

NRES Committee North West - Liverpool Central

Annual Report

01 April 2013 – 31 March 2014

Part 1 – Committee Membership and Training

Name of REC: NRES Committee North West - Liverpool Central

Type of REC: Recognised Type 3

Type of Flag: Paediatric

Chair: Mrs Julie Brake

Vice-Chair: Dr Lyvonne Tume

Alternate Vice-Chair: Dr Stephen Pennefather

REC Manager: Mrs Carol Ebenezer

PRSC Manager: Mrs Carol Ebenezer

REC Assistant: Miss Anna Bannister

Committee Address: HRA NRES Centre - Manchester

3rd Floor Barlow House 4 Minshull Street Manchester M1 3DZ

Telephone: 0161 625 7818 **Fax:** 0161 625 7299

Email: nrescommittee.northwest-liverpoolcentral@nhs.net

Chair's overview of the past year:

The past year of Liverpool Central Research Ethics Committee has been very successful. The commitment of our members continues to show as we did not need to co-opt any members from other committees in the previous 12 months and, in addition to this, Hannah has been co-opted to other committees to ensure quoracy. This is invaluable and ensures committees can continue and applications be reviewed in a timely manner.

I would also like to thank Frank Killen and Hannah Chambers for attending 10 out of the 11 meetings last year. The large time commitment needed for each meeting is recognised and I will take this opportunity to thank everyone for their thorough reviews of all applications, comments, emails between meetings and their final acceptance of the new review forms!

The success of our committee is down to its members and over the last year we have lost some valuable members. Carmel Dersch – our social secretary, left after 5 years' service this year and Duane Mellor left after moving out of the area. Their input and discussion during meetings has been missed.

We have been very fortunate in having new members who have fitted into the committee extremely well. Ann Williams joined us from the Cheshire committee when it closed and Simon Alford joined as a new member in December.

As in previous years I have tried to raise the profile of the committee with local researchers and encouraged observers from research teams, universities and healthcare providers to attend a REC meeting. This way they can use their experience to improve their research applications, de-mystify what happens at a REC meeting and also share this with their colleagues. In the past 12 months we have had 10 observers, one of whom hoped to become a member and we have had great feedback from them on how useful it was.

PR sub committees are also still working well and we continue undertaking this sub-committee work via email. As mentioned in last year's report I took part in a pilot looking at the information required for a PR review and whether this can be reduced. The pilot has been completed and we await the results.

The HRA are also looking at systems to help improve proposals before reaching the local RECs. Pilots happened early in 2014 and we wait with anticipation the results hoping that any changes will help with the ethical review of research proposals for committee members and researchers alike.

Dr Stephen Pennefather and Helen Wong will have done their 10 years next year so will be leaving the committee at some point. Their contribution to meetings has been invaluable and Helen's ability to explain statistics and Dr Pennefather's ability to explain medical procedures and terminology has been very helpful.

Once again the committee has run smoothly this year due to the work and co-ordination of the REC manager Carol Ebenezer and REC Assistant, Anna Bannister.

NRES Committee North West - Liverpool Central Membership:

Name	Occupation	Expert or	Dates	
		Lay	Appointed	Resigned
Mr Simon Alford	Lecturer	Lay	03/12/2013	
Mrs Julie Brake	Specialist Diabetes Nurse / Chair	Expert	01/06/2007	
Dr Murthy Burra	Consultant Anaesthetist	Expert	23/09/2011	
Mrs Hannah Chambers	Lay Member	Lay	27/09/2012	
Miss Carmel Dersch	Lay Member	Lay Plus	21/05/2008	20/05/2013
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 Member	Lay Plus	20/11/2011	
Miss Karen Knowles	Biomedical Scientist	Expert	15/07/2010	
Dr Duane Mellor	Lecturer in Dietetics	Expert	26/09/2012	31/10/2013
Dr Stephen Pennefather	Consultant Anaesthetist	Expert	30/03/2005	
Ms Jennifer Preston	Consumer Liaison Manager	Lay Plus	14/09/2007	
Dr Lyvonne Tume	Senior Nursing Research Fellow Paediatric ICU	Expert	15/07/2010	
Mrs Ann Williams	Lay Member	Lay	01/05/2013	
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

