

# NRES Committee Yorkshire & The Humber - Leeds West

## Annual Report

**01 April 2013 – 31 March 2014**

## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	NRES Committee Yorkshire & The Humber - Leeds West
<b>Type of REC:</b>	Type III
<b>Type of Flag:</b>	CTIMPs in Patients Phase 1 Studies in Patients Medical Devices Research involving Adults Lacking Capacity Research involving Children Qualitative Research
<b>Chair:</b>	Dr Rhona Bratt
<b>Vice-Chair:</b>	Dr Sheila E. Fisher
<b>Alternate Vice-Chair:</b>	Dr Vera Neumann
<b>Co-ordinator:</b>	Miss Laura Kirkbride from 01 April 2013 to May 2013 Mr Neil McCaffery from May 2013 to 31 September 2013 Miss Sarah Grimshaw from 01 October 2013 onwards
<b>Assistant Co-ordinator:</b>	Miss Sarah Dunn from May 2013 to September 2013 Miss Christie Ord from 01 October 2013 onwards
<b>Committee Address:</b>	Jarrow REC Centre Room 002, Jarrow Business Centre Rolling Mill Road Jarrow NE32 3DT
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## Chair's overview of the past year:

This is my fifth and final annual report as Chair of the Leeds (West) Research Ethics Committee.

After an almost complete freeze on recruitment of members we have been joined by eight new members during the year Mike Clarke, Dianne Farrar, Emma Lundy and Heather Rostron as expert members alongside Danni Collingridge Moore, Jan Geddes, Caroline McGee and Vishal Sharma as Lay members. They bring with them a very wide range of clinical and non-clinical experience and a willingness to take part in the robust discussions so important for ethical review of NHS research.

A number of members of the committee have left in the course of this year and their contribution must not be forgotten or go unappreciated. In particular, Annie Topping and Reema Harrison have taken the opportunity to work abroad for a number of years but we hope both will return to the UK and to the Leeds West Committee in the future. It is a requirement of our committees that members serve no more than 10 years and although that is good practice it does mean that we lose members of very wide experience and knowledge. This year, it is with great regret, we had to say good-bye to Howard Bird who had served a 10-year term on the Leeds West Committee. The knowledge and thoughtful contributions of these members will be greatly missed.

Amidst the many changes the committee has had to undergo there has been a core of stability and in particular I have had the good fortune to receive the continued support of Vice Chairs, Sheila Fisher and Vera Neumann.

Last year we had to suspend our involvement with the Proportionate Review programme because of the low number of members able to take part. After a period when new members were able to gain experience and undertake training we have resumed our work with PR.

The administration of our Committee has moved to a new centre and, after some staff changes at the start of the year, we now have the very capable and experienced REC Manager, Sarah Grimshaw. She has steered us through some very difficult reviews but most challenging of all has, with her colleagues at the Jarrow Centre, taken us successfully through our tri-annual audit – the committee received notice of its full accreditation in February 2014.

The Committee continues to show a balance of professionalism, support of the researcher and research, as well as a great deal of good humour, and I cannot thank them enough for continuing to do such outstanding work - I can truly say Leeds West is the best.

## NRES Committee Yorkshire & The Humber - Leeds West Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Professor Howard Bird	Consultant Rheumatologist	Expert	24/11/2003	24/11/2013
Dr Rhona Bratt	Retired Multimedia Project Manager	Lay Plus	07/01/2005	
Mr David Bryant	Pharmacist	Expert	07/05/2010	07/06/2013
Dr Michael Clarke	Senior Dento Legal Advisor	Expert	17/06/2013	
Ms Danni Collingridge Moore	Research Fellow	Lay	01/11/2013	
Dr Martin Elliott	Consultant Paediatric Oncologist	Expert	01/04/2010	
Dr Diane Farrar	Research Programme Manager - Maternal and Child Health	Expert	18/06/2013	
Dr Sheila E. Fisher	MHRA Committee on Safety of Devices	Expert	20/07/2007	
Dr Jan Geddes	Retired Senior Research Fellow	Lay	12/06/2013	
Dr Reema Harrison	Lecturer in Psychology	Lay	18/07/2011	30/06/2013
Ms Sarah Kirkland	Research Governance Facilitator	Lay Plus	01/02/2013	
Miss Emma Lundy	Advanced Clinical Pharmacist (Oncology and Clinical Trials)	Expert	09/10/2013	
Dr Caroline Magee	Communications Consultant (Biobanking)	Lay	15/08/2013	
Mr Jerry Masterson	Practice Learning Facilitator	Expert	10/06/2011	24/05/2013
Dr Vera Neumann	Consultant in Rehabilitation Medicine	Expert	20/07/2007	
Dr Jane Orton	Consultant Oncologist	Expert	29/04/2008	
Mrs Heather Rostron	Senior Research Nurse	Expert	22/10/2013	
Mr Vishal Sharma	Research Fellow	Lay	07/10/2013	
Professor Anne Topping	Director, Centre for Health and Social Care Research	Expert	04/02/2010	22/10/2013
Mr Anthony Warnock-Smith	Retired solicitor	Lay Plus	01/12/2012	

### Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Ms Jo Abbott	Senior Nurse Manager, Public Health	Expert	14 June 2013

## NRES Committee Yorkshire & The Humber - Leeds West: Members' Declarations of

Name	Declaration of Interest	Date
Mr Vishal Sharma	Currently employed by Bradford Teaching Hospitals Foundation Trust as a Research Fellow at the Bradford Institute for Health Research	31/03/2014
Dr Sheila E Fisher	Chair of Medicines and Healthcare Products Regulatory Agency (MHRA) Committee on Safety of Devices. In that role Dr Fisher is working to build academic partnerships around safe introduction of healthcare devices to the NHS and in discussion with some streams of NIHR funding for research. The agency has a complementary role in approval of clinical studies/trials to that of NRES. There is no potential for personal gain in these roles. Dr Fisher undertakes peer-review for a number of funders, governmental and charitable, of research applications.	06/11/2013
Dr Diane Farrar	Dr Farrar works as a research fellow and is involved in several research projects surrounding maternal and child health, including the Born in Bradford project. She is the CI for a HTA-funded project examining the identification and treatment of gestational diabetes and is also managing a team of research midwives recruiting to a number of clinical obstetric and gynaecology trials.	03/07/2013
Mrs Heather Rostron	Work on NIHR adopted studies (paediatrics) and member of the NIHR CSG (general paediatrics).	23/10/2013
Dr Jane Orton	None	08/11/2013
Mr Anthony Warnock-Smith	None.	08/11/2013
Dr Vera Neumann	None.	08/11/2013
Dr Rhona Bratt	None.	08/11/2013
Dr Michael Clarke	Senior dento-legal advisor, Dental Protection, Medical Protection Agency.	08/11/2013
Dr Jan Geddes	None.	08/11/2013
Ms Sarah Kirkland	Research governance facilitator at Bradford District Care Trust. This was previously approved by Leigh Pollard.	08/11/2013
Dr Caroline Magee	None.	08/11/2013
Miss Emma Lundy	Emma's current job is as a clinical trials pharmacist. This role involves managing the pharmacy aspects of clinical trials in Leeds Teaching Hospitals NHS Trust. She is involved in the set up and ongoing management of clinical trials which are being run in her workplace. These trials will already have the necessary ethical and regulatory approvals in place being submitted for set up.	03/11/2013
Ms Danni Collingridge Moore	Reviewer for the NIHR HTA funding stream and a peer reviewer for Age and Ageing.	27/11/2013
Dr Martin Elliott	Trustee of the Candlelighter's Charity and Neuroblastoma Allian Charity. Member of the NIHR Neuroblastoma Clinical Studies Group. Clinical Trials Lead for Paediatric Oncology at Leeds General Infirmary.	17/01/2014

**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>
May	10/05/2013	9
June	14/06/2013	7
July	12/07/2013	10
August	09/08/2013	10
September	13/09/2013	9
October	11/10/2013	9
November	08/11/2013	13
December	13/12/2013	14
January	17/01/2014	12
February	14/02/2014	12
March	14/03/2014	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>
January	06/01/2014	3
March	26/03/2014	3

2 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 Vera Neumann	11
Dr Rhona Bratt	10
Dr Jane Orton	10
Dr Sheila E. Fisher	9
Dr Jan Geddes	9
Mr Anthony Warnock-Smith	8
Ms Sarah Kirkland	7
Dr Caroline Magee	7
Dr Diane Farrar	6
Dr Martin Elliott	6
Dr Michael Clarke	6
Professor Anne Topping	6
Professor Howard Bird	6
Miss Emma Lundy	5
Mr Vishal Sharma	4
Mrs Heather Rostron	4
Ms Danni Collingridge Moore	3

**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>
Dr Sheila E. Fisher	2
Ms Sarah Kirkland	1
Dr Caroline Magee	1
Dr Jane Orton	1
Dr Rhona Bratt	1

## Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Mr Anthony Warnock-Smith	04/07/2013 - 04/07/2013	Induction, NRES
Dr Caroline Magee	09/09/2013 - 09/09/2013	Induction, Hugh Davies
Dr Caroline Magee	27/11/2013 - 27/11/2013	National Members Training Day, HRA
Dr Caroline Magee	16/01/2014 - 16/01/2014	Research Involving Adults Who Lack Capacity (including research in emergency situations), HRA
Dr Caroline Magee	21/01/2014 - 21/01/2014	Equality & Diversity
Ms Danni Collingridge Moore	03/02/2014 - 03/02/2014	Equality & Diversity
Dr Diane Farrar	06/11/2013 - 06/11/2013	Equality & Diversity
Miss Emma Lundy	05/03/2014 - 05/03/2014	Induction, HRA
Mrs Heather Rostron	22/01/2014 - 22/01/2014	Equality & Diversity
Mrs Heather Rostron	05/03/2014 - 05/03/2014	Induction, HRA
Dr Jan Geddes	09/09/2013 - 09/09/2013	Induction, HRA
Dr Jan Geddes	15/01/2014 - 15/01/2014	Equality & Diversity
Dr Jane Orton	27/11/2013 - 27/11/2013	National Members Training Day
Dr Martin Elliott	01/07/2013 - 31/07/2013	Preparation and Presentation of Paediatric Oncology CTIMPs
Dr Martin Elliott	03/12/2013 - 03/12/2013	GCP Training
Dr Michael Clarke	05/03/2014 - 05/03/2014	Induction, HRA
Ms Sarah Kirkland	08/07/2013 - 08/07/2013	Data Analysis for Researchers, R & D Skills Programme HRA
Ms Sarah Kirkland	27/11/2013 - 27/11/2013	National Members Training Day
Ms Sarah Kirkland	08/10/2013 - 08/10/2013	GCP Refresher
Dr Sheila E. Fisher	27/11/2013 - 27/11/2013	National Members Training Day
Dr Rhona Bratt	02/10/2013 - 02/10/2013	Researcher Training Day
Dr Rhona Bratt	27/11/2013 - 27/11/2013	National Members Training Day
Dr Rhona Bratt	11/12/2013 - 11/12/2013	National NRES Chairs Day
Dr Rhona Bratt	05/02/2014 - 05/02/2014	Researcher Training Day
Dr Vera Neumann	10/12/2013 - 10/12/2013	Quantitative Research Methods and Statistics



**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	17	29.31
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	41	70.69
<b>Total Applications Reviewed</b>	<b>58</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	7
Number of student applications reviewed	15
Number of paediatric applications reviewed	8
Number of device applications reviewed	9
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	11
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	4	6.90
Favourable Opinion with Additional Conditions	12	20.69
Unfavourable Opinion	7	12.07
Provisional Opinion	34	58.62
Invalid	0	0.00
No Opinion Pending Consultation with Referee	0	0.00
Provisional Opinion Pending Consultation with Referee	1	1.72
Not Requiring Review by NHS REC	0	0.00
<b>Total</b>	<b>58</b>	<b>100</b>
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:**

<b>Status of applications at date of generation of report</b>	<b>Number</b>	<b>%</b>
Further Information Favourable Opinion with Standard Conditions	32	55.17
Further Information Favourable Opinion with Additional Conditions	3	5.17
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	4	6.90
Favourable Opinion with Additional Conditions	12	20.69
Unfavourable Opinion	7	12.07
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	0	0.00
<b>Total</b>	<b>58</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>5</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	4	80.00
Favourable Opinion with Additional Conditions	0	0.00
No Opinion transfer to full committee for review	1	20.00
Provisional Opinion	0	0.00
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>5</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	5.27
<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>	29
<b>Number of days taken to final decision - mode</b>	25
<b>Number of SSAs (non-Phase 1) reviewed</b>	0
<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%
<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>	103
<b>Number of substantial amendments over 35 days</b>	1
<b>Number of substantial amendments over 35 days as a % of total substantial amendments</b>	1.0%
<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>	1
<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>	1
<b>Number of proportionate review applications over 14 days as a % of total</b>	25.0%

