

National Research Ethics  
Service

  
*Health Research Authority*

# NRES Committee East Midlands - Leicester

## Annual Report

**01 April 2013 – 31 March 2014**

## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	NRES Committee East Midlands - Leicester
<b>Type of REC:</b>	Recognised to review CTIMPs in Patients – Type III
<b>Type of Flag:</b>	CTIMPs IRB – Independent Review Board
<b>Chair:</b>	Professor Geoff Dickens
<b>Vice-Chair:</b>	Mr John Baker
<b>REC Manager:</b>	Maria Morledge and Wendy Rees
<b>PRSC Co-ordinator:</b>	Miss Leni Robson and Miss Joanne Unsworth
<b>REC Assistants:</b>	Miss Leni Robson and Miss Joanne Unsworth
<b>Committee Address:</b>	The Old Chapel Royal Standard Place Nottingham NG1 6FS
<b>Telephone:</b>	0115 8839368 or 0115 8839436
<b>Email:</b>	<a href="mailto:nrescommittee.EastMidlands-Leicester@nhs.net">nrescommittee.EastMidlands-Leicester@nhs.net</a>

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

This has been a very interesting and challenging first year as the Chair of the Leicestershire NHS REC. The early part of the year was characterise by frequent changes of Co-ordinator which may have led to some inconsistency and a lengthier period of settling in than may ideally have been the case. I am pleased to say that this has been rectified and a regular co-ordinator is now in situ with evidence of succession planning which is welcome. Over the course of the year I have lost a number of Committee members who have come to the end of their tenure or who have otherwise had to bow out and I shall miss their thoughtful insights and diverse opinions. Special mention should go to Dr Iain Williamson and Ms Madeline Wang in this regard. My Vice-Chair Mr John Baker acts as an excellent deputy. From the start of my tenure the Ethics Officer Pilot was already well underway. This was an interesting and useful exercise; I hope it is something that NRES will support, though my preference would be for the ethics officer to provide advice at an earlier stage if at all possible.

## 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	
Mr Steve Barrett	Research Coordinator	Lay	22/07/2008	
Dr Paul Beeson	Senior Lecturer	Lay	07/12/2012	
Miss Stephanie Deveney	Occupational Therapist	Expert	01/12/2011	
Professor Geoff Dickens	Research Manager & Head of Nursing Research	Expert	07/06/2013	
Mrs Sandra Hall	Principal Lecturer in Clinical Pharmacy & Pharmacy Practice	Expert	20/10/2006	
Dr Sally Hinchliffe	Medical Statistician	Expert	12/07/2013	
Dr Nicola James	Independent Research Consultant	Expert	10/01/2014	
Dr Michelle Pyer	Researcher	Expert	01/09/2011	11/04/2013
Mrs Madeline Wang	Patient Advocate	Lay Plus	01/04/2011	22/11/2013
Mrs Valerie Webb	Nurse	Expert	01/02/2005	11/03/2014
Ms Rose Webster	Education and Practice Development Lead for Acute Care	Expert	01/04/2003	01/05/2013
Dr Iain Williamson	Senior Lecturer in Psychology	Expert	25/05/2008	31/12/2013

### Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Reverend Keith Lackenby	Lay member	Lay Plus	05/04/2013
Mr John Aldridge	Senior Lecturer in Nursing	Expert	07/06/2013
Mr Ken Willis	Medical Devices Manager	Lay Plus	07/06/2013
Reverend Keith Lackenby	Lay member	Lay plus	04/10/2013
Mrs Anne Walker	Lay Member	Lay Plus	01/11/2013
Reverend Keith Lackenby	Lay Member	Lay Plus	01/11/2013

