

NRES Committee North West - Liverpool East

Annual Report

01 April 2011 – 31 March 2012

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee North West - Liverpool East
Type of REC:	Type III
Type of Flag:	Paediatric, RTB
Chair:	Mrs Jean Harkin
Vice-Chair:	Professor Neil Pender
Alternate Vice-Chair:	Mrs Glenys J Hunt
Co-ordinator:	Miss Helen Penistone
PRSC Co-ordinator:	N/A
Assistant Co-ordinator:	Ms Jo Foxall Dant
Committee Address:	HRA NRES Centre North West Barlow House 3rd Floor 4 Minshull Street Manchester M1 3DZ
Telephone:	0161 625 7832
Fax:	0161 625 7299
Email:	helen.penistone@northwest.nhs.uk

Chair's overview of the past year:

We had a few changes in members over the year, with 2 resignations, one of which was Paul Baines, who had served for 10 years on the committee and made a great contribution during that time. At the end of the year also our Jean chaired her last meeting, again after serving 10 years on the committee, 5 of them as chair – quite an achievement. We also had one member transfer to another committee, and one new member. We did manage however to retain a loyal core of membership. We also had a change of co-ordinator, with Helen taking over from Rinat in August, initially Helen was just covering Rinat's maternity leave, but we were very happy to find that she is staying with us permanently.

The committee reviewed 63 applications in total, 13 of which were CTIMPS. Out of those there was only 1 unfavourable opinion, although many of the others had to be amended and were eventually approved, with or without conditions. The average number of applications reviewed per meeting was 5.73 (higher than the north-west average, which was 5.3). All were reported and reviewed within the allowed timescale – for which Rinat / Helen and all the members should be commended.

Well done to all, and keep up the good work.

NRES Committee North West - Liverpool East Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr Paul Baines	Vice Chair / Consultant Intensivist	Expert	01/09/2001	21/12/2011
Mr John Bridson	Clinical Ethicist	Expert	21/06/2007	
Dr Zoe Edwards	Clinical Psychologist	Expert	21/02/2011	
Mr Paul Flodman	Law Lecturer	Lay	25/08/2010	24/05/2011
Ms Carole Griffith	Physiotherapist Case Manager	Expert	13/09/2007	
Mrs Jean Harkin	Chair / Solicitor	Lay Plus	16/05/2002	
Mrs Maureen Hendry	Pharmacist	Expert	12/07/2010	
Mrs Glenys J Hunt	Alternate Vice Chair / Solicitor	Lay	22/08/2005	
Mr Chris Irving	Biomedical Scientist	Expert	08/09/2010	
Professor Ebrahim Khalil Naderali	Professor of Human Physiology	Expert	21/02/2011	
Mr Alex Newgrosh	Quality Assurance Manager	Lay Plus	16/09/2010	
Mr Peter Owen	Lay Member	Lay Plus	18/07/2010	Transferred to GM West 16/12/2011
Professor Neil Pender	Professor of Orthodontics	Expert	27/08/2005	
Mrs Jean Pownceby	Lay Member	Lay Plus	11/01/2006	
Dr Richard Sarginson	Consultant (Anaesthesia/PICU)	Expert	16/02/2005	
Ms Karen Tripp	Research Governance Administrator	Lay	13/10/2011	
Dr Peter Walton	Lay Member	Lay	14/05/2008	

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Mr Jimmy Burns	Co-opted Lay Member (GM East)	Lay Plus	15/03/2012

Member Bank

Name	Occupation	Expert or Lay	Meeting date attended

NRES Committee North West - Liverpool East: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Professor Neil Pender	None	19/01/2012
Dr Richard Sarginson	I am involved in ongoing research projects at Alder Hey. These have been reviewed by other ethics committees. I am not involved in any research management organisations.	15/09/2011
Dr Peter Walton	None	15/12/2011
Dr Zoe Edwards	None	22/12/2011
Ms Karen Tripp	None	31/10/2011
Mrs Jean Pownceby	None	01/01/2012
Mr Chris Irving	None	19/01/2012
Mrs Maureen Hendry	None	19/01/2012
Dr Peter Walton	None	19/01/2012
Mrs Glenys J Hunt	None	19/12/2011
Professor Ebrahim Khalil Naderali	Advisor to Eli-Lilly, Boehringer-Ingelheim and Nanomedpharma Ltd. A member of Liverpool Hope University. Editor of ISRN Obesity Journal.	15/12/2011
Ms Carole Griffith	Volunteer with local swimming club. Member of a Liverpool Research Group	31/12/2011

