



# *Health Research Authority*

**NRES Committee East Midlands -  
Derby 1**

**Annual Report**

**01 April 2011 – 31 December 2011**

## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	NRES Committee East Midlands - Derby 1
<b>Type of REC:</b>	Type III
<b>Type of Flag:</b>	CTIMP, Paediatric, RDB, HTA
<b>Chair:</b>	Mr Peter Korczak (Chair)
<b>Vice-Chair:</b>	Dr Helen Sammons (Vice Chair)
<b>Alternate Vice-Chair:</b>	None
<b>Co-ordinator:</b>	Mrs Carol Marten
<b>PRSC Co-ordinator:</b>	Mrs Carol Marten
<b>Assistant Co-ordinator:</b>	N/A
<b>Committee Address:</b>	Research Ethics Office The Old Chapel Royal Standard Place Nottingham NG1 6FS
<b>Telephone:</b>	0115 8839436
<b>Fax:</b>	0115 8839294
<b>Email:</b>	carol.marten@nottspct.nhs.uk

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

## NRES Committee East Midlands - Derby 1 Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr Peter Allmark	Principal Lecturer	Expert	23/12/2002	
Dr Charles Beck	Specialist Registrar in Public Health	Expert	01/11/2010	
Mr John Beswick	Lay member	Lay Plus	27/05/2004	05/05/2011
Dr Helen Busby	Researcher	Expert	07/04/2010	
Mr Peter Fox	Principal Pharmacist	Expert	23/12/2006	
Ms Karon Glynn	Head of Mental Health	Expert	03/06/2008	
Mr David Grenz	Lay Member	Lay Plus	01/08/2011	
Dr Brian Hands	General Practitioner	Expert	01/11/2007	
Dr David Henson	Principal Clinical Biochemist	Expert	10/06/2008	
Mr Peter Korczak (Chair)	Consultant Maxillo-facial Surgeon	Expert	31/03/2004	
Dr Simona Lampariello	Paediatric Intensivist	Expert	15/08/2008	03/11/2011
Mrs Janet Mallett	Lay Member	Lay Plus	01/09/2011	
Mrs Judith Neal	Lay member	Lay Plus	15/08/2008	01/12/2011
Dr Helen Sammons (Vice Chair)	Senior Lecturer	Expert	23/12/2006	
Dr Nick Taub	Statistician	Expert	04/02/2009	
Mrs Anne Walker	Lay Member	Lay Plus	01/09/2011	
Ms Kay Wheat	Academic Lecturer	Lay Plus	01/04/2006	
Mr Terence Wiseman	Lay Member	Lay Plus	19/01/2004	07/08/2011

### 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

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

<b>Month</b>	<b>Date</b>	<b>Number of Members Present at Meeting</b>
May	05/05/2011	10
June	02/06/2011	11
July	07/07/2011	9
August	04/08/2011	14
September	01/09/2011	11
October	06/10/2011	7
November	03/11/2011	12
December	01/12/2011	11

8 full committee meetings were held during the reporting period.

**Proportionate Review Sub Committee Meetings held during 01 April 2011 - 31 December 2011:**

<b>Month</b>	<b>Date</b>	<b>Number of Members Present at Meeting</b>
May	05/05/2011	4
June	02/06/2011	3
July	07/07/2011	4
August	04/08/2011	5
September	01/09/2011	4
October	06/10/2011	4
November	03/11/2011	5
December	01/12/2011	4

8 proportionate review sub-committee meetings were held during the reporting period.

**Attendance of Members: 01 April 2011 – 31 December 2011:**

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Brian Hands	7
Dr David Henson	7
Dr Nick Taub	7
Dr Helen Sammons (Vice Chair)	6
Mr Peter Korczak (Chair)	6
Mrs Judith Neal	6
Ms Karon Glynn	6
Mr Peter Fox	5
Mr David Grenz	5
Dr Peter Allmark	5
Dr Helen Busby	5
Mr Terence Wiseman	4
Dr Charles Beck	4
Ms Kay Wheat	4
Dr Simona Lampariello	3
Mrs Anne Walker	2
Mrs Janet Mallett	2
Mr John Beswick	1

**Number of inquorate meetings held: 0**

**Attendance of Members at proportionate review sub-committee meetings:  
01 April 2011 – 31 December 2011:**

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr David Henson	7
Dr Nick Taub	7
Dr Helen Sammons (Vice Chair)	5
Mr David Grenz	4
Mr Peter Korczak	3
Mr Peter Korczak (Chair)	3
Mr Terence Wiseman	3
Mrs Janet Mallett	1

## Training 01 April 2011 – 31 December 2011:

Name of Member	Date	Event(s) attended
Mr Terence Wiseman	20/06/2011 - 20/06/2011	Equality and Diversity, NRES
Ms Karon Glynn	23/06/2011 - 23/06/2011	Equality and Diversity, NRES
Dr David Henson	12/07/2011 - 12/07/2011	Equality and Diversity, NRES
Dr Helen Sammons (Vice Chair)	01/07/2011 - 01/07/2011	Equality and Diversity – On Line, NRES
Dr Peter Allmark	14/07/2011 - 14/07/2011	Equality & Diversity, Sheffield Hallam University
Dr Helen Sammons (Vice Chair)	07/09/2011 - 07/09/2011	Chairing Skills, NRES
Mr Peter Korczak (Chair)	06/10/2011 - 06/10/2011	East Midlands Training Day - Statistics, Personal Identifiable Data & MCA, East Midlands REC Centre
Dr Helen Sammons (Vice Chair)	06/10/2011 - 06/10/2011	East Midlands Training Day - Statistics, Personal Identifiable Data & MCA, East Midlands REC Centre
Dr Peter Allmark	06/10/2011 - 06/10/2011	east Midlands Training Day - Statistics, Personal Identifiable Data & MCA, East Midlands REC Centre
Mr Terence Wiseman	06/10/2011 - 06/10/2011	East Midlands Training Day - Statistics, Personal Identifiable Data & MCA, East Midlands REC Centre
Ms Kay Wheat	06/10/2011 - 06/10/2011	East Midlands Training Day - Statistics, Personal Identifiable Data & MCA, East Midlands REC Centre
Mr Peter Fox	06/10/2011 - 06/10/2011	East Midlands Training Day - Statistics, Personal Identifiable Data & MCA, East Midlands REC Centre
Dr Brian Hands	06/10/2011 - 06/10/2011	East Midlands Training Day - Statistics, Personal Identifiable Data & MCA, East Midlands REC Centre
Ms Karon Glynn	06/10/2011 - 06/10/2011	East Midlands Training Day - Statistics, Personal Identifiable Data & MCA, East Midlands REC Centre
Dr David Henson	06/10/2011 - 06/10/2011	East Midlands Training Day - Statistics, Personal Identifiable Data & MCA, East Midlands REC Centre
Mrs Judith Neal	06/10/2011 - 06/10/2011	East Midlands Training Day - Statistics, Personal Identifiable Data & MCA, East Midlands

		REC Centre
Dr Nick Taub	06/10/2011 - 06/10/2011	East Midlands Training Day - Statistics, Personal Identifiable Data & MCA, East Midlands REC Centre
Dr Helen Busby	06/10/2011 - 06/10/2011	East Midlands Training Day - Statistics, Personal Identifiable Data & MCA, East Midlands REC Centre
Dr Charles Beck	06/10/2011 - 06/10/2011	East Midlands Training Day - Statistics, Personal Identifiable Data & MCA, East Midlands REC Centre
Dr Helen Busby	17/06/2011 - 17/06/2011	Equality and Diversity, University of Leicester
Mr Peter Korczak (Chair)	06/12/2011 - 06/12/2011	Chairs Training Course, NRES
Dr Helen Busby	11/10/2011 - 11/10/2011	Nuffield Council on Bioethics report - Human Bodies Donation for Medical Research, Nuffield Council on Bioethics
Mrs Anne Walker	28/06/2011 - 28/06/2011	NRES Statistics Training for NRES REC Members , NRES
Mrs Anne Walker	19/05/2011 - 19/05/2011	NRES - Research with Adolescents , NRES
Mrs Janet Mallett	06/10/2011 - 06/10/2011	East Midlands Training Day - Statistics, Personal Identifiable Data & MCA, East Midlands REC Centre
Mrs Janet Mallett	01/08/2011 - 01/08/2011	Equality and Diversity, 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	25.00
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	1	2.50
Research Database	10	25.00
Others	19	47.50
<b>Total Applications Reviewed</b>	<b>40</b>	<b>100.0</b>

