

**NRES Committee West Midlands -
Staffordshire**

Annual Report

01 April 2011 – 31 March 2012

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee West Midlands - Staffordshire
Type of REC:	Authorised
Type of Flag:	MCA, Paediatric
Chair:	Dr Kathryn Kinmond
Vice-Chair:	Dr Mark Gunning
Alternate Vice-Chair:	Mr Victor Scofield
Co-ordinator:	Laura Brown
PRSC Co-ordinator:	N/A
Assistant Co-ordinator:	N/A
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Chair's overview of the past year:

The year 2011-2012 has again seen many changes for NRES particularly in its operating procedures and formal structures. The Health research Authority (HRA) was launched as a special Health Authority in December 2011 with NRES at its core. This has resulted in changed ways of working at both national and local levels. Nationally, new positions of 'Research Ethics Officers' were advertised and recruited. At a local level, the coordinators' office in south Birmingham was closed in March 2012 with coordination for the Staffordshire REC moving to the northwest office in Manchester. Two temporary coordinators have worked with the Staffordshire REC since that time. It is anticipated that a permanent coordinator will be in post by September 2012. Currently there are fifteen committee members; six lay members and nine expert members. Attendance at the meetings is good and there is a sound and useful balance of skills and expertise evidenced. The Staffordshire REC meets on the second Wednesday of each month in Stone Staffordshire to review an average of five applications at each meeting. This is the maximum number of applications the committee feel comfortable reviewing if rigour and quality is to be maintained.

The Staffordshire committee continues to work closely with the network of West Midlands committees; the Chairs meet thrice annually to discuss issues pertinent to the work of the RECs both locally and nationally. However, since the closure of the west midlands coordinators' centre the committees are now no longer all serviced by the same centre and this has impacted the network in terms of the identity that had been developed as a west midlands sector.

The Staffordshire REC has a culture of excellence, good humour and good practice. Its members are highly professional and passionate about the work undertaken. I believe the committee is very well placed to develop further into the future.

Dr Kathryn Kinmond
Chair Staffordshire REC

May 2012

NRES Committee West Midlands - Staffordshire Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Miss Nicola Brooks	Solicitor	Lay Plus	01/05/2010	
Mr Michael Dale	Retired	Lay Plus	12/05/2010	
Mr Robert Edgar	Engineer (Retired)	Lay Plus	12/05/2010	
Mrs Shirley Ann Goldstraw	Lecturer in Midwifery	Expert	12/05/2010	
Dr Mark Gunning	Consultant Cardiologist	Expert	01/05/2010	
Dr Jackie-Anne Kilding	Community Paediatrician	Expert	01/05/2010	
Professor Paul Kingston	Professor of Ageing and Mental Health	Expert	27/04/2011	
Dr Kathryn Kinmond	Senior Lecturer	Lay Plus	01/05/2010	
Dr Aswath Kumar	Consultant Paediatrician	Expert	01/12/2010	
Dr Arabinda Kundu	Head of Contraceptive & Sexual Health Service	Expert	01/05/2010	
Mrs Meena Nachiappan	Company Secretary	Lay Plus	01/05/2010	
Dr Laofe Oladele Ogundipe	Consultant Psychiatrist	Expert	01/05/2010	
Dr Sandie Sandbrook	Senior Lecturer	Expert	01/05/2010	
Mr Victor Scofield	Legal Advisor, Banking (Retired)	Lay Plus	01/05/2010	
Professor Monica Spiteri	Consultant Physician	Expert	01/05/2010	
Mr Dewi Williams	Lecturer in Law	Lay Plus	01/05/2010	21/07/2011

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

Name	Declaration of Interest	Date
Dr Sandie Sandbrook	None	14/12/2011
Mrs Shirley Ann Goldstraw	None	14/12/2011
Prof Paul Kingston	None	14/12/2011
Miss Nicola Brooks	None	14/12/2011
Professor Monica Spiteri	Member of the British Thoracic Society Professional Standard and Organisation Committee	14/12/2011
Professor Monica Spiteri	Lung research group at Keele University and University Hospital of North Staffordshire	14/12/2011
Dr Mark Gunning	Principal Investigator of multi-centre cardiology trials at UHNS	14/12/2011
Dr Mark Gunning	Steering Committee of multi-centre cardiology trials	14/12/2011
Mr Michael Dale	None	14/12/2011
Dr Kathryn Kinmond	None	14/12/2011
Dr Laofe Oladele Ogundipe	None	14/12/2011
Dr Jackie-Anne Kilding	None	14/12/2011
Dr Arabinda Kundu	None	14/12/2011
Dr Aswath Kumar	None	14/12/2011
Mr Robert Edgar	None	14/12/2011

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

Month	Date	Number of Members Present at Meeting
April	13/04/2011	11
May	11/05/2011	13
June	08/06/2011	10
July	13/07/2011	9
August	10/08/2011	9
September	14/09/2011	11
October	12/10/2011	10
November	09/11/2011	7
December	14/12/2011	13
January	11/01/2012	9
February	08/02/2012	11

11 full committee meetings were held during the reporting period.

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

Name	Number of Meetings Attended
Dr Kathryn Kinmond	10
Dr Jackie-Anne Kilding	10
Dr Laofe Oladele Ogundipe	8
Mrs Meena Nachiappan	8
Professor Monica Spiteri	8
Dr Mark Gunning	8
Miss Nicola Brooks	8
Mr Robert Edgar	8
Mr Michael Dale	8
Mr Victor Scofield	8
Mrs Shirley Ann Goldstraw	7
Dr Arabinda Kundu	7
Dr Aswath Kumar	6
Dr Sandie Sandbrook	5
Professor Paul Kingston	4

Number of inquorate meetings held: 0

Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Miss Nicola Brooks	06/06/2011	Equality & Diversity, AF Brooks & co
Miss Nicola Brooks	08/06/2011	Children in Research, Staffordshire REC
Miss Nicola Brooks	14/09/2011	MCA DVD, NRES
Mr Michael Dale	14/09/2011	MCA DVD, NRES
Mr Robert Edgar	08/06/2011	Children in Research, Staffordshire REC
Mr Robert Edgar	14/09/2011	MCA DVD, NRES
Mrs Shirley Ann Goldstraw	08/06/2011	Children in Research, Staffordshire REC
Mrs Shirley Ann Goldstraw	16/06/2011	Qualitative Research, Staffordshire REC
Mrs Shirley Ann Goldstraw	19/10/2011	Equality & Diversity, Keele University
Mrs Shirley Ann Goldstraw	14/09/2011	MCA DVD, NRES
Dr Mark Gunning	14/09/2011	MCA DVD, NRES
Professor Paul Kingston	14/09/2011	MCA DVD, NRES
Dr Jackie-Anne Kilding	08/06/2011	Children in Research, Staffordshire REC
Dr Jackie-Anne Kilding		Self Directed Learning, Self Directed Learning Log
Dr Jackie-Anne Kilding	14/09/2011	MCA DVD, NRES
Dr Jackie-Anne Kilding	09/11/2011	Qualitative Research, Staffordshire REC
Dr Kathryn Kinmond	08/06/2011	Children in Research, Staffordshire REC
Dr Kathryn Kinmond	06/12/2011	NRES Chairs National Training Day, NRES
Dr Kathryn Kinmond	12/10/2011	NRES update meeting, NRES
Dr Kathryn Kinmond	14/09/2011	MCA DVD, NRES
Dr Kathryn Kinmond	09/11/2011	Qualitative Research, Staffordshire REC
Dr Aswath Kumar	08/06/2011	Children in Research, Staffordshire REC
Dr Aswath Kumar	14/09/2011	MCA DVD, NRES
Dr Aswath Kumar	09/11/2011	Qualitative Research, Staffordshire REC
Dr Arabinda Kundu	08/06/2011	Children in Research,
Dr Arabinda Kundu	14/09/2011	MCA DVD, NRES
Dr Arabinda Kundu	09/11/2011	Qualitative Research, Staffordshire REC
Mrs Meena Nachiappan	08/06/2011	Children in Research, Staffordshire REC
Mrs Meena Nachiappan	15/07/2011	Equality & Diversity, NRES
Mrs Meena Nachiappan	14/09/2011	MCA DVD, NRES
Dr Laofe Oladele Ogundipe	14/09/2011	MCA DVD, NRES

Dr Laofe Oladele Ogundipe	09/11/2011	Qualitative Research, Staffordshire REC
Dr Sandie Sandbrook	19/04/2011	Equality & Diversity, University of Wolverhampton
Dr Sandie Sandbrook	14/09/2011	MCA DVD, NRES
Dr Sandie Sandbrook	09/11/2011	Qualitative Research, Staffordshire REC
Mr Victor Scofield	12/10/2011	NRES update meeting, NRES
Mr Victor Scofield	14/09/2011	MCA DVD, NRES
Mr Victor Scofield	08/06/2011	Qualitative Research, Staffordshire REC
Professor Monica Spiteri	08/06/2011	Children in Research, Staffordshire REC
Professor Monica Spiteri	14/09/2011	MCA DVD, NRES
Professor Monica Spiteri	09/11/2011	Qualitative Research, Staffordshire REC

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	5
Number of studies withdrawn prior to the meeting	2
Number of student applications reviewed	31
Number of paediatric applications reviewed	9
Number of device applications reviewed	0
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	8
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	7.14
Favourable Opinion with Additional Conditions	0	0.00
Unfavourable Opinion	15	26.79
Provisional Opinion	37	66.07
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	1	1.79

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	35	62.50
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	4	7.14
Favourable Opinion with Additional Conditions	0	0.00
Unfavourable Opinion	14	25.00
Provisional Opinion	1	1.79
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	1	1.79
No decision entered on RED	0	0.00
Number of studies withdrawn after the meeting	1	1.79
Total	56	100
Number of studies sent back to full committee meeting for final opinion	1	1.79

Table 5: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.09
Number of applications for full ethical review over 60 days	1
Number of applications over 60 days as a % of total	1.79%
Number of days taken to final decision - average	32
Number of days taken to final decision - mode	23
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 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	37
Number of substantial amendments over 35 days	4
Number of substantial amendments over 35 days as a % of total substantial amendments	10.8%
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	3
Number of modified amendments over 14 days	0
Number of modified amendments over 14 days as a % of total modified amendments	0.0%

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/0079	Seeking healthcare for foot pain	23
11/WM/0088	Headache, light and circadian rhythms, Version 1	33
11/WM/0090	The well-being of mothers of children with learning disabilities	43
11/WM/0092	Role and involvement of social support networks in addiction treatment	44
11/WM/0104	Evaluating the qualitative impact of a unique bundle of dementia care	23
11/WM/0119	Dopaminergic medication and recognition memory in Parkinson's	25
11/WM/0121	Supporting Failing Memory in Parkinson's Disease Version 1	31
11/WM/0127	EURO-WABB	33
11/WM/0140	End-User views on using technology to improve Hand Hygiene compliance	38
11/WM/0206	Study of Immunogenetic factors in Multiple Sclerosis	28
11/WM/0208	Evaluating the impact and sustainability of the Productive Ward (V1)	49
11/WM/0210	How are relationships negotiated by people with dementia? [v. 2.0]	30
11/WM/0213	Drug Misuse treatment and recovery: What are carers views on recovery?	31
11/WM/0215	Nurses' knowledge, attitudes & beliefs of pain management in practice 1	48
11/WM/0217	N-acetylcysteine in Donation after Cardiac Death Liver Transplantation	54
11/WM/0230	Giving Students Responsibility on Clinical Placement	43
11/WM/0232	Individualised rehabilitation (Ver01)	22
11/WM/0233	Feasibility of Multinational Biological Studies in Children (Pilot)	23
11/WM/0251	Os-Stretch for the management of calf contracture	32
11/WM/0253	Extensor Mechanism Efficiency following PFA and TKA (V2:02/11)	50
11/WM/0256	(duplicate) The Influence of Religion on Dementia Care in South Asian	34
11/WM/0264	Chronic venous leg ulceration and quality of life - Phase 3 (v1)	21
11/WM/0269	WHiP Project	50
11/WM/0271	Validation of a Long-Term Post-Stroke Checklist	29
11/WM/0272	Does SMS text messaging appointment reminders affect DNA rates	26
11/WM/0318	Priorities of staff and service users in mental health assessment	33
11/WM/0326	The Intergenerational Family Experience of Fronto-temporal Dementia	39
11/WM/0331	Kinematic comparison of walking mode in low back pain individuals	37
11/WM/0332	Mental Health and Single Bout Exercise V 1.0	44

11/WM/0401	Therapeutic effectiveness of hydroxyurea in children with sickle cell	36
11/WM/0417	Investigation of determinants of enhanced ACL rehabilitation	96
12/WM/0018	Acute Ambulatory Heart Failure Clinic Study	43
12/WM/0020	SWAP - Study of Work And Pain, Version 1.0 5th January 2012	55
12/WM/0021	The PMR Study - version 1.0	28
12/WM/0023	COPS Study, Version No 1	36

Favourable Opinion with Standard Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/WM/0082	Involve to Evolve: evaluating education on children's database consent	16
11/WM/0094	Endothelial function of the radial artery following catheterisation	16
11/WM/0386	Immunohistochemical detection of CMV in inflammatory bowel disease	45
11/WM/0420	FASTER v1.0	44

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/WM/0120	How are relationships negotiated by people with dementia?	19
11/WM/0134	To gain an understanding of the barriers to accessing dental services	26
11/WM/0139	Pilot study Final Version 1.0	33
11/WM/0211	South Asian Experiences of Dementia and Religion	19
11/WM/0216	Acute Ambulatory Heart Failure Clinic Study	19
11/WM/0229	A review of Elderly Care within an Emergency Department	20
11/WM/0231	A Good Start in Life	20
11/WM/0239	What are the experiences of health care professionals regardingFGM V.1	21
11/WM/0353	The impact of clinical review meetings on cervical cancer patients	22
11/WM/0413	The use of acellular dermal grafts to augment rotator cuff repair	23
11/WM/0414	Molecular assessment of Rb gene mosaicism V.1	22
11/WM/0416	Exploring experiences of fathers in the labour ward & Neonatal Unit	22
11/WM/0423	Experiences of post traumatic growth in spinal cord injury partners	48
12/WM/0008	Roche BP25612:Cognitive and Functioning Changes In Individuals With DS	21

Provisional Opinion		
REC Reference	Application Short Title	Number of Days on Clock
11/WM/0418	Comparison of hospital and community-based rehabilitation programmes.	N/A

Withdrawn after the meeting		
REC Reference	Application Short Title	Number of Days on Clock
11/WM/0317	Symptom profiles of polycystic ovaries and polycystic ovary syndrome	21

Not Requiring Review by NHS REC		
REC Reference	Application Short Title	Number of Days on Clock
11/WM/0325	What are the Nurses experiences of caring for women who have FGM Ver 2	23

Table 7: Items exceeding timelines:

Full applications for ethical review over 60 day timeline		
REC Reference	Application Short Title	Number of Days on Clock
11/WM/0417	Investigation of determinants of enhanced ACL rehabilitation	96

Substantial Amendments over 35 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
10/H1203/13/AM01	Chronic venous leg ulceration and health related quality of life (V2)	AM01	36
09/H1203/82/AM02	Efficacy of Juice Plus+ in reducing post op wisdom tooth morbidity	Efficacy of Juice Plus + in reducing post op wisdo	37
09/H1203/77/AM01	Saliva-based Point-of-Care bioSensor for COPD; version 1.0	AM01 Development of a novel Saliva-based point of	38
06/Q2604/109/AM11	The Stroke Oxygen Study (version 1)	AM11	39