

**South Central - Hampshire B Research Ethics  
Committee**

**Annual Report**

**01 April 2016 - 31 March 2017**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	South Central - Hampshire B Research Ethics Committee
<b>Type of REC:</b>	RECs recognised to review CTIMPS in patients - type iii
<b>Type of Flag:</b>	Research Tissue Bank, IRB Registered
<b>Chair:</b>	Dr Vincenzo Libri (01/08/2016 – Present) Professor Ron King ( until 31/07/2016)
<b>Vice-Chair:</b>	Dr Andrew Scott
<b>Alternate Vice-Chair:</b>	Mr Brian Birch
<b>REC Manager:</b>	Mrs Vicky Canfield-Duthie (until 01/03/2017) Dr Sarah Graves (from 01/03/2017 )
<b>REC Assistant:</b>	Miss Elizabeth Hearn (until 01/03/2017) Mr Alex Martin (from 01/03/2017 )
<b>Committee Address:</b>	Level 3 Block B Whitefriars Lewins Mead Bristol BS1 2NT
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## Chair's overview of the past year:

2016 represented a fruitful year for the Hampshire B Committee, with many milestones and progress made. This year the main Committee has dealt with 41 applications, all within the 60-day time limit, although it is slightly disappointing to note that 5 exceeded the key performance target of 40 days. Proportionate Review Sub-Committees dealt with 18 validated applications with 1 application exceeding the target. Ordinary Sub-Committees dealt with no less than 115 Substantial Amendments with 19 extending past 28 days but none as long as 35 days. In addition, the Sub-Committee dealt with 11 modified amendments with only one exceeding the 14-day target. Whilst the work of the Committee can be assessed only in part in such numerical terms, these figures indicate a continuing commitment to undertaking its review work for the HRA both diligently and efficiently. All contributing members, as well as those backing them up in the South Central office, are to be congratulated on this.

There have been several changes in membership during the year. I took over from Professor Ron King in July 2016 after he served the Committee over the previous ten years with passion and dedication. It is a privilege and a great pleasure to serve as a member and new Chair of the Hampshire B Committee and, with this opportunity, I would like to express my sincere gratitude to the hard working members of the Committee for their invaluable support, professionalism and diligent reviews, often at a short notice, as well as their high attendance rates and good range of participation in educational and other HRA activities.

The Committee bolstered its Lay membership, welcoming Dr Alex Gregory and Ms Maisie Gibson in August closely followed by Mrs Samantha Trace in September 2016. They provide valuable diversity to the Committee and challenge us to think about applications from their perspective. Dr Di Nicola, who joined the Committee as an expert in early 2016 transferred to Oxford C Committee in September 2016. Dr Mark Cassidy decided to retire from the REC community following four years of service after securing a new post in March 2017. Mrs Vicky Canfield-Duthie provided excellent support to the Committee for 9 months before moving onto Oxford B at the beginning of 2017. The Committee was supported by Mrs Claudia Bywater, deputy regional manager, for one month until we welcomed our newly appointed REC manager, Dr Sarah Graves, at the end of February 2017. We are now also supported by experienced REC assistant, Mr Alex Martin. A special thanks to Sarah and Alex for their invaluable support, without whom none of our progress could be made.

I look forward to continuing working with all Committee members and, jointly, contributing to our common undertaking of promoting respect for research volunteers and protecting their well-being and rights.

## South Central - Hampshire B Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Diane Ackerley	Retired Doctor	Expert	01/01/2016	
Mrs Lisa Armstrong	Senior Lecturer Social Work	Lay	10/12/2015	10/06/2016
Mrs Ravina Barrett	Pharmacist	Expert	25/11/2015	
Mr Brian Birch	Consultant Urological Surgeon	Expert	01/04/2013	
Mrs Janet Brember	Pharmacist	Expert	01/04/2013	
Ms Julie Brinton	Speech and Language Therapist	Expert	23/02/2015	
Mr Mark Cassidy	Senior Lecturer in Radiography	Expert	01/04/2013	29/03/2017
Dr Alessandro Di Nicola	Lecturer in Philosophy	Lay Plus	01/01/2016	11/09/2016
Ms Sue Edwards	Contract Manager, Research and Innovation Services	Lay	27/01/2015	
Ms Maisie Gibson	Graduate	Lay Plus	01/08/2016	
Dr Alex Gregory	Lecturer in Philosophy	Lay Plus	01/08/2016	
Mrs Angela Iveson	Acute Oncology Clinical Nurse Specialist	Expert	01/04/2013	
Professor Ron King	Mathematician (Retired)	Lay Plus	01/04/2013	31/07/2016
Dr Vincenzo Libri	Medical Consultant in Clinical Pharmacology	Expert	31/08/2016	
Mr Geoff Lowndes	Chartered Engineer (Retired)	Lay Plus	01/04/2013	
Dr Julie Merriman-Jones	Research Scientist & lab manager	Expert	24/06/2016	
Miss Becci Petch	Clinical Trial Coordinator	Lay	08/02/2016	
Dr Andrew Scott	Course Leader, M.Sc. Clinical Exercise Science	Expert	01/04/2013	
Mrs Samantha Trace	Research Assistant	Lay Plus	01/09/2016	

