

# NRES Committee North West - Greater Manchester East

## 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 East
<b>Type of REC:</b>	Authorised
<b>Type of Flag:</b>	none
<b>Chair:</b>	Mr Francis Chan
<b>Vice-Chair:</b>	Professor Janet Marsden
<b>Alternate Vice-Chair:</b>	Dr Philip Lewis
<b>Co-ordinator:</b>	Elaine Hutchings
<b>PRSC Co-ordinator:</b>	Elaine Hutchings
<b>Assistant Co-ordinator:</b>	Nicola Burgess
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### Chair's overview of the past year:

During the year under review, there have been many changes, including the introduction of GAfREC 2 and the Proportionate Review System. While the latter did reduce slightly the number of applications reviewed at each REC meeting, it placed an increased workload demand on members. This is particularly tough in view of the prevailing economic situation.

In addition, the number of studies which border on being audit or service evaluation studies has reduced but remained significant and this obviously continues to place an unnecessary additional burden on the REC.

The number of applications reviewed at each REC meeting in the second half of the year has decreased slightly to between 6 and 7. This has allowed more time to discuss the applications in detail. However, when the number of application at the meeting is above 6, the majority of Committee members still experience difficulty in allocating sufficient time for reading the applications and engaging in debate at the monthly meetings which can now last an inordinate amount of time.

The Committee lost the services of Om Sanehi but was pleased to welcome Steve Agius. The concerns over the level of membership continue to exist and it is hoped that NRES will assist by recruiting new members, both expert and lay.

Finally, I would like to expressive my unreserved gratitude to the Committee members, Prof Janet Marsden, the vice chair, Dr Philip Lewis, the alternate vice chair and Elaine Hutchings, the REC coordinator, for their continuing dedications and support. Without them, the committee would not be able to accomplish its work.

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

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr Steven Agius	Senior Research Fellow in Medical Education	Lay	01/09/2011	
Mr David Asher	Community Locum Pharmacist	Expert	07/07/2010	
Mr James Burns	Retired	Lay Plus	14/07/2010	
Mr Francis Chan	Consultant Orthopaedic Surgeon	Expert	01/09/2009	
Dr Jacqueline Crowther	Research Assistant	Expert	06/10/2009	
Dr Mary Dolan	Nurse Lecturer	Expert	11/10/2009	
Dr Michael Hollingsworth	Retired Senior Lecturer in Pharmacology	Lay	05/10/2009	
Mr Christopher Houston	Lay Member	Lay Plus	03/10/2009	
Mr Simon Jones	Podiatrist	Expert	01/09/2009	
Dr Priyadarshan Joshi	Consultant Psychiatrist	Expert	05/10/2009	
Dr Philip Lewis	Consultant Cardiologist	Expert	02/08/2010	
Professor Janet Marsden	Professor of Ophthalmology and Emergency Care	Expert	02/10/2009	
Dr Om Sanehi	Consultant in Anaesthesia	Expert	01/09/2009	17/05/2011
Mr Howard Shilton	Clinical Nurse	Expert	06/10/2009	
Mrs Mary Speake	Renal Research Sister	Expert	08/10/2009	

**Deputy Members: None**

**Co-opted Members: None**

Name	Occupation	Expert or Lay	Meeting date attended

**Member Bank: None**

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

Name	Declaration of Interest	Date
Mr Howard Shilton	Chair of the University of Manchester Faculty REC.	27/05/2011
Dr Steven Agius	I am employed by the NHS Northwest as a senior research fellow in medical education. I am therefore closely involved with in education research, including applying to ethics committees for approval. I also oversee the administrations of the SHA's research governance committee, of which I am a member.	15/08/2011
Mr David Asher	Share in AstraZeneca PLC Shares in GlaxoSmithKline PLC Donor to: Brain and Spine Foundation, British Travel Association, Cancer Research UK, Neuro-Disability, Beechwood Cancer Research, British Red Cross, East Cheshire Hospice, Stroke association. Membership of Pharmaceutical & general Provident Society Ltd and Liverpool Victoria Friendly Society Ltd. Works as a Locum Community Pharmacist (Self-employed)	14/05/2011
Professor Janet Marsden	Occasional consultancy with Alcan, Pfizer, Novartis.	01/05/2011
Mr Simon Jones	Declared no Interest	14/05/2011
Mrs Mary Speake	Declared no interest.	15/05/2011
Dr Philip Lewis	R & D committee member.	25/05/2011
Dr Michael Hollingsworth	My children work for Astra Zeneca Pharmaceuticals.	11/05/2011
Mr Christopher Houston	Declared no interests	11/05/2011
Mr Francis Chan	No declarations of interest.	17/05/2011
Dr Mary Dolan	No declarations of interest.	21/05/2011
Mr James Burns	Member of the Royal Marsden Hospital.	01/10/2011
Dr Jacqueline Crowther	Volunteer with the Alzheimer's Society. Manuscript reviewer for Palliative Medicine Journal	13/03/2012
Dr Priyadarshan Joshi	Declared no interest.	11/05/2011

