

National Research Ethics
Service


Health Research Authority

NRES Committee London - Fulham

Annual Report

01 April 2013 – 31 March 2014

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee London - Fulham
Type of REC:	Recognised
Type of Flag:	CTIMP, IRB, RTB
Chair:	Dr Charles Mackworth-Young
Vice-Chair:	Dr Frank Miskelly
Alternate Vice-Chair:	The Rev'd Nigel Griffin
REC Manager:	Miss Shehnaz Ishaq
REC Assistant:	Miss Diane Catterall
Committee Address:	HRA NRES Centre Manchester Barlow House 3rd Floor, 4 Minshull Street Manchester M1 3DZ
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Chair's overview of the past year:

During the year the committee lost four of its members – two expert, two lay plus. Initially we were not allowed to recruit more members, but permission has now been granted. This will be particularly valuable in replacing the expert member who is a radiologist.

The committee has continued to work well as a group, and has been stimulated by the variety of studies submitted.

The committee has been excellently supported by Miss Shehnaz Ishaq, whose administrative skills are first rate. She has recently accepted promotion within NRES. This is richly deserved. She will be much missed by the committee.

NRES Committee London - Fulham Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mrs Marian Cohen	Retired Lawyer	Lay Plus	15/07/2010	18/04/2013
Prof Alison Crombie	Anthropologist Nurse	Expert	18/05/2005	13/09/2013
Dr Kanagasabai Ganeshaguru	Retired Scientist	Lay	01/06/2006	
The Rev'd Nigel Griffin	Parish Priest	Lay Plus	01/06/2006	
Dr Shaun Griffin	Director of Communications and Public Affairs	Expert	01/11/2008	
Dr Akil Jackson	Physician	Expert	01/10/2007	
Mr David Leonard	Pharmacist	Expert	28/04/2005	
Dr Charles Mackworth-Young	Physician (Chairman)	Expert	01/01/2005	
Dr Colin Michie	Paediatrician	Expert	27/03/2006	
Dr Frank Miskelly	Physician (Vice-Chairman)	Expert	01/04/2005	
Dr Shirlony Morgan	Psychiatrist	Expert	16/11/2009	
Professor Sandra Oliver	Retired Organisational Psychologist	Lay Plus	16/05/2011	03/10/2013
Lady Alexandra Roche	Lay Member	Lay Plus	23/02/2005	
Mrs Gillian Sichau	Occupational Therapist	Expert	01/07/2010	
Mrs Katie Wilkinson	Clinical Trials Centre Manager	Lay	09/11/2007	
Mrs Marney Williams	Lay Member	Lay Plus	11/06/2013	
Dr Ruth Williamson	Radiologist	Expert	07/05/2009	01/04/2014

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended

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

Name	Declaration of Interest	Date
The Rev'd Nigel Griffin	None	24/12/2013
Dr Colin Michie	Owns company which sponsors PhD studentships at the University of Oxford. Member of Research Achievement Panel at GOSH. Expert member of NICE panels x2 (Public Health)	24/12/2013
Lady Alexandra Roche	Director of Redhead Properties; undertakes ethics of Future Health	24/12/2013
Dr Charles Mackworth-Young	Consultant Physician Charing Cross Hospital and Chelsea and Westminster Hospital. Medical Director, King Edward VII Hospital. Chairman of Imperial College Peer Review Committee	24/12/2013
Mrs Marney Williams	The Stroke Association: Membership of the Committee that plans the UK Stroke Forum (Stroke MDT conference) Member Lay Panel of NIHR Stroke Research Network (SRN). Member of SRN Primary Care Clinical Studies Group and associated writing groups (3). Lay Member of an Imperial NHS Trust/ Health Foundation research study forum	24/12/2013
Mrs Katie Wilkinson	Operations Manager for the Clinical Research Facility at St George's University	24/12/2013
Mrs Gillian Sichau	None	24/12/2013
Dr Frank Miskelly	None	31/01/2014
Dr Shirlony Morgan	None	31/01/2014
Dr Shaun Griffin	Exec Director Health Research Authority; Director Human Tissue Authority	31/01/2014
Dr Kanagasabai Ganeshaguru	None	31/01/2014
Dr Akil Jackson	Employee of Chelsea & Westminster Hospital seconded to St Stephens Aids Trust Research Charity	31/01/2014
Mr David Leonard	None	27/02/2014
Dr Ruth Williamson	Peer reviewer for British Journal of Radiology Peer reviewer for European Journal of Radiology	24/12/2013

