

**NRES Committee North West -
Liverpool East**

Annual Report

01 April 2013 – 31 March 2014

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee North West - Liverpool East
Type of REC:	Type 3
Type of Flag:	RTB, Paediatric
Chair:	Mrs Glenys J Hunt
Vice-Chair:	Professor Neil Pender
Alternate Vice-Chair:	Dr Peter Walton
REC Manager:	Miss Helen Penistone
REC Assistant:	Ms Rachel Katzenellenbogen
Committee Address:	HRA NRES Centre Manchester Barlow House 3rd Floor 4 Minshull Street Manchester M1 3DZ
Telephone:	0161 625 7832
Fax:	0161 625 7299
Email:	nrescommittee.northwest-liverpooleast@nhs.net

Chair's overview of the past year:

We reviewed 50 studies in full committee this year, out of which almost one – third were CTIMPS, which are often complicated and tricky. I would especially like to thank our pharmacist, Maureen Hendy, for her input into these reviews. Out of the 50, 14 were paediatric studies, so we could utilise our special expertise. In addition there were 16 studies dealt with by Proportionate Review. Out of the whole 66, only 1 was given an unfavourable opinion, although all of the remainder needed further information and/or amendment before being granted a favourable opinion. We have a loyal core of committee members, although have sadly had to say goodbye to a few this year. We will particularly miss the input from Chris Irving and Carole Griffiths. The only factor that has let the Committee down is our attendance on training courses, and area which many of us (including me) need to do better. As usual we have been given marvellous support by our administrator, Helen Penistone, who makes the whole process so much easier and more efficient.

NRES Committee North West - Liverpool East Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mr John Bridson	Clinical Ethicist	Expert	21/06/2007	
Dr Zoe Edwards	Clinical Psychologist	Expert	21/02/2011	
Mrs Elizabeth Gordon	Retired	Lay	01/06/2013	
Ms Carole Griffith	Physiotherapist Case Manager	Expert	13/09/2007	16/08/2013
Mrs Maureen Hendry	Pharmacist	Expert	12/07/2010	
Mrs Glenys J Hunt	Lay member	Lay	22/08/2005	
Mr Chris Irving	Biomedical Scientist	Expert	08/09/2010	21/03/2014
Dr S.M. Mostafa	Retired	Expert	01/05/2013	15/11/2013
Professor Ebrahim Khalil Naderali	Professor of Human Physiology	Expert	21/02/2011	
Mr Alex Newgrosh	Quality Assurance Manager	Lay Plus	16/09/2010	
Professor Neil Pender	Professor of Orthodontics	Expert	27/08/2005	
Mrs Jean Pownceby	Lay Member	Lay Plus	11/01/2006	
Miss Kimberley Saint	Trainee Clinical Scientist	Lay	27/09/2012	
Dr Richard Sarginson	Consultant (Anaesthesia/PICU)	Expert	16/02/2005	
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
Ms Hannah Chambers	Lay Member	Lay	20/06/2014

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

Name	Declaration of Interest	Date
Ms Carole Griffith	none	17/05/2013
Dr S.M. Mostafa	None	12/05/2013
Mrs Elizabeth Gordon	None	14/06/2013
Mr Chris Irving	Whiston Hospital Department of Histopathology involvement in clinical trials / supply of research material. Close work with Whiston Hospital R&D Department.	19/11/2013
Professor Neil Pender	Reviews for MRC grants	21/11/2013
Mr Alex Newgrosh	None	20/11/2013
Mrs Glenys J Hunt	None	16/11/2013
Mrs Maureen Hendry	None	25/11/2013
Dr Richard Sarginson	None	21/11/2013
Dr Zoe Edwards	None	02/12/2013
Mrs Jean Pownceby	Trustee of voluntary organisation, Liverpool Citizen Advocacy. No current research plans	16/01/2014
Dr Peter Walton	Lay representative on NICE Committees	16/01/2014
Miss Kimberley Saint	Work at Central Manchester University Hospital NHS Trust.	16/01/2014
Mr John Bridson	Member of Board of Trustees of the UK Clinical Ethics Network Member of the Biomedical Ethics and Society Research Group, Institute of Psychology, Health and Society, University of Liverpool. Member of the Cardiology Research Committee, RLBUHT. Clinical ethicist at RLBUHT	20/03/2014

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

Month	Date	Number of Members Present at Meeting
April	18/04/2013	8
May	16/05/2013	11
June	20/06/2013	9
August	15/08/2013	10
September	19/09/2013	12
October	17/10/2013	8
November	21/11/2013	9
December	12/12/2013	10
January	16/01/2014	11
March	20/03/2014	12

