

NRES Committee Yorkshire & The Humber - Humber Bridge

Annual Report

01 April 2011 – 31 March 2012

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee Yorkshire & The Humber - Humber Bridge
Type of REC:	Authorised
Type of Flag:	Paediatric
Chair:	Dr Lynn Cawkwell
Vice-Chair:	Dr Stephen Beer
Alternate Vice-Chair:	None
Co-ordinator:	Mrs Nicola Mallender-Ward
PRSC Co-ordinator:	Mrs Nicola Mallender-Ward
Assistant Co-ordinator:	Mr Marc Neal
Committee Address:	Yorkshire and the Humber Research Ethics Office First Floor Millside Mill Pond Lane Leeds LS6 4RA
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Chair's overview of the past year:

First, I would like to express my sincere thanks to the members of the Humber Bridge Committee for their hard work, effort and commitment over the last year. In addition, our co-ordinator Mrs Nicola Mallender-Ward has done an excellent job of keeping us highly organised and well-informed. I believe that taking on the role of Chair during the past year was made easier due to the support of the Committee members and especially Dr Stephen Beer, who is now the Vice Chair of the Committee.

The past year has once again been an active one with an average of 5 applications in each of 10 Full Committee meetings in addition to a number of excursions for Committee members to attend training courses. This year has also seen the onset of a change in the work pattern of the Committee, with the recent introduction of Proportionate Review. As it is still "early days" for the Committee with regards to dealing with the work-load from this fast-track system, I will defer my comments on this to next year. I look forward to another interesting and worthwhile year serving the Committee and meeting researchers.

Dr Lynn Cawkwell PhD

NRES Committee Yorkshire & The Humber - Humber Bridge Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Reverend Annabel Barber	Chaplain	Lay Plus	12/04/2010	
Dr Stephen Beer	Consultant Physician	Expert	12/04/2010	
Mrs Kate Bollington	Customer Services Manager	Expert	01/08/2010	
Dr Lynn Cawkwell	Senior Lecturer in Cancer Genetics	Expert	12/04/2010	
Dr Fiona Cowdell	Senior Research Fellow	Expert	01/12/2011	
Mr Michael Davidson	Retired Senior Personnel Manager	Lay Plus	12/04/2010	
Dr Karen Dunderdale	Assistant Director of Nursing	Expert	23/06/2010	
Mrs Dorothy Fagge	Specialist in Health Education	Lay	13/08/2010	
Mr Michael Hockey	Consultant in Accident & Emergency	Expert	23/06/2010	
Dr David Horton	Consultant Radiologist / Chair of the REC	Expert	12/04/2010	24/10/2011
Dr Sandeep Kapoor	Consultant Paediatrician	Expert	12/04/2010	
Mrs Joanna Wild	Social Work - Psychosocial Palliative Care	Lay	12/04/2010	28/04/2011
Mrs Wendy Witter	Farm Administrator	Lay Plus	01/05/2010	
Dr Ian Woollands	Clinical Director, Occupational Health	Expert	12/04/2010	31/10/2011

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 - Humber Bridge: Members' Declarations of

Name	Declaration of Interest	Date
Dr Lynn Cawkwell	None	01/03/2012
Dr Stephen Beer	Member of Diabetes UK Member of European Society of Cardiology	22/02/2012
Mrs Wendy Witter	None	30/12/2011
Reverend Annabel Barber	None	01/03/2012
Mrs Kate Bollington	None	30/12/2011
Dr Fiona Cowdell	Trustee of Help and Care (Dorset based charity) Senior Research Fellow Faculty of Health & Social Care - University of Hull Member of Hull & East Yorkshire Hospitals NHS Trust R&D Committee	30/12/2011
Dr Sandeep Kapoor	Owns shares in pharmaceutical companies	14/12/2011
Mr Michael Davidson	None	26/01/2012
Mr Michael Hockey	Medical Officer providing cover for Lyndsey Lodge Hospice	14/12/2011
Dr Karen Dunderdale	None	01/03/2012
Mrs Dorothy Fagge	None	01/03/2012

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

Month	Date	Number of Members Present at Meeting
April	27/04/2011	10
May	25/05/2011	8
June	22/06/2011	7
July	27/07/2011	8
September	21/09/2011	7
November	23/11/2011	8
December	14/12/2011	7
January	25/01/2012	8
February	22/02/2012	7
March	21/03/2012	8

10 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	03/02/2012	3
March	09/03/2012	3
March	21/03/2012	3

3 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 Kate Bollington	9
Mrs Wendy Witter	9
Reverend Annabel Barber	8
Dr Lynn Cawkwell	8
Dr Sandeep Kapoor	8
Dr Stephen Beer	8
Mr Michael Davidson	7
Dr Ian Woollands	5
Mrs Dorothy Fagge	5
Dr Fiona Cowdell	4
Mr Michael Hockey	3
Dr David Horton	2
Dr Karen Dunderdale	1
Mrs Joanna Wild	1

Number of inquorate meetings held:

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

Name	Number of Meetings Attended
Dr Lynn Cawkwell	2
Mr Michael Davidson	2
Mrs Kate Bollington	1
Reverend Annabel Barber	1
Dr Sandeep Kapoor	1
Dr Stephen Beer	1
Dr Fiona Cowdell	1

Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Dr David Horton	20/04/2011 - 20/04/2011	Joint Chair's Meeting, NRES
Dr Lynn Cawkwell	07/09/2011 - 07/09/2011	Chairing Skills, NRES
Mrs Wendy Witter	08/09/2011 - 08/09/2011	Qualitative Research and Ethical Review training, NRES
Dr Stephen Beer	19/01/2012 - 19/01/2012	Good Clinical Practice (GCP) Refresher
Dr Stephen Beer	10/02/2012 - 10/02/2012	Diversity, Equal Opportunities and Human Rights
Reverend Annabel Barber	28/03/2012 - 28/03/2012	Members National Training Day, NRES
Dr Stephen Beer	28/03/2012 - 28/03/2012	Members National Training Day, NRES
Mrs Kate Bollington	28/03/2012 - 28/03/2012	Members National Training Day, NRES
Mr Michael Davidson	28/03/2012 - 28/03/2012	Members National Training Day, NRES
Dr Karen Dunderdale	28/03/2012 - 28/03/2012	Members National Training Day, NRES
Mr Michael Hockey	28/03/2012 - 28/03/2012	Members National 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	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	50	100.00
Total Applications Reviewed	50	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	9
Number of student applications reviewed	25
Number of paediatric applications reviewed	7
Number of device applications reviewed	0
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	2	4.00
Favourable Opinion with Additional Conditions	11	22.00
Unfavourable Opinion	5	10.00
Provisional Opinion	32	64.00
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	50	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	48.00
Further Information Favourable Opinion with Additional Conditions	3	6.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	4.00
Favourable Opinion with Additional Conditions	11	22.00
Unfavourable Opinion	5	10.00
Provisional Opinion	4	8.00
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	1	2.00
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	50	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	1	16.67
Favourable Opinion with Additional Conditions	1	16.67
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	4	66.67
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	5.00
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	36
Number of days taken to final decision - mode	30

Number of SSAs (non-Phase 1) reviewed	3
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	33
Number of substantial amendments over 35 days	1
Number of substantial amendments over 35 days as a % of total substantial amendments	3.0%

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	9
Number of modified amendments over 14 days	2
Number of modified amendments over 14 days as a % of total modified amendments	22.2%

Number of proportionate review applications for ethical review over 14 days*	2
Number of proportionate review applications over 14 days as a % of total	33.33%

***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/0111	Motor Learning During Gait Re-Education Post Stroke V2	48
11/YH/0113	Evaluation of a new blood test for lung cancer Version 1	60
11/YH/0126	Patient body weight and complications of ileostomy formation.	42
11/YH/0169	Corneal confocal microscopy in glaucoma Version 6	36
11/YH/0176	Maintenance of human atrial tissue in a microfluidic system.	43
11/YH/0214	Brighton ROCC	49
11/YH/0219	Effects of combining cocoa and soy in type 2 diabetes	43
11/YH/0223	Evaluate the efficacy of heel wedges to control knee hyperextension	44
11/YH/0268	Sudden Gains in CBT for Panic Disorder (Version 10)	53
11/YH/0272	Healthy Start: Understanding the use of vouchers and vitamins v1	45
11/YH/0277	Cannabis use in the daily life of people with psychosis	45
11/YH/0284	Experiences of adhering to aerosol therapy in adolescents with CF	38
11/YH/0285	Comparison of Digit IV to wrist with mid palmar to wrist in early CTS.	37
11/YH/0286	Describing decision making about lung cancer treatment	40
11/YH/0308	BUDI vs GET: Effects on QoL, mood and inflammation in Crohn's Disease	34
11/YH/0347	The role of dynamic mechanical loading on bone mineral density (v.1)	31
11/YH/0355	DALMS as an indication for colectomy	27
11/YH/0425	Biomarkers of vascular disease	43
11/YH/0426	procoagulant mechanisms of chemotherapy in multiple myeloma	39
11/YH/0431	Physiofun: Integrating virtual reality gaming in therapy programmes v1	32
11/YH/0433	Assessment of Pregnancies Exposed to ellaOne®	30
11/YH/0436	Predicting the risk of post-operative diplopia	37
11/YH/0455	PARTICIPATION IN PRENATAL SCREENING FOR DOWN'S SYNDROME. Version 1.0.	24
12/YH/0023	Everyday functioning in individuals with Type 1 Diabetes	47
12/YH/0092	PCD; Patients' & Parents' experiences of physiotherapy v1.1	11
12/YH/0094	The impact of psoriatic arthritis on income, employment, hou version 1	13
12/YH/0172	Genetics of Inflammatory Bowel Disease	17
12/YH/0173	South Asian Parents experience of their child's diagnosis of Autism 1	15

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/YH/0350	Scripted debriefing(BAT):Simulation training in neonatal emergencies	36
11/YH/0351	Scripted debriefing(CPT)for simulation training in neonatal emergency	30
11/YH/0368	Significance of danger molecules for inflammatory skin diseases	26

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/0172	Investigating CPD for dentists	29
11/YH/0282	Cellular regeneration of scaffolds	29
12/YH/0137	Qualitative Study Of The Impact Of Weight Loss Surgery On Body Image	10

Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/YH/0115	Humidified warm CO2 insufflation for laparoscopic anti-reflux surgery	36
11/YH/0161	Hypoglycaemia T2DM	30
11/YH/0167	Influence of contextual framing effects on MiniCEX score judgements	33
11/YH/0174	Involving relatives in the mental healthcare team of people with BD.	30
11/YH/0218	Therapists' experiences of therapeutic mistakes	28
11/YH/0333	Living with faecal incontinence: Ten year follow-up	22
11/YH/0428	Short Versus Standard Exam Time Breast MRI Study	24
12/YH/0014	Capillary sampling for anti-Xa assays in children on LMWH (V1)	55
12/YH/0021	Novel molecular mechanisms leading to Osteogenesis Imperfecta - V1	48
12/YH/0109	Prescribing of opioids for non-cancer pain in general practice	29
12/YH/0149	Lymphoma and myeloma: promoting early diagnosis	19
12/YH/0171	Community matron patient study. Version 1	12

Unfavourable Opinion		
REC Reference	Application Short Title	Number of Days on Clock
11/YH/0112	Brighton ROCC	41
11/YH/0114	BUDI vs GET: Effects on QoL, mood and inflammation in Crohn's disease	37

11/YH/0175	MLASS Study	30
12/YH/0033	Evaluation of pre-written consent forms for elective lap chole	30
12/YH/0135	Asgard Support Worker in Primary Care V1.0	28

Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
12/YH/0016	FlyBar	N/A
12/YH/0017	ScuBar	N/A
12/YH/0082	Total Dose of Radiation Exposure in patients receiving haemodialysis.	N/A
12/YH/0104	Metabolic Changes in CABG: Effect of Pyruvate Dehydrogenase	N/A
12/YH/0173	South Asian Parents experience of their child's diagnosis of Autism 1	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
12/YH/0057	RANKL in RA and its relationship with bone DEXA	N/A

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

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

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
12/YH/0172	Genetics of Inflammatory Bowel Disease	17
12/YH/0173	South Asian Parents experience of their child's diagnosis of Autism 1	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
11/YH/0113/AM01	Evaluation of a new blood test for lung cancer Version 1	Amend 1	37

Modified Amendments over 14 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
10/H1304/46/AM04/1	Development of a new instrument for measuring upper limb Activity	AM04 modified	19
10/H1304/46/AM09/1	Development of a new instrument for measuring upper limb Activity	modified amendment	15