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

Month	Date	Number of Members Present at Meeting
April	15/04/2013	11
May	20/05/2013	14
June	10/06/2013	7
July	15/07/2013	12
September	16/09/2013	11
October	21/10/2013	11
November	18/11/2013	12
December	16/12/2013	9
January	20/01/2014	9
February	17/02/2014	11
March	17/03/2014	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
May	20/05/2013	3
June	10/06/2013	3
July	15/07/2013	3
September	16/09/2013	3
October	21/10/2013	3
November	18/11/2013	3
December	16/12/2013	3
January	20/01/2014	3
February	17/02/2014	3
March	17/03/2014	3

10 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 Charles Mackworth-Young	11
Dr Kanagasabai Ganeshaguru	9
Lady Alexandra Roche	9
Mr David Leonard	9
Mrs Gillian Sichau	8
Dr Ruth Williamson	8
Dr Akil Jackson	8
Dr Frank Miskelly	8
The Rev'd Nigel Griffin	8
Dr Shirlony Morgan	7
Mrs Katie Wilkinson	7
Dr Shaun Griffin	6
Mrs Marney Williams	6
Dr Colin Michie	5
Professor Sandra Oliver	4
Prof Alison Crombie	3
Mrs Marian Cohen	1

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 Charles Mackworth-Young	5
Lady Alexandra Roche	5
Dr Kanagasabai Ganeshaguru	4
Dr Frank Miskelly	3
The Rev'd Nigel Griffin	3
Dr Ruth Williamson	2
Dr Shaun Griffin	2
Dr Shirlony Morgan	1
Dr Akil Jackson	1
Dr Colin Michie	1
Mr David Leonard	1
Mrs Gillian Sichau	1
Mrs Katie Wilkinson	1

Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
The Rev'd Nigel Griffin	09/06/2013 - 14/06/2013	International Colloquium: Supporting & caring for persons with intellectual & developmental disabilities: Ethical considerations and practical recommendations
The Rev'd Nigel Griffin	10/09/2013 - 10/09/2013	Chair's training, HRA
Dr Charles Mackworth-Young	10/05/2013 - 10/05/2013	Equality & Diversity, HRA/NRES
Dr Ruth Williamson	05/11/2013 - 05/11/2013	Training - Human Tissue Act (Advanced Training in the use of Tissues in Research), HRA
Lady Alexandra Roche	23/05/2013 - 23/05/2013	Equality & Diversity, HRA
Mrs Katie Wilkinson	02/10/2013 - 02/10/2013	Researcher Training Day, HRA
Mrs Marney Williams	18/09/2013 - 18/09/2013	Induction, HRA
Dr Frank Miskelly	12/07/2013 - 12/07/2013	Equality & Diversity, Equality & Diversity
Dr Frank Miskelly	13/11/2013 - 13/11/2013	Personal Data in Research - A workshop, HRA
Mr David Leonard	19/07/2013 - 19/07/2013	Equality & Diversity, HRA
Dr Akil Jackson	20/11/2013 - 20/11/2013	National Members Training Day, HRA
Mr David Leonard	20/11/2013 - 20/11/2013	Lunchtime workshop on informed consent, Joint Research Office - Imperial College London
Mr David Leonard	06/02/2014 - 06/02/2014	Lunchtime workshop on monitoring and study documentation, Joint Research Office - Imperial College London
Mrs Gillian Sichau	31/05/2013 - 31/05/2013	Equality & Diversity, HRA
The Rev'd Nigel Griffin	09/05/2013 - 09/05/2013	Equality & Diversity, HRA
Mrs Gillian Sichau	04/12/2013 - 04/12/2013	Human Tissue Act (Use of samples in Research) An Introductory Level, HRA
Mrs Marney Williams	29/09/2013 - 29/09/2013	Equality & Diversity, HRA (E-Learning)
Dr Kanagasabai Ganeshaguru	27/09/2013 - 27/09/2013	Equality & Diversity, HRA - Online e-learning
Dr Kanagasabai Ganeshaguru	13/06/2013 - 13/06/2013	GCP & Regulatory requirements for Clinical Trials: A Refresher Session , T Symons Associates Ltd
Mrs Katie Wilkinson	05/11/2013 - 05/11/2013	Equality & Diversity, Employers
Professor Sandra Oliver	01/10/2013 - 01/10/2013	Attended ethics clinic at imperial college London
Dr Ruth Williamson	21/10/2013 - 21/10/2013	Equality & Diversity, Imperial

		College
Dr Colin Michie	01/04/2013 - 01/04/2013	Equality & Diversity, Trust
Dr Colin Michie	07/11/2013 - 07/11/2013	RCPCH: Paediatric Education Special Interest Group, Trust
Dr Colin Michie	20/05/2013 - 20/05/2013	Shared Ethical Debate 13 - CTIMP“ Is Liceko ® more effective than Lyclear against head lice?”, HRA
Dr Kanagasabai Ganeshaguru	19/02/2014 - 19/02/2014	Reviewing CTIMPs, HRA
Mrs Katie Wilkinson	14/11/2013 - 14/11/2013	Good Clinical Practice, Employers
Dr Shirlony Morgan	25/03/2014 - 25/03/2014	Research involving the disadvantaged and vulnerable, HRA
Lady Alexandra Roche	13/02/2014 - 13/02/2014	Assessing the Consequences (benefits and harms), HRA
Mrs Marney Williams	13/02/2014 - 13/02/2014	Assessing the consequences (benefits and harms) of Research, 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:

Applications for full ethical review – Study Type	Number	%
Clinical Trial of Investigational Medicinal Product	18	29.03
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	1	1.61
Research Database	0	0.00
Others	43	69.35
Total Applications Reviewed	62	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	7
Number of studies withdrawn prior to the meeting	9
Number of student applications reviewed	16
Number of paediatric applications reviewed	6
Number of device applications reviewed	0
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	6	9.68
Favourable Opinion with Additional Conditions	9	14.52
Unfavourable Opinion	3	4.83
Provisional Opinion	44	70.97
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	41	66.13
Further Information Favourable Opinion with Additional Conditions	2	3.23
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	6	9.67
Favourable Opinion with Additional Conditions	9	14.52
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	1	1.61
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	16
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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	7	43.75
Favourable Opinion with Additional Conditions	5	31.25
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	4	25.00
Unfavourable Opinion	0	0.00
Total	16	100

Table 7: 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	22.44
Number of days taken to final decision - mode	22
Number of SSAs (non-Phase 1) reviewed	6
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	140
Number of substantial amendments over 35 days	0
Number of substantial amendments over 35 days as a % of total substantial amendments	0.0%
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	0
Number of modified amendments over 14 days as a % of total modified amendments	0.0%
Number of proportionate review applications for ethical review over 14 days	0
Number of proportionate review applications over 14 days as a % of total	0.0%

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/0406	HepFree 2	22
13/LO/0426	Use of naso-pulmonary flow-volume loops to assess nasal obstruction	41
13/LO/0478	Blood pressure, inflammation and cognition in Alzheimer's disease	22
13/LO/0479	Ischaemia-reperfusion injury in the pathogenesis of muscle wasting	24
13/LO/0480	Do healthy hearts normally function at the peak of the Starling curve?	27
13/LO/0535	A Phase 3 Study of Pacritinib in Patients with Myelofibrosis	22
13/LO/0671	Long-term extension study to evaluate safety and efficacy of DAC HYP	30
13/LO/0672	Shivering following neuraxial blockade in obstetric patients	39
13/LO/0706	UK Multicentre Study of Children with Opsoclonus Myoclonus Syndrome v1	29
13/LO/0768	Increasing participation in everyday life	22
13/LO/0814	Buprenorphine Research into Injectable Opioids BRIO	19
13/LO/0978	BME Parents/Carer Experiences of Engaging in Multisystemic Therapy	22
13/LO/0984	A study of practices, knowledges and experiences of HIV treatment.	41
13/LO/1007	A randomised trial of follow up timing in otitis externa management	22
13/LO/1128	Actigraphy via Smartphone	6
13/LO/1283	TAMIGA - Bevacizumab GBM Study	35
13/LO/1305	Wave intensity analysis in the pulmonary artery	26
13/LO/1408	Clinical and cost effectiveness in replacing ACT with FACT	38
13/LO/1479	ASPRES (Version 1)	26
13/LO/1502	DIPSS: Development of a high blood pressure management website	13
13/LO/1517	Dolomites	27
13/LO/1566	A Pilot Study - Does Bowel Preparation Affect the microbiome? v1	33
13/LO/1573	Intraoperative Laparoscopic NIR ICG Anastomotic Perfusion Assessment	20
13/LO/1574	An evaluation of genetics and epigenetics in the aetiology of IUGR 1.0	48
13/LO/1687	ARCADIA. Association of ncRNAs with CAD and type 2 diabetes	39
13/LO/1699	The impact of cancer treatment on an individual's ability to work.	43
13/LO/1703	Can we see how pain killers work using brain imaging? Version 1	21
13/LO/1764	Viscoseal and PDGF after Knee Arthroscopy	21
13/LO/1793	Impact of mode of delivery on infant health	23

