Number of substantial amendments over 35 days	2
Number of substantial amendments over 35 days as a % of total substantial amendments	1.6%
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	4
Number of modified amendments over 14 days	1
Number of modified amendments over 14 days as a % of total modified amendments	25.0%
Number of proportionate review applications for ethical review over 14 days	4
Number of proportionate review applications over 14 days as a % of total	18.2%

Table 8: 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
13/LO/0382	inCASA v1.0	33
13/LO/0485	CT327 Phase IIb Atopic Dermatitis Study	42
13/LO/0687	The accounts of women offenders with a dual diagnosis	20
13/LO/0689	A study of the impact of Fallopian tube pathology	34
13/LO/0705	A case study exploring the provision of maternal high dependency care	42
13/LO/0716	CL3-78989-005. EYEGUARD-A study	44
13/LO/0751	STudying Autism and ADHD Risk in Siblings (STAARS)	27
13/LO/0839	The psychological impact of first permanent molar extraction	13
13/LO/0929	Involving people with dementia in systematic reviews	23
13/LO/0986	A Phase 1/2a study of Oral TSR-011 in Solid Tumors and Lymphomas	42
13/LO/1086	Neurocognitive decline following treatment of aortic stenosis	42
13/LO/1089	FREELUNG v4.0	50
13/LO/1092	Delayed HIV testing in HIV-positive sub-Saharan Africans.	44
13/LO/1140	Longitudinal Quality of Life in Multiple Myeloma	35
13/LO/1306	Migration and Health: Latin American men selling sex in London	36
13/LO/1336	Phase 3 Study of Solifenacin Succinate and Mirabegron SYNERGY	31
13/LO/1340	Defining a gold standard for ischaemia	48
13/LO/1368	Circulating vitamin D and adipose tissue inflammation	34
13/LO/1371	Families' experiences of dementia	14
13/LO/1447	iPSC in Inherited Cardiac Disease	28
13/LO/1524	0117 Phase 3 study of tenofovir alafenamide vs placebo in HIV-1 adults	35
13/LO/1705	Epilepsy in infancy	30
13/LO/1706	Peri-operative psychology and post-operative pain study (4P)V12.1	17
13/LO/1786	Millennium Cohort Study Sixth Sweep - Pilot Survey	48
13/LO/1869	The Culture of TYA Care across Five Principal Treatment Centres	34
14/LO/0091	Profile and management of Hidradenitis Suppurativa (HS)	68
14/LO/0092	OTX015_104	32
14/LO/0103	ComPAKT: A Phase I trial of olaparib in combination with AZD5363	40
14/LO/0170	British Autism Study of Infant Siblings: 7-year Follow-up (BASIS-7) v1	78

14/LO/0284	Patients' management of lifestyle change in coronary heart disease	11
14/LO/0308	Serum Archive for Emerging Zoonoses (SAfEZ).	51
14/LO/0456	Physical activity levels of rural dwelling older adults V1	10
14/LO/0511	CBT for Insomnia: exploring mode of delivery and sleep outcomes v1	58

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/LO/1642	Interpersonal Model of OCD- Version 1	56
14/LO/0187	Phase I/II study in advanced solid tumours or multiple myeloma TAS-120	34
08/H0718/54+5	Queen Square Brain Bank for Neurological Disorders (QSBB) and NeuroRes	27

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/0487	Computerised self-help for vaginismus	23
13/LO/0638	Impact of using social media to increase patient information provision	8
13/LO/0711	Feasibility study to measure Airway Clearance Technique	22
13/LO/0843	Assessment of toe flexor tendon dysfunction after flat foot surgery	9
13/LO/0846	Smoothelin & Vimentin in Transurethral Resection Bladder Tumours V1	9
13/LO/1026	Addressing educational needs in parents of children with food allergy	8
13/LO/1030	POSSUM in vascular surgery study	14
13/LO/1031	play@home reach evaluation	7
13/LO/1033	NICS-2. Screen and non-screen cancers and biological differences	3
13/LO/1088	Magnetic resonance imaging and cerebrovascular disease: POPPY substudy	36
13/LO/1148	SPIRIT 3 - study to evaluate best use of TKIs in chronic phase CML	28
13/LO/1195	Optimisation of Classification scheme & Local Treatment of Uveitis. v1	14
13/LO/1200	Evaluation of self-efficacy on physiotherapy after knee replacement.	18
13/LO/1203	Urinary markers for food high in unsaturated fat.	7
13/LO/1766	EMR 100070-001: Phase I study of MSB0010718C in solid tumors	30
13/LO/1815	Preventable Incidents, Survival and Mortality Study 2 (PRISM2)	30
14/LO/0096	Longitudinal Study of Young People in England (LSYPE)	16

