

National Research Ethics
Service


Health Research Authority

**NRES Committee North West -
Greater Manchester West**

Annual Report

01 April 2013 – 31 March 2014

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee North West - Greater Manchester West
Type of REC:	Authorised
Type of Flag:	Qualitative
Chair:	Dr Lorraine Lighton (Chair)
Vice-Chair:	Mr Ian Beaumont (Vice Chair)
Alternate Vice-Chair:	Mr Jonathan Deans
REC Manager:	Anna Bannister
Committee Address:	HRA NRES Centre Manchester Barlow House 3rd Floor 4 Minshull Street Manchester M1 3DZ
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Chair's overview of the past year:

This year has been challenging for the Research Ethics Committee. Owing to administrative difficulties during the first half of the year, the REC failed to meet deadlines for provision of opinions to researchers on more than one occasion. This was particularly distressing to a Committee which prides itself on the service it provides to applicants and which has previously had an excellent reputation for timely responses. I am pleased to report that since October 2013 we have had admirable Co-ordinator support from Anna Bannister, who has managed the backlog and ensured that we are now back on track. I am confident that we have now returned to the previous high quality of service.

As with many RECs, ensuring that all members meet the attendance requirements can be challenging, and this is particularly important when there are vacancies on the Committee. Unfortunately we had to cancel a meeting in October 2013 because of a lack of quorum. This year we have appointed two new members to the Committee, which will help to ensure there are always sufficient members in attendance. Jayne Hardacre, an R&D Practice Development & Support Lead, and Seonaid Beddows, a Research Governance and Administration Manager, are already proving to be valuable members. Thank you to all the members, and those co-opted from other RECs who have attended some meetings to ensure we are quorate, for their time and commitment preparing for meetings, providing input into the REC's deliberations, and making the job of the Chair such a pleasant one. I should like to express particular thanks to Anna Bannister for her help during the last few months.

NRES Committee North West - Greater Manchester West Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr Joshua Adedokun	Consultant In Anaesthesia and Pain Medicine	Expert	01/10/2009	
Mr Ian Beaumont (Vice Chair)	Retired Pharmacist	Lay	01/09/2009	
Mrs Seonaid Beddows	Research Governance and Administration Manager	Lay	01/12/2013	
Mrs Maureen Benbow	Senior Lecturer	Expert	21/05/2013	15/10/2013
Mr Jonathan Deans	Consultant in Head & Neck Surgery	Expert	23/05/2013	
Dr Peter Donnelly	Lay Member	Lay Plus	10/09/2009	
Mr Mark Garrod	Project Consultant and Pension Fund Trustee	Lay Plus	01/09/2011	
Mrs Jayne Hardicre	R&D Practice Development & Support Lead	Expert	27/06/2013	
Mr Michael Harnor	Lay member	Lay Plus	01/09/2009	
Dr Lorraine Lighton (Chair)	Consultant in Communicable Diseases	Expert	01/09/2009	
Dr Barry Miller	Consultant Anaesthetist	Expert	01/09/2009	
Mrs Patricia Morgan	Lay Member	Lay	01/09/2009	
Dr Peter Owen	Lay Member	Lay Plus	01/01/2012	
Mr Iestyn Shapey	Transplant Surgery Registrar	Expert	18/01/2012	
Dr Gideon Smith	Consultant in Public Health Medicine	Expert	20/08/2010	

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Mr Jimmy Burns	Co-opted Lay Member (GM East)	Lay Plus	05/07/2013 & 05/09/2013
Mrs Christine Holly	Co-opted Lay Member (GM South)	Lay	05/07/2013

