

NRES Committee North West - Liverpool Central

Annual Report

01 April 2011 – 31 March 2012

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee North West - Liverpool Central
Type of REC:	Type II
Type of Flag:	None
Chair:	Professor Sobhan Vinjamuri
Vice-Chair:	Mrs Julie Brake
Alternate Vice-Chair:	Dr Stephen Pennefather
Co-ordinator:	Mrs Carol Ebenezer
PRSC Co-ordinator:	Mrs Carol Ebenezer
Assistant Co-ordinator:	Miss. Diane Catterall
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Chair's overview of the past year:

The past year has seen continued changes within NRES, with the publication of the revised GAFREC in September 2011 and the establishment of the Health Research Authority in December 2011 as a Special Health Authority, with NRES at the centre of this new NHS organisation.

As well as the changes to NRES our Committee has had some changes not least it being Sobhan's last year as Chair. Sobhan has been with the committee for 10 years and was our Chair for the last 3 years. He will be missed as an excellent chair and mentor for committee members. I Replaced Sobhan as Chair on 1st April this year , which means that the Vice Chair position became vacant and we are awaiting appointment into this position. We also received resignations from Sheila Gill, Jo Charing, Ronald Anderson and Fred Mostafa (who moved to new committee) and we are grateful for their valuable contributions made. However as previous members leave new members have been appointed and we welcome Dr Murthy Burra, Duane Mellor, Professor Donald Kelly and Dr Dave King.

Our Committee's first PR sub committee was held in March and it was decided to undertake this sub-committee work via email we will review this as the year goes on and discuss committee members' preferences for PR sub-committee work.

The commitment of our committee members is apparent in the fact that we have had to co-opt only twice over this last year and congratulations to Frank Killen who has attended every meeting over the past year.

In the previous Chair's comments it was highlighted that the Committee was faced with having type III status removed following a drop in CTIMP applications, we are still awaiting the outcome of this recommendation and whether or not we retain the status.

Our committee has met all targets and deadlines again this year and this is down to the continued hard work and commitment from the committee members and the valuable support from our committee co-ordinator Carol and joined in May 2011 by Diane Catterall.

I am looking forward to my first year as Chair of our Committee with the support of excellent committee members and the ever hard working Carol. I hope the transition will be very smooth.

NRES Committee North West - Liverpool Central Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Professor Ronald Anderson	Lay member	Lay Plus	21/03/2007	01/06/2011
Mrs Julie Brake	Specialist Diabetes Nurse / Vice Chair	Expert	01/06/2007	
Dr Murthy Burra	Consultant Anaesthetist	Expert	23/09/2011	
Mrs Joanne Charing	Lay member	Lay Plus	03/07/2007	04/05/2011
Miss Carmel Dersch	Lay Member	Lay Plus	21/05/2008	
Mrs Sheila Gill	Lay Member	Lay Plus	01/09/2008	28/06/2011
Mr Derek Hollingsbee	Pharmacist	Expert	23/11/2006	
Professor Donald Kelly	Retired Vet	Lay Plus	23/09/2011	
Mr Frank Killen	Lay Member	Lay Plus	13/09/2007	
Dr Charles King		Lay Plus	20/11/2011	
Miss Karen Knowles	Biomedical Scientist	Expert	15/07/2010	
Mr Duane Mellor	Dietician	Expert	01/2/2012	
Dr Fred Mostafa	Consultant Anaesthetist/Intensivist	Expert	31/08/2001	31/08/2011
Mrs Jennifer Newman	Consumer Liaison Manager	Lay Plus	14/09/2007	
Dr Stephen Pennefather	Consultant Anaesthetist	Expert	30/03/2005	
Dr Lyvonne Tume	Lecturer Practitioner of Paediatric ICU	Expert	15/07/2010	
Professor Sobhan Vinjamuri	Consultant in Nuclear Medicine	Expert	01/04/2002	31/03/2012
Dr Helen Wong	Statistician	Expert	15/02/2005	

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Mr James Burns	Retired	Lay Plus	05/10/2011, 06/07/2011

Member Bank

Name	Occupation	Expert or Lay	Meeting date attended

NRES Committee North West - Liverpool Central: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Mrs Julie Brake	None	07/12/2011
Dr Murthy Burra	President of pre-operative association Reviewer for British Journal of Anaesthesia	11/01/2012
Miss Carmel Dersch	Chair, Liverpool Chinese Community Health Committee	06/12/2011
Mr Derek Hollingsbee	own shares in Bristol-Myers Squibb Inc USA	19/12/2011
Professor Donald Kelly	None	07/12/2011
Mr Frank Killen	None	06/12/2011
Miss Karen Knowles	None	07/12/2011
Dr Charles King	None	07/12/2011
Mr Duane Mellor	Senior Lecturer nutrition and dietetics Chester University Volunteer Diabetes UK	01/02/2012
Mrs Jennifer Newman	None	01/01/2012
Dr Stephen Pennefather	Member of Liverpool Heart & Chest Hospitals R & D Committee Peer reviewer for British Journal of Anaesthesia, European Journal of Cardiothoracic Surgery, Journal of Clinical Anaesthesia, Journal of Critical Care and Journal of Medical Case Reporting	07/12/2011
Dr Lyvonne Tume	None	07/12/2011
Professor Sobhan Vinjamuri	Trust lead for clinical audit peer reviewer for NIHR member of Trust's techniques and medical devices committee	07/12/2011
Dr Helen Wong	None	07/12/2011

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

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

11 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
March	13/03/2012	4

1 proportionate review sub-committee meetings was held during the reporting period.

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

Name	Number of Meetings Attended
Mr Frank Killen	11
Mrs Julie Brake	10
Professor Sobhan Vinjamuri	10
Mrs Jennifer Newman	9
Mr Derek Hollingsbee	9
Dr Stephen Pennefather	9
Dr Helen Wong	9
Dr Lyvonne Tume	9
Miss Carmel Dersch	9
Miss Karen Knowles	8
Professor Donald Kelly	6
Dr Charles King	4
Dr Fred Mostafa	4
Professor Ronald Anderson	3
Dr Murthy Burra	4
Mr Duane Mellor	2
Mr James Burns (Co-opted member)	2
Mrs Joanne Charing	2
Mrs Sheila Gill	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 Lyvonne Tume	1
Miss Carmel Dersch	1
Mr Derek Hollingsbee	1
Professor Sobhan Vinjamuri	1

Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Mr Derek Hollingsbee	01/11/2011 - 01/11/2011	Reviewing CTIMPS, NRES
Mr Frank Killen	01/11/2011 - 01/11/2011	Reviewing CTIMPS, NRES
Mr Frank Killen	13/05/2011 - 13/05/2011	On line equality and diversity , NRES
Dr Lyvonne Tume	26/01/2012 - 26/01/2012	Medical Devices, NRES
Professor Sobhan Vinjamuri	26/01/2012 - 26/01/2012	Medical Devices, NRES
Miss Karen Knowles	19/06/2011 - 19/06/2011	On line Equality and Diversity Training, NRES
Miss Karen Knowles	29/11/2011 - 29/11/2011	Adolescents in research, NRES
Dr Lyvonne Tume	29/11/2011 - 29/11/2011	Ethical issues in research involving adolescents, NRES
Dr Murthy Burra	22/02/2012 - 22/02/2011	Member Induction Training, NRES
Dr Lyvonne Tume	05/10/2011 - 05/10/2011	SOPs and GAfREC, NRES/REC
Mr Frank Killen	05/10/2011 - 05/10/2011	SOPs and GAfREC, NRES/REC
Mrs Jennifer Newman	05/10/2011 - 05/10/2011	SOPs and GAfREC, NRES/REC
Miss Carmel Dersch	05/10/2011 - 05/10/2011	SOPs and GAfREC, NRES/REC
Dr Helen Wong	05/10/2011 - 05/10/2011	SOPs and GAfREC, NRES/REC
Miss Karen Knowles	05/10/2011 - 05/10/2011	SOPs and GAfREC, NRES/REC
Mr Derek Hollingsbee	05/10/2011 - 05/10/2011	SOPs and GAfREC, NRES/REC
Mrs Julie Brake	05/10/2011 - 05/10/2011	SOPs and GAfREC, NRES/REC
Professor Donald Kelly	05/10/2011 - 05/10/2011	SOPs and GAfREC, NRES/REC
Mr Derek Hollingsbee	26/01/2012 - 26/01/2012	Medical Devices, NRES
Dr Charles King	22/02/2012 - 22/02/2012	Induction, NRES
Professor Donald Kelly	22/02/2012 - 22/02/2012	Induction, NRES
Dr Lyvonne Tume	21/03/2012 - 21/03/2012	NRES Training day for new REC Chairs, NRES
Mrs Julie Brake	28/03/2012 - 28/03/2012	Members Training Day, NRES
Mr Duane Mellor	01/04/2011 - 31/03/2012	Self directed learning log

