

**NRES Committee North West -  
Preston**

**Annual Report**

**01 April 2013 – 31 March 2014**

## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	NRES Committee North West - Preston
<b>Type of REC:</b>	Authorised
<b>Type of Flag:</b>	None
<b>Chair:</b>	Dr Patricia Wilkinson
<b>Vice-Chair:</b>	Mr Ken Cook (temporary appointment whilst Vice-Chair on leave of absence)
<b>Alternate Vice-Chair:</b>	Ms Eleanor Jolley
<b>REC Manager:</b>	Mrs Carol Ebenezer
<b>PRSC Manager:</b>	Mrs Carol Ebenezer
<b>REC Assistant:</b>	Miss Anna Bannister
<b>Committee Address:</b>	HRA NRES Centre - Manchester Barlow House 3rd Floor 4 Minshull Street Manchester M1 3DZ
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## Chair's overview of the past year:

The work of the committee carries on. Most meetings have between 4 and 6 applications, and the proportionate review work in between. The March meeting had to be cancelled due to lack of applications.

There have been several changes in membership over the past year. The Vice Chair was granted leave of absence in May for work related reasons. A temporary Vice Chair has been appointed from another committee but has only been required to chair the meeting once so far. In July we welcomed another 2 lay members. Another member has taken leave from the Committee to take part in a research project. Another member gained promotion at work; unfortunately this meant she had to resign from the Committee.

With all the people leaving, on temporary or permanent basis, this has meant we have been tight for a quorum on occasions and have had to co-opt. The Committee is now looking to recruit new members. Our new members have settled in well. They are now taking a full part in meetings and acting as lead reviewers.

We continue with the Proportionate Review. With the re-organisation of the Committee new people have become involved and have fitted in well. We are still waiting for the outcome of the pilot to see if reduced paperwork can be used as the applications are not shorter to read. The researchers contacted, when necessary, are quick to reply with clarifications and answers to queries. Again with the sub-committee work, new people have become involved and this seems to be going well.

Carol continues to keep the Chair in order and to the timescales, with reminders if necessary. She also ensures that the Committee runs smoothly and adheres to the SOPs. Unfortunately she lost her assistant so was doing well on her own for a while. Another assistant, Maggie, has now been appointed.

We continue to receive usually positive feedback from the researchers, especially those who attend the meetings, about the helpfulness of the Committee and the comments and suggestions that they receive.

## NRES Committee North West - Preston Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mr David Abbotts	Lay member	Lay Plus	13/09/2010	
Professor Anoop Chauhan	Consultant Cardiologist	Expert	10/07/2008	
Mr Ken Cook	Acute Care Manager (retired)	Expert	23/07/2013	
Mr John Dalton	Lay Member	Lay Plus	13/10/2005	
Mrs Debbie Foord	Service Improvement Manager	Expert	01/10/2005	
Mr Mike Hammond	Lay Member	Lay Plus	13/10/2005	
Mr Aidan Cabezas-Hayes	Lay Member	Lay Plus	04/06/2013	
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	31/01/2014
Dr Rob Monks	Senior Lecturer Department of Nursing	Expert	08/08/2009	
Professor Videsh Raut	Consultant Orthopaedic Surgeon	Expert	01/02/2007	
Mrs Vasanthi Vasudevan	Diabetes Research Nurse	Expert	12/01/2012	
Dr Patricia Wilkinson	General Practitioner/ Chair	Expert	01/10/2005	
Dr Hawys Williams	Lay Member	Lay	05/07/2013	

### Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended

### Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Mrs Valerie Skinner		Lay	24/05/2013

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

Name	Declaration of Interest	Date
Mr Ken Cook	None	31/07/2013
Dr Rob Monks	Nil of note member of staff University of Central Lancashire	03/12/2013
Dr Patricia Wilkinson	None	21/01/2014
Ms Joanna Marshall	None	29/01/2014
Dr Hawys Williams	I am employed by Arthritis Research UK, the leading UK funder of research into the cause, treatment and cure of arthritis, as a Research Governance Officer I may be involved in future ethics applications for medical research	29/01/2014
Mr David Abbotts	None	29/01/2014
Professor Anoop Chauhan	Shares in Glaxo/Vectura/Unigen; Consultant at Blackpool Victoria Hospital Involved in R & D in Blackpool Victoria Hospital	29/01/2014
Mrs Kate Kilshaw	None	29/01/2014
Mr John Dalton	Directorships and trusteeships of company/charities potentially conducting research	29/01/2014
Mrs Debbie Foord	None	29/01/2014
Professor Videsh Raut	Consultancy with Arthrocare Inc Member of Lancs Hospital R & D Dept.	02/05/2014
Ms Eleanor Jolley	None	29/04/2014
Mrs Vasanthi Vasudevan	Research nurse Blackpool Victoria Hospital	29/04/2014
Mr Aidan Cabezas-Hayas	None	24/06/2013

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

<b>Month</b>	<b>Date</b>	<b>Number of Members Present at Meeting</b>
April	26/04/2013	10
May	24/05/2013	9
June	28/06/2013	10
July	26/07/2013	11
August	23/08/2013	9
September	27/09/2013	10
October	25/10/2013	10
November	22/11/2013	8
January	24/01/2014	9
February	28/02/2014	10

10 full committee meetings were held during the reporting period.

**Proportionate Review Sub Committee Meetings held during 01 April 2013 - 31 March 2014:**

<b>Month</b>	<b>Date</b>	<b>Number of Members Present at Meeting</b>
May	31/05/2013	4
August	09/08/2013	5
October	18/10/2013	3
January	03/01/2014	5
February	17/02/2014	4
March	14/03/2014	4

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

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mrs Debbie Foord	9
Mrs Kate Kilshaw	8
Mrs Vasanthi Vasudevan	8
Ms Joanna Marshall	8
Dr Patricia Wilkinson	8
Dr Rob Monks	7
Mr David Abbotts	7
Mr John Dalton	6
Mr Aidan Cabezas-Hayes	6
Professor Videsh Raut	6
Dr Hawys Williams	6
Ms Eleanor Jolley	5
Professor Anoop Chauhan	5
Mr Ken Cook	4
Mr Mike Hammond	1

**Number of inquorate meetings held: 0**

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Patricia Wilkinson	6
Mr David Abbotts	6
Professor Videsh Raut	3
Mr Ken Cook	2
Dr Rob Monks	2
Mr Aidan Cabezas-Hayes	2
Dr Hawys Williams	1
Mrs Vasanthi Vasudevan	1

## Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Dr Hawys Williams	09/09/2013 - 09/09/2013	Induction, NRES
Mrs Debbie Foord	27/11/2013 - 27/11/2013	National Members' Training Day, NRES
Mr Ken Cook	10/09/2013 - 10/09/2013	Chairing Skills, NRES
Mrs Vasanthi Vasudevan	27/11/2013 - 27/11/2013	Members National Training Day, NRES
Dr Hawys Williams	31/10/2013 - 31/10/2013	Qualitative Research and Ethical Review, NRES
Dr Patricia Wilkinson	11/12/2013 - 11/12/2013	National NRES Chairs Training Day, NRES
Dr Hawys Williams	04/11/2013 - 04/11/2013	Ethics and GCP Forum, NRES
Ms Eleanor Jolley	27/11/2013 - 27/11/2013	Members National Training Day, NRES
Mrs Vasanthi Vasudevan	14/10/2013 - 14/10/2013	Research Masterclass, NIHR
Mrs Vasanthi Vasudevan	19/02/2014 - 19/02/2014	Reviewing CTIMPs, HRA
Mrs Kate Kilshaw	12/03/2014 - 12/03/2014	Improving Informed Consent and Patient Information Sheets, 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:**

<b>Applications for full ethical review – Study Type</b>	<b>Number</b>	<b>%</b>
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	55	100.00
<b>Total Applications Reviewed</b>	<b>55</b>	<b>100</b>

**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	8
Number of student applications reviewed	21
Number of paediatric applications reviewed	7
Number of device applications reviewed	3
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:**

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	2	3.64
Favourable Opinion with Additional Conditions	25	45.45
Unfavourable Opinion	2	3.64
Provisional Opinion	26	47.27
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
<b>Total</b>	<b>55</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:**

Status of applications at date of generation of report	Number	%
Further Information Favourable Opinion with Standard Conditions	26	47.27
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	3.64
Favourable Opinion with Additional Conditions	25	45.45
Unfavourable Opinion	2	3.64
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
<b>Total</b>	<b>55</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>13</b>
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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	46.15
Favourable Opinion with Additional Conditions	5	38.46
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	2	15.38
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>13</b>	<b>100</b>

**Table 7: Other Management Information for the reporting period:**

<b>Average number of applications reviewed per full meeting</b>	5.50
<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>	25
<b>Number of days taken to final decision - mode</b>	24
<b>Number of SSAs (non-Phase 1) reviewed</b>	11
<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>	0
<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%
<b>Number of substantial amendments reviewed</b>	47
<b>Number of substantial amendments over 35 days</b>	2
<b>Number of substantial amendments over 35 days as a % of total substantial amendments</b>	4.3%
<b>Number of Section 30 applications reviewed</b>	0
<b>Number of Section 30 applications over 60 days</b>	0
<b>Number of Section 30 applications over 60 days as a % of total Section 30 applications</b>	0%
<b>Number of modified amendments reviewed</b>	1
<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%
<b>Number of proportionate review applications for ethical review over 14 days</b>	0
<b>Number of proportionate review applications over 14 days as a % of total</b>	0.0%

**Table 8: Breakdown of current status of all 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>
13/NW/0295	Comorbid Cerebrovascular Disease in Idiopathic Parkinson's Disease	27
13/NW/0339	Measuring Proteins Contributing to Renal Stone Formation	24
13/NW/0357	Monitoring of metal-backed glenoid components using RSA	25
13/NW/0386	Analysis of the utility of a suicide risk assessment in an A&E setting	26
13/NW/0413	Sexual Health Needs Assessment for Vale Royal	23
13/NW/0437	Inter-rater reliability of a non-invasive cardiac output device	5
13/NW/0544	Optimal device therapy for heart failure using computer decision aid	23
13/NW/0545	Three dimensional analysis of periodontal healing tissue healing.	30
13/NW/0557	Stress in service users with LD in a forensic setting	44
13/NW/0587	Does a Dementia Group Increase Relationship Satisfaction in couplehood	34
13/NW/0591	EPIDEPSO Version 1.0_17 December 2012 (Protocol CNT01275PSO4034)	29
13/NW/0633	Midazolam for treatment of therapy resistant MTD and VCD	19
13/NW/0663	Evaluating Patient Perspectives and Opinions on Research for SCI.	40
13/NW/0665	Group physiotherapy versus standard care physiotherapy following RCR	25
13/NW/0668	Interaction between young people's online experiences and wellbeing	44
13/NW/0679	The effect of early PV re-isolation on AF recurrence V1	27
13/NW/0684	A mechanistic study using GTN to investigate digital ulcer physiology	27
13/NW/0711	RCT: PRP versus CS injection in GTPS	29
13/NW/0736	Role of Toll-like Receptors expression in assisted conception-1	52
13/NW/0746	Experiences of males completing DBT in a High Secure setting	24
13/NW/0801	WoundWand	19
13/NW/0859	Detecting muscle twitches with ultrasound imaging	39
13/NW/0882	Looking at Insight in individuals with Asperger's Disorder.	13
13/NW/0887	Observational study BOTOX in patients with chronic migraine.	21
14/NW/0022	Non-invasive ventilation for acute exacerbations in adult CF	24
14/NW/0034	Individual risk based screening for diabetic retinopathy: WS E	27
14/NW/0061	Hammer Toe Correction with Excision Arthroplasty. Version-1	24
14/NW/0113	Medication safety implications of a technological intervention, v.1	26

Further Information Favourable Opinion with Additional Conditions		
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REC Reference	Application Short Title	Number of Days on Clock
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Further Information Unfavourable Opinion		
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REC Reference	Application Short Title	Number of Days on Clock
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Favourable Opinion with Standard Conditions		
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REC Reference	Application Short Title	Number of Days on Clock
13/NW/0279	ENCEPH UK Intervention RCT V1.0	29
13/NW/0433	Impact of digital mammography on microcalcification assessment.	2
13/NW/0445	Extent of T-wave inversions in ECG of children with ASD	1
13/NW/0728	ROLO The Renoprotective value of Leukodepletion in Heart Valve surgery	24
13/NW/0757	Prof Mendelow Backswing Comparative Effectiveness Research study	10
13/NW/0883	Version 1: Health risk behaviours in young adults with CHD	4
13/NW/0885	In-house donation of saliva for oral health research	6
14/NW/0100	Feasibility study on the use of telemedicine for psychiatric patients	13