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

Name	Declaration of Interest	Date
Miss Karen Knowles	none	11/12/2013
Mrs Julie Brake	None	11/12/2013
Dr Lyvonne Tume	Member of HTA topic identification panel for	11/12/2013
	Maternal and Child Health	
Professor Donald Kelly	None	11/12/2013
Mr Frank Killen	None	11/12/2013
Dr Charles King	None	11/12/2013
Dr Murthy Burra	Immediate Past President of the Pre-Operative	11/12/2013
	Association Involved in research activities of pre-	
	operative association	
Mrs Hannah Chambers	Trustee of Resolve Cymru	11/12/2013
Dr Stephen Pennefather	None	11/12/2013
Mr Simon Alford	As an employee of the University of Chester,	19/12/2013
	faculty of Health & Social Care, I will undertake	
	health research which on occasions requires NHS	
	ethics. This could lead to a conflict of interest,	
	which will be declared in the appropriate manner	
Dr Helen Wong	None	14/01/2014
Mr Derek Hollingsbee	Holds shares in Bristol-Myers Squibbs	14/01/2014
Dr Duane Mellor	Volunteer Diabetes UK. Peer reviewer for NIHR.	14/01/2014
	Lecturer at University of Nottingham.	
Ms Jennifer Preston	None	08/01/2014
Mrs Ann Williams	Member of Food Standard Agency Social Science	20/02/2014
	Research Committee. Commissioner of adult social	
	services for Liverpool City Council and sometimes	
	commission evaluation studies.	

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

Month	Date	Number of Members Present at Meeting
April	03/04/2013	12
May	01/05/2013	13
June	05/06/2013	10
July	03/07/2013	10
September	04/09/2013	12
October	02/10/2013	8
November	06/11/2013	9
December	04/12/2013	9
January	08/01/2014	12
February	05/02/2014	11
March	05/03/2014	10

¹¹ full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
April	29/04/2013	3
June	04/06/2013	4
July	09/07/2013	5
September	17/09/2013	4
October	22/10/2013	3
November	26/11/2013	3
December	12/12/2013	4
January	13/01/2014	4
February	19/02/2014	3
March	17/03/2014	4

¹⁰ proportionate review sub-committee meetings were held during the reporting period.

Attendance of Members: 01 April 2013 - 31 March 2014:

Name	Number of Meetings Attended
Mr Frank Killen	10
Mrs Hannah Chambers	10
Professor Donald Kelly	9
Mrs Julie Brake	9
Dr Charles King	9
Dr Stephen Pennefather	9
Miss Karen Knowles	9
Mr Derek Hollingsbee	8
Dr Lyvonne Tume	8
Mrs Ann Williams	8
Dr Helen Wong	7
Dr Murthy Burra	7
Ms Jennifer Preston	6
Dr Duane Mellor	3
Miss Carmel Dersch	2
Mr Simon Alford	2

Number of inquorate meetings held: 0

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

Name	Number of Meetings Attended
Mrs Julie Brake	9
Dr Lyvonne Tume	7
Ann Williams	4
Mrs Hannah Chambers	4
Dr Duane Mellor	3
Dr Murthy Burra	2
Ms Jennifer Preston	2
Professor Donald Kelly	1
Dr Charles King	1
Dr Helen Wong	1
Mr Derek Hollingsbee	1
Mr Frank Killen	1

Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Dr Charles King	24/07/2013 - 24/07/2013	Equality & Diversity, NRES on line
Mr Derek Hollingsbee	27/11/2013 - 27/11/2013	National Members' Training Day, NRES
Dr Lyvonne Tume	11/12/2013 - 11/12/2013	National Chairs Training Day, NRES
Dr Murthy Burra	31/10/2013 - 31/10/2013	Qualitative research, NRES
Mrs Julie Brake	16/01/2014 - 16/01/2014	Adults Lacking Capacity , NRES
Dr Stephen Pennefather	16/01/2014 - 16/01/2014	Adults Lacking Capacity in research, NRES
Miss Karen Knowles	27/11/2013 - 27/11/2013	National Members Training Day, HRA
Mr Frank Killen	27/11/2013 - 27/11/2013	National Members Training Day, HRA
Mrs Hannah Chambers	29/10/2013 - 29/10/2013	Members National Training Day, HRA
Mrs Hannah Chambers	12/03/2014 - 12/03/2014	Improving Consent and Patient Information Sheets, HRA
Dr Charles King	12/03/2014 - 12/03/2014	Improving patient consent and information sheets, HRA
Mr Simon Alford	05/03/2014 - 05/03/2014	Induction, HRA
Professor Donald Kelly	12/03/2014 - 12/03/2014	Improving Patient Information and Consent Forms, 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:

Applications for full ethical review – Study Type	Number	%
Clinical Trial of Investigational Medicinal Product	16	28.57
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	40	71.43
Total Applications Reviewed	56	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	4
Number of student applications reviewed	15
Number of paediatric applications reviewed	6
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	1.79
Favourable Opinion with Additional Conditions	10	17.86
Unfavourable Opinion	1	1.79
Provisional Opinion	44	78.57
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	56	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	44	78.57
Conditions		
Further Information Favourable Opinion with Additional	0	0.00
Conditions		
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	1.79
Favourable Opinion with Additional Conditions	10	17.86
Unfavourable Opinion	1	1.79
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	56	100

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

Total Applications Reviewed	23

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	15	65.22
Favourable Opinion with Additional Conditions	3	13.04
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	5	21.74
Unfavourable Opinion	0	0.00
Total	23	100

Average number of applications reviewed per full meeting	5.09
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	24
Number of days taken to final decision - mode	22
Number of SSAs (non-Phase 1) reviewed	22
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	119
Number of substantial amendments over 35 days	0
Number of substantial amendments over 35 days as a % of	0.0%
total substantial amendments	
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	1
Number of proportionate review applications over 14 days as a % of total	4.3%

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
13/NW/0192	Assessing risk of self-harm/suicide in a high secure setting.	25
13/NW/0195	Parental Psychological Trauma Following Accidental Injury to Child	21
13/NW/0216	Safety and Efficacy of Elobixibat in Constipation - Echo 2	24
13/NW/0234	EMPHASIS-lung	22
13/NW/0258	Measurement of organ retraction forces during surgery	27
13/NW/0282	Understanding Immunity to Typhoid (Version 1)	25
13/NW/0283	Global Leaders Study V1.0	31
13/NW/0293	Surviving Aneurysm Surgery (SAS Trial) V1	22
13/NW/0299	Lung Function and Pain After Lung Surgery	27
13/NW/0336	Bonding experiences in mothers of babies with congenital heart disease	11
13/NW/0338	Medtronic Registry for Epilepsy (MORE)	6
13/NW/0368	Effect of excision of the fat pad in total knee replacement surgery.	16
13/NW/0375	Hospital Discharge and Pathways of Care for Homeless People	44
13/NW/0376	Exploration of the Attitudes and Aspirations of Clients in OST	39
13/NW/0392	Mr Bubbles	19
13/NW/0457	Microbial Diversity and Abundance Analysis of HCP	22
13/NW/0484	Community integration following brain injury.	44
13/NW/0489	Motor Fatigue in Multiple Sclerosis	42
13/NW/0490	Exploratory Study of PRX167700 in Subjects with Knee Osteoarthritis	23
13/NW/0494	An evaluation of a water fluoridation scheme in Cumbria-Topical Effect	22
13/NW/0501	Oral Azacitidine in Subjects with AML in Complete Remission	26
13/NW/0567	Suitability of Nitisinone in Alkaptonuria(SONIA2)	16
13/NW/0572	RCT Ultrasound Guided Injection for Trochanteric Bursitis.	20
13/NW/0582	Nerve Decompression for Irreparable Rotator Cuff Tears.	16
13/NW/0607	ODYSSEY CHOICE	20
13/NW/0608	Assessing a new measure for stroke - version 1 01.06.13	41
13/NW/0611	Use of continous glucose monitoring in post cardiac surgical patients	21
13/NW/0666	FATIGUE	39
13/NW/0692	CARMELINA DM CV outcome study 1218.22	20

13/NW/0699	Phase 2 efficacy study of CC-4047+dexamethasone in renal impairment	20
13/NW/0712	Investigating the Incretin System in Cystic Fibrosis	22
13/NW/0749	Prevalence of ischaemia in patients referred to chest pain clinic	45
13/NW/0755	Treatment of mild GDM	22
13/NW/0762	REGULATE - REG1 Anticoagulation vs. Bivalirudin in PCI	20
13/NW/0764	Estimating Aspirin resistance in high risk women (EARTH)	36
13/NW/0803	Stress and wellbeing after childbirth (STRAWB)Version 2.0	22
13/NW/0826	Transcutaneus Posterior Tibial Nerve Stimulation v.1.0	22
13/NW/0862	Better design better life 1	11
13/NW/0865	Making sense of complex results in a haematological oncology setting	28
13/NW/0868	Exploring the psychological needs of pregnant women with FGM	31
14/NW/0004	Corneal confocal microscopy in burning mouth syndrome	27
14/NW/0008	Go-colitis	28
14/NW/0020	Standard dose versus higher and extended dose of Radium 223 in CRPC.	27
14/NW/0028	Identifying best composite prognosticators in fibrosing lung diseases	15
14/NW/0030	A comparative study of two dressings for central venous catheters	12
14/NW/0045	What do young people expect to happen after a referral to CAMHS	28
14/NW/0051	How physical activity affects sarcopenia in obese people with diabetes	27
14/NW/0125	LGBT Youth Suicide Prevention Project V1	22
14/NW/0138	OPTIMIZE RO-2455-302-RD Roflumilast for severe COPD	17

Further Information	on Favourable Opinion with Additional Conditions	
REC Reference	Application Short Title	Number of Days on Clock

Further Information	on 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
13/NW/0340	Effects of tonsillectomy on voice and speech.	4
13/NW/0454	Child sexual abuse in a cohort of children under 8 years of age.	5
13/NW/0538	Lung cancer circulating biomarkers	7
13/NW/0540	The MOVE trial - MetabOlites in VitrEous fluid	12

13/NW/0542	Oxygen consumption during an Incremental Shuttle Walk Test	8
13/NW/0689	Neuropsychological profiles of children with selective eating	12
13/NW/0761	Investigation of Endothelial Progenitor Cells	6
13/NW/0763	Biphasic aPTT waveform analysis: an early detection marker for sepsis?	1
13/NW/0768	Anxiety, depression and QOL in radiotherapy patients	3
13/NW/0832	AS 500 study	3
13/NW/0834	Urinary Metanephrine/Creatinine Ratio on Early Morning Random Sample	6
13/NW/0861	Evaluation of a new tool to assess surgical performance. v1	8
14/NW/0014	The Use of Human Primary Cells for Anti-Infectives Drug Discovery	27
14/NW/0118	Distress and access to services in the South Asian population (v1)	5
14/NW/0123	FILTR Study - Field triage tool for ruptured aneurysms	7
14/NW/0181	The information needs of patients with chronic kidney disease- vs 1	3

Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
13/NW/0200	Risk assessment evaluation	16
13/NW/0203	Assessment, Support, Mangagement Depression in Advanced Cancer	16
13/NW/0280	INjection versus SplinTing in Carpal Tunnel Syndrome (INSTinCTS)	20
13/NW/0740	Skin microbiome of children with cystic fibrosis	19
13/NW/0742	CPP-ACP toothpaste trial v1.1	19
13/NW/0819	Vitamin D status of gastrostomy-fed children	10
13/NW/0833	STUMP UP	3
14/NW/0027	Improving the health of homeless people; a qualitative study	5
14/NW/0031	Maternal anxiety, infant feeding and appetite V1	20
14/NW/0050	Six Electrode ECG Electrode Positioning Study.	36
14/NW/0106	Assessing and managing pain in children who have complex needs	16
14/NW/0133	Routine HIV testing in colposcopy clinics - Liverpool	14
14/NW/0177	Why don't patients take medicines? Exploring beliefs and attitudes	3

Unfavourable Opinion				
REC Reference	Application Short Title	Number of Days on Clock		
13/NW/0486	Evaluating Patient Perspectives and Opinions on Research for SCI.	22		

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					
N (B 11 B 1 1 NUO DEO						
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	_	ation Short Title		Number of Days on Clock			
Proportionate review applications for ethical review over 14 days timeline							
REC Reference	Applica	ation Short Title	Number of Days on Clock				
14/NW/0028	Identify	ing best composite prognosticator	15				
SSAs (non Phase 1) over 25 days timeline							
REC Reference	Applica	ation Short Title		Number of Days on Clock			
SSAs (Phase 1) over 14 days timeline							
REC Reference	ence Application Short Title			Number of Days on Clock			
Substantial Amendments over 35 day timeline							
Amendment Refe	erence	Application Short Title	Amendment Title	Number of Days on			
				Clock			
		er 14 day timeline					
Amendment Refe	erence	Application Short Title	Amendment Title	Number of Days on			
				Clock			
Section 30 application over 60 day timeline							
Amendment Refe	erence	Application Short Title	Amendment Title	Number of Days on			
				Clock			