

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

Annual Report

01 April 2013 – 31 March 2014

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee North West - Greater Manchester East
Type of REC:	Authorised
Type of Flag:	Qualitative Research
Chair:	Mr Francis Chan
Vice-Chair:	Professor Janet Marsden
Alternate Vice-Chair:	Dr Philip Lewis
REC Manager	Elaine Hutchings
PRSC Co-ordinator:	Elaine Hutchings
REC Assistant	Sian Goodwin
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Chair's overview of the past year:

During the year 2013-4, the continuing reduction in number of full REC applications received overall reflected the changes encompassed in the Harmonised Edition of GAfREC and the introduction of the Proportionate Review System, which is now operating smoothly with the support of the members.

As in the previous year, the Committee took part in shared ethical debate exercises and discussions, and provided feedback to NRES on these.

Members were encouraged to attend appropriate training and provided summaries of these to the remainder of the Committee members, which proved to be most useful. The kind cooperation of the members is reflected in the fact that all members complied with the training requirements.

This year we were joined by Trevor Benn and Clementinah Rooke when GM North was disbanded, but unfortunately Clementinah found the venue difficult to get to and had to discontinue her membership. Trevor has provided invaluable assistance to the Committee particularly in the matter of statistics. The Committee was sorry to receive the resignation of Dr Joshi because of pressure of work near the end of the year following many years of dedicated and constructive work on this Research Ethics Committees, in particular on studies involving psychology/ psychiatry. The REC hopes that NRES will be proactive in the recruitment of new members to return the Committee to a full complement.

NRES Committee North West - Greater Manchester East Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mr David Asher	Retired Pharmacist	Lay	07/07/2010	
Mr R Trevor Benn	Retired Statistician	Lay Plus	24/05/2013	
Mr James Burns	Retired	Lay Plus	14/07/2010	
Mr Francis Chan	Consultant Orthopaedic Surgeon	Expert	01/09/2009	
Dr Jacqueline Crowther	Research Associate	Expert	06/10/2009	
Dr Mary Dolan	Retired Nurse Lecturer	Lay	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	Specialist Podiatrist - Paediatrics	Expert	01/09/2009	
Dr Priyadarshan Joshi	Consultant Psychiatrist	Expert	05/10/2009	07/02/2014
Dr Philip Lewis	Consultant Cardiologist	Expert	02/08/2010	
Professor Janet Marsden	Professor of Ophthalmology and Emergency Care	Expert	02/10/2009	
Mrs Clementinah Rooke	Postgraduate Researcher	Expert	16/07/2013	19/11/2013
Mrs Mary Speake	Clinical Research Practice Educator	Expert	08/10/2009	

Deputy Members: None

Name	Occupation	Expert or Lay	Meeting date attended

Co-opted Members: None

Name	Occupation	Expert or Lay	Meeting date attended

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

Name	Declaration of Interest	Date
Mr David Asher	Small number of shares in Astrazeneca and GSK	17/01/2014
Mr R Trevor Benn	Public Governor of Clatterbridge Centre Foundation Trust. PPI Member of the NW Regional Steering Committee of DeNDRON. Review research proposals for NIHR Evaluation Trials and Studies Co-ordinating Centre and NIHR Central Commissioning Facility; an honorarium is received for each review	17/01/2014
Mr James Burns	No declarations of interest	21/01/2014
Mr Francis Chan	No declarations of interest	21/01/2014
Dr Jacqueline Crowther	Volunteer with the Alzheimer's Society. Abstract reviewer for Society for Academic Primary Care SAPC	16/01/2014
Dr Mary Dolan	No declarations of interest	21/01/2014
Dr Michael Hollingsworth	No declarations of interest	19/02/2014
Mr Christopher Houston	No declarations of interest	17/01/2014
Dr Philip Lewis	Member of R&D Committee, Stockport NHS Foundation Trust	18/02/2014
Professor Janet Marsden	Consultant with Quintiles Member of MoDREC	18/02/2014
Mrs Mary Speake	Clinical Research Practice Educator for Greater Manchester Comprehensive Local Research Network.	19/01/2014
Mr Simon Jones	No declarations of interest	18/02/2014

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

Month	Date	Number of Members Present at Meeting
April	16/04/2013	8
May	21/05/2013	9
June	18/06/2013	10
July	16/07/2013	12
August	20/08/2013	11
September	17/09/2013	7
November	19/11/2013	12
January	21/01/2014	10
February	18/02/2014	9
March	18/03/2014	9

10 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	04/04/2013	3
May	13/05/2013	3
June	20/06/2013	3
October	04/10/2013	3
November	12/11/2013	3
December	12/12/2013	3
January	13/01/2014	3
February	10/02/2014	5
March	14/03/2014	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
Dr Michael Hollingsworth	9
Mr Francis Chan	9
Mr James Burns	8
Dr Philip Lewis	8
Dr Jacqueline Crowther	8
Dr Mary Dolan	8
Mr Christopher Houston	8
Mr David Asher	8
Mr R Trevor Benn	7
Mr Simon Jones	6
Dr Priyadarshan Joshi	6
Mrs Mary Speake	5
Professor Janet Marsden	5
Mrs Clementinah Rooke	2

Number of inquorate meetings held: None

**Attendance of Members at proportionate review sub-committee meetings:
01 April 2013 – 31 March 2014:**

Name	Number of Meetings Attended
Professor Janet Marsden	7
Mr David Asher	5
Dr Jacqueline Crowther	4
Mr Simon Jones	4
Mrs Mary Speake	3
Dr Michael Hollingsworth	3
Mr Francis Chan	2
Mr Christopher Houston	1

Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Dr Jacqueline Crowther	17/04/2013 - 17/04/2013	Reviewing Psychiatric Mental Health Research, NRES
Mr James Burns	02/05/2013 - 02/05/2013	Ethical Issues of Research Involving Children, NRES
Dr Mary Dolan	30/07/2013 - 30/07/2013	Human Tissue Act (Use of human tissue samples) an introductory level, NRES
Mrs Mary Speake	19/09/2013 - 19/09/2013	Medical Devices training day, NRES
Mr Simon Jones	19/09/2013 - 19/09/2013	Medical Devices training day, NRES
Dr Philip Lewis	19/11/2013 - 19/11/2013	Self- Directed training - IRAS training
Mr Christopher Houston	14/03/2014 - 14/03/2014	Personal Data in Research (Workshop), NRES
Mr Francis Chan	11/12/2013 - 11/12/2013	National Training Day for NRES Committee Chairs, NRES
Dr Mary Dolan	10/12/2013 - 10/12/2013	Quantitative Research Methods and Statistics: A HRA Workshop, HRA
Mr David Asher	10/12/2013 - 10/12/2013	Quantitative Research Methods and Statistics: A HRA Workshop, HRA
Mr James Burns	20/11/2013 - 20/11/2013	National Members Training Day, HRA
Dr Jacqueline Crowther	27/11/2013 - 27/11/2013	National Members Training Day, HRA
Dr Michael Hollingsworth	27/11/2013 - 27/11/2013	National Members Training Day, HRA
Mrs Mary Speake	27/11/2013 - 27/11/2013	National Members Training Day, HRA
Mr R Trevor Benn	27/11/2013 - 27/11/2013	National Members Training Day, HRA
Dr Mary Dolan	12/11/2013 - 12/11/2013	Researcher Training Day, HRA
Mr Christopher Houston	12/11/2013 - 12/11/2013	Researcher Training Day, HRA
Mr James Burns	10/03/2014 - 10/03/2014	Improving Informed Consent & Participant Information Sheets - a Collaborative HRA, NIHR, MRC Workshop, HRA
Mr Francis Chan	12/03/2014 - 12/03/2014	Improving Informed Consent & Participant Information Sheets, HRA, NIHR & MRC Workshop
Mr Francis Chan	25/03/2014 - 25/03/2014	Research Involving the Disadvantaged and Vulnerable, HRA
Mrs Mary Speake	12/03/2014 - 12/03/2014	Improving Informed Consent & Participant Information Sheets, HRA, NIHR & MRC Workshop
Professor Janet Marsden	01/05/2013 - 01/05/2014	Self-Directed training about Involving Children in Research
Professor Janet Marsden	31/12/2013 - 31/12/2013	Self-Directed training - MODREC meetings
Mr Christopher Houston	12/02/2014 - 12/02/2014	Equality & Diversity, Fairfield General Hospital

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	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	44	100.00
Total Applications Reviewed	44	100

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	9
Number of student applications reviewed	19
Number of paediatric applications reviewed	3
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	4.55
Favourable Opinion with Additional Conditions	18	40.91
Unfavourable Opinion	2	4.55
Provisional Opinion	22	50.00
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	44	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	18	40.91
Further Information Favourable Opinion with Additional Conditions	4	9.09
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	4.55
Favourable Opinion with Additional Conditions	18	40.91
Unfavourable Opinion	2	4.55
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	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	44	100

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

Total Applications Reviewed	18
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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	6	33.33
Favourable Opinion with Additional Conditions	1	5.56
No Opinion transfer to full committee for review	8	44.44
Provisional Opinion	3	16.67
Unfavourable Opinion	0	0.00
Total	18	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	4.40
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	22
Number of days taken to final decision - mode	17
Number of SSAs (non-Phase 1) reviewed	2
Number of applications for SSA review over 25 days	0
Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)	0.0%
Number of SSAs (Phase 1) reviewed	0
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%
Number of substantial amendments reviewed	80
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	5
Number of modified amendments over 14 days	0
Number of modified amendments over 14 days as a % of total modified amendments	0.0%
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/0264	Beliefs and Psychosis: An Interview and Diary Study	32
13/NW/0342	Associations between trauma, attachment and relationships with voices.	17
13/NW/0351	The evaluation of hearing deficits following chemoradiation	34
13/NW/0399	Boosting uptake of NHS Health Checks	8
13/NW/0419	Physical health and long term mental illness version 1	45
13/NW/0450	TeleHealth IN Knowsley for Heart Failure – THINK-HF study	30
13/NW/0495	Investigation of postoperative troponin I levels	31
13/NW/0505	Dietary polyphenols to reduce inflammation in the elderly (STUDY 2)	23
13/NW/0571	CaFI:Family Intervention for African Caribbeans with schizophrenia-V1	35
13/NW/0649	Diabetic foot ulcer prevention	37
13/NW/0650	Approach and avoidance motivation in alcohol dependence	33
13/NW/0773	RCT of daily wax treatment in patients with scleroderma	18
13/NW/0784	iBeep: Investigating the Benefits of Exercise in Early Psychosis	22
13/NW/0798	Evaluation of the Gastroparesis Cardinal Symptom Index in PD	12
14/NW/0033	Staff use of de-escalation techniques in mental health	18
14/NW/0035	REQUIRE	17
14/NW/0040	ExOTIC study (Exploration of Tele-monitoring in COPD)	14
14/NW/0052	REACT Study: Recognition of Excessive bleeding At ChildbirTh	34
14/NW/0087	MRI and Histology of Pancreata Pre-transplantation	10
14/NW/0093	PROPANE STUDY	16
14/NW/0162	Collagen production in Dupuytren's fibrosis: Carpal Tunnel control	20

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
13/NW/0268	MBCT groups for Psychosis: Feasibility and acceptability study	16
13/NW/0434	Energy cost of walking in diabetes	21
13/NW/0441	Can Attention Training reduce emotional distress after cancer	15
13/NW/0788	Cognition and everyday function in early dementia	24

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
13/NW/0273	Linking oral health of Bradford 3 year olds with their birth data	2
13/NW/0352	Analysis of collagen production in Dupuytren's fibrosis	27
13/NW/0362	Effect of Lateral WEDGE insoles on OA knee pain and joint loading	27
13/NW/0394	Significant others and sickness absence due to back pain	6
13/NW/0725	Interactions between midwives and women at labour onset-Version 1	2
13/NW/0726	PROM for Adult Orthodontic Patients	6
13/NW/0731	Seroepidemiology of common childhood viruses	3
14/NW/0038	Patients use of pain relief prior to attending minor injuries unit	3

Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
13/NW/0244	Treatment decision-making in psychosis: service users 'experiences v3.	8
13/NW/0277	Psychological and treatment experiences in Rheumatoid Arthritis	22
13/NW/0331	SMARTPIF - Diabetic insole design	17
13/NW/0364	Mast cell/Langerhans' cell interactions in human skin	24
13/NW/0398	Angina, Coronary Revascularisation and Anxiety Study	5
13/NW/0401	Attachment and trauma in adults with ID	17
13/NW/0493	Bio-ACT	20
13/NW/0500	MRI in preoperative radiotherapy for soft tissue sarcoma (MISTS)	20
13/NW/0512	The use of Oil in Baby SkincaRE (OBSeRvE) Pilot Study	20
13/NW/0513	Investigation into hidden hearing loss	20
13/NW/0564	Lupus Extended Autoimmune Phenotype Study (LEAP)	35
13/NW/0577	Objective Cough Monitoring in Children	24
13/NW/0584	An examination of a Therapeutic Research Group for psychosis	21
13/NW/0782	TERSC (version 1.0)	16
14/NW/0012	Viscoseal Post-Arthroscopic Release of Adhesive Capsulitis Shoulder v1	14
14/NW/0064	T1 mapping in Fabry disease	17
14/NW/0081	Psychological adjustment to glioblastoma multiforme in adults v1.0	21
14/NW/0160	Primary Care Trial Efficacy of Alternative Modalities (PCTEAM)	17
14/NW/0175	The organisation and delivery of 24/7 care	11

Unfavourable Opinion		
REC Reference	Application Short Title	Number of Days on Clock
13/NW/0672	Review and Evaluation of Service Specification of an IAPT service	20
14/NW/0077	Primary Care Trial Efficacy of Alternative Modalities (PCTEAM)	16

Provisional Opinion		
REC Reference	Application Short Title	Number of Days on Clock

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
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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 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

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