



National Patient Safety Agency

National Research Ethics Service

NRES Committee East Midlands - Derby 2

Annual Report

01 April 2011 – 31 December 2011

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee East Midlands - Derby 2
Type of REC:	Authorised
Type of Flag:	None
Chair:	Mr Phil Hopkinson
Vice-Chair:	None
Alternate Vice-Chair:	None
Co-ordinator:	Mrs Carol Marten
PRSC Co-ordinator:	Mrs Carol Marten
Assistant Co-ordinator:	N/A
Committee Address:	The Old Chapel Royal Standard Place Nottingham NG1 6FS
Telephone:	0115 8839436
Fax:	0115 8839294
Email:	carol.marten@nottspct.nhs.uk

Chair's overview of the past year:

December 2011 saw the termination of the Derby 2 Research Ethics Committee as part of the NRES programme of organisational restructuring that has led to the merger and closures of various ethics committees around the country. I would like to take this opportunity to pay tribute to all the people who have given their time to serve on this committee over the years and also to thank the various administrators that this committee has had for their hard work and support for the committee members. As the restructuring of NRES continues and innovations such as the ethics officer role are introduced the number of ethics committees continues to be reduced and it is interesting to consider what the research ethics review process will look like in several years' time. In my opinion the research ethics committee with its mix of members from various backgrounds and specialities provides the best tool for reaching a decision about complex ethical issues yet devised and I hope that they will continue to be the mainstay of this process whatever else changes. Lastly, thank you to those researchers who have submitted their projects to the Derby 2 committee in its various guises over the years and I hope that the dialogue they have had with it has been both constructive and worthwhile.

NRES Committee East Midlands - Derby 2 Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mr Phil Hopkinson	Acting Patient Safety Manager	Expert	26/08/2004	31/12/2011
Mrs Janet Mallett	Lay member	Lay	12/11/2009	31/12/2011
Dr Kristian Pollock	Senior Research Fellow	Expert	10/10/2007	31/07/2011
Dr Ian Ross	Consultant Gastroenterologist	Expert	23/10/2008	31/08/2011
Mrs Anne Walker	Lay Member	Lay Plus	21/05/2003	31/12/2011
Mr Clive Wilkinson	Lay Member	Lay Plus	08/02/2010	01/09/2011

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended
None			

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Rev Keith Lackenby	Lay Member	Lay	19 April 2011

Member Bank

Name	Occupation	Expert or Lay	Meeting date attended
N/A			

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

Month	Date	Number of Members Present at Meeting
April	19/04/2011	3
May	17/05/2011	3
June	21/06/2011	4
July	19/07/2011	4
August	16/08/2011	3
October	18/10/2011	3
November	15/11/2011	3

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

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

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

Name	Number of Meetings Attended
Mr Phil Hopkinson	7
Mrs Anne Walker	4
Dr Ian Ross	4
Dr Kristian Pollock	2
Mr Clive Wilkinson	2
Mrs Janet Mallett	2
Rev Keith Lackenby	1
Mrs Janet Mallet	1

Training 01 April 2011 – 31 December 2011:

Name of Member	Date	Event(s) attended
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:

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	0	0.00
Total Applications Reviewed	0	100.0

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	6
Number of studies withdrawn prior to the meeting	3
Number of student applications reviewed	0
Number of paediatric applications reviewed	0
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:

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	0	0.00
Unfavourable Opinion	0	0.00
Provisional Opinion	0	0.00
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
Total	0	100%
Number of studies sent back to full committee meeting for final opinion	1	

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	0	0.00%
Further Information Favourable Opinion with Additional Conditions	0	0.00%
Further Information Unfavourable Opinion	0	0.00%
Favourable Opinion with Standard Conditions	0	0.00%
Favourable Opinion with Additional Conditions	0	0.00%
Unfavourable Opinion	0	0.00%
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%
Total	0	100%

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

Total Applications Reviewed	27	100.0
------------------------------------	-----------	--------------

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

Decisions taken at proportionate review sub-committee meetings	Number	%
Favourable Opinion with Standard Conditions	12	44.44
Favourable Opinion with Additional Conditions	7	25.93
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	7	25.93
Unfavourable Opinion	1	3.70
Total	27	100%

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	0.00
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	
Number of days taken to final decision - mode	
Number of SSAs (non-Phase 1) reviewed	0
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%
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	40
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	1
Number of modified amendments over 14 days	0
Number of modified amendments over 14 days as a % of total modified amendments	0.0%
Number of proportionate review applications for ethical review over 14 days*	9
Number of proportionate review applications over 14 days as a % of total	33.33%

***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:

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/EM/0143	The Role of Unlearning in Healthcare Managers' Decision Makingv1	15
11/EM/0167	Volunteer services for hearing aid adjustment	14
11/EM/0177	Young people's perspectives of orthodontic treatment version 3.1	9
11/EM/0247	SCPHN's experience of practice based learning.	16
11/EM/0295	Understanding networks. What makes a clinical network work? Version 1	20
11/EM/0299	Assessment of visual function in Chronic Fatigue Syndrome (CFS)	32
11/EM/0423	Defining Normal Parameters for the Male Nipple Areola Complex - Ver.1	14

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

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/0139	Attitudes of GP towards E-Learning	6
11/EM/0142	Heads Above the Parapet - Midwifery Leadership Development version 1	6
11/EM/0144	Evaluation of QOF incentivised screening for depression	5
11/EM/0169	Evaluation of an inflammatory bowel disease integrated care pathway	7
11/EM/0217	Review of occlusion therapy for intermittent exotropia.	19
11/EM/0218	Gestural abilities of children with specific language impairment :V1	23
11/EM/0257	PAX6 haploinsufficiency and corneal epithelial stem cell dysfunction.	9
11/EM/0262	The experience of working with compulsive hoarding - version one.	12
11/EM/0294	A pilot study of health trainers with patients with diabetes	22
11/EM/0303	Doctors and Patients' views on a heart polypill (V6-6.6.11)	13
11/EM/0378	The experience of parenting a daughter diagnosed with an ASD	13
11/EM/0427	Depression in Primary Care (Version 1)	7

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

11/EM/0222	Education and Employment in CF survey	13
11/EM/0236	Epistaxis: Reducing the length of stay of patients with nasal packs	19
11/EM/0284	service User Involvement within Specialist Commissioned Services in the	12
11/EM/0298	Does referral to secondary care affect QoL in IBS	16
11/EM/0371	Dementia web-based self-management programme	9
11/EM/0420	ICBP MODULE 4: Root causes of diagnosis and treatment delay in cancer	8
11/EM/0422	Functional Outcomes after Rectal Cancer Surgery	8

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/EM/0258	11/EM/0258 Staff preparation for growth in dementia patients 01.07.11.	8

Provisional Opinion

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

Further information response not complete

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

Withdrawn after the meeting

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

Invalid Application

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

No Opinion Pending Consultation with Referee

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

Not Requiring Review by NHS REC

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

Table 9: Items exceeding timelines:

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

Proportionate review applications for ethical review over 14 days timeline		
REC Reference	Application Short Title	Number of Days on Clock
11/EM/0143	The Role of Unlearning in Healthcare Managers' Decision Makingv1	15
11/EM/0217	Review of occlusion therapy for intermittent exotropia.	19
11/EM/0218	Gestural abilities of children with specific language impairment :v1	23
11/EM/0236	Epistaxis: Reducing the length of stay of patients with nasal packs	19
11/EM/0247	SCPHN's experience of practice based learning.	16
11/EM/0294	A pilot study of health trainers with patients with diabetes	22
11/EM/0295	Understanding networks. What makes a clinical network work? Version 1	20
11/EM/0299	Assessment of visual function in Chronic Fatigue Syndrome (CFS)	32
11/EM/0298	Does referral to secondary care affect QoL in IBS	16

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

Section 30 application over 60 day timeline			
----------------------------------------------------	--	--	--

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