

# NRES Committee Yorkshire & The Humber - Bradford Leeds

## Annual Report

**01 April 2013 – 31 March 2014**

## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	NRES Committee Yorkshire & The Humber - Bradford Leeds
<b>Type of REC:</b>	Authorised
<b>Type of Flag:</b>	MCA
<b>Chair:</b>	Dr Janet Holt
<b>Vice-Chair:</b>	Dr Rhona Bratt (March 2014)
<b>Alternate Vice-Chair:</b>	N/A
<b>REC Manager:</b>	Ms Hayley Henderson (April – February 2014) Ms Gillian Mayer (February 2014 – Present)
<b>PRSC Co-ordinator:</b>	N/A
<b>REC Assistant:</b>	Christie Ord – (July – October 2013) Kerry Dunbar – (November – December 2013) Sarah Prothero (February 2014 – Present)
<b>Committee Address:</b>	North East REC Centre Room 002 Jarrow Business Centre Viking Industrial Park Rolling Mill Road Jarrow NE32 3DT
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### Chair's overview of the past year:

The Bradford Leeds Committee was formed out of a merger of Bradford and Leeds Central Committees and held its first meeting on 23<sup>rd</sup> July 2013. Throughout the year we have welcomed six new members who have joined those who transferred from Bradford and Leeds Central. The committee is now working well with new members supported by those more experienced in review. Subcommittee work has been done by the Chair and other members of the committee and we aim to begin proportionate review in May.

We have had difficulty appointing a Vice-Chair and Alternate Vice-Chair due to a combination of factors. We have a substantial group of new members who are not eligible to serve in these roles at present and the workload of more experienced members has precluded them taking on extra responsibilities. However, we are grateful to Dr Rhona Bratt who has been appointed as a Vice-Chair temporarily. As an experienced REC Chair, Dr Bratt has provided invaluable input to the committee as a whole and particularly welcome support to me as Chair during this first year. Changes in organisational support to the committee meant that we have also experienced a change of REC Manager and were sorry to lose Hayley Henderson who supported the committee as we became established.

The members demonstrate clear commitment to promoting the values of ethical research and I look forward to our second year of working together.

## NRES Committee Yorkshire & The Humber - Bradford Leeds Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mr Sharif Al-Ghazal	Consultant Plastic Surgeon	Expert	01/04/2013	
Professor Diana Anderson	Professor of Biomedical Sciences	Expert	01/04/2013	
Ms Ruby Bhatti	Consultant Solicitor	Lay Plus	20/01/2014	
Dr Rhona Bratt	Retired Multimedia Project Manager	Lay	01/03/2014	
Ms Anne Davies	Clinical Research Consultant	Lay	17/06/2013	
Dr David Dawson	Consultant in Anaesthetics	Expert	01/04/2013	
Dr Stan Dobrzanski	Clinical Services Manager Pharmacy	Expert	01/04/2013	
Mrs Jenny Foggin	Senior Governance & Corporate Affairs Officer	Lay	18/02/2014	
Ms Rebecca Forster	Research Fellow	Lay	07/10/2013	
Mr Simon Gelsthorpe	Head of Psychological Therapies	Expert	01/04/2013	
Mr Jay Gokhale	Consultant General Surgeon	Expert	01/04/2013	
Mr John Green	Senior Research Fellow	Expert	14/06/2013	23/09/2013
Dr Janet Holt	Senior Lecturer	Expert	01/04/2013	
Dr Kirste Mellish	Research Programme Manager	Expert	01/04/2013	
Mr Andrew Scally	Senior Lecturer	Expert	01/04/2013	
Dr Christopher Skidmore	Retired University Lecturer	Lay	02/08/2013	
Mr Robert Thompson	Lay Member	Lay	08/07/2013	

### Co-opted Members:

Name	Occupation	Expert or Lay	Meeting date attended
Paul Hamilton	Retired Government Officer	Expert	23/07/2013
Rhona Bratt	Retired Multimedia Project Manager	Lay Plus	17/09/2013 23/07/2013

**NRES Committee Yorkshire & The Humber - Bradford Leeds: Members' Declarations of Interest:**

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Dr Stan Dobrzanski	None	26/06/2013
Dr Janet Holt	None	28/06/2013
Dr Kirste Mellish	Shareholder in Photopharmica Ltd	26/06/2013
Mr Simon Gelsthorpe	None	05/07/2013
Mr Andrew Scally	None	25/06/2013
Professor Diana Anderson	Scientific Advisor to a University spin-out company "Oncascan" (unpaid)	27/06/2013
Mr John Green	None	01/07/2013
Mr Robert Thompson	None	20/07/2013
Ms Anne Davies	None	09/07/2013
Dr Christopher Skidmore	None	23/08/2013
Dr David Dawson	Contracted Medical Advisor to Philips Respironics Managing Director OSA Risk Management Ltd Shareholder in Astra-Zeneca and Glaxo Smith Kline Member of OSA Advisory Committee of British Lung Foundation	25/09/2013
Ms Rebecca Forster	Involved with research governance for Leeds Community Healthcare NHS Trust. Provision of advice on applications prior to REC application and develop research ideas within the Trust.	14/10/2013
Mr Jay Gokhale	None	17/12/2013
Mr Sharif Al-Ghazal	None	17/12/2013
Mrs Jenny Foggin	None	24/02/2014
Ms Ruby Bhatti	Vice Chair of quality and safety of patients at Bradford NHS. Involved occasionally with R&D at Bradford BRL from a lay person perspective.	24/01/2014
Dr Rhona Bratt	None	28/03/2014

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

Month	Date	Number of Members Present at Meeting
July	23/07/2013	12
August	20/08/2013	8
September	17/09/2013	9
October	15/10/2013	10
December	17/12/2013	12
January	21/01/2014	12
February	18/02/2014	11
March	18/03/2014	14

8 full committee meetings were held during the reporting period.

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

Name	Number of Meetings Attended
Dr Kirste Mellish	8
Mr Andrew Scally	7
Mr Jay Gokhale	7
Mr Simon Gelsthorpe	7
Dr Janet Holt	7
Dr Stan Dobrzanski	6
Dr Christopher Skidmore	6
Mr Robert Thompson	6
Dr David Dawson	5
Mr Sharif Al-Ghazal	5
Ms Anne Davies	5
Ms Rebecca Forster	5
Professor Diana Anderson	5
Ms Ruby Bhatti	3
Dr Rhona Bratt	1
Dr John Green	1
Mrs Jenny Foggin	1

Number of inquorate meetings held: 0

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

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Mr Sharif Al-Ghazal	12/01/2013 – 12/01/2014	A SDLF submitted to record training on ionising radiation regulation and compliance and training on handling confidential data
Ms Anne Davies	09/09/2013 - 09/09/2013	Induction (HRA)
Ms Rebecca Forster	05/03/2014 – 05/03/2014	Induction (HRA)
Mr Jay Gokhale	24/05/2013 - 24/05/2013	GCP and Statutory Instrument Update Training (A signed SDLF submitted to record this)
Mr John Green	09/09/2013 - 09/09/2013	Induction (HRA)
Mr John Green	01/09/2013 - 01/09/2013	Equality & Diversity On-line Training Module (HRA)
Dr Janet Holt	02/10/2013 - 02/10/2013	Facilitate a Researcher Training Day (HRA)
Dr Janet Holt	27/11/2013 - 27/11/2013	National Members' Training Day (HRA)
Dr Janet Holt	01/11/2013 - 01/11/2013	Equality & Diversity On-line Training Module (HRA)
Dr Janet Holt	12/11/2013 - 12/11/2013	Researcher Training Day (HRA)
Dr Kirste Mellish	27/11/2013 - 27/11/2013	National Members' Training Day (HRA)
Mr Andrew Scally	01/04/2013 – 31/03/2014	A signed SDLF submitted to record involvement in ethical research related issues including: production of an article on ethical research in children, delivering training sessions, assisting university staff and students with research proposals, involvement in a working group and society relating to ethical research.
Mr Robert Thompson	12/11/2013 - 12/11/2013	Researcher Training Day (HRA)
Mr Robert Thompson	31/10/2013 - 31/10/2013	Qualitative Research and Ethical Review (HRA)
Mr Robert Thompson	09/09/2013 - 09/09/2013	Induction (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:**

<b>Applications for full ethical review – Study Type</b>	<b>Number</b>	<b>%</b>
Clinical Trial of Investigational Medicinal Product	0	0.00
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	35	100.00
<b>Total Applications Reviewed</b>	<b>35</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	2
Number of student applications reviewed	13
Number of paediatric applications reviewed	6
Number of device applications reviewed	4
Number of prisoner applications reviewed	0
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:**

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	2	5.71
Favourable Opinion with Additional Conditions	7	20.00
Unfavourable Opinion	0	0.00
Provisional Opinion	26	74.29
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>35</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	21	60.00
Further Information Favourable Opinion with Additional Conditions	1	2.86
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	5.71
Favourable Opinion with Additional Conditions	7	20.00
Unfavourable Opinion	0	0.00
Provisional Opinion	4	11.43
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>35</b>	<b>100</b>



**Table 5: Other Management Information for the reporting period:**

<b>Average number of applications reviewed per full meeting</b>	4.38
<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>	34
<b>Number of days taken to final decision - mode</b>	23
<b>Number of SSAs (non-Phase 1) reviewed</b>	7
<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%
<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>	53
<b>Number of substantial amendments over 35 days</b>	1
<b>Number of substantial amendments over 35 days as a % of total substantial amendments</b>	1.9%
<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>	1
<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%

**Table 6: 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/YH/0199	Parents' understanding of current and future treatments for CF	24
13/YH/0226	The HAPI 'Hip Arthroscopy Pre-habilitation Intervention' Study.	58
13/YH/0241	Single-port versus conventional laparoscopic colorectal surgery	56
13/YH/0264	RCT of Accel-Heal treatment on Recalcitrant VLU Version 1	44
13/YH/0265	Quantitative coronary angiography in coronary heart disease	51
13/YH/0271	SILO2 (Signal Intensity Lung washOut)	46
13/YH/0310	Genotype and phenotype in inherited neurodegenerative disease	20
13/YH/0318	Neurotech Vital RCT - BMR-11-1002	18
13/YH/0342	The educational experiences of children with cystic fibrosis V1	48
13/YH/0344	Placental origins of adverse pregnancy outcome	32
13/YH/0345	Is a primer needed for orthodontic bonding? A multi-centre RCT	34
13/YH/0405	Forced air warming vs BARRIER® EasyWarm in perioperative hypothermia	29
13/YH/0413	Patient-professional partnerships and back pain self-management v1.0	33
13/YH/0416	EASE study	23
13/YH/0426	Rebound therapy and gross motor skills. (version 1)	48
13/YH/0427	Measuring adherence to medication for ADHD (MAMA) study	23
14/YH/0013	HELIX - the Human Early Life eXposome	25
14/YH/0038	VERISMART trial	46
14/YH/0039	Pilot study of activity monitoring in Idiopathic Pulmonary Fibrosis	28
14/YH/0043	Support needs of people with LD who offend: A focus group exploration	39
14/YH/0044	Impact of bariatric surgery on cognitive function	37

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
13/YH/0269	The EuroCYST Initiative	57

<b>Further Information Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<b>Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
13/YH/0272	Process of assimilation in clients with an intellectual disability	43
14/YH/0074	Is the waterlow score a predictor for mortality in medical admissions?	42

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
13/YH/0268	Circadian glucose in gestational diabetes	36
13/YH/0270	HeadUp Evaluation	34
13/YH/0338	ECO Trial	21
13/YH/0417	SYSTEMATIC: NAATS of pooled self-taken versus clinician-taken swabs - 1	24
14/YH/0010	Investigating human host-microbiome interactions in periodontitis.	21
14/YH/0015	Impact of suicide by people receiving MH services on their family (v1)	15
14/YH/0040	Attune™ Primary TKA Survivorship	23

<b>Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<b>Provisional Opinion</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
14/YH/0067	The effects of mindfulness training on the symptoms of MS (v1)	N/A
14/YH/0076	BALANCED	N/A
14/YH/0079	Do people pass on ESBL infections to others in their household?	N/A
14/YH/0083	A single blind, randomised UK pilot study	N/A

<b>Provisional Opinion Pending Consultation with Referee</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<b>Further information response not complete</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<b>Withdrawn after the meeting</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<b>Invalid Application</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<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 7: 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>
11/YH/0210/AM01	Exercise effects on claudication (RCT)	Change of PI and amendments to documentation	37
<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>