

National Research Ethics
Service


Health Research Authority

NRES Committee West Midlands - The Black Country

Annual Report

01 April 2013 – 31 March 2014

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee West Midlands - The Black Country
Type of REC:	Authorised
Type of Flag:	Paediatric
Chair:	Dr Hilary Paniagua
Vice-Chair:	Dr Joseph Arumainayagam
Alternate Vice-Chair:	Vacant
REC Manager:	Miss Shehnaz Ishaq
PRSC Manager:	Miss Shehnaz Ishaq
REC Assistant:	Miss Diane Catterall
Committee Address:	HRA NRES Centre Manchester 3rd Floor, Barlow House 4 Minshull Street Manchester M1 3DZ
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Chair's overview of the past year:

2013/2014 was a full year for the committee with eleven full meetings which reviewed a total of 42 projects. The majority were given favourable or favourable with conditions as an opinion with only 3 given an unfavourable opinion. A quorum has been achieved for each meeting but on two occasions, we have had to rely on co-opted members to reach a quorum. During the year we lost Veronica Wells after a short illness. Veronica had served on the Dudley then Black Country committee for over 10 years. As a lay member she brought a humble but often incisive perspective to our meetings, and I will miss her saying 'I'm only a lay member but...' before a telling observation. Thanks to Tony Zalin who managed to attend more meetings than any of us (9) and to Nanek, Hilary and Mark who managed 8. We will need to look to the possibility of recruiting new members in the next year. Shehnaz has organised us all with skill and charm and her minutes require the least editing of any I have had to check in my 10 years as chair. Finally I am grateful for Hilary taking over as chair of the group. I have hugely enjoyed being part of this ethics committee over the years and will replace it with a role in the local R&D department, so look forward to interacting with ethics from the other side.

NRES Committee West Midlands - The Black Country Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr Joseph Arumainayagam	Consultant and Honorary Senior Clinical Lecturer in HIV and GUM	Expert	01/04/2007	
Mrs Chris Bell	Lay Member	Lay Plus	01/04/2007	
Dr Nicola Erb	Consultant Rheumatologist	Expert	01/01/2009	
Dr Jeff Neilson	Consultant Haematologist	Expert	01/04/2007	28/02/2014
Dr Hilary Paniagua	Chair of the research ethics committee, School of Health and Wellbeing	Expert	01/04/2007	
Mr Nanak Singh Sarhadi	Consultant Plastic Surgeon	Expert	01/06/2009	
Dr Julian Sonksen	Consultant in Anaesthesia and Critical Care	Expert	01/01/2008	
Reverend Mark Stobert	Hospital Chaplain	Lay Plus	01/04/2007	
Dr David Vallance	Clinical Biochemist	Expert	01/04/2007	
Mrs Jennifer Walton	Retired Research Nurse	Lay	01/11/2010	
Mrs Veronica A Wells	Lay Member	Lay	01/04/2007	10/06/2013 (Member passed away)
Dr Tony Zalin	Expert Member	Expert	01/01/2009	

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Mr Michael Andrews	Retired Company Secretary	Lay Plus	2 December 2013
Miss Sarah Jane Jones	Lay Member	Lay	1 July 2013

NRES Committee West Midlands - The Black Country: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Dr Jeff Neilson	Part of local R&D process	24/12/2013
Dr Julian Sonksen	None	24/12/2013
Dr Tony Zalin	Medical translator	24/12/2013
Reverend Mark Stobert	Support Dudley Group NHS Foundation Trust - R&D Directorate	24/12/2013
Dr Hilary Paniagua	Chair of the Wolverhampton University's Ethics Committee for the School of Health.	24/12/2013
Mrs Jennifer Walton	Have investments through investment organisations	24/12/2013
Dr Joseph Arumainayagam	None	24/12/2013
Mrs Chris Bell	None	24/12/2013
Dr David Vallance	Member of the Dudley Group of Hospitals R&D Committee.	29/01/2014
Mr Nanak Singh Sarhadi	involved in clinical research	29/01/2014
Dr Nicola Erb	None	27/11/2013

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

Month	Date	Number of Members Present at Meeting
April	08/04/2013	7
June	03/06/2013	8
July	01/07/2013	8
October	07/10/2013	9
November	04/11/2013	8
December	02/12/2013	7
January	06/01/2014	9
February	03/02/2014	8
March	03/03/2014	8

9 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
May	08/05/2013	3
June	25/06/2013	3
July	26/07/2013	3
September	30/09/2013	3
October	30/10/2013	3
January	15/01/2014	3
February	27/02/2014	3

7 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
Dr Tony Zalin	9
Mr Nanak Singh Sarhadi	8
Dr Hilary Paniagua	8
Reverend Mark Stobert	8
Mrs Jennifer Walton	7
Dr David Vallance	6
Dr Jeff Neilson	6
Dr Joseph Arumainayagam	5
Dr Julian Sonksen	5
Mrs Chris Bell	4
Dr Nicola Erb	4

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
Dr Hilary Paniagua	5
Dr Jeff Neilson	4
Mrs Jennifer Walton	3
Reverend Mark Stobert	2
Dr David Vallance	2
Mr Nanak Singh Sarhadi	2
Mrs Chris Bell	2
Dr Joseph Arumainayagam	1

Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Dr Nicola Erb	24/09/2013 - 24/09/2013	Quantitative Research Training Day, HRA
Mrs Jennifer Walton	31/10/2013 - 31/10/2013	Qualitative Research and Ethical Review, HRA
Mrs Jennifer Walton	30/07/2013 - 30/07/2013	Human Tissue Act (Use of Samples in Research), HRA
Dr David Vallance	13/11/2013 - 13/11/2013	Personal data in research - A workshop, HRA
Reverend Mark Stobert	07/10/2013 - 07/10/2013	Nottingham REC Centre Local Training day, HRA
Mrs Chris Bell	23/10/2013 - 23/10/2013	Nottingham REC Centre Training Day, HRA
Dr Hilary Paniagua	20/11/2013 - 20/11/2013	National Members Training Day for NRES Committee Members, HRA
Dr Tony Zalin	29/09/2013 - 29/09/2013	Self-Directed Learning translation of correspondence focussed on research ethics issues., SDL
Dr Tony Zalin	29/09/2013 - 29/09/2013	Self-Directed Learning - Read BMJ and Ben Goldacre's work and various other journals, SDL
Mr Nanak Singh Sarhadi	10/03/2014 - 14/10/2013	Improving Informed Consent & PIS - HRA, NIHR & MRC workshop, 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	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	42	100.00
Total Applications Reviewed	42	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	11
Number of studies withdrawn prior to the meeting	8
Number of student applications reviewed	27
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	1	2.38
Favourable Opinion with Additional Conditions	14	33.33
Unfavourable Opinion	3	7.14
Provisional Opinion	24	57.14
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	42	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	20	47.62
Further Information Favourable Opinion with Additional Conditions	4	9.52
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	2.38
Favourable Opinion with Additional Conditions	14	33.33
Unfavourable Opinion	3	7.14
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	42	100

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

Total Applications Reviewed	11
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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	5	45.45
Favourable Opinion with Additional Conditions	4	36.36
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	2	18.18
Unfavourable Opinion	0	0.00
Total	11	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	4.66
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	31
Number of days taken to final decision - mode	27
Number of SSAs (non-Phase 1) reviewed	7
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	81
Number of substantial amendments over 35 days	10
Number of substantial amendments over 35 days as a % of total substantial amendments	12.3%
Number of Section 30 applications reviewed	1
Number of Section 30 applications over 60 days	0
Number of Section 30 applications over 60 days as a % of total Section 30 applications	0.0%
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	0.0%

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/WM/0115	(duplicate) Prevalence of HIV among High Grade cervical Smears abnormal	50
13/WM/0118	VTE in care homes (VTEC)	48
13/WM/0213	Autism and Psychosis	40
13/WM/0214	Emotional Contagion: The effect of group dynamics on chronic pain 1.0	35
13/WM/0243	Trastuzumab and vascular endothelial function	35
13/WM/0259	A Prospective Observational Study of Chronic Thoracotomy Pain v1.0	41
13/WM/0380	Perceptions of patients towards their confinement and treatment	32
13/WM/0398	Spontaneous Space Closure After First Permanent Molar Extraction	12
13/WM/0422	The place of psychological interventions in weight management services	17
13/WM/0423	Posttraumatic Growth and the Role of the Therapeutic Relationship v1	29
13/WM/0429	Physical activity and muscle metabolism in old obese adults.	29
13/WM/0467	Dejour Test validity study & its use in respiratory failure.	37
13/WM/0470	glycaemic abnormalities in sleep apnoea	34
13/WM/0513	People with both Intellectual Disabilities and Dementia	16
14/WM/0005	Treatment Readiness in Adolescents Residing in Forensic Services	34
14/WM/0011	IIH:WT	31
14/WM/0025	Long term effect of OASIS on QoL & bowel function	15
14/WM/0030	The lived experience of Vocal Cord Dysfunction	27
14/WM/0031	Dealing with the aftermath of matricide	30
14/WM/0056	Working Memory Training in Type 2 Diabetes	23
14/WM/0065	Mechanisms underpinning diurnal variation in human muscle performance	19

