

**NRES Committee North East -
Newcastle & North Tyneside 1**

Annual Report

01 April 2011 – 31 March 2012

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee North East - Newcastle & North Tyneside 1
Type of REC:	Type III REC
Type of Flag:	CTIMPs in Patients Research Tissue Banks Research Databases Phase 1 Studies in Patients Adults Lacking Capacity Children
Chair:	Mr Chris Turnock
Vice-Chair:	Dr Simon Woods
Alternate Vice-Char:	Dr Mike Bone
Co-ordinator:	Miss Laura Kirkbride
PRSC Co-ordinator:	Miss Laura Kirkbride
Assistant Co-ordinator:	Miss Sarah Grimshaw
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Chair's overview of the past year:

Once again the committee's has experienced a high workload this year and I should like to convey my sincerest thanks to all of our members the Newcastle and North Tyneside 1 Committee who, once again, devote substantial amounts of their own time to the committee's work. In particular, members have made sure application reviews have been timely and distributed in advance of full committee meetings to facilitate the committee's deliberations in reaching an opinion on ethical aspects of research proposals seeking the committee's opinion.

During the year, two committee members departed. Sebastian Sethe resigned following changing job and relocating to London, and Patricia Higgins found it too difficult for her to meet the demands of committee workload. I would like to convey my thanks to Sebastian for his contributions to the Committee over recent years. We have been fortunate to recruit four new members, Alison Chalmers as lay member, Annette Haimes as expert member and Anne Scadeng as lay plus member.

The Committee continues to receive a considerable number of applications for ethical opinion in a range of areas, including Clinical Trials, Mental Capacity Act, Research Database and Research Tissue Bank related work. In my opinion, the committee continues to undertake positive discussions with researchers seeking the committee's opinion. Not only does the committee find that such applications generate considerable ethical debate, but collaborates with applicants to address legal frameworks, e.g. Human Tissue Act, Mental Capacity Act. The committee's experience in these areas has helped strengthen ethical nature of such applications.

Participation in the Proportionate Review continues to be by and large successful with up to four applications being considered by a sub-committee meeting. Communication between sub-committee members and also with applicants has been effectively conducted by use of e-mail. The committee has been able to obtain sufficient volunteers from within the committee to ensure sub-committee meetings have been quorate.

Finally, the committee's Co-ordinator, Laura Kirkbride, and her assistant Sarah Grimshaw continue to provide the committee with excellent support, for which I and members are very grateful.

NRES Committee North East - Newcastle & North Tyneside 1 Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Professor Alan Boddy	Professor of Cancer Pharmacology	Expert	01/01/2006	N/A
Dr Mike Bone	Consultant Physician	Expert	01/07/2006	N/A
Miss Alexandra Brown	Student	Lay Plus	03/03/2011	N/A
Dr Thomas J Chadwick	Clinical Trials Statistician	Expert	01/10/2009	N/A
Mrs Alison Chalmers	Development Worker	Lay	10/10/2011	N/A
Dr Pamela Davies	Principal Lecturer	Lay Plus	01/12/2010	N/A
Dr Etta Drews	Senior Lecturer in Psychology	Lay	01/03/2008	N/A
Dr Annette Hames	Consultant Clinical Psychologist	Expert	14/09/2011	N/A
Ms Patricia Higgins	Lay Member (Retired)	Lay Plus	01/11/2011	14/03/2012
Dr Raj Mohindra	Consultant Cardiologist	Expert	25/01/2011	N/A
Mr Gary Player	Advanced Practitioner - Cytology	Expert	13/11/2006	N/A
Mr Christopher Roy-Toole	Lay Member (Retired)	Lay Plus	01/11/2006	N/A
Mrs Anne Scadeng	Lay Member (Retired)	Lay Plus	14/09/2011	N/A
Dr Sebastian Sethe	Legal & Regulatory Officer	Lay	01/04/2009	14/09/2011
Professor J Mark Thomason	Professor of Prosthetics and Oral Rehabilitation	Expert	24/10/2003	N/A
Mr Chris Turnock	Learning & Teaching Advisor	Expert	01/03/2002	N/A
Dr Simon Woods	Senior Lecturer/Director of Learning	Lay	23/10/2003	N/A
Professor Matt Wright	Reader	Expert	01/12/2010	N/A

NRES Committee North East - Newcastle & North Tyneside 1: Members' Declarations of

Name	Declaration of Interest	Date
Professor Alan Boddy	Active Clinical & Translational Researcher in the field of Cancer Treatment.	07/03/2012
Dr Mike Bone	Director and Board Member: Appointing Authority for Independent Phase I Research Ethics Committees (paid) Director MB Consulting (Northeast) Ltd Board Member and Vice-Chairman: European Forum for Good Clinical Research (Unpaid)	07/03/2012
Miss Alexandra Brown	None	07/03/2012
Dr Thomas J Chadwick	Professional duties for Newcastle University Peer Reviewer for NIHR Funding Bodies	07/03/2012
Mrs Alison Chalmers	None	07/03/2012
Dr Pamela Davies	None	07/03/2012
Dr Etta Drews	None	07/03/2012
Dr Annette Hames	None	07/03/2012
Dr Raj Mohindra	1. Principal Investigator - PARADIGM-HF Study (Novartis) 2. Current Member Clinical Ethics Advisory Group (Clinical Ethics Committees - RVI & Freeman Hospitals)	07/03/2012
Mr Gary Player	On the Advisory Board for BD Diagnostics - Women's Health and Cancer, unpaid	07/03/2012
Mr Christopher Roy-Toole	None	07/03/2012
Mrs Anne Scadeng	None	07/03/2012
Professor J Mark Thomason	Trustee of UKCat	07/03/2012
Mr Chris Turnock	None	07/03/2012
Dr Simon Woods	As an academic, sometimes called upon to provide peer review for colleagues work or for research council/other funding body applications. To date none of this work has conflicted with my role as an NHS REC Member.	07/03/2012
Professor Matt Wright	Pfizer European Food Safety Authority – Expert British Toxicology Society Biochemical Society	07/03/2012

Month	Date	Number of Members Present at Meeting
April	12/04/2011	11
May	10/05/2011	10
June	14/06/2011	10
August	09/08/2011	9
September	13/09/2011	11
October	11/10/2011	10
November	08/11/2011	10
December	13/12/2011	12
January	10/01/2012	14
March	13/03/2012	12

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

Month	Date	Number of Members Present at Meeting
April	08/04/2011	3
May	13/05/2011	3
June	17/06/2011	4
July	22/07/2011	3
August	25/08/2011	3
September	29/09/2011	3
November	04/11/2011	3
December	09/12/2011	3
February	03/02/2012	3
February	14/02/2012	3
February	17/02/2012	4
March	09/03/2012	4

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

Attendance of Members: 01 April 2011 – 31 March 2012:

Name	Number of Meetings Attended
Dr Thomas J Chadwick	9
Mr Chris Turnock	9
Mr Christopher Roy-Toole	8
Mr Gary Player	8
Professor Alan Boddy	8
Dr Simon Woods	8
Dr Raj Mohindra	8
Miss Alexandra Brown	7
Dr Etta Drews	7
Dr Pamela Davies	6
Professor Matt Wright	6
Professor J Mark Thomason	5
Dr Mike Bone	5
Dr Annette Hames	4
Mrs Alison Chalmers	4
Mrs Anne Margaret Scadeng	4
Dr Sebastian Sethe	3

Number of inquorate meetings held: 0

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

Name	Number of Meetings Attended
Mr Chris Turnock	11
Dr Simon Woods	7
Dr Etta Drews	5
Professor J Mark Thomason	5
Dr Sebastian Sethe	2
Dr Mike Bone	2
Dr Pamela Davies	1
Dr Raj Mohindra	1
Dr Matt Wright	1
Dr Thomas J Chadwick	1
Mr Christopher Roy-Toole	1
Professor Alan Boddy	1

Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Professor Alan Boddy	19/09/2011	NRES Update Session, NRES
		North East RECs - Training Meeting, North East REC Centre
	31/10/2011	GCP Refresher, NIHR
Miss Alexandra Brown	10/01/2012	Induction, NRES
	07/07/2011	Equality & Diversity, NHS
	13/03/2012	Mental Capacity Act DVD, NRES
Dr Thomas J Chadwick	22/11/2011	NRES Adults Lacking Capacity (including research in emergency situations) workshop for RECs, NRES
	14/02/2012	North East RECs - Training Meeting, North East REC Centre
Mrs Alison Chalmers	08/02/2012	Induction, NRES
		North East RECs Training Meeting, North East REC Centre
Dr Pamela Davies	21/06/2011	Ethics Training, Northumbria University
Dr Etta Drews	07/12/2011	NRES Statistics Training for NRES REC Members, NRES
Dr Annette Hames	08/02/2012	Induction, NRES
		North East RECs Training Meeting, North East REC Centre
Ms Patricia Higgins	14/02/2012	North East RECs Training Meeting, North East REC Centre
Dr Raj Mohindra	22/06/2011	Induction, NRES
	18/07/2011	Equality & Diversity, N/A
		North East RECs - Training Meeting, North East REC Centre
Mr Gary Player	07/07/2011	Equality & Diversity, Local Trust
	14/02/2012	North East RECs - Training Meeting, North East REC Centre
Mr Christopher Roy-Toole	19/09/2011	Update Session, NRES
	13/02/2012	Ethics & GCP Forum, Institute of Clinical Research
	14/02/2012	North East RECs - Training Meeting, North East REC Centre
Mrs Anne Scadeng	08/02/2012	Induction, NRES
		North East RECs Training Meeting, North East REC Centre
Professor J Mark Thomason	01/06/2011	Equality & Diversity, SameDifference
	01/06/2011	Working Together, SameDifference
	01/06/2011	Sensitive Service Provision, SameDifference
Mr Chris Turnock	02/11/2011	'The Nuts and Bolts of running a REC', NRES
	19/09/2011	NRES Update Session, NRES
	14/02/2012	North East RECs - Training Meeting, North East REC Centre
Dr Simon Woods	09/12/2011	Nuffield Council Workshop on Children & Clinical Trials, Nuffield Council

	10/02/2012	Formulating Legal Models on Adolescent Consent and Refusal, The University of Leeds
	14/02/2012	North East RECs - Training Meeting, North East REC Centre

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	9	19.57
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	2	4.35
Research Database	4	8.70
Others	31	67.39
Total Applications Reviewed	46	100

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	2
Number of student applications reviewed	16
Number of paediatric applications reviewed	8
Number of device applications reviewed	0
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	1	2.17
Favourable Opinion with Additional Conditions	6	13.04
Unfavourable Opinion	2	4.35
Provisional Opinion	37	80.43
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	46	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	27	58.70
Further Information Favourable Opinion with Additional Conditions	2	4.35
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	2.17
Favourable Opinion with Additional Conditions	6	13.04
Unfavourable Opinion	2	4.35
Provisional Opinion	5	10.87
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
Number of studies withdrawn after the meeting	2	4.35
Total	46	100

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

Total Applications Reviewed	33
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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	22	66.67
Favourable Opinion with Additional Conditions	7	21.21
No Opinion transfer to full committee for review	3	9.09
Provisional Opinion	0	0.00
Unfavourable Opinion	1	3.03
Total	33	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	4.18
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	40
Number of SSAs (non-Phase 1) reviewed	1
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	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	72
Number of substantial amendments over 35 days	3
Number of substantial amendments over 35 days as a % of total substantial amendments	4.2%
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	3.33%

***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:

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/NE/0050	Is mandibular molar infiltration a mental and incisive nerve block?	28
11/NE/0051	Determination of the Mental Foramen Position in Dental Radiographs	25
11/NE/0057	Health Screening of People in Police Custody (Re-evaluation)	48
11/NE/0059	Anti-NMDA antibodies in Psychosis	24
11/NE/0082	Assessing cognition in patients with mitochondrial disease	54
11/NE/0119	Is seeing believing?	40
11/NE/0137	The Associations of Neurocardiovascular Instability in Older People	50
11/NE/0141	Acne Research Database: Improved Baseline Assessments in Acne	44
11/NE/0145	Follow up of LHON patients- SNT-II-003-OFU	28
11/NE/0179	UK National Registry for Myotonic Dystrophy v1.0	40
11/NE/0212	B0151003 Crohn's Disease ANDANTE Study	24
11/NE/0214	PARAGON	34
11/NE/0216	Biology of cerebrospinal fluid - Non malignant controls	40
11/NE/0220	PeLSR study v 1 (Pelvis Lying and Standing Radiograph study)	51
11/NE/0228	IoN	37
11/NE/0246	A pilot study of methods to review diabetes care in care homes (III)	37
11/NE/0249	Reversal of over-anticoagulation with vitamin K	40
11/NE/0294	Skin Biobank - eye research	39
11/NE/0295	Brachial artery velocity variation to predict fluid responsiveness	50
11/NE/0318	Understanding an integrated care pathway in palliative care.	40
11/NE/0324	Use of Alky-capped silicon Nanocrystals in diagnosis of malignancy	51
11/NE/0329	Investigating Spatial Memory in Major Depressive Disorder v 1.0	51
11/NE/0352	Newcastle Institute of Transplantation Tissue Biobank	22
11/NE/0354	RAD001 in combination with BEZ235 in patients with advanced tumours	26
12/NE/0004	A study of OCA in Patients with Primary Biliary Cirrhosis (747-301)	23
12/NE/0006	Strategies to incRease confidence InDependence and Energy (STRIDE)	27
12/NE/0086	Is Auricular Acupuncture Effective in Reducing MRI Anxiety?	27

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/NE/0054	Should we be freezing embryos? (Version no. 2)	34
12/NE/0009	Study of GDC-0941 for the treatment of non-small cell lung cancer	29

Favourable Opinion with Standard Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/NE/0060	The genetic and molecular basis of DNA repair/transcription disorders	21
11/NE/0085	Identifying & developing quality metrics for training in O&G	10
11/NE/0088	Measuring DNA concentration in Colonic Surgical Specimens- Version 1.0	10
11/NE/0089	Research Promotion in an NHS Foundation Trust	8
11/NE/0092	Prospective comparative evaluation of vascular service models	8
11/NE/0125	Tackling Age-Related Decline in Perception of Emotion Cues	7
11/NE/0126	Psychological needs of patients attending a diabetic foot clinic	7
11/NE/0167	Work-related quality of life	13
11/NE/0168	Assessment of intervention fidelity of the Diabetes Manual delivery.	12
11/NE/0169	Reluctant goal engagement in major depression: exploring predictions	12
11/NE/0222	Exploring professionalisation in pharmacy pre-registration training	12
11/NE/0298	Bone Cancer Aetiology and Survival: Part 1	10
11/NE/0339	TwistDx RPA: impact of clinical samples on assay function	8
11/NE/0379	Parent group intervention to manage RBs in children with ASD.	11
11/NE/0380	Investigation of the MicroRPM in Clinical Management of Facial Palsy.	11
12/NE/0034	Strengthening parent and infant relationships in a health care setting	12
12/NE/0041	AF-PROMS	11
12/NE/0067	Health visiting: voice of service users	12
12/NE/0068	Cognitive-behavioural approaches in routine care	9
12/NE/0069	Does personal development of Physiotherapists affect clinical outcomes	9
12/NE/0105	Psychosocial experiences of melanoma patients	10
12/NE/0107	3D and 2D assessment of the RV in chemotherapy patients	10
12/NE/0111	Psychological Health and Irritable Bowel Syndrome	8

Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/NE/0127	Understanding service users' experiences of group psychotherapy	7
11/NE/0143	Clinical Outcomes for DMD Infants	21
11/NE/0151	Virtual Reality Augmented Exercise in Multiple Sclerosis Patients	20
11/NE/0166	Influences on Down's syndrome screening uptake: A European comparison	12
11/NE/0215	Development of a Patient Reported Outcome Measurement for Adult ABI	20
11/NE/0236	Treatment of LSCD using cultured limbal epithelium expanded ALSC. V3.0	21
11/NE/0254	Employment: the experience of people diagnosed with bipolar II disorder	49
11/NE/0265	Psychological Profiling for Awake Surgery	18
11/NE/0266	Treatment Locality for AYA's with Cancer Version 1.0	9
11/NE/0268	Attitudes to smoking in patients with Crohn's Disease V1	7
11/NE/0291	Cellular and Molecular Mechanisms in Chronic Lung Diseases Version 1	57
12/NE/0039	Screening of endolymphatic sac tumours in von Hippel-Lindau syndrome	12
12/NE/0059	Transition of young people with complex health needs	12

Unfavourable Opinion		
REC Reference	Application Short Title	Number of Days on Clock
11/NE/0094	Immunological studies on plastic surgery skin	21
11/NE/0335	Working age adults: Psycho-education programme following stroke	22
12/NE/0106	Norfolk and Norwich Stroke Register	8

Provisional Opinion		
REC Reference	Application Short Title	Number of Days on Clock
11/NE/0184	Establishment of the TPP ResearchOne Database	N/A
12/NE/0057	Cardiac energetics and function in normal human ageing	N/A
12/NE/0078	An Investigation into the Health of Carriers of X-linked CGD	N/A
12/NE/0087	MOT115816 Gastroparesis and Parkinson's disease	N/A
12/NE/0088	Hull and East Yorkshire Hospitals Colorectal Cancer Surgery Database	N/A

Withdrawn after the meeting		
REC Reference	Application Short Title	Number of Days on Clock
11/NE/0120	D-Dimer, Antithrombin & Protein S testing for DVT&PE in pregnancy - Version 1	53
11/NE/0368	Investigating care staff and client interactions	20

Table 9: Items exceeding timelines:

Proportionate review applications for ethical review over 14 days timeline			
REC Reference	Application Short Title	Number of Days on Clock	
11/NE/0265	Psychological Profiling for Awake Surgery	18	

Substantial Amendments over 35 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
08/H0902/21/AM02	Antiplatelet Therapy in Older People - Version 1	Version 1.2, 07/03/11	36
10/H0906/67/AM03	Eculizumab in adults with atypical Haemolytic-Uraemic Syndrome	Amendment no2 to the Protocol, final version dated	36
10/H0906/29/AM06	DMD114117	D2010-0186-A03 (YM2009/00278/05, Amendment 4, 4 June 2011)	36