

# NRES Committee London - Camberwell St Giles

**Annual Report** 

01 April 2013 - 31 March 2014

#### Part 1 - Committee Membership and Training

Name of REC: NRES Committee London - Camberwell St Giles

Type of REC: Authorised REC

Type of Flag: Qualitative Research

Research involving adults lacking capacity to consent

Chair: Mr John Richardson

Vice-Chair: Mr Evan Stone QC

Alternate Vice-Chair: Ms Sally Gordon Boyd

**REC Manager:** 01/04/2013 to 01/10/2013 – Ms Christine Hobson

01/10/2013 to Present - Mr Thomas Fairman

PRSC REC Manager: 01/04/2013 to 01/10/2013 – Ms Christine Hobson

01/10/2013 to Present - Mr Thomas Fairman

Assistant Co-ordinator: 01/10/2013 to Present – Miss Elizabeth Hearn

Committee Address: Bristol Research Ethics Centre

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

Having completed three years as Chair of Camberwell St Giles REC, I continue to be grateful for the privilege of being involved in its work.

First, it is good to meet and correspond with such a fine group of members who attend regularly and use their talents generously. I was sorry when two of these, Professor Veena Kumari and Professor Nelarine Cornelius, stepped down after long periods of service but Dr Alison McRae and Dr Nick Nicolaou joined us and quickly made their contribution. Debates are informed and lively and I trust that our decisions are careful, clear and fair.

Second, we have had more stability in administrative support. I was concerned when Christine Hobson, yet another able Co-ordinator, decided that her future was in Australia but the Bristol office, of which I must speak highly, initially ensured temporary help then appointed Tom Fairman as our REC Manager. I am immensely grateful to Tom, who, with assistance from Elizabeth Hearn, has shown remarkable knowledge and commitment. Minutes are both accurate and sensitive to the tone of our discussions, replies to gueries are prompt, and I am proud that we offer an understanding and efficient service to those who come to us for advice or review.

Which prompts a third reason for gratitude, namely the enthusiasm and knowledge of researchers and the quality of the research they present. We meet a wide range of people, from students carrying out their first project to experienced professors, well-known in their field. I hope we treat them all with the same rigour, fairness and courtesy and I have many good memories of their willingness to engage with us. Some researchers have been known to say that they are pleasantly surprised' by the committee, which I take to be a compliment!

Fourth, though they are unseen by us personally, I am grateful for the willingness of participants to be involved in research. It is our responsibility to protect their welfare, safety, rights and dignity and I trust that we serve them well.

We will consider carefully the facts and figures in this annual report, building on our achievements and dealing with those things that need our attention. I look forward to my fourth year with confidence.

### NRES Committee London - Camberwell St Giles Membership:

Name	Occupation	Expert or	Da	tes
	-	Lay	Appointed	Resigned
Dr Ana Bajo	Research Psychologist	Expert	07/03/2013	
Mrs Jennifer Bostock	Philosopher of Psychiatry	Lay	01/12/2008	
Prof Nelarine Cornelius	Prof. of Human Resource Management & Organisation Studies	Lay Plus	01/05/2009	10/11/2013
Ms Biddy Gillman	Retired Biology Teacher/ Head of year 12	Lay Plus	11/03/2013	
Ms Sally Gordon Boyd	Medical Ethicist	Lay	31/05/2011	
Ms Alison Higgs	Lecturer - Social Work, Faculty of HSC	Lay Plus	31/03/2011	
Professor Veena Kumari	Professor of Experimental Psychology	Expert	16/12/2009	01/09/2013
Dr Alison Macrae	Solicitor	Expert	07/06/2013	
Dr Nick Nicolaou	Consultant Paediatric Orthopaedic Surgeon	Expert	22/06/2013	
Mr John Richardson	Retired Director of COREC: Ecumenical Officer for Churches Together in South London	Lay	25/03/2011	
Mrs Hemawtee Sreeneebus	Clinical Research Nurse	Expert	07/03/2013	
Mr Evan Stone QC	Retired Queen's Counsel	Lay	08/10/2010	
Dr Mark Tanner	Consultant Psychiatrist	Expert	07/02/2013	
Mr James Uwalaka	Development QA Associate	Lay	11/04/2011	
Mr Thomas Walters	Clinical Research Nurse	Expert	20/03/2013	
Mr Jonathan Watkins	Independent Social Worker	Expert	17/08/2005	

### **Co-opted Members**

Name	Occupation	Expert or Lay	Meeting date attended
Ms Julie Lockhart	PPI Representative	Lay Plus	16/08/2014 19/04/2013

### NRES Committee London - Camberwell St Giles: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Mr Thomas Walters	Currently work as a band 7 research nurse for the biomedical research centre (BRC) faculty, coordinating	06/07/2013
	translational research (specifically on imaging, co-	
	diagnostics and biomarkers research). The BRC is part	
	of Guys and St Thomas' Foundation Trust and Kings	
Mr John Richardson	College London None	28/01/2014
Dr Ana Bajo	None	28/01/2014
Mr Thomas Walters	None	28/01/2014
Ms Biddy Gillman	None	28/01/2014
Ms Sally Gordon Boyd	Shareholdings in Astra Zeneca and GSK	28/01/2014
Dr Nick Nicolaou	Member of the British Orthopaedic Association,	28/01/2014
	European Paediatric Orthopaedic Society, member	
	of the British Society for Children's Orthopaedics,	
	member of the British Limb reconstruction society.	
	Lead for research, Orthopaedic Directorate,	
	Maidstone and Tunbridge Wells NHS Trust	
Mr Evan Stone QC	Shareholdings in Astra Zeneca	28/01/2014
Mrs Jennifer Bostock	Honorary Contracts with KCL, University of Oxford	28/01/2014
	and University of Kent Lay Member of School of	
	Public Health Research; The Quality and	
	Outcomes of Person Centred Care Policy Research Unit (QORU); The centre for Diet and	
	Activity Research (CEDAR) (University of	
	Cambridge)National Institute of Health Research -	
	Funding Committee lay member Research Design	
	Service PPI Consultant; Mental Health Research	
	Network – Trainer I National Institute of Care	
	Excellence lay Member	
Mr Jonathan Watkins	Works as a consultant with Healthprom.org, The	30/01/2014
	Coram Children's Legal centre and Oxford Policy	
	Development and may be involved in research in	
	developing and transitional countries through this.	
	Supervise social work students at London Met	
	University for their master's dissertations. These may need REC review.	
Mrs Hemawtee Sreeneebus	Work as a clinical research nurse at Guy's and St	28/01/2014
Wild Fielliawiee Orecheebas	Thomas' NHS Trust and are involved in sending	20/01/2014
	applications to ethics committee's and R and	
	DHelps in writing the protocols and information	
	sheets.	
Ms Alison Higgs	Lecturer with the Open University	31/03/2014
Mr James Uwalaka	Novartis – Development Quality Assurance	31/03/2014
	AssociateDirector – O P J U Limited (owner)	
Dr Mark Tanner	None	31/03/2014
Dr Alison Macrae	None	31/03/2014

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

Month	Date	Number of Members Present at Meeting
April	19/04/2013	7
May	17/05/2013	7
June	21/06/2013	11
July	19/07/2013	11
August	16/08/2013	10
October	18/10/2013	10
November	15/11/2013	13
December	13/12/2013	10
January	17/01/2014	7
February	21/02/2014	10
March	21/03/2014	9

<sup>11</sup> 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
July	03/07/2013	3
July	31/07/2013	3
August	28/08/2013	3
October	30/10/2013	4
November	27/11/2013	3
December	23/12/2013	4
February	03/02/2014	5
March	09/03/2014	5

<sup>8</sup> 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
Mr John Richardson	11
Ms Sally Gordon Boyd	11
Ms Biddy Gillman	10
Dr Ana Bajo	8
Mr Evan Stone QC	7
Mr James Uwalaka	7
Mr Thomas Walters	7
Mrs Hemawtee Sreeneebus	7
Dr Mark Tanner	6
Dr Nick Nicolaou	5
Mrs Jennifer Bostock	5
Ms Alison Higgs	5
Mr Jonathan Watkins	5
Dr Alison Macrae	5
Professor Veena Kumari	3
Prof Nelarine Cornelius	1

#### Number of inquorate meetings held: 0

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

Name	Number of Meetings Attended
Mr John Richardson	5
Ms Sally Gordon Boyd	5
Mr Evan Stone QC	3
Mrs Jennifer Bostock	3
Mr Thomas Walters	3
Dr Alison Macrae	3
Dr Ana Bajo	3
Dr Mark Tanner	2
Mrs Hemawtee Sreeneebus	2
Ms Alison Higgs	1

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

Name of Member	Date	Event(s) attended
Mr Thomas Walters	04/07/2013 - 04/07/2013	Induction, NRES
Mrs Hemawtee Sreeneebus	04/07/2013 - 04/07/2013	Induction, NRES
Ms Sally Gordon Boyd	02/05/2013 - 02/05/2013	Clinical Research in Children, GOSH
Ms Sally Gordon Boyd	26/04/2013 - 26/04/2013	Clinical research now and in the future: Can the UK lead the way?, RSM
Prof Nelarine Cornelius	13/11/2013 - 13/11/2013	Personal Data in Research - A Workshop, NRES
Dr Mark Tanner	04/09/2013 - 04/09/2013	Research Involving Adults Who Lack Capacity (including research in emergency situations), HRA
Ms Biddy Gillman	18/09/2013 - 18/09/2013	Induction, HRA
Dr Alison Macrae	18/09/2013 - 18/09/2013	Induction, HRA
Mr James Uwalaka	20/11/2013 - 20/11/2013	National Members Training Day, NRES
Mrs Jennifer Bostock	31/01/2014 - 31/01/2014	Attended National Institute of Care Excellence – Public involvement public health/research, NICE
Mrs Jennifer Bostock	21/11/2013 - 21/11/2013	Attended National Institute of Health Research – Health Services and Design Research programme works, NICE
Mrs Jennifer Bostock	15/11/2013 - 15/11/2013	Attended School of public health research (university of Sheffield). Public involvement in research, University of Sheffield
Dr Ana Bajo	03/03/2014 - 03/03/2014	Induction, HRA
Dr Ana Bajo	27/03/2014 - 27/03/2014	Qualitative analysis, HRA
Dr Ana Bajo	17/02/2014 - 17/02/2014	Missing Data analysis, HRA
Mr John Richardson	05/02/2014 - 05/02/2014	NRES Researcher Training Day, Facilitated, HRA
Dr Ana Bajo	17/02/2014 - 17/02/2014	Introduction to missing data analysis, Biomedical Research Centre
Dr Ana Bajo	27/02/2014 - 27/02/2014	Qualitative Data Analysis, Biomedical Research Centre
Dr Ana Bajo	03/03/2014 - 03/03/2014	Induction, HRA
Mr John Richardson	25/03/2014 - 25/03/2014	Training - Research Involving the Disadvantaged and Vulnerable: a Workshop for Researchers and Revie, HRA
Dr Nick Nicolaou	01/03/2014 - 01/03/2014	British Society for Childrens Orthodeadics Meeting, British

	Society for Childrens Orthodeadics
Ms Alison Higgs	Chaired Ethics Interest Group at OU, Open University

#### 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	53	100.00
Total Applications Reviewed	53	100

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

Number of applications made invalid by co-ordinator	8
Number of studies withdrawn prior to the meeting	10
Number of student applications reviewed	22
Number of paediatric applications reviewed	11
Number of device applications reviewed	0
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	1	1.89
Favourable Opinion with Additional Conditions	20	37.74
Unfavourable Opinion	2	3.77
Provisional Opinion	30	56.60
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	53	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	25	47.17
Conditions		
Further Information Favourable Opinion with Additional	5	9.43
Conditions		
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	1.89
Favourable Opinion with Additional Conditions	20	37.74
Unfavourable Opinion	2	3.77
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	53	100

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

Total Applications Reviewed	20

# Table 6: Decisions given at proportionate review sub-committee meetings held within the reporting period:

Decisions taken at proportionate review sub-	Number	%
committee meetings		
Favourable Opinion with Standard Conditions	8	40.00
Favourable Opinion with Additional Conditions	2	10.00
No Opinion transfer to full committee for review	4	20.00
Provisional Opinion	6	30.00
Unfavourable Opinion	0	0.00
Total	20	100

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

Average number of applications reviewed per full meeting	4.82
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	30
Number of days taken to final decision - mode	25
Number of SSAs (non-Phase 1) reviewed	4
Number of applications for SSA review over 25 days	1
Number of applications for SSA review over 25 days as % of	25.0%
all non-Phase 1 (SSAs)	
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	0%
all Phase 1 (SSAs)	
Number of substantial amendments reviewed	54
Number of substantial amendments over 35 days	2
Number of substantial amendments over 35 days as a % of	3.7%
total substantial amendments	
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	0%
total Section 30 applications	
[	
Number of modified amendments reviewed	3
Number of modified amendments over 14 days	0
Number of modified amendments over 14 days as a % of	0.0%
total modified amendments	
	0
Number of proportionate review applications for ethical	0
review over 14 days	0.007
Number of proportionate review applications over 14 days	0.0%
as a % of total	

Table 8: Breakdown of current status of all applications reviewed within the reporting period:

Further Information Favourable Opinion with Standard Conditions		
<b>REC Reference</b>	Application Short Title	Number of Days on Clock
13/LO/0373	Neurocognitive and fMRI Correlates of ADHD in Autism	33
13/LO/0465	Decision Aid for young people who Self-Harm (DASH)	46
13/LO/0481	TGF-beta superfamily signalling in muscle weakness in PAH	52
13/LO/0493	Keeping Well: Online CBT for pregnant women with depressive symptoms	39
13/LO/0651	Biomarker-based exclusion of VAP for improved antibiotic stewardship	44
13/LO/0876	Future-Directed Thinking in First Episode Psychosis	35
13/LO/0891	Probiotics and Gut Health - Version number 1	38
13/LO/1051	Improving cognitive functioning in borderline personality disorder	30
13/LO/1063	Attention processes in social anxiety.	11
13/LO/1153	Experiences of Stigma in Forensic Psychiatric Patients	4
13/LO/1262	Development of high throughput sequencing for MRD analysis in ALL	43
13/LO/1271	Molecular Analysis of Colorectal Cancers and Metastatic Tumours	25
13/LO/1397	Attitudes towards exercise during pregnancy. Version 1.	10
13/LO/1481	MARS 2	29
13/LO/1492	Cognitive Bias Modification Training in Eating Disorders.	29
13/LO/1494	Optimisation of paediatric PM imaging	34
13/LO/1595	CBT vs Standardised Medical Care to treat Dissociative Seizures	40
13/LO/1631	Group Schema Therapy for Borderline Personality Disorder	41
13/LO/1698	What helps children and young people manage their diabetes?	48
13/LO/1737	INvestigation of JEtrea® in patients with Confirmed Vitreoma Traction	10
13/LO/1855	Stakeholders' views and experiences of perinatal mental health care	30
13/LO/1878	Dietary interventions for IBD	34
14/LO/0085	Neuropsychological mediators of stress following discharge from ICU	32
14/LO/0128	The effect of oxytocin on social processing in anorexia nervosa.	25
14/LO/0186	Heart rate variability & n-3 fatty acid status: haemodialysis patients	41
14/LO/0238	Characterisation & Clinical Outcome of Mentally-Disordered Offenders	41
14/LO/0241	Immunity after Yellow Fever vaccination - YETI research	8
14/LO/0325	Brain signatures of resilience and staying well	38
14/LO/0442	Influence of iron therapy on platelet count and function in IBD	9

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
13/LO/1016	Anti-psychotics and global coagulation assays	46
13/LO/1370	Version 1.0 - Investigating neonatal opiate abstinence syndrome (NAS).	82
13/LO/1733	SO-FIT	14
14/LO/0084	MEANDER	30
14/LO/0112	Living Together with Dementia: a Psychosocial Intervention for Couples	26
14/LO/0246	ROLCOL 1.0	12
14/LO/0501	SHARED study v1	28

<b>Further Information</b>	on Unfavourable Opinion	
<b>REC Reference</b>	Application Short Title	Number of Days on Clock

