

NRES Committee Yorkshire & The Humber - Leeds East

Annual Report

01 April 2011 – 31 March 2012

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee Yorkshire & The Humber - Leeds East
Type of REC:	Type iii
Type of Flag:	Phase 1 in patients, Research Involving Children, Research Tissue Banks, IRB registered
Chair:	Dr Carol Chu
Vice-Chair:	Mrs Alison Barraclough
Alternate Vice-Char:	Prof Alan Ebbutt
Co-ordinator:	Miss Jade Thorpe
PRSC Co-ordinator:	Miss Jade Thorpe
Assistant Co-ordinator:	Present – Shobhana Ningo – Temp – Feb 2012 to present
Committee Address:	Yorkshire and Humber REC Office First Floor, Millside Mill Pond Lane Meanwood Leeds LS6 4RA
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Chair's overview of the past year:

The past year has been busy but the committee has been more settled latterly back in Bexley Wing. We have been lucky to welcome new members Vicky Green, Victoria Ajayi, Deborah Fox, Tom Wilson, Emily Griffiths and Ken Brodlie. We also welcomed Elizabeth Opondo who was with us from July until November. We were also sad to say goodbye to Lynne Parker whom we thank very much for her valued input. The new members have made a huge difference to the committee meetings which have been fully quorate all year. The number of studies per meeting has reduced which allows the committee to concentrate more time on difficult studies. We have had a busy time in the subcommittee and now have meetings every two weeks. We have also started proportionate review.

There have been problems with members being able to attend enough training days and some members have found it difficult to attend meetings which has led to us changing the time of the meeting to start at 5pm. We have also greatly missed a pharmacist member but are very grateful to Jon Silcock for his help.

There have been major changes in the work of the committees but I feel that Leeds East has risen to the challenge and is looking forward to further new developments

NRES Committee Yorkshire & The Humber - Leeds East Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mrs Victoria Ajayi	Assistant Contracts Manager	Lay Plus	18/04/2011	
Mrs Alison Barraclough	Clinical Studies Officer	Lay	01/01/2005	
Professor Kenneth Brodlie	Retired Professor of Visualization	Lay Plus	13/06/2011	
Dr Carol Chu	Chair	Expert	22/11/2004	
Prof Alan Ebbutt	Statistician	Expert	31/07/2007	
Dr Deborah Jane Fox	Senior Lecturer in Nursing	Expert	01/04/2011	
Miss Vicky Green	Care Co-ordinator	Expert	18/04/2011	
Ms Emily Griffiths	Performance & Development Manager	Lay Plus	25/04/2011	
Dr Stuart Jamieson	Consultant Neurologist	Expert	31/07/2007	
Prof Sally Kinsey	Professor of Paediatric Haematology	Expert	03/02/2005	
Professor Rob Newell	Professor of Nursing Research and Director of Postgraduate Research	Expert	19/12/2007	
Miss Elizabeth Opondo	Specialist Rotational Pharmacist	Expert	11/07/2011	01/11/2011
Mrs Lynne Parker	Senior Clinical Research Associate	Lay	01/01/2010	06/09/2011
Mr Roly Squire	Consultant Paediatric Surgeon	Expert	31/07/2007	
Mr Tom Wilson	Consultant ENT Surgeon	Expert	18/04/2011	

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 - Leeds East: Members' Declarations of

Name	Declaration of Interest	Date
Dr Carol Chu	None	20/12/2011
Mrs Alison Barraclough	None	20/12/2011
Prof Alan Ebbutt	Receives a pension from GlaxoSmithKline	20/12/2011
Professor Rob Newell	Bridge - Bradford charity providing detoxification and therapy to people with substance misuse. Chair of board of trustees British Association of Psycho Therapy. Member of board of trustees. Chair - University of Bradford Research Ethics Committee	20/12/2011
Mr Roly Squire	None	20/12/2011
Prof Sally Kinsey	Trustee of Candle lighter charity (Yorkshire children's cancer charity) which funds research	20/12/2011
Dr Stuart Jamieson	York University - Intellectual interest in developing research of software for use in movement disorders. This is potentially intellectual property which could become clinically liable.	20/12/2011
Mr Tom Wilson	None	20/12/2011
Miss Vicky Green	None	20/11/2011
Ms Emily Griffiths	None	20/12/2011
Mrs Victoria Ajayi	None	20/12/2011
Dr Deborah Jane Fox	As Senior Lecturer at Leeds Metropolitan University, she is faculty representative on ethics committee and support staff in design and conduct of research	20/12/2011
Professor Kenneth Brodlie	None	20/11/2011

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

Month	Date	Number of Members Present at Meeting
May	03/05/2011	10
June	07/06/2011	12
July	05/07/2011	10
August	02/08/2011	10
September	06/09/2011	11
October	04/10/2011	10
November	01/11/2011	8
December	06/12/2011	12
February	07/02/2012	10
March	06/03/2012	10

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	24/02/2012	3

1 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 Carol Chu	10
Prof Alan Ebbutt	10
Mr Roly Squire	9
Mr Tom Wilson	8
Miss Vicky Green	8
Ms Emily Griffiths	8
Mrs Victoria Ajayi	7
Dr Deborah Jane Fox	7
Dr Stuart Jamieson	6
Mrs Alison Barraclough	6
Professor Kenneth Brodlie	6
Professor Rob Newell	6
Prof Sally Kinsey	5
Mrs Lynne Parker	4
Miss Elizabeth Opondo	3

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 Carol Chu	1
Mr Tom Wilson	1
Professor Kenneth Brodlie	1

Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Mrs Victoria Ajayi	07/07/2011 - 07/07/2011	Induction
Mrs Victoria Ajayi	08/09/2011 - 08/09/2011	NRES Qualitative Research, NRES
Dr Deborah Jane Fox	17/01/2012 - 17/01/2012	NRES Adults Lacking Capacity (including research in emergency situations)
Miss Vicky Green	07/07/2011 - 07/07/2011	NRES Members Induction Training, NRES
Mr Tom Wilson	07/07/2011 - 07/07/2011	NRES Members Induction Training, NRES
Ms Emily Griffiths	07/07/2011 - 07/07/2011	Induction, NRES
Prof Sally Kinsey	02/02/2012 - 02/02/2012	NRES Human Tissue Act training; PO5001, NRES
Ms Emily Griffiths	02/02/2012 - 02/02/2012	NRES Human Tissue Act training; PO5001, NRES
Ms Emily Griffiths	23/02/2012 - 23/02/2012	Reviewing Clinical Trials of Investigational Medicinal Products; PO1101, NRES
Dr Carol Chu	08/11/2011 - 08/11/2011	4hr talk to palliative care registrars on medico legal aspects of end of life, Self Directed Learning
Dr Carol Chu	03/03/2012 - 03/03/2012	1 hr Talk on end of life ethics. Withdrawal of clinically assisted medication.
Mrs Alison Barraclough	28/03/2012 - 28/03/2012	NRES Members National Training Day, NRES
Mr Roly Squire	28/03/2012 - 28/03/2012	NRES Members National Training Day, NRES
Prof Alan Ebbutt	28/03/2012 - 28/03/2012	NRES Members National Training Day, NRES
Professor Kenneth Brodlie	29/03/2012 - 29/03/2012	Induction, 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	23.33
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	2	3.33
Research Database	0	0.00
Others	44	73.33
Total Applications Reviewed	60	100

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	4
Number of student applications reviewed	23
Number of paediatric applications reviewed	18
Number of device applications reviewed	0
Number of prisoner applications reviewed	1
Number of applications involving adults unable consent reviewed	1
Number of applications reviewed funded by the US DHHS	3

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	4	6.67
Favourable Opinion with Additional Conditions	11	18.33
Unfavourable Opinion	0	0.00
Provisional Opinion	45	75.00
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	60	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	40	66.67
Further Information Favourable Opinion with Additional Conditions	5	8.33
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	4	6.67
Favourable Opinion with Additional Conditions	11	18.33
Unfavourable Opinion	0	0.00
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	60	100

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

Total Applications Reviewed	2
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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	2	100.00
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	0	0.00
Unfavourable Opinion	0	0.00
Total	2	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	6.00
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	28
Number of days taken to final decision - mode	22

Number of SSAs (non-Phase 1) reviewed	0
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%

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	151
Number of substantial amendments over 35 days	8
Number of substantial amendments over 35 days as a % of total substantial amendments	5.3%

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	18
Number of modified amendments over 14 days	1
Number of modified amendments over 14 days as a % of total modified amendments	5.6%

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/0036	Empowering adolescent patients in undergraduate education	50
11/YH/0133	Develop-Scoring system-management-severe-L A Toxicity-Human simulator	38
11/YH/0138	Stem cell Trial of recovery EnhanceMent after Stroke 3 (STEMS 3)	48
11/YH/0177	Participation in leisure: perspectives of children with disabilities	26
11/YH/0181	A study of occupation-based practice	35
11/YH/0191	Dental Anxiety amongst Paediatric Cardiology patients V2	31
11/YH/0203	Millennium Cohort Study Fifth Sweep - Dress Rehearsal and Main Survey	35
11/YH/0240	Effects of thoracic epidurals on SMA flow	32
11/YH/0241	Effects of thoracic epidurals on IMA flow.	32
11/YH/0247	Memory Processes and Post Traumatic Stress Disorder(PTSD)after Stroke	36
11/YH/0248	Bone Mineral Density: A Sub-study of START	25
11/YH/0254	Expectations of families attending a specialist obesity clinic	25
11/YH/0258	DNA bank for genetic studies in idiopathic focal dystonia	26
11/YH/0260	COSMIC Version 1.0	28
11/YH/0290	STOMP: SCLC Trial of Olaparib (AZD2281) as Maintenance Programme.	23
11/YH/0292	Replacing spine radiographs with DXA V1	26
11/YH/0296	Fungal contamination of nebulisers	25
11/YH/0312	Young fathers experiences of fatherhood version 2	56
11/YH/0319	Fanconi and related DNA repair pathways in brain tumours	22
11/YH/0327	Complement C3 in Diabetes	25
11/YH/0336	OBI-1-302 Congenital Haemophilia A Study	22
11/YH/0337	Phase IB Study to Evaluate Safety and Pharmacokinetics of MOR103 in MS	27
11/YH/0343	Hepatitis C Rimantadine + Antiviral Combination Therapy -HepRIACT v2.0	28
11/YH/0344	Views of patients and carers when heart failure becomes more severe	24
11/YH/0363	ELSSI	52
11/YH/0373	A study of selumetinib in patients with Kaposi's sarcoma	31
11/YH/0374	Exploring individual experiences of preparedness for bariatric surgery	26
11/YH/0375	Phase 2 Open-label study of BMN 110 in patients < 5 years old. v1	29
11/YH/0376	High volume saline injections for achilles tendinopathy.	27
11/YH/0380	Body weight and bone in children and adults	26
11/YH/0399	Investigating the clinical and laboratory aspects of tooth whitening	25

11/YH/0401	Gemcitabine in combination with LDE225 in pancreatic adenocarcinoma	22
11/YH/0404	RCT of Open Stabilisation versus TPS	22
11/YH/0432	Shoulder feasibility study	22
11/YH/0440	Study of Solifenacin Suspension in children with Overactive Bladder	25
11/YH/0441	Piloting & Feasibility of New Interventions for Young People with T1DM	22
12/YH/0076	The effect of hearing impairment on the useful field of view test (v1)	18
12/YH/0086	IMPROVE-PC LTHT Trial	27
12/YH/0111	UCL Eastman Biobank	28
12/YH/0126	MOR-008 Safety & Effects of BMN110 in Patients with Morquio A Syndrome	20

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/YH/0122	Investigating the Faith Centre at St James's Hospital (Version 1)	23
11/YH/0144	Phase 3b Trial of ATV Powder boosted with RTV in HIV-infected children	27
11/YH/0145	Study of IB1001 in paediatric patients with Haemophilia B	45
11/YH/0226	Involving fathers in ante-natal screening (Version 1).	56
11/YH/0429	LIA Hip Study	29

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
11/YH/0159	eRAPID cognitive interview study	52
11/YH/0183	Magnetic Resonance Imaging Biomarkers of Ataxia	15
11/YH/0287	Magnetoencephalography appearances in breathless patients Version 1	22
12/YH/0063	CoDIR: Human tissue 1.0	17

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/YH/0129	experience of the transition process from male to female	32
11/YH/0134	Impact of enteral tube feeding on CF Version 1	20
11/YH/0189	Young Mothers' Experiences of Relationship Abuse	29
11/YH/0294	Understanding of alcohol unit among trainee doctors in Yorkshire	17

11/YH/0340	ASSSIST	20
11/YH/0367	Investigations of therapeutic products on protection of enamel surface	24
11/YH/0395	Liver Fibrosis Progression: A Sub-study of START	21
12/YH/0040	Voices & dissociation in early psychosis: A case-control study v.1	17
12/YH/0077	Use of the NCDR to assess the processes & outcomes of cervical cancer	21
12/YH/0117	Plantar Plate Histology in Rheumatoid Arthritis Version 1	17
12/YH/0118	Mechanical factors that may contribute to toe dactylitis in PsA	17
12/YH/0121	Piloting the 'CALF' Medicines Survey questionnaires	8
12/YH/0122	Educating young people to make decisions about biologics (V1)	9

Unfavourable Opinion

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

REC Reference	Application Short Title	Number of Days on Clock
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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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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	
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
10/H1306/5/AM03	Study of BPL's FX in FX deficient patients requiring surgery Version 1	sub amend - changes to protocol	44
10/H1306/43/AM03	Effects of sleep deprivation in pregnancy	sub amend - extend proj into postnatal period	38
09/H1306/83/AM11	Optimisation of Hydromorphone Naloxone Ratio for the treatment of pain	sub amend- include poster	43
10/H1306/29/AM01	The Use of Lugol's Iodine in Surgery for Oral/Oropharyngeal Carcinoma	sub amend - change to dataset	37
10/H1306/62/AM03	Safety of Long Term Dosing of Romiplostim in MDS subjects	sub amend change of investigator	36
09/H1306/78/AM07	Phase I in Leukaemia/Lymphoma Patients NO21279 version E	changes to protocol, PIS, BSR PIS, + medication di	36
10/H1306/87/AM07	Safety and efficacy of BMN110 in patients with Morquio A syndrome	changes to PIS + Informed Consent Form	40

10/H1306/15/AM08	NEAT 001	sub amend new ci	201
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Modified Amendments over 14 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
10/H1306/34/AM10/1	Phase Ib/II E7080 Stage IV Melanoma	mod amend - change to pis	15

Section 30 application over 60 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock