

**NRES Committee East Midlands -
Nottingham 2**

Annual Report

01 April 2013 – 31 March 2014

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee East Midlands - Nottingham 2
Type of REC:	Recognised to review CTIMPs in patients – type iii
Type of Flag:	Research Involving Children
Chair:	Dr Martin Hewitt
Vice-Chair:	Dr Simon Roe
Alternate Vice-Chair:	Dr Frances Game
Co-ordinator:	Tracy Leavesley/Miss Liza Selway
PRSC Co-ordinator:	Miss Rachel Nelson/Mrs Carolyn Halliwell
Assistant Co-ordinator:	Miss Rachel Nelson/Mrs Carolyn Halliwell
Committee Address:	The Old Chapel Royal Standard Place Nottingham NG1 6FS
Telephone:	0115 8839425/0115 8839330
Email:	NRESCommittee.EastMidlands-Nottingham2@nhs.net

Chair's overview of the past year:

The last year was again stimulating and challenging. The committee membership, as expected, again changed. New members joined Mrs Jane Hennebury, Dr Simon Deerey and Professor Jane Brown and we look forward to working closely with them.

This committee supported the assessment of the Pilot Officer. This approached made clear demands on committee members and required us to consider a different way of working. Our members look forward to hearing the conclusions of this pilot study and the future implications for working practice.

The system of Proportionate Review is now clearly well-established but certainly adds significantly to the workload of committee members but clearly has merit for the researchers.

We are grateful for the continued support of the REC centre staff and recognised their important role in ensuring that the work of the ethics review continues smoothly. We are aware that the administration team has also been through a period of great change. We look forward to working together in the coming year and trust we will rise to the challenges presented.

NRES Committee East Midlands - Nottingham 2 Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Professor Jayne Brown	Professor of Palliative Care	Expert	30/01/2014	
Ms Gill Bumphrey	Clinical Trials Pharmacist	Expert	01/12/2012	
Miss Shamim Byrne	Gynaecologist/Obstetrician	Expert	14/12/2009	
Mr Simon Deery	Junior Doctor	Expert	24/02/2014	
Dr Frances Game	Consultant Physician	Expert	27/07/2004	
Mrs Jane Hennebury	Lawyer	Lay Plus	03/02/2014	
Dr Martin Hewitt	Consultant Paediatric Oncologist	Expert	23/07/2002	
Dr Asam Latif	Research Pharmacist	Expert	17/01/2012	
Mrs Veronica Lyon	Lay member	Lay Plus	22/01/2013	
Dr Simon Roe	Consultant Nephrologist	Expert	23/07/2002	
Dr John Shaw	Lay Member	Lay	01/09/2011	
Miss Catherine Shenton	Lay Member	Lay Plus	09/03/2010	
Mrs Sally Ann Smith	Retired Audit Manager	Lay Plus	16/04/2010	
Dr Alison Thorpe	Research and Governance Facilitator	Expert	01/09/2011	
Ms Margret Vince	Translator	Lay Plus	25/10/2006	

NRES Committee East Midlands - Nottingham 2: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Professor Jane Brown	A committee member of the Faculty Ethics Committee at De Montfort University Leicester. Review research proposals for the NHR charitable organisation	24/03/2014
Dr John Shaw	Member of PAG/PPI at Nottingham Digestive Diseases – QMC	24/01/2014
Mrs Jane Hennebury	None	24/02/2014
Dr Asam Latif	None	24/01/2014
Mrs Margaret Vince	Self-Employed translator and occasionally may translate documents from clinical trials (usually SAE's)	24/01/2014
Mrs Sally Ann Smith	None	27/01/2014
Dr Simon Roe	Head of Service, Renal and Transplant Unit, Nottingham University Hospitals NHS Trust. Joint Clinical Director for Cardiovascular Disease, East Midlands Strategic Clinical Network	24/01/2014
Mrs Gillian Bumphrey	Small number of shares AstraZeneca Involvement with Nova Laboratories Ltd Employed part-time as Clinical Trials Pharmacist with the Nottingham Clinical Trials Unit	01/02/2014
Dr Frances Game	None	19/11/2013
Ms Shamin Bryne	None	28/02/2014
Mrs Veronica Lyon	None	24/01/2014
Dr Martin Hewitt	None	27/01/2014
Miss Catherine Shenton	None	30/01/2014

