

National Research Ethics  
Service

  
*Health Research Authority*

# NRES Committee East of England - Hatfield

## Annual Report

**01 April 2013 – 31 March 2014**

## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	NRES Committee East of England - Hatfield
<b>Type of REC:</b>	Recognised
<b>Type of Flag:</b>	Phase 1 in Health Volunteers Phase 1 in Patients
<b>Chair:</b>	Professor Barry Hunt
<b>Vice-Chair:</b>	Dr Ian Skidmore
<b>Alternate Vice-Chair:</b>	Mr David Grayson
<b>REC Manager:</b>	Miss Kathryn Murray (03/02/2014 onwards) Miss Sarah Grimshaw (01/04/2013 – 02/02/2014)
<b>REC Assistant:</b>	Mrs Sally Dunn (03/02/2014 onwards) Miss Christie Ord (07/10/2013 – 02/02/2014) Miss Kerry Dunbar (01/04/2013 – 06/10/2013)
<b>Committee Address:</b>	Room 002, TEDCO Business Centre Rolling Mill Road Jarrow Tyne and Wear NE32 3DT
<b>Telephone:</b>	0191 4283564
<b>Email:</b>	nrescommittee.eastofengland-hatfield@nhs.net

## Chair's overview of the past year:

The newly established NRES Committee East of England – Hatfield was formed through the merger of the Hertfordshire and Welwyn Committees and met for the first time on 10<sup>th</sup> April 2013. The membership of this new committee derived almost equally from the two merged committees. From April 2013 through to March 2014 the Committee reviewed 38 applications and met on 10 occasions.

Of the applications reviewed less than 15% were of the Phase 1 type; this statistic contrasts markedly with the activity of the Welwyn Committee in the previous year where the corresponding figure approached 50%. Even though the Hertfordshire Committee had not been recognized for Phase 1 review there was a feeling among the membership that the expertise in Phase 1 could be further utilized in the future. As part of the development of the Committee's review portfolio a proportionate review sub-committee was established and met 8 times from July 2013. This substantially built upon the expertise within the Hatfield Committee and 19 applications were reviewed in this way. Additionally individual members attended relevant meetings organised by NRES.

For two meetings it proved necessary to co-opt a lay member to ensure the appropriate number of attendees and the Committee was grateful of the support of colleagues from other committees. As a result of interviews held a new member was appointed to the committee in December. The Committee was sorry that three members resigned within the year and thanks those individuals for their important contributions. Additionally within the year there were changes in the NRES management support. While such personnel changes are unsettling the Committee always felt well supported by each of the individual REC managers and their Assistants.

## NRES Committee East of England - Hatfield Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr Roger Aubrey	Retired medical doctor	Expert	01/04/2013	
Professor Anwar Baydoun	Pharmacologist	Expert	01/04/2013	
Mr Michael Buck	Retired Solicitor & Chartered Arbitrator	Lay Plus	01/04/2013	23/01/2014
Mrs Elspeth Coult	Registered Nurse	Expert	01/04/2013	
Professor Soraya Dhillon	Pharmacologist	Expert	01/04/2013	31/03/2014
Mr David Grayson	Retired Local Government Administrator	Lay Plus	01/04/2013	16/01/2014
Professor Barry Hunt	Pro-Vice Chancellor (International) (Retired)	Expert	01/04/2013	
Dr Wassim Matta	General Practitioner	Expert	01/04/2013	
Mrs Barbara Newman	Retired Compliance and Training Advisor (Clinical Pharmacology)	Lay	01/04/2013	
Dr Gordon Nichols	Business Manager	Lay Plus	01/04/2013	31/12/2013
Dr Patricia Scott	Senior Lecturer DHRes	Expert	22/10/2013	
Dr Ian Skidmore	Retired Company Director	Lay Plus	01/04/2013	
Ms Melanie Whittick	Pharmacist	Expert	01/04/2013	

### Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Dr Elizabeth Lund	Principal Research Scientist	Lay	12/06/2013
Ms Julie Lockhart	PPI Representative	Lay Plus	11/09/2013
Dr C E Chu	Clinical Geneticist and Medicolegal Advisor	Expert	30/10/2013 (PR)

