

NRES Committee West Midlands - Solihull

Annual Report

01 April 2013 – 31 March 2014

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee West Midlands - Solihull
Type of REC:	Authorised
Type of Flag:	Paediatrics
Chair:	Dr Rex J Polson
Vice-Chair:	Dr Timothy Priest
Alternate Vice-Chair:	Dr Richard Mupanemunda
REC Manager:	Maria Morledge/Wendy Rees
PRSC Co-ordinator:	Miss Leni Robson/Miss Joanne Unsworth
REC Assistant:	Miss Leni Robson/Miss Joanne Unsworth
Committee Address:	East Midlands REC Centre The Old Chapel Royal Standard Place Nottingham NG1 6FS
Telephone:	0115 8839368 and 0115 8839436
Email:	nrescommittee.westmidlands-solihull@nhs.net

Chair's overview of the past year:

NRES West Midlands – Solihull Research Ethics has had another busy and interesting year and that I am grateful to the committee members for all their hard work and enthusiasm throughout the year. Researchers continue to attend our meetings, which is very beneficial to members and investigators. I am also grateful to the Nottingham REC office for kindly taking on the administration for our committee and providing such excellent support which is very much appreciated.

NRES Committee West Midlands - Solihull Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr Raj D K Dhaliwal	Dentist	Expert	10/07/2013	
Mrs Lynne Gray	Senior Biomedical Scientist	Expert	11/07/2007	
Mrs Rosemary Harris	Solicitor (non-practising)	Lay Plus	11/07/2007	
Mrs Theresa Hyde	Retired Head Teacher	Lay Plus	11/07/2007	
Dr Jennifer Lim	Social Scientist	Expert	12/01/2011	
Mrs Irene Linder	Assistant Manager, Local Authority - Retired	Lay Plus	11/07/2007	
Ms Veronica Morgan	Midwife	Expert	11/07/2007	
Dr Richard Mupanemunda	Consultant Paediatrician	Expert	11/07/2007	
Dr Rex J Polson	Consultant Physician - Chair	Expert	11/07/2007	
Dr Timothy Priest	Consultant in Pain Management - Vice Chair	Expert	11/07/2007	
Mr Rajeshwar Singh	Chartered Engineer - Retired	Lay Plus	11/07/2007	
Ms Gill Tomlinson	Head of Radiology, Solihull Hospital	Expert	11/07/2007	

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Mr Robert Johnson	Lay	Lay	12/03/2014

NRES Committee West Midlands - Solihull: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Dr Raj D K Dhaliwal	None	04/09/2013
Dr Rex J Polson	None	11/12/2013
Dr Timothy Priest	None	11/12/2013
Dr Richard Mupanemunda	None	11/12/2013
Mr Rajeshwar Singh	None	11/12/2013
Dr Raj D K Dhaliwal	None	11/12/2013
Mrs Irene Linder	None	11/12/2013
Mrs Lynne Gray	None	11/12/2013
Mrs Theresa Hyde	None	11/12/2013

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

Month	Date	Number of Members Present at Meeting
April	10/04/2013	8
May	08/05/2013	8
June	12/06/2013	10
July	10/07/2013	8
August	14/08/2013	9
September	04/09/2013	9
October	09/10/2013	8
November	06/11/2013	8
December	11/12/2013	8
February	12/02/2014	9
March	12/03/2014	8

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	10/04/2013	3
May	08/05/2013	3
June	12/06/2013	3
July	10/07/2013	3
August	14/08/2013	3
October	09/10/2013	3
November	06/11/2013	3
February	12/02/2014	3
March	12/03/2014	3

9 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 Timothy Priest	11
Mrs Irene Linder	10
Dr Rex J Polson	10
Dr Richard Mupanemunda	8
Mrs Rosemary Harris	8
Ms Gill Tomlinson	8
Mr Rajeshwar Singh	8
Ms Veronica Morgan	7
Mrs Lynne Gray	7
Dr Jennifer Lim	5
Dr Raj D K Dhaliwal	5
Mrs Theresa Hyde	5

Number of inquorate meetings held: None

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

Name	Number of Meetings Attended
Dr Timothy Priest	7
Dr Rex J Polson	6
Mrs Irene Linder	5
Ms Gill Tomlinson	3
Ms Veronica Morgan	2
Mrs Theresa Hyde	2
Mrs Lynne Gray	1
Mrs Rosemary Harris	1

Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Mr Rajeshwar Singh	18/06/2013 - 18/06/2013	Value Experience and Beliefs in Ethical Decision Making, UKCEN
	19/06/2013 - 19/06/2013	UK Clinical Ethics Network 13th Annual Conference 2013, UKCEN
Ms Gill Tomlinson	24/09/2013 - 24/09/2013	Quantitative Research Methods and Statistics, HRA
Dr Raj D K Dhaliwal	23/10/2013 - 23/10/2013	West Midlands Regional Training Day, Nottingham REC Centre
Mrs Rosemary Harris	19/06/2013 - 19/06/2013	Aston University - NICE Interventional Procedures Advisory Committee
Mrs Lynne Gray	12/03/2014 - 12/03/2014	Improving Informed Consent & Participant Information Sheets, Health Research Authority

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	58	100.00
Total Applications Reviewed	58	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	7
Number of student applications reviewed	25
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	4	6.90
Favourable Opinion with Additional Conditions	8	13.79
Unfavourable Opinion	6	10.34
Provisional Opinion	40	68.97
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	58	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	38	65.52
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	4	6.90
Favourable Opinion with Additional Conditions	8	13.79
Unfavourable Opinion	6	10.34
Provisional Opinion	1	1.72
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	1	1.72
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	58	100

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

Total Applications Reviewed	22
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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	6	27.27
Favourable Opinion with Additional Conditions	4	18.18
No Opinion transfer to full committee for review	5	22.73
Provisional Opinion	7	31.82
Unfavourable Opinion	0	0.00
Total	22	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.27
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	36
Number of days taken to final decision - mode	32
Number of SSAs (non-Phase 1) reviewed	5
Number of applications for SSA review over 25 days	1
Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)	20.0%
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	58
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	8
Number of modified amendments over 14 days	1
Number of modified amendments over 14 days as a % of total modified amendments	12.5%
Number of proportionate review applications for ethical review over 14 days*	1
Number of proportionate review applications over 14 days as a % of total	5.9%

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/0136	e-nose assessment of VOC's in colorectal cancer patients	52
13/WM/0154	Taste preferences of young children with PKU	56
13/WM/0155	CMR DCM	26
13/WM/0164	CBT older adults	34
13/WM/0170	Assessment of inflammatory markers in Cardiovascular disease	29
13/WM/0177	Proximal(upper part)humerus fracture and physiotherapy	39
13/WM/0178	Understanding "villitis of unknown aetiology"	35
13/WM/0188	Preparation for Labour	32
13/WM/0206	Patient self-management in primary care patients with COPD - an RCT	46
13/WM/0219	Emotional Intelligence and Sociotropy-Autonomy in Hypochondriasis.	37
13/WM/0226	Examining endogenous antioxidants in well trained cyclists	51
13/WM/0227	PROACTIVE study	28
13/WM/0248	Influence of periodontal condition on Oral Health Quality of Life	12
13/WM/0249	Wellbeing in pregnancy study	11
13/WM/0253	Molecular assessment of Rb gene mosaicism V.2	32
13/WM/0268	IMPROVED	30
13/WM/0272	Renal Dietetic Qualitative Study	30
13/WM/0274	The lived experience of malignant melanoma	31
13/WM/0275	Ultrasound measurement of popliteal flow in lower limb immobilisation.	33
13/WM/0293	Reactions to caring for a spouse or partner with dementia	48
13/WM/0294	(duplicate) Diagnosis and recovery from schizophrenia.	60
13/WM/0296	Learning disabled offenders' experience of the TSOP	60
13/WM/0314	Endoscopic screening for Barrett's Oesophagus in Primary Care	55
13/WM/0315	MeTEOR; Meniscal Transplantation and its Effect on Osteoarthritis Risk	38
13/WM/0333	Function of genetic modifiers of AATD	34
13/WM/0343	Assessing the agreement between tonometers	36
13/WM/0344	PuP Evaluation	44
13/WM/0351	Self-injurious behaviour in Autism Spectrum Disorder_V2_04.07.13	34
13/WM/0409	Experience of Dissociation in Early Psychosis. Version 1.	29

13/WM/0417	Clot structure in heart failure	50
13/WM/0420	Patient Need for Information about Medicine on Discharge from Hospital	14
13/WM/0440	Exhaled breath condensate metabolomics in rheumatoid arthritis	45
13/WM/0442	Experience of psychiatric services among psychotic patients and carers	23
13/WM/0456	A PROSPECTIVE PATIENT QUALITY OF LIFE ASSESSMENT IN AORTIC SURGERY	11
13/WM/0471	Vaginoscopy Against Standard Treatment (VAST)	52
13/WM/0473	The experience of caring for Patients with an intrathecal catheter	54
13/WM/0476	Non-invasive Pre-natal Testing	36
14/WM/0035	Colour Contrast Sensitivity for the Early Detection of ARMD (CEDAR)	41
14/WM/0036	EMDR for people with learning disabilities version 1	40
14/WM/0054	Optic disc pit maculopathy	18
14/WM/0083	LORIS, Version 1.0 14th February 2014	57
14/WM/0087	Men's experiences of obesity - version 1	32
14/WM/0088	Resistance training rest interval and muscle hypertrophy	23
14/WM/0098	Review of medication incidents for aminoglycoside and glycopeptide abx	11

Favourable Opinion with Standard Conditions		
REC Reference	Application Short Title	Number of Days on Clock
13/WM/0172	Receiver Operating Characteristic (ROC) analysis of remote monitoring	11
13/WM/0194	Investigating fracture patterns of the Skull Base	14
13/WM/0196	Memory and self-concept after psychosis version 1.0	13
13/WM/0225	Which healthy heart diet for people living with HIV?	27
13/WM/0288	Measurement of human placental lactogen (hPL) Version 1.0	13
13/WM/0289	Longitudinal Cardiovascular Health	11
13/WM/0340	PRO-REHAB: Development and Pilot Trial V1	41
13/WM/0460	ReDUce Study V1.0, 01.10.13	10
13/WM/0485	STARS-CRC	42
14/WM/0089	Covered metallic stents for benign bile duct strictures	23

Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
13/WM/0153	Consent for research by substitute decision makers (v 1.0)	26
13/WM/0171	To evaluate impact of recovery coaching in an acute hospital setting 1	11
13/WM/0197	CSF PCR for neonatal meningitis	13
13/WM/0331	Physical activity intervention flexibility and body composition	38
13/WM/0348	"Patient experience of elective surgery for abdominal aortic aneurysm"	10
13/WM/0412	Surveillance of Childhood Acute Rheumatic Fever (SCARF)	21
13/WM/0418	Friends, Family, and Health 4 U: vs 1.1	12
13/WM/0439	Fibrocytes in glomerulonephritis(FIG) study	27
13/WM/0452	Experiences of using a friends and family support group	32
13/WM/0472	Hypofibrinogenaemia and risk of post partum haemorrhage	49
14/WM/0032	COPD Screener study V 2.0	20
14/WM/0062	Looking After a Loved One Receiving Palliative Care; A Male Experience	22

Unfavourable Opinion		
REC Reference	Application Short Title	Number of Days on Clock
13/WM/0191	The development and validation of The Myeloma pain assessment tool .	20
13/WM/0228	Collection of residual and donor samples for assay development	28
13/WM/0233	experience of psychiatric services among psychotic patients and cares	25
13/WM/0414	COPD Screener study V 1.0	25
14/WM/0026	The Diabetes Matrix Pathway	20
14/WM/0033	Informing stakeholders about mild cognitive impairment	26

Provisional Opinion		
REC Reference	Application Short Title	Number of Days on Clock
13/WM/0465	Perception of Decisions in Transplantations	N/A

Further information response not complete		
REC Reference	Application Short Title	Number of Days on Clock
13/WM/0441	ASPIRe	N/A
14/WM/0102	Patient experiences of musculoskeletal physiotherapy v1.0	N/A

Table 9: Items exceeding timelines:

Proportionate review applications for ethical review over 14 days timeline		
REC Reference	Application Short Title	Number of Days on Clock
14/WM/0054	Optic disc pit maculopathy	18

SSAs (non Phase 1) over 25 days timeline		
REC Reference	Application Short Title	Number of Days on Clock
13/WM/0326	PresVIEW™ SCLERAL IMPLANT TO IMPROVE NEAR VISUAL ACUITY IN PRESBYOPIA	26

Modified Amendments over 14 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
10/H1206/4/AM10/1	Benefits of exercise in type 1 diabetes	Amendment 12	17