

NRES Committee North East - Newcastle & North Tyneside 2

Annual Report

01 April 2013 – 31 March 2014

Name of REC:	NRES Committee North East - Newcastle & North Tyneside 2
Type of REC:	Type iii
Type of Flag:	CTIMPs, MCA
Chair:	Dr Alasdair MacSween
Vice-Chair:	Mr Michael Wyatt
Alternate Vice-Chair:	None
Co-ordinator:	Mrs Joan Brown
PRSC Co-ordinator:	Mrs Joan Brown
Assistant Co-ordinator:	Miss Kerry Dunbar
Committee Address:	Room 002 JARROW Business Centre Rolling Mill Road Jarrow NE32 3DT
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Chair's overview of the past year:

I took over from Professor Philip M Preshaw as Chair of the Committee in September 2013 having served as a member prior to that. I have found this Committee to be highly efficient and have been very impressed by members' commitment. Members participate in well informed and reasoned debate on the ethical issues raised and respect each other's opinions. Members easily reach consensus decisions in a reasoned manner. In my experience the opinions reached by members accord with the general consensus in the wider REC community and society in general.

The committee has been well supported by the REC Centre in its work and this looks set to continue with the changes in staffing introduced recently. Gillian and Sarah, and now Joan and Kerry, have all done a great job and I have every confidence in them and members going forward. My sole concern is that Mr Michael Wyatt, Vice-Chair, is coming to the end of his tenure in June 2014 and we have yet to arrange a successor. So far no member has been prepared to volunteer for this role and it would be of concern if no successor were found.

NRES Committee North East - Newcastle & North Tyneside 2 Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mr Chris Barron	NCRN Team Lead	Expert	16/07/2007	
Dr Catherine F M Bartley	Consultant in Anaesthesia and Intensive Care	Expert	01/03/2003	28/02/2014
Mrs Ann Boardman	Retired Educationalist	Lay Plus	01/02/2010	
Mr Andrew Brenikov	Historian	Lay Plus	01/04/2008	
Mrs Jane Curry	Head of Cardiac and Respiratory Services	Expert	01/10/2013	
Dr Sumaira MacDonald	Consultant Vascular Radiologist/Honorary Clinical Senior Lecturer	Expert	09/07/2003	31/10/2013
Dr Alasdair MacSween	Principal Lecturer in Research Governance	Expert	01/04/2013	
Mrs Gaynor Mitchell	Part-time Biology Lecturer (Retired)	Lay Plus	01/06/2011	
Mr Peter Morton	Voluntary Worker/Former Contracts-Procurements Manager	Lay Plus	01/09/2008	31/05/2013
Mrs Susan P Phillips (had 18 months leave of absence from 01.01.2011 – 01/08/2013)	Clinical Lead Pharmacist	Expert	13/10/2003	
Professor Philip M Preshaw	Professor of Periodontology and Consultant in Restorative Dentistry	Expert	01/03/2003	31/08/2013
Ms Vicky Ryan	Statistician	Expert	15/07/2011	
Dr Jared Thornton	Clinical Trials Co-ordinator	Lay	12/07/2011	
Dr Ray Wainwright	Volunteer Researcher	Lay	01/04/2013	
Mr Michael Wyatt	Consultant General and Vascular Surgeon	Expert	01/03/2003	

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended
Mrs Nermin Basta	Research Assistant/Statistician	Expert	29/05/2013, 24/07/2013, 23/10/2013, 20/11/2013

NRES Committee North East - Newcastle & North Tyneside 2: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Dr Alasdair MacSween	Alasdair is currently employed as principal lecturer at Teesside University	06/02/2014
Mrs Ann Boardman	No interests declared.	06/02/2014
Ms Vicky Ryan	No interests declared.	06/02/2014
Dr Ray Wainwright	Ray's wife is currently serving on a Regional Committee of Cruse Bereavement Advisory Service. Ray himself is not active in any charity or voluntary service.	06/02/2014
Mrs Gaynor Mitchell	Gaynor is a member of the League of Friends of Prudhoe Hospital (Ferndene) as well as being a member of the Carers Management Board CSSL Ltd.	06/02/2014
Mr Andrew Brenikov	No interests declared.	06/02/2014
Mr Chris Barron	Manager the late phase Oncology Trials Team at Sir Bobby Robson Cancer Trials Research Centre, Freeman Hospital, Newcastle Hospitals Trust.	12/02/2014
Mrs Jane Curry	Sits on the R&D business committee for CDD NHS FT. Clinically supervises a number of research projects with Durham University.	12/02/2014
Mr Michael Wyatt	No interests declared	25/02/2014
Mrs Susan P Phillips	No interests declared	28/02/2014
Mr Chris Barron	Manager the late phase Oncology Trials Team at Sir Bobby Robson Cancer Trials Research Centre, Freeman Hospital, Newcastle Hospitals Trust.	12/02/2014
Mrs Jane Curry	Sits on the R&D business committee for CDD NHS FT. Clinically supervises a number of research projects with Durham University.	12/02/2014
Mr Michael Wyatt	No interests declared	25/02/2014
Mrs Susan P Phillips	No interests declared	28/02/2014
Dr Jared Thornton	Staff member - Sir Bobby Robson Cancer Trials Research Centre, Freeman Hospital.	06/02/2014

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	10
July	24/07/2013	7
August	21/08/2013	9
September	18/09/2013	8
October	23/10/2013	9
November	20/11/2013	9
December	18/12/2013	8
January	22/01/2014	9
February	19/02/2014	7

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
April	17/04/2013	3
May	22/05/2013	3
July	17/07/2013	3
August	14/08/2013	3
September	11/09/2013	3
October	15/10/2013	3
November	13/11/2013	3
December	11/12/2013	3
January	06/01/2014	3
February	05/02/2014	3
February	19/02/2014	3
March	03/03/2014	3

12 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
Mr Andrew Brenikov	10
Dr Ray Wainwright	8
Dr Alasdair MacSween	7
Mr Chris Barron	7
Dr Catherine F M Bartley	6
Mr Michael Wyatt	6
Mrs Ann Boardman	6
Ms Vicky Ryan	6
Dr Jared Thornton	5
Professor Philip M Preshaw	5
Dr Sumaira MacDonald	4
Mrs Gaynor Mitchell	4
Mrs Nermine Basta	4
Mrs Susan P Phillips	4
Mrs Jane Curry	3
Mr Peter Morton	1

Number of inquorate meetings held: None**Attendance of Members at proportionate review sub-committee meetings:**

Name	Number of Meetings Attended
Dr Jared Thornton	6
Mr Michael Wyatt	6
Mrs Gaynor Mitchell	5
Dr Ray Wainwright	4
Mr Chris Barron	3
Professor Philip M Preshaw	3
Ms Vicky Ryan	2
Mr Andrew Brenikov	2
Dr Alasdair MacSween	2
Dr Sumaira MacDonald	1
Mrs Ann Boardman	1
Mrs Susan P Phillips	1

Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Mr Andrew Brenikov	04/09/2013 - 04/09/2013	MCA, NRES/HRA
Dr Alasdair MacSween	11/12/2013 - 11/12/2013	National Chair's Training Day, NRES/HRA
Mrs Susan P Phillips	20/11/2013 - 20/11/2013	National Members' Training Day, NRES/HRA
Mr Andrew Brenikov	24/09/2013 - 24/09/2013	Quantitative Research Methods and Statistics: A Health Research Authority Workshop, NRES
Mrs Gaynor Mitchell	04/11/2013 - 04/11/2013	Ethics and GCP Forum: Adapting to Structural Changes
Mrs Nermine Basta	19/02/2014 - 19/02/2014	Reviewing CTIMPs, HRA
Mrs Jane Curry	05/03/2014 - 05/03/2014	Induction, HRA
Ms Vicky Ryan	09/10/2013 - 09/10/2013	Data & Safety Monitoring in Research , Lancaster University
Mrs Ann Boardman	14/03/2014 - 14/03/2014	Improving Informed Consent Training - A Collaborative Workshop, HRA
Dr Ray Wainwright	21/01/2014 - 21/01/2014	Equality & Diversity, HRA – Approximately 2 hours
		Self-Directed Learning - Approximately 1 & half hours including reading, checking and assessments
	03/03/2014 - 03/03/2014	Self-Directed Learning - Research Data & Confidentiality E-learning Course - Approx 2 hours, HRA
Dr Jared Thornton	19/02/2014 - 19/02/2014	CTIMP Training, HRA
Mr Michael Wyatt	01/04/2013 - 30/11/2013	SDL completed: Review and feedback on scientific publications submitted to two international journals – <i>20 hours</i> Equality and Diversity – <i>1 hour</i> Safeguarding Children & Adults Level 1 – <i>1 hour</i> Appraisal and feedback on scientific papers/presentations for Faculty Meeting for Health Education North East – <i>6 hours</i>

Part 2: REC workload and activity during the reporting period.

List of Training Events Organised Locally by the Co-ordinator:

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	9	18.37
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	40	81.63
Total Applications Reviewed	49	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	3
Number of studies withdrawn prior to the meeting	8
Number of student applications reviewed	17
Number of paediatric applications reviewed	5
Number of device applications reviewed	1
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	8
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	10.20
Favourable Opinion with Additional Conditions	8	16.33
Unfavourable Opinion	4	8.16
Provisional Opinion	32	65.31
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	49	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	30	61.22
Further Information Favourable Opinion with Additional Conditions	2	4.08
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	5	10.20
Favourable Opinion with Additional Conditions	8	16.33
Unfavourable Opinion	4	8.16
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
Total	49	100

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

Total Applications Reviewed	28
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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	21	75.00
Favourable Opinion with Additional Conditions	4	14.29
No Opinion transfer to full committee for review	1	3.57
Provisional Opinion	2	7.14
Unfavourable Opinion	0	0.00
Total	28	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	4.90
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	32
Number of days taken to final decision - mode	27
Number of SSAs (non-Phase 1) reviewed	0
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%
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	82
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	2
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*	1
Number of proportionate review applications over 14 days as a % of total	3.7%
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*	1
Number of proportionate review applications over 14 days as a % of total	3.7%

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/NE/0106	ASPIRE	60
13/NE/0108	Patient factors contributing to gastrostomy retention in head and neck	34
13/NE/0109	An exploration of compassion as an essential component of nursing	28
13/NE/0115	Ciprofloxacin in subjects with Non-Cystic Fibrosis Bronchiectasis	34
13/NE/0118	Bioequivalence Study of DOXIL®/CAELYX®	28
13/NE/0120	Preparatory auditory attention in hearing-impaired children: Version 1	47
13/NE/0141	Comorbidity between PTSD and anxiety and depression v2	25
13/NE/0142	What do women with secondary breast cancer tell their children?	25
13/NE/0197	Ranibizumab for DMO PRP trial (RDP trial)	25
13/NE/0237	Practice Nurse Collaborative Care Qualitative Evaluation	36
13/NE/0238	Effects of AMG 145 Treatment on Atherosclerotic Disease GLAGOV	35
13/NE/0239	Diagnosis of Alzheimer's disease by measuring blood proteins	39
13/NE/0248	A single-arm study to assess effect and tolerability of SLT on OIC	28
13/NE/0252	Visual hallucinations: an EEG and non-invasive stimulation study	53
13/NE/0255	Clinical course of C.difficile infection	35
13/NE/0261	Experiences of chronic low back pain and intimate partner violence v.2	41
13/NE/0299	EuroHyp-1	40
13/NE/0326	MitoCohort	34
13/NE/0327	Apomorphine s.c. infusion in Parkinson's to control motor symptoms.	39
13/NE/0339	Glycerine Trinitrate for Retained Placenta (GOT-IT Trial)	37
13/NE/0352	Exploring the relationship between alcohol and sexual decision-making	36
13/NE/0353	Skeletal Muscle Mitochondrial Function in Pulmonary Hypertension	34
13/NE/0359	Visual hallucinations, visuo-perceptual function and attention	45
13/NE/0360	4080 DEVOTE Degludec CV Outcome Study	46
13/NE/0361	OPTIMAL - Optimising Renal outcome in Myeloma renal failure	54
14/NE/0009	Infantile FSHD Study	32
14/NE/0011	STRIDER	33
14/NE/0023	Inferior Vena Cava Collapsibility Index In Severe Sepsis v3	24
14/NE/0043	Textured insoles for gait and balance impairment in MS	24
14/NE/0055	FORENSIC FACIAL RECONSTRUCTION USING COMPUTER TOMOGRAPHY (CT) SCAN V 3	42
14/NE/0059	Understanding adhesion formation, version 1	8

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
13/NE/0298	Experience of therapeutic relationship in Behavioural Family Therapy	40
13/NE/0358	Feasibility study to develop and test a Cultural Health Check Toolkit	33

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
13/NE/0135	The role of coping styles in the management of chronic pain.	8
13/NE/0171	Efficacy of a CBM-I tas	8
13/NE/0172	Understanding the barriers to physical activity in haemodialysis patients	8
13/NE/0173	Management of pain in sickle cell disease	8
13/NE/0188	Survival of children born with congenital heart disease	22
13/NE/0198	REDEXAM - reducing painful eye examinations in preterm infants	22
13/NE/0208	Contribution of muscle and liver glycogen storage during daily eating	26
13/NE/0229	Induction of protective immunoglobulin responses in the nasal mucosa	9
13/NE/0230	Notifications of occupational asthma in the West Midlands	10
13/NE/0231	South Asian Patients' Experiences of MSK Physiotherapy v1.0	9
13/NE/0232	Behavioural Activation and Goal Setting Study (BAGS)	8
13/NE/0233	A 4D Flow MR Study of PFO causing desaturation - Case Study	7
13/NE/0244	Knee-body image following a total knee replacement.	9
13/NE/0251	Individual and carer perceptions of Autism diagnosis in adulthood	9
13/NE/0253	Participants' experience of an ex class following bariatric surgery	7
13/NE/0310	Arrhythmia and systemic ventricular function in atrial switch for TGA	27
13/NE/0316	Henoch-Schönlein purpura nephritis (HSN) Study	8
13/NE/0345	Older HF patients initiated on ivabradine in UK: Quality of Life	7
13/NE/0362	Women's experience of giving birth in relation to perineal outcome	10
13/NE/0375	Biological markers of renal involvement in systemic sclerosis (v.1.0)	14
14/NE/0014	Access to GP Electronic Medical Records on-line: Patient Perspectives	8
14/NE/0039	Identifying the elements of effective hospital management of self-harm	5
14/NE/0041	CRPS Dyads	9
14/NE/0045	TUBE Trial	24
14/NE/0074	Postoperative respiratory failure: a case control study	9

14/NE/0075	Assessment of MBL deficiency in pancreatic islet auto-transplantation	12
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Favourable Opinion with Additional Conditions		
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REC Reference	Application Short Title	Number of Days on Clock
13/NE/0144	THRIFT v1.2	23
13/NE/0155	Magneto encephalography (MEG) in musical hallucination	35
13/NE/0190	Comparing MRI scan and X-rays in Acromioclavicular joint dislocations	22
13/NE/0204	Impact of obesity surgery on biomarkers of risk of colorectal cancer	22
13/NE/0264	Frailty assessment in patients with HCC	27
13/NE/0265	Frailty assessment in the elderly with Upper GI cancer	27
13/NE/0276	Mobility of older people in hospital version 1	8
13/NE/0295	The study of dynamic and static elements of hip fracture	21
13/NE/0301	A mixed method analysis of endings in Cognitive Analytic Therapy (V1)	27
13/NE/0312	Focus Groups in Parkinson's disease	7
13/NE/0364	Patient, carer and acute medical team perspectives' on A&E use	12
14/NE/0040	Vancomycin pharmacokinetics in PICU using scavenged samples	5

Unfavourable Opinion		
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REC Reference	Application Short Title	Number of Days on Clock
13/NE/0127	Pilot of an Assessment Tool for Autistic Spectrum Conditions in Adults	27
13/NE/0203	1072nm Transcranial Phototherapy as a treatment for dementia	23
13/NE/0343	How is clinical decision making enacted? A pilot study.	28
14/NE/0006	How is clinical decision making enacted? A pilot study.	27

Provisional Opinion		
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REC Reference	Application Short Title	Number of Days on Clock
14/NE/0077	Mapping; what makes a good experience? Version two. 14/NE/0063.	N/A

Provisional Opinion Pending Consultation with Referee		
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REC Reference	Application Short Title	Number of Days on Clock
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Further information response not complete		
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REC Reference	Application Short Title	Number of Days on Clock
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Withdrawn after the meeting		
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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

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
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Proportionate review applications for ethical review over 14 days timeline

REC Reference	Application Short Title	Number of Days on Clock
14/NE/0077	Mapping; what makes a good experience? Version two. 14/NE/0063.	15

SSAs (non Phase 1) over 25 days timeline

REC Reference	Application Short Title	Number of Days on Clock
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SSAs (Phase 1) over 14 days timeline

REC Reference	Application Short Title	Number of Days on Clock
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Substantial Amendments over 35 day timeline

Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
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Modified Amendments over 14 day timeline

Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
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Section 30 application over 60 day timeline

Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
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