

NRES Committee North West - Greater Manchester South

Annual Report

01 April 2011 – 31 March 2012

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee North West - Greater Manchester South
Type of REC:	Recognised
Type of Flag:	CTIMP, ALC, Medical Devices, IRB Registered
Chair:	Dr Ann Wakefield
Vice-Chair:	Mrs Sarah Duff
Alternate Vice-Chair:	Vacant
Co-ordinator:	Elaine Hutchings
PRSC Co-ordinator:	N/A
Assistant Co-ordinator:	Nicola Burgess
Committee Address:	Northwest Centre for Research Ethics Committees 3rd Floor - Barlow House 4 Minshull Street Manchester M1 3DZ
Telephone:	0161 625 7820
Fax:	0161 625 7299
Email:	elaine.hutchings@northwest.nhs.uk

Chair's overview of the past year:

The year 2011-2012 has been a busy one for the Committee, with business demands still high. However, it has been less turbulent given that with effect from September 2011, a Vice Chair was appointed to a vacancy that had stood empty for two years. In May 2012, we are holding interviews to appoint a new Alternate Vice Chair, a vacancy that has remained unfilled for eighteen months. In respect of our existing members, one of our lay members returned in October 2011, which restored a better lay/expert balance to our Committee since the loss of so many members due to ill health in the previous year. In addition, we recruited a further lay plus member to the Committee, Mr John Pegington. Finally, I will be chairing my final meeting in June 2012 as my 10-year term of office comes to an end in August 2012, and a new Chair is currently being sought.

NRES Committee North West - Greater Manchester South Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Miss Elizabeth Arkell	Pharmacist	Expert	20/03/2008	
Dr Anne Armstrong	Consultant Medical Oncologist	Expert	06/11/2008	
Dr Kathryn Berzins	Research Associate	Expert	24/11/2010	
Dr Susan Davidson	Consultant and Honorary Senior Lecturer in Clinical Oncology	Expert	28/09/2004	
Mrs Sarah Duff	Consultant Surgeon	Expert	23/12/2009	
Mr Richard Hovey	Lay member	Lay Plus	31/01/2007	
Mrs Valerie Moffat	Lay Member	Lay	02/10/2005	16/05/2011
Mr John Pegington	Accountant	Lay Plus	25/05/2011	
Mr David Ryder	Medical Statistician	Expert	01/06/2006	
Mrs Hilary Stratton-Powell	Practice Educator	Expert	01/01/2004	
Miss Nessa Thomas	Research Practitioner	Expert	12/11/2010	
Dr Stephanie Tierney	Research Fellow	Expert	01/09/2011	
Dr Ann Wakefield	Senior Lecturer	Expert	01/08/2002	
Mrs Dorothy Wright	Lay Member	Lay Plus	05/09/2004	

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended
Ms Carolanne O'Sullivan	Pharmacist	Expert	13/10/2011 10/11/2011 12/01/2012 08/01/2012

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Mr David Asher	Pharmacist	Expert	14 July 2011
Mr Howard Shilton	Lecturer in Nursing	Expert	14 July 2011

Member Bank: None

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

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Name	Declaration of Interest	Date
Miss Elizabeth Arkell	Manager of pharmacovigilance pharmacist who has responsibilities for the adverse drug reaction monitoring of CTIMPs and NIMPs - both UHSM and pharma sponsored studies.	04/05/2011
Dr Kathryn Berzins	Sessional interviewer for the personal social services unit, University of Manchester. Paid to complete interviews with service users for several national and European studies that have gained ethical approval.	11/05/2011
Dr Susan Davidson	Declared no interests	03/10/2011
Mrs Sarah Duff	Declared 'I am a General Surgeon and Colorectal Consultant at the University Hospital of South Manchester and as such may know individual researchers seeking ethics committee approval'	08/05/2011
Mr Richard Hovey	Declared no interests	23/05/2011
Mr John Pegington	Only declared interest: 'My wife works at a research dietician at the Nightingale Centre at Wythenshawe Hospital'.	25/05/2011
Mrs Hilary Stratton-Powell	Declared: holds some shares n GlaxoSmithKline Beecham	11/05/2011
Mr David Ryder	Declared: "Employed as a statistician within the Christie CTU. May be involved with funding and/or ethical applications for future clinical trials; (if named, these will go to a different ethical committee, otherwise I would declare an interest as soon as I saw any such application".	07/10/2011
Dr Anne Armstrong	Declared interest: "I have been on an advisory board for 2 drugs used for breast cancer".	05/10/2011
Miss Nessa Thomas	Declared interest: "I am employed as a research practitioner by the North West Stroke Research Network. I have frequent contact with health professionals within Pennine Acute Hospitals Trust who have interests in research and are carrying out their own research as well as working on NIHR portfolio studies. I will shortly be seconded to Salford University School of Health, Sport and Rehabilitation for a specific project".	09/05/2011
Mrs Dorothy Wright	Declared interests: Partner F B Wright & Associates (Legal health & safety consultancy).Member Stockport Mind. Chaplaincy volunteer Stepping Hill Hospital. Member Chartered Institute of Library and Information Professionals	02/05/2011
Dr Ann Wakefield	Declared no interests	06/05/2011
Dr Stephanie Tierney	Declared interest: " I am a health services researcher at the University of Manchester."	26/06/2011

