

# NRES Committee North West - Greater Manchester North

## Annual Report

**01 April 2011 – 31 March 2012**

## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	NRES Committee North West - Greater Manchester North
<b>Type of REC:</b>	Authorised
<b>Type of Flag:</b>	None
<b>Chair:</b>	Dr Peter Klimiuk (Chair)
<b>Vice-Chair:</b>	Mr Ken Cook (Vice Chair)
<b>Alternate Vice-Chair:</b>	Dr Cheryl Hunter (Alternate Vice Chair)
<b>Co-ordinator:</b>	Ms Cynthia Carter
<b>PRSC Co-ordinator:</b>	Ms Cynthia Carter
<b>Assistant Co-ordinator:</b>	Mr Ashley Totenhofer
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### Chair's overview of the past year:

I feel we have worked well as a NRES Committee over the past year.

The dynamics of the Committee have worked in a very satisfactory manner. All members of the Committee make a very useful contribution. Presentations by lead reviewers are competent and comprehensive.

We have lost one of our expert members, Annie Herbert, who has to relocate to another area. She is a medical statistician and her statistical critique will be missed.

Overall, I feel we have managed our workload in a timely and professional manner. Proportionate Review has been assimilated and taken on as a new way of working.

## NRES Committee North West - Greater Manchester North Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mr John Addison	Librarian	Lay Plus	13/10/2009	
Dr Victor Ameh	Consultant in Emergency Medicine	Expert	21/10/2010	
Mr R Trevor Benn	Retired Statistician	Lay Plus	09/10/2009	
Mrs Yvonne Clowes	Clinical Research Manager (Infectious Diseases)	Expert	26/10/2009	19/05/2011
Mr Ken Cook (Vice Chair)	Acute Care Manager - Later Life	Expert	12/10/2009	
Mrs Debbie Hamburger	Retired Social Worker	Lay Plus	19/10/2009	
Miss Annie Herbert	Medical Statistician	Expert	13/10/2009	
Dr Cheryl Hunter (Alternate Vice Chair)	Senior Research Assistant	Expert	01/09/2009	
Dr Peter Klimiuk (Chair)	Consultant Rheumatologist	Expert	01/09/2009	
Mr Rodney Lighton	Software Engineer	Expert	09/09/2010	
Dr Jillian McCarthy	Senior Lecturer in Health & Social Care	Expert	15/10/2009	
Mr Jack Ramsay	Lay Member	Lay	01/09/2009	
Ms Clementinah Rooke	Postgraduate Researcher & Bank Nurse	Expert	01/09/2009	
Dr Narveshwar Sinha	Staff Grade Ear Nose & Throat Surgeon	Expert	10/10/2009	30/06/2011
Dr Mahesh Yadav	Consultant Paediatrician & Neonatal Lead	Expert	07/10/2009	
Mr Mohammed Zubair	Research Policy Officer	Expert	01/09/2009	

### Deputy Members

None

### Co-opted Members

None

### Member Bank

None

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

Name	Declaration of Interest	Date
Mr R Trevor Benn	I am a public governor for Clatterbridge Centre for Oncology Foundation Trust. I am a member of the North West regional steering committee of DENDRON, a NIHR sponsored body which promotes research in neurodegenerative diseases. I give them some assistance in developing and informally advising on research proposals. I review research proposals for the NIHR Evaluation Trials & Studies Coordinating Centre (NETSCC) and for the NIHR Central Commissioning Facility (CCF). The above activities have not so far given rise to any conflict of interest. I would of course declare an interest to the Chair if it seemed of any relevance.	25/01/2012
Ms Clementinah Rooke	None	24/01/2012
Dr Peter Klimiuk (Chair)	None	24/01/2012
Mr Ken Cook (Vice Chair)	Senior manager in Manchester Mental Health & Social Care NHS Trust where research is conducted	24/01/2012
Dr Cheryl Hunter (Alternate Vice Chair)	I am currently working for the NHS as a researcher on a five year NIHR Programme Grant called CHOICE (Choosing Health Options in Chronic Care Emergencies) until September 2013	20/12/2011
Mr John Addison	Help provide occasional critical appraisal and interpreting statistics training sessions in collaboration with Pennine Acute NHS Trust statistician. Attend occasional meetings of the Pennine Acute R&D Committee as library representative	05/01/2012
Dr Victor Ameh	I have been since 2005 and am currently a peer reviewer for the Emergency Medicine Journal (EMJ)	26/05/2011
Dr Victor Ameh	1. Peer reviewer for the Emergency Medicine Journal 2. Expert adviser for the Tameside Hospital R&D Committee	06/01/2012
Mrs Debbie Hamburger	None	23/12/2011
Miss Annie Herbert	Healthmob Inc (based in Boston, all research carried out in USA) - Consultancy Review for Juvenile Diabetes Research Foundation, Journal of Medical Ethics, Biomed Central (Cardio disorders), Cochrane Bone, Joint & Muscle Group Member of Royal Statistical Society. Member of Pennine Acute NHS Trust R&D Committee	24/01/2012
Mr Rodney Lighton	None	24/01/2012
Dr Jillian McCarthy	On Authorised Leave from the Committee from January 2011 to May 2012	24/05/2011
Mr Jack Ramsay	Member of Research Governance at Royal Bolton	20/06/2011

