

# NRES Committee London - Camden & Islington

**Annual Report** 

01 April 2013 - 31 March 2014

#### Part 1 - Committee Membership and Training

Name of REC: NRES Committee London - Camden & Islington

Type of REC: Authorised

Type of Flag: Adults Lacking Capacity, Paediatric and Qualitative Research

Chair: Mrs Rosie Glazebrook

Vice-Chair: Ms Heidi Chandler

Alternate Vice-Char: Ms Eleni Yerolaki

**Co-ordinator:** Mrs Joan Brown (June 2013 to February 2014)

Mrs Hayley Henderson (3<sup>rd</sup> February 2014)

PRSC Co-ordinator: Mrs Joan Brown (June 2013 to February 2014)

Mrs Hayley Henderson (3<sup>rd</sup> February 2014)

**Assistant Co-ordinator:** Mrs Sally Dunn (3<sup>rd</sup> February 2014)

Ms Christie Ord October 2013 - February 2014

Committee Address: North East REC Office

Room 002

Jarrow Business Centre

Rolling Mill Road

**Jarrow** 

Tyne & Wear NE32 3DT

**Telephone:** 0191 4283545

**Email:** nrescommittee.london-camdenandislington@nhs.net

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

Our committee strives to be friendly, hardworking and fair. We make every effort to ensure that researchers are not daunted when they meet us, and we want to make sure that there is an open and honest discussion on points raised. We have received positive feedback from a number of research teams who commented on our positive approach and helpful advice.

Members of our committee have wide-ranging expertise. In particular, we have lay and clinical members who have skills and experience in paediatrics, qualitative research and mental capacity act work and we are currently flagged in these areas.

The quality of most of the research studies we see is good, well thought out and well presented. The changes we most often ask for are ones more to do with the information provided to potential participants: and mainly to make it more likely they will agree to take part. There is often room for improvement and it would be helpful if research teams had earlier input from patients/members of the public in developing materials for potential participants.

Our committee continues to work well and our members are very committed and put in a lot of work in preparation for meetings, sub-committee meetings and the proportionate review caseload. Those researchers who attend our meetings see us for only a short time, but they rapidly realise that we have looked at their applications very carefully and can help them improve them still further.

We are sorry to say goodbye to Alicia Etchegoyen, a committee member, and Joan Brown, our REC manager, and thank them both for their hard work. I would like to welcome Catherine Max as a new member.

## NRES Committee London - Camden & Islington Membership:

Name	Occupation	Expert or	Dates	
		Lay	Appointed	Resigned
Dr Afia Ali	Psychiatrist	Expert	01/10/2011	
Dr Sati Ariyanayagam	Consultant Physician	Expert	01/07/2011	
Ms Heidi Chandler	Research Co-ordinator	Lay	24/07/2008	
Dr Janice Christie	Senior Lecturer in Public Health & Primary Care / Programme Director	Expert	04/08/2011	
Dr Claudia Cooper	Senior Clinical Lecturer in Older People's Mental Health	Expert	26/05/2009	02/06/201 4
Dr Sangeeta Dave	Senior Clinical Research Associate	Expert	01/10/2011	
Dr Alicia Isabel Etchegoyen	Psychiatrist	Expert	01/10/2011	23/10/201 3
Mrs Rosie Glazebrook	Consumer Marketing	Lay	01/01/2013	
Ms Catherine Max	Independent Consultant (Sustainability, Health and Social Care)	Lay	12/06/2013	
Dr Jacqueline Maxmin	GP	Expert	01/05/2013	
Dr Manoj Nanji	Biospecimen Coordinator - IBIS II	Expert	29/07/2010	07/01/201 4
Mrs Frances Percival	Professional & Scientific Consultant	Expert	18/04/2011	
Dr Andy Petros	Consultant Paediatric Intensivist	Expert	01/09/2011	
Mr Jonathan Simons	Investment Manager	Lay Plus	07/03/2013	
Ms Mary Watkinson	Teacher	Lay Plus	06/02/2013	
Ms Eleni Yerolaki	Specialist Counsellor	Lay Plus	20/06/2006	
Ms Biddy Youell	Head of Child Psychotherapy	Expert	06/04/2009	

