

National Research Ethics  
Service

  
*Health Research Authority*

**NRES Committee East Midlands -  
Northampton**

**Annual Report**

**01 April 2013 – 31 March 2014**

## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	NRES Committee East Midlands - Northampton
<b>Type of REC:</b>	RECs recognised to review CTIMPS in patients - type iii
<b>Type of Flag:</b>	RECs recognised to review CTIMPS in patients - type iii
<b>Chair:</b>	Mr Ken Willis
<b>Vice-Chair:</b>	Mr Mike Newman
<b>Alternate Vice-Chair:</b>	Mr John Aldridge
<b>Co-ordinator:</b>	Jessica Parfremment/Dawn Denton/Rebecca Morledge
<b>PRSC Co-ordinator:</b>	Miss Victoria Strutt
<b>Assistant Co-ordinator:</b>	Miss Victoria Strutt
<b>Committee Address:</b>	The Old Chapel Royal Standard Place Nottingham NG1 6FS
<b>Telephone:</b>	0115 883 9440
<b>Email:</b>	NRESCommittee.EastMidlands-Northampton@nhs.net

## Chair's overview of the past year:

I am pleased with performance of the Northampton committee. We have had numerous changes in support arrangements and membership, however these changes have been accepted and adopted in a way that ensured that the committee core business continued in an efficient and effective manner and this gives me pride in the efforts of the members and support team.

My thanks go out for the support from other committees when co-opted members have been required, which was not frequent.

I would also like to thank John Aldridge for taking over the role as chair so effectively at short notice.

We have dealt with a wide range of interesting and diverse applications which have all brought their challenges when reviewing them. Many applications would have been granted a favourable opinion at first review if the NRES guidelines regarding documentation had been more effectively followed. The majority of applications that receive a provisional opinion is in my opinion is due to the researcher failing to look at the documentation package from a participants eyes in order to ensure that all facts are given and any possible doubts are covered within the participant information leaflet. This is very difficult especially at student level and academic support could be vital at this stage of the research development.

We have reviewed some novel and interesting topics as well as clinical research intended to reduce suffering and improve the quality of people's lives and I hope that as a committee we support research by helping to allay doubt and resolve any ethical issues prior to research commencement, I look forward to meeting next years' challenges as well as the opportunity to discuss the research proposals with the research representatives at forthcoming meetings.

## NRES Committee East Midlands - Northampton Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mr John Aldridge	Senior Lecturer in Nursing	Expert	24/04/2008	
Ms Elaine Blackshaw	Clinical Trial Manager	Expert	29/02/2008	26/02/2013
Mr Alan Caswell	Lay Member	Lay	01/12/2011	
Mrs Jeanne-Anne Charly	Staff Nurse	Expert	08/07/2013	
Dr Belinda Cupid	Head of Research -MND Association	Lay	20/12/2012	
Mr James Simon Deery	Student	Lay	20/12/2012	03/12/2013
Mrs Lorenza Francescut	Research Technician	Lay	15/04/2008	06/06/2013
Ms Elizabeth Gibbons	Senior Research Officer	Expert	13/07/2011	
Ms Sarah Hamill	cardiology research nurse	Expert	20/03/2014	
Dr Brendan Laverty	Lay Member	Lay	11/03/2014	
Mr Stuart Campbell Watson	Retired Senior Lecturer in Education	Lay Plus	20/12/2012	
Mrs Sarah Elizabeth Westwater-Wood	Lecturer	Expert	20/12/2012	
Mr Ken Willis	Medical Devices Manager	Lay Plus	17/01/2005	
Mr Mike Newman	Consultant Gynaecologist	Expert	08/04/2005	10/04/2014

### Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Mrs Janet Mallet	Lay Member	Lay Plus	18/04/2013
John Baker	Lay Member	Lay Plus	17/10/2013

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

Name	Declaration of Interest	Date
Mr Ken Willis	None	14/02/2014
Mr Alan Caswell	None	14/02/2014
Mr Stuart Campbell Watson	None	14/02/2014
Dr Belinda Cupid	None	14/02/2014
Mrs Sarah Elizabeth Westwater-Wood	University of Nottingham lecturer, propose and supervise undergraduate research. MRC fund holder for a concluding project Supervise undergraduate research proposal screening for ethical issues	14/02/2014
Mr John Aldridge	None	14/02/2014
Mrs Jeanne-Anne Charly	None	14/02/2014
Ms Elizabeth Gibbons	Researcher at University of Oxford	14/02/2014
Ms Sarah Hamill	none	21/03/2014
Mr Brendan Laverty	None	21/03/2014

