

NRES Committee Yorkshire & The Humber - Leeds West

Annual Report

01 April 2011 – 31 March 2012

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee Yorkshire & The Humber - Leeds West
Type of REC:	Recognised Type 3
Type of Flag:	Mental Capacity, Medical Devices, Paediatrics, Phase 1 in patients
Chair:	Dr Rhona Bratt
Vice-Chair:	Dr Sheila E. Fisher
Alternate Vice-Chair:	Dr Vera Neumann
Co-ordinator:	Mrs Elaine Hazell
PRSC Co-ordinator:	
Assistant Co-ordinator:	Mr Marc Neal
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Chair's overview of the past year:

This is my third annual report as Chair of the Leeds (West) Research Ethics Committee. My thanks go to our retiring Vice-chair, Michael Rivlin, our new Vice Chair, Sheila Fisher and our Alternate Vice chair Vera Neuman, for their support in the past 12 months. Two members left having served 10 years on the committee. I would like to thank Michael Rivlin for his 10 years' service to the research ethics service bringing his experience of the academic ethics world as well as his strong community connections. Ken Shenderoy, as a GP, brought a vast range of experience to the committee as well as a wicked sense of humour. The contributions of Ken and Michael are greatly missed. We have had the good fortune to have new members join us, Reema Sirriyeh and Jerry Masterson. They bring very different skills and experience with them and their contributions are greatly appreciated by the committee.

It should like to thank the committee coordinator, Elaine Hazell, for her work and for her skill in navigating us through the move towards the proportionate review system so successfully.

Research becomes ever more varied and complex and the committee members have attended many training courses to continue their professional development in Research Ethics review. The work of the committee took place in an environment of ever-greater changes but the members' steadfast commitment to reviewing the research continued as always; calm, courteous and professional. All I can say to the committee is thank you for all you work.

NRES Committee Yorkshire & The Humber - Leeds West Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Miss Brygitta Atraszkiewicz	Information Analyst	Lay Plus	14/08/2009	
Professor Howard Bird	Consultant Rheumatologist	Expert	24/11/2003	
Dr Rhona Bratt	Retired Multimedia Project Manager	Lay Plus	07/01/2005	
Mr David Bryant	Pharmacist	Expert	07/05/2010	
Dr Martin Elliott	Consultant Paediatric Oncologist	Expert	01/04/2010	
Dr Sheila E. Fisher	NCRI Associate Director for PPI	Expert	20/07/2007	
Mr Peter Margerison	Retired Solicitor	Lay Plus	06/01/2006	
Mr Jerry Masterson	Practice Learning Facilitator	Expert	10/06/2011	
Dr Wendy Neil	Consultant Psychiatrist	Expert	25/05/2007	
Dr Vera Neumann	Consultant in Rehabilitation Medicine	Expert	20/07/2007	
Dr Jane Orton	Consultant Oncologist	Expert	29/04/2008	
Dr Michael Rivlin	Medical Ethics Lecturer Lay Member,	Lay	10/12/2001	31/12/2011
Dr Ken Shenderay	General Practitioner	Expert	01/02/2002	31/01/2012
Dr Reema Sirriyeh	Research Fellow	Lay	18/07/2011	
Professor Anne Topping	Director, Centre for Health and Social Care Research	Expert	04/02/2010	

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended

Member Bank

Name	Occupation	Expert or Lay	Meeting date attended

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

Dr Rhona Bratt	None	30/03/2012
Miss Brygitta Atraszkiewicz	None	30/03/2012
Declaration of Interest	Declaration of Interest	Date
Professor Howard Bird	Associate Director of the National Cancer Research Institute and NIHR Cancer Research Network. Peer Reviewer for MRC, Cancer Research UK and NIHR.	30/03/2012
Dr Vera Neumann	None	30/03/2012
Dr Martin Elliott	None	30/03/2012
Dr Reema Sirriyeh	None	30/03/2012
Dr Rhona Bratt	None	30/03/2012
Miss Brygitta Atraszkiewicz	None	30/03/2012
Professor Howard Bird	None	30/03/2012
Dr Vera Neumann	None	30/03/2012
Dr Martin Elliott	None	30/03/2012
Dr Reema Sirriyeh	None	30/03/2012
Dr Wendy Neil	None	30/03/2012
Dr Jane Orton	None	30/03/2012
Mr Peter Margerison	None	30/03/2012
Mr Jerry Masterson	None	30/03/2012
Professor Anne Topping	None	30/03/2012
Mr David Bryant	None	30/03/2012
Dr Wendy Neil	None	30/03/2012
Mr Peter Margerison	None	30/03/2012

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

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

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
February	10/02/2012	3
March	30/03/2012	3

2 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 Rhona Bratt	11
Dr Jane Orton	10
Dr Sheila E. Fisher	9
Dr Vera Neumann	9
Mr Peter Margerison	9
Professor Howard Bird	8
Miss Brygitta Atraszkiewicz	8
Dr Martin Elliott	8
Dr Wendy Neil	7
Mr Jerry Masterson	7
Professor Anne Topping	7
Dr Reema Sirriyeh	6
Mr David Bryant	4
Dr Ken Shenderoy	3
Dr Michael Rivlin	2

Number of inquorate meetings held: none

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

Name	Number of Meetings Attended
Dr Reema Sirriyeh	1
Dr Martin Elliott	1
Dr Rhona Bratt	1
Dr Sheila E. Fisher	1
Dr Wendy Neil	1
Professor Howard Bird	1

Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Miss Brygitta Atraszkiewicz	06/06/2011 - 06/06/2011	Equality & Diversity, Core learning
Dr Rhona Bratt	28/06/2011 - 28/06/2011	Statistics for REC members, NRES
Miss Brygitta Atraszkiewicz	26/08/2011 - 26/08/2011	Medical devices, NRES
Dr Reema Sirriyeh	25/10/2011 - 25/10/2011	Equality & Diversity, Core learning
Professor Anne Topping	23/10/2011 - 23/10/2011	Equality & Diversity, University of Huddersfield
Dr Vera Neumann	08/11/2011 - 08/11/2011	Chairing Skills, NRES
Dr Sheila E. Fisher	15/07/2011 - 15/07/2011	Equality & Diversity, Core learning
Dr Reema Sirriyeh		Induction, NRES
Dr Jane Orton	28/03/2012 - 28/03/2012	NRES Members National Training Day, NRES
Dr Wendy Neil	28/03/2012 - 28/03/2012	NRES Members National training day, NRES
Mr Jerry Masterson	22/02/2012 - 22/02/2012	Induction
Mr Peter Margerison	02/02/2012 - 02/02/2012	HTA , NRES
Dr Sheila E. Fisher	17/01/2012 - 17/01/2012	Adults lacking capacity, NRES
Dr Sheila E. Fisher	02/02/2012 - 02/03/2012	HTA, NRES
Dr Sheila E. Fisher	21/03/2012 - 21/03/2012	Training Day for new REC Chairs, NRES
Dr Sheila E. Fisher	28/03/2012 - 28/03/2012	NRES Members National Training day, NRES
Dr Martin Elliott	28/03/2012 - 28/03/2012	NRES National Members Training day, NRES
Dr Rhona Bratt	06/12/2011 - 06/12/2011	Chairs National training day, NRES
Dr Rhona Bratt	28/03/2012 - 28/03/2012	NRES National Members Training day, NRES
Professor Howard Bird	28/03/2012 - 28/03/2012	NRES National Members Training day, NRES
Miss Brygitta Atraszkiewicz	23/02/2012 - 23/02/2012	Reviewing CTIMPs, NRES
Miss Brygitta Atraszkiewicz	28/03/2012 - 28/03/2012	NRES National Members Training day, 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:

Applications for full ethical review – Study Type	Number	%
Clinical Trial of Investigational Medicinal Product	14	20.00
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	56	80.00
Total Applications Reviewed	70	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	3
Number of studies withdrawn prior to the meeting	7
Number of student applications reviewed	19
Number of paediatric applications reviewed	18
Number of device applications reviewed	16
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	6
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	6	8.57
Favourable Opinion with Additional Conditions	9	12.86
Unfavourable Opinion	4	5.71
Provisional Opinion	51	72.86
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	70	100
Number of studies sent back to full committee meeting for final opinion	1	

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	39	55.71
Further Information Favourable Opinion with Additional Conditions	7	10.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	6	8.57
Favourable Opinion with Additional Conditions	9	12.86
Unfavourable Opinion	4	5.71
Provisional Opinion	2	2.86
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	1	1.43
Number of studies withdrawn after the meeting	2	2.86
Total	70	100

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

Total Applications Reviewed	5
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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	0	0.00
Favourable Opinion with Additional Conditions	4	80.00
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	1	20.00
Unfavourable Opinion	0	0.00
Total	5	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	6.36
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	28
Number of days taken to final decision - mode	19
Number of SSAs (non-Phase 1) reviewed	31
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	156
Number of substantial amendments over 35 days	3
Number of substantial amendments over 35 days as a % of total substantial amendments	1.9%
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	19
Number of modified amendments over 14 days	3
Number of modified amendments over 14 days as a % of total modified amendments	15.8%
Number of proportionate review applications for ethical review over 14 days*	0
Number of proportionate review applications over 14 days as a % of total	0.00%

***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/YH/0054	The association between nutritional status and outcomes after a stroke	22
11/YH/0056	CALMS-2 Study, version 2	29
11/YH/0067	Skinspection B -version 1.3	21
11/YH/0080	Translation of the SDQ into British Sign Language	37
11/YH/0085	SuperNOVA Protocol version AC, dated 8 Feb 2011	25
11/YH/0131	Predictor of post operative outcome in peripheral vasc. surg. patients	22
11/YH/0143	Evaluation of the meaning and purpose attributed to clinical supervisi	42
11/YH/0147	Microvisk bench validation of POC monitor for INR	30
11/YH/0148	The use of SeriScaffold™ in IBR Implant Surgery- Ver A 18 March 2011	27
11/YH/0151	CT330/ 14-DRM-HSF-10-002 CORN TREATMENT	40
11/YH/0153	Revamilast – Phase IIb study in Active RA	22
11/YH/0190	Bite force evaluation in young children following dental treatment	29
11/YH/0199	S15L-003 Juvederm Volbella with Lidocaine v1.0	27
11/YH/0200	AV Optimisation by an electrogram method in dual chamber pacemakers V1	28
11/YH/0252	Effect of Denosumab on Osteolytic Lesion Activity in THA	22
11/YH/0253	Effectiveness of CoSeal® in reducing adhesions post Kasai procedure	28
11/YH/0289	Increasing Uptake of the Seasonal Flu Jab for Health Professionals	37
11/YH/0291	Pectoralis muscle biopsy in CHF patients	36
11/YH/0295	Metformin in Tuberous Sclerosis Complex (MiTS) V1.0	22
11/YH/0298	Development of a pressure ulcer PROM	36
11/YH/0322	Does an e-learning module improve adherence to RebiSmart? Version 2	27
11/YH/0346	fEITER Study 1	43
11/YH/0385	B1971009 Phase 3 study to assess Meningococcal B Vaccine	22
11/YH/0386	Breast cancer, sexuality and intimacy	26
11/YH/0390	RH01352 - A 12 week clinical study in the relief of tooth sensitivity.	27
11/YH/0398	Can we reduce SPECT Myocardial Perfusion Acquisition time? ver1.0	25
11/YH/0402	The ATLAS Neck Pain Trial	30
11/YH/0405	NKTR-118 vs Placebo Relieving OIC in Patients with cancer-related pain	33
11/YH/0409	Minuteman Interspinous Process Implant versus Surgical Decompression	20
11/YH/0412	Preventing avoidable hospital admissions from care homes	28

11/YH/0424	Vibration in boys with a history of fracture version 1	25
11/YH/0442	ENCHANTED	24
11/YH/0443	Effectiveness of physiotherapy for rotator cuff disorders	56
11/YH/0445	Parental involvement in a child's acute pain care.	32
12/YH/0007	Bioavailability Study of Capecitabine in Adult Solid Tumour Patients	29
12/YH/0011	Efficacy of Pomalidomide in Systemic Sclerosis (SSC), amend.1 08NOV11	30
12/YH/0015	Non-comparative study of primary TKA functional performance	29
12/YH/0020	Shire 318 - Open Label Study to Provide Continued Access to SPD503	33
12/YH/0034	Do oralight exercises improve swallowing function in those with an ID	19

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/YH/0024	MED and Epidural Bupivacaine	60
11/YH/0082	Features of diagnostic decision making in emergency care. V1	39
11/YH/0142	Cladribine Safety Registry	38
11/YH/0146	Post hospital discharge medicines use review project	42
11/YH/0276	RCT of assistive technology for children with CP	26
11/YH/0415	THE EVALUATION OF A NURSE/PHARMACIST MANAGED PAIN CLINIC	26
11/YH/0451	Psoriasis Topical Treatment Optimising Programme (PSO-TOP; v1.0)	37
12/YH/0107	Biomarker Identification in patients with vascular disease	10

Further Information Unfavourable Opinion		
REC Reference	Application Short Title	Number of Days on Clock

Favourable Opinion with Standard Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/YH/0192	Early Neonatal Care Practice of Preterm Infants (less than 32 weeks)	21
11/YH/0381	Characterization of protein binding with amoxicillin	19
11/YH/0413	The epidemiology of viral RTIs in immunocompromised patients	26
11/YH/0449	Comparison of haemodialysis and peritoneal dialysis in babies	21
12/YH/0099	Modelling the physiology of the critically ill	15
12/YH/0124	Variation in care for bowel & blood cancers at the end of life	27

Favourable Opinion with Additional Conditions		
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REC Reference	Application Short Title	Number of Days on Clock
11/YH/0180	Validation of BSL versions of GAD-7, PHQ-9 and WSAS	19
11/YH/0187	An Augmentative and Alternative Communication (AAC) Evidence Base	19
11/YH/0306	Place of care and death in haematological malignancy	29
11/YH/0310	Changes in the surface of enamel exposed to acid	24
11/YH/0318	Recovery and the Learning to Live Again project	24
11/YH/0383	Mapping Services for Children and Young People with Life Limiting Conditions	23
12/YH/0002	Antibody localisation in ex-vivo colorectal cancer	28
12/YH/0022	MIDSHIPS (v1.0)	19
12/YH/0083	Does GM-CSF restore neutrophil phagocytosis in critical illness?	26
12/YH/0106	Evaluation of NHS Bowel Cancer Screening patient information materials	5
12/YH/0185	A study exploring patient experiences of parenteral nutrition	12
12/YH/0187	London 2012 – The Oral health of Olympic athletes	11
12/YH/0188	Observational Study 24h symptoms COPD	12

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/YH/0077	MLASS Study	20
11/YH/0301	An assessment of Head and neck cancer patients' expectations (1.0)	28
11/YH/0326	Version 1: Investigating care staff and client interactions	24
12/YH/0084	GATE FEVER	23

Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/YH/0437	(duplicate) The Role of Parental Risk Factors in the Aetiology of Cran	N/A
12/YH/0120	Developing a transition path for young adults with haemoglobinopathies	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
11/YH/0201	Hypopituitarism and Traumatic Brain Injury	19
11/YH/0299	Cranial Pressure - Volume Compliance	24

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
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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

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
05/Q1205/148/AM09	Safety evaluation of tacrolimus in atopic dermatitis (Version 2)	implementation of protocol am 1; birthday, patient	36
09/H1307/90/AM03	Effect of Velcade on Myeloma related Bone Disease (protocol 2.0)	additional risks of Velcade	39
07/H1307/142/AM01	Identification of potential therapeutic targets in Haematological Malignancies	extension/title change/scope of data extended	48

Modified Amendments over 14 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
08/H1307/108/AM22/1	Efficacy and Safety of Romiplostim Treatment of Thrombocytopenia	modified amendment	16
09/H1311/75/AM05/1	Acupuncture, counselling and usual GP care for depression	Clarification and justification	17
09/H1307/54/AM08/1	Open-label study of Denosumab in	Increase sample size and update	32

	Subjects with Giant Cell Tumor	PIS	
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Section 30 application over 60 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock