

# NRES Committee West Midlands - Solihull

**Annual Report** 

01 April 2011 – 31 March 2012

#### 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

**Co-ordinator:** Ms Trish Wheat

PRSC Co-ordinator: N/A

Assistant Co-ordinator: N/A

Committee Address: East Midlands REC Centre

The Old Chapel

Royal Standard Place

Nottingham NG1 6FS

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#### Chair's overview of the past year:

NRES West Midlands – Solihull Research Ethics has enjoyed a further productive and busy year. We are pleased that for almost all of the studies being reviewed the researchers have attended our meetings, which has been of great benefit to members and investigators alike.

Dr Sanju George has had to step down from the Committee due to the pressure of his clinical duties; and the committee are now keen to welcome new members. Sadly at the end of March 2012, with the closure of the REC Offices in Redditch, we said goodbye to Karen Green who has served as Co-ordinator for our Committee so superbly for many years and also to Hazel Reed who has ably supported Karen more recently. We are now looking forward to working with our new Coordinators who are based in Nottingham.

#### NRES Committee West Midlands - Solihull Membership:

Name	Occupation	Expert or	Da	tes
	_	Lay	Appointed	Resigned
Dr Sanju George	Consultant Psychiatrist	Expert	20/11/2007	01/11/2011
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	Lay Plus	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 David O'Brien	GP	Expert	11/07/2007	
Dr Rex J Polson	Consultant Physician - Chair	Expert	11/07/2007	
Dr Timothy Priest	Consultant in Anaesthesia & 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	

## **Deputy Members**

Name	Occupation	Expert or Lay	Meeting date attended
None			

#### **Co-opted Members**

Name	Occupation	Expert or Lay	Meeting date attended
None			

#### **Member Bank**

Name	Occupation	Expert or Lay	Meeting date attended
N/A			

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

Name	Declaration of Interest	Date
Dr Timothy Priest	Investigator, Solihull Hospital Pain Management Research Unit	07/12/2011
Mrs Irene Linder	None	07/12/2011
Ms Gill Tomlinson	None	07/12/2011
Mr Rajeshwar Singh	None	07/12/2011
Mrs Rosemary Harris	None	07/12/2011
Dr Rex J Polson	Works as a Consultant	07/12/2011
	Physician/Gastroenterologist in the Heart of England NHS Foundation Trust and as such may occasionally become involved in research.	
Mrs Theresa Hyde	Sits on education tribunals as an independent member [Voluntary]. Works as a voluntary tutor for the Expert Patient Programme NHS BEN PCT. Works as a voluntary tutor for the Expert Patient Programme in Shropshire for Health Yourself	07/12/2011
Dr Jennifer Lim	None	07/12/2011
Dr David O'Brien	Partner - Richmond Medical Centre, Solihull. Small number of pharmaceutical shares - GSK, AstraZeneca. Member of MIDREC Management Group.	07/12/2011
Richard Mupanemunda	None	07/12/2011
Mrs Lynne Gray	None	07/12/2011
Ms Veronica Morgan	Magistrate at Solihull and Birmingham Courts. Chair of Pan Birmingham user partnership group. Trust Convener and mid wife at Heart of England Foundation trust.	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	8
May	11/05/2011	12
June	08/06/2011	10
July	13/07/2011	10
September	14/09/2011	9
October	12/10/2011	8
November	09/11/2011	12
December	07/12/2011	8
January	11/01/2012	8
February	08/02/2012	10

<sup>10</sup> full committee meetings were held during the reporting period.

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

Name	Number of Meetings Attended
Dr Rex J Polson	10
Ms Gill Tomlinson	9
Dr Richard Mupanemunda	8
Dr David O'Brien	8
Dr Timothy Priest	8
Mr Rajeshwar Singh	8
Mrs Irene Linder	8
Mrs Lynne Gray	8
Mrs Rosemary Harris	8
Mrs Theresa Hyde	7
Ms Veronica Morgan	6
Dr Jennifer Lim	5
Dr S George	2 (resigned 01/11/2011)