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

Month	Date	Number of Members Present at Meeting
April	14/04/2011	10
May	12/05/2011	10
June	09/06/2011	10
July	14/07/2011	9
September	08/09/2011	11
October	13/10/2011	11
November	10/11/2011	11
December	08/12/2011	11
January	12/01/2012	11
February	09/02/2012	11
March	08/03/2012	11

11 full committee meetings were held during the reporting period.

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

Name	Number of Meetings Attended
Miss Nessa Thomas	11
Mr David Ryder	11
Mr Richard Hovey	11
Mrs Sarah Duff	10
Dr Ann Wakefield	10
Dr Anne Armstrong	9
Dr Kathryn Berzins	9
Dr Susan Davidson	9
Miss Elizabeth Arkell	8
Mr John Pegington	8
Dr Stephanie Tierney	6
Mrs Hilary Stratton-Powell	7
Mrs Dorothy Wright	4
Mrs Valerie Moffat	1

Number of inquorate meetings held: None

Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Mrs Sarah Duff	26/01/2012 - 26/01/2012	NRES Medical Devices training, NRES
Mrs Sarah Duff	28/02/2012 - 28/02/2012	NRES Qualitative & Ethical Review, NRES
Mrs Sarah Duff	08/11/2011 - 08/11/2011	Chairing Skills, NRES
Miss Nessa Thomas	28/06/2011 - 28/06/2011	NRES Statistics Training for NRES REC Members, NRES
Miss Nessa Thomas	28/02/2012 - 28/02/2012	NRES Qualitative & Ethical Review, NRES
Miss Nessa Thomas	06/07/2011 - 06/07/2011	NRES Researcher Training Day, NRES
Miss Nessa Thomas	26/01/2012 - 26/01/2012	NRES Medical Devices Training, NRES
Miss Elizabeth Arkell	28/06/2011 - 28/06/2011	NRES Statistics Training for NRES REC Members, NRES
Mrs Sarah Duff	23/06/2011 - 23/06/2011	GCP Training for non-CTIMPs, NIHR - NCRN
Dr Stephanie Tierney	02/10/2011 - 02/10/2011	Equality & Diversity, NRES
Dr Anne Armstrong	08/11/2011 - 08/11/2011	GAfREC Harmonised version, REC Co-ordinator
Miss Elizabeth Arkell	08/09/2011 - 08/09/2011	GAfREC Harmonised version, REC Co-ordinator
Dr Kathryn Berzins	08/09/2011 - 08/09/2011	GAfREC Harmonised version, REC Co-ordinator
Dr Susan Davidson	08/09/2011 - 08/09/2011	GAfREC Harmonised version, REC Co-ordinator
Mrs Sarah Duff	08/09/2011 - 08/09/2011	GAfREC Harmonised version, REC Co-ordinator
Mr Richard Hovey	08/09/2011 - 08/09/2011	GAfREC Harmonised version, REC Co-ordinator
Mr John Pegington	08/09/2011 - 08/09/2011	GAfREC Harmonised version, REC Co-ordinator
Mr David Ryder	08/09/2011 - 08/09/2011	GAfREC Harmonised version, REC Co-ordinator
Miss Nessa Thomas	08/09/2011 - 08/09/2011	GAfREC Harmonised version, REC Co-ordinator
Dr Stephanie Tierney	08/09/2011 - 08/09/2011	GAfREC training, REC Co-ordinator
Dr Ann Wakefield	08/09/2011 - 08/09/2011	GAfREC Harmonised version, REC Co-ordinator
Mrs Dorothy Wright	28/03/2012 - 28/03/2012	NRES Members National Training Day
Mr John Pegington	28/09/2011 - 28/09/2011	Equality & Diversity, NHS
Dr Anne Armstrong	23/11/2011 - 23/11/2011	Equality & Diversity, Christie Hospital
Dr Susan Davidson	23/02/2012 - 23/02/2012	Reviewing CTIMPs
Miss Elizabeth Arkell	28/06/2011 - 28/06/2011	Statistics Training, NRES
Dr Stephanie Tierney	22/02/2012 - 22/02/2012	Induction, NRES
Mrs Hilary Stratton-	10/11/2011 - 10/11/2011	SOPs training, NRES - Co-

Powell		ordinator
Mr David Ryder	10/11/2011 - 10/11/2011	SOPs training, NRES - Co-ordinator
Dr Ann Wakefield	10/11/2011 - 10/11/2011	SOPs training, NRES - Co-ordinator
Dr Stephanie Tierney	10/11/2011 - 10/11/2011	SOPs training, NRES - Co-ordinator
Miss Nessa Thomas	10/11/2011 - 10/11/2011	SOPs training, NRES - Co-ordinator
Mr John Pegington	10/11/2011 - 10/11/2011	SOPs training, NRES - Co-ordinator
Mr Richard Hovey	10/11/2011 - 10/11/2011	SOPs training, NRES - Co-ordinator
Mrs Sarah Duff	10/11/2011 - 10/11/2011	SOPs training, NRES - Co-ordinator
Dr Susan Davidson	10/11/2011 - 10/11/2011	SOPs training, NRES - Co-ordinator
Dr Kathryn Berzins	10/11/2011 - 10/11/2011	SOPs training, NRES - Co-ordinator
Dr Anne Armstrong	18/11/2011 - 18/11/2011	SOPs training, NRES - Co-ordinator

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	11	17.46
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	52	82.54
Total Applications Reviewed	63	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	0
Number of studies withdrawn prior to the meeting	4
Number of student applications reviewed	21
Number of paediatric applications reviewed	3
Number of device applications reviewed	11
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	1	1.59
Favourable Opinion with Additional Conditions	7	11.11
Unfavourable Opinion	1	1.59
Provisional Opinion	54	85.71
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	63	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	34	53.97
Further Information Favourable Opinion with Additional Conditions	17	26.98
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	1.59
Favourable Opinion with Additional Conditions	7	11.11
Unfavourable Opinion	1	1.59
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	1	1.59
Not Requiring Review by NHS REC	0	0.00
No decision entered on RED	2	3.17
Number of studies withdrawn after the meeting	0	0.00
Total	63	100

Table 5: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.25
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	25
Number of SSAs (non-Phase 1) reviewed	37
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)	5.4%
Number of SSAs (Phase 1) reviewed	2
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	91
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	4
Number of modified amendments over 14 days	0
Number of modified amendments over 14 days as a % of total modified amendments	0.0%

Table 6: 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
11/NW/0106	Cardiac structure, function and innervation in diabetes and IGT	24
11/NW/0161	Clinical Assessment of a Device for Screening Respiratory Symptoms	27
11/NW/0163	Efficacy of the Weber test (version 1)	31
11/NW/0190	Padd™ device in assessment of PAD in presence and absence of diabetes	30
11/NW/0240	A qualitative exploration of nurse-led chemotherapy clinics	38
11/NW/0244	Validation of potential markers of disease in systemic sclerosis	40
11/NW/0258	Re-infection and longterm outcomes in ivdus after hepatitis c treatment	54
11/NW/0312	The effectiveness of an orthodontic brace for a receding chin Version 1	25
11/NW/0319	Procalcitonin and band count in critically ill with suspected sepsis.	28
11/NW/0328	Sleep Apnoea CardioVascular Endpoints (SAVE) Study	27
11/NW/0335	Health Improvements through Health Checks Study (HltPES)	24
11/NW/0337	Investigation into the effects of caffeine on late AER.	32
11/NW/0362	Anterior knee pain and foot orthoses in walking and step descent	34
11/NW/0370	Effects of Provent on OSA during CPAP withdrawal (version 1.0)	21
11/NW/0374	The characterisation of cough in lung cancer	47
11/NW/0390	SC IL-1Ra in SAH	25
11/NW/0416	Lunar study - examining tracheostomy positioning and outcome.	25
11/NW/0529	Project Lion Regulatory Clinical Evaluation PR3083536	53
11/NW/0609	Common electrolyte homeostasis in Cardiomyopathy and Health	27
11/NW/0621	An evaluation of parenting approaches for mothers with mental illness	26
11/NW/0623	Dissociation and Trauma Point Prevalence Study	32
11/NW/0714	Indacaterol as either PulmoSpheres or lactose-blend powder in asthma	22
11/NW/0724	NICE induced neuronal plasticity in MCI	55
11/NW/0747	LuAA21004 v agomelatine in adults with Major Depressive Disorder	34
11/NW/0769	Feasibility and suitability of questions for relatives of ICU patients	25
11/NW/0798	The Salford Lung Study (COPD)	23
11/NW/0799	IL-6 in CSF drain infections	33
12/NW/0001	The isovolumic contraction velocity in the critical care setting	32
12/NW/0003	ELISAT - Version 1 dated 20/09/2011	29
12/NW/0015	Manchester Advanced Maternal Age Study (MAMAS)	48

12/NW/0019	Lumax 740 PME/Master Study	36
12/NW/0027	Phase II study to evaluate efficacy & safety of new treatment for COPD	21
12/NW/0168	Cardiac Safety of Foster & Glycopyrrolate vs Foster in COPD	23
12/NW/0173	The influence of cytokine biomarkers on sciatica	28

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/NW/0257	Trans-abdominal intrapartum Fetal ECG in Obese women.	42
11/NW/0260	SDF imaging in cardiac surgery	23
11/NW/0270	The experience of postnatal depression in African mothers in the UK	24
11/NW/0309	Post marketing study to evaluate Inductigraft in PLF: APOLLO	34
11/NW/0320	Experiences of Psychological Therapy by South Asian service users	23
11/NW/0333	The role of free fetal DNA in the prediction of pre-eclampsia	50
11/NW/0413	OCT primary PCI registry	22
11/NW/0456	Living with Ankylosing Spondylitis throughout the life course	22
11/NW/0541	Assessment of levodopa-induced dyskinesia using a novel device- V2	37
11/NW/0699	Determining effect of Apical vs Septal pacing using cardiac MR	24
11/NW/0703	Social Economical Decision Making in Patients with Major Depression	33
11/NW/0770	Immunosuppressive cells and MIC-1 in pancreatic & colorectal cancer	28
11/NW/0782	POUT	28
12/NW/0035	The effect acupuncture on the Achilles tendon in Achilles tendinopathy	26
12/NW/0047	Evaluation of a transdiagnostic anxiety group V1.0	35
12/NW/0103	The effect of exenatide on central GLP-1 receptor activation.version 1	28
12/NW/0143	CVT-301 in Subjects with Parkinson's Disease	40

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
11/NW/0200	SLE - Efficacy and Safety of Sifalimumab	21

Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock

11/NW/0151	MRI Measurement of the Heart v1.0	21
11/NW/0226	Evaluation of Cell Selection System for Umbilical Cord Blood Version 1	22
11/NW/0611	Microstructure measurements of white matter using diffusion MRI	25
11/NW/0669	Deaf with dementia	19
11/NW/0680	PROPEL	19
11/NW/0707	Adolescents' views of their ASD diagnosis and CAMHS input.	19
11/NW/0823	The mortality of workers with occupational lead exposure (MR33)	19

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/NW/0148	The impact of alcohol interventions on offending behaviour. V1	43

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
12/NW/0112	Effects of Geko device on venous physiology	N/A

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
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Table 7: 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	
11/NW/0801	A trial to assess the anti-inflammatory effects of roflumilast in COPD	26	
12/NW/0121	Tiotropium + Olodaterol (Torracto [TM]) in COPD	37	
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