

# NRES Committee North West - Greater Manchester Central

## 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 Central
<b>Type of REC:</b>	Type 1 & Type 3
<b>Type of Flag:</b>	Paediatrics and Research Tissue Banks
<b>Chair:</b>	Professor S J Mitchell
<b>Vice-Chair:</b>	Ms N Harwood
<b>Alternate Vice-Chair:</b>	Dr J D Grainger
<b>Co-ordinator:</b>	Mrs Kath Osborne
<b>Assistant Co-ordinator:</b>	Laura Brown
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### Chair's overview of the past year:

Greater Manchester Central is a well established committee and the members have a high level of commitment to meet the requirements of SOPs and GafREC.

From April 2011 – March 2012, 12 committee meetings took place and 71 applications were reviewed. The number of amendments for the year increased, although this could be due to Capenhurst and Yorkshire Independent Committees closing and ongoing studies being merged with GM Central.

Following an audit in July 2011 the Committee received full accreditation for the third time.

During the year there were seven committee members who resigned and five new members were recruited. Members' attendance at meetings is monitored and no problems have been encountered. All members are aware of the training requirements, which is also monitored.

As Chairman of GM Central REC, I would like to thank the Co-ordinator, Assistant Co-ordinator, Vice Chair, Alternate Vice Chair and members for their continued support and commitment to the work of the committee.

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

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr N M Asbury	Post Doctoral Researcher	Lay	08/07/2010	12/01/2012
Dr L Brabin	Reader in Women's Health	Lay	04/10/2004	08/08/2011
Mr A C C Gibbs	Honorary Lecturer in Medical Statistics	Lay Plus	24/03/2010	
Dr B Duran-Jimenez	Paediatric Clinical Trials Pharmacist	Expert	01/01/2012	
Mrs S R First	Senior Lecturer	Expert	11/11/2011	
Dr J D Grainger	Consultant Paediatric Haematologist	Expert	08/10/2009	
Ms N Harwood	Clinical Team Manager	Expert	01/03/2004	
Ms J Longden	Advanced Nurse Practitioner	Expert	29/03/2010	13/06/2011
Miss C Mason	Student Social Work	Lay Plus	12/01/2012	
Professor S J Mitchell	Consultant Neonatologist	Expert	15/10/2004	
Dr J Ormrod	Lecturer / Staff Support Counsellor	Expert	06/09/2006	
Mrs E Oughton	Senior Clinical Research Nurse	Expert	18/11/2008	29/02/2012
Dr B Potrata	Research Fellow	Lay	17/11/2008	
Mrs F Randles	Clinical Research Site Manager	Lay	19/11/2009	07/10/2011
Dr R G Rawbone	Retired Occupational Physician	Expert	06/11/2008	
Dr S Roberts	Senior Lecturer in Medical Statistics	Expert	28/02/2002	30/06/2011
Ms J M Shaw	Senior Lecturer - Broadcast Journalism	Lay Plus	17/06/2011	
Dr P Stanford	Lecturer	Expert	09/01/2012	
Ms A Swan	Directorate Pharmacist	Expert	16/11/2000	12/12/2011
Dr I A Whiteman	G.P.	Expert	10/12/2007	31/07/2011

### Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Mr R Hovey	Business Analyst	Lay	09/05/2011 05/09/2011 10/10/2011

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

Name	Declaration of Interest	Date
Dr L Brabin	Consultancies undertaken for GSK (HPV vaccination). Reviews MRC proposals and occasionally applications from other funders.	01/06/2011
Mrs F Randles	Clinical Research Associate for Quintiles Ltd., contracted out to Pfizer. Shareholder - Shire Pharmaceuticals (value approximately £1,000).	02/06/2011
Dr N M Astbury	Mars Inc (UK) University of Manchester Northumbria University	23/06/2011
Dr B Potrata	Co-owner of Visible Research Ltd	12/12/2011
Mrs E Oughton	Voluntary Committee member at The Christie. Liaise with R & D at SRM (Salford Royal Foundation) and other R & D departments in North West Trust in current role lead research nurse.	12/12/2011
Dr J D Grainger	Medical Adviser ITP Support Association Manchester Children's SAB Central Manchester Research Governance	07/12/2011
Ms N Harwood	Works in the Wellcome Trust Clinical Research Facility as a Clinical Team Manager although not directly involved in studies overall. Any conflict of interests with specific projects will be declared.	12/12/2011
Dr P Stanford	Lay advisor, patient information Epilepsy Action. Member of Royal College of Nursing, British Pain Society, Collaborative Action Research Network, (professional membership only). Involvement in research projects as part of lecturer role at the University of Manchester. Receives ad hoc invitations to review research applications from funding bodies. Receives ad hoc invitations to review journal articles submitted with a view to publication.	11/01/2012
Dr B Duran-Jimenez	Actual position is "Clinical Trials Pharmacist". As a result sometimes a PI may seek advice in the design of protocols etc. PI support on designing protocols and feasibility of trials within Pharmacy.	09/01/2012
Mrs S R First	Supervision of master's student possibly undertaking research as part of the MSc programme. Possibly contributing to bids for research funding made by academics at the University of Bolton.	09/01/2012
Professor S J Mitchell	None	12/12/2011
Dr R G Rawbone	None	12/12/2011
Ms A Swan	None	12/12/2011
Dr J Ormrod	None	12/12/2011
Mr A C C Gibbs	None	12/12/2011
Miss C Mason	None	16/01/2012

