

**NRES Committee North East - County  
Durham & Tees Valley**

**Annual Report**

**01 April 2011 – 31 March 2012**

## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	NRES Committee North East - County Durham & Tees Valley
<b>Type of REC:</b>	Authorised
<b>Type of Flag:</b>	Paediatrics
<b>Chair:</b>	Dr A MacSween
<b>Vice-Chair:</b>	Mr S Chandler
<b>Alternate Vice-Chair:</b>	
<b>Co-ordinator:</b>	Mrs Joan Brown
<b>Assistant Co-ordinator:</b>	Miss Sarah Grimshaw – 11.02.12 - present
<b>Committee Address:</b>	Room 002 TEDCO Business Centre Viking Industrial Park Rolling Mill Road Jarrow Tyne & Wear NE32 3DT
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### Chair's overview of the past year:

*Following the retirement of the previous Chair (Dr Drury) after many, many years of exemplary service to NRES, I took up the position of Chair in mid July 2011. I had previously been the Vice-Chair of the Committee and Steven Chandler was appointed as Vice-Chair in early October 2011. At present the committee operates without an Alternate Vice-Chair but we continue to encourage members to consider the position. Despite these major changes the Committee has functioned smoothly and members appear to have taken it all in their stride. The main issue, over my tenure this year, has been around PRSC in that a relatively small number of members have carried the burden of this work. Members recently agreed to adopt a system where the schedule of PRSC meetings for each year ahead is set and then distributed to all. Members can then book-in for Committees which suit their diaries. Members agreed that this would be fairer, as they would know how many PRSC there were in the year and how many each members should undertake to ensure equity, and also thought it would be easier for them to plan ahead. We are in the process of organising this and of course we must wait to see how it works but I am hopeful it will help avoid monthly calls for volunteers and balance the workload between members more evenly over the coming year.*

*I have enjoyed my period as Chair and the Committee so far and look forward to the future. The Committee works very well which is attributable not only to our member's commitment, energy and expertise but the excellent level of support we enjoy from our coordinator (Joan Brown) and all at the NE NRES REC centre.*

## NRES Committee North East - County Durham & Tees Valley Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr EA Baker	Clinical Research Scientist	Expert	01/04/2010	
Mrs J Bedlington	Charity Manager	Lay Plus	01/12/2010	
Mr S Chandler	Retired Consultant Medical Physicist	Lay	01/04/2010	
Mr P Dean	Chief Pharmacist	Expert	01/04/2010	
Dr John Drury	Consultant Pathologist	Expert	01/04/2010	15/07/2011
Mrs R Duncan	University Lecturer	Expert	01/04/2010	
Dr S Gupta	Consultant Neonatologist	Expert	01/04/2010	
Dr Chidambara Harikumar	Consultant Neonatologist	Expert	01/04/2010	
Mr Brian Houston	Senior Lecturer in Physiotherapy	Expert	01/04/2010	
Mrs F Hutchison	Principal Teacher	Lay Plus	01/04/2010	
Dr A MacSween	Principal Lecturer in Research Governance	Expert	01/04/2010	
Mr M Roff	Retired Chartered Engineer	Lay Plus	01/04/2010	
Mrs Julie Ryan	Pathology Quality Manager	Expert	01/04/2010	
Dr E Scott	Research Advisor	Expert	01/04/2010	
Mr S Wadhvani	Consultant in A&E	Expert	01/04/2010	13/12/2011
Dr Ray Wainwright	Volunteer Researcher	Lay	01/11/2011	
Mrs Sophie Welch	Research Governance & Policy Officer	Lay	01/04/2010	

### Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Dr Sebastian Sethe	Legal and Regulatory Officer	Lay	14/07/2011

## NRES Committee North East - County Durham & Tees Valley : Members' Declarations of

Name	Declaration of Interest	Date
Dr EA Baker	North Tees & Hartlepool NHS Foundation Trust R&D Peer Review Committee	01/02/2012
Mrs J Bedlington	Honorary Treasurer & Governor of Liversnorth Charity - Liver Patient Support Group	01/02/2012
Mr S Chandler	None	01/02/2012
Mr P Dean	Trust R&D Member NPSG Member Occasional Pharmaceutical Industry Sponsorship recipient for meetings, subject to ABPI guidance	01/02/2012
Mrs Rachel Duncan	Currently on leave of absence - no DOI submitted yet	
Dr S Gupta	Deputy Director R&D - North Tees & Hartlepool NHS Foundation Trust MRCN North East Area Deputy Lead Neonatal CSG (MCNR)- UK Lead for Neonatal Cardiology Research Member of European Scientific Committee for Neonatal Resuscitation Member of ESPR, SPR & ERS	01/02/2012
Dr Chidambara Harikumar	Fellow of the RCPCH	07/02/2012
Mr Brian Houston	Senior Lecturer in Physiotherapy	12/01/2012
Mrs F Hutchison	None	01/02/2012
Dr A MacSween	Chair Teesside University School of Health & Social Care Research Governance & Ethics Committee Vice-Chair Teesside University Research Ethics Committee	01/02/2012
Mr M Roff	Ordinary shareholder in Astra Zeneca	01/02/2012
Mrs Julie Ryan	Senior Biomedical Scientist - Microbiology	10/01/2012
Dr Eileen Scott	Currently on leave of absence – no DOI submitted yet	
Dr Ray Wainwright	Volunteer researcher (unpaid) with Department of Academic Psychiatry, RVI, Newcastle. User-volunteer attending meetings organised by Tees, Esk & Wear Valleys NHS Trust	01/02/2012
Mrs Sophie Welch	MSF Supporter Research governance responsibilities at Durham University and member of School of Medicine & Health Ethics Sub Committee	01/02/2012

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

Month	Date	Number of Members Present at Meeting
April	12/04/2011	11
May	10/05/2011	10
June	14/06/2011	14
August	09/08/2011	8

September	13/09/2011	10
October	11/10/2011	10
December	13/12/2011	8
January	09/01/2012	7
March	12/03/2012	10

9 full committee meetings were held during the reporting period.

**Proportionate Review Sub Committee Meetings held during 01 April 2011 - 31 March 2012:**

Month	Date	Number of Members Present at Meeting
April	01/04/2011	3
April	12/04/2011	3
July	14/07/2011	3
August	19/08/2011	3
September	23/09/2011	3
October	28/10/2011	3
November	25/11/2011	3
January	20/01/2012	3
February	13/02/2012	3
March	09/03/2012	3
March	23/03/2012	3

11 proportionate review sub-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 A MacSween	8
Mr S Chandler	8
Mrs Sophie Welch	7
Mrs F Hutchison	7
Dr EA Baker	7
Mr M Roff	7
Mr P Dean	7
Mr Brian Houston	6
Mrs J Bedlington	6
Mrs Julie Ryan	6
Dr S Gupta	5
Dr Chidambara Harikumar	5
Dr John Drury	3
Dr Ray Wainwright	3
Mr S Wadhvani	2
Mrs R Duncan	1

**Number of inquorate meetings held: 0**

**Attendance of Members at proportionate review sub-committee meetings:  
01 April 2011 – 31 March 2012:**

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr EA Baker	4
Mrs J Bedlington	6
Mr S Chandler	7
Mr P Dean	1
Dr John Drury	1
Mr Brian Houston	1
Mrs F Hutchison	1
Dr A MacSween	5
Mr M Roff	2
Mrs Julie Ryan	2
Dr Sebastian Sethe	1
Mrs Sophie Welch	2

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

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr EA Baker	05/07/2011 - 05/07/2011	Equality & Diversity, NRES
Dr EA Baker	19/09/2011 - 19/09/2011	NRES Update Session - Half Day Training, NRES
Dr EA Baker	22/09/2011 - 22/09/2011	Consent, Risks & Decisions in Health Research, NRES
Dr EA Baker	09/01/2012 - 09/01/2012	MCA DVD review - after main REC meeting - half day's training, NRES
Dr EA Baker	28/03/2012 - 28/03/2012	NRES Members National Training Day, NRES
Mrs J Bedlington	19/09/2011 - 19/09/2011	NRES Update Session - Half Day Training, NRES
Mrs J Bedlington	09/01/2012 - 09/01/2012	MCA DVD review - after main REC meeting - half day's training, NRES
Mrs R Duncan	19/10/2011 - 19/10/2011	Medical Devices Training, NRES
Mr P Dean	29/06/2011 - 29/06/2011	Equality & Diversity, NRES
Mr P Dean	07/11/2011 - 07/11/2011	Introduction to Clinical Research & Good Clinical Practice, PHLEX
Mr S Chandler	06/12/2011 - 06/12/2011	Chairing Skills, NRES - Chairs National Training Day
Mr S Chandler	09/01/2012 - 09/01/2012	MCA DVD review - after main REC meeting - half day's training, NRES
Dr S Gupta	01/04/2011 - 01/04/2011	GCP Training, North Tees & Hartlepool NHS Foundation Trust
Dr S Gupta	09/01/2012 - 09/01/2012	MCA Members DVD - review after main REC meeting - half day's training, NRES
Dr Chidambara Harikumar	14/06/2011 - 14/06/2011	NRES - Single Issue Ethical Debate - Confidentiality, NRES
Mrs F Hutchison	23/03/2012 - 23/03/2012	MCA DVD review at home - 90 minutes self directed learning, NRES
Mrs F Hutchison		Equality & Diversity
Dr A MacSween	15/09/2011 - 15/09/2011	Human Tissue Act, NRES
Dr A MacSween	19/09/2011 - 19/09/2011	NRES Update Session - Half Day Training, NRES
Dr A MacSween	09/01/2012 - 09/01/2012	MCA DVD review - after main REC meeting - half day's training, NRES
Dr A MacSween	29/02/2012 - 29/02/2012	NRES Personal Date in Research, NRES
Mr M Roff	09/01/2012 - 09/01/2012	MCA DVD review after main REC meeting - half day's

		training, NRES
Mr M Roff	28/03/2012 - 28/03/2012	NRES Members Training Day, NRES
Dr Ray Wainwright	09/01/2012 - 09/01/2012	MCA DVD review - after main REC meeting - half day's training, NRES
Dr Ray Wainwright	28/03/2012 - 28/03/2012	NRES Members National Training Day, NRES
Mrs Sophie Welch	31/01/2012 - 31/01/2012	NRES Phase 1 Training, NRES
Mrs Sophie Welch	28/03/2012 - 28/03/2012	NRES Members National 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:**

<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	34	100.00
<b>Total Applications Reviewed</b>	<b>34</b>	<b>100</b>

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

Number of applications made invalid by co-ordinator	4
Number of studies withdrawn prior to the meeting	8
Number of student applications reviewed	20
Number of paediatric applications reviewed	4
Number of device applications reviewed	0
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	0	0.00
Favourable Opinion with Additional Conditions	1	2.94
Unfavourable Opinion	1	2.94
Provisional Opinion	32	94.12
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>34</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	20	58.82
Further Information Favourable Opinion with Additional Conditions	6	17.65
Further Information Unfavourable Opinion	1	2.94
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	1	2.94
Unfavourable Opinion	1	2.94
Provisional Opinion	3	8.82
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	1	2.94
Number of studies withdrawn after the meeting	1	2.94
<b>Total</b>	<b>34</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>28</b>
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**Table 6: Decisions given at proportionate review sub-committee meetings held within the reporting period:**

<b>Decisions taken at proportionate review sub-committee meetings</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	10	35.71
Favourable Opinion with Additional Conditions	8	28.57
No Opinion transfer to full committee for review	4	14.29
Provisional Opinion	6	21.43
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>28</b>	<b>100</b>

**Table 7: Other Management Information for the reporting period:**

<b>Average number of applications reviewed per full meeting</b>	3.40
<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>	38
<b>Number of days taken to final decision - mode</b>	37
<b>Number of SSAs (non-Phase 1) reviewed</b>	1
<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>	37
<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>	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%
<b>Number of proportionate review applications for ethical review over 14 days*</b>	5
<b>Number of proportionate review applications over 14 days as a % of total</b>	20.83%

**\*NB – Proportionate Review Service was in pilot phase until September 2011 and was an aim not a target**

**Table 8: 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/NE/0058	Reproductive loss in multiple pregnancies	35
11/NE/0071	NHS Staff Attitude to Consultant Pay Systems	47
11/NE/0080	Stroke Physicians Barriers to Research Participation	23
11/NE/0081	Cortisol and cognition in primary sleep disorders	38
11/NE/0101	Medication adherence in heart failure	47
11/NE/0108	Factors affecting nausea and vomiting as a result of chemotherapy (v1)	46
11/NE/0149	Exercise training, optimising the benefits. Version 1.0	46
11/NE/0193	Artificial language learning in aphasia	37
11/NE/0230	Participation in Bowel Cancer Screening Programmes, Version 1	49
11/NE/0237	The efficacy of CBT based interventions for ISB for adults with LD	21
11/NE/0238	GPs' perception & use of IAPT. Version 1.	31
11/NE/0262	Minimally Invasive Oesophageal Adeno carcinoma Sentinel Node Biopsy4.0	48
11/NE/0264	Objective assessment of upper limb function in Parkinson's disease	49
11/NE/0276	Platelet aggregation after on or off bypass surgery	36
11/NE/0289	Survey of Neurological outcomes post VAD insertion in children	32
11/NE/0297	Using a consultation aid in Oncology clinical practice	14
11/NE/0299	Troponin release after anthracycline chemotherapy in breast cancer V.1	46
11/NE/0302	Crossover study of automated control of inspired oxygen in newborns	27
11/NE/0383	VAR CWA v1.0	48
12/NE/0003	Validation of a parent-child mealtime interaction assessment (1)	54
12/NE/0011	Local/Regional Anaesthesia and Arteriovenous Fistula Survival	26
12/NE/0029	Clinical performance of Filtek Supreme XTE dental restorations	13
12/NE/0135	Impact of Neurofibromatosis 1 on Quality of Life	9

<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/NE/0146	Speech in Parkinson's and depression (version 2.0)	51
11/NE/0147	Therapists' thinking processes during therapy	37
11/NE/0225	Psychological wellbeing and future disorientation in cancer survivors	43

11/NE/0247	Anxiety in Autism	25
11/NE/0270	Therapeutic Processes in CBT with people with learning disabilities	47
11/NE/0364	CHUMS Study	19
11/NE/0366	The Development of an orthodontic questionnaire	27
11/NE/0374	BSRBR-AS	33

#### Further Information Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/NE/0369	The concept of remission for people with a diagnosis of schizophrenia	37

#### Favourable Opinion with Standard Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/NE/0076	Does a GP's experience affect their attitude towards annual appraisal?	12
11/NE/0077	Speech Development in Unilateral Cleft Lip and Palate	9
11/NE/0078	Understanding the harms and benefits of Warfarin through metaphor	7
11/NE/0096	Diabetic patient views on depression screening (QOF DEP1 domain)	8
11/NE/0098	Difference in hip strength in males with patellofemoral pain syndrome	7
11/NE/0256	Collection of clinical remnant samples (version 1)	16
11/NE/0322	Gene variants in IL 28B and ABCB11 to predict HCV recurrence	12
12/NE/0027	Mattress Validation Study. Protocol A, Version 1.	13
12/NE/0112	Analysis of cancer testis antigens expression patterns in placenta -V1	12
12/NE/0115	Venous invasion in colorectal cancer	7

#### Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/NE/0075	IDEA CETL/CIHM Ethics Inquiry	8
11/NE/0138	The impact of client suicide for Mental Health Nurses - version 2	37
11/NE/0191	Parent/carer experiences of Autistic Spectrum Condition assessment	16
11/NE/0251	Public involvement in research: assessing impact	8
11/NE/0259	Translational approaches to Cystinuria	11
11/NE/0296	Metabolic Control in Diabetes: Family Functioning & Resiliency	12
11/NE/0326	COPD Patient experience and outcomes using the LTC6 and CAT	13
11/NE/0365	Intrauterine contraception insertion pain experience	17

12/NE/0062	Non-invasive and invasive blood pressure monitoring	7
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#### Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/NE/0100	Useful components of CBT for sex offenders in LD community	45

#### Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
12/NE/0080	Evaluation of Durham Palliative Care Discharge Facilitator Service	N/A
12/NE/0091	Does the HCR-20 risk assessment predict ward based violence? (V1)	N/A
12/NE/0097	A pilot study of PEG feeding in advanced pancreatic cancer-Version 1	N/A
12/NE/0104	Building a research culture in the NHS: Researcher perspectives	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
12/NE/0092	Electrocardiographic Placement of V5 Electrode	20

#### 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:**

<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>	
11/NE/0191	Parent/carer experiences of Autistic Spectrum Condition assessment	16	
11/NE/0256	Collection of clinical remnant samples (version 1)	16	
11/NE/0364	CHUMS Study	19	
11/NE/0365	Intrauterine contraception insertion pain experience	17	
11/NE/0366	The Development of an orthodontic questionnaire	21	
<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>