

**London - Surrey Research Ethics Committee**

**Annual Report**

**01 April 2017 - 31 March 2018**



## Part 1 – Committee Membership and Training

**Name of REC:** London - Surrey Research Ethics Committee

**Type of REC:** Authorised REC

**Type of Flag:** None

**Chair:** Mrs Chrissie Lawson

**Vice-Chair:** Dr John Morton Broughall

**Alternate Vice-Chair:** Mr Robin Walsh

**REC Manager:** Mr Rajat Khullar

**REC Assistant:** Rebecca Howling

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## Chair's overview of the past year:

## London - Surrey Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr John Morton Broughall	Retired (Ex Medical Scientific Liaison)	Lay	01/08/2016	
Dr Cynthia Ruth Butlin	Retired Medical Practitioner	Expert	19/09/2016	
Dr Michelle Chen	Senior R&D Manager	Lay	14/12/2017	
Miss Elizabeth Cheshire	Consultant in Emergency Medicine	Expert	01/06/2010	31/12/2016
Dr Benedict Creagh-Brown	Consultant Physician	Expert	08/04/2014	
Dr Penny Gibson	Consultant Paediatrician	Expert	01/03/2018	
Miss Hayley-Jo Grafton	Psychology student	Lay Plus	22/08/2016	
Ms Wendy Joy	Retired Support Worker	Lay Plus	12/01/2011	03/02/2017
Mrs Sheila Kiss	Senior Vice President , Health Engagement and Communication	Lay	01/03/2018	
Mrs Chrissie Lawson	Nurse Specialist	Expert	01/05/2006	
Miss Deborah Malins	Managing Director (retired)	Lay	19/01/2016	
Mr Michael Morris	Managing Partner of Law Firm	Lay Plus	04/10/2007	04/10/2017
Ms Rosemary Murphy	Vice President Business Intelligence	Lay	01/08/2016	
Ms Janet Oakeshott	Retired Specialist Nurse	Lay	01/04/2014	30/06/2017
Mr Michael Pettit	Senior Lecturer in Pharmacy Practice	Expert	10/12/2015	
Mr Richard Robinson	Retired volunteer in advice agency and town councillor	Lay Plus	01/08/2016	01/09/2016
Mr Robin Walsh	Retired Professor of Physical Chemistry	Lay Plus	29/05/2013	

## London - Surrey Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Ms Stephanie Ellis BEM	Former Civil Servant	Lay Plus	06/06/2017, 27/06/2017, 05/09/2017
Dr John Keen	GP	Expert	PRSC 15/08/2017, 19/09/2017
Mr John Lynch	Non - NHS & Voluntary Sector Activity	Lay	PRSC 15/08/2017
Dr John Sheridan	Consultant Toxicologist and Chemist	Lay	PRSC 20/06/2017
Dr John Andrew Sutton	Medical Director	Expert	05/09/2017 SC 01/12/2017

## London - Surrey Research Ethics Committee: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Dr John Broughall	Volunteer for Antibiotic Research UK (ANTRUK). Charity raises money to fund research into methods of overcoming antibiotic resistance. All in vitro studies, no clinical work.	06/02/2018
Dr Cynthia Ruth Butlin	I work in a voluntary capacity as an associate hospital manager for Sussex Partnership NHS foundation trust. With regards to Shareholdings - None that I am aware of likely to be doing research in NHS	06/03/2018
Dr Penny Gibson	None	21/03/2018
Ms Hayley Jo-Grafton	Psychology Student at University of Surrey	06/03/2018
Mrs Chrissie Lawson	None	06/02/2018
Miss Deborah Malins	None	01/02/2018
Ms Rosemary Murphy	5 per cent ownership of a CRO called CMED.	06/02/2018
Mr Mike Pettit	Senior Lecturer in Pharmacy Practice, University of Sussex Associate General Pharmaceutical Council External Examiner Robert Gordon University Consultant Pharmacist, Brighton and Sussex University Hospitals NHS Trust	06/03/2018
Mr Robin Walsh	None	06/03/2018

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

Month	Date	Number of Members Present at Meeting
April	04/04/2017	7
May	02/05/2017	9
June	06/06/2017	7
June	27/06/2017	7
July	04/07/2017	10
September	05/09/2017	8
October	03/10/2017	7
November	07/11/2017	7
December	05/12/2017	8
February	06/02/2018	7
March	06/03/2018	9

