

National Research Ethics
Service


Health Research Authority

**NRES Committee West Midlands -
Edgbaston**

Annual Report

01 April 2013 – 31 March 2014

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee West Midlands - Edgbaston
Type of REC:	Recognised to review CTIMPS in Patients – type iii
Type of Flag:	Medical Device Study Phase 1 in Patients Research Involving Children
Chair:	Mr Paul Hamilton
Vice-Chair:	Dr Ronald Jubb
Alternate Vice-Chair:	Professor John Marriott
Co-ordinator:	Miss Rebecca Morledge/Miss Helen Wakefield
PRSC Co-ordinator:	Miss Rebecca Morledge/Miss Helen Wakefield
Assistant Co-ordinator:	Miss Rebecca Morledge/Miss Rachel Nelson
Committee Address:	The Old Chapel Royal Standard Place Nottingham NG1 6FS
Telephone:	0115 8839695
Email:	nrescommittee.westmidlands-edgbaston@nhs.net

Chair's overview of the past year:

It has been a relatively stable year for the committee with no major NRES initiatives imposing upon, or threatening the stability of, the committee. Theresa Hyde resigned during the reporting period for personal reasons. We have been very well supported by a number of staff from the Nottingham REC Centre.

The committee continues to process a large number of substantial amendments and I greatly appreciate the support of the Vice-Chair and Alternate Vice-Chair in this work. Proportionate review is well embedded in the committee and members share the work on a rota basis.

NRES Committee West Midlands - Edgbaston Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mr Chris Foy	Medical Statistician	Expert	01/05/2010	
Mr Paul Hamilton	Retired Local Government Officer	Lay Plus	08/12/2007	
Dr Adrian Hamlyn	Consultant Physician & Hepatologist	Expert	01/02/2007	
Mrs Theresa Hyde	Retired Head Teacher	Lay Plus	23/02/2006	18/11/2013
Miss Sarahjane Jones	Lay Member	Lay	05/02/2013	
Dr Ronald Jubb	Retired Consultant Rheumatologist	Expert	22/09/2004	
Dr Nigel Langford	Consultant Clinical Pharmacologist & General Physician	Expert	19/11/2008	
Professor John Marriott	Pharmaceutical Chemist/Academic Pharmacist	Expert	09/01/2008	
Mrs Alison Parsons	Lay Member	Lay Plus	01/01/2013	
Mr Philip Russell	Retired Head Teacher	Lay Plus	05/11/2008	
Dr Eric Silove	Retired Paediatric Cardiologist	Expert	16/01/2006	
Miss Heather Small	Heart Study Co-ordinator	Expert	20/02/2009	
Dr Michael Wolffe	Optometrist	Expert	01/04/2008	

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Reverend Keith Lackenby	Retired Reverend	Lay	20/11/2013

NRES Committee West Midlands - Edgbaston: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Dr Eric Silove	None	08/12/2013
Dr Nigel Langford	Employee of University Hospitals Leicester. Member of British Pharmacological Society and Society of Acute Medicine. Member of the Health Technology Assessment Committee C for NICE.	01/12/2013
Mr Philip Russell	Patient Services (PALS) representative. Member of At Heart of England NHS Trust. Volunteer at Good Hope Hospital, Sutton Coldfield.	01/12/2013
Mr Paul Hamilton	I have been an NRES Ethics Officer this year (2013). The current phase has just ended.	17/12/2013
Mr Chris Foy	Employed to advise NHS researchers in Gloucestershire and elsewhere in south west England on the design and conduct of their studies. Member of 2gether NHS Foundation Trust's Research and Development Committee.	18/12/2013
Professor John Marriott	Pharmacy Research lead, University of Birmingham Medical School. Member of the NIHR Research for Patient Benefit Scrutiny Committee (West Midlands).	01/12/2013
Dr Adrian Hamlyn	Member of the British Medical Association.	01/12/2013
Mrs Alison Parsons	None	01/12/2013
Miss Sarahjane Jones	Research Fellow, Birmingham City University. PhD Student, University of Warwick. Group Leader, Endometriosis UK. Research Mentor, Birmingham Community Healthcare, Research and Development Dept.	01/12/2013
Dr Ronald Jubb	None	01/12/2013
Dr Michael Wolffe	Trustee and Vice Chair, Partially Sighted Society. Trustee and Chair, Look - Federation of Families of Visually Impaired Children. Institute of Optometry REC. Vision 20/20 UK Research Committee. Chair BSI Committee CH/172. Membership of 150 TC/172/5C7. Leader of ISO Committee - Light Hazards Task Group.	01/12/2013
Miss Heather Small	None	15/01/2014

