

NRES Committee Yorkshire & The Humber - Leeds Central

Annual Report

01 April 2011 – 31 March 2012

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee Yorkshire & The Humber - Leeds Central
Type of REC:	Authorised
Type of Flag:	None
Chair:	Dr Margaret L Faull
Vice-Chair:	Dr Janet Holt
Alternate Vice-Char:	Dr Chris Bennett
Co-ordinator:	Mrs Nicola Mallender-Ward
PRSC Co-ordinator:	Mrs Nicola Mallender-Ward
Assistant Co-ordinator:	Mr. Marc Neal
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Chair's overview of the past year:

During this year the NRES Committee Yorkshire & the Humber - Leeds Central was able to recruit some new members, although unfortunately the clinical member previously granted leave of absence for a year by the Strategic Health Authority was unable to return because of the financial pressures at the trust where he is employed. The reduced numbers continued to put a strain on the remaining members of the Committee, although the Committee was successful in always having a quorum at meetings. Also unfortunately, because of the Committee not being permitted to recruit, the proportion of lay members to clinical was not at the level required by the regulations.

Members of the Committee have attended a large number of training courses on a variety of subjects. I attended the annual one-day training course in London for chairs from throughout the United Kingdom, which was a valuable learning experience, I was away overseas for the half-day meeting for chairs of committees in the region and I am grateful to Dr Janet Holt for attending in my place; these meetings enable chairs and vice-chairs to exchange views on the running of committees, to receive up-to-date information about recent developments regarding ethics committees from Joan Kirkbride, Head of Operations, England.

I should also like to thank Dr Holt for her work chairing the sub-committee dealing with substantial amendments, as well as all the members of the Committee for their dedication to ensuring that all applications receive a full, impartial and comprehensive assessment and that the interests of participants are always borne in mind. I would especially like to thank Nicola Mallender-Ward, our Co-ordinator, for her efficiency in dealing with all aspects of the work of the Committee.

Margaret L. Faull
Chair, NRES Committee Yorkshire & the Humber - Leeds Central

NRES Committee Yorkshire & The Humber - Leeds Central Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mrs Jenny Baston	Research Sister - Paediatric Oncology	Expert	22/12/2011	
Dr Chris Bennett	Consultant Clinical Geneticist	Expert	31/07/2007	
Mr Mick Burns	Senior Commissioning Manager	Expert	08/12/2008	
Dr Emily Clavering	CT2 Psychiatrist	Expert	01/12/2011	
Dr Margaret L Faull	Chair	Lay	01/03/2007	
Mr Mark Godley	IT Consultant	Lay	31/03/2009	
Dr Janet Holt	Senior Lecturer	Expert	31/07/2007	
Ms Sarah Kirkland	NHS Service Improvement Facilitator	Lay	31/03/2009	
Mr Vernon Long	Consultant Ophthalmologist	Expert	31/07/2007	18/04/2011
Mrs Claire M Ramsden	Health visitor	Expert	31/07/2007	
Dr Jinous Tahmassebi	Senior Lecturer and Specialist in Paediatric Dentistry	Expert	31/03/2009	

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Mr Michael Davidson	Retired Senior Personnel Manager	Lay Plus	17/06/2011 15/07/2011 19/08/2011
Dr Rhona Bratt	Retired Multimedia Project Manager	Lay Plus	17/06/2011

Member Bank

Name	Occupation	Expert or Lay	Meeting date attended

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

Name	Declaration of Interest	Date
Dr Margaret L Faull	Non-Executive Director, Mid Yorkshire NHS Hospitals Trust Non-Executive Director, Local Care Direct	21/01/2012
Dr Janet Holt	None	20/01/2012
Dr Chris Bennett	None	01/03/2012
Mr Mark Godley	None	20/01/2012
Ms Sarah Kirkland	None	01/02/2012
Dr Jinous Tahmassebi	Senior Lecturer at Leeds Dental Institute (PhD Supervision) Member of British Society of Paediatric Dentistry	02/01/2012
Mrs Jenny Baston	None	01/02/2012
Mr Mick Burns	None	01/03/2012
Dr Emily Clavering	None	01/03/2012
Mrs Claire M Ramsden	None	01/02/2012

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

Month	Date	Number of Members Present at Meeting
May	20/05/2011	9
June	17/06/2011	7
July	15/07/2011	7
August	19/08/2011	8
October	21/10/2011	8
December	16/12/2011	8
February	17/02/2012	7
March	16/03/2012	8