## South Central - Hampshire B Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended

## South Central - Hampshire B Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended

## South Central - Hampshire B Research Ethics Committee: Members' Declarations of Interest

Name	Declaration of Interest	Date
Dr Diane Ackerley	None	22/02/2017
Mrs Ravina Barrett	Retirement Pension and savings may hold shares in index listed firms involved in the conduct of healthcare research. As an academic involved in pharmacy practice research (self-directed, university funded)	23/02/2017
Mr Brian Birch	Acted as a paid advisor (ad hoc) for Astellas and Janssen. I have either received honoraria to speak at, chair and attend meetings or liaised/received educational material from representatives of the following companies over the last 10-15 years: Astellas, Pfizer, Ipsen, Glaxo Smith Kline, Sanofi, Lilly, Bayer, Amgen, Ferring, Takeda, AstraZeneca, Janssen-Cilag, Janssen	27/02/2017
Mrs Janet Brember	None	22/02/2017
Ms Julie Brinton	Paid consultancy for Advanced Bionics, manufacturers of cochlear implants. Parent Company is Sonus.	22/02/2017
Ms Sue Edwards	None	31/03/2017
Ms Maisie Gibson	None	23/02/2017
Dr Alex Gregory	Consultancy contract with Lundbeck Ltd. Presently scheduled only to give one talk at a mental health workshop. Lecturer at Southampton University.	22/02/2017
Dr Vincenzo Libri	GSK shares received while employed by GSK between 2004-2009. No shares received since termination of employment (March 2009). Member of the Clinical Trials Advisory Panel of Alzheimer's Research UK (ARUK)	08/12/2016
Mr Geoff Lowndes	None	22/02/2017
Dr Julie Merriman-Jones	University of Southampton, Faculty of Medicine Ethics Committee (FoMEC) – Ethical reviewer. University of Southampton, Faculty of Medicine, Animal Welfare and Ethical Review Board (AWERB) – member: sub-committee Scientific & Ethical Review Group (SERG) – ethical reviewer.	21/02/2017
Miss Becci Petch	Study start up associate with ICON plc (CRO) May 2017 onwards, Clinical Trial Coordinator, Macmillan Survivorship Research Group October 2015 – May 2017.	02/03/2017
Dr Andrew Scott	None	21/01/2017
Mrs Samantha Trace	None	31/03/2017

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

Month	Date	Number of Members Present at Meeting
April	27/04/2016	12
May	25/05/2016	9
July	27/07/2016	11
August	31/08/2016	9
September	28/09/2016	14
November	30/11/2016	12
December	14/12/2016	9
January	25/01/2017	10
February	22/02/2017	12
March	29/03/2017	12

10 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	27/04/2016	3
May	25/05/2016	3
August	31/08/2016	3
November	30/11/2016	3
January	11/01/2017	3
February	15/02/2017	3
March	15/03/2017	3

7 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	06/04/2016	2
April	20/04/2016	2
May	04/05/2016	2
May	13/05/2016	3
May	18/05/2016	2
June	01/06/2016	2
June	15/06/2016	2
July	06/07/2016	2
July	21/07/2016	2
August	04/08/2016	2
August	18/08/2016	2
September	08/09/2016	2
September	22/09/2016	2
October	06/10/2016	2

October	20/10/2016	3
November	03/11/2016	2
November	17/11/2016	2
December	08/12/2016	2
December	22/12/2016	3
January	05/01/2017	3
January	13/01/2017	2
January	26/01/2017	2
February	23/02/2017	4
February	28/02/2017	2
March	09/03/2017	2
March	21/03/2017	2
March	22/03/2017	2
March	23/03/2017	2

28 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**

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Diane Ackerley	10
Mrs Lisa Armstrong	1
Mrs Ravina Barrett	6
Mr Brian Birch	6
Mrs Janet Brember	7
Ms Julie Brinton	10
Mr Mark Cassidy	5
Dr Alessandro Di Nicola	3
Ms Sue Edwards	8
Ms Maisie Gibson	5
Dr Alex Gregory	7
Mrs Angela Iveson	3
Professor Ron King	3
Dr Vincenzo Libri	5
Mr Geoff Lowndes	7
Dr Julie Merriman-Jones	6
Miss Becci Petch	8
Dr Andrew Scott	5
Mrs Samantha Trace	5

