

NRES Committee North West - Haydock

Annual Report

01 April 2011 – 31 March 2012

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
Co-ordinator:	Mr Noel Graham
Assistant Co-ordinator:	Miss. Helen Penistone to February 2012 Miss Josephine Foxall Dant from March 2012
Committee Address:	Health Research Authority NRES North West Centre 3rd Floor - Barlow House 4 Minshull Street Manchester M1 3DZ
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Chair's overview of the past year:

I have been in Chair since October 2010 and the past year seems to have gone very quickly. The Committee has seen several changes in membership and we have welcomed two new members; Sandie Reilly and Simon Marwood and appreciate their input in discussion. It was sad to see one of our two statisticians, Alan Rigby, leave the committee in February after finishing 2 terms of office. Alan was literally a part of furniture sitting next to researchers at the meeting and giving them useful advice and help in designing their studies and he was equally helpful in giving his opinion on all aspects of the ethical review process. Alan will be sadly missed, and currently Linda Ashcroft is providing extra support to the Committee on statistical issues.

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. The Vice chair - Tim Sprosen - has changed jobs and moved to Imperial College London and partly abroad to sunny Qatar. We still manage to communicate with him with the modern (may be not so modern) technology of e-mails. Tim provides good overview on data and biobank issues. He also provides training for NRES (HRA) on these issues. We will also be asking him to provide training for the Committee in this area in the near future.

The Co-ordinator - Noel Graham – in addition to his work with the Committee provided additional support to the North West Centre prior to the appointment of the new Centre Manager. We also noted that the Assistant Co-ordinator - Helen Penistone - has moved on to manage another Committee and we appreciate her efforts in ensuring smooth running of the REC. Noel has been provided with additional administrative support following Helen's departure.

After seeing an increase in work load last year, we have noted a drop in research applications. We are being reminded that it is a national trend, which is partly due to introduction of proportionate review (PR). This may be a blessing in disguise for the time being as in the past the Committee has had a very heavy workload.

Finally, I would like to end by formally thanking current and previous Members for their dedication to the work of the REC.

NRES Committee North West - Haydock Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mrs Linda Ashcroft	Senior Statistician	Expert	10/12/2010	
Dr Caroline Carlisle	Research Nurse	Expert	03/03/2008	
Mr Stephen Edgar	Designer	Lay Plus	13/11/2009	
Dr Michael U Eshiett	Consultant Physician	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 and Head of Hospice Service	Expert	20/08/2010	
Dr Ben Johnson	Consultant Psychiatrist	Expert	20/08/2010	
Dr Simon Marwood	Senior Lecturer in Physiology	Expert	25/08/2011	
Mr Charles Otim	Research Support Officer	Lay Plus	21/09/2010	
Dr David Pilling	Consultant Radiologist	Expert	10/12/2010	
Mrs Sandra Reilly	Headteacher - retired	Lay Plus	13/10/2011	
Mr Alan Rigby	Medical Statistician	Expert	01/04/2002	
Dr Valerie E Siddall	Retired Senior Manager - Pharmaceutical Industry	Lay Plus	05/11/2009	
Dr Tim S Sprosen	Chief Scientific Officer	Expert	07/12/2006	

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Mr James Burns	Retired Lay Member	Lay	06/09/2011

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

Name	Declaration of Interest	Date
Dr Simon Marwood	Declared that he is a researcher himself so he is likely to submit an IRAS application for ethical review. At this time he will submit to a different REC.	07/11/2011
Mr Alan Rigby	A member of the NICE Committee on Health Technology Appraisal. Some consultancy work for pharmaceutical companies. Reviewer for a number of medical journals; The Lancet, Disability & Rehabilitation. Reviewer for HTA, reviewer for medical charities.	12/12/2011
Dr David Pilling	None	13/12/2011
Professor Ravi S Gulati	None	12/12/2011
Dr Caroline Carlisle	Volunteer with Breast Cancer Care.	13/12/2011
Mrs Linda Ashcroft	None	13/12/2011
Mrs Chris Haywood	None	13/12/2011
Mrs Sandra Reilly	None	13/12/2011
Dr Valerie E Siddall	Small shareholder in AstraZeneca Plc. Speaker for Macmillan Cancer Care, former employee of AstraZeneca Plc.	13/12/2011
Ms Pat Harvey	None	13/12/2011
Dr Michael U Eshiett	None	02/09/2011
Dr Ben Johnson	None	03/01/2012
Mr Charles Otim	None	13/12/2011
Mr Stephen Edgar	Lay member PPI at Liverpool Biomedical Research Centre. Peer review proposals for research benefit patients programme.	13/12/2011
Dr Tim S Sprosen	Consultancy with Imperial College London; consultants for Biobank Qatar. Member of Steering Committee & Co-Chair of Follow-up Working Group for UK Biobank.	10/08/2011

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

Month	Date	Number of Members Present at Meeting
April	12/04/2011	12
May	10/05/2011	10
June	14/06/2011	12
July	12/07/2011	10
August	09/08/2011	9
September	06/09/2011	8
October	11/10/2011	11
December	13/12/2011	12
February	14/02/2012	12
March	13/03/2012	11

10 full committee meetings were held during the reporting period.

Attendance of Members: 01 April 2011 – 31 March 2012:

Name	Number of Meetings Attended
Mr Charles Otim	10
Mr Stephen Edgar	9
Mrs Chris Haywood	9
Professor Ravi S Gulati	9
Dr Caroline Carlisle	8
Dr Michael U Eshiett	8
Ms Pat Harvey	8
Dr Ben Johnson	7
Dr Valerie E Siddall	7
Mr Alan Rigby	7
Mrs Linda Ashcroft	7
Dr David Pilling	7
Dr Tim S Sprosen	5
¹ Dr Simon Marwood	1 out of 3
Mrs Sandra Reilly	3 out of 3*

All Members attendances were out of a possible 10 meetings unless stated above where Members were appointed part way through the reporting period

Number of inquorate meetings held: 0

Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Dr Caroline Carlisle	22/09/2011 - 22/09/2011	NRES Informed Consent and Explaining Risk in Randomised Trials training, NRES
Dr Valerie E Siddall	08/09/2011 - 08/09/2011	NRES Qualitative Research and Ethical Review training, NRES
Dr David Pilling	22/10/2011 - 22/10/2011	Equality & Diversity, NRES
Professor Ravi S Gulati	28/06/2011 - 28/06/2011	NRES Statistics training, NRES
Mr Charles Otim	29/11/2011 - 29/11/2011	NRES Research Involving Adolescents , NRES
Mrs Sandra Reilly	22/02/2012 - 22/02/2012	Induction, NRES
Mrs Chris Haywood	23/02/2012 - 23/02/2012	Reviewing Clinical Trials of Investigational Medicinal Products, NRES
Dr David Pilling	29/03/2012 - 29/03/2012	Induction, NRES
Mrs Linda Ashcroft	26/01/2012 - 26/01/2012	Medical Devices Training, NRES
Mr Alan Rigby	27/09/2011 - 27/09/2011	NRES Update Session , 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	21	33.33
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	6	9.52
Research Database	10	15.87
Others	26	41.27
Total Applications Reviewed	63	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	3
Number of student applications reviewed	16
Number of paediatric applications reviewed	3
Number of device applications reviewed	0
² Number of prisoner applications reviewed	1
Number of applications involving adults unable consent reviewed	5
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	8	12.70
Favourable Opinion with Additional Conditions	3	4.76
Unfavourable Opinion	8	12.70
Provisional Opinion	44	69.84
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	63	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	37	58.73
Further Information Favourable Opinion with Additional Conditions	3	4.76
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	8	12.70
Favourable Opinion with Additional Conditions	3	4.76
Unfavourable Opinion	8	12.70
Provisional Opinion	4	6.35
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	63	100

Table 5: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	6.30
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	131
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	6
Number of modified amendments over 14 days	0
Number of modified amendments over 14 days as a % of total modified amendments	0.0%

Table 6: 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/NW/0145	Genetic Polymorphisms of Late Radiotoxocity in Head and Neck Cancer	48
11/NW/0154	Behavioural Symptoms in Early and Late onset dementia Version 1.1	28
11/NW/0187	Advanced Stent-Graft Techniques for Aneurysm Repair	43
11/NW/0221	Unplanned care for minor illness	27
11/NW/0249	Ocular Oncology Biobank	31
11/NW/0266	Is the AP competence based model of assessment fit for purpose	35
11/NW/0267	Stage II of an audit of an antenatal mental health clinic	29
11/NW/0271	Colorectal cancer database	47
11/NW/0279	HLA Antibodies and correlation with graft function in Renal Transplant	27
11/NW/0292	Safety and Efficacy Study of ESBA1008 versus LUCENTIS®	45
11/NW/0298	Phase III GA101 or rituximab plus chemo in 1st line indolent NHL	28
11/NW/0339	Evaluation of the new "Fit Note":construction of national database V1	22
11/NW/0347	Liverpool PBRU Control Patient Biobank	23
11/NW/0348	Liverpool PBRU Volunteer Ethics	25
11/NW/0351	Physical activity in patients with inoperable lung cancer vs1	32
11/NW/0369	ALSPAC Focus on Fathers	39
11/NW/0442	Metformin in non-diabetic women with endometrial cancer	25
11/NW/0443	PACE	31
11/NW/0455	Feasibility of a Circuit-class Exercise Programme after Stroke	32
11/NW/0457	The effects of Mindfulness-based cognitive therapy on relationships v1	27
11/NW/0472	A Phase III, open-label multicentre trial in late stage NSCLC patients	30
11/NW/0500	Pharmacogenomic signatures of treatment response in psoriasis.	24
11/NW/0508	Bronchial allergen challenge study to investigate allergic response	34
11/NW/0548	RIAltO version 3	31
11/NW/0551	VALUeD, version 1.0	32
11/NW/0582	Effect of implant position on magnetic resonance image distortion	34
11/NW/0591	Study of ADC3680B in patients with mild to moderate asthma	22
11/NW/0597	PHI/II Study MLN9708 with Melphalan & Prednisone in Multiple Myeloma	30
11/NW/0606	Phase 1 Dose Escalation Study of Dexanabinol in Advanced Cancer	22
11/NW/0614	Homicide by patients with schizophrenia: a case-control study	22

11/NW/0676	ACLIDINIUM BROMIDE vs placebo in patients with COPD	26
11/NW/0683	Plastic and Reconstructive Surgery Research Skin and Tissue Bank	23
11/NW/0690	Bardoxolone Methyl Evaluation in Patients with Chronic Kidney Disease	53
12/NW/0119	rhLAMAN-04	20
12/NW/0123	Proteomics analyses in obstructive sleep apnoea with obesity	23
12/NW/0196	The variability of endometrial cancer biomarkers over time	27
12/NW/0202	Primary culture cancer tissue bank - to contain ascitic fluid, pleural	21

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/NW/0489	WA21093-Phase III Ocrelizumab Vs Rebif in Relapsing Multiple Sclerosis	31
11/NW/0490	WA21092-Phase III Ocrelizumab Vs Rebif in Relapsing Multiple Sclerosis	31
11/NW/0523	Investigating Patients For Paroxysmal Atrial Fibrillation In Stroke	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/NW/0259	UK validation of the Thoracoscore and ESOS risk scoring systems	32
11/NW/0382	UK Biobank: a large scale prospective epidemiological resource of 500,	16
11/NW/0605	The influence of ivabradine on the symptoms of neuropathic pain IISNeP	21
11/NW/0607	Chemotherapy- related Neurotoxicity	29
11/NW/0832	The Health and Occupation Research Network	33
11/NW/0840	Memantine: Pilot Study of Memantine in chronic cough patients	21
11/NW/0866	STH Respiratory Medicine Research Database	22
12/NW/0134	Study of a new medicine for children who bruise and bleed easily	17

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/NW/0480	ASTUTE - Acute Stroke Telemedicine: Utility, Training & Evaluation	18
11/NW/0835	E7050-702 Phase Ib/II study of E7050 Carcinoma Head and Neck	21
11/NW/0868	Long-Term Efficacy & Safety of CT-P13 in Rheumatoid Arthritis patients	22

Unfavourable Opinion		
REC Reference	Application Short Title	Number of Days on Clock
11/NW/0150	Paroxysmal AF after Stroke.	28
11/NW/0331	ASTUTE - Acute Stroke Telemedicine: Utility, Training & Evaluation	23
11/NW/0365	Prostate Diagnostic Database	23
11/NW/0430	Effect of beta-blockade on cardiorespiratory performance	27
11/NW/0447	A comprehensive evaluation of new HIV diagnoses	24
11/NW/0513	Improving the evidence base for oral assessment in stroke patients.	30
11/NW/0705	Sheffield Community and Hospital COPD Patient Cohort Database v1.0	19
12/NW/0195	Cerner Health Facts	22

Provisional Opinion		
REC Reference	Application Short Title	Number of Days on Clock
12/NW/0120	Nottingham Chondrocalcinosis Collection	N/A
12/NW/0125	Investigation of the role of alcohol metabolism in pancreatitis	N/A
12/NW/0138	The health & social care needs of people with dementia; 18m follow up	N/A
12/NW/0162	Window Trial of AZD8931 in resectable non-small cell lung cancer	N/A

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 7: Items exceeding timelines:

Full applications for ethical review over 60 day 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
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