

**NRES Committee North East -
Newcastle & North Tyneside 2**

Annual Report

01 April 2011 – 31 March 2012

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee North East - Newcastle & North Tyneside 2
Type of REC:	Type III
Type of Flag:	CTIMP, MCA, Phase I in Patients
Chair:	Professor Philip M Preshaw
Vice-Chair:	Mr Michael Wyatt
Alternate Vice-Char:	Mr Peter Morton
Co-ordinator:	Ms Gillian Mayer
PRSC Co-ordinator:	Ms Gillian Mayer
Assistant Co-ordinator:	N/A
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Chair's overview of the past year:

2011-12 has been a challenging, but successful year for the committee. We have consolidated our membership into a strong, cohesive and functional group, and we have left behind the worries of previous years when we were sometimes at risk of not being quorate. We have welcomed new members to the committee who bring a wealth of valuable experience in a range of disciplines that are highly relevant to the Committee.

The workload of the Committee has increased compared to the previous year. This has resulted from the successful introduction of the Proportionate Review system, and we were one of the first committees in the country to take on this responsibility. So, although the number of applications reviewed at the main committee meetings has reduced slightly compared to the previous year, our overall throughput has increased significantly. All members of the committee have embraced the PR concept, and we have introduced very successful working practices to manage this commitment.

All members of the committee have met the attendance requirements in this year and all have taken on significant responsibility for meeting the annual training requirements.

Furthermore, I am very pleased that the number of days taken to final decision continues to reduce, with, in this reporting year, a mean of 24 days. This represents excellent service and support of the research community.

Anecdotally, I can report that our committee continues to be held in high regard by local researchers, on account of our sensible and pragmatic approach, and the supportive and positive context of our meetings.

The main challenge we face at the moment is the workload. While PR is a very positive step, I feel that a large burden has been placed on our committee members over the last 12 months. And, although the committee members have been very willing to take on this challenge, I hope, as more committees around the country begin to engage with the PR process, that our workload will reduce. After all, the committee is made up of individuals, all of whom are very busy, who volunteer their time to participate in the work of the committee. As an additional comment, large quantities of information seem to flow from NRES head office on a very regular basis, which are also very difficult and challenging for volunteer committee members to deal with. I believe that some thought should be given to stemming this tide, to make the information more focussed and succinct.

Final thanks, as always, go to Gillian Mayer, our outstandingly excellent coordinator. Her work is of the very highest standard, and I would not be able to fulfil my role without her excellent support.

NRES Committee North East - Newcastle & North Tyneside 2 Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mr Chris Barron	NCRN Team Lead	Expert	16/07/2007	
Dr Catherine F M Bartley	Consultant in Anaesthesia and Intensive Care	Expert	01/03/2003	
Mrs Nermine Basta	Research Assistant/Statistician	Expert	01/08/2011	
Mrs Ann Boardman	Retired Educationalist	Lay Plus	01/02/2010	
Mr Andrew Brenikov	Historian	Lay Plus	01/04/2008	
Rev Nigel M Goodfellow	Head of Chaplaincy	Lay Plus	01/03/2003	
Dr Robert Jefferson	Consultant in Environmental Medicine	Expert	01/03/2008	
Dr Sumaira MacDonald	Consultant Vascular Radiologist/Honorary Clinical Senior Lecturer	Expert	09/07/2003	
Mrs Gaynor Mitchell	Part-time Biology Lecturer (Retired)	Lay Plus	01/06/2011	
Mr Peter Morton	Voluntary Worker/Former Contracts-Procurements Manager	Lay Plus	01/09/2008	
Mrs Susan P Phillips	Clinical Lead Pharmacist	Expert	13/10/2003	
Professor Philip M Preshaw	Professor of Periodontology and Consultant in Restorative Dentistry	Expert	01/03/2003	
Ms Vicky Ryan	Statistician	Expert	15/07/2011	
Dr Akash Sinha	Paediatrics Specialist Registrar	Expert	01/07/2011	
Dr Jared Thornton	Clinical Trials Co-ordinator	Lay	12/07/2011	
Mr Michael Wyatt	Consultant General and Vascular Surgeon	Expert	01/03/2003	

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended
Mrs Nermine Basta	Research Assistant/Statistician	Expert	16 September 2011 - (attended as an Observer with statistician Vicky Ryan) 16 November 2011 18 January 2012

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Mr Paddy Stevenson	Research Operations Manager	Expert	22 June 2011
Dr John Newton	Retired	Lay Plus	13 April 2011 22 June 2011
Dr Sumanto Haldar	Research Scientist	Lay	13 April 2011
Mr Malcolm Khan	Law Lecturer	Lay	22 June 2011
Mrs Cheryl Anderson	Dental Practice Manager	Lay Plus	22 June 2011
Dr Mike Bone	Consultant Physician	Expert	01 July 2011

Member Bank: N/A

Name	Occupation	Expert or Lay	Meeting date attended

Number of inquorate meetings held: None

NRES Committee North East - Newcastle & North Tyneside 2: Members' Declarations of Interests

Name	Declaration of Interest	Date
Mr Chris Barron	Currently manages the late phase oncology trials unit at Sir Bobby Robson Cancer Trials Research Centre, Freeman Hospital, Newcastle upon Tyne Hospitals NHS Foundation Trust	18/01/2012
Dr Catherine F M Bartley	Supervision of trainees, giving advice about research and ethics applications	19/12/2011
Mrs Nermine Basta	No interest declared	10/01/2012
Mrs Ann Boardman	No interests declared	17/01/2012
Mr Andrew Brenikov	No interests declared	20/12/2011
Rev Nigel M Goodfellow	Governor of Liver North, based at Freeman Hospital, Newcastle Hospitals NHS Foundation Trust. This is a charity to support research into liver disease and also patients and their relatives	23/02/2012
Dr Robert Jefferson	Ethical researcher so will be looking for ethical approval for work in the future	14/01/2012
Mrs Susan P Phillips	No interests declared	12/02/2012
Professor Philip M Preshaw	Member of Editorial Advisory Board for Diabetes Research and Wellness Foundation -a charity that is involved with research into diabetes Panel Member for the NIHR Doctoral Panel Awards	03/01/2012
Dr Sumaira MacDonald	No interests declared	21/12/2011
Mrs Gaynor Mitchell	Member of League of Friends (Ferndene) for Prudhoe Hospital – this organisation will not be involved in research	29/12/2011
Mr Peter Morton	General advisor in the Citizens Advice Bureau - although unlikely to be involved in research this could be a possibility	20/12/2011
Ms Vicky Ryan	No interest declared	27/01/2012
Dr Akash Sinha	No interests declared	15/01/2012
Dr Jared Thornton	No interests	18/01/2012
Mr Michael Wyatt	No interests declared	24/12/2011

Meetings for Full Ethical Review 01 April 2011 - 31 March 2012:

Month	Date	Number of Members Present at Meeting
April	13/04/2011	7
May	18/05/2011	7
June	22/06/2011	8
July	20/07/2011	10
September	21/09/2011	7
November	16/11/2011	12
December	14/12/2011	10
January	18/01/2012	11
February	22/02/2012	8
March	21/03/2012	13

10 full committee meetings were held during the reporting period.

Proportionate Review Sub Committee Meetings held during 01 April 2011 - 31 March 2012:

Month	Date	Number of Members Present at Meeting
April	13/04/2011	4
April	21/04/2011	3
May	27/05/2011	3
July	01/07/2011	3
August	05/08/2011	3
September	09/09/2011	3
October	14/10/2011	3
November	16/11/2011	3
December	21/12/2011	3
January	18/01/2012	4
February	20/02/2012	3
March	21/03/2012	3

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

Attendance of Members at full REC meetings: 01 April 2011 – 31 March 2012:

Name	Number of Meetings Attended
Mr Andrew Brenikov	9
Professor Philip M Preshaw	8
Mr Peter Morton	7
Mrs Ann Boardman	7
Mr Chris Barron	7
Dr Robert Jefferson	7
Dr Akash Sinha	6
Mr Michael Wyatt	6
Mrs Gaynor Mitchell	5*
Dr Catherine F M Bartley	5*
Dr Jared Thornton	5*
Dr Sumaira MacDonald	5*
Rev Nigel M Goodfellow	4*
Ms Vicky Ryan	4*
Mrs Nermine Basta	2*

*All members met statutory requirements of at least two thirds attendance of annual meetings held, including PR attendances. Members who joined the REC mid-way through the reporting year also met statutory requirements.

**Attendance of Members at proportionate review sub-committee meetings:
01 April 2011 – 31 March 2012:**

Name	Number of Meetings Attended
Professor Philip M Preshaw	7
Rev Nigel M Goodfellow	7
Mr Andrew Brenikov	5
Mr Michael Wyatt	4
Dr Sumaira MacDonald	4
Mr Peter Morton	2
Mrs Gaynor Mitchell	2
Dr Robert Jefferson	2
Dr Mike Bone	1
Mr Chris Barron	1

Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Mr Chris Barron	28/06/2011 - 28/06/2011	Statistics Training (NRES)
Dr Catherine F M Bartley	28/03/2012 - 28/03/2012	National Members' Training Day (NRES)
Mrs Nermine Basta	22/02/2012 - 22/02/2012	Induction (NRES)
Mrs Ann Boardman	22/09/2011 - 22/09/2011	NRES Informed Consent and Explaining Risk in Randomised Trials (NRES)
Mrs Ann Boardman	02/02/2012 - 02/02/2012	Human Tissue Act (NRES)
Mrs Ann Boardman	21/09/2011 - 21/09/2011	MCA DVD (NRES)
Mr Andrew Brenikov	19/09/2011 - 19/09/2011	HRA Update Session (NRES)
Mr Andrew Brenikov	21/09/2011 - 21/09/2011	MCA DVD (NRES)
Mr Andrew Brenikov	22/09/2011 - 22/09/2011	NRES Informed Consent and Explaining Risk in Randomised Trials (NRES)
Rev Nigel M Goodfellow	27/03/2012 - 27/03/2012	National Members' Training Day (NRES)
Dr Sumaira MacDonald	24/02/2012 - 24/02/2012	MCA DVD (NRES)
Mrs Gaynor Mitchell	19/10/2011 - 19/10/2011	Medical Devices (CLRN)
Mrs Susan P Phillips	19/09/2011 - 19/09/2011	NRES Update Session (NRES)
Professor Philip M Preshaw	14/02/2012 - 14/02/2012	North East REC Centre Training Event (Newcastle & North Tyneside 1 REC)
Ms Vicky Ryan	10/01/2012 - 10/01/2012	Induction (NRES)
Ms Vicky Ryan	21/09/2011 - 21/09/2011	MCA DVD (NRES)
Ms Vicky Ryan	14/02/2012 - 14/02/2012	North East REC Centre Training Event (Newcastle & North Tyneside 1 REC)
Dr Akash Sinha	11/10/2011 - 11/10/2011	Induction (NRES)
Dr Jared Thornton	19/09/2011 - 19/09/2011	HRA Update Session (NRES)
Dr Jared Thornton	21/09/2011 - 21/09/2011	MCA DVD (NRES)
Dr Jared Thornton	14/01/2012 - 14/01/2012	Induction (NRES)
Mr Michael Wyatt	21/09/2011 - 21/09/2011	MCA DVD (NRES)

Self-Directed Learning Forms Completed

Dr Robert Jefferson
Professor Philip M Preshaw
Dr Sumaira MacDonald
Mr Peter Morton
Mr Michael Wyatt

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	7	15.56
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	38	84.44
Total Applications Reviewed	45	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	4
Number of studies withdrawn prior to the meeting	5
Number of student applications reviewed	16
Number of paediatric applications reviewed	2
Number of device applications reviewed	1
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	3
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	2.22
Favourable Opinion with Additional Conditions	16	35.56
Unfavourable Opinion	6	13.33
Provisional Opinion	22	48.89
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	45	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	20	44.44
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	2.22
Favourable Opinion with Additional Conditions	16	35.56
Unfavourable Opinion	6	13.33
Provisional Opinion	1	2.22
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	1	2.22
Number of studies withdrawn after the meeting	0	0.00
Total	45	100

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

Total Applications Reviewed	37
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Table 6: Decisions given at proportionate review sub-committee meetings held within the reporting period:

Decisions taken at proportionate review sub-committee meetings	Number	%
Favourable Opinion with Standard Conditions	24	64.86
Favourable Opinion with Additional Conditions	9	24.32
No Opinion transfer to full committee for review	2	5.41
Provisional Opinion	2	5.41
Unfavourable Opinion	0	0.00
Total	37	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	4.50
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	24
Number of days taken to final decision - mode	19
Number of SSAs (non-Phase 1) reviewed	0
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%
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	46
Number of substantial amendments over 35 days	1
Number of substantial amendments over 35 days as a % of total substantial amendments	2.2%
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	3
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*	0
Number of proportionate review applications over 14 days as a % of total	0.00%

***NB – Proportionate Review Service was in pilot phase until September 2011 and was an aim not a target**

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
11/NE/0073	Study of Primary Hypercholesterolemia or Mixed Dyslipidemia Patients	28
11/NE/0079	ASL Validation	45
11/NE/0122	A randomised study looking at ticagrelor therapy in STEMI patients	35
11/NE/0124	Monofer® versus Intravenous Iron Sucrose in CKD-5D	28
11/NE/0131	Additional pain control using Surgically Placed Wound Catheters (SPWC)	36
11/NE/0164	IV-AID IV fluid and the Acutely Intoxicated.	29
11/NE/0165	Mental Health Care Coordination Project (Phase 2 & 3)	36
11/NE/0187	Quality of life in survivors of childhood or young adult cancer	22
11/NE/0195	The efficacy of a self-esteem group.	28
11/NE/0207	PM1183-B-001-10 (v 2.0 dated 04/February/2011)	20
11/NE/0271	Cognitive Behaviour Therapy for bipolar depression	41
11/NE/0281	Patient reported outcome measure in orthodontic patients	14
11/NE/0331	EACH	32
11/NE/0360	A natural history study of dysferlinopathy	20
11/NE/0373	Adenosine testing to DEtermine the need for Pacing Therapy (ADEPT-ILR)	19
11/NE/0381	Haemodynamic assessment by Perfusion Index (HAPI)	20
12/NE/0007	GM-CSF mediated reversal of impaired neutrophil phagocytosis (V 1.1)	27
12/NE/0019	Microbubbles for sentinel node detection in vulvar cancer	16
12/NE/0063	AAIDED - Version 1	31
12/NE/0070	Highly accelerated quantitative MRI	21
12/NE/0110	The DEMO-POD Study	32

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

Further Information 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
11/NE/0097	Evaluation of guided self-help service	8
11/NE/0107	The Journey to Becoming a Health Trainer v6	6
11/NE/0109	Information and education for patients with bronchiectasis V1.0	8
11/NE/0142	Improving access and reducing barriers to care for children with ASD	10
11/NE/0189	Experiences of adults receiving chemotherapy for colorectal cancer	12
11/NE/0192	Current Lab Method vs. Enrichment Broth for Isolation of P.aeruginosa	10
11/NE/0232	Risk of poor birth condition and maternal socioeconomic position	10
11/NE/0234	Gene expression profiling of Burkitt Lymphoma	10
11/NE/0235	Examination of meningococcal antigens as potential vaccine targets V1	10
11/NE/0279	Inflammatory markers, drug and antibody levels in Crohn's disease	12
11/NE/0307	BmPROM: a reliability and validity study	13
11/NE/0309	HbF & ROP (Version 1.1)	11
11/NE/0312	MelResist Version 1.0	12
11/NE/0340	Easy and accurate manual blood pressure measurement. V1	28
11/NE/0348	Role of prion protein in neurodegenerative disease	9
11/NE/0351	Respiratory patients decisions regarding choice of care provider	8
11/NE/0388	Patient experiences following diagnosis of a polyp cancer: version 1	9
11/NE/0390	Mining genome-wide association data	8
11/NE/0392	The Use of Inhalation Devices for Chronic Obstructive Pulmonary Disease	7
12/NE/0020	Religion and spirituality in a high secure forensic inpatient service	9
12/NE/0022	Risk perception and place of birth during high risk pregnancy	9
12/NE/0023	Pathogenesis of blistering viral infections of the skin	10
12/NE/0083	Bone Cancer Aetiology and Survival: Part 2	7
12/NE/0122	Prognostic Biomarkers In Periodontal Disease	10
12/NE/0123	EORTC Quality of Life Head and Neck Module v4	9

Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/NE/0072	The evaluation of Cognitive Behavioural Therapy for voices	19
11/NE/0099	Factors that influence patient choice of growth hormone devices	6
11/NE/0111	What helps adults with coeliac disease stick to a gluten-free diet? V1	7
11/NE/0129	Neutrophil function in idiopathic bronchiectasis	21
11/NE/0132	A pilot randomised controlled trial of The Lifestyle Course (TLC)	21
11/NE/0155	Exploring spiritual needs of day-care patients. Version no 0.04	35
11/NE/0172	Quality and Quantity of Life in Laryngeal Cancer	22
11/NE/0178	Breathing test repeatability in bronchiectasis	15
11/NE/0188	SUSUROL: Focus Groups	12
11/NE/0205	RADiANT: Reducing alcohol drinking in ANTenatal women v 1.0	21
11/NE/0206	Extra Physiotherapy In Critical Care (EPICC)	19
11/NE/0233	Helping older women make informed decisions about breast screening	10
11/NE/0257	Cueing for swallowing in Parkinson's disease	20
11/NE/0277	Clients' perspectives towards the label 'learning Disability'	27
11/NE/0280	Exploring the bioethical implications of oncofertility treatments.	20
11/NE/0282	Clinical decision-making in COPD exacerbations v0.1	11
11/NE/0308	3D Ultrasound of Intrauterine Contraceptive Devices - Version One.	11
11/NE/0337	Investigating progression of mitochondrial disease in muscle. (V1.1)	26
12/NE/0017	The impact of FLT3 and NPM1 status in Acute Myeloid Leukaemia	19
12/NE/0021	Ethnic Differences in Illness Perception of Hypertension	9
12/NE/0028	POP12251-PK & Safety of Cabazitaxel in patients with solid tumours	19
12/NE/0043	Detect InSpect ChAracterise Resect and Discard 2: DISCARD 2	19
12/NE/0051	Safety & efficacy study of Debio 0932 in combination with SOC in NSCLC	19
12/NE/0081	Patient preferences for osteoporosis treatment - Maastricht study v.2	7
12/NE/0082	Prospective invasive mould disease audit (PIMDA)- Version 1.0	7

Unfavourable Opinion		
REC Reference	Application Short Title	Number of Days on Clock
11/NE/0128	Quality and quantity of life in laryngeal cancer	22
11/NE/0213	Doctors' perceptions of bullying in the NHS	15
11/NE/0341	Attachment style, loneliness and psychotic-like experiences	28

11/NE/0377	Dynamic Cardiac Imaging and Relationship to Physiological Measurements	20
12/NE/0065	The Roles of Sleep and Cortisol in CFS/ME	14
12/NE/0076	Dynamic Cardiac Imaging and Relationship to Physiological Measurements	23

Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
12/NE/0071	SLICE Study	N/A
12/NE/0124	Expectations of orthodontic treatment and ethnicity	N/A

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
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Not Requiring Review by NHS REC

REC Reference	Application Short Title	Number of Days on Clock
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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 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
11/NE/0111/AM02	What helps adults with coeliac disease stick to a gluten-free diet? V1	Amendment 1 (9.12.11)	55

Researcher had been informed of decision a few days after the meeting however due to an oversight by the Co-ordinator following technical problems the letter was not issued.

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