

NRES Committee North West - Cheshire

Annual Report

01 April 2011 – 31 March 2012

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee North West - Cheshire
Type of REC:	Authorised
Type of Flag:	None
Chair:	Mr Jonathan Deans
Vice-Chair:	Mr Peter Ward
Alternate Vice-Chair:	Dr Noel Murphy
Co-ordinator:	Miss Shehnaz Ishaq
PRSC Co-ordinator:	Miss Shehnaz Ishaq
Assistant Co-ordinator:	Mr. Ashley Totenhofer
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Chair's overview of the past year:

Our Committee has had a busy and fulfilling year. We are now 15 strong, with 9 expert and 6 lay members. There have been no resignations and we have been joined by one new expert member. Nine meetings were held at which 45 submissions were examined. The high quality of these is demonstrated by the fact that only three unfavourable opinions were given. There were also 2 proportionate review meetings carried out on line this year at which 4 submissions were assessed and given favourable or provisional opinions. In addition 7 SSAs and 48 substantial amendments were scrutinised and a further 34 applications were dealt with under the heading of "other activity". All the applications received were processed within the required time frame. Nine of our members were able to attend 6 or more meetings and 13 members underwent training during the year.

Our Co-ordinator, Shehnaz Ishaq, has now been seconded to another committee and her place has been taken by Diane Catterall to whom we all extend a very warm welcome. We hope to see Shehnaz again later in the new year. Sadly Ashley Totenhofer our Assistant Co-ordinator has moved on to bigger things and we all wish him well for the future. I for one would like to thank him for all he has done for the committee.

Finally I would like to thank all the members of the committee who made my job as Chairman a most lively and entertaining experience. Much hard and painstaking work has been done during the year by a group of diverse and dedicated individuals all of whom care deeply about Research and Ethics. I look forward to the privilege of continuing to Chair our meetings throughout the coming year.

NRES Committee North West - Cheshire Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mrs Maureen Benbow	Senior Lecturer	Expert	08/11/2006	
Dr Nick Bronnert	GP	Expert	08/11/2006	
Rev'd Stephen Burmester	Vicar	Lay Plus	08/11/2006	
Mr Jonathan Deans	Consultant ENT Surgeon	Expert	08/11/2006	
Dr Sue Elves	Consultant Clinical Psychologist	Expert	08/11/2006	
Mrs Elizabeth Gordon	Lay Member	Lay Plus	07/07/2010	
Mr Ezzat Kozman	Consultant Member	Expert	08/11/2006	
Dr Fred Mostafa	Consultant Anaesthetist/Intensivist	Expert	01/09/2011	
Dr Noel Murphy	Consultant Paediatrician	Expert	08/11/2006	
Dr Jane Richardson	University Lecturer in Health Research	Lay	03/05/2007	
Mrs Pam Rushworth	Pharmacist Member	Expert	08/11/2006	
Dr Lenny Thornton	Consultant Member	Expert	08/11/2006	
Mr Peter Ward	Lay member	Lay Plus	08/11/2006	
Mrs Jean Welch	Lay Member	Lay	08/11/2006	
Mrs Ann Williams	Lay Member	Lay	08/11/2006	

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Mr Howard Shilton	Clinical Nurse	Expert	11/08/2011
Dr Valerie E Siddall	Retired Senior Manager - Pharmaceutical Industry	Lay Plus	11/08/2011

Member Bank

Name	Occupation	Expert or Lay	Meeting date attended

NRES Committee North West - Cheshire: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Rev'd Stephen Burmester	Rev'd Burmester is the company secretary to Logic Squared Ltd; an international training company in the field of clinical research. He is married to the director of the company who is also a director in Pharmaschool, an international organisation offering training in Clinical Practice Guidelines and trial design.	19/08/2011
Mr Peter Ward	None	19/08/2011
Mrs Maureen Benbow	None - Maureen is a reviewer for Birmingham Human Biomedical Research Committee but this has no impact on her REC membership	19/08/2011
Dr Sue Elves	Sue Elves teaches on the D Clin Psych course at the University of Liverpool and sometimes advise on research projects. In the event that a project comes before the committee on which she has advised on; she will declare an interest and not take part in the review of the study.	19/08/2011
Dr Sue Elves	None	03/01/2012
Dr Fred Mostafa	None	07/09/2011
	None	03/01/2012
Mrs Pam Rushworth	Member of Research and Development Committee at Countess of Chester Hospital	09/09/2011
	Lead Clinical Trial Pharmacist 7 hours a week, funded by Cheshire and Merseyside CLRN at Countess of Chester Hospital	09/09/2011
Dr Jane Richardson	Member of ESRC (Economic and Social Research Council) peer review committee	09/09/2011
	Member of RDS (Research Design Service) Advisory Group West Midlands Hub (Keele University)	09/09/2011
	Reviewer for NIHR Research for Patient Benefit	09/09/2011
	None	03/01/2012
Dr Nick Bronnert	None	22/09/2011
	None	04/01/2012
Dr Lenny Thornton	None	03/01/2012

Mr Peter Ward	None	03/01/2012
Mrs Jean Welch	Shareholdings in Astrazeneca and Glaxosmithkline Trustee - Dialhouse Chester Voluntary work - RNIB	03/01/2012
Mrs Pam Rushworth	Member of Research and Development Committee at Countess of Chester Hospital. Lead Clinical Trial Pharmacist 7 hours a week, funded by Cheshire and Merseyside CLRN at Countess of Chester Hospital.	04/01/2012
Mrs Elizabeth Gordon	None	13/01/2012
Mr Ezzat Kozman	Tunbridgewells Friendly Society	13/01/2012
Mr Jonathan Deans	None	11/01/2012
Dr Noel Murphy	None	31/03/2012

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

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

9 full committee meetings were held during the reporting period.

Proportionate Review Sub Committee Meetings held during 01 April 2011 - 31 March 2012:

Month	Date	Number of Members Present at Meeting
February	19/02/2012	4
March	20/03/2012	3

2 proportionate review sub-committee meetings were held during the reporting period.

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

Name	Number of Meetings Attended
Dr Sue Elves	8
Mrs Elizabeth Gordon	8
Mrs Jean Welch	8
Mr Jonathan Deans	8
Mr Peter Ward	7
Dr Lenny Thornton	7
Dr Nick Bronnert	6
Mr Ezzat Kozman	6
Mrs Ann Williams	6
Dr Jane Richardson	5
Mrs Maureen Benbow	5
Mrs Pam Rushworth	5
Rev'd Stephen Burmester	5
Dr Fred Mostafa	4
Dr Noel Murphy	4
Dr Valerie E Siddall (Co-opted member)	1
Mr Howard Shilton (Co-opted member)	1

Number of inquorate meetings held:

Attendance of Members at proportionate review sub-committee meetings: 01 April 2011 – 31 March 2012:

Name	Number of Meetings Attended
Dr Sue Elves	1
Dr Jane Richardson	1
Dr Nick Bronnert	1
Mr Jonathan Deans	1
Mr Peter Ward	1
Mrs Jean Welch	1
Mrs Maureen Benbow	1

Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Mrs Maureen Benbow	12/07/2011 - 12/07/2011	Equality & Diversity, Equality & Diversity Training
Mr Ezzat Kozman	19/09/2011 - 19/09/2011	Equality & Diversity, Core Learning
Mrs Elizabeth Gordon	29/11/2011 - 29/11/2011	Ethical Issues in Adolescent Research, NRES
Dr Nick Bronnert	29/11/2011 - 29/11/2011	Ethical Issues in Adolescent Research , NRES
Mr Peter Ward	29/11/2011 - 29/11/2011	Ethical Issues in Adolescent Research , NRES
Mrs Elizabeth Gordon	07/11/2011 - 07/11/2011	Equality & Diversity, Tribunal Service
Dr Lenny Thornton	02/02/2012 - 02/02/2012	Human Tissue Training, NRES
Dr Fred Mostafa	02/06/2011 - 02/06/2011	Equality & Diversity, Core Learning Unit
Mrs Jean Welch	17/01/2012 - 17/01/2012	Adults Lacking Capacity Training, NRES
Rev'd Stephen Burmester	26/01/2012 - 26/01/2012	Medical Devices, NRES
Mr Jonathan Deans	06/12/2011 - 06/12/2011	Chairs Training, NRES
Mrs Pam Rushworth	17/01/2012 - 17/01/2012	Adults Lacking Capacity, NRES
Mr Ezzat Kozman	14/03/2012 - 14/03/2012	NRES Members National Training Day - London, NRES
Dr Fred Mostafa	29/02/2012 - 29/02/2012	Personal Data in Research, NRES
Dr Jane Richardson	01/04/2011 - 31/03/2012	Self Directed Learning – the ethics of reusing qualitative data and secondary analysis of qualitative data.
Mrs Maureen Benbow	23/09/2011 - 23/09/2011	SOPs & GAfREC Training, NRES
Mrs Maureen Benbow	01/03/2012 - 01/03/2012	Adults Lacking Capacity Training, NRES
Mrs Maureen Benbow	28/03/2012 - 28/03/2012	NRES Members National Training Day , NRES
Mr Jonathan Deans	09/11/2011 - 09/11/2011	SOPs & GAfREC training, NRES
Dr Nick Bronnert	09/11/2011 - 09/11/2011	SOPs & GAfREC, NRES
Mrs Elizabeth Gordon	09/11/2011 - 09/11/2011	SOPs & GAfREC, NRES
Dr Fred Mostafa	09/11/2011 - 09/11/2011	SOPs & GAfREC, NRES
Dr Noel Murphy	09/11/2011 - 09/11/2011	SOPs & GAfREC, NRES
Dr Jane Richardson	09/11/2011 - 09/11/2011	SOPs & GAfREC, NRES
Mrs Pam Rushworth	09/11/2011 - 09/11/2011	SOPs & GAfREC, NRES
Dr Lenny Thornton	09/11/2011 - 09/11/2011	SOPs & GAfREC, NRES
Mr Peter Ward	09/11/2011 - 09/11/2011	SOPs & GAfREC, NRES
Mrs Jean Welch	09/11/2011 - 09/11/2011	SOPs & GAfREC, NRES
Dr Jane Richardson	28/02/2012 - 28/02/2012	First National MCA/DOLS Conference, Providing Partnership Service in Bedfordshire Essex and Luton

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	45	100.00
Total Applications Reviewed	45	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	2
Number of studies withdrawn prior to the meeting	4
Number of student applications reviewed	25
Number of paediatric applications reviewed	2
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	3	6.67
Favourable Opinion with Additional Conditions	13	28.89
Unfavourable Opinion	3	6.67
Provisional Opinion	26	57.78
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	45	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	21	46.67
Further Information Favourable Opinion with Additional Conditions	5	11.11
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	3	6.67
Favourable Opinion with Additional Conditions	13	28.89
Unfavourable Opinion	3	6.67
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	45	100

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

Total Applications Reviewed	4
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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	0	0.00
Favourable Opinion with Additional Conditions	3	75.00
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	1	25.00
Unfavourable Opinion	0	0.00
Total	4	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.00
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	34
Number of days taken to final decision - mode	40
Number of SSAs (non-Phase 1) reviewed	7
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	48
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	1
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*	1
Number of proportionate review applications over 14 days as a % of total	25.00%