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

Month	Date	Number of Members Present at Meeting
April	18/04/2013	8
May	16/05/2013	8
June	20/06/2013	8
July	18/07/2013	8
September	19/09/2013	9
October	17/10/2013	7
November	21/11/2013	8
December	19/12/2013	7
January	16/01/2014	9
February	20/02/2014	9
March	20/03/2014	9

11 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	18/04/2013	3
May	16/05/2013	3
July	18/07/2013	3
September	19/09/2013	3
October	17/10/2013	3
November	21/11/2013	3
December	19/12/2013	3
January	16/01/2014	3
February	20/02/2014	3
March	20/03/2014	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 Alan Caswell	11
Mr John Aldridge	11
Mr Ken Willis	10
Mr Stuart Campbell Watson	10
Mrs Sarah Elizabeth Westwater-Wood	9
Dr Belinda Cupid	9
Ms Elizabeth Gibbons	8
Mrs Jeanne-Anne Charly	6
Mr Mike Newman	6
Mr James Simon Deery	5
Mrs Lorenza Francescut	1
Ms Sarah Hamill	1
Dr Brendan Laverty	1
Mr John Baker	1

**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 Ken Willis	10
Mr John Aldridge	9
Mr Stuart Campbell Watson	3
Ms Elizabeth Gibbons	2
Dr Belinda Cupid	2
Dr Stuart Watson	1
Mr Alan Caswell	1
Mrs Jeanne-Anne Charly	1
Mrs Lorenza Francescut	1

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

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr Belinda Cupid	23/04/2013 - 23/04/2013	Induction, HRA
Mr Stuart Campbell Watson	23/04/2013 - 23/04/2013	Induction, hra
Mrs Sarah Elizabeth Westwater-Wood	23/04/2013 - 23/04/2013	Induction, HRA
Mr James Simon Deery	10/07/2013 - 10/07/2013	Induction, HRA
Mr James Simon Deery	09/07/2013 - 09/07/2013	Qualitative Research and Ethical Review, HRA
Mr James Simon Deery	29/04/2013 - 29/04/2013	Equality & Diversity, HRA
Mrs Jeanne-Anne Charly	09/09/2013 - 09/09/2013	Induction, HRA
Mr Alan Caswell	07/10/2013 - 07/10/2013	Nottingham REC Centre Local Training Event, HRA
Mr Stuart Campbell Watson	07/10/2013 - 07/10/2013	Nottingham REC Centre Local Training Event, HRA
Mrs Sarah Elizabeth Westwater-Wood	07/10/2013 - 07/10/2013	Nottingham REC Centre Local Training Event, HRA
Mr John Aldridge	23/10/2013 - 23/10/2013	Nottingham REC Centre Local Training Event, HRA
Mrs Jeanne-Anne Charly	07/10/2013 - 07/10/2013	Nottingham REC Centre Local Training Event, HRA
Mr Ken Willis	08/11/2013 - 08/11/2013	NREAP / Chairs Network Meeting - Half Day, HRA
Mr John Aldridge	23/10/2013 - 23/10/2013	Equality & Diversity
Mr Alan Caswell	07/10/2013 - 07/10/2013	Equality & Diversity, HRA
Mrs Jeanne-Anne Charly	07/10/2013 - 07/10/2013	Equality & Diversity, HRA
Mr Stuart Campbell Watson	07/10/2013 - 07/10/2013	Equality & Diversity, HRA
Mrs Sarah Elizabeth Westwater-Wood	07/10/2013 - 07/10/2013	Equality & Diversity, HRA
Mr Ken Willis	06/10/2013 - 22/12/2013	Reading statistical Methods in medical research
Mr Ken Willis	03/01/2014 - 03/01/2014	Medical statistics - Reading Medical Statistics in Medical Research

## 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	22	42.31
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	30	57.69
<b>Total Applications Reviewed</b>	<b>52</b>	<b>100</b>

