

**NRES Committee West Midlands -  
South Birmingham**

**Annual Report**

**01 April 2011 – 31 March 2012**

## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	NRES Committee West Midlands - South Birmingham
<b>Type of REC:</b>	Medical Device Study , Research Involving Children
<b>Type of Flag:</b>	Authorised REC
<b>Chair:</b>	Dr Simon Bowman
<b>Vice-Chair:</b>	Dr John David Cochrane
<b>Alternate Vice-Chair:</b>	Reverend Barry Clarke
<b>Co-ordinator:</b>	Ms Heather Harrison
<b>PRSC Co-ordinator:</b>	N/A
<b>Assistant Co-ordinator:</b>	Mr Stephen Briggs
<b>Committee Address:</b>	The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS
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### Chair's overview of the past year:

This year has seen major changes to the organizational arrangements for NRES including the establishment of the HRA. We have also seen changes locally with the move of our administrative support from Redditch to Nottingham. We would like to express our thanks to Rosa Downing for her many years of hard work as the Committee co-ordinator and also to our new co-ordinator Heather Harrison and her colleagues for a seamless transition.

The work of the Committee, however, has continued essentially unchanged. This report sets out the detail of the studies that we have reviewed, the training of members and other key pieces of information about our work.

This past year two members - Dr Sue Kelly and Dr Mary Glover retired from the committee and we were joined by Mr Liviu Hanu-Cernat. I would also like to also thank Dr John Cochrane, Vice-Chair and Rev'd Barry Clark, Alternate Vice-Chair and all the members of the Committee for their support and hard work.

## 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	
Dr Simon Bowman	Rheumatologist	Expert	01/10/2007	
Ms Philippa Burgon	Lay Member	Lay Plus	18/05/2010	
Rev'd Dr Barry Clark	Hospital Chaplain	Lay Plus	10/07/2009	
Dr John David Cochrane	Retired GP	Expert	20/02/2007	
Dr Mary Glover	Counsellor - Psychotherapist	Lay	20/09/2005	09/08/2011
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	
Dr Sue Kelly	Senior Lecturer - Physiotherapy	Expert	20/08/2002	16/08/2011
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	
Mrs Liz Thomas	Medicines Management	Expert	07/07/2004	
Mr Sunil Solomon Thomas	Consultant Plastic Surgeon	Expert	27/11/2008	
Dr Tracey Toms	Specialist Registrar in Rheumatology/Research Fellow	Expert	01/06/2009 MAT leave 01/09/2011	
Dr Ben Wrigley	Specialist Registrar/Research Fellow in Cardiology	Expert	15/11/2010 Sabbatical 01/09/2011	

### Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended
None			

### Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Dr Ronald Jubb	Consultant Rheumatologist	Expert	21/02/2012
Mr Philip Russell	Retired Head Teacher	Lay Plus	20/03/2012
Mr Chris Foy	Medical Statistician	Expert	20/03/2012
Mr Paul Hamilton	Retired Local Government Officer	Lay Plus	21/02/2012

### Member Bank

Name	Occupation	Expert or Lay	Meeting date attended
N/A			

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

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Mrs Andal Thirumalai	None	13/12/2011
Mrs Liz Thomas	None	13/12/2011
Dr Dalvina Hanu-Cernat	None	13/12/2011
Mr Liviu Marius Hanu-Cernat	None	13/12/2011
Miss Rosemarie Seadon	Clinical trials pharmacist at queen Elizabeth Hospital Birmingham	15/12/2011
Dr John David Cochrane	None	15/12/2011
Rev'd Dr Barry Clark	Chair of management group for HIEC, a West Midlands research project.	30/12/2011
Rev'd Dr Barry Clark	PPI lead for CLAHRC a West Midlands research project	30/12/2011
Rev'd Dr Barry Clark	Vice chair of management steering group for CLAHRC	30/12/2011
Rev'd Dr Barry Clark	On steering group for REFER and ASPIRE trials	30/12/2011
Ms Philippa Burgon	Lay member of scientific committee of South West research design service - Taunton	19/12/2011
Mr Michael Andrews	None	13/12/2011
Dr Simon Bowman	Trustee of British Society for Rheumatology	13/12/2011
Dr Simon Bowman	Trustee of British Sjogren's Syndrome Association	13/12/2011
Dr Simon Bowman	Research lead for division C of University Hospital Birmingham	13/12/2011
Dr Simon Bowman	Medical Advisory Board for Merk Sorono in 1st in patients clinical trial research.	13/12/2011
Dr Simon Bowman	Clinical trial of rituximab in Sjogren's syndrome	13/12/2011
Yvonne Searle	None	30/12/2011

**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	19/04/2011	11
May	17/05/2011	8
June	21/06/2011	10
August	16/08/2011	10
September	20/09/2011	8
October	18/10/2011	8
December	13/12/2011	10
January	17/01/2012	7
February	21/02/2012	8
March	20/03/2012	9

10 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>
Mr Michael Andrews	10
Dr Simon Bowman	9
Dr Yvonne Searle	9
Dr John David Cochrane	9
Ms Philippa Burgon	7
Rev'd Dr Barry Clark	6
Dr Dalvina Hanu-Cernat	6
Mrs Andal Thirumalai	6
Mrs Liz Thomas	5
Miss Rosemarie Seadon	4
Mr Sunil Solomon Thomas	4
Dr Sue Kelly	3
Mr Liviu Marius Hanu-Cernat	3
Dr Dawn Chaplin	2
Dr Mary Glover	1
Dr Ben Wrigley - Sabbatical 01/09/2011	1

**Number of inquorate meetings held: None**

**Training 01 April 2011 – 31 March 2012:**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Mr Michael Andrews	17/05/2011 - 17/05/2011	MCA Video training, NRES
Dr Simon Bowman	17/05/2011 - 17/05/2011	MCA Video Training, NRES
Ms Philippa Burgon	17/05/2011 - 17/05/2011	MCA Video Training, NRES
Dr. John David Cochrane	17/05/2011 - 17/05/2011	MCA Video Training, NRES
Dr Sue Kelly	17/05/2011 - 17/05/2011	MCA Video Training, NRES
Dr Yvonne Searle	17/05/2011 - 17/05/2011	MCA Video Training, NRES
Mrs Liz Thomas	17/05/2011 - 17/05/2011	MCA Video Training, NRES
Miss Rosemarie Seadon	17/05/2011 - 17/05/2011	MCA Video Training, NRES
Dr Simon Bowman	16/06/2011 - 16/06/2011	Qualitative Research Training, West Midlands REC Centre
Mr Sunil Solomon Thomas	16/06/2011 - 16/06/2011	Qualitative Research Training, West Midlands REC Centre
Mr Michael Andrews	16/06/2011 - 16/06/2011	Qualitative Research Training, West Midlands REC Centre
Rev'd Dr Barry Clark	17/05/2011 - 17/06/2011	MCA Video, NRES
Mr Michael Andrews	17/06/2011 - 17/06/2011	MCA DVD, NRES
Rev'd Dr Barry Clark	14/03/2012 - 14/03/2012	NRES Committee Members Study Day, NRES
Ms Philippa Burgon	12/10/2011 - 12/10/2011	NRES Update session with Janet Wisely, NRES
Dr Simon Bowman	12/10/2011 - 12/10/2011	NRES Update session with Janet Wisely, NRES
Dr. John David Cochrane	14/03/2012 - 14/03/2012	NRES Members National Training Day - London, NRES
Ms Philippa Burgon	14/03/2012 - 14/03/2012	NRES Members training day, NRES
Miss Rosemarie Seadon	04/04/2011 - 04/04/2011	Equality and Diversity online Training
Dr Tracey Toms	28/02/2012 - 28/02/2012	Clinical Governance, Self Directed Learning
Dr Tracey Toms	28/02/2012 - 28/02/2012	Equality & Diversity, Self Directed Learning
Mrs Liz Thomas	01/01/2012 - 01/03/2012	Researching And Evaluating My Practice, Keele University
Dr Yvonne Searle	01/11/2011 - 01/11/2011	Ethics in Clinical Practice Workshop, Warwick University Medical School
Mr Liviu Marius Hanu-Cernat	06/12/2011 - 06/12/2011	Private study on NRES guidance on consent sheets, Self Directed Learning
Mr Liviu Marius Hanu-Cernat	14/01/2012 - 20/01/2012	Approval of Research involving the use of ionising radiation, private study of NRES guidance, Self Directed Learning
Mr Liviu Marius Hanu-Cernat	31/01/2012 - 31/01/2012	Private Study of the Mental Capacity Act 2005, Self Directed Learning
Mr Liviu Marius Hanu-Cernat	28/02/2012 - 28/02/2012	NRES guidance on information



		sheets for research - Private Study, Self Directed Learning
Mr Michael Andrews	28/03/2012 - 28/02/2012	NRES Members National Training Day – Leeds Conference

## 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	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	61	100.00
<b>Total Applications Reviewed</b>	<b>61</b>	<b>100</b>

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

Number of applications made invalid by co-ordinator	2
Number of studies withdrawn prior to the meeting	6
Number of student applications reviewed	28
Number of paediatric applications reviewed	10
Number of device applications reviewed	6
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	1
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	4	6.56
Favourable Opinion with Additional Conditions	7	11.48
Unfavourable Opinion	1	1.64
Provisional Opinion	49	80.33
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>61</b>	<b>100</b>
Number of studies sent back to full committee meeting for final opinion	1	

**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	46	75.41
Further Information Favourable Opinion with Additional Conditions	3	4.92
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	4	6.56
Favourable Opinion with Additional Conditions	7	11.48
Unfavourable Opinion	1	1.64
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>61</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	6.10
<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>	24
<b>Number of days taken to final decision - mode</b>	20
<b>Number of SSAs (non-Phase 1) reviewed</b>	14
<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>	0.0%
<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>	77
<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>	1.3%
<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%

**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/0053	The Experience of Young People's Transition from CAMHS to AMHS	16
11/WM/0086	GP Endorsement of Bowel Screening	17
11/WM/0087	Emergency Care Handover (ECHO) v1	22
11/WM/0089	assessment of simultaneous interarm differences in blood pressure	17
11/WM/0091	Self-compassion and mental health in older people-version 1	21
11/WM/0100	Validation of the 3D laser to measure breast volume in situ	35
11/WM/0102	Corticosteroids in knee osteoarthritis; an observational study	17
11/WM/0105	Pilot study of earFold implant for correction of prominent ears	18
11/WM/0125	The DARC Study (Version 1)	38
11/WM/0155	The SNAP Study - Studying fracture risk in sick children version 1.0	21
11/WM/0161	Time of day and vaccination	24
11/WM/0172	Novel biomarkers of liver fibrosis (NOBLES)	20
11/WM/0174	Incorporation Of Tisseel Sealant In Split Skin Grafts	24
11/WM/0178	Antenatal screening for hepatitis C virus infection	38
11/WM/0181	Parents' experiences of their child's cancer	34
11/WM/0235	OPERA	20
11/WM/0236	An evaluation of C-BIT within Solihull services v1	21
11/WM/0238	CAD/CAM suprastructures	20
11/WM/0240	Conservative Kidney Management Assessment of Practice Patterns CKMAPPS	20
11/WM/0242	Quality of Life post Gastrostomy placement in Motor Neuron Disease	25
11/WM/0277	Evaluation of the Transmedics Heart Organ Care System	20
11/WM/0280	Stakeholder Perceptions of Success and Goals in Supported Housing	24
11/WM/0286	Tissue sampling in image-negative symptomatic breast disease. v1	18
11/WM/0296	A study to consider visual habituation responses in paediatrics.	20
11/WM/0297	Young offenders experiences of anger and aggression version 1	37
11/WM/0312	Neuroimaging and Theory of Mind in Huntington's Disease	17
11/WM/0335	Stool collection for quality assurance testing	22
11/WM/0336	Study of eye and neck VEMPs [a balance test] in school age children	32
11/WM/0339	understanding the religious and spiritual needs of young people with ca	20
11/WM/0388	Orthoses and ankle bracing on tibialis posterior tendon dysfunction.	28

11/WM/0393	Gynaecology Oncology Research	22
11/WM/0410	Comparative Acne Study	30
11/WM/0411	mCPP, appetite, & fMRI BOLD signals	22
11/WM/0412	Long term growth of children with PKU	42
12/WM/0006	Life experiences of young people who have offended - version 1	31
12/WM/0010	PRiDE Study ver.1	41
12/WM/0012	The behavioural response to inflammation	36
12/WM/0013	Psychology Study of Obesity	21
12/WM/0022	RCT stage 1 TTTS	39
12/WM/0024	histological analysis of matrigel	56
12/WM/0027	Pilot study of transcutaneous tibial nerve stimulation for FI Version1	33
12/WM/0044	PCI follow up and post PCI chest pain	26
12/WM/0054	V-Compas	41
12/WM/0059	Preventing excessive weight gain in pregnant women	20
12/WM/0064	ENTICE-001 European New Texture Breast Implant Study v1.0	27
12/WM/0065	The Centrality of Traumatic Psychotic Experiences	23

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/WM/0284	Factors influencing cannabis use in adolescents	18
11/WM/0288	Metabolism and ageing v2	19
12/WM/0050	A noninvasive method for jaundice screening to reduce blood tests	26

#### 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
11/WM/0107	Caregivers experience of a Dementia trial, V 3.0 16/02/11	16
11/WM/0124	Predictors of Length of Stay In a Medium Secure Psychiatric Service	17
11/WM/0179	Non weight-bearing subchondral stress fracture lateral femoral condyle	26
11/WM/0243	The role of Nm23-H1 as a haemopoietic stem cell survival factor	20

#### Favourable Opinion with Additional Conditions

<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/WM/0150	Achieving normal glucose in hospital settings	20
11/WM/0237	Inflammation and metabolic disease	20
11/WM/0287	DESKTOP III	17
11/WM/0321	Control Of Working Memory In Depressed And Non-depressed participants.	17
11/WM/0322	Pharmacology of immunosuppressants following heart transplantation	17
11/WM/0394	Measurement of hepcidin in weight management clinic patients (V2)	22
12/WM/0009	The meaning of perfectionism for clients with eating disorders [V 1]	31

#### **Unfavourable Opinion**

<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
11/WM/0316	Developing PROMs for People Nearing the End of Life	16

#### **Provisional Opinion**

<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
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#### **Provisional Opinion Pending Consultation with Referee**

<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
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#### **Further information response not complete**

<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
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#### **Withdrawn after the meeting**

<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
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#### **Invalid Application**

<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
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#### **No Opinion Pending Consultation with Referee**

<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
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<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>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>
11/WM/0100/AM01	Validation of the 3D laser to measure breast volume in situ	AM01	47

<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>