	Link Governor at Royal Bolton	
Mr Jack Ramsay	Bolton Research Ethics	05/01/2012
Dr Mahesh Yadav	None	24/01/2012
Mr Mohammed Zubair	I am currently the University of Manchester Research point of contact for all MHRA related matters. I am also an authorised NRES signatory for University of Manchester IRAS applications	13/03/2012

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

Month	Date	Number of Members Present at Meeting
April	18/04/2011	9
May	23/05/2011	10
June	27/06/2011	10
August	22/08/2011	7
September	26/09/2011	9
October	24/10/2011	7
November	28/11/2011	8
January	23/01/2012	7
March	26/03/2012	7

9 full committee meetings were held during the reporting period.

### Proportionate Review Sub Committee Meetings held during 01 April 2011 - 31 March 2012:

Month	Date	Number of Members Present at Meeting
June	03/06/2011	5
July	01/07/2011	3
August	08/08/2011	3
September	09/09/2011	3
October	14/10/2011	3
November	18/11/2011	3
December	22/12/2011	3
January	27/01/2012	3
March	06/03/2012	3

10 proportionate review sub-committee meetings were held during the reporting period.

**Attendance of Members: 01 April 2011 – 31 March 2012:**

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Peter Klimiuk (Chair)	9
Mr John Addison	8
Mr Ken Cook (Vice Chair)	8
Mr Rodney Lighton	8
Dr Victor Ameh	7
Mr R Trevor Benn	7
Ms Clementinah Rooke	6
Dr Cheryl Hunter (Alternate Vice Chair)	5
Mrs Debbie Hamburger	5
Dr Mahesh Yadav	4
Mr Mohammed Zubair	3
Dr Narveshwar Sinha	2 of 3
Miss Annie Herbert	2 of 2

**Number of inquorate meetings held: Nil**

**Attendance of Members at proportionate review sub-committee meetings:  
01 April 2011 – 31 March 2012:**

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Cheryl Hunter (Alternate Vice Chair)	7
Dr Peter Klimiuk (Chair)	4
Mr Ken Cook (Vice Chair)	4
Mr R Trevor Benn	4
Mr Rodney Lighton	4
Mrs Debbie Hamburger	3
Mr John Addison	2
Mr Mohammed Zubair	1

## Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Mr Ken Cook (Vice Chair)	28/03/2012 - 28/03/2012	NRES Members National Training Day, NRES
Mrs Debbie Hamburger	28/03/2012 - 28/03/2012	NRES Members National Training Day, NRES
Mr Rodney Lighton	28/03/2012 - 28/03/2012	NRES Members National Training Day, NRES
Dr Cheryl Hunter (Alternate Vice Chair)	28/03/2012 - 28/03/2012	NRES Members National Training Day, NRES
Mr R Trevor Benn	17/01/2012 - 17/01/2012	Adults Lacking Capacity to Consent, NRES
Dr Peter Klimiuk (Chair)	08/09/2011 - 08/09/2011	Qualitative Research, NRES
Mr John Addison	28/06/2011 - 28/06/2011	Statistics, NRES
Dr Cheryl Hunter (Alternate Vice Chair)	28/06/2011 - 28/06/2011	Statistics, NRES
Ms Clementinah Rooke	28/06/2011 - 28/06/2011	Statistics, NRES
Mr Rodney Lighton	08/09/2011 - 08/09/2011	Qualitative Research, 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:**

<b>Applications for full ethical review – Study Type</b>	<b>Number</b>	<b>%</b>
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	44	100.00
<b>Total Applications Reviewed</b>	<b>44</b>	<b>100</b>

**Table 2: Other REC activity during the reporting period:**

Number of applications made invalid by co-ordinator	9
Number of studies withdrawn prior to the meeting	1
Number of student applications reviewed	20
Number of paediatric applications reviewed	5
Number of device applications reviewed	1
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	1
Number of applications reviewed funded by the US DHHS	0

**Table 3: Decisions given at meetings held within the reporting period:**

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	7	15.91
Favourable Opinion with Additional Conditions	2	4.55
Unfavourable Opinion	1	2.27
Provisional Opinion	34	77.27
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
<b>Total</b>	<b>44</b>	<b>100</b>
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:**

<b>Status of applications at date of generation of report</b>	<b>Number</b>	<b>%</b>
Further Information Favourable Opinion with Standard Conditions	29	65.91
Further Information Favourable Opinion with Additional Conditions	2	4.55
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	7	15.91
Favourable Opinion with Additional Conditions	2	4.55
Unfavourable Opinion	1	2.27
Provisional Opinion	2	4.55
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	1	2.27
<b>Total</b>	<b>44</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>32</b>
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**Table 6: Decisions given at proportionate review sub-committee meetings held within the reporting period:**

<b>Decisions taken at proportionate review sub-committee meetings</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	12	37.50
Favourable Opinion with Additional Conditions	4	12.50
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	16	50.00
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>32</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	4.89
<b>Number of applications for full ethical review over 60 days</b>	0
<b>Number of applications over 60 days as a % of total</b>	0.00%
<b>Number of days taken to final decision - average</b>	32
<b>Number of days taken to final decision - mode</b>	27
<b>Number of SSAs (non-Phase 1) reviewed</b>	0
<b>Number of applications for SSA review over 25 days</b>	0
<b>Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)</b>	0%
<b>Number of SSAs (Phase 1) reviewed</b>	0
<b>Number of applications for SSA review over 14 days</b>	0
<b>Number of applications for SSA review over 14 days as % of all Phase 1 (SSAs)</b>	0%
<b>Number of substantial amendments reviewed</b>	57
<b>Number of substantial amendments over 35 days</b>	2
<b>Number of substantial amendments over 35 days as a % of total substantial amendments</b>	3.5%
<b>Number of Section 30 applications reviewed</b>	0
<b>Number of Section 30 applications over 60 days</b>	0
<b>Number of Section 30 applications over 60 days as a % of total Section 30 applications</b>	0%
<b>Number of modified amendments reviewed</b>	1
<b>Number of modified amendments over 14 days</b>	0
<b>Number of modified amendments over 14 days as a % of total modified amendments</b>	0.0%
<b>Number of proportionate review applications for ethical review over 14 days*</b>	6
<b>Number of proportionate review applications over 14 days as a % of total</b>	18.75%

**\*NB – Proportionate Review Service was in pilot phase until September 2011 and was an aim not a target**

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

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/NW/0185	Chemotherapy-induced changes in cognitive function	46
11/NW/0186	The effect of retinoic acid on Langerhans' cell function in aged skin	35
11/NW/0189	BMAC:a case series with adolescents at risk of suicide/self-harm. V1.	32
11/NW/0193	Clinical features of Depression in Huntington's Disease - Version6	55
11/NW/0295	Assessing a New Activity Pacing Questionnaire (APQ)	42
11/NW/0300	Exploring clinicians' personal models of self-care and co-morbidity	60
11/NW/0301	Family carers of people with dementia - version 1	45
11/NW/0304	Evaluation of ECG algorithms to diagnose Atrial Fibrillation	43
11/NW/0305	MEPA Validation Study	35
11/NW/0361	Leadership Development Programmes. Are they of perceived value?	21
11/NW/0415	Positive psychological factors in adolescence	52
11/NW/0418	Relationship of biomarkers and HRQOL in patients on Haemodialysis	41
11/NW/0425	Carotenoid supplementation and normal ocular health	36
11/NW/0450	Is centralised administration an effective process for an NHS Trust?	7
11/NW/0520	Corticosteroid injection for subacromial impingement syndrome	23
11/NW/0528	The UK Calciphylaxis Study	33
11/NW/0563	Supporting self-care in patients with multimorbidity	31
11/NW/0573	Tone-burst evoked Measurements of Cochlear Microphonics in Infants	25
11/NW/0624	Strategies to increase cervical screening uptake (STRATEGIC) version 1	31
11/NW/0633	Investigation of factors underlying hearing loss - a LOLIPOP substudy	13
11/NW/0650	Predicting fetal compromise in women perceiving reduced fetal movement	38
11/NW/0664	ReMIT Pilot Study	30
11/NW/0665	ESNEE Clinical Study	27
11/NW/0679	The TRAPID-AMI study	32
11/NW/0715	The experience of participation in creative activities	14
11/NW/0716	The Acceptability and Feasibility of Baby Triple P on a MBU	18
11/NW/0717	Clinically meaningful QoL changes in neuropathic pain	20
11/NW/0719	A study of the patient's experience of isolation for infection control	15
11/NW/0723	Saccadic Eye Movements in Alzheimer's disease	35
11/NW/0725	Experiences of CBT in individuals with religious/spiritual beliefs	32

