

NRES Committee North West - Preston

Annual Report

01 April 2011 – 31 March 2012

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee North West - Preston
Type of REC:	Authorised
Type of Flag:	None
Chair:	Dr Patricia Wilkinson
Vice-Chair:	Mr Mike Hammond
Alternate Vice-Chair:	Ms Eleanor Jolley
Co-ordinator:	Mrs Carol Ebenezer
PRSC Co-ordinator:	Mrs Carol Ebenezer
Assistant Co-ordinator:	Miss. Diane Catterall
Committee Address:	Barlow House 3rd Floor 4 Minshull Street Manchester M1 3DZ
Telephone:	0161 625 7818
Fax:	0161 625 7299
Email:	carol.ebenezer@northwest.nhs.uk

Chair's overview of the past year:

The past year has continued to be busy. We have usually had a very good turnout from members, only having to co-opt on 1 occasion. The member who took a sabbatical from the Committee returned after completing her course. One member was unfortunately unable to continue owing to work commitments. Unfortunately, he was also the Alternate Vice Chair. However, the member who returned had previously fulfilled that role and, with the unanimous agreement of the Committee, agreed to take that role on again. Another member has moved to Yorkshire so we had to say goodbye to her. Since she was a stalwart member of our subcommittee, this has left a hole which other members are filling. We have also been joined by another expert member.

Carol and Diane have carried on the administration work of the Committee, keeping things running smoothly and the Chair in order. They had worked together very well and Diane was very helpful, in meetings, alongside Carol. However, Diane was appointed as acting co-ordinator of another Committee, so we now have Anna working alongside Carol.

The Committee continues to do sub-committee work (amendments and SSAs) and responses to provisional opinions by electronic means. This has been appreciated by the Committee, who find it easier, quicker and more convenient, which, usually a much quicker turn round time.

Over the past year the Committee has started to undertake Proportionate Review. After a few initial misgivings the members who undertake this have found no major problems. The researchers have been helpful on clarifying points when required. Although the turn round time is less the time taken for members to review applications seems to be about the same as for written meetings.

We continue to receive positive feedback from researchers, especially those who attend the meetings. This is both about the helpfulness of the comments made and the friendly nature of the Committee.

I wish to finish by thanking all the members for their hard work and commitment over the past year

NRES Committee North West - Preston Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mr David Abbotts	Lay member	Lay Plus	13/09/2010	
Dr Anoop Chauhan	Consultant Cardiologist	Expert	10/07/2008	
Mrs Maggie Clifton	Lay Member	Lay	01/10/2005	31/01/2012
Mr John Dalton	Lay Member	Lay Plus	13/10/2005	
Dr Sam Dearman	Psychiatrist	Expert	20/10/2009	21/06/2011
Mrs Debbie Foord	Service Improvement Manager	Expert	01/10/2005	
Mr Mike Hammond	Lay Member	Lay Plus	13/10/2005	
Mr John Ireland	Lay Member	Lay	24/09/2009	
Ms Eleanor Jolley	Lay Member	Lay	01/10/2005	
Mrs Kate Kilshaw	Radiographer	Expert	25/09/2009	
Ms Joanna Marshall	Nurse Specialist in Acute Pain	Expert	01/10/2005	
Dr Rob Monks	Senior Lecturer Department of Nursing	Expert	08/08/2009	
Mr Videsh Raut	Consultant Orthopaedic Surgeon	Expert	01/02/2007	
Mrs Vasanthi Vasudevan	Diabetes Research Nurse	Expert	12/01/2012	
Dr Patricia Wilkinson	General Practitioner	Expert	01/10/2005	

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Mrs Maureen Benbow	Senior Lecturer	Lay	23/09/2011
Mr James Burns	Lay Member	Lay	24/02/2012
Mrs Valerie Skinner	Nurse (retired)	Lay	23/09/2011

Member Bank

Name	Occupation	Expert or Lay	Meeting date attended

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

Name	Declaration of Interest	Date
Mr David Abbotts	None	16/12/2011
Dr Anoop Chauhan	Consultant cardiologist at Lancashire Cardiac Centre Blackpool Teaching Hospitals	08/12/2011
Mr John Dalton	Director of Stonehill Consultants Ltd - not engaged in research Trustee of two charities related to health care - Norm Uk (Educational) Genital Autonomy (Human Rights)	30/03/12
Mrs Debbie Foord	None	16/12/2011
Mr Mike Hammond	None	10/12/2011
Mr John Ireland	None	16/12/2011
Ms Eleanor Jolley	None	16/12/2011
Mrs Kate Kilshaw	None	16/12/2011
Ms Joanna Marshall	None	16/12/2011
Dr Rob Monks	Senior Lecturer at UCLAN and therefore supervise students in individual research projects	16/12/2011
Mr Videsh Raut	Member of Colne Teaching Hospital R & D committee	27/01/2012
Mrs Vasanthi Vasudevan	Diabetes research nurse, Blackpool Teaching Hospitals, and involved in diabetes research, R & D Member of diabetes research network	14/01/2012
Dr Patricia Wilkinson	None	16/12/2011

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

Month	Date	Number of Members Present at Meeting
April	15/04/2011	10
May	27/05/2011	10
June	24/06/2011	8
August	26/08/2011	9
September	23/09/2011	10
October	28/10/2011	11
November	25/11/2011	12
December	16/12/2011	8
January	27/01/2012	10
February	24/02/2012	9

10 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
June	20/06/2011	3
July	27/07/2011	3
September	02/09/2011	3
October	07/10/2011	3
November	11/11/2011	3
November	25/11/2011	3
December	16/12/2011	3
January	19/01/2012	3
February	23/02/2012	4
March	29/03/2012	3

10 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
Mr David Abbotts	10
Ms Joanna Marshall	9
Mrs Debbie Foord	9
Dr Anoop Chauhan	8
Dr Patricia Wilkinson	8
Dr Rob Monks	8
Mr John Ireland	7
Mr Mike Hammond	7
Mrs Kate Kilshaw	7
Mr John Dalton	6
Mrs Maggie Clifton	5
Mr Videsh Raut	5
Mrs Vasanthi Vasudevan	2
Ms Eleanor Jolley	2
Mrs Maureen Benbow (Co-opted from Cheshire)	1
Mrs Valerie Skinner (Co-opted from Lancaster)	1
Dr Sam Dearman	1
Mr James Burns (Co-opted from GM East)	1

Number of inquorate meetings held: None

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

Name	Number of Meetings Attended
Dr Patricia Wilkinson	10
Mr Mike Hammond	8
Mrs Maggie Clifton	4
Mr David Abbotts	5
Dr Rob Monks	3
Mr John Ireland	1

Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Mrs Debbie Foord	18/05/2011 - 18/05/2011	Equality and Diversity Training, Lancashire Care NHS Foundation Trust
Mr David Abbotts	08/09/2011 - 08/09/2011	Qualitative Research for NRES committee members, NRES
Mr Mike Hammond		MCA video from NRES
Mr Videsh Raut		MCA video from NRES, NRES
Mrs Kate Kilshaw	28/03/2012 - 28/03/2012	NRES Members National Training Day, NRES
Ms Joanna Marshall	23/09/2011 - 23/09/2011	SOPs and GfREC, NRES/REC
Dr Rob Monks	23/09/2011 - 23/09/2011	SOPs and GfREC, NRES/REC
Mr David Abbotts	23/09/2011 - 23/09/2011	SOPs and GfREC, NRES/REC
Mr Videsh Raut	23/09/2011 - 23/09/2011	SOPs and GfREC, NRES/REC
Mrs Debbie Foord	23/09/2011 - 23/09/2011	SOPs and GfREC, NRES/REC
Mr Mike Hammond	23/09/2011 - 23/09/2011	SOPs and GfREC, NRES/REC
Mr John Dalton	23/09/2011 - 23/09/2011	SOPs and GfREC, NRES/REC
Dr Patricia Wilkinson	06/12/2011 - 06/12/2011	Chair's Training, NRES
Dr Patricia Wilkinson	23/09/2011 - 23/09/2011	SOPs and GfREC, NRES/REC
Mr Mike Hammond	12/01/2012 - 12/01/2012	Equality & Diversity, DB Learning
Dr Rob Monks	13/02/2012 - 13/02/2012	Ethics & GCP Forum, Institute of Clinical Research
Mr John Ireland	11/05/2011 – 11/05/2011	Equality and Diversity on line NRES
Mr John Ireland		Self directed learning log
Mrs Debbie Foord	29/02/2012 - 29/02/2012	Personal Data in Research, NRES
Ms Eleanor Jolley	29/11/2011 - 29/11/2011	Adolescents in Research, NRES

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	49	100.00
Total Applications Reviewed	49	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	4
Number of student applications reviewed	26
Number of paediatric applications reviewed	4
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	1	2.04
Favourable Opinion with Additional Conditions	8	16.33
Unfavourable Opinion	4	8.16
Provisional Opinion	36	73.47
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	49	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	31	63.27
Further Information Favourable Opinion with Additional Conditions	5	10.20
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	2.04
Favourable Opinion with Additional Conditions	8	16.33
Unfavourable Opinion	4	8.16
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	49	100

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

Total Applications Reviewed	31
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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	8	25.81
Favourable Opinion with Additional Conditions	19	61.29
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	4	12.90
Unfavourable Opinion	0	0.00
Total	31	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	4.90
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	25
Number of days taken to final decision - mode	20
Number of SSAs (non-Phase 1) reviewed	16
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	37
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	0
Number of modified amendments over 14 days	0
Number of modified amendments over 14 days as a % of total modified amendments	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	0.00%

***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/0191	Patient preferences and priorities in epilepsy care Vs.1	26
11/NW/0202	Macro-interventions into micro-cultures: The WHO/UNICEF BFHI	21
11/NW/0208	MEd Dissertation: An Exploration of Practice Education	36
11/NW/0210	Use of iPS cells as a model system for eye disease	28
11/NW/0214	Heart failure and physical activity	31
11/NW/0306	The role of groups in violence and anti-social behaviour	21
11/NW/0308	Does Carotid Artery Plaque Volume and Morphology predict Stroke? V1	39
11/NW/0311	How do medical students experience the PAL interaction?	37
11/NW/0393	Narratives of people with a heart/lung transplant and ICU delirium	23
11/NW/0398	Clinicians' views on personality disorder in adolescence (v1)	22
11/NW/0407	Evaluation of the Multilayer Aneurysm Repair System	17
11/NW/0408	Understanding mood management: A computer-based questionnaire study	24
11/NW/0410	LDH isoenzyme as a prognostic tool in haematological malignancies v1.0	23
11/NW/0503	Reducing the number of GAs required for tooth extraction for children	8
11/NW/0510	Communication in Physiotherapy Sessions v1.0	25
11/NW/0579	Living with a pituitary tumour: a narrative analysis	44
11/NW/0580	Resources that create positive refugee mental health and wellbeing	28
11/NW/0587	An exploration of social interactions in help seeking behaviour	36
11/NW/0599	Joint Thinking: Experience of Consultation	7
11/NW/0663	Examining the effect of oral followed by intragastric glucose	15
11/NW/0678	Transition pathways for young people with complex mental health needs	16
11/NW/0736	Randomised Controlled Trial of Method of Levels Cognitive Therapy	25
11/NW/0742	COINCIDE	24
11/NW/0789	Smartpastebio vs AH Plus: Which will have the apical seal of approval?	6
11/NW/0817	Perceptions of recovery for individuals with an acquired brain injury	24
11/NW/0826	The use and impact of computerised systems within the birth suite	30
11/NW/0885	Platelet Aggregation in a Phase I Oncology Patient Population	27
12/NW/0058	Skin thickness in patients with EpiPens	29
12/NW/0067	Comorbid cerebrovascular disease in idiopathic Parkinson's disease	26
12/NW/0075	Microsatellite instability, HSCT for Fanconi Anaemia and SCC	26

12/NW/0147	How do individuals make sense of changing skin conditions? Version 1	46
12/NW/0151	The repeatability of lipopolysaccharide nasal challenges	20
12/NW/0152	Nurse-Relative communication in Critical Care 001	28
12/NW/0153	Post Operative Pain Relief Following Knee Arthroplasty	16
12/NW/0164	To examine the effect of functional-based pulmonary rehabilitation	0

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/NW/0183	Risk-based intervals in screening for diabetic retinopathy	33
11/NW/0399	Psychological factors in foot and ankle disorders	29
11/NW/0727	Understanding service quality in health care	25
11/NW/0741	Staff-client interactions within a breast cancer assessment clinic	23
12/NW/0077	Momentary Self Compassionate and Self Attacking Thoughts in Psychosis	33

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/0432	Comparison of anti-CCP antibodies and their relation to RF assay	7
11/NW/0433	A Woman's Decision To Know The Sex Of Her Child Prior To Birth	5
11/NW/0509	A study into whether nephrectomy accelerates cardiovascular disease	2
11/NW/0521	Palliative care professionals' experiences of end of life phenomena	1
11/NW/0673	Post-Ictal Psychosis - A Case Control Study	15
11/NW/0710	M2PK isoenzyme expression in pancreatic cancer	6
11/NW/0848	Isotopic composition of human teeth for geographical tracking	2
12/NW/0072	Do adjunct techniques lead to upstaging in colorectal cancer?	6
12/NW/0167	Analysis of post-intervention letters written by nonoffending partners	6

Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/NW/0310	The referral and care options for patients with kidney disease	25
11/NW/0429	Questionnaire of dental practitioners re referral patterns -vers 1	0
11/NW/0437	TRACHEAL STENOSIS: A QUESTIONNAIRRE SURVEY	11

11/NW/0505	SELF REPORTED OUTCOMES IN GYNAECOLOGICAL ONCOLOGY PATIENTS	2
11/NW/0590	Experiences of apathy in Parkinson's disease	23
11/NW/0613	Clients' views of maintaining change	7
11/NW/0615	The South Asian patient experience of Living with COPD	14
11/NW/0626	AAEE: Adult ADHD, Employment and Education.	10
11/NW/0648	ENDCAT trial of telephone follow-up	18
11/NW/0709	Safety Biomarkers for Neoadjuvant Chemotherapy	7
11/NW/0788	PEGASUS: Eliciting patients' expectations of breast reconstruction	5
11/NW/0796	V1 Impact of Intensive Interaction on Sheffield day service provision	2
11/NW/0811	The sources of return venous emboli from the haemodialysis circuit	19
11/NW/0843	Evaluation of a group ACT approach for emotional dysregulation V1	2
11/NW/0847	PRIMO v1	2
11/NW/0865	Evaluation of a Male Step-Down Unit	20
11/NW/0871	Bridge Builder Evaluation	20
11/NW/0894	Would targeted follow-up for hip fracture patients improve their care	8
12/NW/0029	Brief group therapy for psychosis in acute care	19
12/NW/0073	ASD transitions, aspirations and outcomes	10
12/NW/0074	Personal Health Budgets for Wheelchairs	6
12/NW/0080	Development of a reliable rating scale for conversation skills	6
12/NW/0156	Evaluating the Impact of a Somali Language Maternity Information DVD	6
12/NW/0163	Alcohol Outcomes Study	16
12/NW/0165	GP referral to IAPT: qualitative study	5
12/NW/0265	The Everyday Geographies of Living With Diabetes	6
12/NW/0266	Presentation, time to diagnosis & quality of life in children with SDS	5

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/NW/0209	Views of people about mental health and employment	22
11/NW/0307	Levels of lipoprotein(a) and high sensitivity CRP in ACS patients	34
11/NW/0566	The Impact of Specialist Palliative Day Care on Attendee Well-being	37
11/NW/0809	Alcohol Outcomes Study	20

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
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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