

**NRES Committee East Midlands -
Leicester**

Annual Report

01 April 2011 – 31 March 2012

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee East Midlands - Leicester
Type of REC:	III
Type of Flag:	IRB, CTIMP, Paediatric
Chair:	Dr Carl Edwards
Vice-Chair:	Mr John Baker
Alternate Vice-Chair:	None
Co-ordinator:	Miss Jessica Parfremment
PRSC Co-ordinator:	Miss Jessica Parfremment
Assistant Co-ordinator:	Miss Georgia Copeland
Committee Address:	The Old Chapel Royal Standard Place Nottingham NG1 6FS
Telephone:	01158839425
Fax:	01158839294
Email:	jessica.parfremment@nottspct.nhs.uk

Chair's overview of the past year:

The committee has performed well this year, with some changes in membership we were pleased to welcome new members to support us as other members moved on, they have showed a level of commitment and skill that is to be commended. The last year saw 69 applications reviewed by the committee and it reflects well on the quality of the administrative support the committee has had that only 1 application exceeded the 60 day deadline and then by just a single day.

Involvement in the process of the creation of the HRA and the implicit recognition of the efforts of NRES in improving the UK clinical research governance process has been very rewarding. We look forward to the new year and the new challenges that it promises around the implementation of proportionate review within the committee and the pilot of ethics officer roles.

NRES Committee East Midlands - Leicester Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Miss Alison Armstrong	Consultant Orthopaedic Surgeon	Expert	08/05/2008	
Mr John Baker	Radiation Protection Advisor and Senior Lecturer (retired)	Lay	06/10/2006	
Dr Jonathan Barratt	Senior Lecturer and Honorary Consultant Nephrologist	Expert	05/10/2004	01/04/2011
Mr Steve Barrett	Research Coordinator	Lay	22/07/2008	
Dr Martin Dennis	Consultant Vascular Surgeon	Expert	02/04/2003	
Miss Stephanie Deveney	Occupational Therapist	Expert	01/12/2011	
Dr Carl Edwards	Implementation Fellow	Lay	01/04/2003	
Dr Jayprakash Gosalakkal	Consultant Paediatric Neurologist	Expert	10/06/2008	14/01/2012
Mrs Sandra Hall	Principal Lecturer in Clinical Pharmacy & Pharmacy Practice	Expert	20/10/2006	
Mr Ian Long	Solicitor	Lay Plus	21/04/2008	01/10/2011
Mr Mark McCarthy	Consultant Vascular Surgeon / Honorary Senior Lecturer	Expert	14/08/2008	
Dr Michelle Pyer	Researcher	Expert	01/09/2011	
Mrs Madeline Wang	Patient Advocate	Lay Plus	01/04/2011	
Mrs Valerie Webb	Nurse	Expert	01/02/2005	
Ms Rose Webster	Cardio Respiratory Education Lead	Expert	01/04/2003	
Dr Iain Williamson	Senior Lecturer in Psychology	Expert	25/05/2008	

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended
N/A			

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Mr Ken Willis	Medical Devices Manager	Lay	03/06/2011
Mr Robert Oldroyd	Lay member	Lay Plus	05/08/2011
Ms Elaine Blackshaw	Clinical Trial Manager	Expert	06/01/2012
Mr Robert Johnson	Expert Member	Expert	03/06/2011
Mr John Aldridge	Senior Lecturer in Nursing	Expert	01/04/2011

Member Bank

Name	Occupation	Expert or Lay	Meeting date attended
N/A			

NRES Committee East Midlands - Leicester: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Mr John Baker	None	13/01/2012
Ms Rose Webster	None	02/12/2011
Mrs Valerie Webb	None	21/07/2011
Mrs Sandra Hall	None	08/12/2011
Miss Alison Armstrong	None	24/08/2011
Dr Iain Williamson	None	08/12/2011
Mr Steve Barrett	None	02/12/2011
Miss Alison Armstrong	None	02/12/2011
Mrs Madeline Wang	None	08/12/2011
Dr Michelle Pyer	None	08/12/2011
Mr Ken Willis	None	15/12/2011
Mr John Aldridge	None	16/12/2011
Ms Elaine Blackshaw	None	15/12/2011
Mr Robert Oldroyd	None	13/12/2011
Mr Mark McCarthy	None	09/01/2012
Miss Stephanie Deveney	None	04/01/2012
Dr Carl Edwards	None	02/12/2011

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

Month	Date	Number of Members Present at Meeting
April	01/04/2011	9
May	06/05/2011	9
June	03/06/2011	7
July	01/07/2011	8
August	05/08/2011	10
September	02/09/2011	10
October	07/10/2011	10
November	04/11/2011	9
December	02/12/2011	12
January	06/01/2012	10
February	03/02/2012	9

11 full committee meetings were held during the reporting period.

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

Name	Number of Meetings Attended
Mr John Baker	12
Mr Steve Barrett	10
Mrs Madeline Wang	9
Dr Carl Edwards	9
Dr Iain Williamson	8
Mrs Sandra Hall	8
Dr Jayprakash Gosalakkal	7
Miss Alison Armstrong	7
Mrs Valerie Webb	7
Ms Rose Webster	6
Mr Ian Long	3
Dr Martin Dennis	3
Dr Michelle Pyer	3
Mr Mark McCarthy	3

Number of inquorate meetings held: - None

Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Mr John Baker	07/09/2011 - 07/09/2011	NRES Training Day for New REC Chairs, NRES
Mr Steve Barrett	01/11/2011 - 01/11/2011	NRES Reviewing CTIMPs, NRES
Mrs Sandra Hall	01/11/2011 - 01/11/2011	NRES Reviewing Clinical Trials of Investigational Medicinal Products , NRES
Dr Iain Williamson	24/06/2011 - 24/06/2011	The Higher Education Agency Subject Network for Sociology, Anthropology and Politics, C-SAP
Ms Rose Webster	01/06/2011 - 01/06/2011	Equality & Diversity, De Montfort University
Dr Carl Edwards	01/12/2011 - 01/12/2011	MCA Training
Mrs Madeline Wang	01/12/2011 - 01/12/2011	MCA Training
Mr John Baker	01/12/2011 - 01/12/2011	MCA Training
Dr Michelle Pyer	12/01/2012 - 12/01/2012	MCA
Mr Steve Barrett	06/01/2012 - 06/01/2012	MCA
Ms Rose Webster	06/01/2012 - 06/01/2012	MCA
Miss Alison Armstrong	28/03/2012 - 28/03/2012	Members National Training Day - Leeds, NRES
Mr Steve Barrett	14/03/2012 - 14/03/2012	NRES Members National Training Day , NRES
Mrs Sandra Hall	09/03/2012 - 09/03/2012	MCA DVD Training
Miss Stephanie Deveney	29/03/2012 - 29/03/2012	Induction, HRA
Dr Martin Dennis	07/09/2011 - 07/09/2011	Equality & Diversity
Mrs Madeline Wang	01/10/2011 - 21/10/2011	Equality & Diversity
Mrs Valerie Webb	13/06/2011 - 13/06/2011	GCP Refresher Course
Mrs Valerie Webb	20/09/2011 - 20/09/2011	Information Governance Course
Mrs Valerie Webb	22/02/2012 - 22/02/2012	Equality & Diversity
Mrs Valerie Webb	21/09/2011 - 21/09/2011	Risk Management
Mrs Valerie Webb	21/09/2011 - 21/09/2011	Safeguarding Adults , Work
Mrs Valerie Webb	20/09/2011 - 20/09/2011	Safeguarding children , Work
Mr John Baker	13/09/2011 - 13/09/2011	NRES Update Session , NRES
Dr Carl Edwards	13/09/2011 - 13/09/2011	NRES Update Session , NRES
Dr Michelle Pyer	01/01/2012 - 01/01/2012	Equality & Diversity, HR

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	20	28.99
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	49	71.01
Total Applications Reviewed	69	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	2
Number of studies withdrawn prior to the meeting	4
Number of student applications reviewed	16
Number of paediatric applications reviewed	8
Number of device applications reviewed	0
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	1
Number of applications reviewed funded by the US DHHS	1

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	10	14.49
Favourable Opinion with Additional Conditions	6	8.70
Unfavourable Opinion	1	1.45
Provisional Opinion	52	75.36
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	69	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	48	69.57
Further Information Favourable Opinion with Additional Conditions	4	5.80
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	10	14.49
Favourable Opinion with Additional Conditions	6	8.70
Unfavourable Opinion	1	1.45
Provisional Opinion	0	0.00
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	0	0.00
Total	69	100

Table 5: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	6.27
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	12
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	175
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	9
Number of modified amendments over 14 days	1
Number of modified amendments over 14 days as a % of total modified amendments	11.1%

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/EM/0083	Vascular Effects of Infection in Pediatric Stroke (VIPS)	52
11/EM/0084	Asthma and Nocturnal Hypoxia in Sickle Cell Anemia (SAC)- II V16.0	39
11/EM/0093	GWMD09126 - GWP42003:GWP42004 Olanzapine weight gain treatment	31
11/EM/0125	COPD Exercise Endurance Study (DB2114417)	29
11/EM/0126	COPD Exercise Endurance Study (DB2114418)	29
11/EM/0129	ECP Therapy with UVADEX for the Treatment of Patients with cGvHD	41
11/EM/0130	Remote postconditioning in renal transplantation	59
11/EM/0133	The role of illness appraisals for outcomes in Parkinson's Disease	45
11/EM/0135	Pilot CMR study to assess appropriate revascularisation in ACS	43
11/EM/0136	A Safer Ramadan	48
11/EM/0141	SUCCESS STUDY Structured Lifestyle Intervention in PCOS version 1	56
11/EM/0156	An Exploration of Obese Women's Experiences of Childbearing	22
11/EM/0179	The patient experience of surgical site infection	51
11/EM/0180	WA25204 RA with CV outcomes (ENTRACTE Study)	60
11/EM/0213	Nurses decisions to use anticipatory prescriptions	33
11/EM/0219	Secukinumab versus placebo in psoriatic arthritis	40
11/EM/0220	Secukinumab - efficacy and safety in Ankylosing Spondylitis	29
11/EM/0223	Diagnostics Development Unit Observational Study	44
11/EM/0225	R-CHOP vs G-CHOP in previously untreated patients with DLBCL	41
11/EM/0227	Transmission of respiratory viruses to health care workers. Version 1.	46
11/EM/0264	Positioning a photograph of dental models on lateral face photograph	30
11/EM/0267	The biological variability of mid regional pro-adrenomedullin	48
11/EM/0270	Tralokinumab in patients with severe asthma	31
11/EM/0274	CO-RADAR	26
11/EM/0280	Diabetes, depression and distress: The 3-D Study	41
11/EM/0286	GWID10160: GWP42003 IN THE SYMPTOMATIC TREATMENT OF ULCERATIVE COLITIS	27
11/EM/0287	Effect of oxygen on cerebral haemodynamics in cerebrovascular disease	35
11/EM/0300	Nursing Preceptorship	52
11/EM/0309	Effect & Safety of Kappaproct as an add on treatment in UC patients	38

11/EM/0318	Attitudes to influenza vaccination for children	47
11/EM/0320	Efficacy and Safety of Octreolin for Acromegaly	36
11/EM/0321	Fulvestrant with GDC-0941/ GDC-0980 in Metastatic Breast cancer	36
11/EM/0339	Electrophysiology of learning & cognitive control in TS & ADHD (v1)	32
11/EM/0341	Tysabri -High Resolution Imaging and Function of T cells in MS	49
11/EM/0343	CQGE031A2208:Phase II multi-center trial- adults with peanut allergy	42
11/EM/0401	Cognitive Behavioural Therapy for mothers of food allergic children_V1	26
11/EM/0402	QAW039 in moderate to severe asthma.	26
11/EM/0439	Care and Communication	56
12/EM/0005	Terahertz imaging of Microneedles within Basal Cell Carcinoma	47
12/EM/0007	7T MRI in Alzheimer's disease, version 1	48
12/EM/0012	AALPHI version 1	35
12/EM/0014	Preloading Trial	30
12/EM/0015	Endopart version1	56
12/EM/0018	CANTOS:CACZ885M2301 Canakinumab in postMI patients with raised hsCRP	44
12/EM/0019	PROCALCITONIN-HF	45
12/EM/0050	Leicester Cardiovascular Bioresource	27
12/EM/0053	BOX study beta cell function & autoimmunity in type 1 diabetes (Ver.1)	34
12/EM/0063	Use of RAFT in Diagnosis of Female GU Infections	30

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/EM/0313	Oxytocin receptor expression on human sperm and effect on motility	47
12/EM/0008	Parents with Learning Disabilities: Their experience of professionals	54
12/EM/0051	Effectiveness of S78454 in NHL and CLL	30
12/EM/0062	Improving diagnosis and risk stratification of diabetic retinopathy in	38

Further Information Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
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Favourable Opinion with Standard Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/EM/0170	An investigation into the effects of orange juice on insulin sensitivity	12
11/EM/0171	An investigation into the effects of orange juice on insulin	12

11/EM/0172	Obesity-induced cytokine study	12
11/EM/0173	LPS Study	12
11/EM/0174	BBSRC2- Maximising Muscle Maintenance in the Elderly	12
11/EM/0175	Nutritive Blood Flow and Anabolic Resistance	12
11/EM/0283	Use of the SASNOS to track time of onset and type of NBD after ABI-1.	31
11/EM/0326	Body Composition assessment using DEXA	24
11/EM/0327	Body Composition assessment using DEXA - submission 2	24
11/EM/0346	Malignant potential of vulval diseases	37

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/EM/0087	Non-adherence to 5-ASA therapy in patients with ulcerative colitis	27
11/EM/0099	Why do patients participate in clinical trials?	26
11/EM/0195	The learning needs of GP practice staff regarding learning disability	48
11/EM/0228	Hypoglycaemia in People with Type 2 Diabetes Mellitus in Primary Care	30
11/EM/0348	C-peptide Study. Version 1	29
11/EM/0434	Helicobacter Eradication Aspirin Trial (HEAT)	24

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/EM/0352	An Investigation into Ethical Issues of Personal Health Monitoring	37

Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
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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
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Invalid Application		
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REC Reference	Application Short Title	Number of Days on Clock
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No Opinion Pending Consultation with Referee		
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REC Reference	Application Short Title	Number of Days on Clock
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Not Requiring Review by NHS REC		
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REC Reference	Application Short Title	Number of Days on Clock
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Table 7: Items exceeding timelines:

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

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

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

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

Modified Amendments over 14 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
08/H0406/171/AM10/1	Phase 1/2a study of ABT-263 in Chronic Lymphocytic Leukaemia	Modification to previous amendment submission (num	22

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