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

Month	Date	Number of Members Present at Meeting
April	19/04/2011	9
May	17/05/2011	11
June	21/06/2011	10
July	19/07/2011	11
August	16/08/2011	8
September	20/09/2011	9
November	15/11/2011	14
January	17/01/2012	9
February	21/02/2012	11
March	20/03/2012	10

10 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	17/06/2011	3
July	29/07/2011	3
August	18/08/2011	3
September	15/09/2011	3
September	30/09/2011	3
November	03/11/2011	3
December	13/12/2011	3
January	04/01/2012	3
February	16/02/2012	3
March	19/03/2012	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>
Mr David Asher	10
Mr Howard Shilton	9
Mr James Burns	9
Dr Priyadarshan Joshi	9
Mr Christopher Houston	9
Dr Philip Lewis	8
Dr Mary Dolan	8
Mr Simon Jones	8
Mr Francis Chan	7
Dr Michael Hollingsworth	7
Professor Janet Marsden	6
Mrs Mary Speake	4
Dr Steven Agius	4
Dr Jacqueline Crowther	3
Dr Om Sanahi	1

**Number of inquorate meetings held: None**

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Professor Janet Marsden	7
Mr Christopher Houston	5
Mr David Asher	4
Mr Howard Shilton	4
Dr Michael Hollingsworth	4
Mr Francis Chan	3
Mr Simon Jones	2
Mrs Mary Speake	1

**Training 01 April 2011 – 31 March 2012:**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr Michael Hollingsworth	28/06/2011 - 28/06/2011	NRES statistics training for NRES REC members, NRES
Mr Christopher Houston	28/06/2011 - 28/06/2011	Statistics training for NRES REC Members, NRES
Mr James Burns	07/12/2011 - 07/12/2011	Statistics Training for NRES REC Members, NRES
Mr Christopher Houston	27/09/2011 - 27/09/2011	NRES Update, NRES
Mr James Burns	16/08/2011 - 16/08/2011	GAfREC harmonised version, NRES
Dr Priyadarshan Joshi	20/09/2011 - 20/09/2011	SOPs training, Co-ordinator
Dr Priyadarshan Joshi	16/08/2011 - 16/08/2011	GAfREC training, Co-ordinator
Mr Francis Chan	07/09/2011 - 07/09/2011	Chairing Skills, NRES
Mr David Asher	26/01/2012 - 26/01/2012	Medical Devices Training, HRA
Dr Steven Agius	22/02/2012 - 22/02/2012	Induction, HRA
Dr Michael Hollingsworth	28/03/2012 - 28/03/2012	Members National Training Day- Leeds
Dr Steven Agius	21/11/2011 - 21/11/2011	Equality & Diversity
Dr Jacqueline Crowther	28/03/2012 - 28/03/2012	Members National Training Day Leeds
Dr Mary Dolan	28/03/2012 - 28/03/2012	National Training Day
Dr Michael Hollingsworth	27/09/2011 - 27/09/2011	NRES Update Session
Dr Mary Dolan	27/09/2011 - 27/09/2011	NRES Update Session
Dr Steven Agius	27/09/2011 - 27/09/2011	NRES Update Session
Mr Francis Chan	17/01/2012 - 17/01/2012	Adults Lacking Capacity
Dr Jacqueline Crowther	17/01/2012 - 17/01/2012	ALC training, NRES
Mr Christopher Houston	17/01/2012 - 17/01/2012	ALC training
Dr Steven Agius	20/09/2011 - 20/09/2011	SOP's training, NRES
Mr David Asher	16/08/2011 - 16/08/2011	GAfREC Training, NRES
Mr David Asher	20/09/2011 - 20/09/2011	SOP's Training
Mr Howard Shilton	16/08/2011 - 16/08/2011	GAfREC training
Professor Janet Marsden	20/09/2011 - 20/09/2011	SOP's Training
Mr Simon Jones	20/09/2011 - 20/09/2011	SOP's Training, NRES
Mr Simon Jones	16/08/2011 - 16/08/2011	GAfREC training, NRES
Mr Simon Jones	20/09/2011 - 20/09/2011	SOP's Training, NRES
Mr Christopher Houston	16/08/2011 - 16/08/2011	GAfREC training, NRES
Mr Christopher Houston	20/09/2011 - 20/09/2011	SOP's training
Mr Christopher Houston	20/09/2011 - 20/09/2011	SOP's Training, NRES
Dr Mary Dolan	16/08/2011 - 16/08/2011	GAfREC, NRES
Dr Mary Dolan	20/09/2011 - 20/09/2011	SOP's Training, 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	56	100.00
<b>Total Applications Reviewed</b>	<b>56</b>	<b>100</b>

**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	7
Number of student applications reviewed	22
Number of paediatric applications reviewed	6
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	4	7.14
Favourable Opinion with Additional Conditions	15	26.79
Unfavourable Opinion	2	3.57
Provisional Opinion	35	62.50
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>56</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>
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Further Information Favourable Opinion with Standard Conditions	24	42.86
Further Information Favourable Opinion with Additional Conditions	7	12.50
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	4	7.14
Favourable Opinion with Additional Conditions	15	26.79
Unfavourable Opinion	2	3.57
Provisional Opinion	3	5.36
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	1	1.79
Number of studies withdrawn after the meeting	0	0.00
<b>Total</b>	<b>56</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>22</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	7	31.82
Favourable Opinion with Additional Conditions	5	22.73
No Opinion transfer to full committee for review	2	9.09
Provisional Opinion	8	36.36
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>22</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	5.60
<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>	29
<b>Number of days taken to final decision - mode</b>	17

<b>Number of SSAs (non-Phase 1) reviewed</b>	2
<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>	0.0%

<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>	55
<b>Number of substantial amendments over 35 days</b>	0
<b>Number of substantial amendments over 35 days as a % of total substantial amendments</b>	0.0%

<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>	4
<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>	3
<b>Number of proportionate review applications over 14 days as a % of total</b>	15.00%

**\*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/0138	An exploration of midwives views on normality.	58
11/NW/0171	Measuring Quality of Life in Crohn's Disease	35
11/NW/0197	Neuroinflammation and psoriasis	33
11/NW/0204	Mental health professionals' approach to the recovery process. v1.	48
11/NW/0286	NW10000 pilot	54
11/NW/0288	Study of oesophagus non-goblet cell metaplasia.	25
11/NW/0383	What people attend A&E due to mental health problems? v1	28
11/NW/0409	Can a questionnaire help us identify who has knee cap pain v1.7	26
11/NW/0458	Testing cosmetic efficacy	30
11/NW/0470	Novel genetic testing strategy in evaluating relatives of young SCD	38
11/NW/0494	Study of GPs opinions' and factors influencing usage of MCATS version 1	10
11/NW/0498	Risk Factors that determine the failure of decolonisation treatment	7
11/NW/0501	Service User Experiences of a Solution Focused Pain Programme	11
11/NW/0522	The Experience of Heart Transplant as a Young Adult	49
11/NW/0546	Effect of glucose on brain activation: dose response study.version1	51
11/NW/0553	DAKI v1	45
11/NW/0569	ME: Education, Training & Resources in Primary Care	30
11/NW/0638	The NORD project version1.3	47
11/NW/0652	Communication and Healthcare Choice: An Observational Study	31
11/NW/0657	Correlating visual deficits with in vivo LGN activity in glaucoma	25
11/NW/0695	Recovery from Addiction: What are the service users views?	13
11/NW/0696	Patients' experiences of discharge from Countess of Chester Hospital	18
11/NW/0771	Influence of changing the 'dose' of iontophoresis in patients with SSc	28
11/NW/0776	Anti-resorptive treatment and insulin sensitivity (v. 1)	2
11/NW/0777	Relative importance of major adverse cardiovascular events	15
11/NW/0784	Urethral sphincter EMG activity and the menstruation cycle.	25
11/NW/0790	Effect of lateral wedge insoles on bone marrow lesions (INSOLE)	45
12/NW/0048	Health Impact Assessment and Surveillance: Foundry Exposed Workers	33
12/NW/0049	Health Impact Assessment and Surveillance: Silica Exposed Workers	33
12/NW/0052	The supportive care needs of patients with interstitial lung disease	18

12/NW/0130	Predicting the impact of Adverse Childhood Exposures in adult life v1	27
12/NW/0207	Expression of ABCB1/ABCB5 in paediatric inflammatory bowel disease	24

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/NW/0130	Health Professionals views on post-mortem after neonatal death	50
11/NW/0168	FACIAL PALSY TREATMENT BY CROSS-FACIAL MUSCLE ELECTRICAL STIMULATION	33
11/NW/0387	oxygen-enhanced MRI in asthma	46
11/NW/0478	Study of biomarkers for pancreatic cancer in serum/pancreatic juice v1	28
11/NW/0479	A 3-D model to locate the stem cell niche in human pancreas	31
11/NW/0552	The development of diabetes in Cystic Fibrosis	48
12/NW/0136	Analysis of urine for bacteraemia in ICU	4

#### 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/0364	Mucopolysaccharidosis VI Re-Survey Study	24
11/NW/0589	Myocardial Interaction with LVAD: Mock Circulation	2
11/NW/0654	The IMPACT Study (Study 2)	19
11/NW/0694	Modelling outcomes and equity of coronary revascularisation	14
11/NW/0775	New Biomarkers for EBV LPD	9
12/NW/0068	COPD in Primary Care Study	17
12/NW/0141	T-POETIC v1	17
12/NW/0154	Investigating the pH of tuberculosis infected lymph nodes	7
12/NW/0155	Meaningful occupation for people with a Learning Disability (v1)	7
12/NW/0238	A new strategy for the genetic diagnosis of limb abnormalities	10
12/NW/0239	The IMPACT Study (Pulse Wave Velocity sub-study)	7

#### Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/NW/0174	Recovery after wisdom tooth surgery: the patient's perspective	22

11/NW/0269	How social media impacts on the reputation of the NHS v3	22
11/NW/0275	The Oxford Knee Score in prioritising TKRs	22
11/NW/0281	Who Cares?	22
11/NW/0284	Predictive biomarkers for chemoradiotherapy in larynx carcinoma.	28
11/NW/0377	Understanding Physical Symptoms Study (V1)	20
11/NW/0396	Generation of human embryonic stem cells for clinical use	21
11/NW/0404	Parents/carers' experiences of a support programme for ASC	9
11/NW/0462	Balance Improvement Study (Version 1.3)	24
11/NW/0497	Primary Care Clinicians' Attitudes Towards Recruiting Patients to RCTs	11
11/NW/0586	MOMENT	10
11/NW/0617	Experiences of parents whose child has been diagnosed with ASD	4
11/NW/0792	OSCAR project V1.5	20
12/NW/0040	Is the NewChAT-VPI a useful tool for PIC- Version 1?	12
12/NW/0053	Adhesion molecules in Langerhans cell function	8
12/NW/0140	Breast cancer treatment decision making during a consultation	21
12/NW/0206	Impact of Carer Support Needs Assessment tool in hospice home care (2)	17
12/NW/0217	Investigation of the molecular basis of transplant rejection v1	23
12/NW/0220	Prospective Coeliac Disease Diagnostic Evaluation	17
12/NW/0222	3D wound imaging of diabetic foot ulcerations	15

#### Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/NW/0287	The management of the failed total wrist replacement	36
11/NW/0557	Vitamin D levels in bronchiolitis in infants 0-12 months of age.	25

#### Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
12/NW/0024	Carer Support in a Medium Secure Unit	N/A
12/NW/0146	(duplicate) Effectiveness of telemonitoring for triggering hospital at	N/A
12/NW/0221	Delineating the phenotype of Fetal Valproate Syndrome	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

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/0409	Can a questionnaire help us identify who has knee cap pain v1.7	26	
11/NW/0696	Patients' experiences of discharge from Countess of Chester Hospital	18	
11/NW/0777	Relative importance of major adverse cardiovascular events	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
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