

National Research Ethics
Service


Health Research Authority

NRES Committee East Midlands - Derby

Annual Report

01 April 2013 – 31 March 2014

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee East Midlands - Derby
Type of REC:	Recognised to review CTIMPs in Patients – Type III
Type of Flag:	Research Involving Children Research Database Studies Research Tissue Bank Studies CTiMP Studies
Chair:	Mr Peter Korczak
Vice-Chair:	Dr Helen Sammons
Alternate Vice-Chair:	Mrs Janet Mallett
REC Manager:	Tracy Leavesley
PRSC Co-ordinator:	Tracy Leavesley
REC Assistant:	Zoe Birtwistle/Carolyn Halliwell
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Chair's overview of the past year:

Yet another year has passed. More changes and we have lost many valuable members of our committee to new jobs, end of tenure, etc. Recruitment is a priority, particularly of medical members. There seems to be growing difficulty due to the strict interpretation of job plans, such that Trusts wish to ensure they get the maximum value from their medical staff, whilst failing to appreciate the invaluable contribution our clinicians make to the furtherance of good quality research in the UK. We are fortunate that we have a good mix of members and a very strong lay representation, who carry out their role admirably. They have taken on the challenge of the PRs with ease.

We strive to be fair in our deliberations and have generally helped to steer the researchers over the hurdles of REC applications. One way is to adopt a pragmatic approach and hopefully the applicants appreciate this. The role of the committee is to facilitate the research process not to stifle it.

Much of the work is however done in the background by the coordinators/managers and their assistants, and for our committee Tracy Leavesley is outstanding. I thank all committee members for their contributions and we look forward to another successful year.

NRES Committee East Midlands - Derby Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr Charles Beck	Lecturer & Honorary Specialty Registrar in Public Health	Expert	01/05/2011	06/03/2014
Mr Peter Fox	Principal Pharmacist	Expert	23/12/2006	23/12/2013
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 Phil Hopkinson	Retired Mental Health Act Manager	Expert	01/03/2012	
Mr Peter Korczak	Consultant Maxillo-facial Surgeon	Expert	31/03/2004	
Mrs Janet Mallett	Lay Member	Lay Plus	01/09/2011	
Dr Helen Sammons	Associate Professor in Child Health	Expert	22/12/2006	
Dr Penny Smith	Lay Member	Lay Plus	16/01/2013	
Dr Nicholas Taub	Research Fellow in Medical Statistics	Expert	04/02/2009	09/01/2014
Mr Michael Wakeman	Consultant Pharmacist	Expert	01/02/2012	
Mrs Anne Walker	Lay Member	Lay Plus	01/09/2011	
Ms Kay Wheat	Academic Lecturer	Lay Plus	01/04/2006	17/05/2013

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

Name	Declaration of Interest	Date
Mr Peter Korczak	None	07/11/2013
Dr Brian Hands	None	07/11/2013
Dr Helen Sammons	None	29/10/2013
Mrs Anne Walker	None	07/11/2013
Mr David Grenz	None	07/11/2013
Dr Nicholas Taub	Member of advisory panel for NIHR Research Design Service for the West Midlands	07/11/2013
Mrs Janet Mallett	None	07/11/2013
Mr Phil Hopkinson	none	07/11/2013
Dr David Henson	None	07/11/2013
Dr Penny Smith	My husband, Professor Philip Plowden, is Deputy Vice chancellor at the University of Derby and applications might come to the REC from this institution.	07/11/2013
Dr Charles Beck	I am a research active Lecturer in Public Health based at the University of Nottingham and Honorary Specialty Registrar in Public Health based at Public Health England in Nottingham. In accordance with my academic duties I undertake research activities funded by the public and private sectors. I have peer-reviewed grant applications for numerous organisations, including the Food and Health Bureau of the Government of Hong Kong Special Administrative Region for which I am remunerated. I regularly peer-review scientific manuscripts for scientific and medical journals.	08/01/2014
Mr Michael Wakeman	None	15/01/2014

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

Month	Date	Number of Members Present at Meeting
May	02/05/2013	9
June	06/06/2013	12
July	04/07/2013	10
August	01/08/2013	10
September	05/09/2013	10
October	03/10/2013	10
November	07/11/2013	10
December	05/12/2013	10
January	09/01/2014	11
February	06/02/2014	11
March	06/03/2014	10

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
May	02/05/2013	3
June	06/06/2013	3
July	04/07/2013	3
August	01/08/2013	3
September	05/09/2013	4
October	03/10/2013	3
November	07/11/2013	3
December	05/12/2013	3
January	09/01/2014	3
February	06/02/2014	3
March	06/03/2014	3

11 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 Brian Hands	11
Dr David Henson	11
Mrs Anne Walker	11
Mrs Janet Mallett	11
Mr Peter Korczak	9
Mr Phil Hopkinson	9
Dr Penny Smith	9
Mr David Grenz	8
Mr Michael Wakeman	8
Dr Helen Sammons	8
Dr Nicholas Taub	8
Dr Charles Beck	7
Mr Peter Fox	3

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

Name	Number of Meetings Attended
Mrs Janet Mallett	7
Mr Peter Korczak (Chair)	5
Mr Phil Hopkinson	5
Mrs Anne Walker	5
Dr Nicholas Taub	4
Mr David Grenz	4
Dr David Henson	3
Dr Penny Smith	1

Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Dr Penny Smith	23/04/2013 - 23/04/2013	Induction, NRES / HRA
Dr Penny Smith	07/10/2013 - 07/10/2013	HRA Members Training Day, HRA
Dr Penny Smith	07/10/2013 - 07/10/2013	Equality & Diversity, HRA
Mrs Janet Mallett	10/09/2013 - 10/09/2013	Chair's Training, HRA
Mrs Janet Mallett	07/10/2013 - 07/10/2013	HRA Members Training Day, HRA
Mrs Janet Mallett	07/10/2013 - 07/10/2013	Equality & Diversity, HRA
Mrs Anne Walker	19/09/2013 - 19/09/2013	Medical Devices Training Day, HRA
Mrs Anne Walker	07/10/2013 - 07/10/2013	HRA Members Training Day, HRA
Mrs Anne Walker	07/10/2013 - 07/10/2013	Equality & Diversity, HRA
Mrs Anne Walker	25/03/2014 - 25/03/2014	Research Involving the Disadvantaged and Vulnerable: a Workshop for Researchers and Reviewers, HRA
Dr Charles Beck	21/05/2013 - 21/05/2013	Quantitative research design - developing guidance for researchers and RECs, HRA
Dr Charles Beck	07/10/2013 - 07/10/2013	HRA Members Training Day, HRA
Dr Charles Beck	07/10/2013 - 07/10/2013	Equality & Diversity, HRA
Mr David Grenz	07/10/2013 - 07/10/2013	HRA Members Training Day, HRA
Mr David Grenz	07/10/2013 - 07/10/2013	Equality & Diversity, HRA
Dr David Henson	07/10/2013 - 07/10/2013	Equality & Diversity, HRA
Dr David Henson	07/10/2013 - 07/10/2013	HRA Members Training Day, HRA
Dr Helen Sammons	07/10/2013 - 07/10/2013	HRA Members Training Day, HRA
Dr Helen Sammons	07/10/2013 - 07/10/2013	Equality & Diversity, HRA
Dr Nicholas Taub	07/10/2013 - 07/10/2013	HRA Members Training Day, HRA
Dr Nicholas Taub	07/10/2013 - 07/10/2013	Equality & Diversity, HRA
Mr Phil Hopkinson	07/10/2013 - 07/10/2013	HRA Members Training Day, HRA
Mr Phil Hopkinson	07/10/2013 - 07/10/2013	Equality & Diversity, HRA
Mr Peter Korczak	04/10/2013 - 04/10/2013	NREAP / Chair's Meeting, HRA
Mr Peter Korczak	12/11/2013 - 12/11/2013	Equality & Diversity, Employer
Mr Peter Korczak	08/11/2013 - 08/11/2013	East Midlands NREAP/REC Chairs' Network Meeting, HRA
Mr Peter Korczak	27/03/2014 - 27/03/2014	Misconduct in research: A descriptive survey of attitudes, perceptions and associated factors.

Mr Peter Korczak	08/03/2014 - 08/03/2014	Consent and assent in paediatric research in low-income settings - Biomed Ethics
Mr Peter Korczak	05/02/2014 - 05/02/2014	Procedures of recruiting, obtaining informed consent and compensating research participants in Qatar
Mr Peter Korczak	22/01/2014 - 22/01/2014	Patients; perceived purpose of clinical informed consent: Mill's individual autonomy model is preferred.
Mr Peter Korczak	24/12/2013 - 24/12/2013	Study participants incentives, compensation and reimbursement in resources-constrained settings – Biomed Ethics
Mr Peter Korczak	31/03/2014 - 31/03/2014	8 other relevant articles throughout 2013 - Biomed Ethics
Dr Brian Hands	24/09/2013 - 24/09/2013	Nottingham REC Centre Local Training Day, HRA
Dr Brian Hands	24/09/2013 - 24/09/2013	Equality & Diversity, 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	13	22.80
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	6	10.53
Research Database	6	10.53
Others	32	56.14
Total Applications Reviewed	57	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	0
Number of studies withdrawn prior to the meeting	12
Number of student applications reviewed	15
Number of paediatric applications reviewed	4
Number of device applications reviewed	1
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	0	0.00
Favourable Opinion with Additional Conditions	6	10.52
Unfavourable Opinion	5	8.78
Provisional Opinion	46	80.70
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	57	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	43	75.44
Further Information Favourable Opinion with Additional Conditions	1	1.75
Further Information Unfavourable Opinion	1	1.75
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	6	10.54
Unfavourable Opinion	5	8.77
Provisional Opinion	1	1.75
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	57	100

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

Total Applications Reviewed	32
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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	11	34.38
Favourable Opinion with Additional Conditions	6	18.75
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	14	43.75
Unfavourable Opinion	1	3.13
Total	32	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.18
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	28
Number of days taken to final decision - mode	30
Number of SSAs (non-Phase 1) reviewed	1
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	135
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	2
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
05/MRE04/17 +5	Paediatric Intensive Care Audit Network (PICANet)	56
08/H0405/22+5	Children's Cancer and Leukaemia Group (CCLG) Tissue Bank	53
08/H0405/48+5	DAFNE Research Database	55
09/H0405/30+5	Baby Bio Bank	21
13/EM/0159	BREVITY: Brentuximab vedotin in patients with Hodgkin lymphoma	34
13/EM/0177	MRI to study cognitive changes following breast cancer chemotherapy.	37
13/EM/0184	Surrogate decision making in learning disability	9
13/EM/0192	The effects of tinnitus on memory and attention. Version 2	31
13/EM/0193	A feasibility study of 7, 10 and 14 days of IV treatment in bronchiec	31
13/EM/0196	The University of Leicester Cancer Research Biobank.	43
13/EM/0232	Emergency Department Neurocognitive Testing in mild TBI	9
13/EM/0235	MBSR in Parkinson's a feasibility study - Version 1	8
13/EM/0245	Flexitouch dosing systematic evaluation (FlexDose)	59
13/EM/0248	A study to see the effect of OC000459 in people with eczema	27
13/EM/0264	UK LAM Cohort Version 1.0	24
13/EM/0267	Chronic kidney disease and pre-eclampsia	29
13/EM/0272	Centre for Human Reproductive Science - Reproductive Tissue Repository	56
13/EM/0275	HCV Community Study Version 1	12
13/EM/0287	Respiratory Research Database	49
13/EM/0294	Developing a structured intervention for acute mental health admission	34
13/EM/0305	Efficacy & Safety of Liraglutide vs Lixisenatide in Type 2 Diabetes	32
13/EM/0311	Gene and protein expression in the kidney	9
13/EM/0312	Evaluation of Dentifrice Foam	9
13/EM/0313	Paediatric Bipolar Disorder in the US vs.UK V.1	8
13/EM/0314	Treatments for uro-gynaecological problems and patient self-reports v1	8
13/EM/0325	Oral Semaglutide Dose Range in Type 2 (SNAC)	31
13/EM/0338	Vs1 - Mesothelioma; bereaved carers experience of end of life care.	25
13/EM/0352	Do beliefs about medicine predict adherence?	10
13/EM/0355	RAmSES	32
13/EM/0359	Helius in Hypertension-1 Registry Study	37

13/EM/0363	Physiological Effects of Isoeffective Colloid Vs Crystalloid Infusion	26
13/EM/0381	Using ultrasound to predict the results of draining pleural effusions	12
13/EM/0395	Treatment of Advanced Glaucoma Study (TAGS)	41
13/EM/0398	EPIVIN trial (v 1.0)	26
13/EM/0407	The PRIMACY project: Making difficult decisions	31
13/EM/0411	TMAO levels and CAD Risk	29
13/EM/0431	Carers' experiences of supporting a person with heart failure	38
13/EM/0435	Expectations and reality of infant feeding	50
13/EM/0438	The Heel Ulcer Microbiome in Diabetes	33
13/EM/0442	TITRATION - LCZ696 safety and tolerability in HFREF patients	33
13/EM/0464	The Role of Acceptance in Adjustment to Ménière's Disease	14
14/EM/0008	Measurement of Human Gait in an Interactive Environment Ver. 01	42
14/EM/0016	Young Carers and Palliative Care	41
14/EM/0017	GS-US-337-0124: Sofosbuvir/Ledipasvir Fixed-Dose Combination+Ribavirin	29
14/EM/0021	Patients' experience of formulation-sharing with Clinical Psychology	32
14/EM/0031	Infra-red thermal imaging of the surgical wound: ver 1	30
14/EM/0033	CFT for severe and complex mental health problems	45
14/EM/0044	Multidisciplinary fatigue management programme for people with CMT	30
14/EM/0047	Component Analysis of Acceptance and Commitment Therapy	30
14/EM/0063	Phase 1 DESoP with Eribulin with relapsed metastatic cancer patients	23
14/EM/0074	Clinical effects of inhaled mannitol	7
14/EM/0091	Microbiota in Asthma	27
14/EM/0101	1237.16 Tiotropium + Olodaterol (PHYSACTO[™]) in COPD	26
14/EM/0105	High flow nasal oxygen after lung resection surgery	22
14/EM/0106	RESILIENT	27
14/EM/0120	Evaluation of different Informed Consent models in Breast Surgery	8

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/EM/0326	Haemoconcentration of cardiopulmonary bypass blood with Hemosep	34
13/EM/0425	Qualitative outcomes of cultured limbal epithelial transplantation	12

Further Information Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/EM/0194	Sutures vs. sterile strips for closure of shoulder arthroscopy portals	52

Favourable Opinion with Standard Conditions		
REC Reference	Application Short Title	Number of Days on Clock
13/EM/0181	in vitro modelling of hypoplastic left heart syndrome version 1.0	13
13/EM/0190	Ovarian cancer biomarker case-control study	7
13/EM/0191	Identifying biomarkers and risk factors for colorectal cancer	7
13/EM/0279	Body weight and dietary intake in adults undergoing HCV treatment v1.0	7
13/EM/0282	Total inhibin and CA125 in ovarian cancer	7
13/EM/0283	Colorectal and lung cancer biomarker studies	7
13/EM/0380	Role of immunohistochemical markers in subtyping endometrial cancers	4
13/EM/0479	ASPIRE	9
14/EM/0035	Does colour enhance emotional well-being in primary care? V1 16/12/13	6
14/EM/0069	NU:LEVEL	9
14/EM/0117	Anterior resection syndrome following sphincter-preserving surgery	10

Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
13/EM/0154	Scaphoid Waist Internal Fixation for Fractures (SWIFFT) Trial (v1)	37
13/EM/0155	Chronic Kidney Disease Symptoms Study (CKDSX)	42
13/EM/0158	Information effect on patient anxiety levels and satisfaction	31
13/EM/0234	Arthritis Research Database	31
13/EM/0285	The Role of Feedback on Adherence to Amblyopia Treatment - Version 1	34
13/EM/0394	Pramipexole in post-stroke aphasia (re-submission)	41
13/EM/0421	Perceptions of Perineal Repair (version 1)	9
14/EM/0039	Beta-Trace Protein and RRF	6
14/EM/0067	Immune response of lymphocytes to auto-antigens and epitopes	10
14/EM/0068	Designing a Questionnaire to Assess Patient Journey in Chronic Pain	6
14/EM/0116	Determining cognition in haemodialysis	9
14/EM/0118	Diabetes management by young people during alcohol consumption.	9

Unfavourable Opinion		
REC Reference	Application Short Title	Number of Days on Clock
13/EM/0224	Database of pregnancy outcomes in women with a history of psychosis	21
13/EM/0265	Randomised controlled trial of surgical management of haemorrhoids	26
13/EM/0320	Pramipexole in aphasia	21
13/EM/0322	Adductor canal block for day case knee surgeries. version 3.5	21
13/EM/0382	Comparison of K-wire fixation and ORIF for distal radius fractures	4
14/EM/0015	PaMIR: Parkinson MR Imaging Repository	27

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