## NRES Committee East of England - Hatfield: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Professor Barry Hunt	Truster and scientific advisor to ATAXIA UK. Chair of ethics committee of University of Hertfordshire. Research Supervisor.	10/04/2013
Dr Ian Skidmore	Small shareholding in GSK. Board member of medical research Council technology - a charity.	10/04/2013
Ms Melanie Whittick	Shares in GSK, held since working for Glaxo Group Research in previous role.	10/04/2013
Dr Wassim Matta	None Noted	10/04/2013
Mr Michael Buck	Studying for a PhD (long distance) in Federal Government at Hull University involving research methods.	10/04/2013
Mrs Elspeth Coult	None	10/04/2013
Professor Anwar Baydoun	Peer review for MRC research grants and peer review for scientific journals	12/12/2013
Professor Soraya Dhillon	Director Member - Eastern Academic Health Science Network. Member of the General Pharmaceutical Council. Dean in the School of Life and Medical Sciences, University of Hertfordshire.	11/12/2013
Dr Patricia Scott	Senior Lecturer - Centre for Research in Primary and Community Care, University of Hertfordshire. Conducting personal research programme and supervising doctorate candidates.	18/12/2013
Mr David Grayson	Member of viewpoint - Mental Health Charity set up by Herts. MIND Network. Member of Herts Partnership Foundation Trust.	11/11/2013
Dr Roger Aubrey	None	31/03/2014
Mrs Barbara Newman	None	31/03/2014

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

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

10 full committee meetings were held during the reporting period.

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

<b>Month</b>	<b>Date</b>	<b>Number of Members Present at Meeting</b>
July	30/07/2013	3
August	28/08/2013	3
September	25/09/2013	3
October	30/10/2013	3
November	27/11/2013	3
January	23/01/2014	3
February	27/02/2014	3
March	27/03/2014	3

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

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Ian Skidmore	10
Mr David Grayson	10
Ms Melanie Whittick	10
Professor Barry Hunt	9
Professor Soraya Dhillon	8
Mr Michael Buck	8
Mrs Elspeth Coult	8
Dr Roger Aubrey	7
Mrs Barbara Newman	6
Professor Anwar Baydoun	6
Dr Wassim Matta	5
Dr Patricia Scott	2

**Number of inquorate meetings held: None**

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Ian Skidmore	8
Mr David Grayson	8
Dr Roger Aubrey	2
Professor Barry Hunt	2
Professor Soraya Dhillon	1
Dr Wassim Matta	1
Professor Anwar Baydoun	1

**Training 01 April 2013 – 31 March 2014:**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr Roger Aubrey	10/04/2013 - 08/05/2013	Ethical Debate and Application Discussion, Coordinator
Dr Roger Aubrey	20/11/2013 - 20/11/2013	National Members Training Day, HRA
Dr Roger Aubrey	02/12/2013 - 02/12/2013	Equality & Diversity
Mr Michael Buck	20/11/2013 - 20/11/2013	National Members Training Day, HRA
Mrs Elspeth Coult	10/04/2013 - 08/05/2013	Ethical Debate and Application Training, Coordinator
Mrs Elspeth Coult	19/02/2014 - 19/02/2014	Reviewing CTIMPS, HRA
Mrs Elspeth Coult	07/03/2014 - 07/03/2014	Equality & Diversity, HRA - Online Training
Professor Soraya Dhillon	18/09/2013 - 18/09/2013	Induction
Professor Soraya Dhillon	10/03/2014 - 10/03/2014	Improving Informed Consent & Participant Information Sheets
Mr David Grayson	24/09/2013 - 24/09/2013	HRA Member's Training Day, HRA
Dr Patricia Scott	03/03/2014 - 03/03/2014	Induction, HRA
Dr Ian Skidmore	07/10/2013 - 07/10/2013	Regional Training Day
Ms Melanie Whittick	24/09/2013 - 24/09/2013	Regional Training Day



**Part 2: REC workload and activity during the reporting period.**

**Table 1: Applications assigned to a full committee meeting held within the reporting period:**

<b>Applications for full ethical review – Study Type</b>	<b>Number</b>	<b>%</b>
Clinical Trial of Investigational Medicinal Product	17	44.74
Phase 1	5	13.16
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	16	42.11
<b>Total Applications Reviewed</b>	<b>38</b>	<b>100</b>

