

**NRES Committee London -
Camberwell St Giles**

Annual Report

01 April 2011 – 31 March 2012

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee London - Camberwell St Giles
Type of REC:	Authorised
Type of Flag:	Research Involving Adults Lacking Capacity
Chair:	Mr John Richardson
Vice-Chair:	Mr Evan Stone QC
Alternate Vice-Chair:	Ms Sally Gordon Boyd
Co-ordinator:	Charis Bailey
PRSC Co-ordinator:	Not applicable
Assistant Co-ordinator:	Not applicable
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Chair's overview of the past year:

I joined Camberwell St Giles REC as its Chair in April 2011 and have appreciated being involved in its work over the past year.

My first word must be of gratitude to the members. Inevitably, some took the opportunity to leave as we entered a new period with a different Chair and committee name. I was glad however to inherit some excellent people and I particularly express my gratitude to Evan Stone QC who continued as Vice-chair and brought much-valued wisdom and experience to that role. We also welcomed some new members, either by transfer from another committee or as totally fresh to RECs, among them Sally Gordon Boyd who became the committee's Alternate Vice-chair. Work and family commitments meant that three recently-appointed members found it necessary to step down and on some occasions we had to co-opt members of other RECs to ensure quoracy. All the members have contributed to the discussions and decisions in their distinctive ways and I have thoroughly enjoyed the lively sessions.

Though we have a good range of members, I am conscious that we are short of medical expertise. An appeal via the Institute of Psychiatry resulted in fifteen expressions of interest and, though I recognise that NRES, the appointing authority, has limitations on recruitment, I hope that we can follow these up as a matter of urgency so that we become a more rounded committee.

We met eleven times in the year and dealt with the interesting range of applications described elsewhere in this report. We have a particular expertise in reviewing projects involving the Mental Capacity Act and are glad to be flagged by NRES for this purpose. We have engaged in conversation with some excellent researchers and I trust that we have reviewed them all courteously, fairly and thoroughly. I believe that we have come to reasonable decisions on each application and, when follow-up has been necessary, we have done so within the guidelines. Our sub-committee for amendments, comprising Evan Stone, Jennifer Bostock, Veena Kumari and myself has also worked well.

We have been well-served by Co-ordinators and their colleagues. Audrey Adams took responsibility for my first meeting but Charis Bailey took over for the remainder of the year and brought accuracy and understanding to the role. Charis is based in Fulbourn, Cambridge, and there was some initial concern that being outside London might cause problems for researchers. The location has in fact worked well and the support from others in the office, particularly Lynda McCormack, the office manager, has been particularly helpful.

The difference between the office and committee locations has caused a little confusion over accountabilities but, broadly, the administration looks to the East of England while, as Chair, I have made what I feel are useful links with the London network. We have followed the developments in NRES with interest though occasionally suggested ways in which communication of these could be improved. A number of our members have undertaken training but we recognise that there is room for improvement in this aspect of our life.

Throughout the year, we have been clear about our responsibilities to protect participants and promote good research and we look forward to continuing this approach in the coming months.

NRES Committee London - Camberwell St Giles Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mr Sean Bell - Briggs	Student	Lay	11/04/2011	21/11/2011
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	
Mr Tony Eaton	Lay Member	Lay	01/10/2005	15/04/2011
Dr Nicola Fear	Reader in Military Epidemiology	Expert	01/09/2005	
Prof Raymond Feldman	Retired researcher in Cognitive Behaviour Science.	Lay	11/04/2011	
Ms Sally Gordon Boyd	Retired Medical Ethicist	Lay	31/05/2011	
Ms Alison Higgs	Lecturer - Social Work, Faculty of HSC	Lay	31/03/2011	
Dr Theresa Joyce	Consultant Clinical Psychologist	Expert	01/08/2010	14/07/2011
Dr Richard A A Kanaan	Consultant Psychiatrist	Expert	01/05/2009	
Prof. Veena Kumari	Professor of Experimental Psychology	Expert	16/12/2004	
Dr Morven Leese	Reader Emeritus in Statistics	Expert	01/07/2010	
Mr John Richardson	Retired Director of COREC: Ecumenical Officer for Churches Together in South London	Lay	01/04/2011	
Ms Nour Shahara	Masters student in medical ethics and law	Lay Plus	11/04/2011	30/11/2011
Ms Stephanie Stephenson	Research Nurse	Expert	31/05/2011	31/08/2011
Mr Evan Stone QC	Retired Queen's Counsel	Lay	01/03/2007	
Mr James Uwalaka	Deputy Research Study Manager	Lay	11/04/2011	
Mr Jonathan Watkins	Independent Social Worker	Lay Plus	17/08/2005	
Cllr Ian Wingfield	Deputy Leader Southwark Council	Lay	01/06/2009	14/07/2011