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

Number of applications made invalid by co-ordinator	5
Number of studies withdrawn prior to the meeting	2
Number of student applications reviewed	10
Number of paediatric applications reviewed	0
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:**

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	1	1.92
Favourable Opinion with Additional Conditions	8	15.38
Unfavourable Opinion	2	3.85
Provisional Opinion	41	78.85
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>52</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:**

Status of applications at date of generation of report	Number	%
Further Information Favourable Opinion with Standard Conditions	39	75.00
Further Information Favourable Opinion with Additional Conditions	2	3.85
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	1.92
Favourable Opinion with Additional Conditions	8	15.38
Unfavourable Opinion	2	3.85
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>52</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>27</b>
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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	3	11.11
Favourable Opinion with Additional Conditions	6	22.22
No Opinion transfer to full committee for review	2	7.41
Provisional Opinion	14	51.85
Unfavourable Opinion	2	7.41
<b>Total</b>	<b>27</b>	<b>100</b>

**Table 7: Other Management Information for the reporting period:**

<b>Average number of applications reviewed per full meeting</b>	4.73
<b>Number of applications for full ethical review over 60 days</b>	1
<b>Number of applications over 60 days as a % of total</b>	1.92%
<b>Number of days taken to final decision - average</b>	33
<b>Number of days taken to final decision - mode</b>	20

<b>Number of SSAs (non-Phase 1) reviewed</b>	0
<b>Number of applications for SSA review over 25 days</b>	0
<b>Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)</b>	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>	108
<b>Number of substantial amendments over 35 days</b>	0
<b>Number of substantial amendments over 35 days as a % of total substantial amendments</b>	0.0%

<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>	2
<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>	0
<b>Number of proportionate review applications over 14 days as a % of total</b>	0.0%

**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/0125	Biomarker expression and response to Chemo-radiotherapy in NSCLC	22
13/EM/0149	15961 GadaCAD1	20
13/EM/0162	Patient decision making in total joint replacement	11
13/EM/0163	Creatively preparing children for blood-taking	8
13/EM/0183	Communication and Understanding of Distress in Female Forensic Care	35
13/EM/0187	Nottingham Fatigue After Stroke (NotFAST) study	39
13/EM/0195	HGS1006-C1112 Phase 3/4 Study of Belimumab in Black Race SLE Patients	29
13/EM/0200	Investigating the relationship between skin AGE, HbA1C & Periodontitis	59
13/EM/0209	Clozapine and hypogammaglobulinaemia	11
13/EM/0223	Comparing the sensitivity of methods for diagnosing ulnar neuropathy	33
13/EM/0225	Evaluation of ocular surface inflammation with glaucoma drops	40
13/EM/0227	USURP-AF	37
13/EM/0253	C-GLOVES: the effectiveness of compression gloves in arthritis	47
13/EM/0266	Low dose cyclophosphamide +/- nintedanib in advanced ovarian cancer	25
13/EM/0270	ASK SNIFF: ASK SID (Safety netting Intervention Development) study	34
13/EM/0274	Evaluate Effect of a Toothpaste on Chlorhexidine Tooth Staining	26
13/EM/0299	A qualitative study to explore how adolescents cope with Haemophilia	14
13/EM/0324	Evaluation of NeuroText for people with Multiple Sclerosis Version 1	60
13/EM/0344	ExTra CKD	59
13/EM/0346	ZS-004	47
13/EM/0348	Monoprost® compared with Lumigan® in POA glaucoma/ocular hypertension	45
13/EM/0349	MANTA	60
13/EM/0353	Working after Brain Injury Final Version 1.0	45
13/EM/0367	Music in MRI	9
13/EM/0379	Incentive-based Smoking Cessation During Pregnancy	68
13/EM/0414	Study of Eosinophilic Granulomatosis with Polyangiitis and Mepolizumab	33
13/EM/0422	DILICIN	24
13/EM/0423	GWP42004 in Type 2 diabetes	30
13/EM/0424	Study of Pridopidine to reduce symptoms in patients with Huntington's	48

13/EM/0444	Long-term effect of NBUVB on Atopic Eczema Version 1	13
13/EM/0454	Prevalence of Vitamin D deficiency in Psychiatric Outpatients	43
13/EM/0460	Study of Adjuvant Kadcylla vs Herceptin, HER2+ve Primary Breast Cancer	29
13/EM/0461	Experience of Scar Management for Patients with Burn Injuries: IPA	28
13/EM/0468	ELIOT – Easy, Low Instruction Over Time v1.0	27
13/EM/0474	The Easy Read Project Version 1	13
13/EM/0476	ABSORB UK Registry V1	7
14/EM/0010	Social Stories as an intervention for adults with ASD and LD	41
14/EM/0028	Northamptonshire Care Home Improvement Project (NCHIP)	34
14/EM/0029	ECU-NMO-301 Phase3 study:Eculizumab for Relapsing Neuromyelitis Optica	21
14/EM/0030	ECU-NMO-302 Phase 3 Open-Label Extension Study of Eculizumab for NMO	21
14/EM/0046	AWARE	12
14/EM/0066	An indepth view of Metacognitive Training for women with schizophrenia	25
14/EM/0085	Cardiac ASL in Chronic Disease	22
14/EM/0086	Secukinumab in Ankylosing Spondylitis	26
14/EM/0088	Intimate partner violence perpetration by male substance misusers	24
14/EM/0089	Niraparib vs. physician choice in HER2 negative breast cancer	60
14/EM/0096	Service users experience of sport and its effects on mental health	9
14/EM/0098	Final validation EORTC Breast Reconstruction Quality of Life module	12
14/EM/0108	Role of Signal averaged P waves in predicting recurrence of AF.	51
14/EM/0124	GOLMEPsA	23
14/EM/0140	Music questionnaire development	10

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/EM/0144	ADIUVO version 1.0	25
13/EM/0246	Pulmonary AVM Cohort Study	30

#### 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
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13/EM/0164	ACL/Hamstring Reflex	4
13/EM/0403	Analysis of urine biomarkers of renal tubular damage	4
13/EM/0462	RomiCar	40
14/EM/0095	Supporting Ambulance Crews through Electronic Information Provision-P1	9

#### Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/EM/0145	Rheumatoid arthritis patients' views of Methotrexate leaflet	18
13/EM/0146	Effects of a modified Enzira® influenza vaccine, ver A	19
13/EM/0147	CMR Cardiac flow	21
13/EM/0186	Getting the Best from the Fit Note	35
13/EM/0205	VEGF changes in DME	9
13/EM/0207	Intra-centre and inter-centre standardisation of thromboelastography	7
13/EM/0377	[18F]HX4 PET/CT Imaging for Detection of Hypoxia (OXYPET Study) V1	22
13/EM/0383	The MaRACAS Study	23
13/EM/0456	Balloon intercostal drain pilot study	34
13/EM/0475	Metabolomic profiling in renal cell carcinoma	7
13/EM/0477	Pilot of capillary blood glucose testing in screening for diabetes v1	7
14/EM/0019	Measurement of metabolic activities in human tissue and cells	20
14/EM/0100	Cost-effectiveness of laparoscopic and open radical hysterectomy.	8
14/EM/0133	Cystoscopy and urethral dilatation - long term follow up of an RCT	4

#### Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/EM/0366	Validating the Orthostatic Health Questionnaire for use in Clinic	6
13/EM/0429	Saline Infusion Sonography	19
13/EM/0449	A Comparison of Service Provision within the IAPT Programme	7
14/EM/0123	14862A Phase III trial of Lu AE58054 in Alzheimer's Disease	20

#### Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
14/EM/0134	Pre-clinical evaluation of novel anti-leukemia therapies	N/A
14/EM/0141	Maternal and fetal physiology in pregnancy	N/A

<b>Provisional Opinion Pending Consultation with Referee</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
<b>Further information response not complete</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
<b>Withdrawn after the meeting</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
<b>Invalid Application</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
<b>No Opinion Pending Consultation with Referee</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
<b>Not Requiring Review by NHS REC</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

**Table 9: Items exceeding timelines:**

<b>Full applications for ethical review over 60 day timeline</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
13/EM/0379	Incentive-based Smoking Cessation During Pregnancy	68

<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>

<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>

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

<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>

<b>Modified Amendments over 14 day timeline</b>			
<b>Amendment Reference</b>	<b>Application Short Title</b>	<b>Amendment Title</b>	<b>Number of Days on Clock</b>

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