

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

Annual Report

01 April 2013 – 31 March 2014

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee North West - Greater Manchester South
Type of REC:	Recognised
Type of Flag:	CTIMP, Medical Device, ALC, IRB registered
Chair:	Professor Sobhan Vinjamuri
Vice-Chair:	Position Vacant Previously Mrs Sarah Duff (Until January 2014)
Alternate Vice-Chair:	Mrs Dorothy Wright
REC Manager:	Miss Nicola Burgess (Acting)
PRSC Manager:	Miss Nicola Burgess (Acting)
Committee Address:	HRA NRES Centre Manchester 3rd Floor, Barlow House 4 Minshull Street Manchester M1 3DZ
Telephone:	0161 625 7830
Email:	nrescommittee.northwest-gmsouth@nhs.net

Chair's overview of the past year:

This is now my second report as Chairman of GM South. I am pleased to say that the Committee continues to work smoothly with good and regular attendance from the members and excellent administrative support.

As a Committee, we have actively participated in the review of CTIMPs, Medical Device studies, ALC studies and Proportionate Review. There has been good contribution by both expert and lay members.

There has been a high turnover of members over the past year, with several being lost due to an increase in their workplace responsibilities. The new members of the Committee have been a welcome addition and have provided further strength and support to the REC.

We are actively looking for a Vice-Chair to fill the vacant position, and this is likely to be filled in the near future.

NRES Committee North West - Greater Manchester South Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr Anne Armstrong	Consultant Medical Oncologist	Expert	06/11/2008	
Mrs Sarah Duff	Consultant General & Colorectal Surgeon		23/12/2009	09/01/2014
Miss Kathryn Fellows	CRO Monitor	Expert	11/07/2013	
Mrs Christine Holly	Retired Librarian	Lay Plus	09/09/2012	
Mr Richard Hovey	Lay member	Lay Plus	31/01/2007	
Ms Carolanne O'Sullivan	Pharmacist	Expert	28/09/2009	13/05/2013
Mr John Pegington	Senior Commissioning Accountant	Lay Plus	25/05/2011	13/02/2014
Mr David Ryder	Medical Statistician	Expert	01/06/2006	
Ms Joanne Skellern	Lecturer in Learning Disabilities	Expert	13/09/2012	
Mrs Hilary Stratton-Powell	Practice Educator	Expert	01/01/2004	
Miss Nessa Thomas	Research Project Manager	Expert	12/11/2010	
Mrs Lesley Thornton	Retired Clinical Delivery Director	Lay	04/09/2012	
Professor Sobhan Vinjamuri	Consultant in Nuclear Medicine	Expert	01/06/2012	
Mrs Dorothy Wright	Lay Member	Lay Plus	05/09/2004	
Dr Anne O'Brien	Pharmacist	Expert	18/02/2014	

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended
Dr Nathalie Abou-Zeid	Pharmacist	Expert	13/03/2014

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Dr M Hollingsworth	Retired Senior Lecturer in Pharmacology (GM East)	Lay	9/05/2013
Mrs Fran Madders	Retired Clinical Trials Co-ordinator in Radiology (GM Central)	Lay	9/05/13

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

Name	Declaration of Interest	Date
Miss Kathryn Fellows	No declarations of interest were provided	15/07/2013
Miss Nessa Thomas	No declarations of interest.	13/02/2014
Mrs Lesley Thornton	Shares in Astra Zeneca.	13/02/2014
Mrs Christine Holly	Declared no interests.	13/02/2014
Professor Sobhan Vinjamuri	Treasurer of British Nuclear Medicine Society. Related activities:-Reviewer for NIHR-Member of Trust Audit Committee.-Member of Trust's Technologies and Devices Committee.	13/02/2014
Ms Joanne Skellern	Related activities: University of Chester, Faculty of Social Care Research Ethics Committee.	13/02/2014
Mr Richard Hovey	No interests were declared.	13/02/2014

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

Month	Date	Number of Members Present at Meeting
April	11/04/2013	10
May	09/05/2013	9
June	13/06/2013	11
July	11/07/2013	10
September	12/09/2013	9
October	10/10/2013	11
November	14/11/2013	10
December	12/12/2013	9
January	09/01/2014	12
February	13/02/2014	8
March	13/03/2014	9

11 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	23/04/2013	3
May	30/05/2013	3
July	04/07/2013	3
August	08/08/2013	3
September	12/09/2013	3
November	21/11/2013	3
January	09/01/2014	3
February	07/02/2014	3
March	20/03/2014	3

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
Mr Richard Hovey	10
Mr David Ryder	10
Mrs Lesley Thornton	10
Mrs Hilary Stratton-Powell	9
Miss Nessa Thomas	9
Mrs Christine Holly	8
Mrs Dorothy Wright	8
Professor Sobhan Vinjamuri	8
Mrs Sarah Duff	8
Mr John Pegington (now resigned)	7
Ms Joanne Skellern	7
Dr Anne Armstrong	6
Miss Kathryn Fellows (appointed 11/07/13)	5
Dr Anne Obrien (formally appointed 18/02/14)	2
Dr Nathalie Abou-Zeid (formally appointed as deputy member 18/02/14)	1
Ms Carolanne O'Sullivan (now resigned)	1

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
Professor Sobhan Vinjamuri	8
Mr Richard Hovey	5
Mrs Dorothy Wright	4
Mrs Lesley Thornton	4
Mrs Christine Holly	2
Miss Nessa Thomas	1
Mr John Pegington (now resigned)	1
Mrs Sarah Duff (now resigned)	1

Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Professor Sobhan Vinjamuri	30/04/2013 - 30/04/2013	Talk of Ethical Dilemmas in Research & Nuclear Medicine
Mrs Christine Holly	22/04/2013 - 22/04/2013	Induction, NRES
Miss Kathryn Fellows	09/09/2013 - 09/09/2013	Induction, HRA
Mrs Lesley Thornton	08/07/2013 - 08/07/2013	Qualitative Research & Ethical Review, HRA
Mrs Lesley Thornton	26/05/2013 - 26/05/2013	Equality & Diversity, HRA
Professor Sobhan Vinjamuri	13/10/2013 - 13/10/2013	Qualitative Research, HRA
Mrs Dorothy Wright	16/07/2013 - 16/07/2013	Inaugural lectures at University of Manchester, University of Manchester
Mrs Dorothy Wright	07/06/2013 - 07/06/2013	HRA values , HRA
Mrs Dorothy Wright	01/05/2013 - 01/12/2013	Mentoring of New Committee member Joanne Skellern
Miss Nessa Thomas	16/07/2013 - 16/07/2013	Professor Wakefield Inaugural Lectures, University of Manchester
Miss Nessa Thomas	23/09/2013 - 10/01/2014	MSc Module on Good Practice in managing clinical research- Ethics governance Focus, School of Nursing, Midwifery & Social Work
Mr Richard Hovey	19/09/2013 - 19/09/2013	Medical Device Training Day, 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	18	30.00
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	42	70.00
Total Applications Reviewed	60	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	4
Number of studies withdrawn prior to the meeting	5
Number of student applications reviewed	14
Number of paediatric applications reviewed	0
Number of device applications reviewed	7
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	7
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	3.33
Favourable Opinion with Additional Conditions	9	15.00
Unfavourable Opinion	1	1.67
Provisional Opinion	48	80.00
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	60	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	43	71.67
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	1	1.67
Favourable Opinion with Standard Conditions	2	3.33
Favourable Opinion with Additional Conditions	9	15.00
Unfavourable Opinion	1	1.67
Provisional Opinion	2	3.33
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	1	1.67
Not Requiring Review by NHS REC	0	0.00
No decision entered on RED	1	1.67
Number of studies withdrawn after the meeting	0	0.00
Total	60	100

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

Total Applications Reviewed	21
------------------------------------	-----------

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	23.81
Favourable Opinion with Additional Conditions	7	33.33
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	9	42.86
Unfavourable Opinion	0	0.00
Total	21	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.45
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	35
Number of days taken to final decision - mode	32
Number of SSAs (non-Phase 1) reviewed	34
Number of applications for SSA review over 25 days	2
Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)	5.9%
Number of SSAs (Phase 1) reviewed	4
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)	0.0%
Number of substantial amendments reviewed	96
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	3
Number of modified amendments over 14 days	1
Number of modified amendments over 14 days as a % of total modified amendments	33.3%
Number of proportionate review applications for ethical review over 14 days	0
Number of proportionate review applications over 14 days as a % of total	0.0%

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/0213	Feasibility and acceptability study of a parent training intervention	54
13/NW/0239	Disclosure of hepatitis C in HIV co-infected patients	18
13/NW/0241	Investigating methods of transdermal fluid extraction	49
13/NW/0250	Evaluation of ultrasound probe for use in bladder radiotherapy	18
13/NW/0270	Brexpiprazole in patients with major depressive disorder	38
13/NW/0314	Targeting heat shock protein 27 in colorectal cancer	32
13/NW/0334	A Study to Evaluate AMG 785 in Postmenopausal Women with Osteoporosis	28
13/NW/0337	Brexpiprazole in elderly patients with major depressive disorder	38
13/NW/0361	Hand therapy protocols for stabilisation of scapholunate instability	42
13/NW/0391	night time confinement v.1	46
13/NW/0411	D081AC00001 Two Part, Phase 1 study in patients with solid tumours	44
13/NW/0423	Understanding gastrointestinal involvement in systemic sclerosis	45
13/NW/0430	A multi-session CBM-I task for individuals with generalised anxiety	9
13/NW/0440	Bracing for hip OA v1.0	19
13/NW/0460	SC IL-1Ra in Stroke Study	32
13/NW/0480	Isotoxic IMRT Study	26
13/NW/0598	RApid Diagnosis of Infections in the CriticAlly IIL	39
13/NW/0600	Brexpiprazole open-label extension study for patients with MDD	32
13/NW/0609	Alight (AMD light trial)	53
13/NW/0655	Management and Incidence of Epilepsy post Intracerebral Haemorrhage	35
13/NW/0683	A utility study for adult B-cell ALL v1	14
13/NW/0700	Validation of cardiac MRI assessment of left ventricular torsion	53
13/NW/0701	Utilisation of T1 mapping in pacemaker patients using cardiac MRI	60
13/NW/0703	Cognitive behaviour therapy for voices and dissociation	36
13/NW/0714	ECASS-4: ExTEND	35
13/NW/0717	Dementia & cancer Care: experiencing & accessing cancer services	56
13/NW/0747	Impact of near vision and contrast sensitivity on quality of life.	45
13/NW/0751	Monitoring the brain during autonomic challenges using EIT	41
13/NW/0754	Efficacy and safety of the InSpace device in rotator cuff repairs.	38

13/NW/0766	Understanding why people choose not to participate in ANALOGY	53
13/NW/0820	Study of Carfilzomib, Carboplatin, and Etoposide in lung cancer	30
13/NW/0829	TRILOGY - A Phase III Study of CHF5993 in Patients with Severe COPD.	33
13/NW/0830	A Phase I study of Human Pharmacokinetics and Safety of ORY-1001	35
13/NW/0835	ARTFORCE PET Boost Study	39
13/NW/0836	Influence of Expressed Emotion on dementia sufferers' adjustment	26
13/NW/0837	REFRESHED Version 1.0	35
13/NW/0881	In-patient suicide whilst under non-routine observation	57
13/NW/0886	Inpatient to outpatient change in caloric intake in type 2 diabetes	12
13/NW/0890	Prostate cancer visual representation: facilitating decision making	12
13/NW/0893	Implementing shared-decision-making for diabetes care	9
13/NW/0895	Attitudes of HIV positive adults towards latent TB screening version 1	14
14/NW/0003	A study comparing Phrenic Nerve Infiltration vs No infiltration.	43
14/NW/0007	Essure® permanent birth control device	39
14/NW/0011	Investigating biomarkers in cognitively normal elderly participants.	31
14/NW/0024	Enhanced Scheme Evaluation Project (ESEP)	34
14/NW/0032	Multiple Doses of UCB4940 In Subjects With Psoriatic Arthritis	33
14/NW/0037	Visual feedback with optical sensing in lung cancer radiotherapy	38
14/NW/0044	Methodology study of PD markers in prostate cancer(BIOMETHS)	33
14/NW/0063	Cochlear CBAS5477	45
14/NW/0073	European Journey II BCS Safety and Efficacy study; Protocol.º:R11009-7	14
14/NW/0075	The meaning of acceptance for individuals with chronic pain	13

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/NW/0529	Somatoform Disorder in British South Asians: a qualitative study	11

Further Information Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/NW/0425	Management and Incidence of Epilepsy post Intracerebral Haemorrhage	37

Favourable Opinion with Standard Conditions

REC Reference	Application Short Title	Number of Days on Clock
---------------	-------------------------	-------------------------

13/NW/0341	Comparison of CAD on raw and processed digital mammograms (v1.0)	6
13/NW/0431	Function and differentiation of blood cells	5
13/NW/0439	Analysis of mucosal samples from European populations for microbes	6
13/NW/0463	Risk of SCC on skin treated with Ingenol Mebutate or Imiquimod Cream	16
13/NW/0593	Bilirubin and HbA1c in type 1 diabetes	8
13/NW/0675	A study of the effects of AF-219 on airway hyper-reactivity in asthma	28
14/NW/0072	What are the experiences of people with psychogenic syncope?	10

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/NW/0327	Information, Knowledge and Expectations of the Routine Foetal Anomaly	8
13/NW/0384	CIMI-DENT Pilot Trial, Version 1, 01May13	18
13/NW/0429	Succinate and Leukocyte Function	5
13/NW/0482	Inhaled GMP grade Lipopolysaccharide in healthy non smokers	29
13/NW/0592	Patients' Expectations and Experiences of Spinal Mobilisations	9
13/NW/0626	Neuroimaging a single dose of modafinil on brain activity in psychosis	31
13/NW/0632	Inhaled ATP challenge in steroid naïve Asthma patients	27
13/NW/0674	The effects of multiple doses of QBM076 in COPD patients	28
13/NW/0685	Evaluation of a Psychological Programme for people living with an LTC	13
13/NW/0824	Evaluation of automated and manual cross-matching techniques 1.0	4
13/NW/0869	Left ventricular hypertrophy and fibrosis in aortic stenosis	32
14/NW/0005	Efficacy of Gevokizumab in polymyositis/dermatomyositis	34
14/NW/0010	LEE011 + BYL719 with Letrozole in patients with ER+ breast cancer	34
14/NW/0144	Acceptability of Testing Attendees at Colposcopy clinics for HIV	24
14/NW/0189	Individuals' experiences of a novel intervention for low back pain.v1	7
14/NW/0192	The BODY-Q Field-Test	5

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/NW/0316	Risk of SCC on skin treated with Ingenol Mebutate or Imiquimod Cream	21

Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
---------------	-------------------------	-------------------------

13/NW/0644	LND101001 in patients with mild to moderate Alzheimer's Disease	N/A
14/NW/0013	Comparative study of TEG vs. traditional coagulation tests Version 1	N/A

Provisional Opinion Pending Consultation with Referee		
--	--	--

REC Reference	Application Short Title	Number of Days on Clock
---------------	-------------------------	-------------------------

Further information response not complete		
--	--	--

REC Reference	Application Short Title	Number of Days on Clock
---------------	-------------------------	-------------------------

13/NW/0427	Ankle Fracture Study	N/A
------------	----------------------	-----

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

SSAs (non Phase 1) over 25 days timeline		
REC Reference	Application Short Title	Number of Days on Clock
13/NW/0251	Phase 3 study to assess efficacy and safety of tocilizumab in GCA	26
13/NW/0716	An Efficacy and Safety Trial of MK-8931 in Mild to Moderate AD(EPOCH)	28

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
13/NW/0626/AM03/1	Neuroimaging a single dose of modafinil on brain activity in psychosis	Substantial Amendment 1a	24

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