

NRES Committee North West - Lancaster

Annual Report

01 April 2011 – 31 March 2012

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee North West - Lancaster
Type of REC:	Authorised
Type of Flag:	Paediatrics
Chair:	Dr Lisa Booth
Vice-Chair:	Dr Nigel Calvert
Alternate Vice-Chair:	Professor Jois Stansfield
Co-ordinator:	Mrs Carol Ebenezer
PRSC Co-ordinator:	Carol Ebenezer
Assistant Co-ordinator:	Laura Brown
Committee Address:	Barlow House 3rd Floor 4 Minshull Street Manchester M1 3DZ
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Chair's overview of the past year:

Currently the REC membership runs at 9 expert members and 4 lay members and so is similar in constitution as last year, again I ask NRES to look more closely at its recruitment of members with active recruitment of lay members to committees. The lack of lay members has again meant the committee has found itself non-quorate on a couple of occasions and co-option from other committees had to take place. Attendance by members is generally very good and there is excellent support for the PR applications, with 30 PR reviews taking place over the last year. We as a committee are very pleased with our turn around on these applications although this has added a significant workload to REC members, particularly the chair and vice chair. Ten full ethical review meetings took place between April 2011 and March 2012, with a total of 46 applications being reviewed. This reduction in reviews by full committee is almost certainly a consequence of the PR application process, but it has certainly not reduced the workload of committee members over all, particularly when one considers that the sub-committee (who also reviews the PR applications) has also reviewed 67 substantial amendments and 3 SSAs. It is a concern how this workload might affect other committee chairs/vice chairs and sub-committee members should one of the North West RECs close in the near future, I urge NRES to consider all aspects of a committees role, not just that of 'full ethical review' when considering closing established RECs.

Thank you to all the REC members who give their time for attending meetings and for thorough preparation, which ensures that proper consideration is given to each application. A very big thank you to the staff at Barlow House, to Carol and Laura, who provide excellent support for meetings, sub-committees, communications with applicants and members, and all the many other activities which ensure the research ethics process runs smoothly.

Dr Lisa Booth, September 5th 2012

NRES Committee North West - Lancaster Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr Brenda Ashcroft	Lecturer	Expert	20/09/2009	
Mr David Barber	Pharmacist	Expert	01/10/2005	
Dr Lisa Booth	Senior Lecturer	Expert	01/09/2006	
Dr Nigel Calvert	Associate Director of Public Health	Expert	15/11/2005	
Mrs Andrina Lawrence	Lay Member	Lay	01/10/2005	
Dr Brenda Leese	Lay Member	Lay	10/03/2010	
Dr Anas Olabi	Consultant Paediatrician	Expert	01/01/2007	
Susan Page	Senior Clinical Tutor	Expert	13/10/2011	
Mrs Gillian Rimington	Paralegal	Lay Plus	11/11/2011	
Dr John Shakespeare	Retired GP	Expert	13/10/2005	
Mrs Valerie Skinner	Nurse (Retired)	Lay	01/10/2005	
Professor Jois Stansfield	Professor of Speech Pathology	Expert	11/09/2009	
Dr Jane Stuart	Lay Member	Expert	01/10/2005	14/04/2011
Dr Gary Whittle	Consultant in Dental Public Health (retired)	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
Mr James Burns	Lay member	Lay	12/05/2011 08/12/2011

Member Bank

Name	Occupation	Expert or Lay	Meeting date attended
Mrs Gillian Rimington until Nov 2011	Paralegal	Lay Plus	15/07/2011 PRS 19/08/2011 PRS 22/09/2011 PRS 28/10/2011 PRS