***NB – Proportionate Review Service was in pilot phase until September 2011 and was an aim not a target**

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
11/NW/0167	Exploring perceptions of oxygen therapy Version 1	26
11/NW/0180	A Feasibility Study of R.E.A.C.H - version-1	36
11/NW/0241	Interpersonal and Social Experiences of South Asian Women with SLE	33
11/NW/0250	Effect of Beta Blockers on Heart Rate during the Chester Step Test v.1	46
11/NW/0459	Type 2 Diabetes Management among South Asian communities in the UK	21
11/NW/0460	Crohn's Disease and MAP: questionnaire/biopsy study of CD patients	19
11/NW/0524	Violence Scoping Study, Version 1	39
11/NW/0530	Mechanisms of change in compassion focused therapy	42
11/NW/0532	The effects of ketamine on brain perfusion and metabolism	36
11/NW/0544	Food and environmental exposures associated with C diff 078	36
11/NW/0632	Morphological study of adenocarcinoma of the GOJ	43
11/NW/0642	Adults' experiences of neuropsychological assessment	42
11/NW/0643	Cough frequency in Chronic Obstructive Pulmonary Disease	53
11/NW/0647	Views on receiving a diagnosis of dementia from a memory service. (1)	51
11/NW/0739	Maintaining psychological well-being in advanced illness	40
11/NW/0825	Social networks of people living with multiple chronic illnesses V1	42
11/NW/0863	Binocular visual field in patients with strabismus (1)	48
12/NW/0026	Triple P for Type One Diabetes – consumer acceptability survey	35
12/NW/0102	Whole Family Approaches and Mental Health Reablement	38
12/NW/0118	Hot Flushes and Exercise	21
12/NW/0128	Sputum and nasal inflammation markers in severe asthma - Version 1	55
12/NW/0145	The experience of social cognition changes for stroke survivors v1	32

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/NW/0527	The Lived Experiences of Fathers of Children with Autism	44
11/NW/0542	PROGNOSIS	40
11/NW/0767	Stress induced heart attacks in the days following an operation.	40
11/NW/0851	Effects of patellofemoral brace and taping on muscle and knee dynamics	40
12/NW/0011	Proteomic and genomic analysis of rectal tumours	19

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/0166	SEQEL study: DNA damage measurement	37
11/NW/0179	Clinicopathologic differences in uveal melanomas between men and women	42
11/NW/0245	Comparison of a novel 'suffering score' with 'pain score' in the ED	22

Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/NW/0146	Attitudes to drinking in men aged 35-55 in two areas of Stockport	40
11/NW/0164	Could education resolve ethical dilemmas surrounding phase 1 trials?	40
11/NW/0172	The impact of language on adjustment to cancer post treatment	37
11/NW/0248	The use of the internet by adults with learning disabilities. (v4)	42
11/NW/0251	Enablement, hope, depression & HRQOL in palliative day patients v3.2	34
11/NW/0255	Genomic Hybridization for detecting abnormalities in ectopic pregnancy	34
11/NW/0274	Biomarkers of treatment induced heart toxicity in cancer patients v.1	21
11/NW/0526	Cerebrovascular mechanisms of late onset epilepsy	33
11/NW/0649	GemTrans	26
11/NW/0765	Medicines for Neonates; Data Sharing in Neonatal Services	32
11/NW/0768	Scottish Air Pollution and Mortality	33
12/NW/0025	Outcomes of Surgical Management of Bilateral Rheumatoid Wrist Disease	26
12/NW/0095	Unexplained recurrent miscarriage: a retrospective cohort study	18
12/NW/0148	The Educational Needs of Carers of People with Rheumatoid Arthritis	12
12/NW/0225	assessment of patient retention of information of orthognathic surgery	1
12/NW/0245	Obstetric cell salvage; is it safe for vaginal delivery	1

Unfavourable Opinion		
REC Reference	Application Short Title	Number of Days on Clock
11/NW/0469	Narrative analysis of social constructs surrounding obese women	19
11/NW/0641	PRE-DELIRIC trial	26
11/NW/0862	Hot Flushes and Exercise	18

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
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	
12/NW/0145	The experience of social cognition changes for stroke survivors v1	32	
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