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

Month	Date	Number of Members Present at Meeting
April	11/04/2011	10
May	09/05/2011	11
June	13/06/2011	9
July	11/07/2011	8
August	08/08/2011	10
September	05/09/2011	10
October	10/10/2011	9
November	14/11/2011	9
December	12/12/2011	10
January	09/01/2012	10
February	13/02/2012	10
March	12/03/2012	11

12 full committee meetings were held during the reporting period.

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

Name	Number of Meetings Attended
Dr J Ormrod	11
Professor S J Mitchell	12
Ms N Harwood	9
Mr A C C Gibbs	11
Ms A Swan	8
Dr R G Rawbone	11
Dr B Potrata	9
Mrs E Oughton	6
Dr J D Grainger	8
Dr L Brabin	4
Dr N M Astbury	4
Ms J M Shaw	7
Mr R Hovey	3
Dr S Roberts	2
Ms N Harwood	2
Miss C Mason	2
Dr P Stanford	2
Dr I A Whiteman	1
Dr B Duran-Jimenez	3
Mrs S R First	2

Number of inquorate meetings held: 0

### Training 01 April 2011 – 31 January 2012:

Name of Member	Date	Event(s) attended
Dr B Duran-Jimenez	31/03/2012 – 31/01/2012	NRES Phase I training, NRES
Mrs S R First	17/01/2012 – 17/01/2012	NRES Adults Lacking Capacity (including research in emergency situations) workshop for RECs, NRES
Mr A C C Gibbs	10/10/2011 – 10/10/2011	SOPs and GAfREC
Dr J D Grainger	20/05/2011 - 20/05/2011	ED Equality and Diversity, Skills Academy for Health Core Learning Unit
Ms N Harwood	10/10/2011 – 10/10/2011	SOPs and GAfREC
Ms N Harwood	08/11/2011 – 08/11/2011	Chairing Skills, NRES
Professor S J Mitchell	26/04/2011 - 26/04/2011	Good Clinical Practice, Central Manchester University Hospitals NHS Foundation Trust
Professor S J Mitchell	10/10/2011 – 10/10/2011	SOPs and GAfREC
Professor S J Mitchell	07/12/2011 – 07/12/2011	Statistics Training
Dr J Ormrod	10/10/2011 – 10/10/2011	SOPs and GAfREC
Dr J Ormrod	26/01/2012 – 26/01/2012	NRES Medical Devices Training, NRES
Dr B Potrata	13/04/2011 - 13/04/2011	Children and Research: Ethical Issues in Working with Children as a Vulnerable Group, University of Leeds
Dr B Potrata	10/10/2011 – 10/10/2011	SOPs and GAfREC
Dr R G Rawbone	03/06/2011 - 03/06/2011	ED Equality and Diversity, Skills Academy for Health Core Learning Unit
Dr R G Rawbone	27/09/2011 - 27/09/2011	NRES Update Session, NRES
Dr R G Rawbone	10/10/2011 – 10/10/2011	SOPs and GAfREC
Dr R G Rawbone	16/11/2011 - 16/11/2011	Phase I Advisory Group, AAPEC
Dr R G Rawbone	17/11/2011 - 18/11/2011	Future of REC's - Changes and Challenges, AREC
Ms J M Shaw	04/10/2011 – 04/10/2011	Induction, NRES
Ms J M Shaw	10/10/2011 – 10/10/2011	SOPs and GAfREC
Ms A Swan	10/10/2011 – 10/10/2011	SOPs and GAfREC
Dr B Duran-Jimenez	22/02/2012 - 22/02/2012	Induction, NRES
Mrs S R First	22/02/2012 - 22/02/2012	Induction, NRES
Dr J D Grainger	15/02/2012 - 15/02/2012	Good Clinical Practice (GCP) Refresher, National Institute for Health Research
Ms N Harwood	28/03/2012 - 28/03/2012	NRES Members National Training Day - Leeds, NRES
Miss C Mason	22/02/2012 - 22/02/2012	Induction, NRES Induction Training Day
Dr B Potrata	23/02/2012 - 23/02/2012	Reviewing Clinical Trials of Investigational Medicinal

		Products, NRES
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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:**

<b>Applications for full ethical review – Study Type</b>	<b>Number</b>	<b>%</b>
Clinical Trial of Investigational Medicinal Product	34	47.89
Phase 1	4	5.63
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	33	46.48
<b>Total Applications Reviewed</b>	<b>71</b>	<b>100.0</b>

**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	5
Number of student applications reviewed	17
Number of paediatric applications reviewed	15
Number of device applications reviewed	1
Number of prisoner applications reviewed	0
Number of reviewed 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:**

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	1	1.41
Favourable Opinion with Additional Conditions	4	5.63
Unfavourable Opinion	8	11.27
Provisional Opinion	58	81.69
Invalid	0	0.00
No Opinion Pending Consultation with Referee	0	0.00
Not Requiring Review by NHS REC	0	0.00
<b>Total</b>	<b>71</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	53	74.65%
Further Information Favourable Opinion with Additional Conditions	0	0.00%
Further Information Unfavourable Opinion	0	0.00%
Favourable Opinion with Standard Conditions	1	1.41%
Favourable Opinion with Additional Conditions	4	5.63%
Unfavourable Opinion	8	11.27%
Provisional Opinion	5	7.04%
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	0	0.00%
<b>Total</b>	<b>71</b>	<b>100%</b>

**Table 5: Other Management Information for the reporting period:**

<b>Average number of applications reviewed per full meeting</b>	5.92
<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>	26

<b>Number of SSAs (non-Phase 1) reviewed</b>	24
<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>	17
<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>	0.0%

<b>Number of substantial amendments reviewed</b>	106
<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 modified amendments reviewed</b>	20
<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%

**Table 6: Breakdown of current status of 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/0129	Contractual governance of drug users	21
11/NW/0144	TPMT phenotype genotype correlation - Version 1	55
11/NW/0149	TITAN	23
11/NW/0153	Mental health Needs assessment of children in Federation Schools.	53
11/NW/0177	Prucalopride in paediatric patients with constipation	31
11/NW/0218	The Benefit of Minocycline on Negative Symptoms in Schizophrenia	33
11/NW/0227	Access to treatment for South Asian females with eating disorders	25
11/NW/0236	Effect of citrate concentration on PT & APTT	48
11/NW/0247	Sensitivity of OE-MRI to detect treatment responses in COPD patients	31
11/NW/0264	Long-term Outcomes for Women with Obstetric Anal Sphincter Injury	26
11/NW/0334	Eribulin compared to Dacarbazine in patients with soft tissue sarcoma	25
11/NW/0350	Extension Study of TKT028 Evaluating Safety Outcomes of Replagal	52
11/NW/0354	Substrate ablation and remodelling in non-paroxysmal AF	26
11/NW/0366	Pilates in Pregnancy and Beyond version 1	38
11/NW/0367	LAS100977 in patients with persistent asthma	32
11/NW/0378	PGx validation study in GHD and Turner Syndrome pre-pubertal children	17
11/NW/0402	The Dose-Response, Safety and Efficacy of EP-101 in Subjects with COPD	24
11/NW/0423	Open-label study of BMN 701 in patients with late-onset Pompe disease	32
11/NW/0428	Off-the-shelf use of toric IOLs (Version 2)	32
11/NW/0440	DB Study of CNTO 3157 in Healthy and Asthmatic Subjects Prot 25May2011	22
11/NW/0446	ICON Humalog Pilot	25
11/NW/0454	Ocular Melanoma: Coping with uncertainty	26
11/NW/0461	The effect of intermittent rifampicin on raltegravir (RIF RAL)	37
11/NW/0477	Role of urinary DPP activity in the diagnosis of neonatal cholestasis	33
11/NW/0482	Acridinium Bromide/Formoterol Fumarate in patients with stable COPD	35
11/NW/0492	Drug induced pneumonitis in rheumatoid arthritis patients	21
11/NW/0502	HGT-HIT-072	21
11/NW/0625	The safety, tolerability, PK and PD of GSK2339345 in healthy subjects	26
11/NW/0659	PK comparison of Advagraf and Prograf in children	37
11/NW/0666	TRUSTS (EORTC 62091)	29

11/NW/0672	NGR016 phase II study in patients with advanced soft tissue sarcoma	25
11/NW/0684	Long term administration of SBC-102 in children with LAL deficiency	24
11/NW/0731	Paraoxonase and HDL qualities in glycaemia and inflammation	51
11/NW/0737	Approach and avoidance motivation in adolescent clinical anxiety	26
11/NW/0746	Tiotropium + Olodaterol (TOnado[TM] 2) in COPD	23
11/NW/0772	E7050-701 - Phase Ib/II Study of E7050 Hepatocellular Carcinoma	22
11/NW/0773	Intrathecal Enzyme Replacement Therapy for MPS II Extension Study	26
11/NW/0785	Phase Ib/II E7050-703Advanced or Metastatic Solid Tumors/Gastric Cancer	25
11/NW/0855	Evaluation of the BRIGHT intervention in primary care	24
12/NW/0002	Study E7389-G000-302. Randomized Phase 3 study of Eribulin in NSCLC	27
12/NW/0005	Preschool Weight Monitoring and Prevention of Childhood Obesity 1	29
12/NW/0014	FOCUS FH	28
12/NW/0018	Pilot Gaviscon Double Action pH monitoring study	29
12/NW/0020	What are the experiences of people with dementia in employment?	33
12/NW/0044	Study of Anaceptrapib in Heterozygous Familial Hypercholesterolemia	23
12/NW/0082	Tiotropium + Olodaterol (Torracto [TM]) in COPD	25
12/NW/0090	Feasibility trial of a respiratory symptom intervention	24
12/NW/0096	Evaluating the need for ondansetron with docetaxel chemotherapy V1.0	26
12/NW/0104	A study to examine oral doses of RGH-618 in healthy male volunteers	31
12/NW/0105	Single Infusion of MK3415A In Patients With C. Difficile Infection	28
12/NW/0157	Ipilimumab dose comparison study in Metastatic Melanoma	22
12/NW/0160	Gastrointestinal care for patients undergoing pelvic chemoradiotherapy	24
12/NW/0194	Effect of LMTM on CYP450 Substrates & a P-gp in Volunteers	32

#### **Favourable Opinion with Standard Conditions**

<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/NW/0858	South Asian Voices Enabling Dementia Care (SAVE D) - Version 1	21

#### **Favourable Opinion with Additional Conditions**

<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/NW/0160	Clinical pharmacology study of CHF1535 NEXT DPI versus CHF1535 pMDI	18
11/NW/0228	Manchester Asthma and Allergy Study:13-15 year follow up	47

11/NW/0235	The influence of expectation on hearing aid outcomes	26
11/NW/0343	Assessment of age related macular degeneration pre- and post-treatment	24

#### Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/NW/0141	The role of the immune system in mitral regurgitation	18
11/NW/0192	DB Study of CNTO 3157 in Healthy and Asthmatic Subjects Prot 03Mar2011	36
11/NW/0341	Hypogonadism and Endothelial Dysfunction in Type 2 Diabetes.	24
11/NW/0363	Knowledge and Attitudes towards pregnancy in women with IBD	34
11/NW/0434	A qualitative evaluation of care planning	18
11/NW/0499	Bardoxolone Methyl Evaluation in Patients with Chronic Kidney Disease	21
11/NW/0671	Sleep-dependent consolidation of negative memories in depression.	21
11/NW/0744	Trismus Study. Version 1	20

#### Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/NW/0718	The role of the immune system in mitral regurgitation	N/A
12/NW/0006	BAL8557 Versus Voriconazole in Invasive Fungal Disease (WSA-CS-004)	N/A
12/NW/0149	CHF5633 To Treat Respiratory Failure in Premature Babies V2.0 16/11/11	N/A
12/NW/0180	Evaluation of low sodium PDF in hypertensive PD patients	N/A
12/NW/0186	Parents' views and experiences of childhood carrier testing for SCD	N/A