

National Research Ethics  
Service

  
*Health Research Authority*

# NRES Committee London - City & East

## Annual Report

**01 April 2013 – 31 March 2014**

## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	NRES Committee London - City & East
<b>Type of REC:</b>	REC recognised to review CTIMPS in patients - type iii
<b>Type of Flag:</b>	IRB Registered Phase 1 Studies in Patients Research Involving Children
<b>Chair:</b>	Professor Arthur T. Tucker
<b>Vice-Chair:</b>	Dr Louise Abrams
<b>Alternate Vice-Chair:</b>	Professor David Wingate
<b>REC Manager:</b>	Mr Rajat Khullar
<b>PRSC Manager:</b>	Mr Rajat Khullar
<b>Assistant Co-ordinator:</b>	Mr Wai Yeung
<b>Committee Address:</b>	Bristol Research Ethics Committee Centre Whitefriars Level 3, Block B Lewins Mead Bristol BS1 2NT
<b>Telephone:</b>	01173421386
<b>Fax:</b>	01173420445
<b>Email:</b>	nrescommittee.london-cityandeast@nhs.net

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

Chair's overview not available

## NRES Committee London - City & East Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr Louise Abrams	Pharmacology (Vice Chair)	Expert	01/05/2004	
Dr Chandan Alam	Experimental Pathology	Expert	01/02/2005	
Dr Marie E Bardsley	Director	Lay	01/10/2009	
Ms Jane Batchelor	Centre Administrator, Advanced Cardiovascular Imaging	Lay Plus	01/12/2011	
Dr Ayse Baxter	Pharmaceutical Physician	Expert	01/07/2007	
Mr Frank Cross	Consultant General and Vascular Surgeon	Expert	13/11/2008	
Dr Miran Epstein	Senior Lecturer Medical Ethics	Expert	01/05/2004	
Ms Janelle Hill	Non-medical lay member	Lay Plus	01/08/2004	
Professor Atholl Johnston	Professor of Clinical Pharmacology	Expert	01/05/2004	
Professor Malcolm Law	Epidemiologist	Expert	01/04/2004	
Mr John Lynch	Lay Member	Lay	01/10/2007	
Mr Roger Maran	Barrister	Lay Plus	06/10/2011	
Dr Eleni Palazidou	Consultant Psychiatrist & Honorary Senior Lecturer	Expert	01/01/2005	
Professor Kim Piper	Consultant Histopathologist/Professor of Oral Pathology	Expert	01/03/2008	
Dr Melanie Powell	Consultant Clinical Oncologist	Expert	01/04/2004	15/05/2013
Ms Brigid Tucker	Non-Medical Lay Member	Lay Plus	01/08/2004	
Professor Arthur T. Tucker	Lead Clinical Scientist & Reader, (REC Chairman)	Expert	01/07/2004	
Professor David Wingate	Gastroenterologist	Expert	01/05/2004	

### Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended
Dr Ariel Zosmer	Honorary Senior Clinical Lecturer	Expert	07/11/2013, 06/02/2014, 06/03/2014
Ms Clare Barron	Solicitor – in-house legal department	Lay Plus	06/03/2014

## NRES Committee London - City & East: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Professor Arthur T. Tucker	Co-Founder & Managing Director - Seahorse Scientific Services Ltd. Co-Founder & Managing Director - Seahorse Laboratories Ltd. Chief Scientific Officer - Edixomed Ltd. Co-Inventor & Member of Scientific Advisory Board - Sky Medical Technology Ltd. & FirstKind Ltd. Principal Clinical Scientist, Barts Health NHS Trust. Reader, William Harvey Research Institute, QMUL Algaecytes Ltd. Advisor - Barchester Group Ltd. Cardiocity Ltd. FimpacTT AG. Gabriel Scientific Ltd MAC Ltd Tarilian Laser Technology Ltd. TransDermal Solutions Corporation.	27/02/2014
Dr Louise Abrams	None	27/02/2014
Professor David Wingate	Member of Whitechapel Society for the Advancement of research in Gastroenterology. Trustee of Harold Hyam Wingate Foundation	27/02/2014
Dr Chandan Alam	Director - Transdermal Delivery Solutions Corp. , Florida, US. Director, Medical - Cells United, Oslo, Norway	27/02/2014
Dr Miran Epstein	None	27/02/2014
Professor Malcolm Law	None	27/02/2014
Dr Eleni Palazidou	None	27/02/2014
Ms Brigid Tucker	Currently employed by a UK statutory healthcare regulator (General Osteopathic Council) and represent the regulator on the UK National Council for Osteopathic Research (NCOR). As a healthcare regulator, we periodically commission research that informs policy development. This forms part of my remit.	27/02/2014
Dr Ayse Baxter	Principal, AB MedEx Consulting. Clinical and Medical Regulatory Consultancy to Pharmaceutical Industry.	06/02/2014
Professor Atholl Johnston	Positions - Various Pharma Companies Consultant, Director - EspritOther ownership/ involvement- ASI Ltd. , Seahorse Scientific Services Ltd. Queen Mary University of London	06/02/2014
Mr Frank Cross	None	27/02/2014
Professor Kim Piper	None	27/02/2014
Ms Janelle Hill	None	27/02/2014
Dr Marie E Bardsley	Data Manager, Data Sharing Initiative Royal London Hospital. WhitechapelCommission on Publishing Ethics (COPE). Member of Labour Party	27/02/2014

Mr John Lynch	None	27/02/2014
Mr Roger Maran	Shares in GlaxoSmithKline as part of a professionally managed share portfolio.	27/02/2014
Ms Jane Batchelor	Centre Administrator, Advanced Cardiovascular Imaging, William Harvey Research Institute, QMUL	27/02/2014
Dr Ariel Zosmer	None	27/02/2014

**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	04/04/2013	14
May	02/05/2013	11
June	06/06/2013	9
July	04/07/2013	13
September	05/09/2013	10
October	03/10/2013	14
November	07/11/2013	14
December	05/12/2013	15
January	09/01/2014	15
February	06/02/2014	10
March	06/03/2014	13

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>
April	23/04/2013	3
May	21/05/2013	3
June	25/06/2013	3
July	23/07/2013	3
September	24/09/2013	3
October	22/10/2013	3
November	25/11/2013	3
December	23/12/2013	3
January	28/01/2014	3
February	27/02/2014	4
March	27/03/2014	4

11 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>
Professor Arthur T. Tucker	11
Mr Roger Maran	10
Ms Janelle Hill	10
Dr Ayse Baxter	10
Dr Chandan Alam	10
Dr Eleni Palazidou	9
Dr Louise Abrams	9
Dr Marie E Bardsley	9
Ms Jane Batchelor	9
Ms Brigid Tucker	8
Professor David Wingate	8
Dr Miran Epstein	7
Mr Frank Cross	6
Professor Atholl Johnston	6
Professor Malcolm Law	6
Professor Kim Piper	5
Mr John Lynch	5
Dr Ariel Zosmer	3
Ms Clare Barron	1

**Number of inquorate meetings held: 0**

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr Roger Maran	8
Professor Arthur T. Tucker	5
Professor David Wingate	4
Professor Kim Piper	3
Professor Atholl Johnston	3
Ms Brigid Tucker	2
Ms Janelle Hill	2
Dr Louise Abrams	2
Dr Miran Epstein	1
Mr Frank Cross	1
Dr Ayse Baxter	1
Dr Eleni Palazidou	1
Ms Jane Batchelor	1
Dr Ariel Zosmer	1

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

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Professor Arthur T. Tucker	04/04/2013 - 02/05/2013	Reading of NRES Training material on Human Tissue Act and Mental Capacity Act , NRES
Professor Atholl Johnston	04/04/2013 - 02/05/2013	Reading of NRES Training material on Human Tissue Act and Mental Capacity Act , NRES
Dr Ayse Baxter	04/04/2013 - 02/05/2013	Reading of NRES Training material on Human Tissue Act and Mental Capacity Act , NRES
Dr Chandan Alam	04/04/2013 - 02/05/2013	Reading of NRES Training material on Human Tissue Act and Mental Capacity Act , NRES
Dr Chandan Alam	10/07/2013 - 10/07/2013	Attended lectures related to ethics at the ESHRE Conference, London , ESHRE Conference
Professor David Wingate	04/04/2013 - 02/05/2013	Reading of NRES Training material on Human Tissue Act and Mental Capacity Act , NRES
Professor David Wingate		Reading of Ben Goldacre's Bad Pharma and other training, Self Study
Ms Jane Batchelor	04/04/2013 - 02/05/2013	Reading of NRES Training material on Human Tissue Act and Mental Capacity Act , NRES
Ms Janelle Hill	04/04/2013 - 02/05/2013	Reading of NRES Training material on Human Tissue Act and Mental Capacity Act , NRES
Professor Kim Piper	04/04/2013 - 02/05/2013	Reading of NRES Training material on Human Tissue Act and Mental Capacity Act , NRES
Mr Roger Maran	04/04/2013 - 02/05/2013	Reading of NRES Training material on Human Tissue Act and Mental Capacity Act , NRES
Dr Miran Epstein	04/04/2013 - 02/05/2013	Reading of NRES Training material on Human Tissue Act and Mental Capacity Act , NRES
Dr Ayse Baxter	25/03/2014 - 25/03/2014	Research Involving the Disadvantaged and Vulnerable, HRA
Professor Arthur T. Tucker		The right to participate in high-risk research - David Shaw, Self Study and Discussion
Ms Jane Batchelor	24/03/2014 - 24/04/2014	Self Study (Reading) - Ben



		Goldacre - Bad Science, Self Study
Ms Jane Batchelor	24/03/2014 - 24/03/2014	Self Study - Zosia Kmietowicz, Roche says that it will not relinquish control over access to clinica,
Ms Jane Batchelor	24/03/2014 - 24/03/2014	Self Study - Sarah Boseley, Scientists voice fears over ethics of drug trials remaining unpublished ,
Ms Jane Batchelor	24/03/2014 - 24/03/2014	Sile Lane, Why the data on all drug trials must be released (theguardian.com, Tuesday 17 September 2,
Mr Frank Cross	28/02/2014 - 28/02/2014	Introduction to Information Governance e-course at CUH 13th November 2013. , e-course at CUH
Mr Frank Cross	19/11/2013 - 19/11/2013	Mastering Adverse Outcomes workshop, Medical Protection Society 19th November 2013, Medical Protection Society
Dr Louise Abrams	17/03/2014 - 17/03/2014	The right to participate in high-risk research - David Shaw, Self Study
Dr Louise Abrams	06/03/2014 - 06/03/2014	Ben Goldacre - Bad Pharma, Self Reading
Professor David Wingate	22/03/2014 - 22/03/2014	The right to participate in high-risk research - David Shaw, Self Study
Dr Chandan Alam	17/03/2014 - 17/03/2014	The right to participate in high-risk research - David Shaw, Self Study
Professor Malcolm Law	04/04/2013 - 02/05/2013	Reading of NRES Training material on Human Tissue Act and Mental Capacity Act , NRES
Dr Eleni Palazidou	04/04/2013 - 02/05/2013	Reading of NRES Training material on Human Tissue Act and Mental Capacity Act , NRES
Dr Eleni Palazidou	17/03/2014 - 17/03/2014	The right to participate in high-risk research - David Shaw, Self Study
Ms Brigid Tucker	17/03/2014 - 17/03/2014	The right to participate in high-risk research - David Shaw, Self Study
Dr Ayse Baxter	17/03/2014 - 17/03/2014	The right to participate in high-risk research - David Shaw, Self Study
Professor Kim Piper	17/03/2014 - 17/03/2014	The right to participate in high-risk research - David Shaw, Self

		Study
Dr Marie E Bardsley	17/03/2014 - 17/03/2014	The right to participate in high-risk research - David Shaw, Self Study
Mr Roger Maran	17/03/2014 - 17/03/2014	The right to participate in high-risk research - David Shaw, Self Study

**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	20	29.4
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	2	2.94
Research Database	0	0.00
Others	46	67.64
<b>Total Applications Reviewed</b>	<b>68</b>	<b>100</b>

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

Number of applications made invalid by co-ordinator	1
Number of studies withdrawn prior to the meeting	5
Number of student applications reviewed	19
Number of paediatric applications reviewed	14
Number of device applications reviewed	1
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	0
Number of applications reviewed funded by the US DHHS	1

**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	4	5.8
Favourable Opinion with Additional Conditions	7	10.2
Unfavourable Opinion	4	5.8
Provisional Opinion	52	76.47
Invalid	1	1.47
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>68</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	46	67.64
Further Information Favourable Opinion with Additional Conditions	4	5.88
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	4	5.88
Favourable Opinion with Additional Conditions	7	10.29
Unfavourable Opinion	4	5.88
Provisional Opinion	2	2.9
Provisional Opinion Pending Consultation with Referee	0	0.00
Invalid	1	1.4
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>68</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>35</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	8	22.86
Favourable Opinion with Additional Conditions	13	37.14
No Opinion transfer to full committee for review	2	5.71
Provisional Opinion	9	25.71
Unfavourable Opinion	3	8.57
<b>Total</b>	<b>35</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	6.1
<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>	35
<b>Number of days taken to final decision - mode</b>	39
<b>Number of SSAs (non-Phase 1) reviewed</b>	21
<b>Number of applications for SSA review over 25 days</b>	4
<b>Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs)</b>	19.0%
<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>	164
<b>Number of substantial amendments over 35 days</b>	5
<b>Number of substantial amendments over 35 days as a % of total substantial amendments</b>	3.0%
<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>	7
<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/LO/0399	Accelerated forgetting in people with TLE, TEA and/or MTL lesions	44
13/LO/0400	INVASIS	38
13/LO/0425	M14-002 - ABT-450/r/ABT-267 & ABT-333 with and without RBV	27
13/LO/0530	MRI-PET	36
13/LO/0548	Bisphosphonate-related osteonecrosis of the jaw and the Immune system	31
13/LO/0549	FG-4592 in the Treatment of Anemia in Chronic Kidney Disease Patients	33
13/LO/0555	Brain in Pain IV (FM,NCCP)	37
13/LO/0568	Analysing The Paced QRS To Refine Arrhythmic Risk Stratification V1.4	32
13/LO/0582	Abiraterone with Different Steroid Regimens in Prostate Cancer	39
13/LO/0648	Hardiness and Outcome of Self-catheterisation Training (HOST) Study	9
13/LO/0727	LDK378 in children with malignancies that have ALK alteration	42
13/LO/0749	CBT Panic Group: A Pilot V.1	53
13/LO/0811	Acceptability of a first trimester screening test for pre-eclampsia	12
13/LO/0861	Pain Model Validation	39
13/LO/0908	Enzalutamide in Triple Negative Breast Cancer	38
13/LO/0911	Influenza H3N2 Characterisation Study	39
13/LO/0926	Phase 1 study to evaluate safety and efficacy of BMN 190	26
13/LO/1040	Economic analysis of kidney stone disease management	14
13/LO/1162	Exploring perspectives on prescribing in a mental health setting	13
13/LO/1207	Stereotactic radiotherapy for wet AMD (STAR)	34
13/LO/1211	A Phase 1b/II study AEB071 and MEK162 in patients with uveal melanoma	30
13/LO/1245	156-12-203: Phase I Tolvaptan in subjects with SIADH (Hormone)	35
13/LO/1284	ROX CONTROL HTN REGISTRY: Protocol RH-03 Version 1.0, June 19, 2013	35
13/LO/1399	Brain in Pain III (CFS)	39
13/LO/1401	FORECAST - Focal Recurrent Assessment and Salvage Treatment	35
13/LO/1410	ConforMIS CCP 11-001 iDuo G2	37
13/LO/1437	Phase I/II study of [124I]mIBG PET/CT in neuroblastoma.	38
13/LO/1505	ICORG 11-10/TH v THL	39
13/LO/1537	Responses of human immune cells to bacterial infection	13

13/LO/1557	Circulating Tumour Cells in Somatuline Autogel treated NET patients	54
13/LO/1572	Host & Viral factors associated with HIV-1 control v1	28
13/LO/1632	Investigating the link between mental health and immune system	32
13/LO/1720	Enzalutamide in Combination with Exemestane in Advanced Breast Cancer	39
13/LO/1734	Experiences of Hearing Voices Network groups, recovery & group process	29
13/LO/1760	BAMI Platelet Sub-study	52
13/LO/1790	Volunteering in Mental Health Care for People with Psychosis (VOLUME4)	34
13/LO/1801	The Men's Safer Sex (MenSS) Trial: a website to increase condom use	39
13/LO/1883	inGRAINed HEALTH	13
13/LO/1930	The PKG sleep study in patient's with Parkinson's disease, Version 1.0	59
13/LO/1950	The role of the nuclear envelope proteins in cardiovascular ageing	12
14/LO/0021	CE Mark Home Self-Test finger blood Total WBC, HGB, GRN, + Temperature	39
14/LO/0038	Comparing computerised versus non-computerised vision tests	35
14/LO/0047	Assessing a low vision reading aid for macular disease	39
14/LO/0051	Phase 2a study of intravenous CT-P27 post-exposure to Influenza A H3N2	38
14/LO/0132	Robotic Surgery After Focal Ablation Therapy (RAFT)	44
14/LO/0141	iMAP2	35
14/LO/0162	Compassion and the NHS: The Role of a Compassionate Nurse	42
14/LO/0317	NeoAdapt 1	36
14/LO/0318	NeoAdapt 2	37
14/LO/0319	NeoAdapt 3	37
14/LO/0380	Patient questionnaire regarding sudden unexpected death in epilepsy	39
14/LO/0598	The experiences of GTN patients	8

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/LO/0881	Incidence of nocturnal hypoglycaemia and arrhythmia in ESRD patients	48
13/LO/1636	The effects of two marketed drugs on cognitive function	47
14/LO/0122	Safety, tolerability & pharmacokinetics of regorafenib in paediatrics	34
14/LO/0418	CEDAR	38

#### Further Information Unfavourable Opinion

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



<b>Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
13/LO/0506	Incorrect beliefs about the contraceptive implant	
13/LO/0656	Area deprivation and contact with id psychiatry	7
13/LO/0673	The Neutrophil Myeloperoxidase Index, Lobularity Index and Infection	7
13/LO/0961	Cardiac MRI study of adults late after childhood anthracycline therapy	25
13/LO/1045	Educational video for patients about Mohs micrographic surgery	20
13/LO/1165	Multi-modal physiotherapy classes following total knee arthroplasty v1	9
13/LO/1531	Medicines management in primary care	55
13/LO/1681	Neutrophil function and hemolysis in sickle cell disease	10
13/LO/1695	Public perception of long-term illness and decisions to seek help; v1	14
13/LO/1943	PDOPPS	9
13/LO/1953	Antisynthetase syndrome - correlation of HRCT with antibody profiles	4
14/LO/0413	Normal ranges for paediatric bronchoalveolar lavage cytology	11
08/H0704/128+5	Brains for Dementia Research	39
08/H0704/117 +5	The Kings Liver Research Tissue Bank	27

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
13/LO/0393	INSIGHT: Investigation into biomarkers to predict preterm birth	34
13/LO/0675	Reward system function links to physical and mental health	7
13/LO/0738	Optical monitoring of bowel tissue viability (Version 1)	18
13/LO/0816	Bone specific alkaline phosphatase and outcome in dialysis patients	5
13/LO/0817	Validation of a scale of GPs' reassurance during LBP consultations	7
13/LO/1032	Facial morphology in UCLP patients	14
13/LO/1167	Setting survivorship in context: Life after cancer treatment	9
13/LO/1168	Arterial Spin Labelled MR imaging of cerebral blood flow in children	9
13/LO/1223	The ANSeR project	26
13/LO/1241	An assessment of a monoclonal antibody, against Influenza A	26
13/LO/1419	OHIP-14 scores and the required need for specialist dental treatment	27
13/LO/1533	Adding self-help to skin camouflage - impact on social anxiety v3	12
13/LO/1685	A study of the mechanisms that give rise to vascular disease	7

13/LO/1885	Patient Evaluation of the NHS Health Check Programme	6
13/LO/1948	The use of susceptibility weighted MR imaging(SWI)in neonates with HIE	11
14/LO/0044	EZH117208: Phase I Dose Escalation Study of GSK2816126	29
14/LO/0235	Investigating women's views on the management of a breech pregnancy V1	5
14/LO/0272	Oesophageal PPG study	30
14/LO/0403	Effects of message content on intention to quit smoking. (version 1)	7
14/LO/0408	Evaluating the Patient-led roll-out of HeLP-Diabetes	10

#### Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/LO/0330	Optical monitoring of bowel tissue viability 1	27
13/LO/0650	Analysis of Lung Cancer patients' journey from symptoms to diagnosis	8
13/LO/0789	Determining normal neuromuscular junction function in children	26
13/LO/1406	Multimodality imaging of Prostate cancer-VERSION 1 8 JULY 2013 AH-JB	27
13/LO/1744	Phase 2a study of intravenous CT-P27 post-exposure to Influenza A H3N2	28
13/LO/1877	Interpretive phenomenological exploration: imaging patient experience	14
14/LO/0234	Social Marketing drivers that influence individuals with diabetes	2

#### Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
14/LO/0165	Sickle Cell Analgesia Protocol Evaluation (SCAPE)	N/A
14/LO/0399	Retrospective cohort study of management and outcomes of MDR TB	N/A
14/LO/0601	SIPCOD (Version 1)	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
---------------	-------------------------	-------------------------

<b>Invalid Application</b>		
<b>REC Reference</b>	<b>Application Short Title</b>	<b>Number of Days on Clock</b>
13/LO/1612	UCLID	26

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

<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>
13/LO/0626	Furlong Evolution® Hip Trial	26
13/LO/1059	Probiotics and Gut Health - Version number 1	35
13/LO/1136	The Experience of being a Mother with Perinatally Acquired HIV V.1	30
13/LO/1501	A study of allergen extracts in house dust mite associated asthma	33

<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>
10/H0703/50/AM04	Understanding the changes in the brain in motor learning	AM04 Substantial Amendment Dated 16 May 2013	37
07/H0703/160/AM53	Study of MK822 in osteoporotic fracture prevention	Substantial Amendment 53	38
07/H0703/160/AM54	Study of MK822 in osteoporotic fracture prevention	Substantial Amendment 52	38
08/H0703/132/AM14	BO21000 Phase Ib GA101 Safety & efficacy Chemo Combo in B-cell fNHL	AM14 Substantial Amendment dated 12 Nov 2013	36
13/LO/0348/AM01	Mycobacterium tuberculosis phenotype in sputum	AM01 Substantial Amendment 1 Dated 10 Dec 2013	60

<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>