11/NW/0728	Thesis: Experiences of discharge 1	36
11/NW/0729	Norovirus shedding and infectivity - Pilot study(version 1.0)	16
11/NW/0797	Vestibular-evoked potentials produced by sound in deaf patients.	30
11/NW/0802	Clinical study of the PyroTITAN shoulder resurfacing prosthesis V1	29
11/NW/0806	IMPS: Improving support in the next pregnancy after stillbirth	18
11/NW/0813	Use of MRI for the detection of the abnormal trophoblast environment	27
11/NW/0814	Targeted Intervention for Patellofemoral Pain: A Feasibility study	10
11/NW/0815	Result Format for the EMA Binding Test	11
11/NW/0895	Surgical Expertise	12
11/NW/0898	The experience of using diabetic insoles: a qualitative study	15
12/NW/0099	An empirical study of selective eating phenotypes	10
12/NW/0181	First time mothers' experiences of Centering Pregnancy	10
12/NW/0182	Self-care knowledge type 2 diabetes	10
12/NW/0183	Post-diagnosis adaptation and well-being in Asperger's Syndrome	12
12/NW/0184	Does passive smoking during childhood affect rheumatoid arthritis?	13

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/NW/0201	Development of a Questionnaire to measure gas-related symptoms	32
12/NW/0076	Evidence based information and advice to reduce sickness absence (1)	23

#### 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/0181	Angioedema complicating stroke thrombolysis	29
11/NW/0199	s readmission an appropriate outcome measure for Community-Acquired Pn	29
11/NW/0302	Systemic adjuvant therapy for uveal melanoma	36
11/NW/0422	Quality of life and depression.	31
11/NW/0452	HPV Prevalence UK Version 1	7
11/NW/0525	District Nursing psychological support study	18
11/NW/0567	Lipid mediators of UVR-induced skin inflammation	27
11/NW/0576	Attitudes to genetic testing for lung cancer	11

11/NW/0577	Evaluating outcomes in a waiting list CBT group	11
11/NW/0578	FNA BREAST, FORMALIN OR ALCOHOL FIXED CELLS FOR IMMUNOCYTOCHEMISTRY	3
11/NW/0636	A Profile of Patients Attending a Dental Access Centre	13
11/NW/0637	Use of mobilised peripheral blood for liver homing studies	4
11/NW/0807	Prognostic markers in AML	8
11/NW/0808	HPV Vaccination and Cervical Screening Questionnaire	17
11/NW/0899	Diabetic Retinopathy Following Roux-en-Y Gastric Bypass	7
12/NW/0097	Metacognition in speech therapy for children with language impairment	8
12/NW/0098	Alcohol, Diet and Drug Use Preceding Alcoholic Hepatitis	7
12/NW/0101	Arts & Minds: Arts on Prescription	8
12/NW/0227	The EASE BACK study: Phase 1	27

#### Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/NW/0357	Inpatient staff perceptions of a successful journey	4
11/NW/0358	Team Integration in a new Children's Hospital: Version 1	9
11/NW/0449	Nurses' experiences following withdrawal of treatment in the adult ICU	7
11/NW/0781	Face processing in neurodegenerative disease (version 1.0)	17
11/NW/0816	Patients' Opinions on Simulation in Surgical Training	8
12/NW/0232	Oxygen-enhanced MRI biomarkers of hypoxia in renal cancer	26

#### Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/NW/0424	Somatization - assessing perceived anxiety levels in children	27

#### Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
12/NW/0070	Nasal High Flow Oxygen Therapy Study (version 1.0, 06/01/12)	N/A
12/NW/0204	Evaluation of cytology and HPV testing for anal pre-cancer	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
11/NW/0722	Experiences of a CAMHS consultation service: A thematic analysis	28
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
11/NW/0361	Leadership Development Programmes. Are they of perceived value?	21
11/NW/0525	District Nursing psychological support study	18
11/NW/0716	The Acceptability and Feasibility of Baby Triple P on a MBU	18
11/NW/0717	Clinically meaningful QoL changes in neuropathic pain	20
11/NW/0719	A study of the patient's experience of isolation for infection control	15
11/NW/0898	The experience of using diabetic insoles: a qualitative study	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
11/NW/0057/AM02	Knee Osteoarthritis and the Alexander Technique (the KOAT study)	Amendment 2	46
09/H1011/63/AM02	Cognitive Consequences of In Utero Exposure to New Antiepileptic Drugs	Amendment 2	41

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