

**NRES Committee West Midlands -
South Birmingham**

Annual Report

01 April 2013 – 31 March 2014

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee West Midlands - South Birmingham
Type of REC:	Authorised
Type of Flag:	Medical Devices, Paediatric
Chair:	Professor Simon Bowman
Vice-Chair:	Dr John David Cochrane
Alternate Vice-Chair:	Reverend Dr Barry Clark
REC Manager:	Dr Ashley Totenhofer
REC Assistant :	Miss Benita Cooke (April 2013 – October 2013)
Committee Address:	HRA NRES Centre Manchester 3rd Floor Barlow House 4 Minshull Street Manchester M1 3DZ
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Chair's overview of the past year:

This year has seen stability in the administrative support to this committee. We are enormously grateful to Ashley Totenhofer for doing such an excellent job taking over from Heather Harrison. I thank all the members for their contribution to and support of the Committee. We are delighted to welcome Peter Guest to the Committee and Mary Glover who has returned to the Committee after a break.

As the statistics show the committee has operated smoothly this year. We aim for a fast turnaround of applications. We have seen a varied selection of research projects and we look forward to a successful year to come.

NRES Committee West Midlands - South Birmingham Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mr Michael Andrews	Retired Company Secretary	Lay Plus	17/10/2007	
Professor Simon Bowman	Consultant Rheumatologist	Expert	01/10/2007	
Ms Philippa Burgon	Lay Member	Lay Plus	18/05/2010	
Dr Dawn Chaplin	Project Director Birmingham Bereavement Project/Nurse	Expert	21/03/2011	17/05/2013
Reverend Dr Barry Clark	Retired Hospital Chaplain	Lay Plus	10/07/2009	
Dr John David Cochrane	Retired GP	Expert	20/02/2007	
Dr Mary Glover	University Lecturer and Psychotherapist	Lay	22/11/2012	
Dr Peter Guest	Consultant Radiologist	Expert	31/01/2014	
Dr Dalvina Hanu-Cernat	Consultant in Anaesthesia and Pain Medicine	Expert	03/10/2007	
Mr Liviu Marius Hanu-Cernat	Consultant Maxillofacial Surgeon	Expert	18/08/2011	
Miss Rosemarie Seadon	Senior Pharmacist	Expert	16/06/2004	
Dr Yvonne Searle	Consultant Clinical Psychologist	Expert	08/12/2003	
Mrs Andal Thirumalai	Plastic Surgeon	Expert	03/02/2009	
Mr Sunil Solomon Thomas	Consultant Plastic Surgeon	Expert	27/11/2008	

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Dr Raj Dhaliwal	Dentist	Expert	15 October 2013

NRES Committee West Midlands - South Birmingham: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Mr Sunil Solomon Thomas	Vice Chairmen of Friends of Ludhiana (non-Profit Charity) - Supports Christian Medical College, Punjab, India	17/12/2013
Mr Sunil Solomon Thomas	Member of the West Midlands Plastic Surgery Training Committee	17/12/2013
Mr Michael Andrews	None	17/12/2013
Reverend Dr Barry Clark	None	17/12/2013
Dr John David Cochrane	None	17/12/2013
Miss Rosemarie Seadon	Clinical trials pharmacist at Queen Elizabeth Hospital Birmingham	16/01/2014
Ms Philippa Burgon	Lay reviewer for Research Design Service South West (NIHR)	17/01/2014
Professor Simon Bowman	Trustee/Director of British Society for Rheumatology and Sjogrens Syndrome Association	21/01/2014
Professor Simon Bowman	Actively involved in research including collaborations with Pharma companies through clinical role	21/01/2014
Dr Mary Glover	Senior lecturer in Counselling and Psychotherapy: Newman University	21/01/2014
Dr Mary Glover	Business partner; DG & M Glover, Farmers	21/01/2014
Dr Mary Glover	Shares held in Genus and Dairy Crest	21/01/2014
Dr Mary Glover	Member of National Farmers Union	21/01/2014
Dr Mary Glover	Lead reviewer ethics: Newman University dept. of Psychology and Counselling	21/01/2014
Dr Peter Guest	Previously R&D co-ordinator for department of Radiology, Queen Elizabeth Hospital	04/02/2014
Dr Peter Guest	Named radiologist on numerous projects run by hospital. Principle Investigator for commercial and non-commercial studies - this is as a technician - measuring lesions on scans for oncology purposes	04/02/2014
Dr Dalvina Hanu-Cernat	None	13/01/2014
Mr Liviu Marius Hanu-Cernat	None	12/01/2014
Mrs Andal Thirumalai	None	04/03/2014
Dr Yvonne Searle	None	31/03/2014

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

Month	Date	Number of Members Present at Meeting
May	21/05/2013	9
June	18/06/2013	10
July	16/07/2013	7
August	20/08/2013	9
September	17/09/2013	8
October	15/10/2013	7
December	17/12/2013	10
January	21/01/2014	9
February	18/02/2014	9
March	18/03/2014	12

10 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	21/05/2013	3
June	18/06/2013	3
August	20/08/2013	3
September	17/09/2013	3
October	15/10/2013	3
November	19/11/2013	3
December	17/12/2013	3
February	18/02/2014	3
March	18/03/2014	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 John David Cochrane	10
Mr Michael Andrews	10
Professor Simon Bowman	10
Reverend Dr Barry Clark	9
Dr Yvonne Searle	7
Mr Sunil Solomon Thomas	7
Mrs Andal Thirumalai	7
Ms Philippa Burgon	7
Dr Mary Glover	6
Dr Dalvina Hanu-Cernat	6
Miss Rosemarie Seadon	5
Mr Liviu Marius Hanu-Cernat	4
Dr Peter Guest	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
Professor Simon Bowman	9
Reverend Dr Barry Clark	9
Dr John David Cochrane	8
Mrs Andal Thirumalai	1

Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Mr Sunil Solomon Thomas	01/07/2013 - 17/08/2013	Self-Directed Learning - Read 'Bad Pharma'
Mr Sunil Solomon Thomas	18/11/2013 - 18/11/2013	Equality & Diversity, University Hospitals Birmingham NHS Foundation Trust
Miss Rosemarie Seadon	19/09/2013 - 19/09/2013	GCP Training Update, UHB
Mr Michael Andrews	17/12/2013 - 17/12/2013	Self-Directed Learning - Read 'Bad Pharma'
Mr Michael Andrews	19/11/2013 - 19/11/2013	Medical Devices, NRES/MHRA
Professor Simon Bowman	19/11/2013 - 19/11/2013	Medical Devices, NRES/MHRA
Dr John David Cochrane	19/11/2013 - 19/11/2013	Medical Devices, NRES/MHRA
Reverend Dr Barry Clark	19/11/2013 - 19/11/2013	Medical Devices, NRES/MHRA
Dr Yvonne Searle	19/11/2013 - 19/11/2013	Medical Devices, NRES/MHRA
Miss Rosemarie Seadon	19/11/2013 - 19/11/2013	Medical Devices, NRES/MHRA
Dr Dalvina Hanu-Cernat	19/11/2013 - 19/11/2013	Medical Devices, NRES/MHRA
Mr Sunil Solomon Thomas	19/11/2013 - 19/11/2013	Medical Devices, NRES/MHRA
Mrs Andal Thirumalai	19/11/2013 - 19/11/2013	Medical Devices, NRES/MHRA
Ms Philippa Burgon	19/11/2013 - 19/11/2013	Medical Devices, NRES/MHRA
Mr Liviu Marius Hanu-Cernat	19/11/2013 - 19/11/2013	Medical Devices, NRES/MHRA
Dr Mary Glover	19/11/2013 - 19/11/2013	Medical Devices, NRES/MHRA
Professor Simon Bowman	01/06/2013 - 31/12/2013	Assisted Colleagues with completion of IRAS form
Mrs Andal Thirumalai	10/01/2014 - 10/01/2014	Back Care & Ergonomic Research Training, UHB
Dr Peter Guest	05/03/2014 - 05/03/2014	Induction, HRA
Dr Mary Glover	03/07/2013 - 03/07/2013	Equality & Diversity, Newman University
Dr John David Cochrane	23/10/2013 - 23/10/2013	Local Training Day, NRES
Ms Philippa Burgon	07/10/2013 - 07/10/2013	Local Training Day, NRES

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	0	0.00
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	41	100.00
Total Applications Reviewed	41	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	6
Number of studies withdrawn prior to the meeting	18
Number of student applications reviewed	14
Number of paediatric applications reviewed	8
Number of device applications reviewed	8
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	14.63
Unfavourable Opinion	1	2.44
Provisional Opinion	34	82.93
Invalid	0	0.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	41	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	22	53.66
Further Information Favourable Opinion with Additional Conditions	11	26.83
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	6	14.63
Unfavourable Opinion	1	2.44
Provisional Opinion	1	2.44
Provisional Opinion Pending Consultation with Referee	0	0.00
Invalid	0	0.00
Further Information response not complete	0	0.00
No decision entered on RED	0	0.00
Number of studies withdrawn after the meeting	0	0.00
Total	41	100

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

Total Applications Reviewed	17
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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	1	5.88
Favourable Opinion with Additional Conditions	14	82.35
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	2	11.76
Unfavourable Opinion	0	0.00
Total	17	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	4.10
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	24
Number of days taken to final decision - mode	22
Number of SSAs (non-Phase 1) reviewed	4
Number of applications for SSA review over 25 days	1
Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)	25.0%
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	45
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	1
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/WM/0163	Early COPD characterisation and biomarker evaluation (Version 1)	22
13/WM/0187	Evaluation of PICO dressings in foot and ankle arthrodesis	19
13/WM/0237	Liverpool CSCR study version 1	21
13/WM/0250	Evaluating a new type of lung function test device in primary care	22
13/WM/0279	RH01897-Changes in DH plaque accumulation & gingival health over 24wks	28
13/WM/0330	FES in chronic constipation	27
13/WM/0363	Role of shame in paranoid ideation and social anxiety in psychosis	25
13/WM/0367	Effect of Birth after Anal Sphincter Injury on QoL: The BASIQ Study	23
13/WM/0369	The ChilSFree Trial	22
13/WM/0371	Volatile Organic Compounds (VOCs) exhaled by children and young people	22
13/WM/0410	Evaluating Cardiovascular Changes in Hypertension in Obstetrics	20
13/WM/0478	Acute effect of (-)-epicatechin ingestion on eNOS activation	18
13/WM/0486	Prediction of inappropriate myometrial function	22
13/WM/0487	In vivo confocal microscopy and histopathology of the ocular surface	25
14/WM/0003	THE HYDRUS V TRIAL	20
14/WM/0017	Circulating microparticles in atrial fibrillation Version 1	22
14/WM/0018	Health related quality of life and sexually transmitted infections	39
14/WM/0045	PoC Feasibility Trial of ClinTouch-CareLoop Enhanced Management	15
14/WM/0047	"Heel ulcers: pressure ulcers or symptoms of underlying PAD?"	24
14/WM/0058	Restorative Virtual Environments for Rehabilitation 1	17
14/WM/0061	Do active ingredients in a topical anaesthetic reduce patient anxiety?	37
14/WM/0094	Post Authorisation Safety Study of Perampanel in Epilepsy	18

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
13/WM/0205	Virtual restorative environment therapy for burns dressing changes	20
13/WM/0234	ESSBR – Effectiveness of Single Stage Breast Reconstruction	23
13/WM/0239	Social support in families of people with addiction problems.	17
13/WM/0280	The incidence of MGA in the general population as identified by MSE.	21

13/WM/0298	Intermittent cycle training in people with type 1 diabetes	29
13/WM/0317	Acute Care Quality in Chronic Kidney Disease	46
13/WM/0345	Evaluation of A New Blood Glucose Monitoring Device - HUK 5	37
13/WM/0415	A study to test a diet questionnaire to identify children with anaemia	23
13/WM/0427	Emotional literacy in Deaf young people	9
13/WM/0498	Automated closed loop in children and adolescents with type 1 diabetes	21
14/WM/0002	Skin temperature sensor to identify hypoglycaemia.	22
14/WM/0051	G-EYE™ Colonoscopy Clinical Efficacy	20
14/WM/0109	Molecular markers of fat use and storage in myocardial tissue	9

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
13/WM/0252	Sensory processing difficulties in children with DCD (1)	7

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/WM/0202	Leucopatch II	17
13/WM/0209	Wound Pilot Huddersfield - version 1	11
13/WM/0217	Vitamin D in Oesophageal and Gastric Cancer patients	8
13/WM/0238	The QUEST Study (version 1)	22
13/WM/0251	ToPiC-II: The Sensations Provoking Cough	7
13/WM/0255	Gastrointestinal diseases questionnaire	6
13/WM/0328	Women's experience of CBT during the Postnatal period	28
13/WM/0342	Ultrasound of Bowel Motility and Vascularity as Predictors of NEC	42
13/WM/0357	Postural Taping for Osteoporotic Vertebral Fractures (PosTape)	7
13/WM/0387	Monitoring of Forces Generated during Limb Reconstruction	7
13/WM/0406	DuoDERM Extra Thin Film Layer Wear Test (CW-0066-13-U370)	20
13/WM/0435	The use of GMP in the dietary management of PKU	42
13/WM/0436	PDSA Cycles: A scientific and pragmatic approach to improvement	10
13/WM/0475	What happens to CBT therapist competence post training?	8

13/WM/0484	Vaccination treatment and knowledge in patients with bronchiectasis	8
13/WM/0507	ETTAA	6
14/WM/0067	Echocardiographic Predictors of recurrence of subaortic stenosis	6
14/WM/0069	Experiences of people with skin lesions with unclear origin	7
14/WM/0072	Is PFMT effective in the treatment of OAB?	6
14/WM/0105	Study of tissues from women at high risk of gynaecological cancers	5

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/WM/0285	Triple H Project: Opt-out testing in Acute Medical Units	17

Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
14/WM/0080	Exploring the experiences of 'frequent users' of inpatient services	N/A

Provisional Opinion Pending Consultation with Referee

REC Reference	Application Short Title	Number of Days on Clock
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Further information response not complete

REC Reference	Application Short Title	Number of Days on Clock
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Withdrawn after the meeting

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

REC Reference	Application Short Title	Number of Days on Clock
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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	
13/WM/0313	Open-label study of long-term evaluation of AMG145 against LDL	28	
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