

National Research Ethics
Service


Health Research Authority

**NRES Committee London - West
London & GTAC**

Annual Report

01 April 2013 – 31 March 2014

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee London - West London & GTAC
Type of REC:	Recognised to review CTIMPS in Healthy Volunteers – Type I Recognised to review CTIMPs in Patients – Type III
Type of Flag:	Gene Therapy or Stem Cell Clinical Trials Phase I Studies in Healthy Volunteers Phase I Studies in Patients Research Involving Children
Chair:	Dr Catherine Urch
Vice-Chair:	Professor Gary Frost
Alternate Vice-Chair:	None
Co-ordinator:	Miss Andrea Graham
PRSC Co-ordinator:	N/A
Assistant Co-ordinator:	Miss Georgia Copeland
Committee Address:	Nottingham REC Centre The Old Chapel Royal Standard Place NG1 6FS
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Chair's overview of the past year:

The last year has been one of welcoming new members onto the committee, who have enabled us to be quorate and enhanced the discussions. This was tempered with the departure of many long standing members whom we thank for their support, insight and hard work. The committee has continued to be one of the most active with a significant amount number of amendments and advice. The GTAC work has added a new dimension to the debates and we are grateful to Prof Andrew George for overseeing the smooth integration into our regular work.

Our thanks must also go to Andrea and her team who give unfailing efficient and friendly service and without whom none of our work, nor the clinical research would be possible.

NRES Committee London - West London & GTAC Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Miss Maryam Alfa-Wali	Clinical Research Fellow, Academic Surgery Unit	Expert	10/02/2011	01/08/2013
Mr Arden Bhattacharya	Independent Barrister	Lay Plus	15/05/2013	
Professor Bob Brecher	Reader in Moral Philosophy	Lay Plus	23/01/2012	07/08/2013
Dr Tom Cairns	Consultant Nephrologist	Expert	01/06/2007	
Thomas Carroll	Consultant Neurosurgeon	Expert	12/06/2013	
Dr Tanya Carthy	GP	Expert	18/07/2011	21/03/2014
Dr Peter Chow	Consultant Neonatologist	Expert	18/07/2011	01/08/2013
Mr Stephen Cryan	Business Consultant	Lay Plus	23/09/2009	
Dr Simon Day	Statistician	Expert	07/04/2008	17/03/2014
Dr Lydia Drumright	Lecturer	Expert	18/07/2011	
Professor Gary Frost	Chair of Nutrition	Expert	23/09/2009	
Professor Andrew George	Professor of Immunology	Lay	01/11/2012	31/10/2013
Dr Uta Griesenbach	Reader in Molecular Medicine	Expert	30/09/2013	
Ms Victoria Latham	Lead Pharmacist Clinical Trials & Pharmacovigilance	Expert	23/07/2008	
Dr Fraser Macfarlane	Senior Lecturer in Health Care Management	Lay Plus	01/09/2009	
Dr Michael Maier	Head of London School of Psychiatry, Hon. Senior lecturer & Consultant	Expert	22/07/2010	01/08/2013
Ms Cinead Eileen O'Sullivan	Legal Advisor (Solicitor)	Lay Plus	30/09/2013	
Dr Roger David Palmer	Medicolegal Advisor	Expert	10/06/2013	
Ms Alison Simcock	Lay Member	Lay	30/09/2013	
Dr Catherine Urch	Consultant Palliative Medicine (Chair)	Expert	21/12/2007	

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Mr Ron Driver	Retired Lecturer/Statistician	Lay	15 th May 2013

NRES Committee London - West London & GTAC: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Thomas Carroll	Chair of rare disease charity Fanconi Hope Trustee of rare disease charity RSRT-UK	21/08/2013
Dr Uta Griesenbach	Executive board member of the British Society for Gene Therapy and cell therapy. Member of the UK CF Gene Therapy consortium	16/10/2013
Ms Cinead Eileen O'Sullivan	None	11/12/2013
Ms Victoria Latham	Lead Pharmacist for Clinical Trials at Imperial College, London	11/12/2013
Dr Lydia Drumright	Lecturer in CIPM at Imperial College London Consultant for Orbel Health Consultant for Orbel Health. Lecturer at Imperial College, London	11/12/2013
Mr Arden Bhattacharya	None	11/12/2013
Dr Fraser Macfarlane	None	11/12/2013
Dr Roger David Palmer	None	11/12/2013
Dr Simon Day	None	11/12/2013
Ms Alison Simcock	None	11/12/2013
Dr Catherine Urch	Conduct Journal Peer Reviews as requested.	11/12/2013
Professor Gary Frost	Consultant for: Unilever, Nestle, Malaysian Palm Oil Company	11/12/2013
Mr Stephen Cryan	Wife is a NHS Consultant and Scientist at Imperial College	31/03/2014

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

Month	Date	Number of Members Present at Meeting
April	17/04/2013	7
May	15/05/2013	8
June	12/06/2013	9
August	14/08/2013	9
September	11/09/2013	10
October	16/10/2013	7
November	13/11/2013	11
December	11/12/2013	11
January	15/01/2014	10
February	19/02/2014	11
March	12/03/2014	9

11 full committee meetings were held during the reporting period.