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

Name	Declaration of Interest	Date
Dr Sally Hinchliffe	Employed by R&D Department at Royal Derby Hospital as Medical Statistician. Expert reviewer for NIHR Funding Applications.	12/09/2013
Dr Nicola James	None	10/01/2014
Professor Geoff Dickens	Any connection, including any position of authority, in a charity or voluntary body in the field of health and social care involved in or possibly seeking to be involved in the conduct of research: Research manager, St Andrew's Healthcare Any other activities or interests likely to be related to the conduct of research: Professor in Psychiatric Nursing, University of Northampton	06/12/2013
Mr John Baker	None	26/11/2013
Mrs Sandra Hall	None	06/12/2013
Dr Paul Beeson	None	06/12/2013
Miss Stephanie Deveney	None	06/12/2013
Mrs Valerie Webb	Any other activities or interests likely or possibly likely to be related to the conduct of research: Work as a research nurse within NHS Trust	03/12/2013
Mr Steve Barrett	None	01/12/2013
Miss Alison Armstrong	Receive 4 hours per week of salary from local clinical research network to help run portfolio studies for MSK. Receive - 4 hrs of salary per week to UHL Clinical management group research lead for musculoskeletal surgery and spinal surgery to lead on research for the management group, research especially portfolio research and others.	01/01/2014

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

<b>Month</b>	<b>Date</b>	<b>Number of Members Present at Meeting</b>
April	05/04/2013	8
June	07/06/2013	8
July	05/07/2013	8
September	06/09/2013	11
October	04/10/2013	8
November	01/11/2013	7
December	06/12/2013	7
January	10/01/2014	8
February	07/02/2014	9

9 full committee meetings were held during the reporting period.

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

<b>Month</b>	<b>Date</b>	<b>Number of Members Present at Meeting</b>
April	05/04/2013	3
June	07/06/2013	3
July	05/07/2013	3
August	02/08/2013	3
September	06/09/2013	3
October	04/10/2013	3
November	01/11/2013	3
December	06/12/2013	3
January	10/01/2014	3
February	07/02/2014	3

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

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr John Baker	9
Professor Geoff Dickens	8
Mrs Sandra Hall	7
Dr Paul Beeson	7
Mrs Valerie Webb	6
Mr Steve Barrett	6
Dr Sally Hinchliffe	5
Dr Iain Williamson	5
Miss Alison Armstrong	4
Miss Stephanie Deveney	3
Mrs Madeline Wang	3
Dr Nicola James	2

**Number of inquorate meetings held: None**

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr John Baker	8
Professor Geoff Dickens	8
Mrs Sandra Hall	2
Mrs Valerie Webb	2
Mr Steve Barrett	2
Dr Paul Beeson	2
Miss Alison Armstrong	2

**Training 01 April 2013 – 31 March 2014:**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr Paul Beeson	05/04/2013 - 05/04/2013	Shared Ethical Debate, Leicester REC Meeting
	11/04/2013 - 11/04/2013	When is it ethical to carry out medical research in developing countries, University of Northampton
	23/04/2013 - 23/04/2013	Induction, NHS Research Ethics Committee
	28/04/2013 - 28/04/2013	IRAS Training Module
	15/07/2013 - 15/07/2013	NRES Guidance on Information Sheets & Consent Forms
	16/07/2013 - 16/07/2013	IRAS Training Module
Mrs Sandra Hall	26/04/2013 - 26/04/2013	National Institute for Health Research Clinical Trials Toolkit
	29/04/2013 - 29/04/2013	Information paper on NRES informed consent in CTIMPs
Professor Geoff Dickens	08/11/2013 - 08/11/2013	NREAP/REC Chair's Meeting
	19/02/2014 - 19/02/2014	Reviewing CTIMPs, Health Research Authority
Mrs Valerie Webb	24/09/2013 - 24/09/2013	East of England Regional Training Day, East Midlands REC Centre - HRA
Dr Sally Hinchliffe	09/10/2013 - 09/10/2013	East Midlands Regional Training Day, Nottingham REC Centre
Mr John Baker	23/10/2013 - 23/10/2013	West Midlands Regional Training Day, Nottingham REC Centre
Mr Steve Barrett	12/03/2014 - 12/03/2014	Self-Directed Learning - Podcast on data Protection Law
	13/03/2014 - 13/03/2014	Self-Directed Learning log - Listen to University Podcast on Equality Act 2010 & staff/students
	10/03/2014 - 15/03/2014	Self-Directed Learning Log - Nice Guidance

**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	16	37.21
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	27	62.79
<b>Total Applications Reviewed</b>	<b>43</b>	<b>100</b>

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

Number of applications made invalid by co-ordinator	3
Number of studies withdrawn prior to the meeting	6
Number of student applications reviewed	13
Number of paediatric applications reviewed	2
Number of device applications reviewed	4
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:**

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	15	34.88
Unfavourable Opinion	2	4.65
Provisional Opinion	26	60.47
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>43</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	26	60.47
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	15	34.88
Unfavourable Opinion	2	4.65
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
<b>Total</b>	<b>43</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>26</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	5	19.23
Favourable Opinion with Additional Conditions	4	15.38
No Opinion transfer to full committee for review	2	7.69
Provisional Opinion	12	46.15
Unfavourable Opinion	3	11.54
<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>	4.30
<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>	34
<b>Number of days taken to final decision - mode</b>	26
<b>Number of SSAs (non-Phase 1) reviewed</b>	5
<b>Number of applications for SSA review over 25 days</b>	1
<b>Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)</b>	20.0%
<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>	155
<b>Number of substantial amendments over 35 days</b>	1
<b>Number of substantial amendments over 35 days as a % of total substantial amendments</b>	0.6%
<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>	1
<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>	1
<b>Number of proportionate review applications over 14 days as a % of total</b>	4.2%

**Table 8: Breakdown of current status of all 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>
13/EM/0116	Women's expectations/experiences of a good midwife and places of birth	20
13/EM/0226	Extended cohort for e-health, environment and DNA (EXCEED) Study	33
13/EM/0228	BESIDE 905-EC-012 Version 2.0	29
13/EM/0229	Pre-School Use of Integrated Wireless Hearing Aids and Transmitter	38
13/EM/0230	VS-6063 Phase II Mesothelioma study	46
13/EM/0242	Long-stay patients in high and medium secure forensic psychiatric care	28
13/EM/0247	A comparison of MaxPlus Clear and MicroClave IV connectors version 1.	31
13/EM/0259	PREVIEW	40
13/EM/0263	LIME Study (LFB IVIG MMN Efficacy Study)	30
13/EM/0315	Mindfulness and COPD qualitative study	13
13/EM/0316	Patient perceptions of clinical trials in emergency medicine	13
13/EM/0317	SLS Follow-up Interviews	13
13/EM/0318	Investigation into the Attendance of Cardiac Rehabilitation	14
13/EM/0323	Asthma-Tailored Pulmonary Rehabilitation	46
13/EM/0340	ABT-199 Monotherapy in Relapsed/Refractory CLL With the 17p Deletion	33
13/EM/0373	C16017 Ph2 Study of Oral MLN9708 in Patients with Follicular Lymphoma	35
13/EM/0374	A3384 in BAM/BAD	31
13/EM/0375	Triple 6 - A Phase III Study of CHF5993 in Patients with Severe COPD	32
13/EM/0385	Using the Kinect™ to Measure Changes in Arm Movement After Stroke	19
13/EM/0386	Possibility of double vision: two methods of assessment (version 1)	14
13/EM/0392	Recovery after stroke: the role of illness beliefs	48
13/EM/0396	Barriers and facilitators in therapy for people with LD	32
13/EM/0404	Serelaxin vs standard of care in acute heart failure patients	36
13/EM/0439	Commissioning IAPT: equity of access	55
13/EM/0466	Diabetes Self Management Questionnaire Validation (Ethics Submission)	13
13/EM/0469	Developing and testing a tool to measure Therapeutic Engagement (TE)	14
14/EM/0001	TREND	35
14/EM/0005	REMODEL trial	51
14/EM/0006	Assessment of Neonatal Indicators (ANI). Version 1	35