NRES Committee North West - Greater Manchester West: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Dr Peter Owen	None	03/12/2013
Dr Lorraine Lighton (Chair)	One of the named investigators for Wellcome Trust funded project for which REC review will be sought during the next year.	05/12/2013
Mr Ian Beaumont (Vice Chair)	None	06/12/2013
Mrs Seonaid Beddows	Employed by the Christie NHS Trust on behalf of Greater Manchester and Cheshire Cancer Research Network to improve/support the administration and processes involved in collecting data within the regions hospitals for NIHR approved research studies.	06/01/2014
Mr Mark Garrod	Pension Trustee Director for Piramal Healthcare UK Ltd. Employee of Redx Pharma Ltd. Shareholding in GlaxoSmithkline plc. Partner Dr Michelle Harvie (UoM,UHSM) and her team based at the Genesis Breast Cancer prevention centre are involved in research and submit IRAS applications for their research. Her colleagues – Prof. Tony Howell and Prof. Gareth Evans are also known to me personally and are involved in research projects requiring ethics approval.	06/12/2013
Dr Peter Donnelly	None	06/12/2013
Mrs Patricia Morgan	Chairman and Trustee Deep Screen Care Community Vice Chairman ADS	06/12/2013
Mr Jonathan Deans	None	28/05/2013
Mrs Jayne Hardicre	Role in R&D at Salford Royal NHS Foundation Trust. My role involves leading the development and support of researchers through the research training academy.	05/07/2013
Dr Barry Miller	Chair of training Committee for the Faculty of Pain Medicine (In charge of all training in Pain Medicine in the UK). Peer reviewer for British Journal of Anaesthesia	07/03/2014
Michael Harnor	Trustee / Director of the 'British Epilepsy Association', a registered charity and company limited by guarantee. Working name 'Epilepsy Action'. Vice-Chair of the British Epilepsy Association Research Committee. Trustee / Executive member of the 'Greater Manchester Neurological Alliance', a registered charity affiliated to 'The Neurological Alliance'. Current: The lay member for the Neurology, Pain and Psychiatry expert advisory group (EAG), Commission on Human Medicines. (Hosted by MHRA.)	30/12/2013

	<p>Consequent to the above, member of the 'lay members group at the MHRA'. DH 'Revisiting medicines legislation and pharmacy Regulation'. Partners' group meetings and lay focus group meetings. Public Governor, NWAS NHS Trust. NICE Guideline Development and Quality Standards Groups</p>	
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Meetings for Full Ethical Review 01 April 2013 - 31 March 2014:

Month	Date	Number of Members Present at Meeting
April	05/04/2013	8
May	03/05/2013	11
July	05/07/2013	8
August	02/08/2013	11
September	06/09/2013	7
November	01/11/2013	10
December	06/12/2013	8
January	03/01/2014	10
February	07/02/2014	9
March	07/03/2014	9

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	05/04/2013	3
May	03/05/2013	3
July	11/07/2013	3
August	02/08/2013	3
November	01/11/2013	3
December	06/12/2013	3
January	03/01/2014	3
February	07/02/2014	3
March	07/03/2014	4

9 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 Donnelly	9
Dr Peter Owen	9
Mr Ian Beaumont (Vice Chair)	8
Dr Lorraine Lighton (Chair)	8
Mr Mark Garrod	8
Mr Jonathan Deans	7
Dr Gideon Smith	7
Dr Barry Miller	6
Mrs Patricia Morgan	6
Mr Iestyn Shapey	5
Mr Michael Harnor	5
Mrs Jayne Hardicre	4
Dr Joshua Adedokun	3
Mrs Maureen Benbow	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 Lorraine Lighton (Chair)	7
Dr Peter Owen	6
Mr Ian Beaumont (Vice Chair)	5
Dr Gideon Smith	4
Mr Iestyn Shapey	2
Mr Jonathan Deans	2
Mr Mark Garrod	1

Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Dr Peter Owen	27/11/2013 - 27/11/2013	National Member Training Day, HRA
Dr Peter Owen	31/10/2013 - 31/10/2013	Qualitative Research & Ethical Review, HRA
Dr Lorraine Lighton (Chair)	11/12/2013 - 11/12/2013	NRES Chairs Training Day, HRA
Dr Lorraine Lighton (Chair)	10/01/2014 - 10/01/2014	Equality and Diversity, Civil Service
Dr Lorraine Lighton (Chair)	23/01/2014 - 23/01/2014	Self-Directed Learning - Qualitative research training day provided for public health staff by Manchester Metropolitan University
Mrs Jayne Hardicre	31/10/2013 - 31/10/2013	Qualitative Research & Ethical Review, HRA
Mrs Jayne Hardicre	30/07/2013 - 30/07/2013	Human Tissue Act - An Introductory Level, HRA
Mrs Jayne Hardicre	02/07/2013 - 02/07/2013	Equality & Diversity
Mrs Jayne Hardicre	05/03/2014 - 05/03/2014	Induction, HRA
Mrs Patricia Morgan	31/10/2013 - 31/10/2013	Qualitative Research & Ethical Review, HRA
Dr Peter Donnelly	12/11/2013 - 12/11/2013	Researcher Training Day, HRA
Dr Peter Donnelly	27/11/2013 - 27/11/2013	National Members Training Day, HRA
Mr Ian Beaumont (Vice Chair)	10/12/2013 - 10/12/2013	Quantitative Research Methods and Statistics: A Health Research Authority Workshop, HRS
Mr Mark Garrod	30/07/2013 - 30/07/2013	Human Tissue Act - An Introductory Level, HRA
Mr Iestyn Shapey	20/08/2013 - 20/08/2013	Equality & Diversity, NW Foundation School, North Western Deanery
Mr Iestyn Shapey	18/03/2014 - 18/03/2014	Research and Human Tissue Legislation, Medical Research Council
Mr Jonathan Deans	25/03/2014 - 25/03/2014	Research Involving the Disadvantaged and Vulnerable, HRA
Mrs Seonaid Beddows	05/03/2014 - 05/03/2014	Induction, HRA
Mr Michael Harnor	1/04/2013 - 31/03/2014	Self-Directed Learning: attendance at British Epilepsy Association Research Committee meetings; attendance at Neurology, Pain and Psychiatry expert advisory group (EAG), Commission on Human Medicines. (Hosted by