10 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
April	17/04/2013	3
May	31/05/2013	3
June	27/06/2013	3
August	29/08/2013	3
September	29/09/2013	3
November	03/11/2013	3
December	08/12/2013	4
January	07/01/2014	3
February	04/02/2014	3
March	04/03/2014	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 Peter Walton	10
Mr Alex Newgrosh	10
Dr Richard Sarginson	9
Professor Neil Pender	9
Mrs Glenys J Hunt	8
Mr Chris Irving	8
Mr John Bridson	7
Dr Zoe Edwards	7
Mrs Jean Pownceby	7
Mrs Maureen Hendry	7
Miss Kimberley Saint	5
Mrs Elizabeth Gordon	5
Dr S.M. Mostafa	3
Ms Carole Griffith	2
Professor Ebrahim Khalil Naderali	2

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
Dr Peter Walton	5
Mr John Bridson	4
Mrs Glenys J Hunt	4
Dr Richard Sarginson	3
Miss Kimberley Saint	3
Professor Neil Pender	3
Mr Alex Newgrosh	2
Dr Zoe Edwards	2
Mrs Elizabeth Gordon	2
Mrs Jean Pownceby	1
Professor Ebrahim Khalil Naderali	1
Mr Chris Irving	1

Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Mr Chris Irving	30/07/2013 - 30/07/2013	HTA, HRA
Mr Chris Irving	05/11/2013 - 05/11/2013	HTA Advanced, HRA
Miss Kimberley Saint	18/09/2013 - 18/09/2013	Induction, HRA
Professor Neil Pender	21/06/2013 - 21/06/2013	Medical Ethics and Palliative Care presentation , University of Liverpool
Mrs Maureen Hendry	27/11/2013 - 27/11/2013	National Members Training Day, HRA
Miss Kimberley Saint	27/11/2013 - 27/11/2013	National Members Training Day, HRA
Dr Zoe Edwards	01/01/2014 - 01/01/2014	GCP Training
Miss Kimberley Saint	19/08/2013 - 19/08/2013	E&D, Central Manchester Foundation Trust
Miss Kimberley Saint	13/09/2013 - 13/09/2013	Shared Ethical Debate 12 - Final Report, HRA
Mrs Maureen Hendry	19/02/2014 - 19/02/2014	CTIMPs, HRA
Mrs Jean Pownceby	26/02/2014 - 26/02/2014	Equality & Diversity, 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	16	32.00
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	2	4.00
Research Database	0	0.00
Others	32	64.00
Total Applications Reviewed	50	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	13
Number of studies withdrawn prior to the meeting	7
Number of student applications reviewed	17
Number of paediatric applications reviewed	14
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	2	4.00
Favourable Opinion with Additional Conditions	11	22.00
Unfavourable Opinion	1	2.00
Provisional Opinion	36	72.00
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	50	100
Number of studies sent back to full committee meeting for final opinion	1	

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	33	66.00
Further Information Favourable Opinion with Additional Conditions	3	6.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	4.00
Favourable Opinion with Additional Conditions	11	22.00
Unfavourable Opinion	1	2.00
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	50	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	5	31.25
Favourable Opinion with Additional Conditions	6	37.50
No Opinion transfer to full committee for review	2	12.50
Provisional Opinion	3	18.75
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	5.00
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	29
Number of days taken to final decision - mode	20
Number of SSAs (non-Phase 1) reviewed	1
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	105
Number of substantial amendments over 35 days	1
Number of substantial amendments over 35 days as a % of total substantial amendments	1.0%
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	5
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	5
Number of proportionate review applications over 14 days as a % of total	35.7%

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/NW/0220	Cohort apex locator V1	56
13/NW/0240	Reactions & Responses to Diagnoses of Schizophrenia & Bipolar Disorder	38
13/NW/0259	Physical fitness and quality of life in rectal cancer patients	37
13/NW/0265	DESTINY	32
13/NW/0269	Reading difficulties in children with rolandic epilepsy (version1)	20
13/NW/0278	Phase IIIb study of riociguat in patients with chronic thromboembolic	32
13/NW/0325	Psychological processes in psychosis	41
13/NW/0348	Multi Vendor OE-MRI Comparison study	53
13/NW/0349	Stories Parents tell of having a Child with a Tracheostomy	50
13/NW/0365	Improved Pregnancy Outcome via Early Detection (IMPROVED) Biobank	26
13/NW/0369	Assessment of auditory nerve in profoundly deaf patients using EABR	53
13/NW/0408	Is Cervical Vertebral Maturation a valid predictor of growth?	49
13/NW/0552	Packing of perianal abscess cavities study.	18
13/NW/0553	PR Transfer- Predictors of Mortality Following PEG Insertion In Stroke	28
13/NW/0573	IIF-MC-RHAO: Ixekizumab (LY2439821) in Ankylosing Spondylitis Patients	41
13/NW/0583	Evaluation of metformin XR vs metformin IR in monotherapy in T2DM	30
13/NW/0612	Benralizumab treatment in patients with uncontrolled asthma (SIROCCO)	28
13/NW/0621	The early use of Antibiotics in at Risk Children with Influenza-ARCHIE	29
13/NW/0664	Acetazolamide in aortic surgery	30
13/NW/0691	International Burn Scar Outcome Study 1.1	31
13/NW/0722	Dynamic Consent Version 1	25
13/NW/0774	3623 SUSTAIN™ 1 – Monotherapy	29
13/NW/0775	GHD & FGF21 (13/NW/0775)	20
13/NW/0783	Moment-to-moment changes in attachment behaviour.	29
13/NW/0785	Development of a patient decision aid for hearing loss	13
13/NW/0831	CV - Long-term Safety of Naldemedine for the Treatment of OIC	32
13/NW/0854	Nutrition Support for Inactive Crohn's Disease	27
13/NW/0858	AEGEAN study CV185220 v3.0 23 Jan 2013	20
13/NW/0864	Investigating a low carbohydrate/high protein diet in type 2 diabetes	25

14/NW/0017	TERI-PRO	24
14/NW/0018	Cinryze in Prevention of Angioedema Attacks in Children	26
14/NW/0019	Imagining calcinosis in systemic sclerosis	25
14/NW/0076	Comparison of K-wire fixation and ORIF for distal radius fractures	14
14/NW/0128	The Living Airway Biobank (LAB)	31
14/NW/0156	OlympiAD - Olaparib monotherapy V Physicians choice chemotherapy	27

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/NW/0443	Exercise and stroke evaluation	19
13/NW/0558	Impact of schema therapy on narratives in secure settings	50
13/NW/0643	Children's experiences of EMDR in treating trauma	46
14/NW/0015	Leg length Equalisation, Gait and MUSCLE (The LEG MUSCLE study)	25

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/NW/0435	Utility of a non-invasive doppler during pre-operative assessment	9
13/NW/0462	Phase II dose-finding study of APD403 in CINV	27
13/NW/0508	SMS messages to reduce missed appointments in hospitals	7
13/NW/0645	Illness Representations, emotion regulation and wellbeing in ESRD	21
13/NW/0707	ABACUS - colorectal cancer screening uptake: Version 1.1	15
14/NW/0016	EORTC Oral Health Module - Phase 4 International Field Testing	25
14/NW/0143	The analysis of the faecal microbiome in inflammatory bowel disease	18

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/NW/0301	Digital Morphometrics version 2.0	13
13/NW/0303	Bone analysis in MDS patients	16
13/NW/0421	Patient and surgeon decision-making in risk-reducing mastectomy	27
13/NW/0436	Barriers and facilitators in the pathway to care of military veterans	13
13/NW/0447	International Children's Illness and Symptom Study	43

13/NW/0635	Process of change in a non-residential therapeutic community	21
13/NW/0636	Service user experiences of MBT for borderline personality disorder	21
13/NW/0738	Humox Study	19
13/NW/0739	Human Papillomavirus Vaccine in Juvenile Lupus and Dermatomyositis	19
13/NW/0748	Clinical trial for elderly patients with Multiple Diseases (CHROMED)V1	13
13/NW/0791	A Study of GSK1278863 in the treatment of anaemia in Dialysis patients	20
13/NW/0793	A study of GSK1278863 in the treatment of anaemia in non dialysis.	20
13/NW/0839	Midazolam Microtracer PK study in children up to 2 years old	21
13/NW/0851	Proteomic analysis of cystic fluid of craniopharyngioma in children	20
14/NW/0078	Antenatal experiences of morbidly obese women	12
14/NW/0145	The Midwife-Client Relationship	14
14/NW/0146	TETRA - Thymic Epithelial Tumours; a Retrospective Analysis	14

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/NW/0843	Bronchial allergen challenge in asthmatic patients	21

Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
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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 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
13/NW/0303	Bone analysis in MDS patients	16
13/NW/0443	Exercise and stroke evaluation	19
13/NW/0707	ABACUS - colorectal cancer screening uptake: Version 1.1	15
14/NW/0016	EORTC Oral Health Module - Phase 4 International Field Testing	25
14/NW/0143	The analysis of the faecal microbiome in inflammatory bowel disease	18

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
13/NW/0162/AM03	EXPERT: EXPerience of a health website Evaluated in a Research Study	Amendment 3	36

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

