

National Research Ethics  
Service

  
*Health Research Authority*

**NRES Committee East of England -  
Cambridge South**

**Annual Report**

**01 April 2013 – 31 March 2014**

## Part 1 – Committee Membership and Training

**Name of REC:** NRES Committee East of England - Cambridge South

**Type of REC:** Recognised

**Type of Flag:** CTIMPS/Children/IRB

**Chair:** Dr Leslie Gelling

**Vice-Chair:** Dr Frank Wells

**Alternate Vice-Char:** Dr Ian Dumbelton

**REC Manager:** Ms Trish Wheat

**Committee Address:** The Old Chapel  
Royal Standard Place  
Nottingham  
NG1 6FS

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### Chair's overview of the past year:

After a year of significant change to the management and organisation of Cambridge South REC it has been useful to have a year of consolidation. The membership has remained largely unchanged and has developed into a strong, committed and hard working Committee. Members have continued to demonstrate thoroughness in the review of applications and have been supportive of between meeting activities, including sub-committees and proportionate review subcommittees. REC has quickly become a committee demonstrating thoroughness in review and a commitment to providing a high quality service for researchers and for NRES. It is a privilege to Chair Cambridge South REC.

**NRES Committee East of England - Cambridge South Membership:**

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mrs Martha Byrne	Associate Director, GCP, Quality Compliance	Lay Plus	01/04/2011	
Dr Katherine Catford	Specialist Registrar in Paediatrics	Expert	01/10/2011	
Dr Ian Dumbelton	Retired General Medical Practitioner	Expert	01/04/2011	
Dr Leslie Gelling	(Chair) Reader in Research Ethics	Expert	01/04/2011	
Mr Colin Green	Drugs & Therapeutics Pharmaceutical Advisor	Expert	01/04/2011	
Mrs Alison Hall	Project Manager	Lay	01/04/2011	
Mr John Kirkpatrick	Statistician	Expert		
Miss Angela Palmer	Retired Patent Litigator	Lay Plus	01/04/2011	
Mrs Nikki Phillimore	Antibiotic/infection management pharmacist	Expert	01/04/2011	
Miss Carol Smee	Regulatory Advisor	Lay	01/04/2011	
Mr Phil Tempest	Compliance Manager	Lay	01/04/2011	
Dr Frank Wells	(Vice-Chair) Retired Pharmaceutical Physician	Expert	01/04/2011	
Dr Kate Williams	Senior Research Associate	Lay	01/04/2011	
Dr Rashid Zaman	Consultant Psychiatrist and Director of Bedfordshire Centre for Mental Health Research	Expert	01/04/2011	

**Deputy Members**

Name	Occupation	Expert or Lay	Meeting date attended
Miss Poonam Dhokia	Pharmacist	Expert	23/05/2013
			22/08/2013
			26/09/2013
			28/11/2013

**NRES Committee East of England - Cambridge South: Members' Declarations of Interest:**

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Dr Leslie Gelling	Reader in Research Ethics at Anglia Ruskin University. Engaged in research and occasionally seek ethical opinion for research from an NHS REC. Supervises undergraduate, postgraduate and doctoral students who occasionally also need to seek the opinion of an NHS REC	01/12/2013
Dr Rashid Zaman	MHRN (East Anglia)NHS Engagement Lead (Research)Member of Trust R & D also known as Research Approval Group	01/12/2013
Dr Frank Wells	Lead Advisor (honorary) to the Health Research Authority on Integrity, Fraud and Misconduct	01/12/2013
Mrs Nikki Phillimore	None	01/12/2013
Miss Carol Smee	Employed by the Wellcome Trust Sanger Institute which carries out genomic research and acts as study sponsor for some studies. The Sanger Institute also receives core funding from the Wellcome Trust Charitable Foundation	01/12/2013
Mr Phil Tempest	Employed by Amgen Ltd as Compliance Senior Manager. Owns shares in Amgen Ltd and GSK plc.	01/12/2013
Mrs Martha Byrne	Associate Director of Quality compliance - Medimmune, Riverside Building, Granta Park, Cambridge. Member of the Independent professional non-profit making bodies who rely on volunteers o provide advice to members: RQA (Research QA) society independent body providing support for QA functions in academic and private companies. EQAC (EU QA Confederation) - independent voluntary body set up to provide a central Quality Assurance opinion on behalf of independent QA societies to reflection papers and draft legislation circulated via the UK MHRA, EU EMA or US FDA.	01/12/2013
Mr John Kirkpatrick	Controlling director, Insight Statistical Consulting Ltd (registered in England no. 3302037)	01/12/2013
Dr Kate Williams	Voluntary work on research studies for the charity Medical Detection Dogs. Works for University of Cambridge Primary Care Unit	01/12/2013
Miss Angela Palmer	Receives a pension from GlaxoWellcome. Owns GSK shares.	01/12/2013
Dr Ian Dumbelton	Retired GP, Community Governor of Longsands School	01/12/2013
Mrs Alison Hall	Employed by the PHG Foundation, a health policy think tank interested in genomics and its use in healthcare and research. On occasion has been asked to peer review applications for funding from organisations such as the Wellcome Trust. Has also peer reviewed manuscripts for publication in a variety of journals on request	01/12/2013
Mr Colin Green	None	01/12/2013
Dr Katherine Catford	None	01/12/2013

**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	25/04/2013	9
May	23/05/2013	9
June	27/06/2013	10
July	25/07/2013	10
August	22/08/2013	11
September	26/09/2013	8
October	24/10/2013	11
November	28/11/2013	11
January	23/01/2014	12
February	27/02/2014	11
March	27/03/2014	11

11 full committee meetings were held during the reporting period.

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

<b>Month</b>	<b>Date</b>	<b>Number of Members Present at Meeting</b>
June	06/06/2013	3
July	11/07/2013	4
August	08/08/2013	3
September	05/09/2013	3
October	10/10/2013	4
November	07/11/2013	4
December	16/12/2013	3
January	16/01/2014	4
February	17/02/2014	4
March	17/03/2014	3

10 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 Leslie Gelling	11
Mrs Alison Hall	11
Dr Kate Williams	10
Miss Angela Palmer	10
Miss Carol Smee	9
Mr Colin Green	9
Mr John Kirkpatrick	8
Dr Ian Dumbelton	8
Dr Rashid Zaman	7
Dr Frank Wells	7
Mr Phil Tempest	7
Dr Katherine Catford	6
Mrs Nikki Phillimore	5
Mrs Martha Byrne	5

**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 Leslie Gelling	9
Dr Katherine Catford	7
Dr Kate Williams	3
Miss Carol Smee	3
Mrs Alison Hall	3
Mrs Martha Byrne	2
Mrs Nikki Phillimore	2
Miss Angela Palmer	2
Mr Colin Green	1
Mr John Kirkpatrick	1
Carol Smee	1
Dr Ian Dumbelton	1

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

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr Katherine Catford	20/11/2013 - 20/11/2013	National Members Training Day, HRA
Dr Leslie Gelling	24/09/2013 - 24/09/2013	East of England Regional Training Day, Nottingham HRA Office
Dr Frank Wells	24/09/2013 - 24/09/2013	East of England Regional Training Day, Nottingham HRA Office
Dr Ian Dumbelton	24/09/2013 - 24/09/2013	East of England Regional Training Day, Nottingham HRA Office
Mrs Nikki Phillimore	24/09/2013 - 24/09/2013	East of England Regional Training Day, Nottingham HRA Office
Miss Poonam Dhokia (Deputy Member)	24/09/2013 - 24/09/2013	East of England Regional Training Day, Nottingham HRA Office
Miss Angela Palmer	23/09/2013 - 23/09/2013	East of England Regional Training Day, Nottingham HRA Office
Mr John Kirkpatrick	24/09/2013 - 24/09/2013	East of England Regional Training Day, Nottingham HRA Office
	18/09/2014 – 18/09/2014	HRA Induction Training (mandatory), Skipton House, London
Mrs Martha Byrne	21/08/2013 - 21/08/2013	SDL - Internal course , Bio-Ethics - Clinical Trial requirements for Ethics
	27/08/2013 – 27/08/2013	SDL - Internal Course - Code of Conduct Foundations Module - Ethics & Compliance
	07/11/2013 - 08/11/2013	SDL - External Course - Drug Information Association - Pharmacovigilance
	10/2013 – 10/2013	SDL - External Course - IRAS Integrated Research Application System
Dr Kate Williams	24/09/2013 – 24/09/2013	East of England Regional Training Day, Nottingham HRA Office
Mr Colin Green	05/2013 – 05/2013	SDL – Presented a talk to the pre-registration pharmacy students at work around research ethics
	04/2013 – 04/2013	SDL – Discussion with senior pharmacist around the research ethics of obtaining assent/consent in patients unable to consent. Undertaken in relation to a trial being conducted on critically ill patients
	2013	Reading of papers on research ethics published in the journal of Medical Ethics – 5 hours in total
Miss Carol Smee	09/07/2013 – 09/07/2013	SDL - Attended Human Tissue Authority Annual Review Meeting
	27/09/2013 – 27/09/2013	Genomics in Medicine Course