14/LO/0097	National Child Development Study	16
14/LO/0098	Intergenerational & lifecourse influences on health & mortality	16
14/LO/0282	Causes of stillbirth in women of advanced maternal age	12

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/LO/0453	P08034 (MK3034-043): Efficacy & Safety study of Boc/PR in children wit	23
13/LO/0468	Self-Monitoring of Glucose levels in Type 1 and Type 2 Diabetes.	23
13/LO/0510	Sebum excretion in neonates of women with polycystic ovary syndrome.	23
13/LO/0717	CL3-78989-006. EYEGUARD-C study	20
13/LO/0756	Visual perception and habilitational strategies in CVI. Version 1	23
13/LO/0925	Investigating Brown Adipose Tissue Activation in Humans - Version 1	29
13/LO/0928	Body weight, bile salts, bacteria, and bowel inflammation	33
13/LO/1076	The BodyBasics Study	27
13/LO/1098	When cure is not likely	24
13/LO/1159	Post-hospitalisation nutritional support and gait speed in COPD	25
13/LO/1160	Is the 4MGS a useful outcome measure post-PPCI ?	25
13/LO/1161	Is gait speed and sarcopenia prognostic in chronic respiratory disease	25
13/LO/1342	Study of safety and efficacy in adult BRAF mutant melanoma patients	30
13/LO/1547	B-cell subsets of rheumatology patients on Rituximab therapy (Version 1)	8
13/LO/1615	EMPATHY-P	26
13/LO/1621	Immunity and Ageing	26
13/LO/1724	Study of MEDI4736 in Subjects with Melanoma	30
14/LO/0250	Human ex vivo lung perfusion research consortium UK (HELP RCUK)	21
14/LO/0322	Comparative study between HemoSep and conventional cell salvage	26
14/LO/0371	1970 British Cohort Study	27
14/LO/0401	IPTG-01: A new skin cream for impetigo	27
14/LO/0449	'24/7' Care for children in the Community	6

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/LO/1360	BP28947 - Downs Syndrome Screening protocol for study BP27832	50
13/LO/1803	Effectiveness of topical anaesthesia vs placebo for dental injections	30

14/LO/0281	Re-referrals to IAPT service	11
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Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
14/LO/0364	IL-10 Axis in paediatric IBD	N/A
14/LO/0460	Ovarian cancer: response to chemotherapy using functional CT version 1	N/A
14/LO/0462	Pepsin, Bile Acids as biomarkers of microaspiration in fIIPs v1	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
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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 9: Items exceeding timelines:

Full applications for ethical review over 60 day timeline		
REC Reference	Application Short Title	Number of Days on Clock
14/LO/0091	Profile and management of Hidradenitis Suppurativa (HS)	68
14/LO/0170	British Autism Study of Infant Siblings: 7-year Follow-up (BASIS-7) v1	78

Proportionate review applications for ethical review over 14 days timeline		
REC Reference	Application Short Title	Number of Days on Clock
13/LO/1200	Evaluation of self-efficacy on physiotherapy after knee replacement.	18
13/LO/1368	Circulating vitamin D and adipose tissue inflammation	34
13/LO/1706	Peri-operative psychology and post-operative pain study (4P)V12.1	17
13/LO/1869	The Culture of TYA Care across Five Principal Treatment Centres	34

SSAs (non Phase 1) over 25 days timeline		
REC Reference	Application Short Title	Number of Days on Clock
13/LO/1266	Idelalisib in Combination with Rituximab for Previously Treated iNHL	26
13/LO/1267	Idelalisib + Bendamustine + Rituximab for Previously Treated iNHL	26
13/LO/1602	Study of the Safety and Efficacy of Botox® for the Treatment of PE	35
13/LO/1604	Phase 2/3 study of nab-paclitaxel in metastatic breast cancer	26
14/LO/0391	CT327 Phase IIb Atopic Dermatitis Study	28
14/LO/0393	CT327 Phase IIb Atopic Dermatitis Study	28
14/LO/0394	CT327 Phase IIb Atopic Dermatitis Study	28

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
13/LO/0485/AM18	CT327 Phase IIb Atopic Dermatitis Study	Substantial Amendment 8- Change of CI- Dr Hakim	61

13/LO/0716/AM02	CL3-78989-005. EYEGUARD-A study	Substantial Amendment 2-Protocol Amendment	38
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Modified Amendments over 14 day timeline

Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
10/H0718/10/AM02/1	Age associated factors affecting satellite cell behaviour in culture-1	Modified Amendment	21

Section 30 application over 60 day timeline

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