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

Name	Declaration of Interest	Date
Dr Brenda Ashcroft	Expert witness and peer reviewer (midwifery)	08/12/2011
Mr David Barber	None occasional advisory boards for pharmaceutical companies employed one day per week by Lancashire and South Cumbria Cancer Research Network	30/12/2011
Dr Lisa Booth	work for University of Cumbria	08/12/2011
Dr Nigel Calvert	none public health doctor employed by Cumbria PCT and occasionally involved in research projects	08/12/2011
Mrs Andrina Lawrence	collecting for Marie Curie participant in Breakthrough Generations	08/12/2011
Dr Brenda Leese	shares in the venture company Angle PLC	08/12/2011
Dr Anas Olabi	None	06/12/2011
Susan Page	Employed by UCLAN - teach undergraduates but not directly involved in research development. Lead on teaching about research as undergraduate tutor	23/12/2011
Mrs Gillian Rimington	none	08/12/2011
Dr John Shakespeare	none	08/12/2011
Mrs Valerie Skinner	none	08/12/2011
Professor Jois Stansfield	honorary clinical speech and language therapy contract with Pennine NHS Trust Registrant member of the Health Professions Council Education and Training Board Community Governor and Chair of Finance and Personnel Committee Lancastrian School Manchester Professor of Speech Pathology MMU Vice Chair Faculty of Health Psychology and Social Care Ethics Committee Staff reviewer for PhD applications and progression MMU Occasional reviews for ESRC research funding applications	07/12/2011
Dr Gary Whittle	none	07/12/2011

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

Month	Date	Number of Members Present at Meeting
April	14/04/2011	10
May	12/05/2011	9
June	09/06/2011	8
July	14/07/2011	9
September	08/09/2011	9
October	13/10/2011	10
December	08/12/2011	9
January	12/01/2012	9
February	09/02/2012	9
March	08/03/2012	11

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	13/06/2011	3
July	15/07/2011	3
August	19/08/2011	3
September	22/09/2011	3
October	28/10/2011	4
December	02/12/2011	4
December	08/12/2011	4
January	11/01/2012	3
January	12/01/2012	3
February	07/02/2012	4
March	15/03/2012	4

11 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 John Shakespeare	10
Dr Nigel Calvert	9
Mr David Barber	9
Mrs Valerie Skinner	9
Dr Brenda Leese	8
Dr Gary Whittle	8
Dr Anas Olabi	7
Dr Lisa Booth	7
Mrs Andrina Lawrence	7
Dr Brenda Ashcroft	6
Professor Jois Stansfield	5
Mrs Gillian Rimington	3
Susan Page	2
Mr James Burns (Co-opted member)	2
Dr Jane Stuart	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 Nigel Calvert	11
Dr Lisa Booth	8
Professor Jois Stansfield	7
Mrs Gillian Rimington	10
Mrs Valerie Skinner	1
Mr David Barber	1

Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Dr Gary Whittle	28/06/2011 - 28/06/2011	Statistics, NRES
Mr David Barber	01/07/2011 - 01/07/2011	Equality and Diversity on line training, NRES
Dr Lisa Booth	20/07/2011 - 20/07/2011	equality and diversity on line training, NRES
Dr John Shakespeare	17/10/2011	MCA dvd from NRES, NRES
Dr John Shakespeare	30/4/2011	Equality and Diversity on line training, NRES
Dr Gary Whittle	30/4/2011	Equality and Diversity on line training, NRES
Mrs Andrina Lawrence	29/11/2011 - 29/11/2011	Research in adolescents, NRES
Dr Anas Olabi	29/11/2011 - 29/11/2011	Research in adolescents, NRES
Dr Nigel Calvert	29/11/2011 - 29/11/2011	Research in adolescents, NRES
Professor Jois Stansfield	29/11/2011 - 29/11/2011	Research in adolescents, NRES
Mrs Valerie Skinner	28/06/2011 - 28/06/2011	Statistics, NRES
Mrs Valerie Skinner	13/10/2011 - 13/10/2011	SOPs and GAfREC, NRES/REC
Dr Anas Olabi	13/10/2011 - 13/10/2011	SOPs and GAfREC, NRES/REC
Dr Brenda Leese	13/10/2011 - 13/10/2011	SOPs and GAfREC, NRES/REC
Dr John Shakespeare	13/10/2011 - 13/10/2011	SOPs and GAfREC, NRES/REC
Mr David Barber	13/10/2011 - 13/10/2011	SOPs and GAfREC, NRES/REC
Mrs Andrina Lawrence	13/10/2011 - 13/10/2011	SOPs and GAfREC, NRES/REC
Mrs Gillian Rimington	13/10/2011 - 13/10/2011	SOPs and GAfREC, NRES/REC
Dr Lisa Booth	13/10/2011 - 13/10/2011	SOPs and GAfREC, NRES/REC
Susan Page	13/10/2011 - 13/10/2011	SOPs and GAfREC, NRES/REC
Dr Gary Whittle	13/10/2011 - 13/10/2011	SOPs and GAfREC, NRES/REC
Professor Jois Stansfield	13/10/2011 - 13/10/2011	SOPs and GAfREC, NRES/REC
Susan Page	22/02/2012 - 22/02/2012	Induction, NRES
Dr Lisa Booth	01/03/2012 - 01/03/2012	MCA, 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	46	100.00
Total Applications Reviewed	46	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	1
Number of studies withdrawn prior to the meeting	11
Number of student applications reviewed	30
Number of paediatric applications reviewed	13
Number of device applications reviewed	0
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	4.35
Favourable Opinion with Additional Conditions	17	36.96
Unfavourable Opinion	3	6.52
Provisional Opinion	24	52.17
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	46	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	22	47.83
Further Information Favourable Opinion with Additional Conditions	1	2.17
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	4.35
Favourable Opinion with Additional Conditions	17	36.96
Unfavourable Opinion	3	6.52
Provisional Opinion	1	2.17
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	46	100

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

Total Applications Reviewed	30
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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	14	46.67
Favourable Opinion with Additional Conditions	13	43.33
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	3	10.00
Unfavourable Opinion	0	0.00
Total	30	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	4.60
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	20
Number of SSAs (non-Phase 1) reviewed	3
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	67
Number of substantial amendments over 35 days	1
Number of substantial amendments over 35 days as a % of total substantial amendments	1.5%
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*	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/0165	Assessing the needs of carers. Version 1.	52
11/NW/0169	Influence of hydration and heating on nailfold capillary density	54
11/NW/0182	Inflammatory markers in Proliferative Diabetic Retinopathy	32
11/NW/0195	Mental Health Practitioners' attitudes towards implementing CBT. V.1	36
11/NW/0213	T1 mapping validation in people without cardiovascular disease	31
11/NW/0261	social cognitive functioning following childhood brain tumour	22
11/NW/0262	Preventing asthma exacerbations by avoiding mite allergen - Version 1	20
11/NW/0268	OPIS	54
11/NW/0352	Orthoses for people with stroke (OFPAWS)	31
11/NW/0355	Investigation of occlusal changes during dental treatment.	28
11/NW/0474	Self-esteem and health-related outcomes for children with CNS tumours	25
11/NW/0476	Surface ECG AF-waveform analysis / Catheter AF-ablation (version 1.0)	19
11/NW/0481	The Effect of Microwave Radiation on Sperm	50
11/NW/0488	Review of reflective practice in peer community of Programme Directors	2
11/NW/0630	Volunteer management in palliative care	21
11/NW/0635	Focal EEG changes in patients with non epileptic attack disorder (2)	35
11/NW/0662	Experiences and hospital records of patients with medulloblastoma	24
11/NW/0753	Early detection of Diabetic Retinopathy in Diabetic patients	9
11/NW/0846	Family Intervention for south asian relatives	21
12/NW/0050	The impact of weight loss on the malignant potential of endometrium	20
12/NW/0081	Can Photography describe the experience of life with chronic pain?	23
12/NW/0093	Occupational therapy intervention for coordination difficulties	29
12/NW/0126	Serum Autoantibodies in Complex Regional Pain Syndrome, Version 1.0	21
12/NW/0132	Next Generation OCT resources: Version 1.0	8
12/NW/0175	Use of computer game interaction to encourage inhaler compliance	25
Further Information Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/NW/0346	Knowledge and use of alcohol treatment services in Liverpool	28

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/0558	Under utilisation of migrant skills	7
11/NW/0561	A Comparison between Two Irrigation Solutions in Dental Root Canals	7
11/NW/0570	A prospective study of biphosphonates-related osteonecrosis of the jaw	11
11/NW/0687	The impact of a pharmacy technician on pharmacist interventions V1	2
11/NW/0759	Therapeutic targets in metastatic uveal melanoma	7
11/NW/0854	Pain at Home Following Shortstay Surgery in Children	8
11/NW/0856	Resistance Patterns of Uro-Pathogens to Antibiotic in Lincolnshire	9
11/NW/0857	Functional Tests of Menisci	6
11/NW/0861	Pilot study to investigate the preoperative effectiveness of websites.	7
11/NW/0887	Malaysian medical students and Western medical ethics	3
12/NW/0032	Metacognitions in COPD v1	8
12/NW/0036	Assessing inflammatory regulators of vascular disease in arteries	8
12/NW/0039	Are HIV Parameters Associated With Pre-Term Delivery?	22
12/NW/0065	Relational Security and Attachment	8
12/NW/0179	An evaluation of frequency compression in a clinical setting	24
12/NW/0226	Construct validity of the BEBQ	1

Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/NW/0184	Accidental Poisonings in Liverpool	42
11/NW/0203	'Unpacking the home': family carers' reflections on dying at home	34
11/NW/0276	Obsessive Compulsive Treatment Efficacy Trial (OCTET)	29
11/NW/0277	What instigates PLP and affects QOL in lower limb amputees	33
11/NW/0349	Identify if Leadership behaviour influences Quality & Safety	29
11/NW/0353	Psychological Distress and Coping Following Eye Removal Surgery.	24
11/NW/0360	Effects of using a handrail during the Chester Step Test.	25
11/NW/0397	Endodontic posts and resin cements: a microleakage study. Version 1	10
11/NW/0400	Nurses experience of using Paediatric Early Warning Systems.	7
11/NW/0463	Moral reasoning style following traumatic brain injury: Impact of age	18

11/NW/0465	Families' experiences of family therapy: Version 1.1	19
11/NW/0485	A Perspective on Adult Learners in the North West Ambulance Service	7
11/NW/0486	Narratives of experts by experience	6
11/NW/0487	An exploration of clinical nurses undertaking Masters degree research	6
11/NW/0534	stressbusters, an evaluation of service users experience	3
11/NW/0612	The use of global haemostasis assays in rare bleeding disorders	20
11/NW/0631	Assessing accelerated long-term forgetting in epilepsy v1	21
11/NW/0674	FOT in Airways Disease	5
11/NW/0692	Improving the evidence base for oral assessment in stroke patients.	22
11/NW/0704	Case-control Study of Risk Factors for Giardiasis in Northwest England	23
11/NW/0750	Acceptance of chronic pain	7
11/NW/0869	Development and Validation of the Youth Empowerment Scale (YES)	5
12/NW/0031	Physical Activity Levels in Asthmatic Adults	11
12/NW/0033	To explore patients views and experiences of glaucoma management	11
12/NW/0046	The SOCiAL Study version 1	15
12/NW/0117	Inflammation and atherosclerotic plaque morphology in RA	20
12/NW/0129	Development of an intervention for people with non-cardiac chest pain	10
12/NW/0131	Dietary assessment for people with Type 2 diabetes	7
12/NW/0178	A sleep support intervention to improve sleep in critical care.	23
12/NW/0223	CL3-12911-040	2

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/NW/0473	Working age adults: Psycho-education programme following stroke	17
11/NW/0618	Working age adults: Psycho-education programme following stroke	20
11/NW/0702	Development and Validation of the Youth Empowerment Scale (YES)	22

Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
12/NW/0187	Experiences of partners of mothers with mental illness	N/A

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

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	
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
09/H1015/77/AM02	Perceptions affecting medication adherence in young people	changes to consent etc	55
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