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	18	26.87
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	49	73.13
Total Applications Reviewed	67	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	0
Number of studies withdrawn prior to the meeting	5
Number of student applications reviewed	25
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	4	5.97
Favourable Opinion with Additional Conditions	6	8.96
Unfavourable Opinion	1	1.49
Provisional Opinion	56	83.58
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	67	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	54	80.60
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	4	5.97
Favourable Opinion with Additional Conditions	6	8.96
Unfavourable Opinion	1	1.49
Provisional Opinion	1	1.49
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	1	1.49
Total	67	100

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

Total Applications Reviewed	2
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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	2	100.00
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	0	0.00
Unfavourable Opinion	0	0.00
Total	2	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	6.09
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	29
Number of days taken to final decision - mode	22
Number of SSAs (non-Phase 1) reviewed	14
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	128
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	2
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/0139	Effect of cervical external immobilisation device on Driving	44
11/NW/0142	Nurses perceptions of caring for children with long term conditions	53
11/NW/0143	Representing Action in Parkinson's disease	37
11/NW/0152	PATIENT EXPERIENCES OF COMMUNICATION OF A BREAST CANCER DIAGNOSIS	41
11/NW/0157	A study into vitamin D status of adults with Neurofibromatosis Type I	33
11/NW/0173	REACT	21
11/NW/0196	Awareness and Prevalence of Vitamin D deficiency in Muslim girls	43
11/NW/0219	Low dose inhaled allergen challenge in patients with asthma	52
11/NW/0222	Skin preparation regimens in native knee arthroscopy	49
11/NW/0223	Effects of an exercise intervention for adults aged 60+ in Liverpool	32
11/NW/0229	Testing an assay for lactoferrin in vaginal samples	53
11/NW/0246	STAR-Standard vs Modified Sunitinib Treatment in Renal Cancer V1.0	33
11/NW/0273	Consultant perception of 360 degree feedback	23
11/NW/0314	Teaching FY Drs about medical education and their views on teaching	26
11/NW/0327	Liverpool Primary Hepatocyte Project	31
11/NW/0330	Pharmacist Prescribing Study	26
11/NW/0332	Non-invasive testing for chromosome abnormalities	21
11/NW/0338	Effect of Fluticasone Furoate/Vilanterol Inh. Powder 100/25mcg in COPD	27
11/NW/0342	GRC 4039-204, Version 3, 2011-04-07	25
11/NW/0411	Study comparing controlled monotherapy Lacosamide vs Carbamazepine	24
11/NW/0412	Comparing long term safety of LCM vs CBZ-CR in patients from SP0993	24
11/NW/0435	Treatment evaluation of Thinking Minds therapy programme	51
11/NW/0441	Evaluate the Prandial and Time Action Profile of Rapid Acting Insulin	29
11/NW/0445	Counselling stories within the context of the criminal justice process	28
11/NW/0568	Proteomic analyses in uveal melanoma	31
11/NW/0571	Paracetamol in treatment of cystinuria	25
11/NW/0596	Investigation of the Incretin system in South Asians(ISSA-4149)v01	25
11/NW/0603	Extension study of Denosumab in patients with advanced cancer	34
11/NW/0619	Extension to LAL-CL01 in patients with liver dysfunction due to LAL de	22

11/NW/0622	Image Habituation Training for Post Traumatic Stress disorder	38
11/NW/0629	Hearing voices:Service Users' perceptions of origin and maintenance	26
11/NW/0656	NITRO - Version 1	28
11/NW/0670	HOME FIRST - a feasibility study	17
11/NW/0693	GDT Vs ST for Pancreas Transplant	23
11/NW/0745	A Phase 2a study of AT2220 with ERT in Subjects with Pompe Disease	35
11/NW/0757	Group-based CBT for severe asthma	18
11/NW/0758	Comparison of lidocaine vs. pregabalin in CRPS, type 1	41
11/NW/0766	Culture optimisation of human ocular surface stem cells.	34
11/NW/0822	Long Term Prolonged Release Fampridine Treatment and Quality of Life	28
11/NW/0836	Gender and the Expression of Psychotic Experiences, Version 1	24
11/NW/0850	Significant Carer's experiences of end of life preparation	22
12/NW/0022	Quality of Life (QOL) in Dementia (Version 2)	31
12/NW/0023	Delivering Patient-Centred Care to Renal Patients (Version 1)	43
12/NW/0034	CD5024 and Metronidazole in Papulopustular Rosacea	47
12/NW/0045	MAJIC	23
12/NW/0069	MEDI8968 in Chronic Obstructive Pulmonary Disease	29
12/NW/0083	Using the Gecko nerve stimulator to reduce DVT in ankle fractures	38
12/NW/0085	Functional visual problems in children with hemiplegia	22
12/NW/0091	Experiences of Psychosis Relapse: Early Subjective Signs (ExPRESS)	27
12/NW/0189	Labour in Multiple Pregnancy Prediction Study	22
12/NW/0193	A group narrative of lived experience and Acquired Brain Injury	32
12/NW/0203	Effects of minocycline and ketamine on EEG in healthy volunteers V2	34
12/NW/0205	Bone cement project - feasibility study	18
12/NW/0214	TAILoR: TelmisArtan and Insulin Resistance in HIV	24

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
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Further Information Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
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Favourable Opinion with Standard Conditions

REC Reference	Application Short Title	Number of Days on Clock
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11/NW/0316	Health professionals' assessment of parent-infant interactions	19
11/NW/0444	Validation of nailfold capillaroscopy in systemic sclerosis	21
11/NW/0550	Plaque Reduction by Polyols I	23
12/NW/0185	Alcohol and Cognition - Version 1	17

Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/NW/0140	6 week supervised ankle rehabilitation program on ankle instability	20
11/NW/0263	Imagery, goals and memories in clinical anger problems	19
11/NW/0313	Dietary polyphenols to reduce inflammation in the elderly (STUDY 1)	19
11/NW/0681	A qualitative evaluation of care planning in primary care	18
11/NW/0720	The development of novel biomarkers for predicting pre-term labour	16
12/NW/0007	Is trust in gynaecological cancer care linked to attachment? v1	25
12/NW/0215	The relationship between clavicle fracture outcomes and hand dominance	1
12/NW/0216	Understanding Haematopoiesis in Down Syndrome	4

Unfavourable Opinion		
REC Reference	Application Short Title	Number of Days on Clock
11/NW/0225	Aliskiren Study	20

Provisional Opinion		
REC Reference	Application Short Title	Number of Days on Clock
12/NW/0008	Therapy Compliance among Type 2 Diabetics in the Community.	N/A

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
11/NW/0431	Defining the Primary / Secondary Care Interface in Paediatrics	20

Invalid Application		
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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
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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