		MHRA.); attendance at MHRA Lay Members Forum; attendance at NICE Guideline Development and Quality Standards Groups
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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	3
Number of student applications reviewed	28
Number of paediatric applications reviewed	2
Number of device applications reviewed	1
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	0	0.00
Favourable Opinion with Additional Conditions	21	40.38
Unfavourable Opinion	6	11.54
Provisional Opinion	25	48.08
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	20	38.46
Further Information Favourable Opinion with Additional Conditions	2	3.85
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	21	40.38
Unfavourable Opinion	6	11.54
Provisional Opinion	1	1.92
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	2	3.85
Total	52	100

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

Total Applications Reviewed	24
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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	6	25.00
Favourable Opinion with Additional Conditions	9	37.50
No Opinion transfer to full committee for review	1	4.17
Provisional Opinion	7	29.17
Unfavourable Opinion	1	4.17
Total	24	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.20
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	27
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	78
Number of substantial amendments over 35 days	6
Number of substantial amendments over 35 days as a % of total substantial amendments	7.7%
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	7
Number of modified amendments over 14 days	1
Number of modified amendments over 14 days as a % of total modified amendments	14.3%
Number of proportionate review applications for ethical review over 14 days	2
Number of proportionate review applications over 14 days as a % of total	8.7%

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/0201	Hull Endovenous thermoAblative Trial (HEAT)	28
13/NW/0237	Investigation with AAR of the isolated IAS	39
13/NW/0276	PERFECT	10
13/NW/0296	Does IMT further improve the functional capacity of HF patients in CR?	36
13/NW/0298	Electrical remodelling of the sinus node in athletes	36
13/NW/0310	AMEND-IT (version-1)	34
13/NW/0468	Assessment of abdominal aortic aneurysm wall distensibility and stress	31
13/NW/0483	Decision making for heart failure patients who are at end of life	28
13/NW/0485	3D contrast enhanced ultrasound (3D CEUS) for detecting endoleak	32
13/NW/0488	A Study of the Range of Motion of the Lumbar Spine after a L4-5 Fusion	41
13/NW/0534	Effectiveness of Rehabilitation Post ACL Recontruction	6
13/NW/0535	Barriers and facilitators to early initiation of lactation on NICU V1	9
13/NW/0541	Responding to self-harm in young people	56
13/NW/0559	Experiences of pregnant women recieving acupuncture from midwives	57
13/NW/0580	NIPSIGEN - Clinical translation of NIPD for single gene disorders.	14
13/NW/0599	A qualitative exploration of the nature of safety seeking behaviours	25
13/NW/0743	PHS TT-01	24
13/NW/0814	PanORAMA project	52
13/NW/0828	An ethnographic study to understand the impact of patient rounding	32
13/NW/0852	Hand holding during cataract surgery	13
13/NW/0870	The Manchester Parent-Child Preparation Study. Version 1.0	25
13/NW/0871	Experiences of the therapeutic relationship	22
13/NW/0880	Contributory factors in delayed discharge for patients- 13/LO/1937	14
13/NW/0888	Evaluating a planner to aid a community weight management programme	22
14/NW/0046	Exploring the effects of the Recovery, Health and Wellbeing Academy	26
14/NW/0057	Blood lactate responses in heart failure patients (1)	34
14/NW/0082	Understanding IUGR & SGA from the pregnant woman's perspective V1.0	14

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
13/NW/0238	Metacognitive Therapy for Individuals at High Risk of Psychosis	30
13/NW/0522	Recovery in people with a diagnosis of personality disorder.	41

Further Information Unfavourable Opinion		
REC Reference	Application Short Title	Number of Days on Clock