11 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	21/04/2017	3
May	16/05/2017	3
June	20/06/2017	3
July	18/07/2017	3
August	15/08/2017	3
September	19/09/2017	3
October	17/10/2017	3
November	21/11/2017	4
December	19/12/2017	3
February	20/02/2018	5
March	20/03/2018	5

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	10/04/2017	2
April	28/04/2017	2
April	30/04/2017	2
May	12/05/2017	2
June	30/06/2017	6
July	15/07/2017	2
July	21/07/2017	2
August	01/08/2017	4
August	16/08/2017	2

September	01/09/2017	4
September	16/09/2017	2
October	01/10/2017	5
October	10/10/2017	2
October	16/10/2017	2
November	01/11/2017	4
November	16/11/2017	5
December	01/12/2017	7
December	16/12/2017	4
January	01/01/2018	4
January	15/01/2018	4
January	29/01/2018	5
February	15/02/2018	2
March	19/03/2018	4

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

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

Date	Reason	Action taken
06/06/2017	The meeting became inquorate with only 6 members after 4 applications were reviewed as a member had to leave. The last 2 applications were discussed but no decision was made.	Teleconference held on 27/06/2017 to ratify the decision.

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

Name	Number of Meetings Attended
Dr John Morton Broughall	11
Dr Cynthia Ruth Butlin	8
Dr Benedict Creagh-Brown	5
Dr Penny Gibson	1
Miss Hayley-Jo Grafton	8
Mrs Sheila Kiss	1
Mrs Chrissie Lawson	9
Miss Deborah Malins	10
Mr Michael Morris	4
Ms Rosemary Murphy	11
Ms Janet Oakeshott	1
Mr Michael Pettit	6
Mr Robin Walsh	7

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

Name	Number of Meetings Attended
Dr John Morton Broughall	4
Dr Cynthia Ruth Butlin	5
Mrs Chrissie Lawson	11
Miss Deborah Malins	4
Ms Rosemary Murphy	6
Ms Janet Oakeshott	1
Mr Robin Walsh	3

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

Name	Number of Meetings Attended
Dr John Morton Broughall	5
Dr Cynthia Ruth Butlin	9
Dr Benedict Creagh-Brown	2
Miss Hayley-Jo Grafton	3
Mrs Chrissie Lawson	23
Miss Deborah Malins	10
Ms Rosemary Murphy	10
Mr Michael Pettit	2
Mr Robin Walsh	11





**Training 01 April 2017 - 31 March 2018**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr John Morton Broughall	12/12/2017	London - Friends House
Dr Cynthia Ruth Butlin	23/01/2018	Training - Complex Cases
Mrs Chrissie Lawson	02/06/2017	Local Training Day - Oxford A
Miss Deborah Malins	12/12/2017	National Members Training Day
Ms Rosemary Murphy	12/12/2017	National Members Training Day
Mr Michael Pettit	12/12/2017	National Members Training Day
Ms Hayley-Jo Grafton	12/12/2017	National Members Training Day

## 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	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	54	100.00
<b>Total Applications Reviewed</b>	<b>54</b>	<b>100</b>

**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	2
Number of student applications reviewed	23
Number of paediatric applications reviewed	7
Number of device applications reviewed	5
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	5

**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	1	1.85
Favourable Opinion with Additional Conditions	2	3.70
Unfavourable Opinion	5	9.26
Provisional Opinion	45	83.33
Provisional Opinion Pending Consultation with Referee	1	1.85
<b>Total</b>	<b>54</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	39	72.22
Further Information Favourable Opinion with Additional Conditions	3	5.56
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	3.70
Favourable Opinion with Additional Conditions	2	3.70
Unfavourable Opinion	5	9.26
Provisional Opinion	2	3.70
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	1	1.85
<b>Total</b>	<b>54</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>25</b>
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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	0
Number of studies withdrawn prior to the meeting	6
Number of student applications reviewed	13
Number of paediatric applications reviewed	5
Number of device applications reviewed	0
Number of qualitative applications reviewed	8

**Table 7: 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	5	20.00
Favourable Opinion with Additional Conditions	1	4.00
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	19	76.00
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>25</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	4.91
<b>Number of completed applications for full ethical review</b>	53
<b>Number of completed applications for full ethical review over 60 days</b>	1
<b>Number of completed applications over 60 days as a % of total</b>	1.85%
<b>Number of completed applications for full ethical review over 40 days</b>	24
<b>Number of completed applications over 40 days as a % of total</b>	44.44%
<b>Number of days taken to final decision – average (mean)</b>	42
<b>Number of completed proportionate review applications for ethical review</b>	24
<b>Number of completed proportionate review applications for ethical review over 21 days</b>	11
<b>Number of completed proportionate review applications over 21 days as a % of total</b>	45.83%
<b>Number of SSAs (non-Phase 1) reviewed</b>	1
<b>Number of completed applications for SSA review over 25 days</b>	1
<b>Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs</b>	100.00%
<b>Number of SSAs (Phase 1) reviewed</b>	0
<b>Number of completed applications for SSA review over 14 days</b>	0
<b>Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs</b>	0.00%
<b>Number of substantial amendments reviewed</b>	55
<b>Number of completed substantial amendments over 35 days</b>	9
<b>Number of completed substantial amendments over 35 days as a % of total substantial amendments</b>	16.36%
<b>Number of completed substantial amendments over 28 days</b>	31
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	56.36%
<b>Number of modified amendments reviewed</b>	2
<b>Number of completed modified amendments over 14 days</b>	1
<b>Number of completed modified amendments over 14 days as a % of total modified amendments</b>	50.00%
<b>Number of non substantial amendments received</b>	64
<b>Number of substantial amendments received for information</b>	0
<b>Number of substantial amendments received for new sites/PIs</b>	0
<b>Number of annual progress reports received</b>	46
<b>Number of safety reports received</b>	0
<b>Number of Serious Adverse Events received</b>	0

<b>Number of final reports received</b>	<b>5</b>
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**Table 9.1: Breakdown of current status of all full applications reviewed within the reporting period**

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/LO/0524	Ablation of low voltage regions in persistent atrial fibrillation	36
17/LO/0574	PD_manager	33
17/LO/0575	TOLERANCE AND ACCEPTABILITY EVALUATION OF AYMES 'BRUSSELS'	35
17/LO/0583	What are parent expectations of special school transitions v1	62
17/LO/0596	LIGHTMind 2: Low-Intensity Guided Help Through MINDfulness	47
17/LO/0630	Do personality traits modify susceptibility to amyloid load ?	38
17/LO/0762	Influence of self-compassion on self-blame & shame in brain injury	53
17/LO/0765	COMMANDS-03: Exploring NAFLD knowledge in Hull and East Yorkshire	31
17/LO/0791	Malocclusion, peer relations and bullying in school children	53
17/LO/0953	Abreast of Health: Phase 2 – v1.0	44
17/LO/0959	LITTLE JOURNEY TRIAL	27
17/LO/0961	ASAP TOO, Version AA	46
17/LO/0964	Prognostication of patients after subarachnoid haemorrhage	56
17/LO/0966	Insight and social cognition in neurodegenerative diseases	32
17/LO/0978	Target NET	58
17/LO/1023	DEPICT Version 1	29
17/LO/1118	Atomoxetine effects on neurocognitive function in alcohol dependence	56
17/LO/1475	MIRABELLE - MRI and lymph node radiotherapy	32
17/LO/1503	Clients' viewpoints around chronic pain acceptance post drop out.	45
17/LO/1507	ABACus 3 - Awareness and Beliefs About Cancer phase 3	36
17/LO/1513	Development of patient derived xenografts (PDXs) for lung cancer.	54
17/LO/1608	E-CHECKED	51
17/LO/1675	SCENE (Work Package 3)	47
17/LO/1686	Ventricular dysfunction in group 1 pulmonary hypertension	49
17/LO/1689	HIFU - Bone	53
17/LO/1699	D-BIICEP Study v1	59
17/LO/1894	Early biomarkers for ARthritic PAIN to guide improved treatments	40
17/LO/2011	DHOPE-DCD Trial	42
17/LO/2047	The Development of Contextual Cognitive Behavioural Approach to PDN	57
17/LO/2061	CAPOEIRA-I	29
17/LO/2071	The BEACON study	50
17/LO/2084	Unwanted effects of corticosteroids in children with airway disease	55



17/LO/2100	Palliative Care Plan Project: Great North Care Record	31
18/LO/0137	Evaluation of CBT for anxiety in medically unexplained symptoms (1)	40
18/LO/0188	The Extended Spectrum of Apical Hypertrophic Cardiomyopathy	30
18/LO/0202	Family recovery and psychosis	55
18/LO/0211	Neurosurgical transitional care programme	39
18/LO/0394	Pathophysiology of Congenital Bladder Disorders	40
18/LO/0412	PRedicting cancer Immunotherapy Side Effects	37

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
17/LO/1130	STRESSGAP (FEP) version 1	51
17/LO/1886	What factors influence the optometric referral reply rate? - version 1	59
18/LO/0213	Exploring the experience of male caregivers in dementia	40

#### Further Information Unfavourable Opinion

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

REC Reference	Title	Number of Days on Clock
17/LO/1365	Psychotropic drug prescribing for people with intellectual disability	28
17/LO/1788	Muscle response to exercise in cerebral palsy	57

#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
17/LO/0881	Educational Intervention to Promote Testing for Viral Hepatitis in SA	28
17/LO/1918	NESIC Version 1.0	27

#### Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
17/LO/1440	The role of physical activity and diet within Pulmonary Sarcoidosis	27
17/LO/1449	Closed loop control of antimicrobial dosing	28

17/LO/1720	IN DIALOGUES: Inner dialogues in patients with eating disorders	28
18/LO/0176	ACCUMAX Sublingual acne study	28
18/LO/0427	Amicus - POM-003	27

#### Provisional Opinion

REC Reference	Title	Number of Days on Clock
17/LO/0580	Non-surgical Alternatives to Treatment of Failed Medical Abortion	n/a
18/LO/0390	TMR in the prevention of neuroma related limb pain after BKA	n/a

#### 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
17/LO/1107	Real-time Monitoring of Glucose with MicroEye® & ContinuMon®	28

**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/LO/0763	Pilot study for 3D-SI in implant-based breast reconstruction	33
17/LO/0850	Evaluation of assay for ruling out pre-eclampsia	40
17/LO/1044	Inner Speech in children with DLD	33
17/LO/1248	Children's Communication in Hospital	19
17/LO/1413	Screening for uveitis in children with JIA using OCT	21
17/LO/1610	An interactional approach to complaints handling in HSC Trusts V1	27

17/LO/2027	Hospital Experiences of Older Black Caribbean Stroke Patients	21
17/LO/2030	Quality of life in patients with dysfunctional breathing (V.1.0)	29
17/LO/2036	23Na MRI in CKD	19
17/LO/2132	Developing a dialysis vs conservative management decision aid	21
17/LO/2134	COS for adult-acquired APD with normal otology/audiology v6	22
17/LO/2136	Optimise-HFpEF	17
18/LO/0333	A prospective study into the utility of qHBsAg in management of CHB v1	16
18/LO/0336	Adapting START for the black minority community	21
18/LO/0338	PROFILE - NIS to Assess the Patterns of Use of REKOVELLE	22
18/LO/0343	Automatic gaze tracking in Visual Evoked Potential recording	22
18/LO/0479	Understanding pre-diabetes from the patient's perspective	20
18/LO/0481	GO SAFE	15

#### Further Information Favourable Opinion with Additional Conditions

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

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

REC Reference	Title	Number of Days on Clock
17/LO/1256	SOPHOS	10
17/LO/1602	Socioeconomic inequity in living-donor kidney transplantation	29
17/LO/1618	Evaluation of uptake of BRCA testing and use of health care services	27
17/LO/1801	Somatic Mutations in normal and abnormal human cells (Utrecht)	21
18/LO/0592	Analysis of NHS LA data pertaining to surgical deaths	12

#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
17/LO/1599	Implementation of care bundles for preventing surgical site infections	25

<b>Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<b>Provisional Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<b>Further information response not complete</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>

<b>Withdrawn after the meeting</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/LO/0835	Managing the Expectations Gap v1	25

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

<b>Favourable opinion</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
07/H1109/181/AM04	Bacterial biosensors in chemotherapy pre-screening	280417	28/04/2017	7
09/H0701/49/AM18	Post-marketing, Observational Registry of Humira in Psoriasis Patients	12	09/02/2017	35
11/LO/1646/AM02	Quantifying exercise intensity and capacity in ICU patients	SA02	12/10/2017	29
11/LO/1801/AM07	Brain TSPO Function	4	20/11/2017	35
12/LO/0130/AM05	Surplus tissue from patients undergoing eye surgery	4	25/05/2017	11
12/LO/1301/AM05	HAPpy Trial	2	21/04/2017	39
13/LO/0058/AM04	Improving therapy and outcomes in venous diseases	4	02/06/2017	35
13/LO/0314/AM07	Predictors of progression from MCI to AD	2	06/06/2017	52
13/LO/1349/AM13	eGFR-C	SA7	02/02/2017	80
14/LO/0429/AM11	Can genomics predict dysphagia after head and neck radiotherapy? - v1	2	16/10/2017	35
15/LO/0184/AM03	Dietary resistant starch from peas for healthy glucose homeostasis	Substantial Amendment 3 - 23/0	23/05/2017	36
15/LO/0610/AM02	The Clarity-Pro Study	SA01	01/08/2017	34
15/LO/0624/AM04	In vivo Tau pathology in PSP and CBD	3	19/07/2017	35
15/LO/0989/AM01	Targeted Nutritional Interventions to Prevent Diabetes	V2	07/08/2017	8
15/LO/1178/AM02	The QuaRTUS Study	1	20/03/2017	5
15/LO/1178/AM03	The QuaRTUS Study	August 2017	15/09/2017	28
15/LO/1437/AM02	Paternal Weight, Sperm Epigenomics and Fetal Growth	2	03/04/2017	35
15/LO/1968/AM03	Cardiac Troponin I monitoring pilot study	4	11/04/2017	48
15/LO/2051/AM05	The PRIME Study: Positive tRansltions through the MENopause	1.4	22/03/2017	31
15/LO/2082/AM05	The REACT (REtirement in ACTION) study - V1	1.5	26/07/2017	7
15/LO/2082/AM06	The REACT (REtirement in ACTION) study - V1	Version 1.6 06/12/17	09/01/2018	6
16/LO/0591/AM01	Establishment of MRI library to optimise treatment workflows for MRL	Substantial Amendment 1 28.02.	28/02/2017	56
16/LO/1065/AM02	Assessment of Amyloidosis Patient Pathways	Substantial	10/10/2017	29

		Amendment 2		
16/LO/1104/AM01	Self-care and quality of life in Heart Failure (HF)	1	27/02/2017	34
16/LO/1771/AM01	Relapse Prevention (RP) Trial	1	06/07/2017	12
16/LO/1802/AM01	Technology Integrated Health Management (TIHM)	1	08/04/2017	33
16/LO/1802/AM02	Technology Integrated Health Management (TIHM)	2	11/05/2017	3
16/LO/1802/AM07	Technology Integrated Health Management (TIHM)	3	30/11/2017	32
16/LO/1827/AM09	Perioperative Quality Improvement Programme: Patient Study	3.0	28/03/2017	5
16/LO/1827/AM13	Perioperative Quality Improvement Programme: Patient Study	4.0	20/10/2017	35
16/LO/1831/AM01	Vitamin D and shoulder arthroscopy	1	07/09/2017	20
16/LO/1949/AM02	AFAE	1	20/03/2017	16
16/LO/1973/AM01	CEB-VECTRA ECG	1	25/04/2017	7
16/LO/2012/AM02	Feasibility of a RCT of the ACE programme	Substantial Amendment 1: 21/06	21/06/2017	59
16/LO/2177/AM01	Plantar pressure as a risk factor for foot ulceration in diabetes - V1	5.4.2	16/05/2017	47
17/LO/0074/AM01	Foot ulcer treatment with the PulseFlowDF	1	22/09/2017	4
17/LO/0074/AM02	Foot ulcer treatment with the PulseFlowDF	2.0	11/12/2017	20
17/LO/0283/AM01	EurValve Prospective	5.4.2	02/06/2017	30
17/LO/0469/AM01	Burden of PAH-deficiency in adults	1	29/09/2017	27
17/LO/0524/AM01	Ablation of low voltage regions in persistent atrial fibrillation	V003	10/07/2017	4
17/LO/0524/AM02	Ablation of low voltage regions in persistent atrial fibrillation	2ns Amendment	28/07/2017	13
17/LO/0596/AM02	LIGHTMind 2: Low-Intensity Guided Help Through MINDfulness	02	17/01/2018	28
17/LO/0762/AM01	Influence of self-compassion on self-blame & shame in brain injury	1	24/08/2017	9
17/LO/0763/AM01	Pilot study for 3D-SI in implant-based breast reconstruction	1	13/10/2017	22
17/LO/0953/AM01	Abreast of Health: Phase 2 – v1.0	1	24/11/2017	12
17/LO/0961/AM01	ASAP TOO, Version AA	SA01	22/11/2017	28
17/LO/1044/AM01	Inner Speech in children with DLD	1	15/09/2017	33
17/LO/1130/AM01	STRESSGAP (FEP) version 1	1	16/11/2017	39
17/LO/1130/AM02	STRESSGAP (FEP) version 1	2	07/02/2018	29
17/LO/1413/AM01	Screening for uveitis in children with JIA using OCT	1	10/10/2017	33
17/LO/1507/AM01	ABACus 3 - Awareness and Beliefs About Cancer phase 3	1.0	15/11/2017	33
17/LO/1918/AM01	NESIC Version 1.0	1	02/01/2018	22
17/LO/1918/AM02	NESIC Version 1.0	2, 6th Feb 2018	06/02/2018	34

Unfavourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
15/LO/0796/AM04	Neuroimaging predictors of stroke recovery	4	13/10/2017	35
17/LO/0881/AM01	Educational Intervention to Promote Testing for Viral Hepatitis in SA	1	20/07/2017	35

**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
15/LO/0796/AM04/1	Neuroimaging predictors of stroke recovery	2	28/09/2017	6
17/LO/0881/AM01/1	Educational Intervention to Promote Testing for Viral Hepatitis in SA	Amendment 2	24/11/2017	17

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

**Table 11: Items exceeding timelines****Full applications for ethical review over 60 day timeline**

REC Reference	Title	Number of Days on Clock
17/LO/0583	What are parent expectations of special school transitions v1	62

**Proportionate review applications for ethical review over 21 day timeline**

REC Reference	Title	Number of Days on Clock
17/LO/0763	Pilot study for 3D-SI in implant-based breast reconstruction	33
17/LO/0850	Evaluation of assay for ruling out pre-eclampsia	40
17/LO/1044	Inner Speech in children with DLD	33
17/LO/1599	Implementation of care bundles for preventing surgical site infections	25
17/LO/1602	Socioeconomic inequity in living-donor kidney transplantation	29
17/LO/1610	An interactional approach to complaints handling in HSC Trusts V1	27
17/LO/1618	Evaluation of uptake of BRCA testing and use of health care services	27
17/LO/2030	Quality of life in patients with dysfunctional breathing (V.1.0)	29
17/LO/2134	COS for adult-acquired APD with normal otology/audiology v6	22
18/LO/0338	PROFILE - NIS to Assess the Patterns of Use of REKOVELLE	22
18/LO/0343	Automatic gaze tracking in Visual Evoked Potential recording	22

**SSAs (non Phase 1) over 25 day timeline**

REC Reference	Title	Number of Days on Clock
17/LO/1165	The role of plantar pressure a	60

**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
12/LO/1301/AM05	HAPpy Trial	2	21/04/2017	39
13/LO/0314/AM07	Predictors of progression from MCI to AD	2	06/06/2017	52



13/LO/1349/AM13	eGFR-C	SA7	02/02/2017	80
15/LO/0184/AM03	Dietary resistant starch from peas for healthy glucose homeostasis	Substantial Amendment 3 - 23/0	23/05/2017	36
15/LO/1968/AM03	Cardiac Troponin I monitoring pilot study	4	11/04/2017	48
16/LO/0591/AM01	Establishment of MRI library to optimise treatment workflows for MRL	Substantial Amendment 1 28.02.	28/02/2017	56
16/LO/2012/AM02	Feasibility of a RCT of the ACE programme	Substantial Amendment 1: 21/06	21/06/2017	59
16/LO/2177/AM01	Plantar pressure as a risk factor for foot ulceration in diabetes - V1	5.4.2	16/05/2017	47
17/LO/1130/AM01	STRESSGAP (FEP) version 1	1	16/11/2017	39

Modified Amendments over 14 day timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
17/LO/0881/AM01/1	Educational Intervention to Promote Testing for Viral Hepatitis in SA	Amendment 2	24/11/2017	17