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

Month	Date	Number of Members Present at Meeting
April	21/04/2011	11
May	19/05/2011	11
June	16/06/2011	11
August	18/08/2011	11
September	15/09/2011	10
October	20/10/2011	10
November	17/11/2011	9
December	15/12/2011	10
January	19/01/2012	11
February	16/02/2012	10
March	15/03/2012	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
Dr Peter Walton	11
Mr Chris Irving	11
Mr Alex Newgrosh	10
Mrs Glenys J Hunt	9
Mrs Jean Pownceby	9
Mr Peter Owen	8
Mrs Jean Harkin	8
Dr Richard Sarginson	7
Dr Zoe Edwards	7
Professor Neil Pender	7
Mrs Maureen Hendry	6
Professor Ebrahim Khalil Naderali	5
Ms Carole Griffith	4
Ms Karen Tripp	4
Dr Paul Baines	4
Mr Jimmy Burns (Co-opted member)	1
Mr John Bridson	1

Number of inquorate meetings held: 0

Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Mrs Maureen Hendry	05/05/2011 - 05/05/2011	Improving accrual and recruitment conduct in clinical trials with children and other patients unable, University of Liverpool
Dr Paul Baines	05/05/2011 - 05/05/2011	Improving accrual and recruitment conduct in clinical trials with children and other patients unable, University of Liverpool
Mr Peter Owen	28/06/2011 - 28/06/2011	Statistics Training for NRES REC member, NRES
Mr Chris Irving	07/07/2011 - 07/07/2011	New members induction training, NRES
Mr Chris Irving	22/08/2011 - 22/08/2011	Equality & Diversity, NRES
Mrs Glenys J Hunt	20/10/2011 - 20/10/2011	GAfREC and SOPs v.5 discussion, Local Training
Dr Zoe Edwards	20/10/2011 - 20/10/2011	GAfREC and SOPs v5 Discussion, Local Training
Ms Carole Griffith	20/10/2011 - 20/10/2011	GAfREC and SOPs v5 Discussion, Local Training
Mr Chris Irving	20/10/2011 - 20/10/2011	GAfREC and SOPs v5 Discussion, Local Training
Mr Alex Newgrosh	20/10/2011 - 20/10/2011	GAfREC and SOPs v5 Discussion, Local Training
Mr Peter Owen	20/10/2011 - 20/10/2011	GAfREC and SOPs v5 Discussion, Local Training
Professor Neil Pender	20/10/2011 - 20/10/2011	GAfREC and SOPs v5 Discussion, Local Training
Mrs Jean Pownceby	20/10/2011 - 20/10/2011	GAfREC and SOPs v5 Discussion, Local Training
Dr Richard Sarginson	20/10/2011 - 20/10/2011	GAfREC and SOPs v5 Discussion, Local Training
Ms Karen Tripp	20/10/2011 - 20/10/2011	GAfREC and SOPs v5 Discussion, Local Training
Dr Peter Walton	20/10/2011 - 20/10/2011	GAfREC and SOPs v5 Discussion, Local Training
Dr Zoe Edwards	29/11/2011 - 29/11/2011	NRES Research Involving Adolescents, NRES
Professor Neil Pender	29/11/2011 - 29/11/2011	NRES Research Involving Adolescents, NRES
Mrs Glenys J Hunt	29/11/2011 - 29/11/2011	NRES Research Involving Adolescents, NRES
Mr Peter Owen	29/11/2011 - 29/11/2011	NRES Research Involving Adolescents, NRES
Mrs Maureen Hendry	29/11/2011 - 29/11/2011	NRES Research Involving Adolescents, NRES
Mr Chris Irving	29/11/2011 - 29/11/2011	NRES Research Involving Adolescents, NRES

Ms Karen Tripp	22/02/2012 - 22/02/2012	Induction, NRES
Mrs Glenys J Hunt	21/03/2012 - 21/03/2012	NRES Training Day for New REC Chairs, 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	13	20.63
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	50	79.37
Total Applications Reviewed	63	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	3
Number of studies withdrawn prior to the meeting	5
Number of student applications reviewed	24
Number of paediatric applications reviewed	20
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	7	11.11
Favourable Opinion with Additional Conditions	11	17.46
Unfavourable Opinion	1	1.59
Provisional Opinion	44	69.84
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	63	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	40	63.49
Further Information Favourable Opinion with Additional Conditions	3	4.76
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	7	11.11
Favourable Opinion with Additional Conditions	11	17.46
Unfavourable Opinion	1	1.59
Provisional Opinion	1	1.59
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	63	100

Table 5: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.73
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	37
Number of days taken to final decision - mode	20
Number of SSAs (non-Phase 1) reviewed	0
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%
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	83
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	1
Number of modified amendments over 14 days	0
Number of modified amendments over 14 days as a % of total modified amendments	0.0%