#### **Deputy Members**

Name	Occupation	Expert or Lay	Meeting date attended
None			

#### **Co-opted Members**

Name	Occupation	Expert or Lay	Meeting date attended
Dr Frances Goodhart	Consultant	Expert	25/11/2013
Mr Maurice Marchant	Statistician	Lay	25/11/2013

#### **Member Bank**

Name	Occupation	Expert or Lay	Meeting date attended
None			

## NRES Committee London - Camden & Islington: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Mrs Rosie Glazebrook	Board member of the Human Tissue Authority via	14/01/2014
	Public Appointment.	
Dr Andy Petros	None	13/01/2014
Ms Heidi Chandler	Public Contributor on the Maternal, Neonatal and	13/01/2014
	Child Health Topic Identification Panel of the NIHR	
	HTA Funding Programme.	
Ms Heidi Chandler	Lay-Reviewer for NIHR HTA and RfPB funding	13/01/2014
D 1 : 01 : (:	applications.	40/04/0044
Dr Janice Christie	Undertaking a Cochrane systematic review with the	13/01/2014
	Cochrane collaboration and also write summaries	
	of Cochrane reviews for the Cochrane Nursing Care field. Works at City University London where	
	involved in undertaking and supporting others	
	(including students) to undertake research.	
	External examiner for Bournemouth University,	
	Teesside University and also undertaking a	
	periodic review for UCLAN - these universities are	
	all involved in research. Writes peer review journal	
	articles for: Journal of Advanced Nursing, Journal	
	of Health Visiting, Community Practitioners Journal,	
	Nursing research - and other journals on an ad hoc	
	and intermittent basis. Also reviews abstracts for	
	the RCN international research conference. Peer	
	reviewed NIHR grant applications in the past (Not	
	in previous 2 years). Involved in NICE guideline	
	setting "Managing overweight and obesity amongst	
	children and young people" in 2013.	10/01/0011
Catherine Max	Uscrates (Social Change Consultancy) - Associate.	13/01/2014
	Catherine Max Consultancy (Health/Social	
	Care/Sustainable Development - Independent	
	Consultant. Ethox Centre, University of Oxford - Associate. Equinoxcare - Trustee	
Dr Afia Ali	No interests to be declared.	22/01/2014
Ms Mary Watkinson	No Interests to Declare	23/01/2014
Dr Claudia Cooper	Occasionally peer review studies for Camden and	13/01/2014
Di Giaddia Goopei	Islington NHS Foundation Trust	13/01/2014
Mrs Frances Percival	Employee of a research consultancy company - pH	27/01/2014
I wild i railedd i didival	Associates ltd. which conducts non-interventional	2170172011
	research studies on behalf of a range of clients.	
Dr Jacqueline Maxmin	None	28/02/2014
Mr Jonathan Simons	None	31/03/2014
Ms Eleni Yerolaki	None	29/03/2014
Ms Biddy Youell	Head of child and adolescent psychotherapy at the	15/07/2014
_	Tavistock and Portman NHS Foundation Trust.	
	Chair of the association of child psychotherapists.	
Dr Sangeeta Dave	None	30/07/2014

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

Month	Date	Number of Members Present at Meeting
April	22/04/2013	7
May	20/05/2013	9
June	24/06/2013	14
August	19/08/2013	11
September	23/09/2013	8
October	28/10/2013	9
November	25/11/2013	8
December	16/12/2013	10
January	27/01/2014	12
February	24/02/2014	10
March	24/03/2014	10

<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	18/07/2013	3
August	15/08/2013	3
August	21/08/2013	3
September	19/09/2013	3
October	17/10/2013	3
November	14/11/2013	3
December	19/12/2013	3
January	16/01/2014	3
February	12/02/2014	3
March	12/03/2014	3

<sup>10</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
Mrs Rosie Glazebrook	10
Ms Heidi Chandler	9
Ms Mary Watkinson	9
Ms Eleni Yerolaki	8
Mr Jonathan Simons	8
Dr Andy Petros	8
Dr Claudia Cooper	7
Dr Jacqueline Maxmin	7
Catherine Max	7
Dr Janice Christie	7
Mrs Frances Percival	7
Dr Sati Ariyanayagam	6
Dr Afia Ali (maternity leave from January 2014)	5
Dr Alicia Isabel Etchegoyen	3
Dr Sangeeta Dave (Leave of absence from 01.07.13 to 31.12.13)	3
Ms Biddy Youell (leave of absence from 01.10.13 to 31.03.14)	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 Afia Ali	1
Dr Sati Ariyanayagam	2
Ms Heidi Chandler	8
Dr Janice Christie	2
Dr Claudia Cooper	2
Dr Sangeeta Dave	1
Dr Alicia Isabel Etchegoyen	1
Mrs Rosie Glazebrook	4
Dr Jacqueline Maxmin	1
Mrs Frances Percival	1
Dr Andy Petros	1
Mr Jonathan Simons	1
Ms Mary Watkinson	2
Ms Eleni Yerolaki	3

## Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Dr Sati Ariyanayagam	11/12/2013 - 11/12/2013	National Training Day for NRES Committee
		Chairs, HRA
Ms Heidi Chandler	02/10/2013 - 02/10/2013	Researcher Training Day, HRA
Ms Heidi Chandler	12/11/2013 - 12/11/2013	Researcher Training Day, HRA
Ms Heidi Chandler	05/02/2014 - 05/02/2014	Researcher Training Day, HRA
Dr Janice Christie	08/07/2013 - 08/07/2013	Qualitative Research & Ethical Review, HRA
Dr Claudia Cooper	11/06/2013 - 11/06/2013	Research and human tissue legislation, Medical Research Council
Dr Alicia Isabel Etchegoyen	23/04/2013 - 23/04/2013	Equality & Diversity/Update & Ethical Issues Arising from the new Good Medical Practice , GMC Interim Orders Panel
Dr Alicia Isabel Etchegoyen	20/11/2013 - 20/11/2013	National Members Training Day, HRA
Mrs Rosie Glazebrook	06/06/2013 - 06/06/2013	Training for New REC Chairs, HRA
Catherine Max	18/09/2013 - 18/09/2013	Induction, HRA
Catherine Max	20/11/2013 - 20/11/2013	National Members Training Day, HRA
Dr Andy Petros	08/07/2013 - 08/07/2013	Qualitative Research & Ethical Review, HRA
Dr Andy Petros	02/10/2013 - 02/10/2013	Researcher Training Day, HRA
Ms Mary Watkinson	17/04/2013 - 17/04/2013	Ethical Review of Mental Health/Psychiatric Research Training, HRA
Ms Mary Watkinson	08/07/2013 - 08/07/2013	Qualitative Research & Ethical Review, HRA
Ms Eleni Yerolaki	11/12/2013 - 11/12/2013	National NRES Chairs Training Day, HRA
Mrs Frances Percival	01/04/2013 – 03/01/2014	Self-Directed Learning Log 25 hours April 2013 – January 2014 10 hours reading Bad Pharma, 6 hours reviewing Caldicott review, 2 hours preparing and presenting presentation surrounding implications for research practice.
Mr Jonathan Simons		Self-Directed Learning Log April 2013 to March 2014 1.5 hours spent reviewing the Online NRES Adults Lacking Capacity Module.

#### 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	58	100.00
Total Applications Reviewed	58	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	3
Number of student applications reviewed	21
Number of paediatric applications reviewed	13
Number of device applications reviewed	0
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	11
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	3	5.17
Favourable Opinion with Additional Conditions	3	5.17
Unfavourable Opinion	1	1.72
Provisional Opinion	51	87.93
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	58	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	37	63.79
Conditions		
Further Information Favourable Opinion with Additional	4	6.90
Conditions		
Further Information Unfavourable Opinion	1	1.72
Favourable Opinion with Standard Conditions	3	5.17
Favourable Opinion with Additional Conditions	3	5.17
Unfavourable Opinion	1	1.72
Provisional Opinion	5	8.62
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	2	3.45
Not Requiring Review by NHS REC	0	0.00
No decision entered on RED	2	3.45
Number of studies withdrawn after the meeting	0	0.00
Total	58	100

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

Total Applications Reviewed	15
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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-	Number	%
committee meetings		
Favourable Opinion with Standard Conditions	6	40.00
Favourable Opinion with Additional Conditions	4	26.67
No Opinion transfer to full committee for review	1	6.67
Provisional Opinion	4	26.67
Unfavourable Opinion	0	0.00
Total	15	100

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

Average number of applications reviewed per full meeting	5.27
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	31
Number of days taken to final decision - mode	28
Number of SSAs (non-Phase 1) reviewed	7
Number of applications for SSA review over 25 days	0
Number of applications for SSA review over 25 days as % of	0.0%
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	67
Number of substantial amendments over 35 days	0
Number of substantial amendments over 35 days as a % of	0.0%
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 total	0%
Section 30 applications	
[	
Number of modified amendments reviewed	0
Number of modified amendments over 14 days	0
Number of modified amendments over 14 days as a % of total	0%
modified amendments	
	1
Number of proportionate review applications for ethical review	1
over 14 days*	7.00
Number of proportionate review applications over 14 days as	7.1%
a % of total	

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

<b>Further Informati</b>	on Favourable Opinion with Standard Conditions	
REC Reference	Application Short Title	Number of Days on Clock
13/LO/0495	Comparison of MBCT, relaxation and waiting list in tinnitus management	31
13/LO/0532	Cambridge Outcomes Follow-up Study	24
13/LO/0728	How do co-inherited blood conditions affect malaria protection? V1	42
13/LO/0743	A comparison of facial cooling using ice or hilotherapy: a pilot study	35
13/LO/0745	Self-recognition in patients undergoing facial surgery (version1)	33
13/LO/0795	Neurodevelopmental outcome after out of hospital cardiac arrest -V3.2	42
13/LO/0900	An investigation into the mechanisms of lung injury and repair.	28
13/LO/0912	alternative assessments of adequacy	28
13/LO/1124	Aerosure during six-minute walk tests in COPD	36
13/LO/1139	Digital Healthcare Platform for Dementia Diagnosis	36
13/LO/1180	Hepatitis B: views and experiences	32
13/LO/1186	The effect of everyday headache pain on task performance v1	43
13/LO/1259	Utility of near infrared spectroscopy in mitochondrial disease - V4.6	30
13/LO/1307	Minimal volume for a fluid challenge	45
13/LO/1309	Shared decision making in mild to moderate dementia.	39
13/LO/1319	Safety of older patients in home care	11
13/LO/1546	TRACERx	37
13/LO/1564	Dementia and relationships	43
13/LO/1582	Accelerated Long-Term Forgetting in Temporal Lobe Epilepsy	49
13/LO/1598	Sampling antibiotics in renal replacement therapy	52
13/LO/1610	Integrated care for older people with complex needs V1	32
13/LO/1614	Evaluation of a smoking cessation service for mental health patients	17
13/LO/1709	Implementing and evaluating 'My Healthcare Passport'	28
13/LO/1713	The Impact Of Parent Infant Work - On The Mother Infant relationship	57
13/LO/1781	Cultured Chondrocytes Vs. Cultured BMAC	29
13/LO/1868	A pilot qualitative study after bariatric surgery	28
13/LO/1901	Blood oxygen carrying capacity, iron, CPET and POMS - a pilot study	27
13/LO/1902	Oxygen carrying capacity in the clinical setting - a pilot	27
13/LO/1903	ROTEM in pregnancy in women with bleeding disorders	29
14/LO/0017	Vitamin K deficiency in patients undergoing hip surgery	32
14/LO/0023	Co-construction of recovery in a mental health setting	23

14/LO/0106	Investigations into Paediatric Scar Biology	35
14/LO/0107	CORE: Crisis Team Optimisation and Relapse Prevention - Phase 4	17
14/LO/0262	Evaluating clinicians' experience of using rapport measurement tools.	19
14/LO/0266	Infection In Children Attending The Emergency Department (ICED)	28
14/LO/0295	Emotional Logic: Proof of Concept Follow-Up	13
14/LO/0303	The UK-AIH Cohort	16
14/LO/0309	Brain glutamate-GABA system in ASD	19
14/LO/0316	Retinal photography in older HIV positive adults	27
14/LO/0370	COMPASSION pilot intervention study	21
14/LO/0497	What opportunities matter to young people?	14

Further Information Favourable Opinion with Additional Conditions		
<b>REC Reference</b>	Application Short Title	Number of Days on Clock
13/LO/1240	Using ultrasound to measure length of magnetic growth rod in scoliosis	26
13/LO/1785	Family factors associated with posttraumatic stress reactions	24
13/LO/1900	GI symptoms in OC.	29
14/LO/0095	Factors influencing children's psychological wellbeing following TBI	28

Further Information Unfavourable Opinion		
REC Reference	Application Short Title	Number of Days on Clock
13/LO/1047	(April) Screening for Diabetes in Dental Settings	30

Favourable Opinion with Standard Conditions		
REC Reference	Application Short Title	Number of Days on Clock
13/LO/0610	Cancer survival using further data from audits, RTDS and HES - v2	39
13/LO/1175	Intonation in children with cerebral palsy - version 1	9
13/LO/1269	Immunobiology of leprosy version 4	23
13/LO/1314	The Lived Experience of Active Charcot Foot. Version 1.	23
13/LO/1519	DNA methylation in high-grade anal neoplasia	7
13/LO/1662	CT scan of a deceased patients heart	6
13/LO/1941	Patient perspectives of weight regain. v1	6
13/LO/1944	Study of Exposure to Plasma Transfusion: SEPT	7
14/LO/0159	Vit D, Parathomone & Outcome after Hip Fracture	7

Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
13/LO/0472	Ultrasound measurements of vasculature in a healthy population v1.1	42
13/LO/0952	Breath Testing for Hepatic Encephalopathy version 1	23
13/LO/1157	TIGO- A tailored cluster RCT intervention	7
13/LO/1324	Predictive value of PLA2R antibody in nephrotic syndrome	7
13/LO/1823	PIVOTP	11
14/LO/0101	Dolphin Pre-school Study v1	32
14/LO/0502	Relationship between therapist perfectionism and client outcomes V1	8

Unfavourable Opinion		
<b>REC Reference</b>	Application Short Title	Number of Days on Clock
13/LO/0554	Implementing and evaluating 'My Healthcare Passport'	22

Provisional Opinion			
<b>REC Reference</b>	Application Short Title	Number of Days on Clock	
13/LO/0887	Noninvasive assessment of tissue perfusion in high-risk surgery	N/A	
14/LO/0396	89Zr-Bevacizumab PET in paediatric HGG & DIPG	N/A	
14/LO/0417	Effects of psychiatric hospital admission on young people's identity	N/A	
14/LO/0420	Risk factors for DDH - Outcomes at 2 or more years	N/A	
14/LO/0425	Supporting recovery and inclusion through user involvement in dementia	N/A	

Provisional Opinion Pending Consultation with Referee		
REC Reference	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
13/LO/1779	PRP vs HA intra-articular knee injections for cartilage defects	N/A
13/LO/1780	ACIC Vs MCIC	N/A

Withdrawn after t	he meeting	
<b>REC Reference</b>	Application Short Title	Number of Days on Clock

<b>Invalid Application</b>	on	
REC Reference	Application Short Title	Number of Days on Clock
No Opinion Pend	ling Consultation with Referee	
REC Reference	Application Short Title	Number of Days on Clock
Not Requiring Re	eview by NHS REC	
REC Reference	Application Short Title	Number of Days on Clock

## Table 9: Items exceeding timelines:

Full applications for ethic	al review over 60 day timeline		
	ation Short Title		Number of Days on Clock
Proportionate review app	lications for ethical review over	r 14 days timeline	
REC Reference Applica	ation Short Title		Number of Days on Clock
14/LO/0303 The UK	C-AIH Cohort		16
SSAs (non Phase 1) over	25 days timeline		
REC Reference Applica	ation Short Title		Number of Days on Clock
SSAs (Phase 1) over 14 d			
REC Reference   Application Short Title		Number of Days on Clock	
<b>Substantial Amendments</b>	over 35 day timeline		
		Amoundmont Title	Number of Dave on
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
			Clock
<b>Modified Amendments ov</b>	er 14 day timeline		
Amendment Reference	Application Short Title	Amendment Title	Number of Days on
			Clock
Section 30 application ov	er 60 day timeline		
Amendment Reference	Application Short Title	Amendment Title	Number of Days on
			Clock