**Table 2: Other REC activity during the reporting period:**

Number of applications made invalid by co-ordinator	10
Number of studies withdrawn prior to the meeting	11
Number of student applications reviewed	12
Number of paediatric applications reviewed	12
Number of device applications reviewed	0
Number of prisoner applications reviewed	0
Number of reviewed 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:**

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	3	7.50
Favourable Opinion with Additional Conditions	1	2.50
<b>Unfavourable Opinion</b>	<b>6</b>	15.00
<b>Provisional Opinion</b>	<b>30</b>	75.00
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
<b>Total</b>	<b>40</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	29	72.50
Further Information Favourable Opinion with Additional Conditions	1	2.50
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	3	7.50
Favourable Opinion with Additional Conditions	1	2.50
Unfavourable Opinion	6	15.00
Provisional Opinion	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
<b>Total</b>	<b>40</b>	<b>0.00</b>

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

<b>Total Applications Reviewed</b>	<b>26</b>	<b>100.0</b>
------------------------------------	-----------	--------------

**Table 6: Decisions given at proportionate review sub-committee meetings held within the reporting period:**

<b>Decisions taken at proportionate review sub-committee meetings</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	8	30.77
Favourable Opinion with Additional Conditions	3	11.54
No Opinion transfer to full committee for review	1	3.85
Provisional Opinion	13	50.00
Unfavourable Opinion	1	3.85
<b>Total</b>	<b>26</b>	<b>100%</b>

**Table 7: Other Management Information for the reporting period:**

<b>Average number of applications reviewed per full meeting</b>	5.00
<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>	32
<b>Number of days taken to final decision - mode</b>	26
<b>Number of SSAs (non-Phase 1) reviewed</b>	1
<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>	100
<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>	5
<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>	14
<b>Number of proportionate review applications over 14 days as a % of total</b>	56.00%

**\*NB – Proportionate Review Service is currently in pilot phase – 14 day review is an aim not a target**

**Table 8: Breakdown of current status of 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/EM/0105	Once daily oral LY2216684 adjunctive treatment for patients with MDD	34
11/EM/0110	Young refugee people's experiences of mental health services	57
11/EM/0114	Assessment of GI function to a mixed meal by non-invasive imaging	28
11/EM/0128	PERSIST study (PERgoveriS In Stratified Treatment) for ART	33
11/EM/0131	NIV withdrawal in MND: doctors' experiences	47
11/EM/0155	Heavy Menstrual Bleeding CDSS Feasibility Study	22
11/EM/0158	Tobacco Smoke and Multiple Sclerosis	13
11/EM/0160	Experiences of congenitally profoundly deaf CI candidates.	13
11/EM/0161	Handover in patient discharge from critical care v1.0	15
11/EM/0181	Extracranial Blood Flow During Haemodialysis and 7T MR Brain Imaging	26
11/EM/0189	West London Premature Ovarian Failure Database	29
11/EM/0190	Outcomes of thrombolysis in wake up stroke patients	36
11/EM/0191	Employment among dialysis patients in an East Midlands NHS Trust	24
11/EM/0193	Healthcare-Associated Infection Control in the Ambulance Service	16
11/EM/0212	ARID Study	38
11/EM/0229	Parents' perceptions of support needs in the transition to parenthood	38
11/EM/0230	Making Sense of the Child's Lived Experience in Cases of Neglect (v1)	33
11/EM/0231	Enteral nutrition and tolerance to chemotherapy in UGI cancer patients	33
11/EM/0234	Pilot Registry: Investigation & Prevention of Alzheimer's Disease	35
11/EM/0235	A6631029 - Chronic Obstructive Pulmonary Disease (COPD).	26
11/EM/0240	Sharing Haemodialysis Care	20
11/EM/0251	International LAM Registry	30
11/EM/0263	FOLFOX plus curcumin in patients with inoperable colorectal cancer V1	30
11/EM/0269	Aintree asthma patient clinical and research database version 1	42
11/EM/0271	Posterior tibial tendinopathy and associated genetic risk factors v1	37
11/EM/0272	Endoscopic versus conventional open method of saphenous vein harvest	26
11/EM/0276	HPV Triage	21
11/EM/0277	Investigation of the effects of imatinib mesylate on bladder symptoms	15
11/EM/0305	CADMUS - Ustekinumab in adolescent subjects with plaque psoriasis	35
11/EM/0312	Defining the role of Transperineal Template-guided Prostate Biopsy	44
11/EM/0316	DMSA2011: Comparison of 99mTc-DMSA SPECT and Planar Imaging	30

	techniques	
11/EM/0319	Assessment of the Use of Stand-by Emergency Self-Treatment Kits	25
11/EM/0323	HCV Research UK Tissue Bank V1	45
11/EM/0358	EuroNet PHL-LP1	33
11/EM/0362	Exploring the implementation of the Healthy Start vitamin programme	9
11/EM/0393	RADICAL, v1.0	23
11/EM/0394	A pilot clinical trial about the placement experience of TADs	30
11/EM/0398	MK-0431A in Pediatric Patients with Type 2 Diabetes Mellitus	30
11/EM/0436	Setting up the East Midlands Anorexia Nervosa Case Register	20
11/EM/0452	An exploration of adult male experiences of having IBS(version 1)	18
11/EM/0453	Families' experience of family meetings within acute psychiatric wards	10

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/EM/0314	HCV Research UK V1	51

#### Further Information Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
---------------	-------------------------	-------------------------

#### Favourable Opinion with Standard Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/EM/0178	Finding The Right Student	17
11/EM/0186	Evaluating outcomes of interventions that change practice	16
11/EM/0187	NHS Drug and Alcohol Workers: Use and opinions of public health policy	17
11/EM/0243	What are RN's perceptions of clinical competency assessment?	13
11/EM/0278	Integrating a Smartphone Application into a Junior Doctor Workforce	10
11/EM/0307	Short-Term Psychodynamic Psychotherapy in a Frontline Tier 4 Service	22
11/EM/0311	International Epilepsy Database (version 2)	36
11/EM/0345	Cardiovascular risk in patients with severe mental illness	15
11/EM/0353	HCV Research UK Clinical Research Database V1	17
11/EM/0360	Consent to medical students' presence on delivery suite.	10
11/EM/0404	Comparison of electronic and paper AQLQ and ACQ questionnaires	9

#### Favourable Opinion with Additional Conditions

<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/EM/0248	Sev/prof SNHL experiences with digital HA's	9
11/EM/0288	TRYMS	21
11/EM/0317	The VIRASrT Study	23
11/EM/0391	Information provision to low risk women regarding home birth	10

<b>Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/EM/0107	International Epilepsy Database (version 1)	53
11/EM/0164	TRYMS	22
11/EM/0239	Assessment and Mechanism of the Refractory Period in Asthma	26
11/EM/0363	Early lung cancer detection in Corby	9
11/EM/0390	Induction of labour versus expectant management for women over 35 yrs	25
11/EM/0431	COPD and Comorbidities Version 1/2011	21
11/EM/0441	Discussing Sexuality after Traumatic Brain Injury v1	18

<b>Provisional Opinion</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/EM/0429	Protein, DNA and RNA alterations in oropharyngeal cancer in Nottingham	N/A

<b>Further information response not complete</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<b>Withdrawn after the meeting</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<b>Invalid Application</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<b>No Opinion Pending Consultation with Referee</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<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 9: 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>
11/EM/0155	Heavy Menstrual Bleeding CDSS Feasibility Study	22
11/EM/0161	Handover in patient discharge from critical care v1.0	15
11/EM/0178	Finding The Right Student	17
11/EM/0186	Evaluating outcomes of interventions that change practice	16
11/EM/0187	NHS Drug and Alcohol Workers: Use and opinions of public health policy	17
11/EM/0193	Healthcare-Associated Infection Control in the Ambulance Service	16
11/EM/0240	Sharing Haemodialysis Care	20
11/EM/0276	HPV Triage	21
11/EM/0277	Investigation of the effects of imatinib mesylate on bladder symptoms	15
11/EM/0316	DMSA2011: Comparison of 99mTc-DMSA SPECT and Planar Imaging techniques	30
11/EM/0317	The VIRASrT Study	23
11/EM/0319	Assessment of the Use of Stand-by Emergency Self-Treatment Kits	25
11/EM/0345	Cardiovascular risk in patients with severe mental illness	15
11/EM/0452	An exploration of adult male experiences of having IBS(version 1)	18

<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>