

NRES Committee London - Hampstead

Annual Report

01 April 2013 – 31 March 2014

Part 1 - Committee Membership and Training

Name of REC: NRES Committee London - Hampstead

Type of REC: Recognised, Type II, Type III

Type of Flag: Paediatric

Chair: Miss Stephanie Ellis

Vice-Chair: Dr. Manish Saxena

Alternate Vice-Char: Mr Paul Hardiman

REC Manager: Mrs Alka Bhayani (up to 01 December 2013)

Mr Atul Patel (from December 2013)

REC Assistant: Miss Amy Spruce (up to 01 December 2013)

Miss Laura Hewitt (from December 2013)

Committee Address: Skipton House

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Chair's overview of the past year:

This year was my second year as Chair of Hampstead REC. I am grateful to everyone on the committee for their commitment and helpfulness.

Alka Bhayani, our co-ordinator, has moved on and Atul Patel, has joined us and helped us to keep on top of the many applications we have to review.

We strive to be a friendly helpful committee. We recognise that one of the most worrying parts of doing medical research is facing a Research Ethics Committee, especially attending a meeting. It can be a very daunting experience. I am pleased how many researchers come back to us. They will probably never get to the stage of enjoying being reviewed by a REC, but they seem to recognise that we are fair and helpful in our comments.

We continue to have the problem of students who come to us having received little or no support from their supervisors. This is the seventh year I have had to report continuing dissatisfaction with the poor support some researchers receive from their supervisors. We have had a number of researchers whose applications have been given scant scrutiny by anyone and as a result their proposals have not shown their efforts in the best light. Preferable to issuing unfavourable opinions, we prefer to provide the researcher with feedback that helps them change their proposal to one that no longer raises ethical issues. A number of times we have had to write directly to the supervisor to remind them of their responsibilities to their students and get them to provide a more appropriate level of supervision.

Having said that the quality of most of the research is good: very good indeed - well thought out and presented. The changes we most often ask for are ones more to do with the information provided to potential participants and mainly to make it more likely that they will agree to take part.

Our Committee continues to work well. I never cease to be impressed by the commitment of the members. They put in a lot of work, not only during the meeting but before hand when they read everything very carefully. Those researchers who attend our meetings see us for only a short time, but they rapidly realise that we have looked at their applications very carefully and can help them improve them still further.

We were sorry to see Reverend Mitchell go. We were pleased to welcome Dr Etchegoyen and Dr Jacobs as members of our Committee.

NRES Committee London - Hampstead Membership:

Name	Occupation	Expert or	Da	tes
	_	Lay	Appointed	Resigned
Dr Waheeb Atia	Retired Consultant	Expert	01/11/2010	
	Physician			
Mrs Jacqueline Birks	Senior Medical Statistician	Expert	12/10/2008	
Dr Rahul Chodhari	Consultant Paediatrician	Expert	03/04/2008	
Miss Stephanie Ellis	Former Civil Servant	Lay Plus	21/01/2013	
Dr Alicia Isabel Etchegoyen	Psychiatrist	Expert	12/11/2013	
Mr Paul Hardiman	Consultant Gynaecologist/Senior Lecturer in Obstetrics and Gynaecology	Expert	01/09/2010	
Dr Michael Jacobs	Retired Academic Pharmacologist	Lay	14/05/2013	
Miss Monica Jefford	Retired Midwife	Lay	31/08/2011	
Miss Mina Karamshi	Specialist Sister in Radiology	Expert	02/11/2010	
Dr Jane Lees-Millais	General Practitioner	Expert	01/07/2011	
Reverend Robert Mitchell	Lead Chaplain	Lay Plus	01/10/2004	31/12/2013
Ms Anna Osadcow	Clinical Trials Research Pharmacist	Expert	01/01/2013	
Ms Ann Rosenthal	Literary Consultant (Retired)	Lay Plus	01/01/2014	
Dr. Manish Saxena	Clinical Lecturer and Clinical Research Fellow	Expert	01/07/2013	
Mrs Arlene Renee Seaton	Lay Member	Lay Plus	06/02/2013	
Mrs Wendy Spicer	Pharmacist	Expert	01/12/2005	
Dr Latha Padma Weston	Consultant Psychiatrist	Expert	14/12/2011	
Miss Sarah Louisa Wisniewski	General Manager for Emergency Services	Lay Plus	18/05/2011	

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended
Dr Victoria Chapman	Consultant Child and	Expert	16/10/2013
	Adolescent Psychiatrist		20/11/2013
			15/01/2014

NRES Committee London - Hampstead: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Dr Michael Jacobs	No declared interests.	24/06/2013
Miss Stephanie Ellis	None	20/11/2013
Dr Alicia Isabel Etchegoyen	None	12/11/2013
Mrs Arlene Renee Seaton	None	20/11/2013
Ms Anna Osadcow	None	20/11/2013
Dr Jane Lees-Millais	None	16/01/2014
Mrs Wendy Spicer	None	20/11/2013
Miss Mina Karamshi	None	20/11/2013
Dr Rahul Chodhari	Has shares in BT and Vodaphone	19/03/2014
Mr Paul Hardiman	Senior lecturer at UCL and within the role conducts research.	31/03/2014
Dr Waheeb Atia	Member of BMA and a doctor	20/11/2013
Mrs Jacqueline Birks	Shares in Venalis	19/03/2014
Miss Monica Jefford	Shares in BT, Iberdrola, SSE plc Member of St Andrew's Church Croydon Churches Floating Shelter Volunteer Croydon Neighbourhood Care Association Bowel Cancer UK volunteer At The Royal Marsden NHS Foundation Trust: i) PPI Lead for SWLCRN (in transition) - Bank Administration post ii) Patient and Carer Research Review Panel member iii) Patient and Carer Advisory Group member Institute of Cancer Research: Trial Management group member NCRI/N member Cancer Commissioning Team South Partnership Group Member CLRN PPI Stakeholder Implementation Group Member Faculty of Health and Social Care Sciences Kingston University, St George's University of London PPI sessions with radiogaphy students Guys and St Thomas' NHS Foundation Trust: Trainee Chaplain - Bank post Also: Peer Review (various hospitals) - National Cancer Action Team	21/11/2013
Dr Latha Padma Weston	Trustee at Barnet Bereavement Society	15/01/2014
Dr. Manish Saxena	Member of British Hypertension Society chief,	20/11/2013
	principal and co investigator on many academic and commercial pharma sponsored studies.	
Reverend Robert Mitchell	None	20/11/2013
Ms Ann Rosenthal	None	19/03/2014
Miss Sarah Louisa Wisniewski	General Manager for Emergency Services at UCLH, includes providing support for staff undertaking R&D & putting funding/application requests.	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	10
May	15/05/2013	9
June	19/06/2013	12
August	21/08/2013	10
September	18/09/2013	12
October	16/10/2013	10
November	20/11/2013	11
December	18/12/2013	15
January	15/01/2014	12
February	19/02/2014	11

¹⁰ full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
April	17/04/2013	3
May	15/05/2013	3
June	19/06/2013	3
August	21/08/2013	3
September	18/09/2013	4
October	16/10/2013	3
November	20/11/2013	3
December	17/12/2013	3
January	15/01/2014	3

⁹ proportionate review sub-committee meetings were held during the reporting period.

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

Name	Number of Meetings Attended
Dr Waheeb Atia	10
Miss Stephanie Ellis	10
Mrs Jacqueline Birks	9
Mrs Wendy Spicer	8
Ms Anna Osadcow	8
Mrs Arlene Renee Seaton	8
Mr Paul Hardiman	7
Reverend Robert Mitchell	6
Miss Mina Karamshi	6
Miss Monica Jefford	6
Miss Sarah Louisa Wisniewski	6
Dr Jane Lees-Millais	6
Dr Latha Padma Weston	5
Dr Michael Jacobs	5
Dr Rahul Chodhari	4
Dr. Manish Saxena	4
Dr Alicia Isabel Etchegoyen	3
Dr Victoria Chapman	3
Ms Ann Rosenthal	1