Favourable Opinion with Standard Conditions		
REC Reference	Application Short Title	Number of Days on Clock
13/NW/0275	Targeting GSK-3 in antigen-specific immunotherapy	10
13/NW/0356	Reasons for placement and replacement of crowns v 1.0	20
13/NW/0850	Is the classic orthoptic assessment needed for vision screening	12
13/NW/0876	Better Outcomes for Older people with Spinal Trouble - interview study	8
13/NW/0879	Novel biomarkers in neurological conditions	8
14/NW/0152	Characterisation of human IL-10-secreting T cells	12

Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
13/NW/0242	Differentiating Primary Progressive Aphasia	27
13/NW/0290	Voices, conflict and personal goals	25
13/NW/0355	Using the ABLLS-R to evaluate interventions with clients	15
13/NW/0469	AAR and manometry, the order of data collection	27
13/NW/0470	Filling Rates of the Anal Canal and AAR	27
13/NW/0539	Attitudes of first time mothers and Health Visitors toward sleep	27
13/NW/0579	Assessing south Asian parental attitudes towards living donation	12
13/NW/0595	Client's view of CfD - V1.	18
13/NW/0618	Hygienist/therapist triage model in the periodontal department	26
13/NW/0622	Effects of chemotherapy on memory	32
13/NW/0627	Resilience after stroke: evaluation study of a pilot intervention	47
13/NW/0669	Patient and professional perspectives on living with COPD	48
13/NW/0696	Long term outcomes from Persistent AF ablation	48
13/NW/0758	Experience Led Commissioning for specialist maternity services	38

13/NW/0759	Delivering dignity for older people during chemotherapy	20
13/NW/0786	Role of microRNA in response to treatment with IVIG	12
13/NW/0797	Skin Barrier in Polymorphic Light Eruption	24
13/NW/0827	Biological effects of CMR	31
13/NW/0867	Langerhans' Cells in Normal and Psoriasis Skin	27
13/NW/0878	Diet and lifestyle after prostate cancer diagnosis (Version 1)	7
14/NW/0009	FResB&G 1.0	23
14/NW/0043	IACT (Investigating Attention Control Training in Psychosis)	21
14/NW/0053	Digital breast tomosynthesis in screening younger higher risk women	29
14/NW/0074	Prognostic Value of MCE and SPECT version 1	11
14/NW/0089	Increasing Healthy Behaviour in People with IC - Version 1	11
14/NW/0126	Self Directed Triple P for Psychosis: Symptoms, Parenting and Schemas	24
14/NW/0127	How mothers in a Mother and Baby Unit construe nursing staff.	24
14/NW/0150	Locus of Control and well-being	12
14/NW/0154	Circulating Neuroblastoma Tumour Cell Study (Version 2.0)	10
14/NW/0161	Evaluation of a team-based Health Care Assistant education initiative	7

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/NW/0311	The development of Post-surgical pain following Breast Surgery	25
13/NW/0517	GARMIn: The Role of GABAB Receptor Mechanisms in Cough.	27
13/NW/0547	Clinical trial for elderly patients with Multiple Diseases (CHROMED)V1	36
13/NW/0818	Primary care interventions to reduce or delay GA extractions, v1	24
13/NW/0853	Evaluation of a team-based Health Care Assistant education initiative	12
13/NW/0866	TEP versus open minimal suture repair for the Sportsman's groin	30
14/NW/0085	Does cardiopulmonary bypass change olfaction?	24

Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
14/NW/0117	Does Person Centred Counselling Help to reduce symptoms	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

Withdrawn after the meeting		
REC Reference	Application Short Title	Number of Days on Clock
13/NW/0312	Nutritional assessment of oesophagogastric cancer patients	35
13/NW/0546	Patients with Alcohol-Related Liver Disease	27

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 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/0356	Reasons for placement and replacement of crowns v 1.0	20	
13/NW/0355	Using the ABLLS-R to evaluate interventions with clients	15	
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
12/NW/0774/AM01	Developing Patient-Reported Outcome Measures (PROMs) specific to PTSD	Amendment 1	37
11/NW/0421/AM04	Evaluating new genetic techniques for diagnosing retinal dystrophies	Amendment 3	73
12/NW/0587/AM02	Effect of body composition on gastric emptying rate	Amendment 2	70
06/Q1405/38/AM09	Neurostimulation in dysphagic stroke	Amendment 8	43
13/NW/0310/AM01	AMEND-IT (version-1)	Amendment1	40
10/H1014/8/AM07	Neurobiology of resilience to depression	Version 06: August 2013	40

Modified Amendments over 14 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
12/NW/0525/AM01/1	HYST	Modified Amendment 1	28

Section 30 application over 60 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock