

**NRES Committee North East -
Northern & Yorkshire**

Annual Report

01 April 2011 – 31 March 2012

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee North East - Northern & Yorkshire
Type of REC:	Type III
Type of Flag:	Phase 1 CTIMPs, Type III CTIMPs, Prison Research, Paediatrics, GTAC low risk, medical devices, Phase 1 studies in patients and healthy volunteers
Chair:	Professor Peter Heasman
Vice-Chair:	Dr Sarah Bartlett
Alternate Vice-Chair:	Dr Giles McCracken
Co-ordinator:	Miss Hayley Jeffries 13.02.12 - current Miss Kerri Jude (25.4.11 to 4.1.12) Miss Sharon Sevenoaks (1.3.11 to 22.4.11)
Assistant Co-ordinator:	Miss Sarah Grimshaw 13.02.12 - current Miss Kerri Jude for period (1.3.11 to 22.4.11)
Committee Address:	Room 002 TEDCO Business Centre Viking Business Park Rolling Mill Road Jarrow, Tyne & Wear NE32 3DT
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Chair's overview of the past year:

The Health Research Authority (HRA) was established as a non-departmental public body and a Special Health Authority on 1st December 2011. At this time, the National Research Ethics Service transferred its functions to the HRA which will now provide a stable platform on which NRES can perform and develop significant improvements and efficiencies of service. The HRA will also facilitate coordination across regulation and governance functions, with early proposals including a new advice service from the HRA, registration on IRAS as a future platform for a national assurance and registration of researchers and consideration of integrated reporting systems. Exciting times indeed.

These developments for NRES have, perhaps as yet, not impacted significantly upon the day-to-day running of Research Ethics Committees but nevertheless there have been important developments over the last year. The proportionate review scheme began in the North East REC centre in October 2010 and is now virtually complete with a national roll out imminent. The most recent data indicate that 63% of applications reviewed by the Northern and Yorkshire REC were given an outright favourable opinion confirming that the turnaround of applications by our subcommittee is proportionate to the ethical issues under consideration. Further work is on the horizon with pilots to assess the amount of information that researchers need to provide and consequently, that needs to be scrutinised by the REC. We may, therefore, not be too far away from having a truly proportionate system of ethics review which will allow 'fast-tracking' of the less contentious applications and with more robust scrutiny of those research projects that present more challenging ethical issues and debate. For the Northern and Yorkshire REC these would include Phase 1 clinical trials and prison research.

Another great success this year has been the introduction of regional meetings for REC Chairs that have been held in York and hosted by a national research ethics advisor and attended by colleagues from NRES. We have now had 3 meetings, all well attended, and with the purpose of discussing local and national issues that are pertinent to all RECs. The meetings present a unique opportunity for Chairs to interact with each other, to keep up-to-date with national developments and to share experiences of how different RECs approach specific problems. The minutes of the meetings are then fed back to the National Research Ethics Panel for further debate.

During the last 12 months we have also seen some changes in membership of the Northern and Yorkshire REC. Sarah Bartlett has been appointed vice-chair and Giles McCracken alternate vice-chair. We have also welcomed new members Austin Wilcock and Sarah Brown whereas Peter Carey and Tunde Gbdolade have retired from the Committee after 10 years' service. Both Peter, who was vice-chair and Tunde, were members of the original Northern and Yorkshire MREC and have been wholeheartedly committed to research ethics review over the last decade. They have been a pleasure to work alongside and I would like to thank them for their work.

I should also like to thank Kerri Jude who, as interim coordinator, served the committee by providing administrative support over the last year. We have now welcomed Hayley Jeffries to the permanent position of REC coordinator and she joins with our very best wishes for her time with the Northern and Yorkshire REC.

Peter Heasman
April 2012

NRES Committee North East - Northern & Yorkshire Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr Sarah Bartlett	Consultant Child & Adolescent Psychiatrist	Expert	01/07/2008	
Sarah Brown	Principal Statistician	Expert	26/04/2011	
Dr Peter Carey	Consultant Haematologist	Expert	01/11/2001	01/11/2011
Dr Mary Connor	Coaching & Mentoring Consultant	Lay	05/10/2010	
Dr Fiona Douglas	Consultant Clinical Geneticist	Expert	11/04/2003	
Mr Babatunde Gbolade	Consultant Gynaecologist	Expert	01/11/2001	31/10/2011
Mr Malcolm G Harrison	Lay Member	Lay	13/07/2007	
Mrs Janet Hattle	Head of Pharmacy	Expert	01/05/2008	
Professor Peter Heasman	Professor of Periodontology	Expert	01/01/2006	
Mr Malcolm Khan	Lay Member	Lay	01/06/2005	
Dr Giles McCracken	Senior Clinical Lecturer	Expert	01/04/2008	
Dr John Newton	Social Scientist (Retired)	Lay Plus	11/04/2003	
Mr Austin Wilcock	Clinical Governance Co-ordinator (Retired)	Expert	21/09/2011	
Ms Lorraine Wright	Senior Research Nurse	Expert	01/04/2010	

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended
None			

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Sophie Welch	Research Governance & Policy Officer	Lay	24 th June PRSC Meeting
Joan Bedlington	Charity Manager	Lay	29 th July PRSC Meeting

Member Bank

Name	Occupation	Expert or Lay	Meeting date attended
None			

NRES Committee North East - Northern & Yorkshire: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Professor Peter Heasman	None	09/12/2011
Dr Sarah Bartlett	None	10/02/2012
Dr Mary Connor	None	09/12/2011
Dr Fiona Douglas	Member of ECC (Ethics and Confidentiality Committee of National Information Governance Board)	13/01/2012
Mrs Janet Hattle	None	13/01/2012
Mr Malcolm G Harrison	Member of NIHR	13/01/2012
Mr Malcolm Khan	None	09/12/2011
Dr Giles McCracken	Active researcher in dental sciences. Employer of Newcastle University. H&N consultant in the Newcastle Upon Tyne Hospitals NHS Foundation Trust.	09/12/2011
Mr Austin Wilcock	None	07/01/2012
Ms Lorraine Wright	None	09/12/2011
Mr John Newton	None	23/04/2012
Ms Sarah Brown	None	17/05/2012

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

Month	Date	Number of Members Present at Meeting
April	08/04/2011	10
May	13/05/2011	8
June	17/06/2011	10
July	15/07/2011	10
August	12/08/2011	7
October	14/10/2011	11
November	11/11/2011	8
December	09/12/2011	10
January	13/01/2012	11
February	10/02/2012	9
March	09/03/2012	12

11 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	08/04/2011	3
April	15/04/2011	3
June	24/06/2011	3
July	29/07/2011	3
September	02/09/2011	3
November	11/11/2011	3
December	15/12/2011	3
February	10/02/2012	3
March	09/03/2012	3

9 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
Professor Peter Heasman	11
Mrs Janet Hattle	10
Ms Lorraine Wright	10
Dr John Newton	10
Mr Malcolm G Harrison	9
Mr Malcolm Khan	9
Dr Giles McCracken	9
Dr Mary Connor	8
Sarah Brown	8
Dr Sarah Bartlett	7
Dr Fiona Douglas	5
Mr Austin Wilcock	4
Mr Babatunde Gbolade	4
Dr Peter Carey	2

*Fiona Douglas attended 5 full meetings and 6 PRS (attended 2 PRS of sub-committee and reviewed 6 applications).

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
Professor Peter Heasman	6
Mr Malcolm G Harrison	5
Mrs Janet Hattle	3
Dr Sarah Bartlett	3
Dr Peter Carey	2
Dr Fiona Douglas	2
Dr John Newton	1
Dr Mary Connor	1
Mrs Joan Bedlington	1
Mrs Sophie Welch	1
Mr Malcolm Khan	1

Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Sarah Bartlett	01/09/2009 – 31/07/2011	Diploma in Philosophy
Sarah Brown	01/07/2011 – 01/07/2011	Medical Devices
Sarah Brown	01/09/2011 – 01/09/2011	Induction Course
Sarah Brown	01/01/2012 – 01/01/2012	Phase 1 Trials
Sarah Brown	13/01/2012 – 13/01/2012	MCA DVD
Sarah Brown	31/01/2012 – 31/01/2012	Phase 1 Training
Sarah Brown	01/02/2012 – 01/02/2012	Human Tissue Act
Dr Mary Connor	01/01/2012 – 01/01/2012	Writing and publication of coaching and mentoring at work – ethics section
Dr Mary Connor	13/01/2012 – 13/01/2012	MCA Video presentation
Dr Mary Connor	01/02/2012 – 01/02/2012	National conference on mentoring
Dr Fiona Douglas	13/01/2012 – 13/01/2012	MCA DVD
Dr Fiona Douglas	02/02/2012 – 02/02/2012	Embedding a coaching and mentoring culture in Healthcare
Mr Malcolm G Harrison	13/01/2012 – 13/01/2012	MCA DVD
Mr Malcolm G Harrison	31/01/2012 – 31/01/2012	Phase 1 Training, NRES
Mrs Janet Hattle	13/01/2012 – 13/01/2012	MCA DVD
Mrs Janet Hattle	28/03/2012 – 28/03/2012	NRES Members National Training Day, NRES
Professor Peter Heasman	13/01/2012 – 13/01/2012	MCA DVD
Professor Peter Heasman	31/01/2012 – 31/01/2012	Phase 1 Clinical Trials
Professor Peter Heasman	26/03/2012 – 26/03/2012	Covance
Professor Peter Heasman	28/03/2012 – 28/03/2012	Northern Training
Mr Malcolm Khan	13/01/2012 – 13/01/2012	MCA DVD
Dr Giles McCracken	13/01/2012 – 13/12/2010	MCA Training
Dr John Newton	13/01/2012 – 13/01/2012	MCA Training
Mr Austin Wilcock	13/01/2012 – 13/01/2012	MCA Training
Mr Austin Wilcock	29/03/2012 – 29/03/2012	Induction
Ms Lorraine Wright	11/01/2012 – 11/01/2012	Pan Yorkshire Informed Consent Pilot Workshop, NCRN

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	6	13.04
Phase 1	1	2.17
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	39	84.78
Total Applications Reviewed	46	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	5
Number of studies withdrawn prior to the meeting	12
Number of student applications reviewed	15
Number of paediatric applications reviewed	7
Number of device applications reviewed	7
Number of prisoner applications reviewed	13
Number of applications involving adults unable consent reviewed	1
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	2	4.35
Favourable Opinion with Additional Conditions	11	23.91
Unfavourable Opinion	5	10.87
Provisional Opinion	28	60.87
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	24	52.17
Further Information Favourable Opinion with Additional Conditions	1	2.17
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	4.35
Favourable Opinion with Additional Conditions	11	23.91
Unfavourable Opinion	5	10.87
Provisional Opinion	3	6.52
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	46	100

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

Total Applications Reviewed	21
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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	15	71.43
Favourable Opinion with Additional Conditions	1	4.76
No Opinion transfer to full committee for review	2	9.52
Provisional Opinion	3	14.29
Unfavourable Opinion	0	0.00
Total	21	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	30
Number of days taken to final decision - mode	26
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	9
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)	0.0%
Number of substantial amendments reviewed	89
Number of substantial amendments over 35 days	4
Number of substantial amendments over 35 days as a % of total substantial amendments	4.5%
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*	2
Number of proportionate review applications over 14 days as a % of total	10.53%

***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/0104	Exploring CU Traits, aggression and self-harm	48
11/NE/0110	Violent Fantasies in high risk violent and sexual offender groups	37
11/NE/0117	Neuromuscular Electrical Stimulation in Chronic Back Pain Patients	37
11/NE/0135	Group psycho educational CBT for anxiety and depression in older adults	56
11/NE/0148	V2.0 - Seizure Detection and Automatic Magnet Mode Performance Study	26
11/NE/0156	Assessing clinical psychopathy: Developing a new measure - version 1	29
11/NE/0159	Right Hemisphere contributions to Language Understanding	32
11/NE/0174	TRYTON IDE	34
11/NE/0176	Service user involvement in the risk assessment process - Version 1	26
11/NE/0183	Dual Task Performance and Postural Stability in Type 2 Diabetes	36
11/NE/0197	Clinical In-Market Evaluation Of A New NPWT Foam Dressing	30
11/NE/0224	Use of an air warming mask for exercise in patients with COPD V1.0	37
11/NE/0226	GTR and Copaxone equivalence study (GATE)	32
11/NE/0242	Validation of biomarkers for exclusion of VAP	42
11/NE/0248	Piloting a new CAMHS Risk Assessment Suite	23
11/NE/0304	100 Patient study of PICO v Standard care in chronic/sub-acute wounds	43
11/NE/0310	High Frequency Stimulation Study	41
11/NE/0323	Factors influencing recognition of the movement disorder in PD - V.1.	42
11/NE/0328	Tactile acuity training for patients with chronic low back pain	56
11/NE/0344	The impact of delay on serum and plasma potassium	56
12/NE/0001	The potential for Suboxone to reduce diversion of prescribed drugs.	27
12/NE/0010	Study of Brentuximab Vedotin in Paediatric Patients with Lymphoma	26
12/NE/0030	Smoking Cessation in Rheumatoid Arthritis	22
12/NE/0032	Correlates of adolescent fire setting - Version 1	27
12/NE/0052	Surgery after rotator cuff tears: patients views of decision making	15
12/NE/0102	Feasibility Evaluation of Change Drinking	10
12/NE/0109	Increasing South Asian cadaveric organ donation in the North West	10

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/NE/0333	PD dose responses of inhaled Salmeterol and Fluticasone Propionate	28

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
11/NE/0084	Survey of postgrad dental students on gingival retraction techniques	13
11/NE/0090	Cognitive behavioural therapy in fear of falling: Therapy development	13
11/NE/0091	Role of anti-HLA antibodies in allograft rejection	13
11/NE/0102	Change in self-compassion with mindfulness based stress reduction	9
11/NE/0103	Effects of AI on Patients and their Families	14
11/NE/0105	V2:Satisfaction with information about children's medicines for asthma	9
11/NE/0175	RASCAL Study	31
11/NE/0182	IMPROVE-PC: Cardiovascular Healthcare Information Linkage Study	13
11/NE/0229	Staff's views of Psychological Consultation on the McGuinness Unit	11
11/NE/0231	Views of Genetic Service-Users with a Lynch Syndrome diagnosis	13
11/NE/0245	Responding to diversity in 3 Yorkshire prisons: an Appreciative Inquiry	25
11/NE/0272	Information needs about herbal remedies for menopausal symptoms	10
11/NE/0273	Paediatricians' views of psychological support for children with ABI.1	11
11/NE/0274	Normality in orthodontics: the adult patients' perception	15
11/NE/0346	Measuring appearance concern and social dysfunction in chronic pain	12
11/NE/0386	Transcriptional regulation in colorectal cancer	10
12/NE/0058	Bowel cancer screening information: your response (Version 1)	12

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/NE/0046	Evaluation of the Primrose Programme at HMP and YOI Low Newton, Durham	28
11/NE/0160	The LOTUS Study. Rev 10667.A	24
11/NE/0223	DOES THE METHOD OF DELIVERY IMPACT ON THE OHIP-49 SCORES	14
11/NE/0261	The experience of suicidal feelings 1	17
11/NE/0303	NHS Routes to Quit (Criminal Justice Settings) Programme Pilot	29

11/NE/0311	Mirena and Fibroids	22
11/NE/0330	Direct fracture resistance testing of bone in infants and children v1	22
11/NE/0362	RCT of Surgery with tumescent anaesthesia in GSV Stripping	22
11/NE/0363	RCT of Buffered Tumescent Anaesthesia for EVLA	26
12/NE/0002	Hepatitis C Treatment in Prison - A Qualitative Study	18
12/NE/0040	Neuro developmental disorders in HMP Brixton	19
12/NE/0060	Making sense of CTOs: the service-user experience. Version 1	20

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/NE/0040	The impact of incarceration on prisoners' mental health	24
11/NE/0056	STUDY EVALUATING THE IMPACT OF ADREVIEW™ IMAGING IN HEARTFAILURE	24
11/NE/0121	A user evaluation of Unifine® Pentips® diabetes pen needles	27
11/NE/0171	The experience of suicidal feelings 1	28
11/NE/0353	Neuro developmental disorders in HMP Brixton	26

Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
12/NE/0031	Impact of individual characteristics on responsiveness to change (v1)	N/A
12/NE/0085	Prevalence of PSS: a feasibility pilot study	N/A
12/NE/0089	CORTICAL EXCITABILITY IN NEUROPATHIC PAIN	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		
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REC Reference	Application Short Title	Number of Days on Clock
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Not Requiring Review by NHS REC		
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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
11/NE/0274	Normality in orthodontics: the adult patients' perception	15
12/NE/0052	Surgery after rotator cuff tears: patients views of decision making	15

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
09/H0903/50/AM03	Phase 3 Study-Tivozanib in Patients with Advanced Renal Cell Carcinoma	AV-951-09-301, v3 dated 2nd Jun 2011	37
10/H0903/60/AM01	Sigma CR150 vs Sigma CR Knee RCT	Amendment No 3 09 Aug 11 Updated CIP: Final 4	36
09/H0903/54/AM04	Psychotropic medication prescribing patterns in English prisons	Amendment 3, 9 November 2011	36
10/H0903/15/AM13	CAMN107EIC01 ENEST 1st	Amendment No.9 CAMN107EIC01	36

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
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