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

Name	Number of Meetings Attended
Dr Catherine Urch	11
Ms Victoria Latham	9
Dr Simon Day	8
Dr Tanya Carthy	8
Mr Arden Bhattacharya	8
Dr Fraser Macfarlane	7
Dr Roger David Palmer	7
Professor Gary Frost	7
Mr Stephen Cryan	7
Dr Lydia Drumright	6
Ms Cinead Eileen O'Sullivan	5
Ms Alison Simcock	4
Dr Tom Cairns	4
Dr Uta Griesenbach	3
Thomas Carroll	3
Professor Andrew George	2
Professor Bob Brecher	2

Number of inquorate meetings held: None

Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Dr Catherine Urch	29/04/2013 - 29/04/2013	Gene and Advanced Stem Therapy Research in the UK - New Arrangements and Future Improvements, NRES
Dr Fraser Macfarlane	29/04/2013 - 29/04/2013	Gene and Advanced Stem Cell Therapy Research in the UK - New arrangements and future improvements, NRES
Dr Simon Day	05/07/2013 - 05/07/2013	Equality and Diversity , NRES
Ms Victoria Latham	16/07/2013 - 16/07/2013	Equality & Diversity, HRA
Dr Tanya Carthy	11/09/2013 - 11/09/2013	Equality & Diversity, NRES
Dr Lydia Drumright	01/06/2013 - 01/06/2013	Delivered a 2 hour lecture on ethics involving Human Research to Masters Level Students , Imperial College London
Mr Stephen Cryan	21/09/2013 - 21/09/2013	Review of Guidance on Information sheets and Consent Forms , NRES
Mr Stephen Cryan	22/09/2013 - 22/09/2013	Review of guidance on approval of Research involving ionising radiation , NRES
Mr Stephen Cryan	22/09/2013 - 22/09/2013	Review of guidance on research involving medical devices , NRES
Mr Stephen Cryan	23/09/2013 - 23/09/2013	IRAS training module , IRAS
Dr Tom Cairns	01/08/2013 - 01/08/2013	End of life workshop, Imperial College
Dr Tom Cairns	01/08/2013 - 01/08/2013	Edited the end of life protocol for Renal Unit at Hammersmith Hospital, Hammersmith Hospital
Dr Tom Cairns	01/04/2013 - 01/04/2013	Information Governance Training , Imperial College
Dr Tom Cairns	27/09/2013 - 27/09/2013	Currently applying for ethical approval for CTIMP Study
Dr Roger David Palmer	03/03/2014 - 03/03/2014	Induction, HRA
Ms Alison Simcock	03/03/2014 - 03/03/2014	Induction, HRA
Ms Victoria Latham	01/10/2013 - 01/10/2013	Information Governance , NHS
Ms Victoria Latham	01/03/2014 - 01/03/2014	Safeguarding Adults , NHS
Ms Victoria Latham	01/03/2014 - 01/03/2014	GCP , NHS

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	16	24.24
Phase 1	3	4.55
Gene Therapy	6	9.09
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	41	62.12
Total Applications Reviewed	66	100

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	15
Number of paediatric applications reviewed	12
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	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	1	1.52
Favourable Opinion with Additional Conditions	3	4.55
Unfavourable Opinion	10	15.15
Provisional Opinion	52	78.79
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	66	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	48	72.73
Further Information Favourable Opinion with Additional Conditions	2	3.03
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	1.52
Favourable Opinion with Additional Conditions	3	4.55
Unfavourable Opinion	10	15.15
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	2	3.03
Number of studies withdrawn after the meeting	0	0.00
Total	66	100

Table 5: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	6.00
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	33
Number of days taken to final decision - mode	23
Number of SSAs (non-Phase 1) reviewed	14
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	4
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)	0.0%
Number of substantial amendments reviewed	195
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	14
Number of modified amendments over 14 days	3
Number of modified amendments over 14 days as a % of total modified amendments	21.4%

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
13/LO/0357	Phase II Trial of MultiStem in Adults with Ischemic Stroke, 16May2012	53
13/LO/0473	LUNA Trial - Pasireotide LAR and/or Everolimus in Lung NETs	49
13/LO/0677	Disordered eating in children with Gastroenterological disorders	44
13/LO/0680	Does Resilience Training increase the effectiveness of Classic CBT?	48
13/LO/0682	Imaging inflammation in tumours	35
13/LO/0684	Who will relapse into depression following Step 2 IAPT intervention?	29
13/LO/0708	A Study to Evaluate Cardiac Safety of TAS-102 in Advanced Solid Tumour	27
13/LO/0733	AGS-003 Plus Standard Treatment in Advanced RCC (ADAPT)	34
13/LO/0853	Post-operative ovarian adhesion study in women with endometriosis	33
13/LO/0854	Increase in penile dimensions using the AMS LGX penile prosthesis	30
13/LO/0870	Controlled and automatic influences on processing worry cues v1	35
13/LO/0871	Bladder bacterial biofilms in renal transplant patients	35
13/LO/0913	HSV1716 (Sephrevir TM) in combination with TACE in patients with HCC	26
13/LO/1126	Mild cognitive impairment in men following androgen deprivation.	25
13/LO/1141	GRIPHON OL/Protocol AC-065A303	29
13/LO/1174	Efficacy study of CTX0E03 injected into the brain of stroke patients	41
13/LO/1224	PSILODEP-pilot	51
13/LO/1225	PSILODEP-RCT	51
13/LO/1258	A study to test the safety of a new medicine in children with DMD	41
13/LO/1296	Functional MRI at 3T in measuring response in metastatic pNETs	32
13/LO/1308	Treatment Intensities and Targets in Rheumatoid Arthritis Therapy RCT	31
13/LO/1313	The Urinary Microbiome in Overactive Bladder	31
13/LO/1489	Phase 3 study for the treatment of HBeAg-Negative, Chronic Hepatitis B	41
13/LO/1490	TAF vs TDF for the Treatment of HBeAg Positive, Chronic Hepatitis B	41
13/LO/1497	2-Hydroxyglutarate MRS imaging	30
13/LO/1507	Confocal endomicroscopy of fluorescein-stained breast and lymph nodes	37
13/LO/1510	Do gut hormones mediate the beneficial effects of Roux-en-Y bypass?	41
13/LO/1654	FOCUS Study	31
13/LO/1667	Pathophysiology of Dilated Cardiomyopathy	31

13/LO/1677	Dare to Age Well: A Focus on Women	54
13/LO/1679	Inter-rater reliability of two tests of muscle power	36
13/LO/1691	ProCAID	47
13/LO/1807	Reproductive hormones during sustained administration of kisspeptin	26
13/LO/1813	Effect of minocycline on chronic neuroinflammation following TBI v1.0	39
13/LO/1822	Calcineurin resistant EBV specific T cells for Solid Organ Transplant	23
13/LO/1860	LUM001 in paediatric patients with cholestasis	24
13/LO/1893	CARE in Sickle Cell Disease	37
13/LO/1916	Reproduceability of the 11C-PBR28 PET signal	25
13/LO/1918	Brain PET imaging of the adenosine A2A receptor (Ver 1.1)	25
14/LO/0010	Patient iPSCs for Neurodevelopmental Disorders (PiNDs)	28
14/LO/0056	PREOB®-ON3 - A bone cell therapy for hip osteonecrosis	32
14/LO/0067	Dopamine dysregulation following TBI	33
14/LO/0227	LAIV Immuno	23
14/LO/0243	Investigating Immune Mechanisms in Atopic Eczema, Version 1	37
14/LO/0252	CAREGIVERS EXPERIENCES OF FAMILY INTERVENTIONS IN FEP	30
14/LO/0257	i-VAC (Internet Virtual AMD Clinic)	32
14/LO/0273	SPIN Phase 2 Follow up	26
14/LO/0275	Experiences and perceptions of donating to UK Milk Banks	41

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/LO/0460	Intracoronary biomarkers of infarct size in STEMI	32
13/LO/1694	HGT-1410 in Pediatric Patients with Early Stage MPS IIIA	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
13/LO/1171	The survival of teeth following root canal re-treatment	28

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/LO/0421	Hypoxia and the flow field in native arteriovenous fistulae	23
14/LO/0016	Intraoperative confocal endomicroscopy of parathyroid glands	24
14/LO/0411	The National Study of Health and Wellbeing 2014	22

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/LO/0324	Mild cognitive impairment in men following androgen deprivation.	23
13/LO/0461	Renal denervation in hypertensive diabetics improves cardiac function	23
13/LO/0685	Low Intensity GAD Intervention: A Feasibility and Acceptability Study	23
13/LO/0707	GSK2800528 – first doses in humans & comparison with Humira; ver 1	27
13/LO/0779	Psilocybin for depression	26
13/LO/1218	Patient iPSCs for Neurodevelopmental Disorders (PiNDs)	58
13/LO/1854	LAIV Immuno	22
14/LO/0233	The GHB Trial	24
14/LO/0315	Biomarkers of Immunologically Mediated Musculoskeletal Disease	24
14/LO/0409	Phase 1 TAK-079 Single Dose Escalation Study in Healthy Subjects	44

Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
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Provisional Opinion Pending Consultation with Referee

REC Reference	Application Short Title	Number of Days on Clock
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Further information response not complete

REC Reference	Application Short Title	Number of Days on Clock
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Withdrawn after the meeting

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

REC Reference	Application Short Title	Number of Days on Clock
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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	
Proportionate review applications for ethical review over 14 days 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
GTAC185/AM03/1	Efficacy study of PROSTVAC vaccine in patients with prostate cancer	Modified amendment: IBv2.2 18th Dec 12, UK ICF v.4	17
11/LO/1733/AM07/1	Blinatumomab (MT103) in adult patients with relapsed/refractory ALL	Modified Amendment 7	15
07/H0707/105/AM07/1	Quantification of fetal brain growth and development using MRI	Modified Amendment 4.1	15
Section 30 application over 60 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock