

**South West - Cornwall & Plymouth Research
Ethics Committee**

Annual Report

01 April 2016 - 31 March 2017



Part 1 – Committee Membership and Training

Name of REC:	South West - Cornwall & Plymouth Research Ethics Committee
Type of REC:	Authorised
Type of Flag:	Paediatric Qualitative
Chair:	Canon Ian Ainsworth-Smith
Vice-Chair:	Miss Clare Adams
Alternate Vice-Chair:	Mr Robert Wosley
REC Manager:	Miss Georgina Castledine (10/02/2016 – 16/09/2016) Miss Lucy Roberts (03/10/2016 – present)
REC Assistant:	Miss Lucy Roberts (29/07/2015 – 30/09/2016) Mr Stephan Ramey (03/01/2017- 27/04/2017)
Committee Address:	Level 3 Block B Whitefriars Lewins Mead Bristol BS1 2NT
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Chair's overview of the past year:

The Committee has reviewed a range of studies this this year, all of which have provided an opportunity for us to consolidate and develop our experience. In some instances we have also seen applications which have raised new topics and which identify new ethical issues. In addition, we continue to see a growing number of studies submitted for Proportionate Review. We are very grateful to our committee colleagues who help us this with PR between meetings. In common with other committees we have noticed some fall in the number of applications.

As always, we find discussion and interaction with the applicant at the meeting particularly useful and informative and frequently provides a context for our decision. Feedback from applicants suggests that they also find the experience valuable.

We have had a number of changes of membership during the year including our Vice Chair and several other members leaving the Committee. We have fortunately been able to appoint a new Vice Chair and Alternate Vice Chair from our membership, and to recruit new lay and expert members and to maintain the balance in membership which, we hope, produces a comprehensive ethical review.

Our Managers unfailingly provide us with efficient and cheerful support and our members' attendance record points to a committed group of colleagues with a valuable skill mix. My thanks go to them all.

Ian Ainsworth-Smith

South West - Cornwall & Plymouth Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Miss Clare Adams	Consultant Colorectal and General Surgeon	Expert	19/01/2015	
Canon Ian Ainsworth-Smith	Retired Hospital Chaplain	Lay Plus	01/02/2009	
Mrs Suzanne Lesley Blowey	Consultant Nurse Chronic Pain	Expert	01/04/2009	13/10/2016
Mrs Sheila Bullard	Clinical Research Project Manager	Lay	01/04/2009	17/08/2016
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	
Dr Stephen Lewis	Consultant Gastroenterologist	Expert	01/10/2014	
Miss Helen Moore	Support Pharmacist	Expert	01/02/2016	
Mr Louis Pobereskin	Consultant Neurosurgeon	Expert	01/04/2011	02/03/2017
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
Miss Stephanie Ellis	Former Civil Servant	Lay Plus	PRSC 27/06/2016

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

Name	Declaration of Interest	Date
Miss Clare Adams	Member of Plymouth Hospitals NHS Trust Research and Development Steering Committee.	31/03/2017
Canon Ian Ainsworth-Smith	None	31/03/2017
Dr Rachel Clarke	None at the moment but likely to be involved in research as part of work role in the NHS	08/03/2017
Dr Stephen Coles	Currently a fellow of the Royal Society of Medicine	24/08/2016
Mrs Frances Coppin	None	15/11/2016
Dr Stephen Lewis	member of Plymouth Hospitals NHS Trusts R&D subcommittee	08/03/2017
Miss Helen Moore	Study participant in the SWIMS project and the MS register	31/03/2017
Miss Rosalyn Squire	None	31/03/2017
Mrs Caroline Theyer	None	31/03/2017
Mr Duncan Trotter	GSK, Legal & General Global Healthcare & Pharmaceutical, various others in unit trusts.	10/03/2017
Mr Robert Wosley	Member of European Society for Blood and Marrow Transplantation, which conducts research. Inspector for JACIE: Joint Accreditation Committee – ISCT & EBMT (International Society for Cell Therapy & European Society for Blood and Marrow Transplantation) Member of Research Quality Association.	31/03/2017

Meetings for Full Ethical Review 01 April 2016 - 31 March 2017:

Month	Date	Number of Members Present at Meeting
April	19/04/2016	10
May	17/05/2016	9
July	19/07/2016	9
August	16/08/2016	9
November	15/11/2016	8
December	06/12/2016	8
January	17/01/2017	9
February	21/02/2017	7

8 full committee meetings were held during the reporting period.

Proportionate Review Sub-Committee Meetings held during 01 April 2016 - 31 March 2017:

Month	Date	Number of Members Present at Meeting
April	19/04/2016	10
April	25/04/2016	3
May	17/05/2016	3
June	27/06/2016	3
July	25/07/2016	3
August	23/08/2016	3
September	22/09/2016	3
October	26/10/2016	3
November	24/11/2016	3
December	15/12/2016	3
January	20/01/2017	3
March	23/03/2017	3

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

Sub-Committee Meetings held during 01 April 2016 - 31 March 2017:

Month	Date	Number of Members Present at Meeting
April	08/04/2016	2
May	04/05/2016	2
May	12/05/2016	2
May	27/05/2016	2
June	13/06/2016	2
July	07/07/2016	2
August	05/08/2016	2
August	08/08/2016	2
August	15/08/2016	2
August	19/08/2016	2
September	02/09/2016	2

September	07/09/2016	2
September	23/09/2016	2
October	07/10/2016	2
October	17/10/2016	2
October	21/10/2016	2
November	18/11/2016	2
December	15/12/2016	2
January	13/01/2017	2
February	17/02/2017	2
March	10/03/2017	2

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

Details of inquorate meeting held:01 April 2016 - 31 March 2017

None

Attendance of Members at full committee meetings:01 April 2016 - 31 March 2017

Name	Number of Meetings Attended
Miss Clare Adams	7
Canon Ian Ainsworth-Smith	7
Mrs Suzanne Lesley Blowey	2
Mrs Sheila Bullard	3
Dr Rachel Clarke	3
Dr Stephen Coles	5
Mrs Frances Coppin	3
Dr Stephen Lewis	5
Miss Helen Moore	8
Mr Louis Pobereskin	3
Miss Rosalyn Squire	8
Mrs Caroline Theyer	8
Mr Robert Wosley	7

Attendance of Members at proportionate review sub-committee meetings: 01 April 2016 - 31 March 2017

Name	Number of Meetings Attended
Miss Clare Adams	3
Canon Ian Ainsworth-Smith	11
Mrs Suzanne Lesley Blowey	2
Mrs Sheila Bullard	2
Dr Rachel Clarke	1
Dr Stephen Lewis	4
Miss Helen Moore	3
Miss Rosalyn Squire	8
Mrs Caroline Theyer	3
Mr Robert Wosley	5

Attendance of Members at sub-committee meetings: 01 April 2016 - 31 March 2017

Name	Number of Meetings Attended
Miss Clare Adams	6
Canon Ian Ainsworth-Smith	21
Mrs Sheila Bullard	8
Dr Rachel Clarke	1
Miss Rosalyn Squire	4
Mr Robert Wosley	2

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Miss Clare Adams	01/12/2016	Training - National Training Day for Committee Chairs
Miss Clare Adams	22/03/2017	National Members Training Day
Canon Ian Ainsworth-Smith	01/12/2016	Training - National Training Day for Committee Chairs
Canon Ian Ainsworth-Smith	24/02/2017	Local Training - Bristol REC
Canon Ian Ainsworth-Smith	29/03/2017	Training - The Practicalities of Running a REC - a workshop for Chairs and REC Managers (formerly 'Nuts and Bolts')
Mrs Sheila Bullard	19/05/2016	NREAP / REC Chairs' Network Meeting: South West
Dr Rachel Clarke	14/03/2017	Committee Members Induction
Dr Stephen Coles	09/08/2016	Equality and Diversity Awareness
Dr Stephen Coles	14/03/2017	Committee Members Induction
Miss Helen Moore	16/02/2017	Training - National Members Training Day
Miss Helen Moore	16/02/2017	National Members Training Day
Miss Rosalyn Squire	31/03/2017	Completing MSc which involves all aspects of research
Mr Robert Wosley	05/04/2016	42nd Annual Meeting of the European Society for Blood and Marrow Transplantation
Mr Robert Wosley	18/05/2016	Service Line Development – Managing Performance
Mr Robert Wosley	04/07/2016	Trust Update Non-Clinical
Mr Robert Wosley	03/11/2016	JACIE Quality Forum UK & Ireland

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)	3	9.38
Others	29	90.63
Total Applications Reviewed	32	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	9
Number of paediatric applications reviewed	14
Number of device applications reviewed	2
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	4

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	9.38
Favourable Opinion with Additional Conditions	8	25.00
Unfavourable Opinion	3	9.38
Provisional Opinion	18	56.25
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	32	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	16	50.00
Further Information Favourable Opinion with Additional Conditions	2	6.25
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	3	9.38
Favourable Opinion with Additional Conditions	8	25.00
Unfavourable Opinion	3	9.38
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	32	100

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

Total Applications Reviewed	23
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Table 6: Breakdown of PRS applications and other activity during reporting period:

Number of applications made invalid by the REC Manager	2
Number of studies withdrawn prior to the meeting	2
Number of student applications reviewed	10
Number of paediatric applications reviewed	2
Number of device applications reviewed	0
Number of qualitative applications reviewed	6

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	8	34.78
Favourable Opinion with Additional Conditions	4	17.39
No Opinion transfer to full committee for review	2	8.70
Provisional Opinion	9	39.13
Unfavourable Opinion	0	0.00
Total	23	100

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

Average number of applications reviewed per full meeting	4.00
Number of completed applications for full ethical review	32
Number of completed applications for full ethical review over 60 days	0
Number of completed applications over 60 days as a % of total	0.00%
Number of completed applications for full ethical review over 40 days	3
Number of completed applications over 40 days as a % of total	9.38%
Number of days taken to final decision – average (mean)	23
Number of completed proportionate review applications for ethical review	21
Number of completed proportionate review applications for ethical review over 21 days	0
Number of completed proportionate review applications over 21 days as a % of total	0%
Number of SSAs (non-Phase 1) reviewed	2
Number of completed applications for SSA review over 25 days	0
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	0.00%
Number of SSAs (Phase 1) reviewed	0
Number of completed applications for SSA review over 14 days	0
Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs	0.00%
Number of substantial amendments reviewed	36
Number of completed substantial amendments over 35 days	0
Number of completed substantial amendments over 35 days as a % of total substantial amendments	0.00%
Number of completed substantial amendments over 28 days	1
Number of completed substantial amendments over 28 days as a % of total substantial amendments	2.78%
Number of modified amendments reviewed	0
Number of completed modified amendments over 14 days	0
Number of completed modified amendments over 14 days as a % of total modified amendments	0.00%
Number of non substantial amendments received	43
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	0
Number of annual progress reports received	47

Number of safety reports received	0
Number of Serious Adverse Events received	0
Number of final reports received	2

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
16/SW/0080	ACL Radiology Study	30
16/SW/0104	High volume training and the effects of injury on bone density	27
16/SW/0143	Dust, Cadmium and Rheumatoid Arthritis	46
16/SW/0150	FoND Study V1	30
16/SW/0175	CF Skype study - Feasibility	46
16/SW/0207	The familial effects of chronic pain	21
16/SW/0209	Predictors of depression among people with Inflammatory Bowel Disease	12
16/SW/0212	Intraocular lens orientation and pseudophakic negative dysphotopsia	17
16/SW/0233	Identification of Monogenic Diabetes	26
16/SW/0235	Predictive value of the MSIT & SCIT tests in diagnosing paediatric RLS	28
16/SW/0237	Functional vision screening ver 1.0	24
16/SW/0238	Ex-vivo Infection Detection (EVIDEnT)	43
16/SW/0308	Ethnography of antenatal care for the implementation of PFME	18
16/SW/0340	Mind the Gap! The eating disorder primary-secondary care interface	15
17/SW/0049	Is a blended diet beneficial and safe for gastrostomy fed children?	22
17/SW/0050	Children and young people's adjustment to cardiac surgery scars	17

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/SW/0078	WHO reference materials for hepatitis E Virus	30
17/SW/0053	A survey investigating the provision of wound care by HCAs 1.	18

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

Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
16/SW/0312	BNFL worker epidemiology study	14
16/SW/0313	National Registry for Radiation Workers (NRRW)	14

16/SW/0314	UK Nuclear Weapons Test Participants Study (NWTPS)	14
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Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/SW/0236	Integrative trauma-focused group therapy for PTSD	25
16/SW/0315	Attachment, family narratives and psychosis	17
16/SW/0321	Low Cost bespoke insoles - version 1	17
16/SW/0335	EXPLORER: EXPLORing CFS/ME in youngER children (ages 5-7)	12
17/SW/0008	Atypical Face Processing following Early Visual Deprivation (1)	20
17/SW/0009	Pilot Randomised Controlled Trial of Augmented Depression Therapy	20
17/SW/0013	Less to Hold	20
17/SW/0035	Trifecta GT	17

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
16/SW/0140	The familial effects of chronic pain	26
16/SW/0234	Less to Hold	24
16/SW/0341	Qualitative research in Endometriosis	21

Provisional Opinion

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

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

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

REC Reference	Title	Number of Days on Clock
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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
16/SW/0121	A study of adults with type 1 diabetes	17
16/SW/0156	To evaluate acceptability of TRAK supplementing ACL rehab	14
16/SW/0162	Adult Hip Dysplasia: An assessment tool for early diagnosis v1	12
16/SW/0189	What shapes GPs decisions to pursue a diagnosis of dementia? v.01	13
16/SW/0338	Investigating how teachers and therapists (re)teach language to adults	6
16/SW/0347	Control of multi-functional prosthetic hands	14
17/SW/0015	DOACs Qualitative Study v.1.0	17
17/SW/0018	Investigation of genetic and epigenetic marks in cancer	19

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
17/SW/0012	Blood cell mutation analysis in pancreatic disease v1	10

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

Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
16/SW/0124	Human gene therapy for glaucoma using CRISPR-Cas9	13
16/SW/0191	Genetic basis of host susceptibility to meningococcal disease	12
16/SW/0262	OxQUIP	5
16/SW/0263	Accelerating Endogenous Tissue Repair and Regeneration	5
16/SW/0264	Assay Validation for Receptor Tyrosine Kinase Inhibitor Treatment V1	4
16/SW/0307	Palliative Treatments in Renal Cancer	5
16/SW/0336	ABA Infant feeding study version 1.0	7

17/SW/0075	Metabolic insights into PPAR alpha	11
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Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/SW/0127	Pattern of Uncomfortable Loudness Levels in Hyperacusis	6
16/SW/0223	Parent decision-making regarding fever and unscheduled care	11
16/SW/0292	Quality of life for maxillectomy patients with prosthetic obturators	7
17/SW/0074	Minimising Restrictive Practices	11

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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Provisional Opinion

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

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

REC Reference	Title	Number of Days on Clock
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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/AM08	South West impact of multiple sclerosis (SWIMS)	13	11/05/2016	22
12/SW/0227/AM06	Computerised cognitive assessments (CoCoA)	6	02/10/2016	2
13/SW/0093/AM02	White cell azathioprine metabolites for patients on thiopurines	2	28/11/2016	16
13/SW/0201/AM09	Chemotherapy induced cognitive changes in colorectal cancer patients	6	01/05/2016	4
13/SW/0201/AM11	Chemotherapy induced cognitive changes in colorectal cancer patients	7	01/10/2016	10
13/SW/0201/AM12	Chemotherapy induced cognitive changes in colorectal cancer patients	8	30/01/2017	14
13/SW/0236/AM06	Post-authorisation safety study of Esbriet (PASSPORT)	4	24/02/2016	19
13/SW/0240/AM02	Blood Collection (Adaptimmune)	1	04/10/2016	5
14/SW/1083/AM01	Adult stem cell collection for basic science research	1	17/02/2016	12
14/SW/1174/AM02	Silver ion analysis of silver coated endoprosthesis	2	18/07/2016	0
14/SW/1181/AM06	YoDA BRCA: Genetic Testing Decision Aid for young women	4	20/04/2016	9
14/SW/1181/AM07	YoDA BRCA: Genetic Testing Decision Aid for young women	5	17/11/2016	6
15/SW/0047/AM02	Positive Mindfulness Project	2	27/09/2016	28
15/SW/0048/AM07	Environmental Factors in the Aetiology of Autoimmune Liver Disease	3	14/06/2016	2
15/SW/0048/AM08	Environmental Factors in the Aetiology of Autoimmune Liver Disease	4	06/09/2016	21
15/SW/0076/AM01	MONACO	1	28/09/2016	1
15/SW/0095/AM01	3D imaging investigation of cleft lip and palate.	1	07/03/2016	29
15/SW/0101/AM10	SPEAK: Surveying People Experiencing young Adult Kidney failure	5	22/03/2016	19
15/SW/0107/AM01	An intervention to improve prolapse using Femmeze® (v1)	version 2	15/09/2016	12
15/SW/0130/AM03	Two weeks of reduced activity and skeletal muscle health in older men	3	22/07/2016	7
15/SW/0146/AM02	Electronic Battery for Anorexia Nervosa Version 1	2	13/02/2016	7
15/SW/0177/AM03	PREMISE: European Observational Study of Enzalutamide in mCRPC (v2.0)	1	12/12/2016	7
15/SW/0298/AM01	Metacognition in Functional Cognitive Disorder	1	09/07/2016	8

15/SW/0313/AM01	IFN-lambda in neutrophil-mediated pathology in rheumatic diseases	001	10/10/2016	23
15/SW/0315/AM01	Module 5: Urinary incontinence post-prostatectomy	1	24/08/2016	5
16/SW/0019/AM05	The MAmMOTH Study	1	01/07/2016	18
16/SW/0019/AM06	The MAmMOTH Study	2	17/01/2017	9
16/SW/0019/AM07	The MAmMOTH Study	3	23/01/2017	9
16/SW/0019/AM08	The MAmMOTH Study	4	07/02/2017	11
16/SW/0041/AM01	STEPS	1	19/08/2016	1
16/SW/0054/AM01	Expectations Following a Minor Stroke or TIA	1	06/10/2016	21
16/SW/0068/AM03	Identifying depression in older patients in the ED (Version 1)	1	31/10/2016	7
16/SW/0150/AM02	FoND Study V1	1	20/09/2016	7
16/SW/0150/AM03	FoND Study V1	2	02/02/2017	5
16/SW/0162/AM01	Adult Hip Dysplasia: An assessment tool for early diagnosis v1	1	27/07/2016	3
16/SW/0175/AM01	CF Skype study - Feasibility	1	27/01/2017	23

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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Table 10.2: Breakdown of current status of all modified amendments reviewed within the reporting period

Favourable opinion timeline

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

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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Table 11: Items exceeding timelines

Full applications for ethical review over 60 day timeline

REC Reference	Title	Number of Days on Clock
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Proportionate review applications for ethical review over 21 day timeline

REC Reference	Title	Number of Days on Clock
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SSAs (non Phase 1) over 25 day timeline

REC Reference	Title	Number of Days on Clock
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SSAs (Phase 1) over 14 day timeline

REC Reference	Title	Number of Days on Clock
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Substantial Amendments over 35 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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Modified Amendments over 14 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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