

National Research Ethics  
Service

  
*Health Research Authority*

**NRES Committee North East - York**

**Annual Report**

**01 April 2013 – 31 March 2014**

## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	NRES Committee North East - York
<b>Type of REC:</b>	Type I
<b>Type of Flag:</b>	Phase 1 CTIMPs, Type III CTIMPs, Prison Research, Paediatrics, GTAC low risk, medical devices
<b>Chair:</b>	Professor Peter Heasman
<b>Vice-Chair:</b>	Dr Sarah Bartlett
<b>Alternate Vice-Char:</b>	Dr Giles McCracken
<b>REC Managers:</b>	Mrs Helen Wilson (from 1 <sup>st</sup> April 2013 to 2 February 2014) Mrs Hayley Henderson (from 3 <sup>rd</sup> February 2014)
<b>PRSC Co-ordinator:</b>	Mrs Hayley Henderson (from 3 <sup>rd</sup> February 2014)
<b>Assistant Co-ordinator:</b>	Mrs Sally Dunn (from 3 <sup>rd</sup> February 2014) Ms Christie Ord (July 2013 – October 2013) Ms Emma Brown (April 2013 – July 2013)
<b>Committee Address:</b>	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:

It has been another busy year for the York REC and I would like to extend my sincerest thanks to all members of the committee for their considerable contributions to the review processes: the applications for full ethical review, proportionate review, the consideration of amendments and adverse events. The average number of days taken to final decision (28) is nothing short of phenomenal and especially so given that many of the applications comprise phase 1, student-based or prison research which at the best of times are never straight forward. On the issue of student research I would, on behalf of the committee, like to commend sincerely the vast majority of students who attend our meetings and demonstrate not only a profound knowledge of their own IRAS forms and research projects but also a commitment to their research that is unparalleled even amongst those with far more research experience behind them.

As always, the committee has seen a number of changes over the last year with Sarah Brown, Chris Lewis and Austin Wilcock all resigning their positions. I would like to reserve special mention, however, for Fiona Douglas and John Newton who joined the then Northern and Yorkshire REC in April 2003 and have both contributed unbelievable service to the REC over the last decade. My sincerest thanks go to them both.

I would like to welcome new members to the committee Rikesh Patel, Ian Woollands and Linda Chadd

## NRES Committee North East - York Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr Sarah Bartlett	Consultant Child & Adolescent Psychiatrist	Expert	01/07/2008	
Miss Sarah Brown	Principal Statistician	Expert	26/04/2011	30/09/2013
Dr David Cairns	Principal Statistician	Expert	08/10/2013	
Ms Linda Chadd	Library assistant and archivist	Lay Plus	01/10/2013	
Mr Steve Chandler	Retired Consultant Medical Physicist	Expert	01/04/2013	
Dr Mary Connor	Coaching & Mentoring Consultant	Lay Plus	05/10/2010	
Dr Fiona Douglas	Consultant Clinical Geneticist	Expert	11/04/2003	
Mr Malcolm G Harrison	Retired - Lawyer	Lay Plus	13/07/2007	
Mrs Janet Hattle	Head of Pharmacy	Expert	01/05/2008	
Professor Peter Heasman	Professor of Periodontology	Expert	01/01/2006	
Mrs Fan Hutchison	Principal Teacher	Lay Plus	16/12/2012	
Mr Malcolm Khan	Retired Lawyer	Lay Plus	01/06/2005	
Mr Chris Lewis	Plastic Surgery Research Registrar	Expert	11/11/2012	01/12/2013
Dr Giles McCracken	Senior Clinical Lecturer	Expert	01/04/2008	
Dr John Newton	Retired Social Scientist	Lay Plus	11/04/2003	30/09/2013
Dr Rikesh Patel	Clinical Research Fellow	Expert	10/02/2014	
Mr Austin Wilcock	Retired Clinical Governance Co-ordinator	Expert	21/09/2011	23/09/2013
Dr Ian Woollands	Retired Clinical Director, Occupational Health	Expert	17/02/2014	
Ms Lorraine Wright	Senior Research Nurse	Expert	01/04/2010	

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

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Dr Giles McCracken	Active researcher in dental sciences. Employer of Newcastle University. H&N consultant in the Newcastle Upon Tyne Hospitals NHS Foundation Trust.	16/04/2013
Ms Linda Chadd	None.	03/10/2013
Dr David Cairns	Peer reviewer for NIHR RFPB applications Statistical Editor of Clinical Proteomics Journal	01/11/2013
Dr Ian Woollands	None	13/02/2014
Ms Lorraine Wright	None - worked as a research nurse at York Hospital involved in assessing and carrying out research on a day to day basis.	31/03/2014
Mr Steve Chandler	None	31/03/2014
Professor Peter Heasman	None	31/03/2014
Mrs Fan Hutchison	None	31/03/2014
Mr Malcolm G Harrison	None	31/03/2014
Dr Mary Connor	None	31/03/2014
Dr Rikesh Patel	None	31/03/2014
Mr Malcolm Khan	None	31/03/2014
Mrs Janet Hattle	None	31/03/2014

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

Month	Date	Number of Members Present at Meeting
April	12/04/2013	9
May	17/05/2013	10
June	14/06/2013	11
July	12/07/2013	11
August	09/08/2013	9
October	11/10/2013	11
November	08/11/2013	11
December	06/12/2013	12
January	17/01/2014	9
February	14/02/2014	11
March	14/03/2014	13

11 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
May	17/05/2013	3
June	03/06/2013	2 *
July	12/07/2013	3
August	09/08/2013	3
October	11/10/2013	3
January	29/01/2014	3
February	26/02/2014	3
March	26/03/2014	3

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

Uzma – just so you are aware \* indicates meeting set up to consider response to PR provisional opinion. We have tried to have this data cleansed. This comment will need deleting.

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mrs Fan Hutchison	10
Ms Lorraine Wright	10
Dr Mary Connor	9
Dr Sarah Bartlett	8
Dr Ian Woollands	8
Professor Peter Heasman	8
Mrs Janet Hattle	8
Mr Malcolm G Harrison	7
Mr Steve Chandler	9
Mr Malcolm Khan	8
Ms Linda Chadd	6
Dr Giles McCracken	6
Mr Chris Lewis	5
Dr John Newton	4
Dr David Cairns	3
Miss Sarah Brown	3
Mr Austin Wilcock	3
Dr Rikesh Patel	2

**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>
Dr Sarah Bartlett	3
Mr Malcolm Khan	3
Mrs Fan Hutchison	2
Mr Malcolm G Harrison	2
Dr Giles McCracken	2
Dr Ian Woollands	2
Ms Lorraine Wright	2
Professor Peter Heasman	2
Ms Rhona Bratt	1
Mrs Janet Hattle	1
Mr Steve Chandler	1

**Training 01 April 2013 – 31 March 2014:**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr Sarah Bartlett	16/01/2014 - 16/01/2014	Mental Capacity Act, HRA
Miss Sarah Brown	29/04/2013 - 29/04/2013	GTAC Training Day, NRES
Miss Sarah Brown	26/09/2013 - 26/09/2013	Equality & Diversity, Leeds University
Dr David Cairns	03/03/2014 – 03/03/2014	Induction
Ms Linda Chadd	08/01/2014 - 08/01/2014	Equality & Diversity, HRA
Ms Linda Chadd	05/03/2014 - 05/03/2014	Induction, HRA
Mr Steve Chandler	14/08/2013 - 14/08/2013	Equality & Diversity, Newcastle Hospitals NHS Trust
Dr Mary Connor	17/09/2013 - 17/09/2013	Equality & Diversity, HRA
Mr Malcolm G Harrison	17/04/2013 - 17/04/2013	Ethical Review of Mental Health / Psychiatric Research
Mrs Janet Hattle	27/11/2013 - 27/11/2013	National Members Training Day, HRA
Mrs Janet Hattle	27/12/2013 - 27/12/2013	Equality & Diversity, Gateshead Health NHS Foundation Trust
Professor Peter Heasman	18/09/2013 - 18/09/2013	Self Directed Log
Professor Peter Heasman	19/09/2013 - 19/09/2013	Medical Devices, HRA
Mrs Fan Hutchison	18/09/2013 - 18/09/2013	Self Directed Log
Mrs Fan Hutchison	27/11/2013 - 27/11/2013	Members Training Day, HRA
Dr Ian Woollands	20/11/2013 – 20/11/2013	Members Training Day, HRA
Mr Malcolm Khan	27/11/2013 - 27/11/2013	National Training Members Day, HRA
Mr Malcolm Khan	01/09/2013 - 01/09/2013	Self Directed Log
Mr Chris Lewis	12/11/2013 - 12/11/2013	Researcher Training Day, NRES
Mr Chris Lewis	23/04/2013 - 23/04/2013	Induction, NRES
Mr Chris Lewis	14/08/2013 - 14/08/2013	Equality & Diversity, HRA
Dr Giles McCracken	15/07/2013 - 15/07/2013	Equality & Diversity, HRA
Dr Giles McCracken	19/09/2013 - 19/09/2013	Medical Devices, HRA
Dr John Newton	02/10/2013 - 02/10/2013	Equality & Diversity, HRA
Ms Lorraine Wright	15/08/2013 - 15/08/2013	Equality & Diversity, 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	7	13.21
Phase 1	12	22.64
Gene Therapy	1	1.89
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	33	62.26
<b>Total Applications Reviewed</b>	<b>53</b>	<b>100</b>

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

Number of applications made invalid by co-ordinator	6
Number of studies withdrawn prior to the meeting	8
Number of student applications reviewed	15
Number of paediatric applications reviewed	7
Number of device applications reviewed	4
Number of prisoner applications reviewed	9
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	1	1.89
Favourable Opinion with Additional Conditions	8	15.09
Unfavourable Opinion	8	15.09
Provisional Opinion	36	67.92
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>53</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	27	50.94
Further Information Favourable Opinion with Additional Conditions	4	7.55
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	1.89
Favourable Opinion with Additional Conditions	8	15.09
Unfavourable Opinion	8	15.09
Provisional Opinion	3	5.66
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	2	3.77
Number of studies withdrawn after the meeting	0	0.00
<b>Total</b>	<b>53</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>14</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	8	57.14
Favourable Opinion with Additional Conditions	1	7.14
No Opinion transfer to full committee for review	1	7.14
Provisional Opinion	4	28.57
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>14</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	4.82
<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>	28
<b>Number of days taken to final decision - mode</b>	20
<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>	3
<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>	0.0%
<b>Number of substantial amendments reviewed</b>	74
<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>	0
<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%
<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%

**\*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>
13/NE/0093	Both sides of the fence: improving end of life care for prisoners	22
13/NE/0094	PRECISION GOLD	23
13/NE/0102	FAITH Trial	26
13/NE/0104	Product Surveillance Registry Base Protocol, Version 3.	27
13/NE/0143	BAY1002670 Radiolabelled Mass Balance, Metabolism and Excretion Pattern	32
13/NE/0152	PUQALY. An Item Reduction Survey v5.0	47
13/NE/0166	STOP Study: Becoming and Being a Parent	9
13/NE/0167	A Comparison between Primary and Secondary Lymphoedema patients	10
13/NE/0177	LUM001 and placebo with UDCA in patients with PBC - the CLARITY study	23
13/NE/0185	Self-harm and fire-setting in females with Personality Disorder	22
13/NE/0199	Trauma Focused Therapy and Learning Disabilities	47
13/NE/0201	Olaparib maintenance monotherapy in ovarian cancer	27
13/NE/0213	DAC HYP: Japanese Bridging Study	22
13/NE/0249	Human bowel organ cultures in IBD	11
13/NE/0283	Reveal LINQ Usability Study	53
13/NE/0284	PEG Interferon Japanese Bridging Study	24
13/NE/0286	TENS for patients with Complex regional pain syndrome	25
13/NE/0288	Safety of a Novel Patch to treat Herpes Labialis V3.0	31
13/NE/0292	Cardiac MRI in HF-PEF	26
13/NE/0317	Exploring voice hearing in adults with learning disabilities	36
13/NE/0319	Social context and help seeking among patients with symptoms of cancer	30
13/NE/0323	VLA009 Systemic Treatment of Resistant Metastatic Disease (STORM)	26
13/NE/0340	The role of personality and sexual fantasy in sexual offending.	21
13/NE/0350	Vertebroplasty In TRAUma (VITRA) pilot study	29
13/NE/0373	Muscle fibre dysfunction in congenital myopathies	42
14/NE/0001	An Exploration of Functional English in a Prison	22
14/NE/0004	The Prevalence of Non-Communicable Diseases in Prisons	22
14/NE/0008	Randomised, multiple dose, two period crossover study in Obese Subjects	24
14/NE/0033	Infrared imaging to differentiate wrist sprain from wrist fracture	38

14/NE/0042	Single Ascending Dose and Multiple Ascending Dose Study of LNP1892	29
14/NE/0064	Fear of falling and activity levels in younger obese women	11

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/NE/0153	The family experience of childhood vitiligo: An IPA study	56
13/NE/0211	Influences on infant responses to routine immunisation	25
13/NE/0214	Biological markers of radiation exposure following fluoroscopy - pilot	46
13/NE/0234	Effect of Pulsed RF treatment of dorsal root ganglion on fMRI	35

#### 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/0219	Determining the Role of Notch in Steroid Resistant Nephrotic Syndrome	6
13/NE/0246	Use of High Content Screening to Personalize Chemotherapy.	11
13/NE/0304	The negotiation of meaning in family therapy for self-harm	6
13/NE/0307	Optimal follow up for colorectal liver metastases and pancreas cancer	6
14/NE/0021	TA-8995-05: DDI	23
14/NE/0034	Acceptability of interactive, online education in type 1 diabetes	8
14/NE/0036	Coping strategies and mood disturbance in injured athletes	7
14/NE/0095	Observational study on Allergan Natrelle Breast Implants	7
14/NE/0099	Does Diagnosis of Gestational Diabetes Provide a 'Teachable Moment?'	6

#### Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/NE/0111	Single ascending dose + multiple ascending dose study of PQ912	23
13/NE/0174	Baricitinib and OC DDI	20
13/NE/0175	Baricitinib and Rifampicin DDI	20
13/NE/0182	Volume Guarantee® or Volume-Controlled Ventilation, version 6	27
13/NE/0200	Baricitinib and Keto/Flu DDI	20
13/NE/0217	Effect of OAT Inhibition on Baricitinib PK in Healthy subjects	20

13/NE/0320	Validation of SUSS	34
13/NE/0356	Resources for Living (R4L) Pilot	17
14/NE/0031	Premonitory urges in children age 6-10 years with Tics and Tourettes	8

#### Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/NE/0148	Impulsivity and risky behaviours in prisoners	21
13/NE/0149	Real-world reasoning and attachment in offenders	21
13/NE/0191	NOVOCART 3D Plus (N3D) Study	39
13/NE/0218	The effects of exercise and/or antioxidants on outcomes in patients	38
13/NE/0291	Arterial and capillary blood gas in COPD exacerbations	20
13/NE/0329	PK, Safety and Efficacy of IB1001 in patients with severe hemophilia B	24
13/NE/0346	NOVOCART 3D PLUS (N3D) Study	21
14/NE/0080	Mind-mindedness Intervention	20

#### Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
14/NE/0030	Young offenders engagement with mental health services	N/A
14/NE/0050	Improving the experience for women in secure mental healthcare	N/A
14/NE/0083	PK, Bioavailability & Safety of CAM2038 q1w & q4w in healthies	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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<b>No Opinion Pending Consultation with Referee</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<b>Not Requiring Review by NHS REC</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

**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>