14/EM/0007	Help-seeking experiences of adoptive parents Version 1	35
14/EM/0022	ECU-MG-301 Phase 3 Study of Eculizumab in Subjects with GMG	37
14/EM/0034	GO28667 - PH III, OPEN-LABEL, IN RELAPSED/REFRACTORY PATIENTS WITH CLL	46
14/EM/0042	Service users' perceptions of professional peer support work	28
14/EM/0052	STARTREC version 1.0	60
14/EM/0070	The use of the Ret-He measurement in renal patients.	14
14/EM/0071	Group Cohesion in Multifamily Therapy with multilingual families	14
14/EM/0072	Vitamin D and Multiple Sclerosis	12
14/EM/0076	Ownership of mobile technologies by substance misuse patients	14

<b>Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
13/EM/0244	Xpert HPV Assay screening sample evaluation	10
13/EM/0280	Introduction of intravenous Infusion pumps for Platelet Transfusion	7
13/EM/0356	Modelling labour induction timing in prolonged pregnancy (V1)	7
13/EM/0419	Outcome following SAH	7
14/EM/0038	An Exploratory Study of Available Support Pre & Post Adoption	12

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
13/EM/0123	Community Liver Biomarkers Cohort	37
13/EM/0132	Sarilumab in Rheumatoid Arthritis - COMPARE study	19
13/EM/0133	PTSD in COPD	30
13/EM/0150	Newer oral anticoagulants and antiphospholipid syndrome	3
13/EM/0211	BYPaSS: a Bariatric surgery ProSpective cohort Study. Version 1.0.	40
13/EM/0241	An educational programme for assessing risk in stroke patients' homes.	7
13/EM/0254	Visual impairment due to VEGF driven Macular Oedema	27
13/EM/0328	GnRH-antagonist vs co-flare protocol for women of low ovarian reserve	26
13/EM/0339	Hematopoietic Stem Cell Therapy for Inflammatory MS	26
13/EM/0354	Helium thermocoagulation versus electrosurgery for endometriosis.	47
13/EM/0365	Detection of Melanoma using Terahertz Imaging, ver 1.00	26

13/EM/0376	Skin imaging in human disease.	26
13/EM/0397	Virtual Reality for Risk Assessment after Stroke	35
13/EM/0440	Personality Disorder, Anger, Aggression and the Therapeutic Alliance 3	25
13/EM/0457	GE tomosynthesis versus supplementary mammographic views	26
13/EM/0467	Needs and Experiences of Non-English speaking families	13
14/EM/0024	Efficacy and safety of secukinumab in pts with Psoriatic Arthritis	32
14/EM/0037	EVALUATING FATIGUE IN DIALYSIS PATIENTS	9
14/EM/0050	Heart Rate Activity & Compassion Focused Therapy for Eating Disorders	26

#### Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/EM/0124	Pre-School Use of Integrated Wireless Hearing Aids and Transmitter	19
13/EM/0202	Parent and HCP use of language to describe acutely sick children	35
13/EM/0237	Influence of infant dietary patterns on allergy development	6
13/EM/0358	The psychosocial impact of Von Hippel-Lindau disease v1.0	10
13/EM/0360	Vaccination treatment and knowledge in patients with bronchiectasis	9

**Table 9: Items exceeding timelines:**

<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>	
13/EM/0385	Using the Kinect™ to Measure Changes in Arm Movement After Stroke	19	

  

<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>	
13/EM/0179	CANTOS:CACZ885M2301 Canakinumab in postMI patients with raised hsCRP	28	

  

<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>
09/H0406/106/AM16	Ofatumumab vs Rituximab in Relapsed or Refractory DLBCL	Substantial Amendment No 13	36