Meetings for Full Ethical Review 01 April 2013 - 31 March 2014:

Month	Date	Number of Members Present at Meeting
April	22/04/2013	10
May	20/05/2013	10
June	24/06/2013	11
July	22/07/2013	7
September	23/09/2013	12
October	28/10/2013	10
November	25/11/2013	9
December	16/12/2013	10
January	27/01/2014	10
February	24/02/2014	11
March	24/03/2014	13

11 full committee meetings were held during the reporting period.

Proportionate Review Sub Committee Meetings held during 01 April 2013 - 31 March 2014:

Month	Date	Number of Members Present at Meeting
April	22/04/2013	3
May	20/05/2013	3
June	24/06/2013	3
July	22/07/2013	3
September	23/09/2013	3
October	28/10/2013	3
November	25/11/2013	4
January	27/01/2014	3
March	24/03/2014	3

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

Attendance of Members: 01 April 2013 – 31 March 2014:

Name	Number of Meetings Attended
Dr Simon Roe	11
Miss Catherine Shenton	11
Mrs Veronica Lyon	11
Ms Gill Bumphrey	11
Ms Margret Vince	10
Dr John Shaw	10
Dr Martin Hewitt	10
Dr Asam Latif	8
Dr Frances Game	7
Miss Shamim Byrne	7
Mrs Sally Ann Smith	7
Dr Alison Thorpe	5
Mr Simon Deery	2
Mrs Jane Hennebury	2
Professor Jayne Brown	1

Number of inquorate meetings held: None

**Attendance of Members at proportionate review sub-committee meetings:
01 April 2013 – 31 March 2014:**

Name	Number of Meetings Attended
Dr Martin Hewitt	9
Miss Catherine Shenton	3
Ms Margret Vince	3
Dr John Shaw	2
Miss Shamim Byrne	2
Mrs Sally Ann Smith	2
Dr Alison Thorpe	2
Dr Asam Latif	1
Dr Frances Game	1
Dr Simon Roe	1
Mrs Veronica Lyon	1
Ms Gill Bumphrey	1

Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Mrs Veronica Lyon	02/05/2013 - 02/05/2013	Ethical Issues of Research Involving Children, NRES
Mrs Veronica Lyon	23/04/2013 - 23/04/2013	New Members Induction, NRES
Dr Martin Hewitt	06/09/2013 - 06/09/2013	Confidentiality and the use of personal data in research, Joint Oxford Committee
Dr Martin Hewitt	06/09/2013 - 06/09/2013	The Relationship between ethics committees and researchers, Joint Oxford Committee
Dr Martin Hewitt	06/09/2013 - 06/09/2013	What Do Committees base their ethical decision making on?, Joint Oxford Committee
Miss Shamim Byrne	19/09/2013 - 19/09/2013	Medical Devices Training Day, NRES
Mrs Sally Ann Smith	07/10/2013 - 07/10/2013	Regional Training Day , HRA
Mrs Sally Ann Smith	07/10/2013 - 07/10/2013	Equality & Diversity, NRES
Ms Margret Vince	07/10/2013 - 07/10/2013	Regional Training Day , NRES
Ms Gill Bumphrey	23/10/2013 - 23/10/2013	Regional Training Day, NRES
Dr Simon Roe	01/09/2013 - 01/09/2013	Taking part in shared ethical debate
Dr Simon Roe	01/07/2013 - 01/07/2013	NHS Trust Mandatory training- Consent/ Safeguarding Issues/ Mental Capacity Act
Dr Frances Game	01/08/2013 - 01/08/2013	Equality & Diversity
Dr Frances Game	01/07/2013 - 01/07/2013	ICH GCP Online Course
Dr Asam Latif	01/10/2013 - 01/10/2013	Research Ethics Workshop for PhD Students
Dr Martin Hewitt	08/11/2013 - 08/11/2013	NREAP/Chair s Meeting , HRA
Miss Catherine Shenton	07/10/2013 - 07/10/2013	Local Training Day, NRES
Miss Shamim Byrne	19/02/2014 - 19/02/2014	Reviewing CTIMPS, HRA
Mr Simon Deery	29/04/2013 – 29/04/2013	Equality and Diversity, HRA
Mr Simon Deery	10/07/2013 – 10/07/2013	Induction, HRA
Mr Simon Deery	09/07/2013 – 09/07/2013	Qualitative Research and Ethical Review, HRA

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	23	41.07
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	33	58.93
Total Applications Reviewed	56	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	4
Number of studies withdrawn prior to the meeting	6
Number of student applications reviewed	15
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	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	1	1.79
Favourable Opinion with Additional Conditions	26	46.43
Unfavourable Opinion	3	5.36
Provisional Opinion	26	46.43
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	

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	23	41.07
Further Information Favourable Opinion with Additional Conditions	2	3.57
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	1.79
Favourable Opinion with Additional Conditions	26	46.43
Unfavourable Opinion	3	5.36
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	1	1.79
Total	56	100

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

Total Applications Reviewed	24
------------------------------------	-----------

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	6	25.00
Favourable Opinion with Additional Conditions	13	54.17
No Opinion transfer to full committee for review	2	8.33
Provisional Opinion	2	8.33
Unfavourable Opinion	1	4.17
Total	24	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	4.31
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	32
Number of days taken to final decision - mode	24
Number of SSAs (non-Phase 1) reviewed	5
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	3
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)	0.0%
Number of substantial amendments reviewed	118
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	7
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*	0
Number of proportionate review applications over 14 days as a % of total	0.0%

Table 8: 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
13/EM/0134	Sport as Rehabilitation for Traumatic Brain Injury Patients	53
13/EM/0148	Pharmacogenetics and variability in response to clomiphene citrate	19
13/EM/0153	Self-Consciousness in Weight Loss Surgery Patients	42
13/EM/0172	Adverse experience and mental health in adolescents who harm others	30
13/EM/0173	Biomarker development in myotonic dystrophy type 1	33
13/EM/0175	The use of primary cells for oncology drug discovery.	9
13/EM/0189	NALA-Drug Comparator study in HER2+ Metastatic Breast Cancer patients	32
13/EM/0251	Serelaxin when added to standard therapy in acute heart failure	29
13/EM/0291	Non-invasive carbon dioxide monitoring for non-invasive ventilation-2	25
13/EM/0306	TabPIC: Tablet Preferences in Children	10
13/EM/0350	Roche WA 29049	35
13/EM/0364	EQUIP: Training to promote user involvement in care planning 3/4	29
13/EM/0401	Functional MR Lung Imaging Using Hyperpolarised 129Xe	36
13/EM/0408	Vascular changes during colorectal surgery	25
13/EM/0458	BMN 111 in Children with Achondroplasia	59
14/EM/0009	Proactive familial breast cancer risk assessment in primary care (Ph2)	24
14/EM/0023	Phase II Plovamer Acetate Doses Compared to Copaxone in MS Patients	35
14/EM/0032	Efficacy of secukinumab compared to ustekinumab in mod/seve psoriasis.	32
14/EM/0064	Imaging Markers of Brain Network Dysfunction in Multiple Sclerosis	24
14/EM/0065	End of life care planning for children with life-limiting illness	34
14/EM/0073	MK-8835/PF-04971729 vs. Placebo in T2DM Subjects with Stage 3 Chronic	28
14/EM/0075	MRI and Microbiota analysis in Constipation	31
14/EM/0077	CQVA149A3401 Open Label Study of NVA237 or QVA149 in moderate COPD	35
14/EM/0113	TMS Treatment for Depression	43
14/EM/0121	RITUXILUP, Version 1.0	40
Further Information Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
13/EM/0188	IntReALL SR 2010	56

14/EM/0084	The EVARREST™ Paediatric Mild/Moderate Bleeding Study	40
------------	---	----

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
13/EM/0216	Lupus in Young People: Experiences of Diagnosis (1.0)	11
13/EM/0308	MSK patient education for people with lower levels of literacy V10	9
13/EM/0428	CBT-IBS Feasibility Study	28
13/EM/0451	The reliability of live, audio and video recording for cleft speech	11
14/EM/0055	East Sussex pacemaker arrhythmia analysis	8
14/EM/0058	In-house Donation of Saliva for Oral Health Research, version 1.0	8
14/EM/0139	Patient-carer relationships in people living with seizures. Version 1.	8

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/EM/0136	Safety and Efficacy of Elobixibat in Constipation - Echo 1	18
13/EM/0137	Open Label Extension Study of Elobixibat in Constipation - Echo 3	18
13/EM/0167	The enhanced recovery programme: surgical patients' experience.	8
13/EM/0176	Living with severe Crohn's disease: expectations and decision-making	46
13/EM/0203	Use of the Compass of Shame Scale with Female Forensic Patients	33
13/EM/0215	(duplicate) IMPACCT: Promoting Self Management of Pain from Advanced C	11
13/EM/0220	Strategies used to enhance the alliance during video consultations(V1)	7
13/EM/0236	Investigating Nicotine Metabolism in pregnant smokers	26
13/EM/0238	Empathy, frail older people and the Hospital Discharge Process	25
13/EM/0239	RESPITE	23
13/EM/0260	Quality of life tools in children and young people with keratoconus	10
13/EM/0268	VX11-770-109 Roll-Over Study Paediatric CF CFTR gating mutation	23
13/EM/0284	LDK378 vs Chemo in ALK+ NSCLC in patients who failed crizotinib	28
13/EM/0292	Partnerships between families and professionals	23
13/EM/0304	Barrett's oesophagus proliferative markers study	24
13/EM/0321	inpatient to outpatient:the experience of adults with eating disorders	24

13/EM/0351	Grass Pollen Allergen Immunotherapy Tablet (AIT) Time Course Study	35
13/EM/0357	Secukinumab - efficacy and safety in Ankylosing Spondylitis extension	31
13/EM/0369	Does Pain Reconceptualisation occur following PNE?	12
13/EM/0370	DREAMS	8
13/EM/0371	Xarelto (Rivaroxaban) Risk Minimisation Plan Evaluation	11
13/EM/0389	Physical Activity and Respiratory Health (PhARaoH) Study	28
13/EM/0393	Positive Psychology Intervention	33
13/EM/0399	Biomarkers of Acute Serious Illness in Children (BASIC)	33
13/EM/0406	Use of discarded surgical tissue and synovial fluid	7
13/EM/0409	Oncological imaging of response assessment to systemic therapy	12
13/EM/0420	The NERD Study	34
13/EM/0426	COMPOSE I	30
13/EM/0434	UK HARP-III Study	24
13/EM/0443	An evaluation of a mindfulness group intervention for people with ID	38
13/EM/0447	Develop and pilot a model of self management after bowel cancer [V1]	45
13/EM/0448	Experience of caring for children with Cardiac Arrhythmia and an AED 1	12
13/EM/0450	Inactivity induces atrophy/hypotrophy of carpal tunnel tendons	43
13/EM/0452	CATH-B Chinese community Access to Treatment for Hepatitis B	7
13/EM/0459	POSNOC	34
14/EM/0026	British South Asians' Narratives of Hearing Voices Version 1	24
14/EM/0115	Knee Pain and Related Health in the Community Study	24
14/EM/0137	Drop out of Pulmonary Rehabilitation classes V1	8
14/EM/0138	Qualitative study of the experience of transitioning from RRMS to SPMS	14

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/EM/0309	EQUIP: Training to promote user involvement in care planning 3/4	9
13/EM/0391	Phase II Plovamer Acetate Doses Compared to Copaxone in MS Patients	28
13/EM/0446	F16IL2 plus paclitaxel in metastatic Merkel cell carcinoma	31
14/EM/0027	TMS for depression and psychosis	48

Provisional Opinion

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

Provisional Opinion Pending Consultation with Referee		
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
14/EM/0090	COMPOSE II	32

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	
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