8 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
January	20/01/2012	6
March	02/03/2012	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
Mrs Claire M Ramsden	8
Dr Chris Bennett	7
Dr Janet Holt	7
Dr Margaret L Faull	7
Mr Mark Godley	7
Mr Mick Burns	6
Ms Sarah Kirkland	6
Dr Jinous Tahmassebi	4
Dr Emily Clavering	3
Mr Michael Davidson (co-opted member)	3
Mr Vernon Long	2
Dr Rhona Bratt (co-opted member)	1
Mrs Jenny Baston	1

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 Jinous Tahmassebi	2
Ms Sarah Kirkland	2
Dr Chris Bennett	1
Dr Janet Holt	1
Dr Margaret L Faull	1
Mr Mick Burns	1
Mrs Jenny Baston	1

Training 01 April 2011 – 31 March 2012:

Dr Margaret L Faull	20/04/2011 - 20/04/2011	Joint Chair's Meeting, NRES
Ms Sarah Kirkland	13/02/2012 - 13/02/2012	Ethics & GCP Forum, The Institute of Clinical Research
Dr Margaret L Faull	06/12/2011 - 06/12/2011	Chair's National Training Day, NRES
Dr Janet Holt	28/03/2012 - 28/03/2012	Members National Training Day, NRES
Dr Chris Bennett	28/03/2012 - 28/03/2012	Members National Training Day, NRES
Mrs Claire M Ramsden	28/03/2012 - 28/03/2012	Members National Training Day, NRES
Ms Sarah Kirkland	28/03/2012 - 28/03/2012	Members National Training Day, NRES
Ms Sarah Kirkland	27/07/2011 - 27/07/2011	The ethical review of medicines based research, Association of British Pharmaceutical industries
Ms Sarah Kirkland	28/06/2011 - 28/06/2011	Statistics Training for NRES REC Members, NRES
Mr Mark Godley	28/03/2012 - 28/03/2012	Members National Training Day, NRES
Dr Jinous Tahmassebi	28/03/2012 - 28/03/2012	Members National Training Day, NRES
Dr Emily Clavering	29/03/2012 - 29/03/2012	Induction, NRES
Mrs Jenny Baston	22/02/2012 - 22/02/2012	Induction, NRES
Ms Sarah Kirkland	01/04/2011 - 01/04/2011	Equality & Diversity, Leeds Partnerships NHS Foundation Trust
Dr Jinous Tahmassebi	10/11/2011 - 10/11/2011	Equality & Diversity, LTHT/Leeds University
Dr Emily Clavering	01/09/2011 - 01/09/2011	Equality & Diversity, Leeds Partnerships NHS Foundation Trust

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	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	42	100.00
Total Applications Reviewed	42	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	2
Number of studies withdrawn prior to the meeting	9
Number of student applications reviewed	21
Number of paediatric applications reviewed	1
Number of device applications reviewed	1
Number of prisoner applications reviewed	0
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:

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	3	7.14
Favourable Opinion with Additional Conditions	13	30.95
Unfavourable Opinion	5	11.90
Provisional Opinion	21	50.00
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	42	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	20	47.62
Further Information Favourable Opinion with Additional Conditions	1	2.38
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	3	7.14
Favourable Opinion with Additional Conditions	13	30.95
Unfavourable Opinion	5	11.90
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	42	100

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

Total Applications Reviewed	6
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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	2	33.33
Favourable Opinion with Additional Conditions	3	50.00
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	1	16.67
Unfavourable Opinion	0	0.00
Total	6	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.25
Number of applications for full ethical review over 60 days	2
Number of applications over 60 days as a % of total	4.76%
Number of days taken to final decision - average	39
Number of days taken to final decision - mode	24

Number of SSAs (non-Phase 1) reviewed	1
Number of applications for SSA review over 25 days	1
Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)	100.0%

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	37
Number of substantial amendments over 35 days	2
Number of substantial amendments over 35 days as a % of total substantial amendments	5.4%

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	7
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*	1
Number of proportionate review applications over 14 days as a % of total	16.67%

***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/0088	MOVE	63
11/YH/0139	Prevalence of Autism Spectrum Condition Features in Eating Disorders	58
11/YH/0141	Experiences of an exercise programme in a mental health unit	59
11/YH/0206	Ultrasound Vs Nerve stimulation- why is a PNS so effective?	59
11/YH/0246	Nurses' experiences of dementia care on 3 orthopaedic wards.	33
11/YH/0255	Significant Events in Ward Based Reflective Practice Groups	33
11/YH/0261	Patient preference and understanding study	47
11/YH/0265	Relating isotope and bioimpedance measures of ECFV	42
11/YH/0309	3D Dual Phase Perfusion CMR	47
11/YH/0313	Surgical Wounds - identifying appropriate outcomes	46
11/YH/0315	Evaluation of service user involvement in secure care, Yorkshire. v1	49
11/YH/0393	Implicit cognitive processes in people with seizures	38
11/YH/0430	The Prevalence of Eating Disorders in Infertile Women	55
11/YH/0447	Partnership working in palliative care	58
12/YH/0041	FLARE: FLare in psoriatic ARthritis Exercise	18
12/YH/0095	The WYLOW study (version 3)	37
12/YH/0096	The COBID Study (version 3)	37
12/YH/0100	Air leak quantification in patients with spontaneous pneumothorax	32
12/YH/0105	MCP as Anti-Galectin-3 therapy In heart Failure Trial (MAGnIFicenT)	49
12/YH/0131	Bone health in people living with HIV, Version 1	42
12/YH/0150	Role of deflation in lung injury post cardiac surgery	24

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/YH/0102	Immunological Profiling in AIT Recipients Version 1	64

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/0149	Metabolic Diseases Presenting with Hyperferritinaemia v1	45
11/YH/0249	Flexibility and supportive functions of a child's shoe	31
11/YH/0251	MVO following AML: Vitamin D sub-study	33
12/YH/0042	Travelling to see the doctor	13
12/YH/0129	Validation of Palliative Prognostic Index in hospice cancer patients.	11

Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/YH/0150	Parkinson's Disease v1	48
11/YH/0157	ChemR23 and BLT1 receptor expression in colorectal tumours	27
11/YH/0178	Experiences of adjunctive treatments for IBS	28
11/YH/0195	Use of DASH Diet in People with CKD	30
11/YH/0205	Cystic fibrosis arthritis	30
11/YH/0209	Persistence in problem solving in chronic pain.	35
11/YH/0220	Rhinovirus serotypes in patients with cystic fibrosis	30
11/YH/0234	I125 brachytherapy after TURP	24
11/YH/0245	Development of a breast cancer specific Patients Concerns Inventory	24
11/YH/0314	Vitamin D and Fibrin clot structure and function in South Asians	34
11/YH/0444	The effect of a simultaneous curing protocol on microleakage	44
11/YH/0448	ADAPTA- Addressing Drinking Among Patients: comparing Two Approaches	44
11/YH/0452	Development of immuno-proteomic approaches for assessing transplants	40
12/YH/0043	Patient experience of MRSA screening and decolonisation	11
12/YH/0044	The role of the hippocampus in posttraumatic stress disorder. V 2.0	14
12/YH/0130	Angiotensin & Putative Biomarkers in Fibrotic Crohn's disease	8

Unfavourable Opinion		
REC Reference	Application Short Title	Number of Days on Clock
11/YH/0092	Development of a breast cancer specific Patients Concerns Inventory	55
11/YH/0305	Malignant ascitic fluid: cell isolation and tissue factor expression.	28
11/YH/0307	Surgery vs chemoradiotherapy for oropharyngeal carcinoma	29
11/YH/0388	Visceral obesity and outcomes in colorectal cancer	27
12/YH/0132	Best Biomarkers Exercise Stress Test (BBEST) Study	16

Provisional Opinion		
REC Reference	Application Short Title	Number of Days on Clock

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

Further information response not complete		
REC Reference	Application Short Title	Number of Days on Clock

Withdrawn after the meeting		
REC Reference	Application Short Title	Number of Days on Clock

Invalid Application		
REC Reference	Application Short Title	Number of Days on Clock

No Opinion Pending Consultation with Referee		
REC Reference	Application Short Title	Number of Days on Clock

Not Requiring Review by NHS REC		
REC Reference	Application Short Title	Number of Days on Clock

Table 9: Items exceeding timelines:

Full applications for ethical review over 60 day timeline			
REC Reference	Application Short Title	Number of Days on Clock	
11/YH/0102	Immunological Profiling in AIT Recipients Version 1	64	
11/YH/0088	MOVE	63	
Proportionate review applications for ethical review over 14 days timeline			
REC Reference	Application Short Title	Number of Days on Clock	
12/YH/0041	FLARE: FLare in psoriatic ARthritis Exercise	18	
SSAs (non Phase 1) over 25 days timeline			
REC Reference	Application Short Title	Number of Days on Clock	
11/YH/0197	Acupuncture and Manual Therapy for Low Back Pain	28	
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
11/YH/0178/AM02	Experiences of adjunctive treatments for IBS	reminder letter	42
10/H1313/94/AM01	Recollective processes in temporal lobe epilepsy. Version 1.0	add another PI	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