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

Month	Date	Number of Members Present at Meeting
April	17/04/2013	12
June	19/06/2013	8
July	17/07/2013	10
August	21/08/2013	10
September	18/09/2013	11
October	16/10/2013	9
November	20/11/2013	9
December	18/12/2013	10
January	15/01/2014	11
February	19/02/2014	11
March	19/03/2014	9

11 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
April	17/04/2013	3
June	19/06/2013	3
July	17/07/2013	3
August	21/08/2013	3
September	18/09/2013	3
October	16/10/2013	3
November	20/11/2013	3
December	18/12/2013	3
January	15/01/2014	3
February	19/02/2014	3
March	19/03/2014	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 Michael Wolffe	11
Mr Chris Foy	11
Mr Paul Hamilton	11
Dr Adrian Hamlyn	10
Professor John Marriott	10
Mr Philip Russell	9
Mrs Alison Parsons	9
Dr Eric Silove	8
Dr Ronald Jubb	8
Dr Nigel Langford	7
Miss Heather Small	6
Miss Sarahjane Jones	6
Mrs Theresa Hyde	3

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
Mr Paul Hamilton	10
Mr Philip Russell	3
Dr Adrian Hamlyn	3
Mr Chris Foy	3
Professor John Marriott	2
Dr Nigel Langford	2
Dr Ronald Jubb	2
Miss Heather Small	2
Mrs Alison Parsons	2
Mrs Theresa Hyde	1
Dr Michael Wolffe	1

Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Miss Sarahjane Jones	23/04/2013 - 23/04/2013	Induction, NRES / HRA
Dr Eric Silove	23/10/2013 - 23/10/2013	Equality & Diversity, HRA
Mr Paul Hamilton	23/10/2013 - 23/10/2013	Equality & Diversity, HRA
Professor John Marriott	23/10/2013 - 23/10/2013	Equality & Diversity, HRA
Dr Ronald Jubb	24/09/2013 - 24/09/2013	Equality & Diversity, HRA
Dr Nigel Langford	07/10/2013 - 07/10/2013	Equality & Diversity, HRA
Mr Philip Russell	07/10/2013 - 07/10/2013	Equality & Diversity, HRA
Dr Michael Wolffe	07/10/2013 - 07/10/2013	Equality & Diversity, HRA
Mr Paul Hamilton	23/10/2013 - 23/10/2013	Nottingham REC Centre Local Training Event, HRA
Dr Ronald Jubb	24/09/2013 - 24/09/2013	Nottingham REC Centre Local Training Event, HRA
Professor John Marriott	23/10/2013 - 23/10/2013	Nottingham REC Centre Local Training Event, HRA
Dr Eric Silove	23/10/2013 - 23/10/2013	Nottingham REC Centre Local Training Event, HRA
Dr Michael Wolffe	07/10/2013 - 07/10/2013	Nottingham REC Centre Local Training Event, HRA
Dr Nigel Langford	07/10/2013 - 07/10/2013	Nottingham REC Centre Local Training Event, HRA
Mr Philip Russell	07/10/2013 - 07/10/2013	Nottingham REC Centre Local Training Day, HRA
Mrs Alison Parsons	09/09/2013 - 09/09/2013	Induction, NRES
Mr Chris Foy	11/12/2013 - 11/12/2013	National Training Day for NRES Committee Chairs, NRES
Mr Chris Foy	16/01/2014 - 16/01/2014	Training - Research Involving Adults Who Lack Capacity (including research in emergency situations), HRA
Dr Adrian Hamlyn	01/04/2013 - 31/03/2014	Self Directed Learning - Reading, British Medical Journal - Weekly Subscription
Dr Adrian Hamlyn	01/04/2013 - 31/03/2014	Self Directed Learning - Reading, Gut - Specialist Medical Journal - Subscription

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	20	35.71
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	36	64.29
Total Applications Reviewed	56	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	10
Number of studies withdrawn prior to the meeting	11
Number of student applications reviewed	10
Number of paediatric applications reviewed	15
Number of device applications reviewed	2
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	5	8.93
Favourable Opinion with Additional Conditions	8	14.29
Unfavourable Opinion	4	7.14
Provisional Opinion	39	69.64
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	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	35	62.50
Further Information Favourable Opinion with Additional Conditions	1	1.79
Further Information Unfavourable Opinion	2	3.57
Favourable Opinion with Standard Conditions	5	8.93
Favourable Opinion with Additional Conditions	8	14.29
Unfavourable Opinion	4	7.14
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
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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	7	29.17
Favourable Opinion with Additional Conditions	9	37.50
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	8	33.33
Unfavourable Opinion	0	0.00
Total	24	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.09
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	26
Number of days taken to final decision - mode	20
Number of SSAs (non-Phase 1) reviewed	11
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	165
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	32
Number of modified amendments over 14 days	1
Number of modified amendments over 14 days as a % of total modified amendments	3.1%
Number of proportionate review applications for ethical review over 14 days*	2
Number of proportionate review applications over 14 days as a % of total	8.3%

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/WM/0127	Blood Flow in Vascular Patients	21
13/WM/0139	Lower Limb Blood flow geko vs Foot Pump	21
13/WM/0140	Stopping nilotinib treatment for CML patients	23
13/WM/0159	Exploration of the use of CBT for patients with fibromyalgia	20
13/WM/0176	Significance of GDH positive stool samples in context of C.difficile	8
13/WM/0215	Return to Driving Following Oxford Unicompartmental Knee Replacement	29
13/WM/0232	Decitabine for Acute Myeloid Leukaemia in Children	22
13/WM/0235	ATTEST	29
13/WM/0260	Establishing quality markers for ward rounds	15
13/WM/0271	Nutrient handling in health and disease	33
13/WM/0273	Use of bone void fillers in revision mastoid surgery	30
13/WM/0277	The Subjective Experience of Auditory Verbal Hallucinations	28
13/WM/0299	NOSH: Feasibility Study and RCT	10
13/WM/0304	SPIRO - CKD	24
13/WM/0311	Effects of Liraglutide in Young adults with Type 2 DIAbetes (LYDIA)	31
13/WM/0334	Comparison Between Twin-block & Forsus Functional Appliances	35
13/WM/0339	Characterising the immune profile & microenvironment of solid tumours	40
13/WM/0354	Reliability of new strobe lamp in detecting photosensitivity	33
13/WM/0355	Role of Vascular Biomarkers in Heart Failure patients undergoing CRT	31
13/WM/0360	Group Self-Management Intervention for Axial Spondyloarthritis	26
13/WM/0361	Intensive treatment in RA, views of patients and carers v1	14
13/WM/0364	Targeted retreatment of COPD exacerbations	37
13/WM/0400	Steroid tape to treat overgranulating PD exit sites	26
13/WM/0434	Cognition and delirium in COPD	10
13/WM/0438	Providing newborn screening information antenatally	10
13/WM/0451	AMG 337 with MET Amplified Gastric, Esophageal or other solid tumours	23
13/WM/0454	Study to determine the safety and effectiveness of flutiform®(Affirm)	49
13/WM/0480	Effects of Oxyntomodulin on energy expenditure and food intake	22
13/WM/0483	Understanding sex differences in disruptive behaviour version 1	19

13/WM/0491	Proteus study	23
13/WM/0496	The diagnostic value of Hyperventilation during a routine EEG.	20
14/WM/0007	Observational Study to Determine Prognostic Factors in Skin Lymphoma	21
14/WM/0013	Developing a new drug to treat infants hospitalised with RSV infection	33
14/WM/0016	INATE Study	40
14/WM/0042	Feasibility study of a formal occupational health assessment	19
14/WM/0046	Postnatal distress and the expectations and experiences of new mothers	27
14/WM/0049	NN7999-3895 Trial Evaluating Safety & Efficacy of N9-GP in Haem B PUPs	20
14/WM/0050	The Breast Surgery CLI Specimen Analyser study	22
14/WM/0055	Computerised CBT for Adolescent Depression: A Case Series (V1)	31
14/WM/0071	Collaborative telementoring: connecting Da Vinci Si's with the N3 V.1	7
14/WM/0085	Robotic Assisted Fracture Surgery	22
14/WM/0090	Dietary requirement for vitamin D in adolescents aged 14-18years	23
14/WM/0097	Coping and connectedness in families living with addiction problems.	20

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
14/WM/0015	Study of Teduglutide in Pediatric Subjects with Short Bowel Syndrome	30

Further Information Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/WM/0263	AEGEAN study CV185220 v3.0 23 Jan 2013	44
13/WM/0408	RomiCar	27

Favourable Opinion with Standard Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/WM/0149	CoBaT Follow-Up version 1	20
13/WM/0175	White Cell Sequestration During CPB V3	10
13/WM/0208	AMG 557 in SLE Subjects with Active Lupus Arthritis	23
13/WM/0300	Molecular insights into the type 1 diabetes pancreas Version 1	6
13/WM/0301	Phase 1b/II study of buparlisib with chemo in squamous NSCLC patients	21
13/WM/0365	A 3 yr extension study of Secukinumab in Psoriatic Arthritis patients	28
13/WM/0390	Malnutrition in care homes: A feasibility study V2.0	12

13/WM/0411	Identity construction in Care Programme Approach (CPA) review meetings	26
13/WM/0489	Variation in Colon Cancer Epigenetics With Migration (Version 1)	7
13/WM/0511	Physiotherapists & Patients experiences of AP with MSK chronic pain V1	8
14/WM/0024	Peer support system for young people with type 1 diabetes	10
14/WM/0073	Cognitive and behavioural outcomes of very preterm children	9

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/WM/0180	knowledge and attitudes of general practice patients to oral implants	9
13/WM/0181	Mother's feelings towards infant weaning. Version 1	11
13/WM/0231	SNIFFLE Study	20
13/WM/0362	Adults with LD and older parent-carers perceptions of the future	12
13/WM/0374	Effects of increased sunlight exposure on innate and acquired immunity	26
13/WM/0391	Parent and clinician reported outcomes for ENT disease in MPS	10
13/WM/0413	Pulse oximeter respiratory monitoring in preterm infants	26
13/WM/0445	The MOTION Study an Exercise Programme Version 1	21
13/WM/0490	Obstructive Sleep Apnoea and Glaucoma	8
13/WM/0494	Effect of exercise on kidney disease mediated functional impairment	27
13/WM/0500	GreenGeneF Extension study Protocol	19
13/WM/0508	Feasibility of home sampling to detect exacerbation of CF lung disease	9
13/WM/0510	Procalcitonin pharmacokinetics in patients with peritoneal malignancy	9
14/WM/0004	Health Visitors Support for Mothers Experiencing Domestic Abuse	32
14/WM/0028	ACCRUE:A study measuring the societal impact of psoriasis in the UK	8
14/WM/0052	PARTNERS2: collaborative care for people with serious mental illness	19
14/WM/0074	Warfarin reversal in ICH – data pooling project	8

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/WM/0224	Developmental and Educational outcome of babies born at 32-35 weeks	20
13/WM/0433	Peripheral arterial disease in HIV infected patients	27
13/WM/0457	Cebranopadol efficacy and safety in diabetic pain due to nerve damage	21
14/WM/0092	Diet and metabolic Investigations in Human Participants	19

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
13/WM/0262	Chart Review of Deceased Patients with Mucopolysaccharidosis Type IIIB	26
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	
13/WM/0260	Establishing quality markers forward rounds	15	
13/WM/0360	Group Self-Management Intervention for Axial Spondyloarthritis	26	
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
13/WM/0109/AM01/1	NuSurface MCT study	AM01	15
Section 30 application over 60 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock