

**NRES Committee West Midlands -  
Edgbaston**

**Annual Report**

**01 April 2011 – 31 March 2012**

## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	NRES Committee West Midlands - Edgbaston
<b>Type of REC:</b>	Type III
<b>Type of Flag:</b>	Medical Device Study, Phase 1 Studies in Patients, Research Involving Children
<b>Chair:</b>	Mr Paul Hamilton
<b>Vice-Chair:</b>	Dr Ronald Jubb
<b>Alternate Vice-Chair:</b>	Professor John Marriott
<b>Co-ordinator:</b>	Mrs Lisa Gregory (Ms Nikki Murphy from 01/04/2011 – 22/02/2012)
<b>PRSC Co-ordinator:</b>	N/A
<b>Assistant Co-ordinator:</b>	N/A
<b>Committee Address:</b>	The Old Chapel Royal Standard Place Nottingham NG1 6FS
<b>Telephone:</b>	0115 8839368
<b>Fax:</b>	0115 8839294
<b>Email:</b>	<a href="mailto:lisa.gregory@nottspct.nhs.uk">lisa.gregory@nottspct.nhs.uk</a>

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

It has been yet another year of change as NRES became a core part of the new Health Research Authority. Two lay members resigned during the reporting year and I am particularly appreciative of those remaining members, expert and lay, who continue to serve, especially while there is a general hold on member recruitment while NRES prepares for a further round of mergers and closures in 2012. The committee continues to review a range of studies that take advantage of our flagged status in medical devices, phase 1 studies in patients and paediatrics and gives it the opportunity to develop its expertise in these areas of review.

In March 2012, we saw the closure of the West Midlands REC Centre at Redditch and we wished farewell to our co-ordinator, Nikki Murphy, who has served us so well.

## 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	
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	
Mr Philip Russell	Retired Head Teacher	Lay Plus	05/11/2008	
Mrs Krysia Saul	Research Manager	Lay	04/02/2011	17/08/2011
Dr Eric Silove	Retired Paediatric Cardiologist	Expert	16/01/2006	
Miss Heather Small	Heart Study Co-ordinator	Expert	20/02/2009	
Mrs Judy White	Assistant Registrar - Research	Lay	01/08/2009	14/11/2011
Dr Michael Wolffe	Optometrist	Expert	11/10/2007	

### Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended
None			

### Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Mr Michael Andrews (Co-opted from South Birmingham REC)	Retired Company Secretary	Lay	17/08/2011 21/09/2011

### Member Bank

Name	Occupation	Expert or Lay	Meeting date attended
N/A			

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

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Miss Heather Small	None	31/03/2012
Mr Paul Hamilton	None	01/12/2011
Dr Ronald Jubb	None	21/12/2011
Mr Chris Foy	Employed by the NIHR research design service to advise NHS employees on the design, funding and conduct of the research.	21/12/2011
Dr Eric Silove	None	21/12/2011
Dr Adrian Hamlyn	Member of BMA and GMC	21/12/2011
Dr Michael Wolffe	Trustee/treasurer of Vision 20/20 UK	21/12/2011
Dr Michael Wolffe	Trustee Look National	21/12/2011
Dr Michael Wolffe	Trustee Partially Sighted Society	21/12/2011
Dr Michael Wolffe	Member of the Research Ethical Committee of the Institute of Optometry.	21/12/2011
Dr Nigel Langford	None	21/12/2011
Mrs Theresa Hyde		
Professor John Marriott	Formulations Consultant West Midlands Medicines for Children Research Network	31/03/2012
Mr Philip Russell	None	21/12/2011

**Meetings for Full Ethical Review 01 April 2011 - 31 March 2012:**

<b>Month</b>	<b>Date</b>	<b>Number of Members Present at Meeting</b>
April	13/04/2011	12
July	27/07/2011	10
August	17/08/2011	7
September	21/09/2011	7
October	19/10/2011	8
November	16/11/2011	7
December	21/12/2011	9
February	22/02/2012	7
March	21/03/2012	10

9 full committee meetings were held during the reporting period.

**Attendance of Members: 01 April 2011 – 31 March 2012:**

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Ronald Jubb	9
Mr Chris Foy	9
Mr Paul Hamilton	9
Dr Eric Silove	8
Mr Philip Russell	7
Professor John Marriott	7
Dr Michael Wolffe	6
Miss Heather Small	5
Dr Adrian Hamlyn	5
Mrs Judy White	4
Mrs Theresa Hyde	4
Dr Nigel Langford	3
Mrs Krysia Saul	1

**Number of inquorate meetings held: None**

## Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Miss Heather Small	28/06/2011 - 28/06/2011	NRES Statistics Training, NRES
Mrs Krysia Saul	11/10/2011 - 11/10/2011	Induction, NRES
Mr Paul Hamilton	16/06/2011 - 16/06/2011	Qualitative Research, West Midlands REC Centre
Mr Philip Russell	16/06/2011 - 16/06/2011	Qualitative Research, West Midlands REC Centre
Mrs Krysia Saul	16/06/2011 - 16/06/2011	Qualitative Research, West Midlands REC Centre
Dr Eric Silove	16/06/2011 - 16/06/2011	Qualitative Research, West Mids REC Centre
Dr Michael Wolffe	16/06/2011 - 16/06/2011	Qualitative Research, West Mids REC Centre
Mrs Theresa Hyde	16/06/2011 - 16/06/2011	Qualitative Research, West Mids REC Centre
Mr Chris Foy	22/09/2011 - 22/09/2011	Informed consent, NRES
Dr Ronald Jubb	12/10/2011 - 12/10/2011	Managers meeting update, NRES
Professor John Marriott	04/04/2011 - 04/04/2011	Observed other REC working – revised REC application
Professor John Marriott	31/01/2012 - 31/01/2012	Reviewed University of Birmingham Ethics procedures
Mr Chris Foy	12/10/2011 - 12/10/2011	Managers meeting update, NRES
Mr Paul Hamilton	26/09/2011 - 26/09/2011	NRES Update Session, NRES
Dr Nigel Langford	14/12/2011 - 14/12/2011	Symposium on Clinical pharmacology of drug development and clinical research in China. Aspects considered in drug research.
Mr Paul Hamilton	19/01/2012 - 19/01/2012	NRES Shared Ethical Debate Training, NRES
Mr Paul Hamilton	27/07/2011 - 27/07/2011	MCA DVD, NRES
Dr Ronald Jubb	27/07/2011 - 27/07/2011	MCA DVD, NRES
Dr Eric Silove	27/07/2011 - 27/07/2011	MCA DVD, NRES
Dr Adrian Hamlyn	27/07/2011 - 27/07/2011	MCA DVD, NRES
Professor John Marriott	27/07/2011 - 27/07/2011	MCA DVD, NRES
Dr Nigel Langford	27/07/2011 - 27/07/2011	MCA DVD, NRES
Mr Philip Russell	27/07/2011 - 27/07/2011	MCA DVD, NRES
Miss Heather Small	27/07/2011 - 27/07/2011	MCA DVD, NRES
Mr Chris Foy	27/07/2011 - 27/07/2011	MCA DVD, 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:**

<b>Applications for full ethical review – Study Type</b>	<b>Number</b>	<b>%</b>
Clinical Trial of Investigational Medicinal Product	9	21.43
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	33	78.57
<b>Total Applications Reviewed</b>	<b>42</b>	<b>100</b>

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

Number of applications made invalid by co-ordinator	11
Number of studies withdrawn prior to the meeting	4
Number of student applications reviewed	13
Number of paediatric applications reviewed	7
Number of device applications reviewed	9
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	3	7.14
Favourable Opinion with Additional Conditions	7	16.67
Unfavourable Opinion	1	2.38
Provisional Opinion	31	73.81
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>42</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	25	59.52
Further Information Favourable Opinion with Additional Conditions	1	2.38
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	3	7.14
Favourable Opinion with Additional Conditions	7	16.67
Unfavourable Opinion	1	2.38
Provisional Opinion	3	7.14
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	1	2.38
Not Requiring Review by NHS REC	0	0.00
No decision entered on RED	1	2.38
Number of studies withdrawn after the meeting	0	0.00
<b>Total</b>	<b>42</b>	<b>100</b>

**Table 5: Other Management Information for the reporting period:**

<b>Average number of applications reviewed per full meeting</b>	4.67
<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>	29
<b>Number of days taken to final decision - mode</b>	33
<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>	107
<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>	10
<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%

**Table 6: 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>
11/WM/0068	Patient comfort and safety in CECT imaging of abdomen/pelvis	27
11/WM/0081	Parents' perspectives on the transition from CAMHS to AMHS.	43
11/WM/0095	RACE 3 study: Intensive vs. usual rhythm control for AF, Version 1	34
11/WM/0163	REPLY MRI Study Ver No. 1.7	44
11/WM/0198	Accu-Chek Aviva Expert Study	22
11/WM/0201	UK User Evaluation Study of Cellnovo Pump System in Type 1 Diabetes	46
11/WM/0247	Young people's experience of transition to adult drug services	36
11/WM/0248	PREP - Prediction of Risks in Early Onset Pre eclampsia	26
11/WM/0275	Whole Body Vibration as an Osteogenic Treatment for Children.	20
11/WM/0278	Psychology and Behaviour in Atypical Adrenarche and Precocious Puberty	22
11/WM/0279	NECTAR-HF Research Study	26
11/WM/0298	Sympathetic nerve activity in rheumatoid arthritis	24
11/WM/0310	Will the NTproBNP test help diagnose heart failure in pts with CHD?	24
11/WM/0330	Vitamin d open label replacement oesophagectomy.	23
11/WM/0337	Use of ambulatory oxygen in COPD	33
11/WM/0341	Efficacy of Lenalidomide/Dexamethasone +/-Elotuzumab in untreated MM	39
11/WM/0368	Respiratory-sympathetic coupling in human hypertension	26
11/WM/0375	A Phase 1b/2 Study of MEDI-573, with AI comparator in Breast Cancer	33
11/WM/0376	VX-950HPC3006 ( REPLACE) Issue date: 23-Sep-2011	27
11/WM/0377	Fear of falling in pseudophakic and phakic sufferers of AMD	33
11/WM/0380	Atopic eczema-comparing the child's quality of life with their parents	33
11/WM/0389	UK FASHIoN	27
12/WM/0034	Voluma Study Version 1	31
12/WM/0039	Inovate-HF	32
12/WM/0077	Immune cell function and metabolism in rheumatoid arthritis: version1	40
<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/WM/0409	Electronic repositioning in cardiac resynchronisation therapy	29

**Further Information Unfavourable Opinion**

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

**Favourable Opinion with Standard Conditions**

REC Reference	Application Short Title	Number of Days on Clock
11/WM/0249	TEAM TALK AND CULTURAL DIVERSITY IN A CHILD MENTAL HEALTH SERVICE	21
11/WM/0408	A laboratory evaluation of an iodine-impregnated incise drape	27
12/WM/0068	Methodological and ethical issues in quality of life research	37

**Favourable Opinion with Additional Conditions**

REC Reference	Application Short Title	Number of Days on Clock
11/WM/0077	Dietary Intake and Beliefs: Development and Validation of Questionnaire	20
11/WM/0078	Diagnostic test of organic volatiles in NEC - DOVE study	20
11/WM/0080	Family communication about hereditary breast cancer.	20
11/WM/0241	Barriers and benefits to fistula access	21
11/WM/0289	Assessment of the EASH dressing on Venous Leg Ulcers	21
11/WM/0311	Device for Improved Safety during Anaesthesia and Sedation	22
12/WM/0070	Assessing the Cost of Living with Phenylketonuria (PKU) version 1.0	33

**Unfavourable Opinion**

REC Reference	Application Short Title	Number of Days on Clock
11/WM/0255	CT337 / 14-DRM-VCA-11-002 Verruca Treatment	28

**Provisional Opinion**

REC Reference	Application Short Title	Number of Days on Clock
11/WM/0390	Phase 3b Ulcerative Colitis Study in Usual Clinical Practice	N/A
12/WM/0055	Vildagliptin in Type 2 Diabetes	N/A
12/WM/0063	ProMRI AFFIRM Study	N/A

**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
---------------	-------------------------	-------------------------

<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 7: 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>

<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>