

**NRES Committee West Midlands -
The Black Country**

Annual Report

01 April 2011 – 31 March 2012

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 Jeff Neilson
Vice-Chair:	Dr Joseph Arumainayagam
Alternate Vice-Chair:	-
Co-ordinator:	Miss Helen Penistone
PRSC Co-ordinator:	-
Assistant Co-ordinator:	Ms. Jo Foxall Dant
Committee Address:	North West REC Centre 3rd Floor, Barlow House 4 Minshull Street Manchester M1 3DZ
Telephone:	0161 625 7832
Fax:	0161 625 7299
Email:	helen.penistone@northwest.nhs.uk

Chair's overview of the past year:

2011/2012 has been another year of change with the move of the REC administration from Redditch to Manchester and the departure of our co-coordinator Jenny Tyers who served the committee extremely well. The change was very well managed and we now welcome Helen and Jo on their sojourns to the Midlands. The committee membership has been stable over the year, though we did miss temporarily input from Mark and Hilary while they took sabbaticals. Change is in the air again with the likelihood of further re-shuffling of committees and we await the outcome of decisions to be made in the upper reaches of the HRA (Health Research Authority) which NRES now forms part. The other big change will be the introduction of proportionate review and we will need to work out how we do this locally. In the meantime we will continue to meet monthly reviewing 6 or fewer projects.

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	01/04/2007	
Dr Jeff Neilson	Consultant Haematologist	Expert	01/04/2007	
Dr Hilary Paniagua	Chair of the research ethics committee, School of Health and Wellbeing, Wolverhampton Un	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	01/04/2007	
Dr Antonios Stavropoulos-Kalinoglou	Research Fellow in Exercise Physiology	Expert	01/06/2009	
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	01/10/2010	
Mrs Veronica A Wells	Lay Member	Lay	01/04/2007	
Dr Tony Zalin	Expert Member	Expert	01/04/2007	

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended

Member Bank

Name	Occupation	Expert or Lay	Meeting date attended

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

Name	Declaration of Interest	Date
Dr Tony Zalin	None	05/12/2011
Mrs Veronica A Wells	None	05/12/2011
Mrs Jennifer Walton	Occasional work as 'data manager' Cancer Clinical Trials Unit, University Hospital, Stoke -on-Trent.	05/01/2012
Dr Julian Sonksen	None	05/01/2012
Reverend Mark Stobert	None	05/03/2012
Mrs Chris Bell	Quality and Risk Committee Walsall Healthcare Trust.	05/03/2012
Dr Nicola Erb	None	05/12/2011
Dr Joseph Arumainayagam	None	05/12/2011
Mr Nanak Singh Sarhadi	None	05/12/2011
Dr Jeff Neilson	Involved in SSA and peer review projects from the Dudley Group.	05/12/2011
Dr David Vallance	Not available	
Dr Hilary Paniagua	Member on break of service – not available	

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

Month	Date	Number of Members Present at Meeting
April	04/04/2011	9
May	09/05/2011	9
June	06/06/2011	7
July	04/07/2011	7
August	01/08/2011	8
October	03/10/2011	9
November	07/11/2011	7
December	05/12/2011	7
January	09/01/2012	7
March	05/03/2012	10

10 full committee meetings were held during the reporting period.

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

Name	Number of Meetings Attended
Dr Jeff Neilson	10
Mrs Veronica A Wells	10
Mr Nanak Singh Sarhadi	9
Dr Nicola Erb	8
Dr David Vallance	8
Mrs Jennifer Walton	8
Mrs Chris Bell	6
Dr Tony Zalin	5
Dr Joseph Arumainayagam	5
Dr Hilary Paniagua	4
Dr Julian Sonksen	3
Reverend Mark Stobert	3
Dr Antonios Stavropoulos-Kalinoglou	1

Number of inquorate meetings held: 0

Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Dr Nicola Erb	16/06/2011 - 16/06/2011	Qualitative Research, Jenny Tyers
Dr Jeff Neilson	16/06/2011 - 16/06/2011	Qualitative Research, Jenny Tyers
Dr Julian Sonksen	28/02/2012 - 28/02/2012	Qualitative Research and Ethical Review, NRES
Mrs Veronica A Wells	01/08/2011 - 01/08/2011	MCA DVD, NRES
Mrs Jennifer Walton	01/08/2011 - 01/08/2011	MCA DVD, NRES
Mrs Chris Bell	01/08/2011 - 01/08/2011	MCA DVD, NRES
Dr Jeff Neilson	01/08/2011 - 01/08/2011	MCA DVD, NRES
Mr Nanak Singh Sarhadi	01/08/2011 - 01/08/2011	MCA DVD, NRES
Dr David Vallance	01/08/2011 - 01/08/2011	MCA DVD, NRES
Dr Joseph Arumainayagam	01/08/2011 - 01/08/2011	MCA DVD, NRES
Dr Joseph Arumainayagam	12/10/2011 - 12/10/2011	NRES update meeting, NRES
Dr Joseph Arumainayagam	04/07/2011 - 04/07/2011	Single Issue Debate, Jenny Tyers
Dr Nicola Erb	04/07/2011 - 04/07/2011	Single Issue Debate, Jenny Tyers
Dr Jeff Neilson	04/07/2011 - 04/07/2011	Single Issue Debate, Jenny Tyers
Dr Hilary Paniagua	04/07/2011 - 04/07/2011	Single Issue Debate, Jenny Tyers
Mr Nanak Singh Sarhadi	04/07/2011 - 04/07/2011	Single Issue Debate, Jenny Tyers
Dr David Vallance	04/07/2011 - 04/07/2011	Single Issue Debate, Jenny Tyers
Mrs Veronica A Wells	04/07/2011 - 04/07/2011	Single Issue Debate, Jenny Tyers
Dr Joseph Arumainayagam	07/08/2011 - 07/11/2011	GAfREC Update discussion, Jenny Tyers
Dr Joseph Arumainayagam	07/08/2011 - 07/08/2011	MCA DVD, Jenny Tyers
Dr Tony Zalin	01/08/2011 - 01/08/2011	GAfREC update training, Jenny Tyers
Dr Tony Zalin	01/08/2011 - 01/08/2011	MCA DVD, Jenny Tyers
Mrs Chris Bell	01/08/2011 - 01/08/2011	GAfREC updating training, Jenny Tyers
Dr Jeff Neilson	01/08/2011 - 01/08/2011	GAfREC , Jenny Tyers
Mrs Jennifer Walton	01/08/2011 - 01/08/2011	GAfREC Updating Training, Jenny Tyers
Mr Nanak Singh Sarhadi	01/08/2011 - 01/08/2011	GAfREC Updating Training, Jenny Tyers
Dr David Vallance	01/08/2011 - 01/08/2011	GAfREC Updating Training, Jenny Tyers
Mrs Veronica A Wells	01/08/2011 - 01/08/2011	GAfREC Updating Training, Jenny Tyers
Dr Julian Sonksen	31/07/2011 - 31/07/2011	Equality & Diversity, Dudley Group of Hospitals
Dr Hilary Paniagua	01/07/2011 - 01/07/2011	Equality & Diversity, University of Wolverhampton

Dr Tony Zalin	04/04/2011 - 05/04/2011	Self directed learning translating medical texts which necessitates researching into latest developments, Self directed
Dr Tony Zalin	04/07/2011 - 05/07/2011	Self directed learning translating medical texts which necessitates researching into latest developments, Self directed
Dr Tony Zalin	03/10/2011 - 04/10/2011	Self-directed learning translating medical texts which necessitates researching into latest developments, Self directed
Dr Tony Zalin	09/01/2012 - 10/01/2012	Self-directed learning translating medical texts which necessitates researching into latest developments, Self directed

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	56	100.00
Total Applications Reviewed	56	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	2
Number of studies withdrawn prior to the meeting	11
Number of student applications reviewed	26
Number of paediatric applications reviewed	5
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	17	30.36
Favourable Opinion with Additional Conditions	10	17.86
Unfavourable Opinion	1	1.79
Provisional Opinion	28	50.00
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 Conditions	25	44.64
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	1	1.79
Favourable Opinion with Standard Conditions	17	30.36
Favourable Opinion with Additional Conditions	10	17.86
Unfavourable Opinion	1	1.79
Provisional Opinion	2	3.57
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: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.60
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	33
Number of days taken to final decision - mode	25
Number of SSAs (non-Phase 1) reviewed	2
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	50
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	0
Number of modified amendments over 14 days	0
Number of modified amendments over 14 days as a % of total modified amendments	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%

***NB – Proportionate Review Service was in pilot phase until September 2011 and was an aim not a target**

Table 6: 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/WM/0067	Epstein-Barr virus and Multiple Sclerosis-version 1	50
11/WM/0111	Whether education is better than supervision	42
11/WM/0114	COPD Biomarker Identification Study V1.0	54
11/WM/0130	Platelet Aggregometry in Cardiac Surgery.	46
11/WM/0133	Changes in tyrosine phosphorylation induced by Sunitinib or Sorafenib	54
11/WM/0141	Serial sexual offending in a high security hospital population.	56
11/WM/0153	Evaluation of a pilot home treatment team for CAMHS in Birmingham (v1)	34
11/WM/0154	A Critical Analysis of Risk Management embedment in BSMHFT v01/1.5.11	33
11/WM/0160	OPTiONS Registry	43
11/WM/0168	Pathogenic role of T cells in autoimmune renal disease	51
11/WM/0171	Exploring investigation practices and the management of SUIs	33
11/WM/0204	Ocular and Oral Complications of Haemopoietic Stem Cell Transplant	32
11/WM/0219	Identifying Stress in parents of babies admitted to a Neonatal unit V1	42
11/WM/0224	Enzymatic deglycation - an explanation for variation in HbA1c	39
11/WM/0295	A comparison of Signature Guides and Computer Assisted Surgery	44
11/WM/0363	Validation of the Bipolar Affective Disorder Interview (BADI) 1	46
11/WM/0371	Breath analysis in diabetes mellitus version 2	53
11/WM/0383	Structural and functional correlates of diabetic retinopathy	48
11/WM/0396	Exercise capacity & vascular function in HLHS patients	42
11/WM/0399	Anterior segment morphology in Angle Closure	29
11/WM/0424	Body Fat and Breast Cancer v1	53
12/WM/0003	Balloon tuboplasty for treatment of Eustachian tube dysfunction	59
12/WM/0045	Exploring experiences of fathers in the labour ward & Neonatal Unit	53
12/WM/0049	Asthma, Obesity and Obstructive Sleep Apnoea Study	42
12/WM/0051	PROMs for People with a Life Limiting Condition	33
Further Information Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock

Further Information Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
12/WM/0002	Transvaginal ultrasound to confirm Essure sterilisation	44

Favourable Opinion with Standard Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/WM/0071	NOURISH PHASE II TRIAL	31
11/WM/0074	Aston Medication Adherence Study (AMAS)	17
11/WM/0075	Emotional Dsyfunction Following First Episode Psychosis	17
11/WM/0093	Primary Care Osteoarthritis Screening Trial (POST)	23
11/WM/0099	The ethical allocation of gametes donated for fertility treatment	20
11/WM/0101	The development of a human ex vivo model for Acanthamoeba keratitis	20
11/WM/0117	NHS senior managers' expectations of advanced and consultant roles v1	29
11/WM/0158	Human Rights Act 1998: clinicians' attitudes, knowledge and training.	25
11/WM/0169	Clinical outcome of antenatally diagnosed neurological abnormalities	25
11/WM/0190	Use of the Supportive Care Pathway on Intensive care: Staff views	22
11/WM/0205	School nurses working with children on child protection plans	20
11/WM/0227	Determining factors causing weight change in psychiatric inpatients	25
11/WM/0302	Variations of Phenylalanine and Tyrosine in Tyrosinaemia Type 1	25
11/WM/0425	Evaluation of a Weight Management Service 'Family Futures'	35
12/WM/0004	Validation of The Penn Acoustic Neuroma Quality-of-Life Scale	37
12/WM/0046	A social network intervention for opiate users	17
12/WM/0053	Willingness to Participate in Acute Stroke Research Trials (START).	17

Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/WM/0110	Diagnosis of dementia and relative cognitive decline	29
11/WM/0151	Non-invasive cardiovascular monitoring in renal transplant surgery	25
11/WM/0185	Experience of Eating Distress in the context of a history of Trauma	27
11/WM/0186	Grading anterior segment morphology in angle closure	22
11/WM/0191	Health visitor involvement with stillbirth and neonatal death.	22
11/WM/0226	STEERING / RP-OSV-01-EU (v2 22Jun11)	25
11/WM/0313	Factors impacting bereaved families' decisions about organ donation v1	22
11/WM/0355	Improving Fluid Adherence in Peritoneal Dialysis Patients	24
11/WM/0400	Predictors of Functional Outcome in First Episode Psychosis(V.1)	15

12/WM/0047	Disclosing a Diagnosis of Dementia Version 1	17
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Unfavourable Opinion		
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REC Reference	Application Short Title	Number of Days on Clock
11/WM/0320	Anterior segment morphology in Angle Closure	19

Provisional Opinion		
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REC Reference	Application Short Title	Number of Days on Clock
11/WM/0333	Mechanisms of adaptation to training in the elderly	N/A
11/WM/0392	Hair Loss and Quality of Life (Version 1)	N/A

Provisional Opinion Pending Consultation with Referee		
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REC Reference	Application Short Title	Number of Days on Clock
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Further information response not complete		
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REC Reference	Application Short Title	Number of Days on Clock
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Withdrawn after the meeting		
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REC Reference	Application Short Title	Number of Days on Clock
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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		
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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 7: 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