**Table 2: Other REC activity during the reporting period:**

Number of applications made invalid by co-ordinator	7
Number of studies withdrawn prior to the meeting	6
Number of student applications reviewed	8
Number of paediatric applications reviewed	0
Number of device applications reviewed	2
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:**

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	5	13.16
Favourable Opinion with Additional Conditions	6	15.79
Unfavourable Opinion	0	0.00
Provisional Opinion	27	71.05
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
<b>Total</b>	<b>38</b>	<b>100</b>
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:**

<b>Status of applications at date of generation of report</b>	<b>Number</b>	<b>%</b>
Further Information Favourable Opinion with Standard Conditions	25	65.79
Further Information Favourable Opinion with Additional Conditions	2	5.26
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	5	13.16
Favourable Opinion with Additional Conditions	6	15.79
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
<b>Total</b>	<b>38</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>19</b>
------------------------------------	-----------

**Table 6: Decisions given at proportionate review sub-committee meetings held within the reporting period:**

<b>Decisions taken at proportionate review sub-committee meetings</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	12	63.16
Favourable Opinion with Additional Conditions	2	10.53
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	5	26.32
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>19</b>	<b>100</b>

**Table 7: Other Management Information for the reporting period:**

<b>Average number of applications reviewed per full meeting</b>	3.80
<b>Number of applications for full ethical review over 60 days</b>	0
<b>Number of applications over 60 days as a % of total</b>	0.00%
<b>Number of days taken to final decision - average</b>	34
<b>Number of days taken to final decision - mode</b>	30
<b>Number of SSAs (non-Phase 1) reviewed</b>	5
<b>Number of applications for SSA review over 25 days</b>	0
<b>Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)</b>	0.0%
<b>Number of SSAs (Phase 1) reviewed</b>	1
<b>Number of applications for SSA review over 14 days</b>	0
<b>Number of applications for SSA review over 14 days as % of all Phase 1 (SSAs)</b>	0.0%
<b>Number of substantial amendments reviewed</b>	93
<b>Number of substantial amendments over 35 days</b>	1
<b>Number of substantial amendments over 35 days as a % of total substantial amendments</b>	1.1%
<b>Number of Section 30 applications reviewed</b>	0
<b>Number of Section 30 applications over 60 days</b>	0
<b>Number of Section 30 applications over 60 days as a % of total Section 30 applications</b>	0%
<b>Number of modified amendments reviewed</b>	1
<b>Number of modified amendments over 14 days</b>	0
<b>Number of modified amendments over 14 days as a % of total modified amendments</b>	0.0%
<b>Number of proportionate review applications for ethical review over 14 days*</b>	0
<b>Number of proportionate review applications over 14 days as a % of total</b>	0.0%

**Table 8: Breakdown of current status of all applications reviewed within the reporting period:**

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
13/EE/0138	A MAD Study of ASP9226 in Healthy Subjects (Version 1)	41
13/EE/0160	Whole Life Therapy for Poor Personality Function	23
13/EE/0176	Ferumoxitol for Anemia of CKD Trial (FACT)- AMAG-FER-CKD-401	39
13/EE/0199	Study of the Safety and Efficacy of Botox® for the Treatment of PE	36
13/EE/0203	National Cohort Study of Pulmonary Arterial Hypertension	47
13/EE/0208	000004 Ovarian stimulation in women using infertility treatment	43
13/EE/0209	Immune response in repeated cycles of controlled ovarian stimulation	43
13/EE/0215	Understanding the relationships between DXA and HRpQCT	39
13/EE/0241	SIGNATURE Study CAIN457AGB01	25
13/EE/0247	A 4 Week Treatment Period for Patients with Refractory Chronic Cough	27
13/EE/0250	PK study of Fluticasone/Salmeterol combinations (329/209)	22
13/EE/0253	Chronic disease in young adults, a role for palliative care	46
13/EE/0254	Development and validation of shortened EDE-Q	11
13/EE/0255	Digital ulceration as an outcome measure	13
13/EE/0303	Cannabidiol: a novel intervention for cannabis use problems?	41
13/EE/0305	An Attachment Antenatal Group for Adolescent Parents Version 1	30
13/EE/0307	A study to assess the safety, tolerability, PK and POC of Sun S0597	48
13/EE/0309	Efficacy & safety of Semaglutide once-weekly versus Exenatide ER 2mg	42
13/EE/0342	MR30507/09 analgesic response study	41
13/EE/0348	Alnylam ALN-TTRSC-002	41
13/EE/0349	Extension study for Chronic Myeloid Leukaemia	40
13/EE/0379	Constructs in families where one member has an Intellectual Disability	52
13/EE/0397	NIMRAD (NIMorazole/placebo plus RAdiotherapy in head and neck cancer)	53
13/EE/0398	Genetic, protein and transcription profiles of Neuromuscular Disorders	9
13/EE/0431	Optimal Treatment for OCD (OTO) Version 1.0	43
13/EE/0437	Mindfulness meditation introduced in a particular healthcare setting.	8
13/EE/0440	MicroRNAs in the early diagnosis of Gestational Diabetes Mellitus V2	8
14/EE/0034	VICTORY AF	35
14/EE/0059	POST MARKET MULTICENTRIC EVALUATION OF THE AQUESYS XEN IMPLANT	38
14/EE/0063	Diet and ketone metabolism	30

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
13/EE/0171	An observational study to assess cognition in Gaucher Disease.	36
14/EE/0057	Flutiform® Change and Step-Down Study (FFLU-X study) v.1.0	35

<b>Further Information Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<b>Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
13/EE/0113	NIAD-01: A topical gel for the treatment of atopic eczema	30
13/EE/0214	A Long Term Follow-up Study of Subjects previously treated with MK5172	21
13/EE/0311	Attitudes to breast cancer risk assessment and lifestyle advice	9
13/EE/0312	TACTT3	28
13/EE/0354	Women's perceptions of having a prenatal diagnostic test.	9
13/EE/0355	Perioperative nutrition experiences of colorectal surgery patients	10
13/EE/0357	IMPRESS version 1	9
13/EE/0388	Energy expenditure and inflammation in CKD	33
13/EE/0434	Prevalence of vCJD infected blood.	5
13/EE/0446	Root cause analysis of CVD prevention	26
14/EE/0047	Retrospective analysis of coracoacromial morphology using novel method	8
14/EE/0048	Imaging of adult burn injuries	6
14/EE/0049	Haemophilic Arthropathy and the role of Extracellular Histones-V1	7
14/EE/0088	The Efficacy of a Pain Management Programme on Psychological Outcomes	7
14/EE/0131	Kir 2.1 expression in patients with AF and varying BMI (version 2)	12
14/EE/0134	Systems Biology of Coronary Artery Ectasia	11
14/EE/0136	Improving dementia care in African and Caribbean minority ethnic group	10

**Favourable Opinion with Additional Conditions**

REC Reference	Application Short Title	Number of Days on Clock
13/EE/0132	Bioavailability Study of Crushed vs Whole Ticagrelor Tabs	27
13/EE/0242	Helping people with aphasia have better conversations	21
13/EE/0352	Challenges faced by nurses caring for patients with dementia.	22
13/EE/0396	Self-management after stroke: a feasibility study	9
13/EE/0399	The Advanced Paediatric Practitioner in Scotland: An exploratory study	8
13/EE/0401	Pulmonary magnetic resonance imaging in cystic fibrosis [V1.0]	30
13/EE/0405	Diary Study of Auditory Hallucination Triggers in Early Psychosis	26
13/EE/0448	AMPACT2 - An open-label extension to the TACTT3 study	26

**Unfavourable Opinion**

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

**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
---------------	-------------------------	-------------------------

<b>Not Requiring Review by NHS REC</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>



**Table 9: Items exceeding timelines:**

<b>Full applications for ethical review over 60 day timeline</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<b>Proportionate review applications for ethical review over 14 days timeline</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<b>SSAs (non Phase 1) over 25 days timeline</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<b>SSAs (Phase 1) over 14 days timeline</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>

<b>Substantial Amendments over 35 day timeline</b>			
<b>Amendment Reference</b>	<b>Application Short Title</b>	<b>Amendment Title</b>	<b>Number of Days on Clock</b>
11/EE/0353/AM03	Im-Con: Improving Consultations in General Practice (Version 1)	Substantial Amendment 2 - 3/7/13	36

<b>Modified Amendments over 14 day timeline</b>			
<b>Amendment Reference</b>	<b>Application Short Title</b>	<b>Amendment Title</b>	<b>Number of Days on Clock</b>

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