

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

Annual Report

01 April 2013 – 31 March 2014

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee North West - Greater Manchester Central
Type of REC:	Type I and Type 3
Type of Flag:	Paediatrics and Research Tissue Banks
Chair:	Professor S J Mitchell
Vice-Chair:	Dr R G Rawbone
Alternate Vice-Chair:	Dr J Ormrod
REC Manager:	Mrs Kath Osborne
REC Assistant:	Ms Sian Goodwin
Committee Address:	HRA NRES Centre - Manchester 3rd Floor Barlow House 4 Minshull Street Manchester M1 3DZ
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Chair's overview of the past year:

The members continue to have a high level of commitment, particularly in view of the fact that the Committee agreed to review Phase 1 studies when submitted seven days prior to the meeting. A total of 63 applications have been reviewed during the year, an increase of six from last year and sub-committee workload continues to be high.

Due to the closure of GM North REC, five members transferred to GM Central. In total three members have resigned. All members have met their training requirements by attending at least one training session.

As Chairman of GM Central REC, I would like to thank the REC Manager, REC Assistant, Vice Chair, Alternative Vice Chair and members for their continued support and commitment.

NRES Committee North West - Greater Manchester Central Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mr J Addison	Librarian	Lay Plus	01/05/2013	
Mr K Cook	Qi Gong Teacher	Expert	01/05/2013	
Dr B Duran-Jimenez	Paediatric Clinical Trials Pharmacist	Expert	01/01/2012	
Mrs S R First	Senior Lecturer	Expert	11/11/2011	11/11/2013
Mr A C C Gibbs	Honorary Lecturer in Medical Statistics	Expert	24/03/2010	08/07/2013
Mrs D Hamburger	Retired Social Worker	Lay Plus	01/05/2013	
Dr P Klimiuk	Consultant Rheumatologist	Expert	01/08/2013	
Mr R Lighton	Software Engineer	Expert	01/05/2013	
Mrs F E Maders	Retired Clinical Trials Co-ordinator for Radiology	Expert	01/07/2012	
Miss C Mason	Student Social Work	Lay Plus	12/01/2012	31/07/2013
Mrs J McGahan	Research Assistant	Lay	01/11/2012	01/10/2013
Professor S J Mitchell	Consultant Neonatologist	Expert	15/10/2004	
Dr J Ormrod	Lecturer / Staff Support Counsellor	Expert	06/09/2006	
Dr B Potrata	Research Fellow	Lay	17/11/2008	
Dr R G Rawbone	Retired Occupational Physician	Expert	06/11/2008	
Dr P Stanford	Lecturer	Expert	09/01/2012	
Mr I A T Taylor	Consulting Engineer	Lay Plus	04/09/2012	

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Mr R Hovey	Business Analyst	Lay	14/10/2013

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

Name	Declaration of Interest	Date
Miss C Mason	None	29/04/2013
Dr P Klimiuk	None	02/01/2014
Professor S J Mitchell	Member of Independent Scientific Advisory Committee (ISAC) for MHRA Database Research	02/01/2014
Dr R G Rawbone	None	02/01/2014
Dr J Ormrod	None	02/01/2014
Mr K Cook	None	02/01/2014
Mrs D Hamburger	None	02/01/2014
Mr R Lighton	None	02/01/2014
Mrs F E Maders	None	02/01/2014
Dr B Potrata	Co-Owner of Visible Research Ltd. Regular small monetary donations to NSPCC, Guide Dogs and Fight for Sight. Reviewer for several NIHR programmes.	02/01/2014
Mr I A T Taylor	None	02/01/2014
Mr J Addison	Several small scale ISAs which the investment manager handles. Occasional attendance at meetings of the Pennine Acute NHS Trust R & D Committee.	08/01/2014
Dr P Stanford	Lay advisor (information) Epilepsy Action. Membership - Royal College of Nursing, British Pain Society and Collaborative Action Research. Review NIHR, RFPB studies by invitation.	12/02/2014
Dr B Duran-Jimenez	Clinical Trials Pharmacist in UHSM, offering R & D support from pharmacy perspective. Members of UHSM sponsor oversight committee.	13/03/2014

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

Month	Date	Number of Members Present at Meeting
April	08/04/2013	8
May	13/05/2013	9
June	10/06/2013	13
July	08/07/2013	12
September	09/09/2013	9
October	14/10/2013	8
November	11/11/2013	10
December	09/12/2013	10
January	06/01/2014	11
February	17/02/2014	11
March	10/03/2014	12

11 full committee meetings were held during the reporting period.

Attendance of Members: 01 April 2013 – 31 March 2014:

Name	Number of Meetings Attended
Professor S J Mitchell	11
Mrs F E Maders	10
Dr B Potrata	9
Dr J Ormrod	9
Mr R Lighton	9
Dr R G Rawbone	8
Mr I A T Taylor	8
Mr K Cook	8
Mrs D Hamburger	8
Mr J Addison	7
Dr P Klimiuk	7
Dr P Stanford	6
Dr B Duran-Jimenez	6
Mr A C C Gibbs	3
Mrs S R First	2
Miss C Mason	1

Number of inquorate meetings held: None

Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Mr J Addison	12/03/2014 - 12/03/2014	Improving Informed Consent & Participant Information Sheets , HRA
Mr K Cook	10/09/2013 - 10/09/2013	Chairs Training, HRA
Mr K Cook	12/11/2013 - 12/11/2013	Researcher Training Day, HRA
Dr B Duran-Jimenez	29/04/2013 - 29/04/2013	HRA Assessment Feasibility Study, HRA
Mrs S R First	16/08/2013 - 16/08/2013	Equality & Diversity, Health Research Authority
Mrs D Hamburger	16/01/2014 - 16/01/2014	Research Involving Adults Who Lack Capacity (including research in emergency situations), HRA
Dr P Klimiuk	27/11/2013 - 27/11/2013	National Members Training Day, HRA
Mr R Lighton	27/11/2013 - 27/11/2013	National Members Training Day, HRA
Mrs F E Maders	30/07/2013 - 30/07/2013	Human Tissue Act (Use of Human Samples in Research) - An Introductory Level, HRA
Mrs F E Maders	09/09/2013 - 09/09/2013	Induction, NRES
Mrs F E Maders	27/11/2013 - 27/11/2013	National Members Training Day, HRA
Professor S J Mitchell	20/02/2014 - 20/02/2014	Equality & Diversity, Central Manchester University Hospitals NHS Foundation Trust
Dr J Ormrod	27/11/2013 - 27/11/2013	National Members Training Day, HRA
Dr B Potrata	27/02/2014 - 27/02/2014	Introduction to Good Clinical Practice (GCP) e-learning course, National Institute for Health Research
Dr B Potrata	11/03/2014 - 11/03/2014	Medical Devices Training, HRA
Dr R G Rawbone	30/07/2013 - 30/07/2013	Human Tissue Act (Use of Human Samples in Research) - An Introductory Level, HRA
Dr R G Rawbone	10/09/2013 - 10/09/2013	Chairs Training, HRA
Dr P Stanford	30/07/2013 - 30/07/2013	Human Tissue Act (Use of Human Samples in Research) - An Introductory Level, HRA
Dr P Stanford	15/02/2014 - 15/02/2014	Equality & Diversity, Manchester University
Dr P Stanford	23/02/2014 - 23/02/2014	GCP, Epigeum
Dr P Stanford	11/03/2014 - 11/03/2014	Medical Devices Training, HRA
Mr I A T Taylor	27/11/2013 - 27/11/2013	National Members 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	27	42.86
Phase 1	7	11.11
Gene Therapy	0	0.00
Research Tissue Bank	1	1.59
Research Database	0	0.00
Others	28	44.44
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	5
Number of student applications reviewed	13
Number of paediatric applications reviewed	16
Number of device applications reviewed	1
Number of prisoner applications reviewed	0
Number of 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:

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	2	3.17
Favourable Opinion with Additional Conditions	6	9.52
Unfavourable Opinion	4	6.35
Provisional Opinion	51	80.95
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	50	79.37
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	3.17
Favourable Opinion with Additional Conditions	6	9.52
Unfavourable Opinion	4	6.35
Provisional Opinion	1	1.59
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	0	0.00
Total	63	100

Table 5: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.73
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	26
Number of days taken to final decision – mode	24
Number of SSAs (non-Phase 1) reviewed	29
Number of applications for SSA review over 25 days	4
Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)	13.8%
Number of SSAs (Phase 1) reviewed	11
Number of applications for SSA review over 14 days	1
Number of applications for SSA review over 14 days as % of all Phase 1 (SSAs)	9.1%
Number of substantial amendments reviewed	143
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	25
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
13/NW/0199	AMG 145 in patients with Severe Familial Hypercholesterolemia	27
13/NW/0208	ARROVEN - brentuximab vedotin PASS, version 1.1 dated on 14 June 2012	23
13/NW/0217	LEO 39652 - Atopic Dermatitis	24
13/NW/0231	Understanding the impact of sickle cell trait	45
13/NW/0291	Investigation of a therapeutic vaccine (ACIT-1) in late stage cancer	29
13/NW/0297	Hypertriglyceridaemia - cause and effects	29
13/NW/0320	WA28117 Study of Tocilizumab in pcJIA	24
13/NW/0321	WA28118 Study of Tocilizumab in sJIA	24
13/NW/0322	Molecular Imaging of P-gp function in patients with brain tumours	42
13/NW/0323	Endometriosis and Pelvic Vein Incompetence	24
13/NW/0350	Study to compare BE of Dutasteride & Tamsulosin HCl in male volunteers	28
13/NW/0366	Client Perceptions of Therapist Helpfulness V.1	30
13/NW/0385	Cognitive remediation for first episode of psychosis patients	44
13/NW/0396	Fasted Study to compare BE of Dutasteride & Tamsulosin HCl in males	40
13/NW/0410	Consideration of Mindfulness approaches in Child Mental Health	21
13/NW/0424	Depression in ARD v1	19
13/NW/0466	Dental RECUR Trial	20
13/NW/0477	Study of BYL719-LJM716 combination in patients with oesophageal cancer	24
13/NW/0496	Pregabalin in subjects with Primary Generalised Tonic-Clonic seizures	23
13/NW/0497	ARTFORCE Head & Neck study	41
13/NW/0499	Safety, tolerability and PK of RV1162 in healthy and COPD patients.	15
13/NW/0586	IBS-D Rifaximin Re-Treatment Study (TARGET 3)	20
13/NW/0610	Study to examine safety, tolerability & PK of Baclofen and Memantine	26
13/NW/0623	(duplicate) Speed and road conditions on neonates in ambulances.	29
13/NW/0624	The effect of AZD7624 on LPS challenge	30
13/NW/0625	Puerperal psychosis - exploring the role of relationships. Version 1	34
13/NW/0653	MEMO	28
13/NW/0673	The Pharmacodynamic effects of CHF1535 NEXThaler DPI on COPD	44
13/NW/0698	LDK378 vs Chemo in newly diagnosed untreated ALK+ NSCLC patients	40

13/NW/0723	A Comparison of atrophic and hypertrophic facial photoaged skin	27
13/NW/0727	The effects of SEP-363858 on high or low schizotypic characteristics	32
13/NW/0735	Symptom awareness and social cognition in Huntington's disease	51
13/NW/0741	The effects of XEN-D0501 on cough frequency in COPD patients	22
13/NW/0767	Salford Respiratory Biobank	29
13/NW/0777	GWP42003 for treatment of schizophrenia or related psychotic disorders	21
13/NW/0778	ProCervix vs placebo in women with HPV 16 & HPV 18 infection	18
13/NW/0794	Influence of nitrates on bone and endothelial function in diabetes.	25
13/NW/0855	Addition of phenylephrine to JUVÉDERM® VOLIFT® with lidocaine.	25
13/NW/0874	The Midlands and North of England Stillbirth Study - MiNESS	24
14/NW/0001	Continuation Study of Prophylactic BAX 855 in PTP with Haemophilia A	33
14/NW/0006	Calcipotriol+BetamethasoneDipropionateGel scalp/body psoriasis 12-16yr	28
14/NW/0048	Bronchial allergen challenge in asthmatic patients	25
14/NW/0055	Pregabalin Open Label Follow up study of A0081105	24
14/NW/0060	Reproducibility of Cardiac MRI Spectroscopy	24
14/NW/0069	PK & Safety of Naloxegol in Paediatric Patients Receiving Opioids	19
14/NW/0070	A study to evaluate CHF1535 NEXThaler in adult asthmatics	22
14/NW/0071	Imaging in Transforming Gilomas	25
14/NW/0084	TRISKEL	24
14/NW/0115	Patient perceptions of a pledge scheme for weight loss	27
14/NW/0130	RESPONSE	24

Favourable Opinion with Standard Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/NW/0585	EpiHealth Outcomes	19
13/NW/0823	The SCRIBE (Social Cognition Research in Bonding and Emotions) study	21

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/NW/0209	Effects of Indacaterol via EPIC and Concept1 compared to placebo	18
13/NW/0210	Study to Test the Product Robustness of a Dry Powder Inhalation Device	18
13/NW/0730	Neuroinflammation and serotonergic change in HD gene carriers	21

13/NW/0805	1237.25 - Tiotropium/olodaterol vs tiotropium and placebo in COPD	21
13/NW/0811	PK Study in Adolescents and Young Adults Treated with Glucocorticoids	25
13/NW/0838	Predictive Accuracy of Risk Tools for Repeat Self-Harm. VERSION 1	26

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/NW/0446	An exploration of men's experiences of combat-related amputation (1)	17
13/NW/0658	Toxoplasma infection and affective illness with psychosis	21
13/NW/0856	Advance Online Maternal Education for Labour Analgesia v. 1.0	17
14/NW/0002	The Paediatric EVICEL® Soft Tissue Bleeding Study	18

Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
14/NW/0116	Phase III Paediatric CKD study in peritoneal dialysis or haemodialysis	N/A

Table 7: Items exceeding timelines:

SSAs (non Phase 1) over 25 days timeline		
REC Reference	Application Short Title	Number of Days on Clock
14/NW/0094	A study to evaluate CHF1535 NEXThaler in adult asthmatics	40
14/NW/0095	A study to evaluate CHF1535 NEXThaler in adult asthmatics	40
14/NW/0097	TRISKEL	32
14/NW/0098	TRISKEL	29

SSAs (Phase 1) over 14 days timeline		
REC Reference	Application Short Title	Number of Days on Clock
13/NW/0688	A two-part, phase 1 single-dose study to assess doses of IL-31 mAb	21