Favourable Opinion with Standard Conditions		
REC Reference	Application Short Title	Number of Days on Clock
13/LO/0466	Designing a mobile phone intervention to improve adherence -V1	26
13/LO/1208	DAS Calculation-Comparing patient Vs HCP assessment using Tablet PC v1	4
13/LO/1209	Image alignment of tomographic prone and supine breast images V1.3	8
13/LO/1213	Acceptance and cost effectiveness of two treatments in primary teeth	7
13/LO/1894	Genes and Proteins in Neuromuscular Disorders	4
13/LO/1896	Abundances of enzyme and transporters in kidney tissue v1	7
13/LO/1945	Atosiban and magnesium sulphate for preterm labour	8
14/LO/0248	ALX-HPP-502, non-interventional study in patients with Juvenile HPP	9
14/LO/0459	Kinetics of endocan after cardiac surgery	9
13/LO/1370	Version 1.0 - Investigating neonatal opiate abstinence syndrome (NAS).	24

Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
13/LO/0690	Computerised Interventions for Thinking and Anxiety in Delusions	27
13/LO/0709	Proteomics of Silent Cerebral Infarction in SCA (PoSCIS)	35
13/LO/0877	Experiences of negative and positive imagery in early psychosis v1	28
13/LO/0893	Genetic mechanisms in desmoid formation - Version 1	37

42/10/4007	The gradibility of ages formulations for values manufa	24
13/LO/1027	The credibility of case formulations for young people	24
13/LO/1053	Babies with Patau and Edwards syndrome in neonatal units	24
13/LO/1054	The population impact of screening for Down syndrome	24
13/LO/1072	An exploration of patient experiences of bariatric surgery	8
13/LO/1094	ADDRESS-PMR: The Diagnostic Accuracy of Ultrasound in Suspected PMR	24
13/LO/1101	Cognitive deficit & psychiatric co-morbidity and spatial navigation	21
13/LO/1411	Influence of pain & disability on individual HADS item responses	8
13/LO/1445	Social anxiety in autism-spectrum disorders	27
13/LO/1548	Worster Drought Syndrome: Investigation of Genetic Factors: Version 1	27
13/LO/1697	Development of gene therapy for XLP	27
13/LO/1810	Perceptions of Schizophrenia in Forensic and General Adult Settings	25
13/LO/1876	Response assessment in head & neck cancer using multi-parametric MRI	25
14/LO/0068	Transdifferentiation of human muscle fibroblasts	25
14/LO/0075	Well-being in pregnancy	25
14/LO/0127	Thinking about drinking: preventing dehydration in care homes	25
14/LO/0293	Validation of a UK on-line 24h dietary recall tool	25
14/LO/0336	Trauma and psychosis: the role of cognitive processes	25
14/LO/0410	An interview study about a weight management group	25

Unfavourable Opinion		
REC Reference	Application Short Title	Number of Days on Clock
13/LO/1689	Sero-discordant relationship (s) where one partner is HIV positive	26
14/LO/0441	Evaluating cannabinoid-1 (CB1) receptor availability in schizophrenia	4

<b>Provisional Opini</b>	on	
<b>REC Reference</b>	Application Short Title	Number of Days on Clock

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

Further information response not complete		
<b>REC Reference</b>	Application Short Title	Number of Days on Clock

Withdrawn after the meeting			
<b>REC Reference</b>	Application Short Title	Number of Days on Clock	
<b>Invalid Applicatio</b>	n en		
<b>REC Reference</b>	Application Short Title	Number of Days on Clock	
<b>No Opinion Pendi</b>	ing Consultation with Referee		
<b>REC Reference</b>	Application Short Title	Number of Days on Clock	
Not Requiring Review by NHS REC			
<b>REC Reference</b>	Application Short Title	Number of Days on Clock	

### Table 9: Items exceeding timelines:

**REC Reference** 

Full applications for ethical review over 60 day timeline				
REC Reference	Application Short Title	Number of Days on Clock		
Proportionate rev	view applications for ethical review over 14 days timeline			
<b>REC Reference</b>	Application Short Title	Number of Days on Clock		
		-		
SSAs (non Phase 1) over 25 days timeline				
<b>REC Reference</b>	Application Short Title	Number of Days on Clock		
13/LO/0774	A guided self-help intervention for Eating Disorders	28		
	-			

Substantial Amendments over 35 day timeline				
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock	
12/LO/0351/AM02	Psychological wellbeing of facial surgery patients	Amendment 2; 22.02.13	37	
322/03/AM01	Do antidepressants work by acting on cortisol secretion? 4th phase	6th Amendment, 06/03/2013	48	

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	

**Application Short Title** 

Number of Days on Clock