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
13/WM/0198	Chinese people and staff perspective when accessing health services	13
13/WM/0265	(April) Screening for Diabetes in Dental Settings	30
13/WM/0455	Resistance training rest interval and muscle anabolism	46
14/WM/0008	Osteoporosis in Professional Dancers	32
14/WM/0009	Bone Health of Dance Students	32

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
13/WM/0256	Tooth Whitening 2012-0302-v1	12
13/WM/0261	CT Texture analysis of oesophageal cancer	12
13/WM/0309	Chaplains for wellbeing	9
13/WM/0382	Validation of the Modified Microlife Blood Pressure Monitor in PAF	39
13/WM/0449	BLOOD QUEST 2: Creatively preparing children for blood-taking	7
14/WM/0075	What is the impact of therapists' response to resistance talk in MI?	9

Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
13/WM/0119	The experience of being a mother with anorexia	41
13/WM/0128	The use of alcohol whilst in treatment for opiate dependence	28
13/WM/0133	The Impact of Polymyalgia Rheumatica Study version 1.0	27
13/WM/0165	Implications for CBT with post bariatric surgery patients.	22
13/WM/0210	Cerebral blood flow regulation in atrial fibrillation (CBF-AF)	29
13/WM/0258	The Effects of Serum Vitamin D on IVF Outcome	22
13/WM/0310	Women's perspectives of radiotherapy and tissue breast reconstruction	8
13/WM/0389	Understanding Risk factors for the Development of Anorexia Nervosa	34
13/WM/0393	The pre-operative information needs of acoustic neuroma patients	12
13/WM/0426	A patient study of coronary heart disease version 1	17
13/WM/0432	The Experience of fathers on a Neonatal Unit.	24
13/WM/0464	Identifying a Core Outcome Set for Cardiac Arrest Clinical Trials	25
13/WM/0469	Microscopic investigation of the role of vitamin D in skeletal muscle	24
14/WM/0001	EBV infection and lymphomagenesis	42
14/WM/0010	LiverMultiscan with MRI – replacing liver biopsy	28
14/WM/0029	Cardiac echo in heart failure with a preserved LV ejection fraction	9
14/WM/0066	The LYNC study version 1	20
14/WM/0077	Long Term Outcomes in a Cohort of Patients with Anorexia Nervosa	10

Unfavourable Opinion		
REC Reference	Application Short Title	Number of Days on Clock
13/WM/0158	Patient Opinions on Research for SCI.	27
13/WM/0396	Effect of body position on lung function of the human lungs. Version 1	59
13/WM/0459	Bone Health of Dancers	35

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

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
12/WM/0369/AM01	Pilot Brief Intervention on Inpatient Units	5, 23.01.2013	36
12/WM/0369/AM09	Pilot Brief Intervention on Inpatient Units	10, 15.02.2013	36
12/WM/0369/AM08	Pilot Brief Intervention on Inpatient Units	8, 20.12.2012	36
12/WM/0369/AM07	Pilot Brief Intervention on Inpatient Units	6, 23.01.2013	36
12/WM/0369/AM06	Pilot Brief Intervention on Inpatient Units	4, 23.01.2013	36
12/WM/0369/AM05	Pilot Brief Intervention on Inpatient Units	2, 23.01.2013	36
12/WM/0369/AM04	Pilot Brief Intervention on Inpatient Units	1, 23.1.2013	36
12/WM/0369/AM03	Pilot Brief Intervention on Inpatient	7, 23.01.2013	36

	Units		
12/WM/0369/AM02	Pilot Brief Intervention on Inpatient Units	3,23.01.2013	36
12/WM/0369/AM10	Pilot Brief Intervention on Inpatient Units	9, 25.01.2013	36

Modified Amendments over 14 day timeline

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

Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
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