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Diane Ackerley	1
Mrs Ravina Barrett	2
Mr Brian Birch	1
Mrs Janet Brember	1
Ms Julie Brinton	2
Mr Mark Cassidy	1
Ms Sue Edwards	2
Mrs Angela Iveson	1
Professor Ron King	1
Dr Vincenzo Libri	2
Miss Becci Petch	2
Dr Andrew Scott	3
Mrs Samantha Trace	1



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

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Diane Ackerley	3
Mrs Ravina Barrett	5
Mr Brian Birch	8
Mrs Janet Brember	6
Ms Julie Brinton	2
Mr Mark Cassidy	2
Dr Alessandro Di Nicola	1
Ms Sue Edwards	3
Mrs Angela Iveson	3
Professor Ron King	3
Dr Vincenzo Libri	9
Mr Geoff Lowndes	1
Dr Julie Merriman-Jones	3
Miss Becci Petch	1
Dr Andrew Scott	10
Mrs Samantha Trace	2

**Training 01 April 2016 - 31 March 2017**

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr Diane Ackerley	06/04/2016	Quantitative Research Methods and Statistics: A Health Research Authority Workshop
Dr Diane Ackerley	29/06/2016	Local Training Day - Hampshire B
Dr Diane Ackerley	01/02/2017	Medical Devices Training Day
Dr Diane Ackerley	22/03/2017	National Members Training Day
Mrs Lisa Armstrong	29/06/2016	Local Training Day - Hampshire B
Mrs Ravina Barrett	29/06/2016	Local Training Day
Mr Brian Birch	22/03/2017	National Members Training Day
Mrs Janet Brember	30/03/2017	Reading: Cancer drugs survival and ethics BMJ 2106 vol 355
Mrs Janet Brember	30/03/2017	Reading: HRA Breaches Guidance for RECs
Mrs Janet Brember	30/03/2017	Reading: Prisoners as research participants JME Vol. 42 Issue 4
Ms Julie Brinton	29/06/2016	Local Training Day - Hampshire B
Mr Mark Cassidy	11/05/2016	Assessing the Consequences (benefits and harms) of Research
Mr Mark Cassidy	29/06/2016	Local Training Day - Hampshire B
Dr Alessandro Di Nicola	29/06/2016	Local Training Day - Hampshire B
Dr Alessandro Di Nicola	12/07/2016	Research Involving Adults Who Lack Capacity
Dr Alessandro Di Nicola	15/09/2016	Committee Members Induction
Ms Sue Edwards	29/06/2016	Local Training Day - Hampshire B
Ms Maisie Gibson	15/09/2016	Committee Members Induction
Ms Maisie Gibson	22/03/2017	National Members Training Day
Dr Alex Gregory	14/03/2017	Committee Members Induction
Mrs Angela Iveson	29/06/2016	Local Training Day - Hampshire B
Professor Ron King	02/06/2016	NREAP / REC Chairs' Network Meeting: South Central
Dr Vincenzo Libri	01/12/2016	National Training Day for Committee Chairs
Dr Vincenzo Libri	08/01/2017	Training for New REC Chairs
Dr Vincenzo Libri	22/03/2017	National Members Training Day
Mr Geoff Lowndes	29/06/2016	Local Training Day - Hampshire B
Dr Julie Merriman-Jones	29/06/2016	Local Training Day - Hampshire

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Dr Julie Merriman-Jones	30/11/2016	Committee Members Induction
Dr Julie Merriman-Jones	01/02/2017	Medical Devices Training Day
Miss Becci Petch	09/05/2016	Training - Equality and Diversity (e-learning module)
Miss Becci Petch	08/06/2016	Committee Members Induction
Miss Becci Petch	29/06/2016	Local Training Day - Hampshire B
Dr Andrew Scott	29/06/2016	Local Training Day - Hampshire B
Dr Andrew Scott	30/06/2016	Training for New REC Chairs
Mrs Samantha Trace	05/09/2016	Riverside REC Local Training Day
Mrs Samantha Trace	06/12/2016	Committee Members Induction
Mrs Samantha Trace	24/02/2017	Local Training - Bristol REC

## 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	12	29.27
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	2	4.88
Research Database (including renewals)	0	0.00
Others	27	65.85
<b>Total Applications Reviewed</b>	<b>41</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	0
Number of student applications reviewed	13
Number of paediatric applications reviewed	4
Number of device applications reviewed	2
Number of prisoner applications reviewed	1
Number of applications involving adults unable consent reviewed	0
Number of applications reviewed that are funded by the US DHHS	1
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	2	4.88
Favourable Opinion with Additional Conditions	4	9.76
Unfavourable Opinion	1	2.44
Provisional Opinion	33	80.49
Provisional Opinion Pending Consultation with Referee	1	2.44
<b>Total</b>	<b>41</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	24	58.54
Further Information Favourable Opinion with Additional Conditions	6	14.63
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	4.88
Favourable Opinion with Additional Conditions	4	9.76
Unfavourable Opinion	1	2.44
Provisional Opinion	1	2.44
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	3	7.32
<b>Total</b>	<b>41</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>18</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	1
Number of studies withdrawn prior to the meeting	2
Number of student applications reviewed	8
Number of paediatric applications reviewed	0
Number of device applications reviewed	2
Number of qualitative applications reviewed	3

**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	4	22.22
Favourable Opinion with Additional Conditions	6	33.33
No Opinion transfer to full committee for review	1	5.56
Provisional Opinion	7	38.89
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>18</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>	4.10
<b>Number of completed applications for full ethical review</b>	38
<b>Number of completed applications for full ethical review over 60 days</b>	0
<b>Number of completed applications over 60 days as a % of total</b>	0.00%
<b>Number of completed applications for full ethical review over 40 days</b>	5
<b>Number of completed applications over 40 days as a % of total</b>	12.20%
<b>Number of days taken to final decision – average (mean)</b>	32
<b>Number of completed proportionate review applications for ethical review</b>	17
<b>Number of completed proportionate review applications for ethical review over 14 days [please note, the timeline for the review of PR was extended from 14 to 21 calendar days in December 2016]</b>	5
<b>Number of completed proportionate review applications for ethical review over 21 days</b>	1
<b>Number of completed proportionate review applications over 14 days as a % of total</b>	29.41%
<b>Number of SSAs (non-Phase 1) reviewed</b>	2
<b>Number of completed applications for SSA review over 25 days</b>	0
<b>Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs</b>	0.00%
<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>	115
<b>Number of completed substantial amendments over 35 days</b>	0
<b>Number of completed substantial amendments over 35 days as a % of total substantial amendments</b>	0.00%
<b>Number of completed substantial amendments over 28 days</b>	19
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	16.52%
<b>Number of modified amendments reviewed</b>	11
<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>	9.09%

<b>Number of non substantial amendments received</b>	95
<b>Number of substantial amendments received for information</b>	0
<b>Number of substantial amendments received for new sites/PIs</b>	30
<b>Number of annual progress reports received</b>	21
<b>Number of safety reports received</b>	84
<b>Number of Serious Adverse Events received</b>	10
<b>Number of final reports received</b>	6



**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>
16/SC/0213	Posttraumatic growth post lung transplant	38
16/SC/0229	SIMPLANT	38
16/SC/0275	Effect of Multi injections of Elamipretide on Patients with Chronic HF	39
16/SC/0278	Journeys of recovery following an alcohol detoxification programme	41
16/SC/0279	Identifying barriers and facilitators to HIV testing	35
16/SC/0390	Efficacy & safety of ofatumumab vs teriflunomide in RMS (OMB2301)	40
16/SC/0391	Efficacy & safety of ofatumumab vs teriflunomide in RMS (OMB2302)	40
16/SC/0407	Healthy Paths	34
16/SC/0451	Extension study of Patisiran in patients with FAP	35
16/SC/0454	SHP626-201 Volixibat in Adults with Nonalcoholic Steatohepatitis	30
16/SC/0471	Preferences for palliative care discussions in COPD	15
16/SC/0476	Pilot study of Navigated Subthreshold Microsecond Laser for DMO V1	27
16/SC/0510	RISCS - Risks in spinal consenting for surgery	31
16/SC/0619	My Baby Comes Smoke Free - supporting young mothers to quit smoking.	30
16/SC/0629	The ASSIST Study: case finding and 'at risk' case management	22
16/SC/0630	Efficacy and Safety of Filgotinib in Active Crohn's Disease	35
16/SC/0631	Long Term Safety of Filgotinib in Active Crohn's Disease	35
17/SC/0037	Opiate users' views and experiences of opioid medications	27
17/SC/0044	Implementing and Evaluating the GENIE tool in Southampton ICOPD Team.	41
17/SC/0081	Acadia ACP-103-033	43
17/SC/0096	Trial of a group programme intervention for men who abuse women	43
17/SC/0098	Salt-Swap	26
17/SC/0148	Beet the Cold	47
17/SC/0157	Medina PMCF Study	37

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/SC/0160	Pathophysiology of airway diseases (archive samples)	34
16/SC/0185	Experience of caring for a person with brain cancer at the end of life	34
16/SC/0276	Obese pregnant women's understanding of weight gain in pregnancy	32
16/SC/0370	Self control in perinatal mental health V1	33

17/SC/0008	Development of a new clamp	30
17/SC/0088	Mobile Mindfulness for Asthma	27

#### 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/SC/0042	The 99th Centile of highly sensitive troponin in a hospital population	23
17/SC/0156	TED10893	22

#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/SC/0141	Oxford Vaccine Centre Biobank	27
16/SC/0222	Prolonged Effects of ART: a Record Linkage study (PEARL)	27
16/SC/0466	Pregnancy after kidney donation	21
17/SC/0161	LSVT Treatment in Ataxia	25

#### Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
16/SC/0627	Implementing and Evaluating the GENIE tool in Southampton ICOPD Team.	22

#### Provisional Opinion

REC Reference	Title	Number of Days on Clock
17/SC/0158	Epacadostat and nivolumab in Selected Advanced Cancers	n/a

#### Provisional Opinion Pending Consultation with Referee

REC Reference	Title	Number of Days on Clock
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<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>
16/SC/0263	Bilingualism as a predictor of cognitive & brain decline in older age	27
16/SC/0492	Assessing nutrition in children receiving chemotherapy	27
16/SC/0483	MEDI0680 with MEDI4736 and MEDI0680 Alone in Advanced Malignancies	27

**Table 9.2: Breakdown of current status of all PRS 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>
16/SC/0479	Understanding the PAK and the PI3K pathway in pancreatic cancer	14
16/SC/0669	Evaluation of Fat Grafting and Systemic Sclerosis	7
16/SC/0672	Fluorosis in adults: a feasibility study	7
17/SC/0076	Organising general practice for care homes: Qualitative interviews	16
17/SC/0131	Characterisation of Bronchiectasis patients	30

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/SC/0306	Maternity and paternity leave knowledge, plans & experiences V3	12
16/SC/0475	GOLD AF Registry	12

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

<b>Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/SC/0241	Self-rated mental health or medication record predicts suicide?	16
16/SC/0673	CESOTUG Study v1.0	6
17/SC/0017	NITRATE-OCT-CIN Substudy	21
17/SC/0020	Incidence and outcomes of long QT on an acute medical ward	20

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/SC/0242	Admission to a care home from hospitals across Scotland	14
16/SC/0243	Personal perspectives (tinnitus)	10
16/SC/0244	Visual shape categorisation in Autism	10
16/SC/0305	Urine free cortisol method and reference range determination study	7
16/SC/0307	RTGene	8
17/SC/0077	Perfusion mapping in ischaemic heart disease and cardiomyopathy	14

<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>

**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>
05/Q1704/108/AM05	Assessment of correlation between direct ICP and TMD measurements	8	13/01/2016	32
07/H0504/187/AM05	The pathogenesis and immunoregulation of skin cancer.	5	05/08/2016	25
07/Q1704/68/AM05	IELSG26: Study of Primary Mediastinal Lymphoma	Substantial Amendment 3	02/11/2016	14
08/H0504/15/AM55	Response adapted therapy in Hodgkin lymphoma Version number 2.3	Change of PI (59)	01/06/2016	22
08/H0504/73/AM12	A3671024 A study for patients who have received CP-675,206 previously	6	11/03/2016	34
08/H0504/73/AM13	A3671024 A study for patients who have received CP-675,206 previously	Substantial Amendment 7	30/09/2016	26
09/H0501/90/AM16	Head and Neck Cancer: molecular, cellular and immunological mechanisms	9	14/03/2016	19
09/H0504/104+5/AM 04	Cardiovascular Biomedical Research Unit Biobank	Amendment 04	19/08/2016	15
09/H0504/104+5/AM 05	Cardiovascular Biomedical Research Unit Biobank	Amendment 5a	18/10/2016	21
09/H0504/125/AM06	Genetics of Paediatric Inflammatory Bowel Disease	SA5	22/02/2017	19
10/H0501/39/AM06	Myeloid-derived suppressor cells in haematological malignancies	SA5	09/01/2017	22
10/H0504/11/AM05	Prevalence of Food Hypersensitivity in Children	Amendment 5	25/04/2016	25
10/H0504/79/AM47	REMoDL-B v1.0	26	03/02/2016	31
10/H0504/79/AM52	REMoDL-B v1.0	Amendment 28	06/10/2016	28
10/H0504/93/AM15	A Phase III Study of INC424 in Polycythemia Vera Patients	Patient dosing diary V1.0	31/08/2016	14
11/H0504/2/AM05	Rapid Imaging Assessment of the Liver	4	01/03/2016	27
11/SC/0258/AM01	Apoptosis and bicuspid aortic valve associated aortopathy. Version 3	Amendment 1	18/10/2016	30

11/SC/0543/AM04	FOR-DMD	Amendment 4	24/08/2016	19
11/SC/0543/AM05	FOR-DMD	Amendment 5	14/11/2016	14
12/SC/0353/AM08	BREATHE: Breathing REtraining for Asthma, Trial of Home Exercises. V1	AM7	25/11/2015	20
12/SC/0359/AM01	Immune cell dysfunction in severe alcoholic hepatitis	Amendment number 1	09/09/2016	30
12/SC/0391/AM14	COAST - Cisplatin Ototoxicity attenuated by Aspirin Trial	SA10	09/01/2017	22
12/SC/0394/AM16	COMPLEMENT A + B:	Sponsorship transfer from Glax	08/11/2016	8
12/SC/0428/AM10	YoDA Young Onset Dementia Assessment Study	8	03/03/2016	35
12/SC/0492/AM09	OXWATCH- Women and Wellbeing Study	7	19/02/2016	33
12/SC/0580/AM05	Views & Experience of Magnetic Resonance imaging during pregnancy	Amendment 5	24/06/2016	25
13/SC/0041/AM08	Consent and confidentiality in genetic medicine	4	09/11/2016	26
13/SC/0092/AM16	CBAF312A2304 siponimod in secondary progressive multiple sclerosis v1	Substantial Amendment dated 31	31/03/2016	26
13/SC/0092/AM18	CBAF312A2304 siponimod in secondary progressive multiple sclerosis v1	SA update of Pt addendum	25/10/2016	21
13/SC/0102/AM23	MK3475-010-00	SA015	06/12/2016	33
13/SC/0105/AM08	Southampton Women's Survey 10-13yr follow-up	3	29/07/2016	32
13/SC/0105/AM09	Southampton Women's Survey 10-13yr follow-up	4	03/01/2017	16
13/SC/0384/AM12	Tremilimumab in pleural or peritoneal malignant mesothelioma	Substantial Amendment 7	06/09/2016	15
13/SC/0394/AM07	METRIC(MR Enterography or uTRasound In Crohn's disease)	Amendment 5 21 March 2016	23/03/2016	27
13/SC/0409/AM04	SPRING Southampton Pregnancy Intervention for the Next Generation	AM04 Substantial Amendment 1.6	30/03/2016	20
13/SC/0478/AM22	LGX818, MEK162 and LGX818 vs vemurafenib in melanoma patients.	V 13.0 and V 6.0	08/03/2017	25
13/SC/0592/AM03	Barts Pancreas Tissue Bank	Substantial amendment 2	03/06/2016	28
13/SC/0593/AM01	Pancreatic Cancer Research Fund Tissue Bank	Substantial amendment 1	03/06/2016	22
13/SC/0644/AM08	UNBLOCS: UriNary oBstruction relieved by Laser Or Conventional Surgery	Amendment 4	31/05/2016	17

13/SC/0644/AM09	UNBLOCS: UriNary oBstruction relieved by Laser Or Conventional Surgery	Amendment 5	30/09/2016	13
13/SC/0645/AM05	PHOENIX Study - Version 1	4	21/03/2016	25
13/SC/0645/AM06	PHOENIX Study - Version 1	Amendment 05	09/05/2016	32
13/SC/0645/AM08	PHOENIX Study - Version 1	06	12/08/2016	23
14/SC/0039/AM12	PDSAFE trial	Amendment 8	18/10/2016	21
14/SC/0066/AM02	EDICT - Exercise inDuced changes In Colorectal Cancer Tissues	AM02 Substantial Amendment: 2	15/04/2016	15
14/SC/0221/AM06	CONCEPT	AM06 Substantial Amendment: Am	09/03/2016	31
14/SC/0221/AM10	CONCEPT	Amendment 8	21/06/2016	9
14/SC/1034/AM08	Prostate Cancer UK Module 3 Phase 1: Evaluation of existing clamps	7	25/08/2016	14
14/SC/1056/AM02	COMPARE	Amendment 2	18/03/2016	12
14/SC/1169/AM09	SPACE FOR COPD in primary care: a pragmatic trial	Amendment 4	11/08/2016	25
14/SC/1177/AM05	Prostate Cancer UK Module 4 Phase 1: Evaluation of existing products	Amendment 4 dated 24/02/2016	24/02/2016	28
14/SC/1223/AM06	CALIBER	2	09/03/2016	32
14/SC/1223/AM09	CALIBER	Substantial Amendment 3	02/11/2016	13
14/SC/1236/AM03	GO28399 Open label extension study of Vemurafenib	Am 3 - IB 13, PIS V6	29/04/2016	15
14/SC/1334/AM02	PREHEAT Trial - local heat preconditioning and wound healing	2	26/02/2016	7
14/SC/1337/AM11	200977 Study of Albiglutide in patients with Type 2 Diabetes Mellitus	Substantial Amendment 6	07/05/2016	20
14/SC/1337/AM13	200977 Study of Albiglutide in patients with Type 2 Diabetes Mellitus	Substantial Amendment 8	05/09/2016	14
14/SC/1340/AM16	LEGATO-HD (Laquinimod Efficacy and Safety in a GlobAl Trial Of HD)	Updated PIS	07/06/2016	16
15/SC/0084/AM01	Lived experiences during the menopausal transition V2	Amendment 1	16/06/2016	35
15/SC/0085/AM03	Role of vinegar in identifying abnormal cells in Barrett's oesophagus	Amendment 5, substantial 4	12/05/2016	28
15/SC/0101/AM01	Biomedical Research Unit (BRU) Respiratory Biobank	Amendment 01	03/10/2016	7
15/SC/0112/AM03	A community based Liver Service in vulnerable adults	2	21/04/2016	13
15/SC/0253/AM01	TB EYE	Amendment 1	08/12/2016	28
15/SC/0256/AM07	Inhaled Interferon Beta-1a vs placebo in asthma patients	Substantial	21/06/2016	19