**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	18	30.00
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	42	70.00
<b>Total Applications Reviewed</b>	<b>60</b>	<b>100</b>

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

Number of applications made invalid by co-ordinator	5
Number of studies withdrawn prior to the meeting	4
Number of student applications reviewed	18
Number of paediatric applications reviewed	12
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	0	0.00
Favourable Opinion with Additional Conditions	5	8.33
Unfavourable Opinion	3	5.00
Provisional Opinion	52	86.67
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>60</b>	<b>100</b>
Number of studies sent back to full committee meeting for final opinion	1	

**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	44	73.33
Further Information Favourable Opinion with Additional Conditions	3	5.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	5	8.33
Unfavourable Opinion	3	5.00
Provisional Opinion	5	8.33
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>60</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>21</b>
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**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	5	23.81
Favourable Opinion with Additional Conditions	2	9.52
No Opinion transfer to full committee for review	2	9.52
Provisional Opinion	11	52.38
Unfavourable Opinion	1	4.76
<b>Total</b>	<b>21</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	5.45
<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>	42
<b>Number of days taken to final decision - mode</b>	45
<b>Number of SSAs (non-Phase 1) reviewed</b>	4
<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>	0
<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%
<b>Number of substantial amendments reviewed</b>	144
<b>Number of substantial amendments over 35 days</b>	0
<b>Number of substantial amendments over 35 days as a % of total substantial amendments</b>	0.0%
<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>	3
<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/0102	PIVOT Neurocognitive function sub-study v1.0	53
13/EE/0110	(April) Effect of Sulforaphane on prostate CAncer PrEvention (ESCAPE)	60
13/EE/0117	LDE225 and INC424 in Combination in myelofibrosis patients.	52
13/EE/0126	BACE CT-003	35
13/EE/0128	MRI and Inflammatory Biomarkers in First Episode Psychosis (MIB-FEP)	54
13/EE/0137	Predictive Biomarkers of Chronic Venous Ulcer Healing	60
13/EE/0144	Mavrilimumab versus Anti tumor Necrosis Factor in Rheumatoid Arthritis	37
13/EE/0151	An Open-label study of Mavrilimumab in Rheumatoid Arthritis	36
13/EE/0155	Virtual Histology in Vulnerable Atherosclerosis IV	28
13/EE/0165	Evaluation of Arterial Inflammation and Function in OSAHS and COPD.	59
13/EE/0167	Study of Ambrisentan in Chronic Thromboembolic Pulmonary Hypertension	60
13/EE/0168	An Extension Study of a Drug to Treat CTEPH	60
13/EE/0179	Interscalene blockade on cardiovascular reactivity and haemodynamics	47
13/EE/0181	PROGENY - Version 1.1	14
13/EE/0202	Inter-B-NHL Ritux 2010 - Version 1.0	56
13/EE/0210	Understanding lupus: Interferon-alpha related pathways in skin & blood	38
13/EE/0217	Effects of selective site pacing on biventricular haemodynamics.	44
13/EE/0222	Internet use amongst patients with severe mental health illness	45
13/EE/0229	Egg cell surface receptor in human infertility	14
13/EE/0230	What patients want in their psychiatrist. Version I	14
13/EE/0231	N-Acetylcysteine in Idiopathic Pulmonary Fibrosis.1	54
13/EE/0232	Parents' and carers' experiences of attending a sleep workshop	13
13/EE/0238	Metacognition and Memory in Anorexia Nervosa	45
13/EE/0262	PROsPeCTs: Promoting recovery from PTSD in Children and Teenagers	31
13/EE/0268	SUNCARE	50
13/EE/0270	RELIEF	43
13/EE/0271	Use of self-report rating scales in children with ASD (v1)	9
13/EE/0276	Phase 3B study assessing SOF/RBV and SOF/PEG/RBV for Genotype 2 or 3 C	54
13/EE/0314	Functional Outcomes Following Anal Cancer Treatment (FOFACT)	36

13/EE/0323	QUEST v1	39
13/EE/0326	Revacept/CS/02	42
13/EE/0327	Women's experiences of late pregnancy ultrasound.	57
13/EE/0367	BI 655066 in patients with Crohn's disease.	34
13/EE/0374	IMP-3 Expression in Cutaneous Squamous malignancy	13
13/EE/0377	Elagolix in the treatment of menstrual bleeding with Uterine Fibriods	45
13/EE/0403	Clinical Outcomes Following Treatment with Systane® Balance in Dry Eye	46
13/EE/0407	Nanopore quantification of miRNAs isolated from human serum.	6
13/EE/0414	DTI and fMRI in patients with pituitary tumours: a pilot study	34
13/EE/0415	Glucose Lowering In Non-diabetic hyperglycaemia Trial (GLINT)	46
13/EE/0417	Diet and Health Study, 2014	46
13/EE/0418	PANDA RCT	38
14/EE/0001	CONCEPTT Newborn Study	36
14/EE/0006	How do children with Autism remember events?	34
14/EE/0020	NEUCHILD (Version 3.0)	40
14/EE/0033	Home based assessment tool for Myasthenia	35
14/EE/0035	Phase 3 Trial of Fuvestrant(Faslodex®)in women with Breast Cancer	41
14/EE/0036	Depression and anxiety in RA treatment adherence: a correlation?	38
14/EE/0037	An exploration of self-compassion, posttraumatic stress and growth V1.	14
14/EE/0054	Dietary Carbohydrate Loading to Assess Fat Production	45
14/EE/0068	Meningococcal carriage patterns in high risk patients	49
14/EE/0069	Biomarkers of malignancy from pancreatic cysts	57
14/EE/0072	First aid written information in the ED: A RCT version 1.1	14
14/EE/0074	Quality of life in thyroid related strabismus	12
14/EE/0108	An evaluation of a water fluoridation scheme in Cumbria	40
14/EE/0112	Parents' Experiences of Parent Child Interaction Therapy	10

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/EE/0085	The impact of Non Medical Prescribing on patient care and outcomes	45
13/EE/0306	The use of life story work in an age inclusive dementia service	53
13/EE/0325	NIHR BioResource - Rare Diseases	36

<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/0272	Geographical differences in uptake of screening	10
13/EE/0274	2 year use of Aflibercept study for treatment of wet AMD	9
13/EE/0277	Epidemiology of Trichomonas vaginalis in the UK.	9
13/EE/0378	Counting intraepithelial lymphocytes	14
13/EE/0455	Mode of Birth Delivery and Strabismus	7

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
13/EE/0131	Genomic studies of HIV control in the CASCADE Collaboration	29
13/EE/0269	Psychological predictors for early cessation of breastfeeding	29
13/EE/0304	CBD_ADD_IN	28
13/EE/0322	Increasing opportunities for learning (Version 1)	34
13/EE/0330	Parent's and carer's views about weight management for preschoolers.V1	10
14/EE/0012	Lipid Metabolism and Obesity	28
14/EE/0114	PROACT Patient Reported Opinions about Clinical Tolerability	6

<b>Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
13/EE/0094	RELATIONSHIP OF THROMBOPHILIA WITH COMPLICATIONS IN PREGNANCY	29
13/EE/0350	EFFECTIVE PAF	27
13/EE/0363	Depression and anxiety in RA treatment compliance: a correlation?	41
13/EE/0372	Understanding adolescents' lived experience of dental anxiety	13

<b>Provisional Opinion</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
14/EE/0076	Phase 4 Study of effect of Aspirin on Flushing in DMF-Treated Subjects	N/A
14/EE/0078	The Lived Experiences of Women with an Autism Spectrum Disorder	N/A

14/EE/0092	Metabolic Reference Measurements in Childhood and Adolescence	N/A
14/EE/0103	Evaluation of brain 5-HT2C density with PET	N/A
14/EE/0105	EORTC 26101	N/A

#### **Provisional Opinion Pending Consultation with Referee**

<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
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#### **Further information response not complete**

<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
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#### **Withdrawn after the meeting**

<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
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#### **Invalid Application**

<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
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#### **No Opinion Pending Consultation with Referee**

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

<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
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**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>
<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>