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/NW/0178	Exercise intensity and endothelial function in adolescents	41
11/NW/0198	Significant others and patient outcomes in CFS/ME	46
11/NW/0207	Decision Making by Parents Regarding Urgent Care for Children	52
11/NW/0215	LIFT	40
11/NW/0216	Laboratory-based studies in Adult ALL	49
11/NW/0278	Living with an augmented bladder: The experiences of young people (1)	57
11/NW/0285	Self-concept and mood in child cancer and brain tumour patients	36
11/NW/0289	Efficacy of Different Irrigation Techniques in Root canals	35
11/NW/0290	Topographical Variability in Cardiac Genetic Expression	41
11/NW/0322	Adherence to maintenance medication for inflammatory bowel disease	36
11/NW/0323	Phase III extension of Efficacy & Safety of PTC124 in Cystic Fibrosis	33
11/NW/0324	Injury factors as predictors of outcome in a paediatric TBI population	33
11/NW/0325	Demonstrate improvement of constipation-subjects on opioid pain therapy	37
11/NW/0340	Conjunctival melanoma: a multicentre study	57
11/NW/0376	Treatment needs of people with non-epileptic attack disorder v1	57
11/NW/0380	Oxygen-enhanced MR imaging in cervical cancer	49
11/NW/0381	Does acceptance correlate with positive adjustment to cancer?	43
11/NW/0511	LCS12 vs. ENG subdermal implant (Nexplanon) discontinuation rate study	42
11/NW/0514	Levels of lipoprotein(a) in ACS patients	29
11/NW/0533	Hypogonadism and Endothelial Dysfunction in Type 2 Diabetes.	60
11/NW/0539	People with Learning Disabilities and Intimate Relationships	58
11/NW/0547	Mitochondrial function in skeletal muscle in chronic kidney disease	49
11/NW/0549	Effect of purified fish oils on glucose regulation	33
11/NW/0555	Family Focused Therapy for BD: A Clinical Case Series. Version 1.0	34
11/NW/0556	Recovery Focused Therapy for BD: A Clinical Case Series. Version 1.0	38
11/NW/0572	NGAL utility in paediatric oncology patients	53
11/NW/0583	The Holding Children Project	49
11/NW/0592	Experimental Human Pneumococcal Carriage (EHPC)	55
11/NW/0608	A dose-ranging study using QAW039 in patients with allergic asthma	38
11/NW/0640	CLAR-09007 ORAL TESTOSTERONE UNDECANOATE IN HYPOGONADAL	46

	MEN	
11/NW/0701	Investigating the therapeutic mechanism of propranolol on haemangiomas	37
11/NW/0752	Preliminary evaluation of biomarkers for obstructive sleep apnoea.	41
11/NW/0761	Comparing markers of inflammation between brain and blood-version 1	43
11/NW/0783	Asthma parent-child shared decision making	54
11/NW/0803	Mitochondrial ROS and ageing skeletal muscle	27
11/NW/0875	Orthopaedic tissues for research	26
11/NW/0876	Blood biomarkers of spinal cord injury	47
12/NW/0116	Relatives experiences of the transition to critical care.	45
12/NW/0127	A POINT OF CARE TESTING BASED TRANSFUSION ALGORITHM STUDY	48
12/NW/0192	NIRS in cardiac infants on PICU	38

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/NW/0293	Image quality of Low dose Orthopaedic pelvic Computed Tomography -V1	50
11/NW/0708	Employment interventions in secondary mental-health care	41
11/NW/0864	Protocol IMGN0007 amendment 2	49

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/NW/0810	Effects of beta-blockade on cardiopulmonary exercise testing	20
12/NW/0021	Ketamine-ECT Study	20
12/NW/0041	Perceptions of Consultant Practitioners in Radiotherapy	20
12/NW/0060	DERIVE	20
12/NW/0094	CONNECT:CONseNt methods in paediatric Emergency and urgent Care Trials	26
12/NW/0122	URBAN CF	26
12/NW/0137	Everolimus in patients with non functioning NETs (RADIANT-4)	26

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/NW/0217	PECTORALIS MAJOR MUSCLE RECONSTRUCTION WITH ACHILLES	41

	TENDON ALLOGRAFT	
11/NW/0280	Obesity and intrapartum care	29
11/NW/0379	Personal meanings of being 'at risk of psychosis' v3.1	32
11/NW/0554	ADC-PMS-INX-11011 Ease of Use of New BGM with In-Built Calculator	29
11/NW/0646	Motor control dysfunction of the scapula and hand function	27
11/NW/0697	Phase 2/3 BAX326 Study in Paediatric Patients with Hemophilia B	20
11/NW/0706	Caregivers of children with PKU	20
11/NW/0779	How Effective are Antithrombotic Therapies in Primary PCI: HEATppci v1	27
11/NW/0780	Jaundice and Exercise Testing	27
12/NW/0051	PKU-QOL© Questionnaire Validation Study	21
12/NW/0208	Preoperative oral supplementation in colorectal cancer patients.	23

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
12/NW/0059	Preoperative oral supplementation in colorectal cancer patients.	20

Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
12/NW/0169	CARS Study (version 1.0)	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

Table 7: 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