

**NRES Committee North East -  
Sunderland**

**Annual Report**

**01 April 2013 – 31 March 2014**

## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	NRES Committee North East - Sunderland
<b>Type of REC:</b>	Recognised
<b>Type of Flag:</b>	Phase 1 CTIMP Studies in Patients Research Involving Children
<b>Chair:</b>	Mr Paddy Stevenson
<b>Vice-Chair:</b>	Mrs Cheryl Anderson (until resignation on 02/02/2014)
<b>Alternate Vice-Chair:</b>	Miss Christine Bullmore
<b>REC Manager:</b>	Miss Kathryn Murray
<b>REC Assistant:</b>	Miss Sarah Prothero (03/02/2014 onwards) Miss Kerry Dunbar (07/10/2013 – 02/02/2014) Miss Christie Ord (01/04/2013 – 07/10/2014)
<b>Committee Address:</b>	Room 002, Jarrow Business Centre Viking Business Park Jarrow Tyne & Wear NE32 3DT
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### Chair's overview of the past year:

It has been another year of change, sadness and success for the Sunderland Committee. Firstly, it was with great sorrow several members left the Committee after long service, notably Cheryl Anderson who had supported me as Vice Chair since I took over in January 2007. I would also like to thank Sumanto Halder, Karen Horridge and Robert Pullen for all of their services until their retirement from the committee. We were, however, fortunate to welcome John Blenkinsopp, Helen Lucraft and Ross Sayers to the Committee.

Sunderland REC continues its proud tradition of engaging with researchers with its rolling programme of observers attending meetings (six observers attended in this reporting year) and I facilitated another five ethics and consent training days (supported by our Local Research Network).

The work of the Committee continues to remain high quality with no breaches to target and of the 76 (including 26 Proportionate Review) applications, 48 received either a favourable or favourable with conditions decision. Also, despite having a mean average membership of 10 during the year we maintained quoracy at all meetings, with a mean average of 8.7 Members per meeting. Recruiting new Members is ongoing and as always remains a challenge.

Finally, can I thank the Bunny Hill Medical Centre for being our meeting venue as from August 2014 we will be moving to a hotel next to Newcastle Central Station and changing our name to NRES Committee North East - Tyne & Wear South. Many thanks to all who have supported us.

## NRES Committee North East - Sunderland Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mrs Cheryl Anderson	Vice-Chairman	Lay Plus	08/06/2004	28/02/2014
Ms Sophie Barron	Student	Lay Plus	01/01/2013	
Mr John Blenkinsopp	Clinical Effectiveness Advisor	Lay Plus	14/06/2013	
Miss Christine Bullmore	Emergency Planning Co-ordinator	Expert	27/02/2004	
Mr Ian Campbell	Pharmacy	Expert	12/06/2012	
Dr Sumanto Haldar	Research Scientist	Expert	01/11/2009	28/04/2013
Dr Karen Horridge	Consultant Paediatrician (Neurodisability)	Expert	01/08/2009	31/08/2013
Mr Obi Iwuchukwu	Consultant Surgeon	Expert	07/01/2013	
Mrs Debra J Lett	Manager Newcastle Brain Tissue Resource	Lay	19/09/2011	
Dr Helen H Lucraft	Consultant Clinical Oncologist (retired)	Expert	01/07/2013	
Dr Chris Plummer	Consultant Cardiologist	Expert	18/06/2007	
Dr Robert Pullen	Chairman of Sunderland University Ethics Committee	Expert	24/10/2006	30/06/2013
Mr Ross Sayers	Lay Member	Lay	23/07/2013	
Mr Paddy Stevenson	Research Operations Manager	Expert	01/02/2007	
Mrs Sophie Welch	Research Governance & Policy Officer	Lay	01/04/2013	31/08/2013

### Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Mr Steve Chandler	Consultant Medical Physicist (Retired)	Expert	28/10/2013

**NRES Committee North East - Sunderland: Members' Declarations of Interest:**

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Mrs Sophie Welch (left 31/09/2013)	Research governance responsibilities at Durham University and member of School of Medicine, Health and Pharmacy Ethics Sub Committee.	16/04/2013
Dr Helen H Lucraft	None	02/07/2013
Mr John Blenkinsopp	Member of North Tees and Hartlepool NHS Foundation Trust Research and Development Committee and actively support research in the Trust - on occasions as a support/registered researcher.	24/06/2013
Miss Christine Bullmore	No declarations of interest noted	16/01/2014
Mrs Debra J Lett	No declarations of interest noted.	16/01/2014
Ms Sophie Barron	No declarations of interest noted.	16/01/2014
Mr Paddy Stevenson	No declarations of interest noted.	15/01/2014
Dr Chris Plummer	Works within NHS foundation trust which is actively involved in medical research. Conducts research-lead and multicentre research as part of role as consultant cardiologist. His wife is a professor of medical oncology and undertakes a wide variety of research projects as part of her role.	15/01/2014
Mr Ian Campbell	No declarations of interest noted	20/01/2014
Mr Ross Sayers	No declarations of interest noted	29/07/2013
Mr Obi Iwuchukwu	No declarations of interest noted	24/03/2014

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

<b>Month</b>	<b>Date</b>	<b>Number of Members Present at Meeting</b>
April	29/04/2013	10
May	20/05/2013	8
June	24/06/2013	8
July	29/07/2013	10
September	23/09/2013	9
October	28/10/2013	8
November	25/11/2013	10
December	16/12/2013	9
January	27/01/2014	7
March	24/03/2014	8

10 full committee meetings were held during the reporting period.

**Proportionate Review Sub Committee Meetings held during 01 April 2013 - 31 March 2014:**

<b>Month</b>	<b>Date</b>	<b>Number of Members Present at Meeting</b>
April	16/04/2013	3
May	14/05/2013	3
July	16/07/2013	3
August	20/08/2013	3
September	10/09/2013	3
October	15/10/2013	3
December	23/12/2013	3
January	21/01/2014	3
February	18/02/2014	3
March	18/03/2014	3

10 proportionate review sub-committee meetings were held during the reporting period.

**Attendance of Members: 01 April 2013 – 31 March 2014:**

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr Paddy Stevenson	9
Ms Sophie Barron	9
Mr Obi Iwuchukwu	8
Mrs Debra J Lett	8
Miss Christine Bullmore	8
Dr Chris Plummer	8
Mr Ian Campbell	7
Mr John Blenkinsopp	6
Mr Ross Sayers	5
Dr Helen H Lucraft	5
Mrs Cheryl Anderson	5
Mrs Sophie Welch	3
Dr Karen Horridge	3
Dr Robert Pullen	2
Mr Steve Chandler	1

**Number of inquorate meetings held:** None

**Attendance of Members at proportionate review sub-committee meetings:  
01 April 2013 – 31 March 2014:**

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr Paddy Stevenson	8
Mrs Debra J Lett	7
Miss Christine Bullmore	5
Mr Ian Campbell	5
Mrs Cheryl Anderson	2
Ms Sophie Barron	2
Dr Chris Plummer	1

## Training 01 April 2013 – 31 March 2014:

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr Chris Plummer	02/05/2013 - 02/05/2013	Ethical Issues of Research involving Children, NRES
Ms Sophie Barron	09/09/2013 - 09/09/2013	Induction, NRES
Mr Obi Iwuchukwu	19/09/2013 - 19/09/2013	Medical Devices Training, NRES
Dr Helen H Lucraft	18/09/2013 - 18/09/2013	Induction, NRES
Mr Ian Campbell	09/09/2013 - 09/09/2013	Induction, NRES
Mr Obi Iwuchukwu	09/09/2013 - 09/09/2013	Induction, HRA
Miss Christine Bullmore	14/08/2013 - 14/08/2013	Equality & Diversity, City Hospitals Sunderland NHS Foundation Trust
Mr John Blenkinsopp	15/08/2013 - 15/08/2013	Equality & Diversity, North Tees and Hartlepool NHS Trust
Dr Chris Plummer	15/08/2013 - 15/08/2013	Equality & Diversity, Newcastle Hospitals NHS Trust
Dr Helen H Lucraft	20/08/2013 - 20/08/2013	Equality & Diversity, HRA
Ms Sophie Barron	22/08/2013 - 22/08/2013	Equality & Diversity, HRA
Mrs Debra J Lett	28/08/2013 - 28/08/2013	Equality & Diversity, HRA
Miss Christine Bullmore	11/12/2013 - 11/12/2013	Chairing Skills, HRA
Mr Ross Sayers	03/03/2014 - 03/03/2014	Induction, HRA
Mr Paddy Stevenson	12/03/2014 - 12/03/2014	New and Innovative Opportunities for Research Targeting Healthcare, National Institute for Health Research
Mrs Debra Lett	09/05/2013 – 24/10/2013	Self-Directed Learning Log – facilitated and attended two multidisciplinary one day (Five hours each day) Training events around ethics and challenges relating to brain tissue donation for research.

## 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	17	34.00
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	33	66.00
<b>Total Applications Reviewed</b>	<b>50</b>	<b>100</b>

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

Number of applications made invalid by co-ordinator	0
Number of studies withdrawn prior to the meeting	11
Number of student applications reviewed	16
Number of paediatric applications reviewed	8
Number of device applications reviewed	1
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	8	16.00
Favourable Opinion with Additional Conditions	9	18.00
Unfavourable Opinion	1	2.00
Provisional Opinion	32	64.00
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>50</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	26	52.00
Further Information Favourable Opinion with Additional Conditions	5	10.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	8	16.00
Favourable Opinion with Additional Conditions	9	18.00
Unfavourable Opinion	1	2.00
Provisional Opinion	1	2.00
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>50</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>26</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	11	42.31
Favourable Opinion with Additional Conditions	6	23.08
No Opinion transfer to full committee for review	1	3.85
Provisional Opinion	8	30.77
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>26</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	5.00
<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>	27
<b>Number of days taken to final decision - mode</b>	21
<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>	88
<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>	0
<b>Number of proportionate review applications over 14 days as a % of total</b>	0.0%

**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>
13/NE/0110	HILO Trial	23
13/NE/0125	PRESTO Neo.1.C/E	23
13/NE/0132	Access to Confidential Information V 1.00	8
13/NE/0150	A case control/follow up study of Hard to Reach Young People	16
13/NE/0163	A phase 1 PK study of thalidomide	39
13/NE/0178	Pronominal and anaphoric reflexive deficits in aphasia.	44
13/NE/0184	Electrophysiological Studies in Patients with Spinal Electrodes v1	44
13/NE/0202	"Its not pain its discomfort" an investigation	47
13/NE/0206	Development of a CBT intervention for dysphagia	21
13/NE/0207	Long-term swallowing outcomes in head and neck cancer	21
13/NE/0209	Exploring emotion related attention & mindfulness in Bipolar Disorder	24
13/NE/0224	What is special about blood cells in Mast Cell Activation Syndrome?	12
13/NE/0258	Psychological wellbeing in Welsh speaking parents of children with LD	13
13/NE/0269	Maintenance Study of Niraparib/Placebo in Patients with Ovarian Cancer	26
13/NE/0275	RCT of hospital at home versus inpatient care in AECOPD (DECAF 0-1)	23
13/NE/0280	AZ: D0816C00005 - Ph. 1 Study Hepatic Function/Impairment	32
13/NE/0281	AZ: D0816C00006 - Ph. 1 Renal Function/ Impairment	32
13/NE/0293	PK study of Carfilzomib in Patients with Hepatic Impairment	25
13/NE/0296	Feasibility study of new technologies in bone and soft tissue tumours	33
13/NE/0311	Patient stated preferences for cancer treatment	13
13/NE/0330	Regenerys Pilot Study	30
13/NE/0332	Expressive writing and breast reconstructive surgery decision-making	26
13/NE/0342	OPTIMISTIC	29
13/NE/0344	A monotherapy study of ertugliflozin in participants with T2DM	37
13/NE/0351	Pre-Surgical fitness in older volunteers	52
13/NE/0355	AMG145 vs Ezetimibe in Statin Intolerant Hypercholesterolemic Subjects	17
13/NE/0363	The DEMDERA-MDD study	25
13/NE/0371	Validation study of Gerontopole Frailty Screening Tool	13
14/NE/0016	Ibodontant for relief of irritable bowel syndrome (Nak-06)	21

14/NE/0017	Ibodontant for relief of irritable bowel syndrome (Nak-07)	21
14/NE/0024	Young People with IBD: identity, illness perceptions & transition	10
14/NE/0073	BI836845 in women with Breast Cancer.	36

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/NE/0117	FAB: Family focused treatment for Adolescents with Bipolar Disorder	22
13/NE/0158	VaST (Variation in Surgical Technique)	9
13/NE/0270	CD64 as a marker of prosthetic joint infection	20
13/NE/0272	The use of the catastrophizing thoughts questionnaire for tinnitus	7
13/NE/0274	Robot Assisted Training for the Upper Limb after Stroke	33
14/NE/0010	Phase I study of PM01183 with cisplatin in advanced solid tumors.	24
14/NE/0015	Repeatability of the Sbisa bar	29

#### 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/NE/0129	Foot length ratios as a predictor of foot pathology	8
13/NE/0157	Longitudinal data analysis of HRQoL outcomes after stroke	8
13/NE/0162	Diagnosis of Iron deficiency anaemia by red cell distribution width	7
13/NE/0183	Access to carers for inpatients on forensic units	47
13/NE/0186	AZ: D0816C00004 Ph 1 - Effect of Food in Advanced Solid Tumours	26
13/NE/0189	AZ: D0816C00007 Ph 1 - Effect of Inhibitor in Advanced Solid Tumours	26
13/NE/0196	Antibiotic prophylaxis for clean intermittent catheterisation v1.0	17
13/NE/0222	Adipokines in Osteoarthritis	8
13/NE/0226	Use of PROMs in mental health (MH PROMs)	7
13/NE/0256	Schwannoma study	8
13/NE/0259	THALAMOSS	7
13/NE/0271	Psychological impact of food allergy in adults and quality of life	7
13/NE/0297	Real Care Version 1.4	21
13/NE/0315	Children's missed health care appointments v0.1	7

13/NE/0336	Trial of Proton Pump Inhibitors in Throat Symptoms	21
13/NE/0341	Uptake of Pulmonary Rehabilitation on hospital admission for COPD	27
14/NE/0013	A study of imagery mechanisms in people with visual hallucinations	18
14/NE/0025	GWCA1349 Relationship between the Cancer Pain Intensity NRS and EQ-5D	9
14/NE/0088	Validating An Objective Neurobiomarker for Tinnitus Through fMRI	6

### Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/NE/0116	HIT AAA	18
13/NE/0126	ASSIGN NEO.1.C/F	18
13/NE/0154	Transfer of skills; from simulation to bedside.	41
13/NE/0156	HiResolution Bionic Ear Benefit in Adults with Low Frequency Hearing	21
13/NE/0159	Genetic investigation and psychosocial experiences in male infertility	19
13/NE/0161	The Lupus Foot Study	8
13/NE/0223	Immune response in patients with Hepatitis B and C infection	6
13/NE/0257	Adipose tissue percentage and assisted conception outcomes	7
13/NE/0273	Myoelectric-controlled interface for facial nerve paralysis	22
13/NE/0290	iBAT inhibition in PBC with itch	21
13/NE/0308	Improving outcomes in older adults with reduced kidney function	8
13/NE/0369	Bronchiectasis Longitudinal Observational Cohort Study (BLOCS)	10
14/NE/0057	Illness representations of AAA patients	7
14/NE/0065	Follow-up Protocol to Parts A and B Phase II OPN305-102 Study	21
14/NE/0072	U.K. Medication Error and ADE Study_Version 1	55

### Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/NE/0318	Tart Cherry Juice in older adults with dementia.	24

### Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
14/NE/0058	Standardised NBIA Patient Registry and Natural History Study	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
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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:**

<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>