

**NRES Committee West Midlands -  
Coventry & Warwickshire**

**Annual Report**

**01 April 2011 – 31 March 2012**

## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	NRES Committee West Midlands - Coventry & Warwickshire
<b>Type of REC:</b>	Type III
<b>Type of Flag:</b>	Phase 1 Studies in Patients, Research Involving Adults Lacking Capacity, Research Involving Children
<b>Chair:</b>	Dr Helen Brittain
<b>Vice-Chair:</b>	Dr Matthew Dunn
<b>Alternate Vice-Chair:</b>	None
<b>Co-ordinator:</b>	Mrs Lisa Gregory (Rosa Downing 01/04/2011- 01/01/2012)
<b>PRSC Co-ordinator:</b>	N/A
<b>Assistant Co-ordinator:</b>	N/A
<b>Committee Address:</b>	The Old Chapel Royal Standard Place Nottingham NG1 6FS
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### Chair's overview of the past year:

In a year when there have been changes both at national and local levels, the Committee has continued to work well and deal with a heavy volume of work, with enthusiasm and dedication. We have benefited greatly from the support and expertise of Rosa Downing, our co-ordinator until January 2012, when the office in Redditch was closed.

We were especially pleased to be awarded full accreditation at first review in January, due in no small part to the support of Rosa, Toby Buttery and others in the Redditch office.

Following that Lisa Gregory has been a most helpful and expert co-ordinator, and has enabled the transition to a new REC centre with ease.

We look forward to further beneficial changes in the work of NRES.

## NRES Committee West Midlands - Coventry & Warwickshire Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr Jane Appleton	Nurse	Expert	01/04/2010	
Mr Roger Balcombe	Retired Chartered Engineer	Lay Plus	01/04/2010	
Dr Geraldine Brady	Senior Research Fellow	Lay	27/07/2011	
Dr Helen Brittain	Clinical Psychologist Retired	Lay	01/04/2010	
Mrs Barbara Canning	Senior University Lecturer	Lay	01/04/2010	
Mr Roger Cross	Senior Clinical Pharmacist	Expert	01/04/2010	
Dr Matthew Dunn	Consultant Accident and Emergency	Expert	01/04/2010	
Dr John S Fenlon	Reader in Statistics	Expert	25/05/2011	
Mrs Louise Harmer	Clinical Skills Tutor	Expert	01/04/2010	
Mrs Moya Horton	Retired University Lecturer (Physiotherapy)	Lay	01/04/2010	
Mrs Evette Hunkins-Hutchinson	Lecturer Health Care Management	Lay Plus	01/04/2010	
Dr Ashok Roy	Consultant Psychiatrist/Children and Adults lacking Mental Capacity	Expert	01/04/2010	
Dr Gurnam Singh	Principal Lecturer in Social Work	Lay Plus	01/04/2010	

### 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 - Coventry & Warwickshire: Members' Declarations of

Name	Declaration of Interest	Date
Dr John S Fenlon	As Director of the Risk Initiative & Statistical Consultancy Unit (Department of Statistics, University of Warwick), I sometimes provide advice on design and analysis of medical trials undertaken by staff of (or associated with) the University.	26/05/2011
Dr Helen Brittain	Member of the Psychosocial team of British Red Cross.	25/01/2012
Dr Ashok Roy	Clinical Lead, Service development and research, Coventry and Warwickshire Partnership NHS Trust	25/01/2012
Mrs Moya Horton	None	25/01/2012
Dr Jane Appleton	None	25/01/2012
Mr Roger Balcombe	None	25/01/2012
Mrs Barbara Canning	None	25/01/2012
Mr Roger Cross	None	25/01/2012
Dr Matthew Dunn	None	25/01/2012
Mrs Louise Harmer	None	25/01/2012
Mrs Evette Hunkins-Hutchinson	None	25/01/2012
Dr Gurnam Singh	None	25/01/2012
Dr Geraldine Brady	Employed in a University Research Centre so may submit as a CI or research team member.	25/01/2012

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

<b>Month</b>	<b>Date</b>	<b>Number of Members Present at Meeting</b>
April	27/04/2011	9
May	25/05/2011	11
June	29/06/2011	8
July	27/07/2011	11
August	24/08/2011	8
September	28/09/2011	10
October	26/10/2011	9
November	23/11/2011	7
January	25/01/2012	10
February	29/02/2012	12
March	28/03/2012	10

11 full committee meetings were held during the reporting period.

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Helen Brittain	10
Dr Matthew Dunn	10
Mr Roger Cross	10
Dr John S Fenlon	9
Mrs Louise Harmer	9
Dr Gurnam Singh	8
Dr Ashok Roy	8
Mrs Barbara Canning	8
Mr Roger Balcombe	8
Mrs Evette Hunkins-Hutchinson	7
Mrs Moya Horton	7
Dr Jane Appleton	6
Dr Geraldine Brady	5

**Number of inquorate meetings held: None**

**Training 01 April 2011 – 31 March 2012:**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr Helen Brittain	16/06/2011 - 16/06/2011	Qualitative Researcher Training, West Midlands REC Centre
Mrs Barbara Canning	16/06/2011 - 16/06/2011	Qualitative Research Training, West Midlands REC Centre
Dr John S Fenlon	07/07/2011 - 07/07/2011	Induction, NRES
Mr Roger Balcombe	29/06/2011 - 29/06/2011	MCA DVD training, NRES
Mrs Barbara Canning	29/06/2011 - 29/06/2011	MCA DVD, NRES
Dr Helen Brittain	29/06/2011 - 29/06/2011	MCA DVD, NRES
Mr Roger Cross	29/06/2011 - 29/06/2011	MCA DVD, NRES
Dr Matthew Dunn	29/06/2011 - 29/06/2011	MCA DVD, NRES
Dr John S Fenlon	29/06/2011 - 29/06/2011	MCA DVD, NRES
Mrs Louise Harmer	29/06/2011 - 29/06/2011	MCA DVD, NRES
Mrs Moya Horton	29/06/2011 - 29/06/2011	MCA DVD, NRES
Dr Ashok Roy	29/06/2011 - 29/06/2011	MCA DVD, NRES
Dr Helen Brittain	21/03/2012 - 21/03/2012	Training for Chairs, NRES
Mr Roger Cross	12/10/2011 - 12/10/2011	NRES Update, NRES
Mr Roger Cross	28/10/2011 - 28/10/2011	HRA Constitution, NRES
Mr Roger Cross	01/11/2011 - 01/11/2011	NRES CTIMP training, NRES
Mr Roger Balcombe	29/06/2011 - 29/06/2011	MCA DVD, NRES
Mr Roger Balcombe	24/08/2011 - 24/08/2011	GAfREC, NRES
Mr Roger Balcombe	24/08/2011 - 24/08/2011	Shared Ethical Debate, NRES
Dr Helen Brittain	29/06/2011 - 29/06/2011	MCA, NRES
Dr Helen Brittain	24/08/2011 - 24/08/2011	Shared Ethical Debate, NRES
Dr Helen Brittain	24/08/2011 - 24/08/2011	GAfREC, NRES
Mrs Barbara Canning	29/06/2011 - 29/06/2011	MCA, NRES
Mr Roger Cross	29/06/2011 - 29/06/2011	MCA DVD, NRES
Dr Matthew Dunn	29/06/2011 - 29/06/2011	MCA, NRES
Dr John S Fenlon	29/06/2011 - 29/06/2011	MCA, NRES
Dr John S Fenlon	24/08/2011 - 24/08/2011	GAfREC, NRES
Dr John S Fenlon	24/08/2011 - 24/08/2011	Shared Ethical Debate, NRES
Mrs Louise Harmer	29/06/2011 - 29/06/2011	MCA, NRES
Mrs Louise Harmer	24/08/2011 - 24/08/2011	GAfREC, NRES
Mrs Louise Harmer	24/08/2011 - 24/08/2011	Shared Ethical Debate, NRES
Mrs Moya Horton	24/08/2011 - 24/08/2011	Shared Ethical Debate, NRES
Mrs Moya Horton	24/08/2011 - 24/08/2011	GAfREC, NRES
Mrs Evette Hunkins-Hutchinson	24/08/2011 - 24/08/2011	Shared Ethical Debate, NRES
Mrs Evette Hunkins-	24/08/2011 - 24/08/2011	GAfREC, NRES

Hutchinson		
Dr Gurnam Singh	24/08/2011 - 24/08/2011	Shared Ethical Debate, NRES
Dr Gurnam Singh	24/08/2011 - 24/08/2011	GAfREC, NRES
Dr Helen Brittain	12/11/2011 - 12/11/2011	Janet Wisely's Update Meeting, NRES
Dr Geraldine Brady	16/11/2011 - 16/11/2011	Induction, NRES



## Part 2: REC workload and activity during the reporting period.

**Table 1: Applications assigned to a full committee meeting held within the reporting period:**

<b>Applications for full ethical review – Study Type</b>	<b>Number</b>	<b>%</b>
Clinical Trial of Investigational Medicinal Product	10	15.15
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	56	84.85
<b>Total Applications Reviewed</b>	<b>66</b>	<b>100</b>

**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	5
Number of student applications reviewed	25
Number of paediatric applications reviewed	8
Number of device applications reviewed	1
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	2
Number of applications reviewed funded by the US DHHS	0

**Table 3: Decisions given at meetings held within the reporting period:**

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	13	19.70
Favourable Opinion with Additional Conditions	14	21.21
Unfavourable Opinion	4	6.06
Provisional Opinion	35	53.03
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
<b>Total</b>	<b>66</b>	<b>100</b>
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:**

<b>Status of applications at date of generation of report</b>	<b>Number</b>	<b>%</b>
Further Information Favourable Opinion with Standard Conditions	31	46.97
Further Information Favourable Opinion with Additional Conditions	1	1.52
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	13	19.70
Favourable Opinion with Additional Conditions	14	21.21
Unfavourable Opinion	4	6.06
Provisional Opinion	2	3.03
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	1	1.52
<b>Total</b>	<b>66</b>	<b>100</b>

**Table 5: Other Management Information for the reporting period:**

<b>Average number of applications reviewed per full meeting</b>	6.00
<b>Number of applications for full ethical review over 60 days</b>	0
<b>Number of applications over 60 days as a % of total</b>	0.00%
<b>Number of days taken to final decision - average</b>	28
<b>Number of days taken to final decision - mode</b>	22
<b>Number of SSAs (non-Phase 1) reviewed</b>	3
<b>Number of applications for SSA review over 25 days</b>	0
<b>Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)</b>	0.0%
<b>Number of SSAs (Phase 1) reviewed</b>	0
<b>Number of applications for SSA review over 14 days</b>	0
<b>Number of applications for SSA review over 14 days as % of all Phase 1 (SSAs)</b>	0%
<b>Number of substantial amendments reviewed</b>	88
<b>Number of substantial amendments over 35 days</b>	0
<b>Number of substantial amendments over 35 days as a % of total substantial amendments</b>	0.0%
<b>Number of Section 30 applications reviewed</b>	0
<b>Number of Section 30 applications over 60 days</b>	0
<b>Number of Section 30 applications over 60 days as a % of total Section 30 applications</b>	0%
<b>Number of modified amendments reviewed</b>	3
<b>Number of modified amendments over 14 days</b>	0
<b>Number of modified amendments over 14 days as a % of total modified amendments</b>	0.0%
<b>Number of proportionate review applications for ethical review over 14 days*</b>	0
<b>Number of proportionate review applications over 14 days as a % of total</b>	0%

**Table 6: Breakdown of current status of all applications reviewed within the reporting period:**

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/WM/0044	General or Spinal Anaesthesia for Pelvic Surgery (GOSIP trial)	22
11/WM/0098	Organisational factors & their impact on RGN End of Life Care delivery	22
11/WM/0109	Emotional Processing in the Recovery from Anorexia and Bulimia Nervosa	40
11/WM/0138	Health Service & Specialist responses to Survivors of Sexual Violence	43
11/WM/0142	Qualitative Study into MDT experiences of CTO in AOT- Version 1	57
11/WM/0145	CNS 3D/4D study	52
11/WM/0146	Fetal cardiodynamic (cardiac function) study for IUT	30
11/WM/0182	Window 02	51
11/WM/0183	Recovery from Opiate Dependency	17
11/WM/0207	Obstructive Sleep apnoea, age related cognition and driving	38
11/WM/0214	Disturbed Sleep, Stress and Asperger's Syndrome	34
11/WM/0221	Evaluation of the potential association between P. acnes and sciatica	19
11/WM/0222	Changes in children's relationships when a parent acquires a TBI	28
11/WM/0228	SliP Project	16
11/WM/0244	Essence of Nursing	20
11/WM/0265	OZLASE study	24
11/WM/0266	A0221094 Fesoterodine in patients without enough Tolterodine response	28
11/WM/0291	Bridge Project: Evaluating two models of transitional care	22
11/WM/0292	Service Users employed to provide mental health services.	21
11/WM/0306	Response and safety of BMS-820836 in patients with major depression	21
11/WM/0307	Safety & tolerability of BMS-820836 in patients with major depression	21
11/WM/0342	Early Intervention and Prevention of Challenging Behaviour_V2_07.09.11	17
11/WM/0378	Men, infertility and infertility treatment	22
11/WM/0382	Loss experiences of people with learning disabilities	24
11/WM/0387	QUantification of Interstitial lung disease on CT (QUIC) v1.1	26
12/WM/0007	Meal frequency, inflammation and energy expenditure	54
12/WM/0041	Adherence to DMARDs in RA patients	42
12/WM/0042	Horizontal lower eyelid shortening	43
12/WM/0043	Palatally extended graft survival (PEGS)	35
12/WM/0052	Patient experience and spiritual care	30

12/WM/0076	Vacuum-assisted Breast Biopsy Evaluation v1	29
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Further Information Favourable Opinion with Additional Conditions		
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REC Reference	Application Short Title	Number of Days on Clock
11/WM/0301	Long term outcomes following surgery for pelvic organ prolapse	29

Further Information Unfavourable Opinion		
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REC Reference	Application Short Title	Number of Days on Clock
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Favourable Opinion with Standard Conditions		
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REC Reference	Application Short Title	Number of Days on Clock
11/WM/0106	Receiving end of life care at home_v1	21
11/WM/0164	EMPIRE - AntiEpileptic drug Monitoring in PREgnancy	23
11/WM/0166	Advance care planning for people with serious chronic illnesses	22
11/WM/0220	TEAMM: Tackling early morbidity and mortality in myeloma	15
11/WM/0290	Randomised Controlled Trial of Families for Health V1	19
11/WM/0293	Informal carers' willingness to pay for telecare – a case of dementia	19
11/WM/0299	"BCoS-lite"	19
11/WM/0344	Difficult to remove uraemic toxins	16
11/WM/0352	DemScan	16
11/WM/0367	IMMUNOTACE	22
11/WM/0381	De-ESCALaTE HPV_Final Version 1.0_28 Oct 2011	22
11/WM/0385	Hemoglobinopathy screening using mass spectrometry	22
12/WM/0001	WOLLF - Wound Management of Open Lower Limb Fractures	26

Favourable Opinion with Additional Conditions		
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REC Reference	Application Short Title	Number of Days on Clock
11/WM/0085	Thyroid in Bariatric Surgery Version 1	54
11/WM/0096	Neuro-Behcet's disease: a multi-centre retrospective study. V1	20
11/WM/0108	Advance care planning for dementia (V1)	21
11/WM/0131	Medicated Sleep and Wakefulness	27
11/WM/0149	FEMME	28
11/WM/0175	Autologous Stem Cells, Chondrocytes or the Two? (ASCOT)	43
11/WM/0245	Shoulder Arthroplasty Trial	20

11/WM/0343	PD COMM Pilot	16
11/WM/0350	Randomised controlled trial of internal fixation versus arthroplasty	19
12/WM/0011	Improving Psychological Support for People with HF	47
12/WM/0017	Effects of short-term energy restriction on liver lipid (v1)	40
12/WM/0067	MRI study of the effects of hypoxia on cerebral arterial vasculature	20
12/WM/0069	A Compassionate mind approach to Obesity Vers.1	42
12/WM/0072	Tissue specific hypothyroidism and the heart version 1	29

#### Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/WM/0143	Disturbed Sleep, Stress and Asperger's Syndrome	44
11/WM/0351	Coagulation, inflammation and renal function after aneurysm repair	20
12/WM/0016	Preventing excessive weight gain in pregnant women	46
12/WM/0082	DELP-03 - Emollient Gel for the treatment of Atopic Dermatitis	20

#### Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
12/WM/0066	Validation of purine biosensor in detecting acute cerebral ischaemia	N/A
12/WM/0079	Long term continuous infusion ch14.18/CHO plus s.c. aldesleukin (IL-2)	N/A

#### Provisional Opinion Pending Consultation with Referee

REC Reference	Application Short Title	Number of Days on Clock
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#### Further information response not complete

REC Reference	Application Short Title	Number of Days on Clock
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#### Withdrawn after the meeting

REC Reference	Application Short Title	Number of Days on Clock
11/WM/0246	The effects of multiple & single births among parents after IVF/ICSI	20

#### Invalid Application

REC Reference	Application Short Title	Number of Days on Clock
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#### No Opinion Pending Consultation with Referee

REC Reference	Application Short Title	Number of Days on Clock
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<b>Not Requiring Review by NHS REC</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

**Table 7: Items exceeding timelines:**

<b>Full applications for ethical review over 60 day timeline</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<b>Proportionate review applications for ethical review over 14 days timeline</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<b>SSAs (non Phase 1) over 25 days timeline</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<b>SSAs (Phase 1) over 14 days timeline</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<b>Substantial Amendments over 35 day timeline</b>			
<b>Amendment Reference</b>	<b>Application Short Title</b>	<b>Amendment Title</b>	<b>Number of Days on Clock</b>

<b>Modified Amendments over 14 day timeline</b>			
<b>Amendment Reference</b>	<b>Application Short Title</b>	<b>Amendment Title</b>	<b>Number of Days on Clock</b>

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