Favourable Opinion with Additional Conditions		
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REC Reference	Application Short Title	Number of Days on Clock
13/NW/0287	Individual risk based screening for diabetic retinopathy: WS F	24
13/NW/0289	Reasons for the rise in abortions from women of South Asian heritage.	25
13/NW/0294	The AGREE: Helping people get the most from their hearing aids	28
13/NW/0374	Role of Salt Supplementatiopn in Reflex Syncope	21
13/NW/0379	Being out as LGBT with a Learning Difficulty - an IPA study.	26
13/NW/0400	CIUDo: Clinical Utility of Capsaicin Dose Response Curves	18
13/NW/0403	COAST: studying cough in asthma phenotypes	18
13/NW/0449	EDiMaD 1.1	35
13/NW/0456	Perfusion Echo vs FFR for the Assessment of LAD disease (V.1)	32
13/NW/0479	Stories about an LGBT support group in a secure LD service v1	19
13/NW/0516	Exploring the impact of a service development forum for young people	18
13/NW/0526	Quality of Life and family impact of short bowel syndrome	18
13/NW/0543	Cancer risks in the British rubber manufacturing industry	26
13/NW/0549	Psoriasis and disgust	15

13/NW/0551	Ability of biochemical markers to detect alcohol use	21
13/NW/0554	The Parkinson's Pain Study	20
13/NW/0589	Urinary Proteomic analysis for Obstructive Sleep Apnoea:followup study	30
13/NW/0601	Prognostic Markers for Phenylketonuria	12
13/NW/0606	Are human embryo morphokinetics affected by semen quality?	11
13/NW/0806	Effect of cochlear implantation on adults with unilateral deafness v1	16
13/NW/0807	Modifications in the brain following hearing loss in one ear version 1	16
13/NW/0808	Electronic Fetal Monitoring using telemetry REC ref number 13/EE/0409	20
14/NW/0041	Cognitive therapy Or Medication for Psychosis: A Randomised Evaluation	16
14/NW/0042	A physiotherapist-led group treatment for patients with chronic pain.	15
14/NW/0099	The Prevention of Acute Kidney Injury in Primary Care	28
14/NW/0105	The effect of Wii-Fit games on balance in children with cerebral palsy	13
14/NW/0114	Experiences of women undergoing contralateral prophylactic mastectomy	24
14/NW/0121	An exploratory study to establish a rhinovirus challenge model	17
14/NW/0170	Investigating outcome in children with CFS/ME	7
14/NW/0171	The experiences of adults with autism in a talking therapies service.	10

#### Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/NW/0281	Quality of Life and family impact of short bowel syndrome	29
13/NW/0721	WoundWand Debridement	24

#### 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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<b>Invalid Application</b>		
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<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
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<b>No Opinion Pending Consultation with Referee</b>		
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<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
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<b>Not Requiring Review by NHS REC</b>		
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<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
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**Table 9: Items exceeding timelines:**

<b>Full applications for ethical review over 60 day timeline</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<b>Proportionate review applications for ethical review over 14 days timeline</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<b>SSAs (non Phase 1) over 25 days timeline</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<b>SSAs (Phase 1) over 14 days timeline</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<b>Substantial Amendments over 35 day timeline</b>			
<b>Amendment Reference</b>	<b>Application Short Title</b>	<b>Amendment Title</b>	<b>Number of Days on Clock</b>
13/NW/0202/AM04	Incinerators Biomonitoring Study-Version 1	3 additional recruitment information	37
13/NW/0202/AM05	Incinerators Biomonitoring Study-Version 1	4 change sample size	37

<b>Modified Amendments over 14 day timeline</b>			
<b>Amendment Reference</b>	<b>Application Short Title</b>	<b>Amendment Title</b>	<b>Number of Days on Clock</b>

<b>Section 30 application over 60 day timeline</b>			
<b>Amendment Reference</b>	<b>Application Short Title</b>	<b>Amendment Title</b>	<b>Number of Days on Clock</b>