**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/YH/0093	Implant 2 piece IOL device for rehabilitating patients with dry ARMD	29
13/YH/0117	Near Infrared Detection of Spreading Depolarisations in TBI	54
13/YH/0118	QVA149 versus Seretide exacerbation study	28
13/YH/0135	Journeying through Dementia	26
13/YH/0136	ELAD for Treatment of AILD (VTI-208)	32
13/YH/0137	MAXFLEX	22
13/YH/0147	ELAD for Treatment of AAH (VTI-210)	32
13/YH/0159	Adjuvant Pegylated Interferon in Ulcerated Melanoma	49
13/YH/0163	A CBT resource for young people with dental anxiety	38
13/YH/0219	Cognition in Cystic Fibrosis patients and matched controls (Version 1)	36
13/YH/0232	ECho: Efficacy of Inhaled GSK2339345 in Chronic Idiopathic Cough	24
13/YH/0234	A Linguistic Analysis of Supported Conversation Interventions	23
13/YH/0245	An open label trial of azithromycin in chronic productive cough	35
13/YH/0246	ELectrical & Magnetic Stimulation after trauma - the ELMS Trial	35
13/YH/0277	EMMACE-3X	22
13/YH/0317	CUSTOM-DBS	29
13/YH/0334	Hemostasis of Active GI Luminal Tract Bleeding (HALT)(study # 10-017)	34
13/YH/0349	Atrial fibrosis and circulating collagen markers	36
13/YH/0400	Delirium prevention for older people in hospital: a feasibility study	26
13/YH/0401	Cross-over study with NVA237 vs tiotropium in early morning symptoms	30
13/YH/0408	Fitness to Treat (FiTT)	41
14/YH/0004	Evaluation of a foot support for people with extensor spasms (v1)	55
14/YH/0006	Open Label Extension Study of Lacosamide in Paediatric Subjects	45
14/YH/0007	acosamide in Subjects ages 4 years and over and less than 17 with Epil	49
14/YH/0008	The Health Behaviours of Pregnant Gypsy Traveller Women	49
14/YH/0009	Outcomes of surgery for unruptured aneurysm & subarachnoid hemorrhage	55
14/YH/0011	Freedom Study	30
14/YH/0021	REPRISE: Phase 3 study of CAZ-AVI vs Best Available Therapy	27
14/YH/0031	EFSA - DON in urine trial	30

14/YH/0049	Protocol CP-01 Study of SonoLysis Headframe Version 4c Oct 18 2013	20
14/YH/0070	Experiences of relationships in individuals with psychosis	25
14/YH/0078	MICROSHOCK	32

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/YH/0201	Study of Sativex in Children (aged 8-18) with Severe Spasticity	23
13/YH/0292	BRU ACDC-Study	28
13/YH/0309	CORAL XT – Open-label extension trial of the CORAL trial	39

#### 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/YH/0211	A Qualitative Study of Non-Response to Psychological Therapy.	20
13/YH/0366	Efficacy and safety of 11b-HSD1 inhibitor in IIH	25
13/YH/0377	Computerised aphasia therapy RCT (Big CACTUS)	45
13/YH/0429	Increasing uptake of NHS Health Checks in Northamptonshire	14
13/YH/0432	Molecular Diagnostics for neonatal sepsis	16
14/YH/0034	IciCLLe -Assessment of the Mechanism of Action of Ibrutinib	20
14/YH/0101	Targeted Sequencing of Known Cancer Genes in Anaplastic Meningioma	6
14/YH/0104	HbA1c Study	7

#### Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/YH/0153	The impact of robotic surgery on teamwork (v1)	25
13/YH/0214	People with learning disabilities and self-determination (version 1)	20
13/YH/0231	Family's Voice helping family or friends in the last days of life	22
13/YH/0266	M/34273/41, Almirall, COPD, Breezhaler vs. Genuair	25
13/YH/0279	PROMOTE	21
13/YH/0283	High density ECG and atrial health	21
13/YH/0284	Pilot trial of omeprazole in idiopathic pulmonary fibrosis	21

13/YH/0316	Methods for real-time evaluation of respiratory rate	24
13/YH/0337	Do people who use Club Drugs have more Sexually Transmitted Infections	25
13/YH/0347	Facilitators and barriers to active recall for HIV/STI testing of MSM	25
13/YH/0372	Patient Reporting of Safety: A Feasibility Study	25
13/YH/0411	Screening for Cognitive Function in Clinical Practice	24

#### Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
13/YH/0158	Sildenafil in Heart Failure	25
13/YH/0221	Breastfeeding for reduction of Neonatal Abstinence Syndrome (Version1)	19
13/YH/0247	TissuePatch as an Adjunct to Closure of Gastrointestinal Anastomosis.	21
13/YH/0327	Teenagers' perceptions on sub-dermal contraceptive implants (SDI)	26
13/YH/0382	The microcirculation in cirrhosis	24
14/YH/0030	Environmental effects T1DM	20
14/YH/0077	Monitoring cortical microcirculation in acute brain injury	19

#### 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
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<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>	
13/YH/0432	Molecular Diagnostics for neonatal sepsis	16	
<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>
12/YH/0505/AM01	Vertex: Telaprevir With Peginterferon alfa-2b and Ribavirin	Revised CDI2	40
<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>