

**NRES Committee West Midlands -
Coventry & Warwickshire**

Annual Report

01 April 2013 – 31 March 2014

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee West Midlands - Coventry & Warwickshire
Type of REC:	RECs recognised to review CTIMPS in patients - type iii
Type of Flag:	Phase 1 Studies in Patients / Qualitative Research / Research Involving Adults Lacking Capacity / Research Involving Children
Chair:	Dr Helen Brittain
Vice-Chair:	Dr Matthew Dunn
Alternate Vice-Chair:	N/A
Co-ordinator:	Andre Graham/Dawn Denton/Rebecca Morledge
PRSC Co-ordinator:	Victoria Strutt
Assistant Co-ordinator:	Victoria Strutt
Committee Address:	The Old Chapel Royal Standard Place Nottingham NG1 6FS
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Chair's overview of the past year:

The picture for this year seems very similar, with the Committee working hard and enthusiastically to fulfil our role.

There is even greater pressure on time, especially for those working within the NHS, which makes the commitment to the REC even more valued. It would be good to have some new members to fill roles of those who have left, but are grateful for the contribution of such members.

Even with PR fully established, there are still very busy full meetings, and this presents great time pressures for all.

We are glad to have Rebecca Morledge and Vic Strutt now in their roles for the Committee and grateful for their hard work and willingness to grasp the many changes for those working in the office!

We remain aware of the importance of the work of ethics committees, especially in relation to issues around CTIMPs and the national publicity over reporting of such trials.

We enjoyed our thank you lunch together!

We look forward to continuing our work together, and building our relationship with Rebecca and Vic.

NRES Committee West Midlands - Coventry & Warwickshire Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr Jane Appleton	Nurse	Expert	01/04/2010	
Mr Roger Balcombe	Retired Chartered Engineer	Lay Plus	01/04/2010	
Dr Geraldine Brady	Senior Research Fellow	Lay	27/07/2011	
Dr Helen Brittain	Clinical Psychologist Retired	Lay	01/04/2010	
Mrs Barbara Canning	Senior University Lecturer	Lay	01/04/2010	
Mr Roger Cross	Senior Clinical Pharmacist	Expert	01/04/2010	
Dr Matthew Dunn	Consultant Accident and Emergency	Expert	01/04/2010	26/03/2014
Dr John S Fenlon	Statistical Consultant	Expert	25/05/2011	
Mrs Louise Harmer	Clinical Skills Tutor	Expert	01/04/2010	
Mrs Moya Horton	Retired University Lecturer (Physiotherapy)	Lay	01/04/2010	29/05/2013
Mrs Evette Hunkins-Hutchinson	Lecturer Health Care Management	Lay Plus	01/04/2010	
Dr Joanna Long	Research Fellow	Lay	25/09/2013	
Dr Adrian Neal	Clinical Tutor and Clinical Psychologist	Expert	01/01/2013	
Dr Ashok Roy	Consultant Psychiatrist/Children and Adults lacking Mental Capacity	Expert	01/04/2010	12/04/2013
Dr Gurnam Singh	Principal Lecturer in Social Work	Lay Plus	01/04/2010	

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Mr Paul Hamilton	Local Government Officer	Lay Plus	29/05/2013, 28/08/2013
Rev Keith Lackenby	Lay Plus Member	Lay Plus	29/01/2014 (written comments)

NRES Committee West Midlands - Coventry & Warwickshire: Members' Declarations of

Name	Declaration of Interest	Date
Dr Helen Brittain	None	17/02/2014
Dr Matthew Dunn	Occasional direct involvement with research locally Peer Review Emergency Medicine Journal International Journal of Emergency Medicine	17/02/2014
Dr Jane Appleton	Trustee of BASPCAN	17/02/2014
Mr Roger Balcombe	None	17/02/2014
Mrs Barbara Canning	None	17/02/2014
Mrs Louise Harmer	PhD student at Warwick University NHS Employee Teaching medical students and trust staff Due to commence own research during 2014 - 2016	17/02/2014
Mr Roger Cross	None	17/02/2014
Dr John S Fenlon	Statistical Consultant Coventry and Warwick	17/02/2014
Dr Geraldine Brady	Employed by Coventry University as a Researcher Undertakes ethical reviews of student and staff research proposals on behalf of Coventry University	17/02/2014
Dr Joanna Long	None	17/02/2014
Mrs Evette Hunkins-Hutchinson	None	27/02/2014
Dr Adrian Neal	Involved in local clinical psychology research connected to CWPT and Coventry and Warwick Universities	27/02/2014
Dr Gurnam Singh	None	27/03/2014

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

Month	Date	Number of Members Present at Meeting
April	24/04/2013	8
May	29/05/2013	8
June	26/06/2013	8
July	31/07/2013	9
August	28/08/2013	7
September	25/09/2013	7
October	30/10/2013	9
November	27/11/2013	9
January	29/01/2014	7
February	26/02/2014	11
March	26/03/2014	10

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	24/04/2013	3
May	29/05/2013	3
June	26/06/2013	3
July	31/07/2013	3
August	28/08/2013	3
September	25/09/2013	3
October	30/10/2013	3
November	27/11/2013	3
January	29/01/2014	3
February	25/02/2014	3
March	26/03/2014	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 Helen Brittain	10
Dr Matthew Dunn	10
Dr John S Fenlon	9
Mr Roger Balcombe	9
Mr Roger Cross	9
Mrs Louise Harmer	8
Mrs Barbara Canning	7
Dr Jane Appleton	7
Dr Adrian Neal	5
Dr Geraldine Brady	5
Dr Gurnam Singh	5
Mrs Evette Hunkins-Hutchinson	4
Dr Joanna Long	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
Dr Helen Brittain	10
Dr John S Fenlon	8
Mr Roger Cross	6
Mrs Barbara Canning	5
Dr Joanna Long	1
Dr Matthew Dunn	1

Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Dr Helen Brittain	23/10/2013 - 23/10/2016	Nottingham REC Centre Local Training Event, HRA
Dr John S Fenlon	23/10/2013 - 23/10/2013	Nottingham REC Centre Local Training Event, HRA
Dr Adrian Neal	23/10/2013 - 23/10/2013	Nottingham REC Centre Local Training Event, HRA
Mrs Barbara Canning	23/10/2013 - 23/10/2013	Nottingham REC Centre Local Training Event, HRA
Dr Helen Brittain	23/10/2013 - 23/10/2013	Equality & Diversity, HRA
Dr John S Fenlon	23/10/2013 - 23/10/2013	Equality & Diversity, HRA
Dr Adrian Neal	23/10/2013 - 23/10/2013	Equality & Diversity, HRA
Mrs Barbara Canning	23/10/2013 - 23/10/2013	Equality & Diversity, HRA

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	12	21.43
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	44	78.57
Total Applications Reviewed	56	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	7
Number of studies withdrawn prior to the meeting	10
Number of student applications reviewed	17
Number of paediatric applications reviewed	11
Number of device applications reviewed	1
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	13
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	3	5.36
Favourable Opinion with Additional Conditions	15	26.79
Unfavourable Opinion	8	14.29
Provisional Opinion	30	53.57
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	26	46.43
Further Information Favourable Opinion with Additional Conditions	2	3.57
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	3	5.36
Favourable Opinion with Additional Conditions	15	26.79
Unfavourable Opinion	8	14.29
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	2	3.57
Number of studies withdrawn after the meeting	0	0.00
Total	56	100

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

Total Applications Reviewed	31
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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	5	16.13
Favourable Opinion with Additional Conditions	10	32.26
No Opinion transfer to full committee for review	1	3.23
Provisional Opinion	12	38.71
Unfavourable Opinion	3	9.68
Total	31	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	29
Number of days taken to final decision - mode	22

Number of SSAs (non-Phase 1) reviewed	6
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	1
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)	0.0%

Number of substantial amendments reviewed	104
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	0
Number of modified amendments over 14 days	0
Number of modified amendments over 14 days as a % of total modified amendments	0%

Number of proportionate review applications for ethical review over 14 days*	1
Number of proportionate review applications over 14 days as a % of total	3.3%

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/0123	The SEPIA study	26
13/WM/0134	Needs and experiences of siblings of children with anxiety disorders	27
13/WM/0160	Neuroplasticity, depression and diabetes (version 1)	32
13/WM/0186	Mindfulness-based cognitive therapy for recurrent depression	17
13/WM/0220	Remote Mood Monitoring in diabetes	12
13/WM/0230	Saccadic Eye Movements in Normal Pressure Hydrocephalus(SEM-NPH) Trial	23
13/WM/0240	Electrical Muscle Stimulation in Severe Heart Failure Patients: Pilot	31
13/WM/0241	Primary care factors in the use of unplanned secondary care	33
13/WM/0269	Reducing Fear and Anxiety in exacerbation of COPD.	9
13/WM/0286	Patient's experience of sub optimal weight loss post Gastric Band	27
13/WM/0290	CRH receptors in the vasculature and blood cells	35
13/WM/0292	A study to assess the safety, tolerability, PK and PD of LAS190792	28
13/WM/0316	Perioperative Analgesia for Knee Arthroplasty	32
13/WM/0320	Bio-impedence characteristics of colorectal cancer tissue	11
13/WM/0322	PPCI Survey	11
13/WM/0332	Ocular development in children - Version 1	29
13/WM/0373	BMN701 Phase 3 in rhGAA Exposed Subjects with Late Onset Pompe Disease	49
13/WM/0379	Clot structure in atrial fibrillation	59
13/WM/0403	Mothers' Attitudes to the Infant Sleep Environment (MAISE)	12
13/WM/0419	MAMMO-50 version 1.0 [date]	36
13/WM/0421	A Phase I/II Trial of TG01 and Gemcitabine Protocol V5.1	32
13/WM/0424	Co-existing illness, drug treatments and their impact on HbA1c	54
13/WM/0428	Impact of community pharmacists on blood pressure control.	32
13/WM/0448	The value of six month stroke follow-up for people affected by stroke	24
13/WM/0463	Affective Instability in Different Diagnostic Groups: A pilot Study	36
13/WM/0493	Effect of fetal sex/maternal ethnicity on labour induction/onset	12
14/WM/0019	PRONIA	27
14/WM/0020	Experiences of the setting and therapeutic space in Psychotherapy_Ver1	29
14/WM/0022	Phase 2 Study of UX007 in Subjects with LC-FAOD	30

14/WM/0027	The effect of Ticagrelor on the CV outcomes of patient with diabetes	30
14/WM/0040	What do parents think about neonatal research?	11
14/WM/0068	Challenging Behaviour & Family Adjustment in Genetic Syndromes V1	28
14/WM/0082	Has the introduction of Orthodontic Therapists affected outcomes	9
14/WM/0095	Developing and validating a measure of guilt for persons with dementia	25
14/WM/0096	Prevalence Asymptomatic Carriage Clostridium difficile	22
14/WM/0116	Continuity of care post-hospitalisation - Version 1	8

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/WM/0223	Women's experiences of an NHS-led cardiac rehabilitation programme.	14
13/WM/0242	Autophotography study on psychological wellbeing	34
13/WM/0337	Long-term outcomes of venous ulcers after foam sclerotherapy	28
14/WM/0115	Solihull Approach course for parents 14/WM/0115	13

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/0184	Effect of spiral artery remodelling on the placenta	11
13/WM/0375	Patient-centred Pharmacy Services - Educational Project	11
13/WM/0399	Brains in Transition (BrIT)	54
13/WM/0405	MelaTools-Q Study	12
13/WM/0468	Hypertension in Dementia - Feasibility Study	22
14/WM/0023	NON-INTERVENTIONAL CLINICAL RESEARCH STUDY CYT-DEM-01	26
14/WM/0084	ARCAGE-NWE	8
14/WM/0086	ICH: Measurement of intraventricular haemorrhage & prognostic scores	7

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/WM/0143	Study of Moxetumomab Pasudotox in pALL or LL of B-Cell Origin	23
13/WM/0185	Patient Experience of Oral Sunitinib(Sutent®)	9
13/WM/0193	Emotional and neural responses to music in stroke patients	41

13/WM/0200	Exploring self-compassion, coping and carer burden	30
13/WM/0203	Preterm Birth and Attention	23
13/WM/0207	Immune Failure in Critical Therapy (INFECT) study (England)	22
13/WM/0222	Patient's experience of managing cancer related lymphoedema	10
13/WM/0267	Ipswich Touch Test (IpTT) to evaluate at-risk feet in RRT patients	8
13/WM/0318	Imatinib and BYL719 in patients with Gastrointestinal Stromal Tumour.	21
13/WM/0319	Developing a core information set for consent to oral cancer surgery	11
13/WM/0327	Investigating the relationship between hypoxia and metabolism	21
13/WM/0347	Evaluate Clinical Characteristics and Disease Progression in MPS IIIB	28
13/WM/0368	Fruit bioactives for good metabolic and vascular health	28
13/WM/0402	The Living with Brain Injury Group	10
13/WM/0446	Looking Back, moving forward - is there a need to monitor survivors?	7
13/WM/0466	Molecular Genetic Analysis and Clinical Studies (MGAC)	22
13/WM/0492	Evaluation of a Point of Care Test for hCG in blood	7
14/WM/0021	Social Network Intervention For Young People	26
14/WM/0038	Enhancing Surgical Outcomes with Optical Flow Analysis	8
14/WM/0039	Role of Participants in a Patient Participation Group	8
14/WM/0043	A national survey of patient reported outcome after anaesthesia	7
14/WM/0057	BASIL-2. Version 1.0	19
14/WM/0059	Rates of criminal victimisation in first episode psychosis	20
14/WM/0063	Retreatment safety study of radium-223 dichloride in prostate cancer	19
14/WM/0070	Effect of vitamin-D on Bone health of HIV patients	37

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/WM/0156	Helium thermocoagulation versus electrosurgery for endometriosis.	24
13/WM/0161	Autism and psychosis	23
13/WM/0190	Cardiopulmonary Resuscitation Debriefing study (CODE study)	22
13/WM/0221	Ipswich Touch Test (IpTT) to evaluate at-risk feet in RRT patients	14
13/WM/0287	CARMELINA DM CV outcome study 1218.22	26
13/WM/0291	Non Comparative study of ReCell in stable vitiligo	32
13/WM/0324	Awareness of emotional states in others. Version 1.	22
13/WM/0372	DNA damage response defects;discovery of new syndromes	29

13/WM/0450	Evaluation of OBJ Technology to Increase Fluoride Uptake (Version 2.0)	8
13/WM/0497	Decreasing stroke readmission rates using multidisciplinary follow up.	7
14/WM/0060	Palliative Care: Clinicians' EstimateS (P:CES)	19

Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
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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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No Opinion Pending Consultation with Referee

REC Reference	Application Short Title	Number of Days on Clock
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Not Requiring Review by NHS REC

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	
13/WM/0186	Mindfulness-based cognitive therapy for recurrent depression	17	
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
Section 30 application over 60 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock