

**NRES Committee North West -
Haydock**

Annual Report

01 April 2013 – 31 March 2014

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee North West - Haydock
Type of REC:	Recognised Type III
Type of Flag:	CTIMP, ALC, RTB, RD, Phase 1 in Patients
Chair:	Professor Ravi S Gulati
Vice-Chair:	Dr Tim S Sprosen
Alternate Vice-Chair:	Dr Valerie Siddall
REC Manager:	Rinat Jibli
PRSC Manager:	Rinat Jibli
REC Assistant:	Jo Foxall Dant (April – October 2013), Rachel Katzenellenbogen (October 2013 to present)
Committee Address:	HRA NRES Centre - Manchester 3rd Floor - Barlow House 4 Minshull Street Manchester M1 3DZ
Telephone:	0161 625 7819/7827
Fax:	0161 237 9427
Email:	nrescommittee.northwest-haydock@nhs.net

Chair's overview of the past year:

We welcome Moyra Baldwin and Jillian McCarthy to our committee and as far as I can gather they are enjoying and settling well in their roles. They are certainly valuable members of the Committee who bring with them different experiences.

All members old and new are working well together and due to diversity in their work and experience they all bring different dimension in ethical debate. I am grateful to them all. Our Vice Chair Tim Sprosen is settling well in his job in Oxford University. He is now Associate Professor and heads Innovation, Regulation & Knowledge transfer and his current role is helpful to the Committee in many ways. Like last year, this year Tim provided training to us in Risk & Benefits of Research which was well received by members. Linda Ashcroft continues to provide extra support on statistical issues on all projects and we are very grateful to her for this.

Our REC Manager - Rinat Jibli - is providing good support, and is currently on maternity leave nurturing her baby girl. We all wish her well. We welcome Rachel Katzenellenbogen, who initially helped Rinat, but who is currently managing the Committee. We thank her for all her support.

We seem to be maintaining our work load efficiently which is acknowledged by the NRES. We continue to do more proportionate review (PR), and we have re-organised ourselves to have PR and Substantial amendments meeting prior to main meeting which seems to be working well. Like last year we have not encountered any major issues with PR.

I would like to end by formally thanking current and previous Members for their dedication to the work of the REC and welcome new members and Rachel.

NRES Committee North West - Haydock Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mrs Linda Ashcroft	Senior Statistician	Expert	10/12/2010	
Mrs Moyra Ann Baldwin	Retired Senior Lecturer - Oncology	Expert	07/11/2013	
Mr Stephen Edgar	Designer	Lay Plus	13/11/2009	
Dr Michael U Eshiett	Consultant Physician in Neurological Rehabilitation	Expert	23/09/2009	
Professor Ravi S Gulati	Consultant Physician	Expert	20/12/2006	
Ms Pat Harvey	Hospital Chaplain	Lay Plus	20/08/2010	
Mrs Chris Haywood	Nurse & Head of Hospice Services	Expert	20/08/2010	
Dr Ben Johnson	Consultant Psychiatrist	Expert	20/08/2010	
Dr Ezzat Kozman	Consultant Gynaecologist	Expert	01/05/2013	
Dr Simon Marwood	Senior Lecturer in Physiology	Expert	25/08/2011	29/10/2013
Dr Jillian McCarthy	Senior Lecturer in Health Management	Expert	01/05/2013	
Mr Charles Otim	Research Support Officer	Lay Plus	21/09/2010	
Dr David Pilling	Consultant Radiologist	Expert	10/12/2010	
Dr Valerie E Siddall	Retired Senior Manager - Pharmaceutical Industry	Lay Plus	05/11/2009	
Dr Tim S Sprosen	Epidemiologist	Expert	07/12/2006	
Mr Peter Ward	Lay Member	Lay Plus	01/05/2013	

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended

NRES Committee North West - Haydock: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Ms Pat Harvey	None	22/05/2013
Mr Stephen Edgar	Member of Northwest Research Patient Benefit Programme. Member of i4i programme. Member of Northwest People in Research Forum.	22/05/2013
Mr Charles Otim	None	22/05/2013
Mrs Chris Haywood	Key organisational representative member/vice chair: IRIS. Integrated Research Committee for St Helens & Knowsley Specialist Palliative Care of Hospice, Community and Hospital Services. Member of PRiMa: Palliative Care Research in Manchester.	22/05/2013
Dr Michael U Eshiett	None	22/05/2013
Dr David Pilling	None	22/05/2013
Dr Valerie E Siddall	Volunteer speaker for Macmillan Cancer Support. Former employee of AstraZeneca.	22/05/2013
Mr Peter Ward	Daughter and Son-in-Law work in Pharmaceutical Industry.	22/05/2013
Dr Ben Johnson	None	10/05/2013
Dr Tim S Sprosen	1) Employed by the Clinical Trial Service Unit, University of Oxford who conduct a number of large RCTs and observational studies.2) Member of UK Biobank Steering Committee	09/05/2013
Professor Ravi S Gulati	None	08/05/2013
Dr Ezzat Kozman	None	02/09/2013
Dr Jillian McCarthy	Husband is the commercial director for BMI Healthcare Group	30/10/2013
Mrs Linda Ashcroft	Employee of Christie Hospital R&D Clinical Trials Coordination Unit.	01/11/2013
Mrs Moyra Ann Baldwin	None	25/11/2013

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

Month	Date	Number of Members Present at Meeting
April	09/04/2013	10
May	14/05/2013	10
June	11/06/2013	9
July	09/07/2013	9
August	13/08/2013	9
September	10/09/2013	10
October	08/10/2013	12
November	12/11/2013	8
December	10/12/2013	8
February	11/02/2014	11
March	11/03/2014	11

11 full committee meetings were held during the reporting period.

Proportionate Review Sub Committee Meetings held during 01 April 2013 - 31 March 2014:

Month	Date	Number of Members Present at Meeting
April	10/04/2013	3
May	03/05/2013	3
May	07/05/2013	3
June	12/06/2013	3
August	13/08/2013	3
September	11/09/2013	3
January	10/01/2014	3
February	12/02/2014	3
March	12/03/2014	3

9 proportionate review sub-committee meetings were held during the reporting period.

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

Name	Number of Meetings Attended
Mr Stephen Edgar	11
Professor Ravi S Gulati	11
Mrs Chris Haywood	10
Mrs Linda Ashcroft	10
Dr Michael U Eshiett	10
Dr Tim S Sprosen	9
Dr Valerie E Siddall	9
Dr Ezzat Kozman	8
Dr David Pilling	7
Mr Charles Otim	7
Mr Peter Ward	7
Ms Pat Harvey	7
Dr Ben Johnson	5
Dr Jillian McCarthy	5
Mrs Moyra Ann Baldwin	3

Number of inquorate meetings held: 0

**Attendance of Members at proportionate review sub-committee meetings:
01 April 2013 – 31 March 2014:**

Name	Number of Meetings Attended
Professor Ravi S Gulati	9
Dr Tim S Sprosen	8
Mr Stephen Edgar	4
Mrs Chris Haywood	3
Dr Valerie E Siddall	3

Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Dr Michael U Eshiett	10/09/2013 - 10/09/2013	Training for New REC Chairs, HRA
Mrs Chris Haywood	09/04/2013 - 09/04/2013	Equality & Diversity, Core learning
Dr Ezzat Kozman	16/01/2014 - 16/01/2014	Research involving adults who lack capacity (including emergency situations), HRA
Mrs Moyra Ann Baldwin	05/03/2014 - 05/03/2014	Induction
Mr Peter Ward	12/03/2014 - 12/03/2014	Improving Informed Consent

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	21	38.88
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	5	9.25
Research Database	5	9.25
Others	23	42.62
Total Applications Reviewed	54	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	10
Number of paediatric applications reviewed	4
Number of device applications reviewed	0
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	12
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	5	9.25
Favourable Opinion with Additional Conditions	10	18.51
Unfavourable Opinion	3	5.55
Provisional Opinion	36	66.69
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	54	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	34	62.96
Further Information Favourable Opinion with Additional Conditions	1	1.85
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	5	9.25
Favourable Opinion with Additional Conditions	10	18.51
Unfavourable Opinion	3	5.58
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	1	1.85
Total	54	100

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

Total Applications Reviewed	16
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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	15	93.75
Favourable Opinion with Additional Conditions	0	0.00
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	1	6.25
Unfavourable Opinion	0	0.00
Total	16	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.94
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	31
Number of days taken to final decision - mode	27

Number of SSAs (non-Phase 1) reviewed	12
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	147
Number of substantial amendments over 35 days	0
Number of substantial amendments over 35 days as a % of total substantial amendments	0.0%
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	3
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	6.3%

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
13/NW/0159	Neonatal Database Analysis v 1	40
13/NW/0215	PEARL-PRAME as Adjuvant Immunotherapy in Resected NSCLC	39
13/NW/0319	Registry biomarker study in RASopathy patients	24
13/NW/0326	Vacuum-assisted and conventional core biopsy of axillary lymph nodes	24
13/NW/0347	Phase 1/2 study of Azacitabine in subjects with AML / MDS after HSCT	28
13/NW/0353	CONTACT v1.0	26
13/NW/0464	Pharmacokinetic and Pharmacodynamic Trial of IDN-6556 in ACLF	33
13/NW/0502	Assessment of fampridine-PR in NMO	34
13/NW/0503	PICME II	30
13/NW/0550	Cultural Activities for Social Participation in Mental Health Care v1	31
13/NW/0560	H8A-MC-LZAX: Progression of Mild Alzheimer's Disease	45
13/NW/0563	Exercise Testing	35
13/NW/0569	S-1 Combination Therapy in Esophagogastric Cancer Patients	46
13/NW/0588	Airwave Health Monitoring Study Tissue Bank	41
13/NW/0634	GSK2256098 + Trametinib dose escalation study	51
13/NW/0637	Phase 2/3 study of nab-paclitaxel in metastatic breast cancer	38
13/NW/0639	Caring for a dying person at home - the carer's experience	27
13/NW/0697	PiSARRO	39
13/NW/0705	Regorafenib as adjuvant therapy for resected liver metastases	29
13/NW/0718	Targeted Ultrasound in Rheumatoid Arthritis (TURA)	32
13/NW/0733	Evaluation of Homeopathy as an adjunctive treatment for RA Patients	41
13/NW/0760	Cohort study of Intensive Community Support and Community Hospital.	29
13/NW/0821	3M-BRiHT (v.1)	36
13/NW/0841	SPD602 Ph2 Study to assess Liver Iron Concentration	34
13/NW/0842	FAKTION	31
14/NW/0036	ESPAC-5F: European Study Group for Pancreatic Cancer - Trial 5F	35
14/NW/0054	A study of decision-making in care homes	47
14/NW/0056	Progestins for endometrial hyperplasia and cancer	30
14/NW/0065	ROP Phase-II	32

14/NW/0068	Registry of Bronchial Thermoplasty (BT) Version 4.2	32
14/NW/0090	An ethnographic study of tacit knowledge in dementia services	27
14/NW/0096	Fibromyalgia patients' perceptions of treatment outcomes	10
14/NW/0119	Study of PL37 in Peripheral Neuropathic Pain of Diabetic Origin	31
14/NW/0132	Scleroderma and Raynaud's Research Bank	42
14/NW/0139	EPOCH phase 2 qualitative evaluation	42

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/NW/0205	Early Pregnancy Tissue Collection- (08/H1010/28+5)	27

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
08/H1010/55+5	Maternal and Fetal Health Research Centre Biobank	23
09/H1010/2+5	Vascular Governance North West Database (VGNW)	27
13/NW/0286	Attitudes to sharing personal data with the public sector	26
13/NW/0388	Pre-operative anxiety survey of patients having orthopaedic surgery	5
13/NW/0389	Validation of EORTC Questionnaire for Assessment of Cancer Fatigue	4
13/NW/0393	Illness Perception in Idiopathic Pulmonary Fibrosis	1
13/NW/0473	Retrospective 3yr analysis of High Risk Preterm Labour Clinic Patients	4
13/NW/0590	REGARD Study Phase 2	28
13/NW/0614	Risk stratification of children with transient loss of consciousness	6
13/NW/0616	Measuring Visual Disability due to Cataract - V2	7
13/NW/0682	Exploring help-seeking processes for young people who self-harm.	6
13/NW/0702	ABC06: ASC alone or with mFOLFOX for advanced biliary tract cancer	22
13/NW/0844	Transcranial Direct Current Stimulation: Impact on therapy for aphasia	24
14/NW/0025	Influences on Anaesthetic Choice in Cataract Surgery 1.0	11
14/NW/0026	Piloting new approaches: Adult Inpatients Survey Pilot 2014	8
14/NW/0029	Attitudes to mental illness in patients with chronic fatigue syndrome	7
14/NW/0092	RCT assessing intraoperative patient experience in cataract surgery.V1	12

14/NW/0163	Optimising Numeric Pain Rating Scale Administration for Children	9
14/NW/0164	Swallowing comparison following treatment for oropharyngeal cancer	7
14/NW/0166	Incidence of visual impairment after stroke	9

Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
13/NW/0363	Open-label study of long-term evaluation of AMG145 against LDL	23
13/NW/0387	Balancing benefits and risks with multiple medicines	43
13/NW/0418	Human Intervertebral Disc Tissue Bank	23
13/NW/0451	RaDAR: Research Database of Ambulatory Acoustic Recordings	27
13/NW/0519	MDT project	27
13/NW/0641	Selumetinib or Placebo + Docetaxel for KRAS positive NSCLC	28
13/NW/0715	GARMIn: The Role of GABAB Receptor Mechanisms in Cough.	18
13/NW/0737	NGAL in the ED	22
13/NW/0752	Technology in care homes project (version 1.3)	22
14/NW/0147	Aintree Trauma Research Database	31

Unfavourable Opinion		
REC Reference	Application Short Title	Number of Days on Clock
13/NW/0481	Caring for a dying person at home - the carer's experience.	27
13/NW/0491	Evaluation of Intensive Community Support versus Community Hospitals	34
14/NW/0149	Can a calculator improve renal replacement therapy?	26

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

13/NW/0224	Study of Insulin Secretion in Prediabetic Volunteers	22
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Invalid Application		
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REC Reference	Application Short Title	Number of Days on Clock
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No Opinion Pending Consultation with Referee		
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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	
13/NW/0286	Attitudes to sharing personal data with the public sector	26	
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
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