

Research Ethics Service

South West - Cornwall & Plymouth Research Ethics Committee

Annual Report

01 April 2017 - 31 March 2018



Part 1 - Committee Membership and Training

Name of REC: South West - Cornwall & Plymouth Research Ethics Committee

Type of REC: Authorised

Type of Flag: Research Involving Children

Qualitative Research

Chair: Canon Ian Ainsworth-Smith

Vice-Chair: Miss Clare Adams

Alternate Vice-Chair: Mr Robert Wosley

REC Manager: Miss Charlotte Ferris (from 06/02/2018)

Ms Lucy Roberts (until 05/02/2018)

REC Assistant: Ms Kat Hogg (from 19/02/2018 until 30/03/2018)

Ms Stacey Bamford (until 05/02/2018) Mr Stephan Ramey (until 27/04/2017)

Committee Address: Level 3

Block B Whitefriars Lewins Mead Bristol

BS1 2NT

Telephone: 0207 104 8241

Email: nrescommittee.southwest-cornwall-plymouth@nhs.net

Chair's overview of the past year:

We have continued to review a wide variety of studies, submitted by applicants with different levels of research experience. One of our most important functions, in my view, is to act as a rigorous `critical friend` to research. It is always helpful for everyone concerned when investigators are available at our meetings for our discussion of their project. Such contact is crucial to our committee`s shared learning and experience, not to mention being interesting and at times enlightening!

As with other committees, an increasing number of studies are being submitted for Proportionate Review and we are well served by the number of our members who make themselves available between meetings for this purpose.

There has recently been a reduction in our workload due to fewer studies being submitted, part of a current national trend. However, the result of the recent Options Appraisal should address this issue in the future.

As always, I am grateful to my officers and members, who give their time and come from a stimulating mix of backgrounds, which makes our meetings worthwhile – and enjoyable! Our managers consistently provide us and the applicants with friendly and efficient service. We are very much in their debt.

South West - Cornwall & Plymouth Research Ethics Committee Membership

Name	Profession	Expert or	Dates	
		Lay	Appointed	Left
Miss Clare Adams	Consultant Colorectal and General Surgeon	Expert	19/01/2015	
Canon Ian Ainsworth-Smith	Retired Hospital Chaplain	Lay Plus	01/05/2009	
Dr Rachel Clarke	Clinical Psychologist	Expert	01/03/2016	
Dr Stephen Coles	Director and Owner	Expert	25/07/2016	
Mrs Frances Coppin	Retired	Lay	01/10/2016	19/03/2018
Dr Kass Gibson	Lecturer	Lay	04/04/2017	
Dr Stephen Lewis	Consultant Gastroenterologist	Expert	01/10/2014	
Miss Helen Moore	Support Pharmacist	Expert	01/02/2016	
Miss Rosalyn Squire	Research Nurse	Expert	01/04/2011	
Mrs Caroline Theyer	Solicitor	Lay Plus	01/04/2011	
Mr Duncan Trotter	Retired	Lay Plus	07/03/2017	
Mr Robert Wosley	Deputy Service Line Cluster Manager	Lay	01/04/2011	

South West - Cornwall & Plymouth Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended

South West - Cornwall & Plymouth Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended

South West - Cornwall & Plymouth Research Ethics Committee: Members' Declarations of

Name	Declaration of Interest	Date
Miss Clare Adams	Member of Plymouth Hospitals NHS Trust Research and Development Steering Committee. Consultant Surgeon at Plymouth NHS Hospitals Trust	21/06/2017
Canon Ian Ainsworth-Smith	None	20/03/2018
Dr Rachel Clarke	None	09/03/2018
Dr Stephen Coles	Family Member (daughter) who is part of the hepatology and gastroenterology clinical research teams at John Radcliffe Hospital and the Nuffield Institute.	08/03/2018
Dr Kass Gibson	Research active faculty member of the University of St Mark and St John. Deputy Chair of the University's Research Ethics Panel.	04/04/2017
Dr Stephen Lewis	Member of Plymouth Hospitals NHS Trusts R&D sub-committee	08/03/2018
Miss Helen Moore	None	18/03/2018
Miss Rosalyn Squire	None	08/03/2018
Mrs Caroline Theyer	None	14/03/2018
Mr Duncan Trotter	Holdings in biotech and pharmaceutical unit trusts.	08/03/2018
Mr Robert Wosley	Acted on behalf of Plymouth Hospitals NHS Trust as Principal Investigator in the observational study; Exploring children's experiences of their parents' non-terminal cancer with a focus on trauma, resilience and attachment. Member of European Society for Blood and Marrow Transplantation (EBMT) and British Society for Blood and Marrow Transplantation (BSBMT). Member of Research Quality Association (RQA). Person Designate for Haematology under HTA Licence 11093, Plymouth Hospitals NHS Trust. Governance and Accreditation Manager; Clinical Haematology, Immunology and Oncology Services, Plymouth Hospitals NHS Trust. (Overseeing research activity from a Quality Assurance perspective).	23/03/2018

Meetings for Full Ethical Review 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present
		at Meeting
May	16/05/2017	9
July	18/07/2017	9
August	15/08/2017	10
October	17/10/2017	9
January	16/01/2018	9
March	20/03/2018	8

⁶ full committee meetings were held during the reporting period.

Proportionate Review Sub-Committee Meetings held during 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	26/04/2017	3
May	16/05/2017	9
May	19/05/2017	3
June	29/06/2017	3
July	28/07/2017	3
August	25/08/2017	2
October	24/10/2017	3
November	24/11/2017	3
December	22/12/2017	4
February	23/02/2018	3
March	23/03/2018	3

¹¹ proportionate review sub-committee meetings were held during the reporting period.

Sub-Committee Meetings held during 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	21/04/2017	2
May	19/05/2017	2
June	09/06/2017	2
June	30/06/2017	2
July	28/07/2017	2
August	31/08/2017	2
September	30/09/2017	2
October	31/10/2017	2
November	30/11/2017	2
December	31/12/2017	2
January	31/01/2018	2
February	28/02/2018	2
March	31/03/2018	2

13 sub-committee meetings were held during the reporting period.

Details of inquorate meeting held:01 April 2017 - 31 March 2018

None

Attendance of Members at full committee meetings:01 April 2017 - 31 March 2018

Name	Number of Meetings Attended
Miss Clare Adams	5
Canon Ian Ainsworth-Smith	5
Dr Rachel Clarke	5
Dr Stephen Coles	5
Mrs Frances Coppin	4
Dr Kass Gibson	4
Dr Stephen Lewis	3
Miss Helen Moore	5
Miss Rosalyn Squire	4
Mrs Caroline Theyer	4
Mr Duncan Trotter	5
Mr Robert Wosley	5

Attendance of Members at proportionate review sub-committee meetings: 01 April 2017 - 31 March 2018

Name	Number of Meetings Attended
M. Ol Al	
Miss Clare Adams	5
Canon Ian Ainsworth-Smith	9
Dr Rachel Clarke	1
Dr Stephen Coles	3
Mrs Frances Coppin	2
Dr Kass Gibson	1
Dr Stephen Lewis	2
Miss Helen Moore	8
Miss Rosalyn Squire	1
Mrs Caroline Theyer	3
Mr Duncan Trotter	1
Mr Robert Wosley	3

Attendance of Members at sub-committee meetings: 01 April 2017 - 31 March 2018

Name	Number of Meetings Attended
Miss Clare Adams	6
Canon Ian Ainsworth-Smith	13
Mr Robert Wosley	7

Training 01 April 2017 - 31 March 2018

Miss Clare Adams 17/10/2017 Training or New REC Chairs Canon Ian Ainsworth-Smith 17/10/2017 Training for new REC Chairs Canon Ian Ainsworth-Smith 24/11/2017 Training or new REC Chairs Dr Rachel Clarke 05/09/2017 Liaised with an expert by experience in relation to the outcome measures used in current work environment. Dr Rachel Clarke 12/03/2018 facilitated two ICU survivors to make a video of their experiences Dr Rachel Clarke 19/03/2018 Completed online HRA training reviewing the research design of clinical trials Dr Stephen Coles 25/07/2017 Training - Committee Members Induction Dr Kass Gibson 07/12/2017 Exeter Training Day Dr Stephen Lewis 18/03/2018 Equality and Diversity Miss Helen Moore 31/03/2018 Medical Devices Miss Helen Moore 31/03/2018 Research Involving Participants Miss Helen Moore 31/03/2018 Confidentiality and Information Governance Miss Helen Moore 31/03/2018 Research Involving Human Tissue Miss Rosalyn Squire 08/03/2018 Research Involving Exposure to Ionising Miss Rosalyn Squire 08/03/2018 ICH GCP Training	Name of Member	Date	Event(s) attended
Miss Clare Adams 17/10/2017 Training for new REC Chairs' Canon Ian Ainsworth-Smith 24/11/2017 Training - HRA National Chairs' Day and Policy Event Dr Rachel Clarke 05/09/2017 Liaised with an expert by experience in relation to the outcome measures used in current work environment. Dr Rachel Clarke 12/03/2018 facilitated two ICU survivors to make a video of their experiences Dr Rachel Clarke 19/03/2018 Completed online HRA training reviewing the research design of clinical trials Dr Stephen Coles 25/07/2017 Training - Committee Members Induction Dr Kass Gibson 07/12/2017 Exeter Training Day Dr Stephen Lewis 18/03/2018 Medical Devices Miss Helen Moore 31/03/2018 Medical Devices Miss Helen Moore 31/03/2018 Research Involving Participants Lacking Miss Helen Moore 31/03/2018 Research Involving Human Tissue Miss Helen Moore 31/03/2018 Research Involving Human Tissue Miss Helen Moore 31/03/2018 Research Involving Human Tissue Miss Rosalyn Squire 08/03/2018 Research Involving Exposure to Ionising Miss Rosalyn Squire 08/03/2018 GPT Praini	Miss Clare Adams	17/10/2017	Training - Training for New REC
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Dr Rachel Clarke Dr Rachel Clarke	Canon Ian Ainsworth-Smith	24/11/2017	9
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Mr Robert Wosley 01/07/2017 Attended Research Governance – Good Clinical Practice training		31/33/2011	
- Good Clinical Practice training	Mr Robert Woslev	01/07/2017	

		Trust
Mr Robert Wosley	22/03/2018	Equality and Diversity

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	0	0.00
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	21	100.00
Total Applications Reviewed	21	100

Table 2: Breakdown of full applications and other activity during reporting period

Number of applications made invalid by the REC Manager	0
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	8
Number of paediatric applications reviewed	7
Number of device applications reviewed	0
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	0
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	8

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	0	0.00
Favourable Opinion with Additional Conditions	4	19.05
Unfavourable Opinion	3	14.29
Provisional Opinion	14	66.67
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	21	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	13	61.90
Conditions		
Further Information Favourable Opinion with Additional	1	4.76
Conditions		
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	4	19.05
Unfavourable Opinion	3	14.29
Provisional Opinion	0	0.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	0	0.00
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
Total	21	100

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

Total Applications Reviewed	22

Table 6: Breakdown of PRS applications and other activity during reporting period:

Number of applications made invalid by the REC Manager	4
Number of studies withdrawn prior to the meeting	1
Number of student applications reviewed	6
Number of paediatric applications reviewed	2
Number of device applications reviewed	0
Number of qualitative applications reviewed	4

Table 7: 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	4	18.18
Favourable Opinion with Additional Conditions	3	13.64
No Opinion transfer to full committee for review	2	9.09
Provisional Opinion	12	54.55
Unfavourable Opinion	1	4.55
Total	22	100

Table 8: Other Management Information based on the number of completed applications for

Average number of applications reviewed per full meeting	3.50
Number of completed applications for full ethical review	21
Number of completed applications for full ethical review over	0
60 days	
Number of completed applications over 60 days as a % of	0.00%
total	
Number of completed applications for full ethical review over	5
40 days	
Number of completed applications over 40 days as a % of	23.81%
total	
Number of days taken to final decision – average (mean)	30
Number of completed proportionate review applications for	20
ethical review	
Number of completed proportionate review applications for	0
ethical review over 21 days	
Number of completed proportionate review applications over	0.00%
21 days as a % of total	
•	
Number of SSAs (non-Phase 1) reviewed	0
Number of completed applications for SSA review over 25	0
days	-
Number of completed applications for SSA review over 25	0.00%
days as % of all non- Phase 1 SSAs	
Number of SSAs (Phase 1) reviewed	0
Number of completed applications for SSA review over 14	0
days	, and the second
Number of completed applications for SSA review over 14	0.00%
days as % of all Phase 1 SSAs	
Number of substantial amendments reviewed	32
Number of completed substantial amendments over 35 days	0
Number of completed substantial amendments over 35 days	0.00%
as a % of total substantial amendments	
Number of completed substantial amendments over 28 days	1
Number of completed substantial amendments over 28 days	3.13%
as a % of total substantial amendments	
Number of modified amendments reviewed	0
Number of completed modified amendments over 14 days	0
Number of completed modified amendments over 14 days as	0.00%
a % of total modified amendments	
Number of non substantial amendments received	32
Number of substantial amendments received for information	0
Number of substantial amendments received for new	0
sites/Pls	
Number of annual progress reports received	37
Number of safety reports received	0
Number of Serious Adverse Events received	0
NAMED OF DELICUS MARCISC ENGING TECCHACA	U

Number of final reports received	6

Table 9.1: Breakdown of current status of all full applications reviewed within the reporting period

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
17/SW/0110	Retropubic Tape versus Transobturator Tape: 10 year follow up study	35
17/SW/0155	E-learning resource when a parent is dying with cancer	12
17/SW/0158	Can Self-Compassion be cultivated in Armed Forces Veterans?	7
17/SW/0180	The VIBE study	30
17/SW/0185	POP: Palatability Of Prednisolone	51
17/SW/0190	Transmission of pneumococcus within family units (TOP study)	31
18/SW/0007	Competent Paediatric Patients and Refusals of Medical Treatment	37
18/SW/0009	PARC: Containing Antimicrobial Resistance in the CF Clinic	50
18/SW/0012	KineDMD	53
18/SW/0065	Movement and perspective-taking as a diagnostic aid for psychosis	57
18/SW/0067	How therapy goals are co-constructed	46
18/SW/0069	The WATCH study v.1.0	31
18/SW/0070	NEWBIE 1	28

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/SW/0156	Janssen STELARA Study - Protocol CNTO1275PSO4056 (STELLAR Teens)	22

Further Information	on Unfavourable Opinion	
REC Reference	Title	Number of Days on Clock

Favourable Opini	on with Standard Conditions	
REC Reference	Title	Number of Days on Clock

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/SW/0215	Assessment of effectiveness of de-identification of clinical narrative	21
17/SW/0224	Stories of young persons living with parental brain injury	21

17/SW/0238	Change and recovery in adults with a restrictive-type eating disorder	22
18/SW/0073	Nordic Walking for People with Inflammatory Rheumatic Diseases	23

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
17/SW/0109	Management of symptomatic knee osteoarthritis in the obese adult	16
17/SW/0242	Managing long term symptoms with complex causes in primary care	21
18/SW/0010	Clinical Health Psychology Clinic for Endocrinology Patients	23

Provisional Opini	on Carlos Ca	
REC Reference	Title	Number of Days on Clock

Provisional Opini	on Pending Consultation with Referee	
REC Reference	Title	Number of Days on Clock

Further informati	on response not complete	
REC Reference	Title	Number of Days on Clock

Withdrawn after t	he meeting	
REC Reference	Title	Number of Days on Clock

Table 9.2: Breakdown of current status of all PRS applications reviewed within the reporting period

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
17/SW/0092	Dual antiplatelet therapy prescribing in the UK: a mixed methods study	13
17/SW/0101	Noise levels in a district general mixed Intensive Care Unit	21
17/SW/0116	Oxygen Uptake Kinetics in Type 1 Diabetes	19
17/SW/0117	Breath Study	20

17/SW/0124	Designing a trial of bilateral cochlear implantation in adults	9
17/SW/0168	The employment experiences of People with COPD	8
17/SW/0249	Myopia severity and quantity of laser for Retinopathy of Prematurity	12
17/SW/0274	The experience of Tinnitus in BCHA users: A qualitative study	18
17/SW/0275	CYPHP Evelina London Evaluation	16
18/SW/0083	Does Plasma D-Dimer help diagnose periprosthetic joint infection?	15
18/SW/0084	Investigating sleepiness and OSAS in the HIV population in UK	18
18/SW/0086	Urinary function before and after radical prostatectomy (HAARP)	15

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

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

Favourable Opinion with Standard Conditions				
REC Reference	Title	Number of Days on Clock		
17/SW/0143	Parent engagement in Speech and Language Therapy V 1.0	18		
17/SW/0197	Discriminating pituitary from glaucomatous visual fields	8		
17/SW/0296	BUMP Survey	4		
18/SW/0064	Emotion Recognition in At Risk Mental States	16		

Favourable Opinion with Additional Conditions				
REC Reference	Title	Number of Days on Clock		
17/SW/0196	Validation of CoaguChek XS Pro near patient testing device	8		
17/SW/0294	Do peripheral venous pressures reflect femoral in liver transplant?	4		
18/SW/0063	Magnetic resonance imaging of patients with cervical myelopathy	16		

Unfavourable Opinion				
REC Reference	Title	Number of Days on Clock		
17/SW/0115	Grampian Branching Out pilot project evaluation	14		

Provisional Opinion	
REC Reference Title	Number of Days on Clock
Further information response not complete	
REC Reference Title	Number of Days on Clock
Withdrawn after the meeting	
RFC Reference Title	Number of Days on Clock

Table 10.1: Breakdown of current status of all substantial amendments reviewed within the reporting period

Favourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
04/Q2103/8/AM10	South West impact of multiple sclerosis (SWIMS)	15	06/04/2017	23
10/H0203/14/AM05	The Cytokine Profile and Genetics of Diabetic Macular Oedema	3	03/08/2016	12
10/H0203/14/AM07	The Cytokine Profile and Genetics of Diabetic Macular Oedema	6.0	29/11/2017	3
12/SW/0091/AM01	A Visual Analogue Scale for the Assessment of Sleepiness	1	30/05/2017	27
13/SW/0201/AM13	Chemotherapy induced cognitive changes in colorectal cancer patients	Amendment 9: January 2018	01/01/2018	29
13/SW/0272/AM04	Links between perio score and Alzheimers	1	01/03/2017	6
14/SW/0096/AM01	An examination of cancer biomarkers in prostate and bowel tissues	1	01/05/2017	4
15/SW/0047/AM04	Positive Mindfulness Project	3	24/04/2017	8
15/SW/0076/AM03	MONACO	2	23/03/2017	7
15/SW/0130/AM04	Two weeks of reduced activity and skeletal muscle health in older men	4	23/06/2017	2
15/SW/0313/AM02	IFN-lambda in neutrophil-mediated pathology in rheumatic diseases	AM002	08/03/2018	8
16/SW/0019/AM09	The MAmMOTH Study	5	30/03/2017	14
16/SW/0019/AM10	The MAmMOTH Study	Substantial Amendment no. 6	04/10/2017	5
16/SW/0039/AM01	Oesophageal Pacing to check left atrial posterior wall isolation	1	20/09/2017	8
16/SW/0053/AM01	The DALI Follow-up Study (DALIFUS)	1	11/05/2017	14
16/SW/0104/AM01	High volume training and the effects of injury on bone density	1	17/11/2016	13
16/SW/0207/AM02	The familial effects of chronic pain	1	29/06/2017	14
16/SW/0312/AM01	BNFL worker epidemiology study	no 1 26 July 2017	01/08/2017	14
16/SW/0313/AM01	National Registry for Radiation Workers (NRRW)	1	26/07/2017	13
16/SW/0314/AM01	UK Nuclear Weapons Test Participants Study (NWTPS)	No 1 26 July 2017	01/08/2017	14
16/SW/0335/AM02	EXPLORER: EXPLORing CFS/ME in youngER children (ages 5-7)	1	01/04/2017	14
16/SW/0335/AM04	EXPLORER: EXPLORing CFS/ME in youngER children (ages 5-7)	2	01/10/2017	16

16/SW/0335/AM05	EXPLORER: EXPLORing CFS/ME in youngER children (ages	3	01/12/2017	2
	5-7)			
16/SW/0336/AM01	ABA Infant feeding study version 1.0	1	04/04/2017	26
17/SW/0009/AM02	Pilot Randomised Controlled Trial of Augmented Depression	Substantial	12/12/2017	22
	Therapy	Amendment 1		
17/SW/0018/AM01	Investigation of genetic and epigenetic marks in cancer	1	18/07/2017	7
17/SW/0018/AM02	Investigation of genetic and epigenetic marks in cancer	SA2	25/10/2017	4
17/SW/0075/AM01	Metabolic insights into PPAR alpha	SA1	23/08/2017	6
17/SW/0110/AM02	Retropubic Tape versus Transobturator Tape: 10 year follow	1	17/01/2018	7
	up study			
17/SW/0117/AM01	Breath Study	1.0	14/08/2017	1
17/SW/0117/AM03	Breath Study	2.0	13/11/2017	4
17/SW/0124/AM01	Designing a trial of bilateral cochlear implantation in adults	1.0	20/12/2017	15

Unfavourable opinio	n			
Amendment REC	Title	Version	Date	Number of Days on
Reference				Clock

Table 10.2: Breakdown of current status of all modified amendments reviewed within the reporting period

Favourable opinion timeline					
Amendment REC	Title	Version	Date	Number of Days on	
Reference				Clock	

Unfavourable opinion	n timeline			
Amendment REC	Title	Version	Date	Number of Days on
Reference				Clock

Table	11: Items	exceeding	timelines
, and		onocouning	

REC Reference Title Number of Days on Clock

Proportionate review applications for ethical review over 21 day timeline

REC Reference Title Number of Days on Clock

SSAs (non Phase 1) over 25 day timeline

REC Reference Title Number of Days on Clock

SSAs (Phase 1) over 14 day timeline

REC Reference Title Number of Days on Clock

Substantial Amendments over 35 day timeline

Amendment REC	Title	Version	Date	Number of Days on
Reference				Clock

Modified Amendments over 14 day timeline

Amendment REC	Title	Version	Date	Number of Days on
Reference				Clock