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Ms Julie Lockhart	PPI Representative	Lay	21/10/2011
Prof. Elizabeth Meerabeau	Professor of Health Care	Expert	17//2012 16/03/2012 20/04/2012
Mrs Patricia Pank	Retired University Lecturer	Lay	16/03/2012
Dr Elliot Shinebourne	Retired Paediatric Cardiologist	Expert	21/10/2011 20/04/2012

Member Bank

Name	Occupation	Expert or Lay	Meeting date attended

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

Name	Declaration of Interest	Date
Mr John Richardson	NONE	09/12/2011
Mr Evan Stone QC	Shareholdings in Astra Zeneca	08/12/2011
Ms Sally Gordon Boyd	Shareholdings in Astra Zeneca and GSK	09/12/2011
Mrs Jennifer Bostock	Associate/Consultant to the MHRA/ IOP/KCL/Universities of Kent, Oxford, LSE, Healthcare Acquired Infection Research Group. Oxleas MHA Manager (NHS Foundation Trust)NIHR - Peer Review and Committee Member	20/01/2012
Dr Nicola Fear	Secretary of Sussex Data Services Limited (unpaid)Involved in the Peer Review of grant applications that are submitted to funding bodies from within the Dept of Psychological Medicine, Institute of Psychiatry, King's College London and peer review of grant applications for some third sector organisations.	08/12/2011
Prof Raymond Feldman	NONE	09/12/2011
Ms Alison Higgs	Lecturer (Social Work) Open University	31/03/2012
Professor Veena Kumari	Employed by King's College London Involved in multiple research projects	09/12/2011
Dr Richard A A Kanaan	Trustee of Maudsley Philosophy Group Trust Visiting Senior Lecturer at King's College London	09/12/2011
Dr Morven Leese	Shareholdings in Unilever	09/11/2011
Mr James Uwalaka	Deputy Research Study Manager in the West Midlands South CLRN in University Hospitals of Coventry and Warwickshire NHS Trust	20/01/2012

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

Month	Date	Number of Members Present at Meeting
April	15/04/2011	13
May	20/05/2011	9
June	17/06/2011	11
July	15/07/2011	12
August	19/08/2011	11
October	21/10/2011	9
November	18/11/2011	9
December	09/12/2011	9
January	20/01/2012	10
February	17/02/2012	9
March	16/03/2012	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
Mr Evan Stone QC	10
Mr John Richardson	10
Mr James Uwalaka	9
Ms Sally Gordon Boyd	9
Mrs Jennifer Bostock	8
Dr Morven Leese	8
Professor Veena Kumari	8
Prof Raymond Feldman	7
Mr Jonathan Watkins	6
Dr Richard A A Kanaan	6
Mr Sean Bell - Briggs	6
Dr Nicola Fear	5
Ms Nour Shahara	3
Prof Nelarine Cornelius	3
Ms Stephanie Stephenson	3
Ms Alison Higgs	2
Mr Tony Eaton	1
Professor Elizabeth Meerabeau	2
Ms Julie Lockhart	1
Mrs Patricia Pank	1
Dr Theresa Joyce	1
Dr Elliot Shinebourne	1

Number of inquorate meetings held: 0

Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Mr John Richardson	26/09/2011 - 26/09/2011	NRES Update Session, NRES
Dr Nicola Fear	28/09/2011 - 28/09/2011	NRES training, NRES
Dr Nicola Fear	28/09/2011 - 28/09/2011	NRES Phase 1 training, NRES
Mr John Richardson	22/11/2011 - 22/11/2011	NRES Adults Lacking Capacity Training, NRES
Mrs Jennifer Bostock	07/12/2011 - 07/12/2011	NRES Statistics training, NRES
Mr Evan Stone QC	06/12/2011 - 06/12/2011	NRES Chairs National Training day, NRES
Mrs Jennifer Bostock	07/12/2011 - 07/12/2011	NRES Statistics training, NRES
Mr Evan Stone QC	06/12/2011 - 06/12/2011	Chairing Skills, NRES
Ms Sally Gordon Boyd	13/02/2012 - 13/02/2012	Ethics & GCP Forum, NRES
Professor Veena Kumari	21/07/2011 - 21/07/2011	Equality & Diversity, NHS skills academy for health
Mr Evan Stone QC	11/10/2011 - 11/10/2011	Equality & Diversity, NHS
Dr Richard A A Kanaan	18/07/2011 - 18/07/2011	Equality & Diversity, NHS
Mr Sean Bell - Briggs	25/08/2011 - 25/08/2011	Equality & Diversity, NHS
Mr Sean Bell - Briggs	27/07/2011 - 27/07/2011	The ethical review of medicines based research, NHS

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	52	100.00
Total Applications Reviewed	52	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	8
Number of student applications reviewed	26
Number of paediatric applications reviewed	7
Number of device applications reviewed	1
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	10
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	2	3.85
Favourable Opinion with Additional Conditions	4	7.69
Unfavourable Opinion	2	3.85
Provisional Opinion	44	84.62
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	52	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	35	67.31
Further Information Favourable Opinion with Additional Conditions	6	11.54
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	3.85
Favourable Opinion with Additional Conditions	4	7.69
Unfavourable Opinion	2	3.85
Provisional Opinion	3	5.77
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	52	100

Table 5: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	4.73
Number of applications for full ethical review over 60 days	3
Number of applications over 60 days as a % of total	5.77%
Number of days taken to final decision - average	42
Number of days taken to final decision - mode	49

Number of SSAs (non-Phase 1) reviewed	11
Number of applications for SSA review over 25 days	6
Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)	54.5%

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	62
Number of substantial amendments over 35 days	5
Number of substantial amendments over 35 days as a % of total substantial amendments	8.1%

Number of Section 30 applications reviewed	0
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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	2
Number of modified amendments over 14 days	2
Number of modified amendments over 14 days as a % of total modified amendments	100.0%

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/0287	An experimental study of self-focused attention and comparisons in BDD	46
11/LO/0303	Familial Expressed Emotion as an Influence on Child PTSD	62
11/LO/0341	The patterns and predictors of disease disclosure in cancer version 1	65
11/LO/0376	CanTalk V3	43
11/LO/0474	Exercise, Diet and Cognition in Older Adults	49
11/LO/0569	Retinal laser by Pascal Photocoagulator and driving eligibilty	32
11/LO/0573	SOCIAL NETWORKS AND SUPPORT IN PSYCHOSIS, Version 2	46
11/LO/0812	What are the young adult health outcomes for the children of the SLCDS	43
11/LO/0828	The Experience of Aecessing Mental Health Services within a Temple (V1)	43
11/LO/0927	Warwick Hip Trauma Evaluation (WHiTE study) Version 1	41
11/LO/0981	socioeconomic status, ethnicity and advanced retinoblastoma in the UK	41
11/LO/0984	Associations between food allergy risk perception and behaviours	41
11/LO/1042	Relationship of EFA to adults with ADHD	44
11/LO/1056	Oesophageal Reflux and dysmotility in bariatric surgery patients	42
11/LO/1067	HIV testing decision-making, and post-diagnosis wellbeing - version 1	60
11/LO/1262	Managed Outcomes - Type 2 Diabetes Survey	30
11/LO/1270	Locus of Control and Well-being in Acute Psychiatric Inpatients.	54
11/LO/1274	Immunology of the intestine; features associated with autoimmunity	33
11/LO/1275	The influence of topical formulation composition on skin	34
11/LO/1276	Emotional processing of virtual reality aggression	50
11/LO/1294	Analysis of Anterior Chamber Specimens in inflammatory Disorders	42
11/LO/1412	Surveillance of Haemolytic Uraemic Syndrome in Children	18
11/LO/1719	Tactile responses in the trigeminal system.	36
11/LO/1730	Solution-Focused, Smoking Cessation Approach for Pregnant Women. V1	47
11/LO/1732	Inflammometry and Children's Asthma	46
11/LO/1873	Stent Oesophageal Bleeding	40
11/LO/1883	Modulating Interhemispheric Interaction in Dystonia and PD	58
11/LO/1888	Surgical oxidative stress v1	49
11/LO/1899	Evaluating QbTest v1.0	34
11/LO/1995	Cost effectiveness of procalcitonin use in an inner city ICU v.1	52

12/LO/0031	Visual Information-Processing in Adolescents with BDD and OCD	37
12/LO/0133	Stereopsis and manual tasks	53
12/LO/0263	NMES in severe COPD	27
12/LO/0319	Engaging PLD and complex needs in occupations at home: the OT approach	49
12/LO/0330	Decision-making under single-dose Oxytocin in schizophrenia	39

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/LO/0620	The PEOPLE study: case studies	62
11/LO/0631	Patients' perceptions of the nursing contribution in intensive care	39
11/LO/0834	The clinical skills of UK optometrists in glaucoma diagnosis.	49
11/LO/1041	The Use of Chaperones for Intimate Examinations: What do Women Want?	44
11/LO/1731	Adolescent boys experience of the condition hypospadias	53
11/LO/1780	The MID of the SPPB and 4m Gait Speed in chronic lung disease patients	45

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/0822	Impact of Zoledronic acid and IL2 on gamma delta T cells	27
12/LO/0001	A study of suspected scabies outbreaks in residential care facilities	56

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/LO/1981	Physical Activity and Gastrointestinal Investigations	24
11/LO/2007	Now grown up: Adults' lives after childhood liver transplant	24
12/LO/0195	Participants' experiences of multi family group therapy	27
12/LO/0326	Biology of changes in Imminoglobulins in Adults with Sepsis	30

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/LO/0484	A study of suspected scabies outbreaks in residential care facilities	28
12/LO/0341	Concept Elicitation in Patients with Peanut Allergy v1.3	30

Provisional Opinion		
REC Reference	Application Short Title	Number of Days on Clock
12/LO/0092	Implicit learning in early Alzheimer's Disease	N/A
12/LO/0329	Going back to school after admission to psychiatric services	N/A
12/LO/0351	Psychological wellbeing of facial surgery patients	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

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 7: Items exceeding timelines:

Full applications for ethical review over 60 day timeline		
REC Reference	Application Short Title	Number of Days on Clock
11/LO/0341	The patterns and predictors of disease disclosure in cancer version 1	65
11/LO/0303	Familial Expressed Emotion as an Influence on Child PTSD	62
11/LO/0620	The PEOPLE study: case studies	62

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
11/LO/0541	Cognitive reactivity in 'Looked After' children.	77
11/LO/0542	Caring for hospice inpatients: aspects of decision-making	76
11/LO/0842	Neuroimaging of child abuse	33
10/H0807/64	Imaging myelination in typical development and in autism	455
11/LO/0843	The Role of Emotions in Confabulation and Amnesia	53
11/LO/1337	Neuroimaging of child physical abuse	32

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
08/H0807/17/AM07	Adult ADHD	Substantial Amendment 7 - 14/04/2011	43
10/H0807/89/AM01	Smoking cessation and mental health in pregnancy	Substantial Amendment 1 - 27/04/2011	36
08/H0807/53/AM05	IMPACT VERSION 1	Substantial Amendment 6 - 17/03/2011	42

11/LO/0812/AM01	What are the young adult health outcomes for the children of the SLCDS	Amendment 1 (18 November 2011)	38
10/H0807/23/AM02	Injured Spinal Cord Pressure Evaluation (ISCoPE) [v.1]	Amendment_2, 15.11.11	53

Modified Amendments over 14 day timeline

Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
08/H0807/68/AM03/1	Service use and needs among adolescents/young adults with ADHD	Amendment 5 - modified 17 October 2011	18
09/H0807/71/AM02/1	Service use and needs among adolescents/young adults with an ASD	Amendment 4 - modified_10 October 2011	19

Section 30 application over 60 day timeline

Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
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Note: All overruns are correct and have notes on Red to provide explanations.