13/LO/1831	Human mononuclear cell responses to nanoparticles and ions	22
13/LO/1867	Role of bile salt hydrolases in C. difficile infection	28
14/LO/0036	Phase 3 Blinatumomab in Philadelphia negative B-precursor ALL	24
14/LO/0037	Blinatumomab in adult patients with Acute Lymphoblastic Leukaemia	24
14/LO/0059	Developmental Coordination Disorder: A brain imaging study v1	28
14/LO/0099	Impulsive Behaviours; Causal Attributions, Guilt and Shame in BPD.	25
14/LO/0130	Temperature Controlled Laminar Airflow in severe paediatric eczema	19
14/LO/0135	Radium-223 in subjects with bone predominant metastatic CRPC.	30
14/LO/0191	Effect of Aquacel Ag+ Extra Dressing on Wound Bacterial Biofilms	11
14/LO/0258	Ambulatory oxygen and health status in patients with lung fibrosis	19
14/LO/0304	Evaluation of ECSWT treatment for Tendinopathy & Plantar Fasciosis V.2	25
14/LO/0329	Localisation of tinnitus-related activity	7
14/LO/0362	MERIT-1	18
14/LO/0385	Development of a tool to assess OHQoL in CCU	17

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/LO/0419	B3281004 - Pfizer Extension Study	22
13/LO/0661	Insight and metacognition in neuropsychiatric disorders	30

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/0777	The potential of telehealth in managing diabetes care "closer to home"	18
13/LO/1005	Visual outcome of retinal oedema treatment v1.0	41
13/LO/1277	Study of ARN-509 in Prostate Cancer	21
13/LO/1486	Histological assessment of radiotherapy injury to anal canal, version 1	9
13/LO/1577	Assessment of the severity of personality disorder	32
13/LO/1672	CSF infection following EVD placement	8
13/LO/1673	The relationship between BMI and CSF opening pressure	8
13/LO/1839	Cadaveric Testing of a Novel Total Shoulder Replacement (TSR)	8

13/LO/1934	Anorexia nervosa - exploring patient differences at initial assessment	8
14/LO/0345	Generation of human induced pluripotent stem cell-lines by CGaP (WTSI)	7
14/LO/0369	Ripple mapping identifies arrhythmogenic conduction channels	17
14/LO/0507	Patient perceptions of multiple rib fracture rehabilitation	12

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/LO/0763	Psychological Change in Looked After Children	18
13/LO/0771	Intrapartum epidural fixation methods: a randomised controlled trial	18
13/LO/0791	Designing a tissue engineered bone to bone ligament replacement	7
13/LO/0798	A qualitative appraisal of visiting within adult critical care units.	8
13/LO/0940	Exploring the process of change using single case design	8
13/LO/1231	Creative Practice as Mutual Recovery	21
13/LO/1495	Clostridium difficile in infants & children (CDIC) - Version 1.0	12
13/LO/1719	ivabradine & vascular function in patients with cardiovascular risk	21
13/LO/1919	Environment, power, distress and IAPT: A discourse analysis.	21
14/LO/0072	GENPROS	22
14/LO/0108	Southall And Brent REvisited (SABRE) - SABRE V3	18
14/LO/0163	How many patients with HCM meet the criteria for S/C ICD implant	38
14/LO/0169	Investigating early help-seeking for non-emergency cardiac symptoms	7
14/LO/0419	Recall/Reoffending Outcomes for MDOs Version 1	22
08/H0712/34+5	The Human Developmental Biology Resource	22

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/LO/1039	Study of ARN-509 in Prostate Cancer	24
13/LO/1701	The effect of nutrition on osteoarthritis symptoms and bio-markers.	34
13/LO/1715	A Clinical Trial to Test if the Drug OPC-108459 is Safe and Effective	23

Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
14/LO/0093	R2D2 - C-3PO Study	N/A

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
14/LO/0212	Influenza A/Wisconsin/67/2005 (H3N2) Characterisation Study	N/A
Withdrawn after the meeting		
REC Reference	Application Short Title	Number of Days on Clock
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 9: 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
Modified Amendments over 14 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
Section 30 application over 60 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock