

NRES Committee North East - Newcastle & North Tyneside 1

Annual Report

01 April 2013 – 31 March 2014

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee North East - Newcastle & North Tyneside 1
Type of REC:	CTIMP, Phase 1 in Patients, Research Tissue Bank, Research Database, Adults Lacking Capacity, Children
Type of Flag:	Type iii
Chair:	Professor Philip Preshaw
Vice-Chair:	Dr Simon Woods
Alternate Vice-Char:	Dr Mike Bone
REC Manager:	Ms Gillian Mayer
PRSC Co-ordinator:	N/A
REC Assistant:	Sarah Prothero - October 2013 – present (Kerry Dunbar – April-September 2013)
Committee Address:	Jarrow Business Centre Room 002 Rolling Mill Road Jarrow NE32 3DT
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Chair's overview of the past year:

I was appointed Chair of NNT1 REC in September 2013, and as such, I still consider myself to be in the 'learning phases' of working with this committee. It is clear that the committee members are dedicated to their work on the ethics committee, and bring a range of experiences and perspectives to the committee, for which I am very grateful. The number of committee members is quite low, and we sometimes only just achieve quoracy. Several members have left the committee in recent months, either because they reached the end of their term of service, or because they felt over-burdened with the requirements of being a committee member, and could no longer combine these with the demands of their 'day job'. This is a concern, and it is important that NRES is aware that many members struggle to balance ethics committee membership with the rest of their work and home life, and that increasing the demands placed on committee members may have an adverse impact on the membership. Currently two members are on long-term periods of absence from the committee, which increases the burden on the remaining members. I am grateful to those remaining members for their efforts, and I question the wisdom of permitting extended periods of absence for members. I am also grateful to all members for meeting the training requirements of committee membership. Currently the committee has no Vice Chair, but interviews are planned for the near future to resolve this. Final thanks go to Gillian Mayer, the committee manager, and Sarah Prothero, the REC assistant. Their work is consistently outstanding, and they are a pleasure to work with. Gillian is now manager for two committees, a hugely onerous task (even with a REC assistant), and I do have concerns regarding the workload of the REC managers. Despite this, Gillian is highly efficient, responsive, and is a real asset to the REC service, as well as being extremely supportive to committee members, and also to researchers who routinely call on her for advice.

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

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr Liz Baker	Clinical Research Scientist	Expert	01/04/2013	
Mrs Joan Bedlington	Charity Worker	Lay Plus	01/04/2013	
Dr Mike Bone	Consultant Physician	Expert	01/07/2006	
Dr Thomas J Chadwick	Clinical Trials Statistician	Expert	01/10/2009	
Dr Etta Evans	Senior Lecturer in Psychology	Lay	01/03/2008	
Dr Annette Hames	Consultant Clinical Psychologist (Retired)	Lay	14/09/2011	
Ms Heather McGrath	School Research Administrator	Lay	01/12/2012	
Dr Raj Mohindra	Consultant Cardiologist	Expert	25/01/2011	
Dr John Newton	Social Scientist (Retired)	Lay Plus	01/10/2013	31/03/2014
Professor Philip Preshaw	Professor of Periodontology & Consultant in Restorative Dentistry	Expert	01/09/2013	
Mr Christopher Roy-Toole	Lay Member	Lay Plus	01/11/2006	
Mrs Anne Scadeng	Lay Member	Lay Plus	14/09/2011	24/06/2013
Mrs Agnieszka Skotnicka	Pharmacist	Expert	01/08/2013	
Professor J Mark Thomason	Professor of Prosthetics and Oral Rehabilitation	Expert	24/10/2003	24/10/2013
Mr Chris Turnock	Learning & Teaching Advisor	Expert	01/03/2002	31/08/2013
Dr Simon Woods	Senior Lecturer & Director of Learning	Lay	23/10/2003	31/08/2013
Mr Tom Wooldridge	Research Support Staff Lead	Expert	01/09/2013	
Professor Matt Wright	Reader	Expert	01/12/2010	20/11/2013

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

Name	Declaration of Interest	Date
Dr Liz Baker	Member of North Tees Hartlepool NHS Trust. Member of R&D Review Committee.	16/04/2013
Mrs Joan Bedlington	Honorary Treasurer & Governor Liver North - Patient Support Group offering support to patients, carers, family and friends; funding research. Involved in PPI Steering Groups for Research.	15/04/2013
Dr Mike Bone	Consultant Physician, South Tyneside NHS Foundation Trust.	21/02/2014
Dr Thomas J Chadwick	Employment with Newcastle University (within Clinical Trials Unit). Occasional Peer Reviewer (Statistician) for some NIHR funding streams. Occasional Peer Reviewer (Statistician) for some medical research journals. Member of DMEC for two ongoing clinical trials (Stroke-INF, King's College London and Goal-orientated cognitive rehabilitation in early-stage Alzheimer's disease: multi-centre single-blind randomised controlled trial (GREAT), Bangor University).	09/04/2013
Dr Etta Evans	Chair of the University of Sunderland Research Ethics Committee. Student project supervisor (PhD, MPhil, MSc, UG). Personal research activities.	21/02/2014
Dr Annette Hames	None declared	09/01/2014
Ms Heather McGrath	Research Administrator employed by the department of Geography, Politics & Sociology, Newcastle University (incorporate the Policy Ethics and Life Sciences Research Centre - PEALS). Previous posts include Research Support Co-ordinator for the Institute of Neuroscience and Cellular Medicine at Newcastle University, however this member no longer holds these posts.	01/12/2013
Dr John Newton	None declared	01/10/2013
Professor Philip Preshaw	Editorial board member of the DRWF – Diabetes Research and Wellness Foundation Panel member for the NIHR Doctoral Fellowship Programme.	01/09/2013
Mrs Agnieszka Skotnicka	None declared	10/08/2013
Mr Tom Wooldridge	Works for Northumberland, Tyne & Wear CLRN - part of NIHR Clinical Research Network	03/09/2013

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

Month	Date	Number of Members Present at Meeting
May	14/05/2013	8
June	11/06/2013	7
August	13/08/2013	7
September	10/09/2013	9
October	08/10/2013	8
November	12/11/2013	8
December	10/12/2013	9
January	14/01/2014	9
February	11/02/2014	10
March	11/03/2014	8

10 full committee meetings were held during the reporting period

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

Month	Date	Number of Members Present at Meeting
April	03/04/2013	3
May	02/05/2013	3
June	13/06/2013	3
July	11/07/2013	3
August	07/08/2013	3
September	12/09/2013	3
October	10/10/2013	3
November	14/11/2013	3
January	29/01/2014	3
February	11/02/2014	3
February	26/02/2014	3
March	26/03/2014	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
Dr Etta Evans	9
Dr Thomas J Chadwick	9
Ms Heather McGrath	9
Dr Liz Baker (Appointed 01/04/13)	8
Dr Mike Bone	7
Dr Annette Hames	7
Mrs Agnieszka Skotnicka (Appointed 01/08/13)	6
Mrs Joan Bedlington (Appointed 01/04/13)	6
Professor Philip Preshaw (Appointed 01/09/13)	5
Mr Tom Wooldridge (Appointed 01/09/13)	5
Dr John Newton (Appointed 01/10/13)	5
Mr Chris Turnock (Resigned 31/08/13)	3
Dr Simon Woods (Resigned 31/08/13)	2
Professor Matt Wright (Resigned 20/11/13)	2

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
Mrs Joan Bedlington	6
Ms Heather McGrath	5
Dr Annette Hames	4
Dr Mike Bone	4
Dr Simon Woods	4
Professor Philip Preshaw	4
Dr Thomas J Chadwick	3
Dr Etta Evans	2
Dr Liz Baker	1
Professor Matt Wright	1
Mr Andrew Brenikov (Co-opted member)	1
Mr Chris Turnock	1

Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Dr Liz Baker	27/11/2013 - 27/11/2013	National Members' Training Day (Manchester, HRA)
Mrs Joan Bedlington	02/10/2013 - 02/10/2013	Researcher Training Day (London, HRA)
Dr Mike Bone	16/12/2013 - 18/12/2013	Research Ethics Training Module (Organised and delivered module on MSc Pharmaceutical Medicine at Bernard University, Lyon)
Dr Mike Bone	20/02/2014 - 20/02/2014	Equality & Diversity (On-line training module, HRA)
Dr Thomas Chadwick	19/12/2013 – 09/03/2014	A signed SDLF submitted to record reading and review of material in relation to Research Ethics topics
Dr Etta Evans	12/11/2013 - 12/11/2013	Researcher Training Day (Manchester, HRA)
Dr Annette Hames	18/01/2014 - 18/01/2014	Equality & Diversity (On-line training module, HRA)
Dr Annette Hames	18/01/2014 - 18/01/2014	ALC Toolkit (On-line training module, HRA) A signed SDLF submitted to record this training
Dr John Newton	02/10/2013 - 02/10/2013	Equality & Diversity (On-line training module, HRA)
Ms Heather McGrath	16/05/2013 - 16/05/2013	Data Protection and Freedom of Information Course (Newcastle University)
Ms Heather McGrath	19/02/2014 - 19/02/2014	CTIMP Training (London, HRA)
Professor Philip Preshaw	12/03/2014 - 12/03/2014	Adults Lacking Capacity Toolkit (On-line training module, HRA)*
Professor Philip Preshaw	13/03/2014 - 13/03/2014	MRC Data & Tissue Toolkit (On-line training module)*
Professor Philip Preshaw	13/03/2014 - 13/03/2014	MRC Human Tissue in Relation to Research (On-line training module) * A signed SDLF submitted to record these training modules
Mrs Agnieszka Skotnicka	18/12/2013 - 18/12/2013	Equality & Diversity (On-Line training module, HRA)
Mrs Agnieszka Skotnicka	05/03/2014 - 05/03/2014	Induction (Manchester, HRA)
Mr Tom Wooldridge	27/11/2013 - 27/11/2013	National Members' Training Day (Manchester, HRA)
Mr Tom Wooldridge	05/03/2014 - 05/03/2014	Induction (Manchester, 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	7	14.28
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank Renewals	4	8.16
Research Database	5	10.20
Others	33	67.34
Total Applications Reviewed	49	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	10
Number of studies withdrawn prior to the meeting	10
Number of student applications reviewed	11
Number of paediatric applications reviewed	14
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	1	2.04
Favourable Opinion with Additional Conditions	10	20.40
Unfavourable Opinion	3	6.12
Provisional Opinion	35	71.42
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	34	69.38
Further Information Favourable Opinion with Additional Conditions	1	2.04
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	2.04
Favourable Opinion with Additional Conditions	10	20.40
Unfavourable Opinion	3	6.12
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	26
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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	20	76.92
Favourable Opinion with Additional Conditions	4	15.38
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	2	7.69
Unfavourable Opinion	0	0.00
Total	26	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	34
Number of days taken to final decision - mode	23
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	97
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	1
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*	0
Number of proportionate review applications over 14 days as a % of total	0.0%

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
08/H0906/21+5	Human Developmental Biology Resource	26
08/H0906/95+5	Newcastle Dermatology Biobank	32
13/NE/0123	International HIBM Registry	28
13/NE/0124	HIBM Natural History study	38
13/NE/0128	Visual function during gait in Parkinson's disease	45
13/NE/0137	The use of compression bandages in total knee replacement surgery	38
13/NE/0169	Neo1 - TDR12857	33
13/NE/0170	PRO053-CLIN-01: A phase I/II study of Duchenne muscular dystrophy	34
13/NE/0179	An investigation into cognitive and emotional empathy in autism	41
13/NE/0180	IMPACT study in primary dental care	47
13/NE/0212	P-CID	25
13/NE/0225	Pharmacokinetic variation and toxicity in Ewing's sarcoma	39
13/NE/0228	Troponin release after anthracyclines in children (pilot study)	36
13/NE/0235	Intolerance of uncertainty in children and young people	53
13/NE/0242	Development of a blood test for EGFR testing in lung cancer	11
13/NE/0260	Boston Scientific OPTIMIND 2 medical device study	33
13/NE/0262	Pfizer A3921091 - phase 3 Tofacitinib (CP-690,550) for Active PsA	28
13/NE/0263	Pfizer A3921125 - phase 3 Tofacitinib (CP-690,550) for Active PsA	28
13/NE/0282	Endothelial function as an anti-angiogenic drug biomarker	37
13/NE/0285	Safety and tolerability study of 5-ALA/SFC in patients with CIA	28
13/NE/0287	EFFORT Study	31
13/NE/0294	Single ascending dose study of RO6867461 in wAMD	27
13/NE/0321	Hypohydration and cardiorespiratory function	39
13/NE/033325	Conservative versus operative treatment of degenerative meniscal tears	37
13/NE/0331	The use of pulse oximetry to detect dysphagia in ALD	36
13/NE/0348	Retrospective case-notes review of perinatal stroke	25
13/NE/0357	Predicting remission of psoriasis after phototherapy	31
13/NE/0366	Contingency management for groups	38
13/NE/0368	IL27 and IFN λ 3 roles in oral lichen planus pathogenesis	56

14/NE/0002	Ghrelin and dementia in Parkinson's disease	47
14/NE/0005	MAVRIC: Manubrium-limited ministernotomy versus conventional sternotomy	44
14/NE/0026	Biomarkers for UTI	25
14/NE/0052	Establishing a North West England Paediatric Diabetes Registry	33
14/NE/0060	The effectiveness of Korean hand acupuncture for PPGP	30
14/NE/0066	Caring hands project	29
14/NE/0070	Functional evaluation of CMCJ arthritis management	11

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Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
14/NE/0003	International Niemann-Pick disease study	47

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/0112	Improving bowel cancer screening	10
13/NE/0113	Living with secondary cancer	8
13/NE/0145	Why does blood pressure change with repeated measurement?	8
13/NE/0147	Psychosocial and work-related factors and diabetes self-management	6
13/NE/0192	Measuring psychological well-being in CHF patients using GWBI	12
13/NE/0193	Post diagnosis dementia information pack (Berkshire Blue Book)	8
13/NE/0210	Non-Interventional follow-up to VELOUR trial: Translational research	9
13/NE/0215	A database analysis in patients with acute lymphoblastic leukaemia	9
13/NE/0221	Relationship between dental development and CVM in UK subjects	10
13/NE/0241	Staff experiences of cognitive analytic therapy in secure settings	10
13/NE/0277	Young people's and parent's/carer's experience of session rating scales	8
13/NE/0278	Complementary medicine use in rheumatology	8
13/NE/0302	The use of immunocytochemistry within cervical cytology	6
13/NE/0306	Time prepared to wait for CT/GC results and outcomes	6
14/NE/0007	Understanding age inequalities and inequities in the cancer pathway	42
14/NE/0029	Synthetic faeces project	8

14/NE/0038	Health anxiety in cancer patients in remission	8
14/NE/0051	The experiences of Patient Participation Group members	8
14/NE/0094	HLA-G expression in renal transplant patients	10
14/NE/0096	A qualitative study of patients experience of persistent AF	8
14/NE/0101	My way of doing things	14

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
08/H0906/94+5	KCL Haemato-Oncology Tissue Bank	43
08/H0906/136+5	Newcastle Brain Tissue Resource	33
13/NE/0168	Can heart rate predict low blood pressure during Caesarean section?	49
13/NE/0216	Patient experience in early ankylosing spondylitis (AS); A pilot study	5
13/NE/0254	How do severely obese people experience their psychological well being?	39
13/NE/0266	Global FKRIP Registry	27
13/NE/0267	Testing and diagnosis delay for HIV	24
13/NE/0268	DIAMOND-Lewy Work Package 1	23
13/NE/0322	DIAMOND-Lewy Work Package 2: Embedded qualitative studies	27
13/NE/0335	Supporting excellence in end of life care (SEED): Workstreams 1 & 2	23
13/NE/0347	What is important to parents of children with glue ear?	7
14/NE/0053	Reticulocyte haemoglobin equivalent and iron deficiency in pregnancy	7
14/NE/0062	Movement as medicine for CVD prevention	40
14/NE/0068	PROWeSS	8

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/NE/0160	Congenital heart disease genetic study	23
13/NE/0279	Qualitative study of inpatient care in a learning disability service	23
14/NE/0047	International NCL Registry (UK)	29

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	
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