Number of inquorate meetings held: None

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

Name	Number of Meetings Attended
Miss Stephanie Ellis	9
Dr Jane Lees-Millais	6
Dr Rahul Chodhari	5
Reverend Robert Mitchell	3
Mrs Arlene Renee Seaton	2
Mrs Jacqueline Birks	1
Dr. Manish Saxena	1
Miss Monica Jefford	1

Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Ms Anna Osadcow	04/07/2013 - 04/07/2013	Induction, HRA
Dr Jane Lees-Millais	10/04/2013 - 10/04/2013	Equality & Diversity, Local organisation
Ms Anna Osadcow	24/09/2013 - 24/09/2013	Quantitative Research Methods and Statistics: A Health Research Authority Workshop, HRA
Mrs Arlene Renee Seaton	18/09/2013 - 18/09/2013	Induction, HRA
Mrs Jacqueline Birks	27/06/2013 - 27/06/2013	Online course – Information governance, Online
Reverend Robert Mitchell	19/06/2013 - 19/06/2013	13th Annual Conference of the UK Clinical Ethics Network Ethics of Healthcare in a Multicultural So, UKCEN
Dr Waheeb Atia	24/09/2013 - 24/09/2013	Quantitative Research Methods and Statistics: A Health Research Authority Workshop, HRA
Dr. Manish Saxena	07/10/2013 - 07/10/2013	Equality & Diversity, HRA
Miss Monica Jefford	02/11/2013 - 02/11/2013	Equality & Diversity, HRA
Miss Sarah Louisa Wisniewski	20/11/2013 - 20/11/2013	Equality & Diversity, HRA
Dr Alicia Isabel Etchegoyen	20/11/2013 - 20/11/2013	National Members Training Day, Health Research Authority
Miss Stephanie Ellis	02/09/2013 - 02/09/2013	Chairs' NREAP meeting, Health Research Authority
Dr Alicia Isabel Etchegoyen	19/03/2014 - 19/03/2014	Local Training Day - Human Tissue Act
Dr Alicia Isabel Etchegoyen	15/01/2014 - 15/01/2014	Child safeguarding in research context
Miss Stephanie Ellis	15/01/2014 - 15/01/2014	Local Training Day – Child safeguarding in research context
Miss Stephanie Ellis	19/03/2014 - 19/03/2014	Local Training Day - Human Tissue Act
Dr. Manish Saxena	19/03/2014 - 19/03/2014	Local Training Day - Human Tissue Act
Ms Anna Osadcow	15/01/2014 - 15/01/2014	Local Training Day – Child safeguarding in research context
Ms Anna Osadcow	19/03/2014 - 19/03/2014	Local Training Day - Human Tissue Act
Mrs Arlene Renee Seaton	15/01/2014 - 15/01/2014	Local Training Day – Child safeguarding in research context
Mrs Arlene Renee Seaton	19/03/2014 - 19/03/2014	Local Training Day - Human Tissue Act
Mrs Jacqueline Birks	15/01/2014 - 15/01/2014	Local Training Day – Child

		safeguarding in research context
Mrs Jacqueline Birks	19/03/2014 - 19/03/2014	Local Training Day - Human Tissue Act
Dr Jane Lees-Millais	15/01/2014 - 15/01/2014	Local Training Day – Child safeguarding in research context
Dr Latha Padma Weston	15/01/2014 - 15/01/2014	Local Training Day – Child safeguarding in research context
Dr Latha Padma Weston	19/03/2014 - 19/03/2014	Local Training Day - Human Tissue Act
Mr Paul Hardiman	15/01/2014 - 15/01/2014	Local Training Day – Child safeguarding in research context
Mr Paul Hardiman	19/03/2014 - 19/03/2014	Local Training Day - Human Tissue Act
Miss Mina Karamshi	19/03/2014 - 19/03/2014	Local Training Day - Human Tissue Act
Miss Monica Jefford	19/03/2014 - 19/03/2014	Local Training Day - Human Tissue Act
Miss Sarah Louisa Wisniewski	15/01/2014 - 15/01/2014	Local Training Day – Child safeguarding in research context
Dr Rahul Chodhari	19/03/2014 - 19/03/2014	Local Training Day - Human Tissue Act
Mrs Wendy Spicer	19/03/2014 - 19/03/2014	Local Training Day - Human Tissue Act
Dr Waheeb Atia	19/03/2014 - 19/03/2014	Local Training Day - Human Tissue Act
Mrs Wendy Spicer	15/01/2014 - 15/01/2014	Local Training Day – Child safeguarding in research context
Dr Waheeb Atia	15/01/2014 - 15/01/2014	Local Training Day – Child safeguarding in research context

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	14	28.57
Phase 1	2	4.08
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	33	67.35
Total Applications Reviewed	49	100

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	5
Number of student applications reviewed	13
Number of paediatric applications reviewed	6
Number of device applications reviewed	0
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	1
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	3	6.12
Favourable Opinion with Additional Conditions	9	18.37
Unfavourable Opinion	0	0.00
Provisional Opinion	36	73.47
Invalid	0	0.00
No Opinion Pending Consultation with Referee	0	0.00
Provisional Opinion Pending Consultation with Referee	1	2.04
Not Requiring Review by NHS REC	0	0.00
Total	49	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	36	73.47
Conditions		
Further Information Favourable Opinion with Additional	0	0.00
Conditions		
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	3	6.12
Favourable Opinion with Additional Conditions	9	18.37
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	1	2.04
Total	49	100

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

Total Applications Reviewed	19

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

Decisions taken at proportionate review sub-	Number	%
committee meetings		
Favourable Opinion with Standard Conditions	11	57.89
Favourable Opinion with Additional Conditions	2	10.53
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	6	31.58
Unfavourable Opinion	0	0.00
Total	19	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	4.90
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	23
Number of SSAs (non-Phase 1) reviewed	2
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	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	133
Number of substantial amendments over 35 days	1
Number of substantial amendments over 35 days as a % of total substantial amendments	0.8%
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	1
Number of modified amendments over 14 days	0
Number of modified amendments over 14 days as a % of total modified amendments	0.0%
Number of proportionate review applications for ethical review over 14 days	2
Number of proportionate review applications over 14 days as a % of total	10.5%

Table 8: 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/0524	Clinical Pilot Study of Topical Bleosome on BCCs	42
13/LO/0560	BF Spiromax Vs Symbicort Turbohaler in patients with Persistent Asthma	24
13/LO/0566	VX11-770-108 Ivacaftor in 2-5 yr old CF Pts with CFTR Gating Mutation	27
13/LO/0634	Late onset depression: Correlates of dopaminergic function	48
13/LO/0664	A RCT comparing conventional sinus surgery with Balloon si	33
13/LO/0676	Investigation of Skin Barrier function in different body sites, 1.3	37
13/LO/0761	Exploring relationships within the awake craniotomy context (v. 1.0)	13
13/LO/0813	A PET study to assess brain uptake of GSK2647544; version A	22
13/LO/0815	Long Term Antibiotic Therapy on Exacerbation frequency in Stable COPD	23
13/LO/0840	Voice Collective Evaluation Project	29
13/LO/0845	Developing alternative methods to detect influenza antibodies	24
13/LO/0847	IPF-PRoM Study	24
13/LO/0868	ERNEST	25
13/LO/1009	MATRIX	13
13/LO/1085	The London Alpha-1-Antitrypsin Deficiency Cohort	26
13/LO/1091	Non-invasive pressure-volume analysis: NIPVA study version 1.1	25
13/LO/1150	Role of left atrial sites that trigger pulmonary vein ectopy in PAF	29
13/LO/1292	MicroRNAs in Crohn's Disease	46
13/LO/1321	GB28547 - Lebrikizumab in patients with idiopathic pulmonary fibrosis	23
13/LO/1323	A study of Ferriprox to see how safe it is and how well it works	20
13/LO/1331	Does transdermal magnesium correct low serum magnesium?	19
13/LO/1334	FH Study, Version 7	20
13/LO/1335	OM-85-BV Mechanistic study in COPD	27
13/LO/1353	Comparing impact of two arts activities on wellbeing of PWD & carers	17
13/LO/1358	Men with learning disabilities and their perception of fatherhood	13
13/LO/1364	Information sources in IBD	14
13/LO/1453	Exhaled hydrogen sulphide in asthma	20
13/LO/1476	Intraoperative Ureter Imaging with Methylene Blue & NIR Light	25
13/LO/1493	Executive Function Deficits in HIV-Associated Neurological Decline	23

13/LO/1520	Study Of Diabetic Nephropathy with Atrasentan	50
13/LO/1700	VX09-809-102 Lumacaftor Alone and Lumacaftor/Ivacaftor in Adult CF	42
13/LO/1707	Investigating the pathophysiology of mesenteric infarction	35
13/LO/1712	MatImms@Imperial: A mother-infant study of immune responses to vaccine	30
13/LO/1725	Randomised comparison of iFR to FFR	32
13/LO/1935	Psychological Impact and Coping Strategies; 20 Year Review	14
14/LO/0040	CONCYST:Needle-based confocal laser endomicroscopy of pancreatic cysts	17
14/LO/0120	Zibotentan better renal scleroderma outcome study (ZEBRA)	23
14/LO/0121	PAKT	24
14/LO/0126	Treatment expectations - Version 1	43
14/LO/0129	Respiratory and peripheral muscle function in people with lung cancer	33
14/LO/0211	Safety tolerability PK of TMC435/647055 in healthy Japanese volunteers	45
14/LO/0265	Comparison of two root canal irrigation protocols - V01	31

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock

Further Informati	on Unfavourable Opinion	
REC Reference	Application Short Title	Number of Days on Clock

Favourable Opinion with Standard Conditions		
REC Reference	Application Short Title	Number of Days on Clock
13/LO/0482	Reducing the frequency and severity of voices: AVATAR Clinical Trial	23
13/LO/0525	Palatability of Xaluprine	23
13/LO/0616	Narratives of Chronic Pain in Black Minority and Ethnic Gr	8
13/LO/0679	Psychological state before and after aortic root surgery	24
13/LO/0767	Exploring views on bowel cancer screening information.	11
13/LO/0772	Validating an Embedded Reality Version of the Nine Hole Peg Test	11
13/LO/1018	Ehler Danlos Syndrome Hypermobility type and GI food allergies 1	13
13/LO/1509	An investigation of the microorganisms present in diabetic foot ulcers	14
13/LO/1511	MIC programme: module 2, the interview module.	14
13/LO/1514	Improved testing for microsatellite instability in tumour tissue	11
13/LO/1650	Development of a PROM for pituitary surgery	9

13/LO/1655	Effects of ageing on connective tissue metabolism in female prolapse	7
13/LO/1849	Measuring the activity of cancer-promoting proteins in lung cancer	7
14/LO/0156	Ambulatory skin temperature asymmetry measurement using iButtons v1	13

Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
13/LO/0497	ECO APSS	36
13/LO/0618	Online educational tool for diabetes self-care behaviours v1	9
13/LO/1104	PB-102-F02: Extension of the PB-102-F01 study (PRX-102 for ERT in Fabr	22
13/LO/1184	TheraSphere® vs soc Sorafenib in Hepatocellular Carcinoma with PVT	22
13/LO/1318	Persistence of malaria DNA post treatment	16
13/LO/1933	Parent experiences: Autism diagnostic process	25
13/LO/1968	Developing the concept of 'being a carer' for use in cancer care v1	30
14/LO/0208	Sodium Valproate for GSDV Version 1.0 13th January 2014	26
14/LO/0245	The effect of sucrose on liver fat	26
14/LO/0263	Remodelling and ventricular fibrosis in repaired tetralogy of Fallot	38
14/LO/0277	18F-flutemetamol PET and MRI in patients with Multiple Sclerosis	27

Unfavourable Opi	nion	
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	
13/LO/1778	An assessment of hepcidin ELISA as a diagnostic tool for ACD	13	

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 9: 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			
13/LO/1353	Comparing impact of two arts activities on wellbeing of PWD & carers	17	
13/LO/1968	Developing the concept of 'being a carer' for use in cancer care v1	30	

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 Day Clock		Number of Days on Clock	
09/H0720/133/AM16	MDS patients treated with deferasirox for transfusional iron overload	Substantial amendment - Protocol Amendment 04	48

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