		Amendment 4		
15/SC/0256/AM09	Inhaled Interferon Beta-1a vs placebo in asthma patients	Substantial Amendment 2	23/12/2015	11
15/SC/0289/AM03	AMG 319 in HPV negative HNSCC	AM03 Substantial Amendment: CT	17/05/2016	15
15/SC/0291/AM07	MO29518 - A phase II Study of MPDL3280A in Advanced Solid Tumours	SA 08	22/09/2016	18
15/SC/0429/AM01	Prospective study of understudied drugs in children	1	17/02/2016	26
15/SC/0430/AM01	JVDB: Second Line Gastric/Gastroesophageal Cancer	Substantial Amendment 1	17/03/2016	31
15/SC/0442/AM02	The ANODE Trial	1.0	11/03/2016	29
15/SC/0442/AM04	The ANODE Trial	Substantial Amendment 4	22/04/2016	20
15/SC/0442/AM07	The ANODE Trial	Substantial Amendment 8	28/11/2016	7
15/SC/0506/AM03	Mybirthplace ; useful for helping inform womens decision making ? 3.0	version 5	06/07/2016	23
15/SC/0614/AM03	EBC biomarkers and cough in IPF	2	05/05/2016	8
15/SC/0640/AM02	CALYPSO	Amendment 2.0	24/10/2016	13
15/SC/0640/AM03	CALYPSO	3.0	28/11/2016	7
15/SC/0720/AM01	The Six-Minute Walk Test in Pregnant Women – a Reference Range Study	1	08/06/2016	25
15/SC/0725/AM01	Gait Cycle Analysis after Physica KR Total Knee Replacement	AM01 Substantial Amendment 1;	01/03/2016	26
16/SC/0036/AM01	Phase 1b Study of Necitumumab with Pembrolizumab in Advanced NSCLC	1	29/02/2016	27
16/SC/0036/AM02	Phase 1b Study of Necitumumab with Pembrolizumab in Advanced NSCLC	AM02 Substantial Amendment: 2	03/03/2016	14
16/SC/0038/AM02	Anxiety and sexual function	substantial amendment 2	11/09/2016	17
16/SC/0040/AM01	Exploring mindfulness for older adults with dementia and their carers	1	10/04/2016	14
16/SC/0040/AM02	Exploring mindfulness for older adults with dementia and their carers	Amendment two	01/05/2016	20
16/SC/0041/AM01	Integrating palliative care into management of advanced liver disease	Amendment 1	05/12/2016	19



16/SC/0057/AM01	Assessment of the accuracy of an alternative lung function test	1	20/05/2016	22
16/SC/0057/AM02	Assessment of the accuracy of an alternative lung function test	Amendment 2	20/07/2016	28
16/SC/0103/AM02	TrueColours Ulcerative Colitis Version 1.0	Amendment 1	23/08/2016	20
16/SC/0106/AM01	POINT, v1.1 06Aug15	SA1	15/08/2016	21
16/SC/0106/AM02	POINT, v1.1 06Aug15	SA2	20/02/2017	27
16/SC/0222/AM01	Prolonged Effects of ART: a Record Linkage study (PEARL)	Amendment 1	05/01/2017	16
16/SC/0229/AM01	SIMPLANT	1	25/10/2016	14
16/SC/0229/AM03	SIMPLANT	2	18/11/2016	19
16/SC/0275/AM02	Effect of Multi injections of Elamipretide on Patients with Chronic HF	AM02 - Protocol SPIHF-201	01/12/2016	22
16/SC/0278/AM01	Journeys of recovery following an alcohol detoxification programme	Amendment 1	22/11/2016	18
16/SC/0451/AM02	Extension study of Patisiran in patients with FAP	SA2	22/02/2017	29
16/SC/0454/AM01	SHP626-201 Volixibat in Adults with Nonalcoholic Steatohepatitis	SA1	17/02/2017	20
16/SC/0475/AM01	GOLD AF Registry	Amendment 1	11/01/2017	16
16/SC/0629/AM01	The ASSIST Study: case finding and 'at risk' case management	SA1	03/02/2017	23
16/SC/0630/AM01	Efficacy and Safety of Filgotinib in Active Crohn's Disease	SA#1	11/01/2017	21
16/SC/0630/AM03	Efficacy and Safety of Filgotinib in Active Crohn's Disease	SA2	07/03/2017	28
16/SC/0631/AM01	Long Term Safety of Filgotinib in Active Crohn's Disease	SA#1	11/01/2017	21

### Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
08/H0501/85/AM07	Peritoneal Fluid Biology in Health and Disease	Amendment 6	15/12/2016	19
09/H0504/104+5/AM03	Cardiovascular Biomedical Research Unit Biobank	Amendment 03 Aug 2015	15/03/2016	8
13/SC/0081/AM02	What is the experience of Young People being Taught Mindfulness in DBT	AM02 Substantial Amendment 2:	11/01/2016	32
13/SC/0384/AM11	Tremilimumab in pleural or peritoneal malignant mesothelioma	Substantial Amendment 6	17/06/2016	25
13/SC/0643/AM01	Prevalence of cardiac ATTR amyloidosis in the elderly	Amendment 1	20/12/2016	18
14/SC/1340/AM18	LEGATO-HD (Laquinimod Efficacy and Safety in a Global Trial Of HD)	Investigator's Brochure Edition	20/09/2016	33

14/SC/1340/AM20	LEGATO-HD (Laquinimod Efficacy and Safety in a GlobAI Trial Of HD)	12	30/01/2017	25
15/SC/0018/AM01	Does Rapid Mobilisation Improve Length of Stay and Outcomes Post THR?	1	06/06/2016	32
15/SC/0045/AM05	THERAPIST Version 1.0	2	21/03/2016	19
15/SC/0289/AM04	AMG 319 in HPV negative HNSCC	CTA Amendment 04	25/08/2016	28
15/SC/0702/AM01	Growth in gastroschisis	1	19/04/2016	9
16/SC/0141/AM01	Oxford Vaccine Centre Biobank	SA1	06/02/2017	20
16/SC/0451/AM01	Extension study of Patisiran in patients with FAP	SA1	03/02/2017	25
194/99/1/AM01	Bone formation in the young and ageing skeleton	Amendment 4	19/02/2016	27

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

<b>Favourable opinion timeline</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
08/H0501/85/AM07/1	Peritoneal Fluid Biology in Health and Disease	SA7	03/02/2017	8
09/H0504/104+5/AM03/1	Cardiovascular Biomedical Research Unit Biobank	3a	04/05/2016	11
10/H0504/93/AM14/1	A Phase III Study of INC424 in Polycythemia Vera Patients	Modified 05	16/02/2016	5
13/SC/0081/AM02/1	What is the experience of Young People being Taught Mindfulness in DBT	Version 3	25/04/2016	1
13/SC/0384/AM11/1	Tremilimumab in pleural or peritoneal malignant mesothelioma	Modified amendment 6	22/08/2016	8
14/SC/1072/AM01/1	POMP v0.1	Modified Amendment	22/03/2016	8
15/SC/0018/AM01/1	Does Rapid Mobilisation Improve Length of Stay and Outcomes Post THR?	Amendment 2	30/08/2016	6
15/SC/0045/AM05/1	THERAPIST Version 1.0	SA #2	12/07/2016	6

		(RESUBMISSION)		
15/SC/0289/AM04/1	AMG 319 in HPV negative HNSCC	Modified CTA 04	03/10/2016	7
15/SC/0496/AM01/2	Test-retest operator typical error for tHb-mass measurement.	Modified 1.2	28/08/2015	2
15/SC/0702/AM01/1	Growth in gastroschisis	Revised Amendment 1	08/07/2016	28

### 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
17/SC/0131	Characterisation of Bronchiectasis patients	30

**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
15/SC/0702/AM01/1	Growth in gastroschisis	Revised Amendment 1	08/07/2016	28