Number of inquorate meetings held: None

# Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Dr Richard Mupanemunda	16/06/2011 - 16/06/2011	Qualitative Training Day, West
-		Midlands REC Centre
Ms Veronica Morgan	16/06/2011 - 16/06/2011	Qualitative Training Day, West
		Midlands REC Centre
Mrs Theresa Hyde	16/06/2011 - 16/06/2011	Qualitative Training Day, West
		Midlands REC Centre
Mrs Irene Linder	16/06/2011 - 16/06/2011	Qualitative Training Day, West
		Midlands REC Centre
Mr Rajeshwar Singh	16/06/2011 - 16/06/2011	Qualitative Training Day, West
		Midlands REC Centre
Dr Jennifer Lim	04/07/2011 - 04/07/2011	Equality & Diversity, NHS
Dr S George	14/09/2011 - 14/09/2011	MCA DVD and Discussion,
		NRES
Mrs Rosemary Harris	14/09/2011 - 14/09/2011	MCA DVD and discussion,
		NRES
Mrs Theresa Hyde	14/09/2011 - 14/09/2011	MCA DVD and discussion,
5	11/00/0011 11/00/0011	NRES
Dr Jennifer Lim	14/09/2011 - 14/09/2011	MCA DVD and discussion,
Ma Maraisa Marasa	4.4/00/0044 4.4/00/0044	NRES
Ms Veronica Morgan	14/09/2011 - 14/09/2011	MCA DVD and discussion,
Dr David O'Brien	14/09/2011 - 14/09/2011	NRES
Dr David O'Brien	14/09/2011 - 14/09/2011	MCA DVD and discussion, NRES
Dr Rex J Polson	14/09/2011 - 14/09/2011	_
	14/09/2011 - 14/09/2011	MCA DVD and training, NRES MCA DVD and discussion,
Mr Rajeshwar Singh	14/09/2011 - 14/09/2011	NRES
Ms Gill Tomlinson	14/09/2011 - 14/09/2011	MCA DVD and discussion,
		NRES
Dr David O'Brien	12/10/2011 - 12/10/2011	NRES Update Session, NRES
Dr Rex J Polson	03/11/2011 - 03/11/2011	Chair's Meeting, NRES
Dr Timothy Priest	08/12/2011 - 08/12/2011	The Society for Ethics & Law in
		Anaesthesia, Intensive Care &
		Pain Medicine, Society for
		Ethics and Law

#### 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	14
Number of studies withdrawn prior to the meeting	6
Number of student applications reviewed	29
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	5	8.93
Favourable Opinion with Additional Conditions	11	19.64
Unfavourable Opinion	1	1.79
Provisional Opinion	39	69.64
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	36	64.29
Conditions		
Further Information Favourable Opinion with Additional	0	0.00
Conditions		
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	5	8.93
Favourable Opinion with Additional Conditions	11	19.64
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	1	1.79
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:

	<b>5</b> 00
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	27
Number of days taken to final decision - mode	21
Number of SSAs (non-Phase 1) reviewed	4
Number of applications for SSA review over 25 days	0
Number of applications for SSA review over 25 days as % of	0.0%
all non-Phase 1 (SSAs)	
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	0%
all Phase 1 (SSAs)	
Number of substantial amendments reviewed	43
Number of substantial amendments over 35 days	1
Number of substantial amendments over 35 days as a % of	2.3%
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	0%
total Section 30 applications	
Number of modified amendments reviewed	5
Number of modified amendments over 14 days	0
Number of modified amendments over 14 days as a % of	0.0%
total modified amendments	
Number of proportionate review applications for ethical	0
review over 14 days*	
Number of proportionate review applications over 14 days	0%
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Table 6: Breakdown of current status of all applications reviewed within the reporting period:

<b>Further Informati</b>	on Favourable Opinion with Standard Conditions	
<b>REC Reference</b>	Application Short Title	Number of Days on Clock
11/WM/0058	The Molecular Basis of Ocular Surface Disease Version 1.0	29
11/WM/0070	Genetic and Epigenetic Changes Associated With Vulval Cancer	27
11/WM/0072	Aerobic Fitness & CV Health Profile Two years after Cardiac Rehab (v1)	16
11/WM/0103	Implementing GRiST in primary care and the community, version 1	18
11/WM/0115	How parents perceive the relevance of/compliance with exercise program	28
11/WM/0116	Parenting Experiences of Mothers with Mental Health Difficulties: V.1	24
11/WM/0128	Diabetes, depression and BDNF	43
11/WM/0129	Attachment Style, Relationship Continuity and Dementia Care(Version 1)	30
11/WM/0132	An exploration of couplehood and dementia. (Version 1).	28
11/WM/0135	Immune responses in liver cancer following treatment	34
11/WM/0157	Advance Care Planning in Paediatric Patients	22
11/WM/0162	A pilot RCT of an occupational therapy intervention for THR patients	30
11/WM/0165	Staff Attitudes Towards Cannabis Use v1	20
11/WM/0167	Visual Cue training for walking and turning after stroke- pilot RCT	20
11/WM/0173	Intestinal metaplasia and oesophagogastric cancer methylation status	23
11/WM/0199	Primary care Research into Diabetes Evolution (PRIDE)	33
11/WM/0200	Incidence and carriage of resistant pathogens V1	38
11/WM/0202	Exploration of transition for young people with liver transplants	31
11/WM/0218	Delivering Diabetes Care to Ethnic Diversity (DEDICATED) in Coventry	34
11/WM/0257	Phenotyping of T lymphocytes in chronic transplant patients- Version 1	29
11/WM/0259	Comparative study of MRD and EP in pelvic floor dysfunction	23
11/WM/0283	ORO-MOUTH 1.0	26
11/WM/0303	Young People's experiences following their discharge from CAMHS	25
11/WM/0314	Grip strength learning in Tourette Syndrome v1	24
11/WM/0329	Pulp treatment in non-vital primary molars	27
11/WM/0334	Admission to Hospital with COPD: The Patient Experience	32
11/WM/0362	Do people from a Christian background living with M C I have distinctive, identifiable spiritual needs?	27
11/WM/0364	Muir-Torre Study	21

11/WM/0365	Throat and Rectal Swab Specimens to diagnose Norovirus Infection	30
11/WM/0373	Muscle afferent contributions to ventilatory control in COPD patients	22
11/WM/0402	How Should We Manage Extremely Premature Neonates? An Ethical Analysis	27
11/WM/0421	QUITS 1.0	30
11/WM/0422	Factors influencing response to NIV in COPD	34
11/WM/0426	'Big change for the little one' How was it for you?	57
12/WM/0035	Exploring the rehabilitation needs of Pakistani Heart Failure patients	43
12/WM/0036	The consequences of habitual exercise training in Master athletes	48

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

<b>Further Informati</b>	on Unfavourable Opinion	
<b>REC Reference</b>	Application Short Title	Number of Days on Clock

Favourable Opinion with Standard Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/WM/0073	Financial incentives for HPV immunisation	16
11/WM/0136	Attitudes to research at acute hospital admission version 1	22
11/WM/0184	The use of depot medroxyprogesterone acetate	35
11/WM/0196	The Clinical Assessment Study of the Hand (CAS-HA): 6-year follow-up	21
11/WM/0327	Molecular analysis of genes regulating apoptosis	21

Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/WM/0064	Doctors' views and attitudes towards menopause version 1	32
11/WM/0126	The Emotional Coping of Crisis Team Professionals	22
11/WM/0170	Cancer profiling by toponome expression analysis	20
11/WM/0203	Assessing student nurses in practice	29
11/WM/0304	The Birmingham COPD cohort study v2.0	21
11/WM/0315	Donor Panel for EBV immunotherapy	30
11/WM/0403	Targeted case finding for COPD in Primary Care (Target COPD) V2.0	24
11/WM/0404	ColoRectal Early Diagnosis (Version 2)	22

11/WM/0407	Effect of CBT on brain activity related to pain processing: EEG study	21
12/WM/0028	ACTivity during IV antibiotics for Exacerbations in CF (ACTIVE-CF)	20
12/WM/0030	Self-Management Patterns of Cancer Survivors	22
Unfavourable Op		
REC Reference	Application Short Title	Number of Days on Clock
11/WM/0323	Measurement of hepcidin in weight management clinic patients (V1)	21
Dravisional Onin	ion	
Provisional Opin REC Reference		Number of Days on Clask
	Application Short Title	Number of Days on Clock
12/WM/0005 12/WM/0031	Peripheral venous monitoring in sepsis	N/A N/A
12/1/1/1/0031	Pentax Airway Scope versus flexible fibrescope for awake intubation	IN/A
Provisional Opin	ion Pending Consultation with Referee	
REC Reference	Application Short Title	Number of Days on Clock
1120110101010		
<b>Further informat</b>	ion response not complete	
REC Reference	Application Short Title	Number of Days on Clock
11/WM/0370	Object and Place Memory in Children with Autism and ADHD	N/A
Withdrawn after		
REC Reference	Application Short Title	Number of Days on Clock
Toward of Assett and		
Invalid Application		Normalism of David and Olas In
REC Reference	Application Short Title	Number of Days on Clock
No Oninion Pond	ling Consultation with Referee	
REC Reference	Application Short Title	Number of Days on Clock
IVEO IVEIEIGIICE	Application official file	Number of Days off Clock
Not Requiring Re	eview by NHS REC	
REC Reference	Application Short Title	Number of Days on Clock
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# Table 7: Items exceeding timelines:

Full applications for ethic	cal review over 60 day timeline		
	ation Short Title		Number of Days on Clock
	lications for ethical review over 14 o	days timeline	
REC Reference   Applic	ation Short Title		Number of Days on Clock
CCAs (non Diseas 4) such	OF days timedia		
SSAs (non Phase 1) over			Newskar of Davis on Olask
REC Reference Applic	ation Short Title		Number of Days on Clock
SSAs (Phase 1) over 14 d	ays timeline		
	ation Short Title		Number of Days on Clock
<b>Substantial Amendments</b>	over 35 day timeline		
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
09/H1206/107/AM02	Platelet injection after rotator cuff repair	AM02	38
Modified Amendments ov	ver 14 day timeline		
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
Section 30 application ov	1		
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock