

**South Central - Oxford C Research Ethics  
Committee**

**Annual Report**

**01 April 2016 - 31 March 2017**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	South Central - Oxford C Research Ethics Committee
<b>Type of REC:</b>	REC recognised to review CTIMPs in patients -Type III
<b>Type of Flag:</b>	Adults Lacking Capacity Phase 1 in Patients Research Database Research Tissue Bank Qualitative
<b>Chair:</b>	Professor Nigel Wellman
<b>Vice-Chair:</b>	Mrs Susan Lousada
<b>Alternate Vice-Chair:</b>	Dr Lee Potiphar
<b>REC Manager:</b>	Mrs Maeve Ip Groot Bluemink (01/04/16 – 08/01/17) Ms Helen Sivey (09/01/17 – 31/03/17)
<b>REC Assistant:</b>	Ms Sadie McKeown-Keegan (01/04/16 – 08/01/17) Ms Amy Peters (09/01/17 – 31/03/17)
<b>Committee Address:</b>	Level 3, Block B Whitefriars Building Lewins Mead Bristol BS1 2NT
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<b>Email:</b>	<a href="mailto:nrescommittee.southcentral-oxfordc@nhs.net">nrescommittee.southcentral-oxfordc@nhs.net</a>

## Chair's overview of the past year:

As always, Oxford C has remained very busy over the last year, reviewing a wide range of studies ranging from qualitative investigations of health experiences through to large and complex interventional medical and surgical studies including some with novel adaptive designs. The committee has again reviewed a number of emergency studies on critically ill and unconscious patients and this has come to form a significant and growing percentage of our work. We have also reviewed an increasing number of medical device studies over recent years, some of which have been emergency studies or studies which otherwise involved adults lacking capacity and we have arranged training for the committee on the ethical review of medical device studies in the hope of obtaining flagging for the review of this type of application. Throughout the last year, both the full committee and the sub-committee systems have worked well and have continued to deliver sensible and pragmatic decisions which have balanced the protection of the public with the promotion of high quality research for the public good.

As inevitably happens, valued members have retired or otherwise moved on from the committee and we have welcomed new members in their place. Additionally, we have also welcomed back one former member who left and then returned to the fold. Our former Vice-Chair Professor David Scott retired from the NHS and the REC and moved to Africa to help develop the teaching of pharmacy there and the Alternate Vice-Chair Mrs Susan Lousada was appointed to replace David as Vice-chair, with Dr Lee Potiphar stepping up to replace Mrs Lousada as our new Alternate Vice-Chair.

We have maintained the division of labour whereby the Chair manages the main REC and sub-committee business arising from the main REC and the vice-chairs manage the proportionate review work. This arrangement has continued to work well despite fluctuations in our membership over the year. As in previous years. As a chair, I feel very privileged to have had the support of Professor Scott, Mrs Lousada and Dr Potiphar as well as our very committed group of lay and expert members.

There have also been changes in the staffing of the committee over the last year, with our former REC manager Mrs Maeve Ip Groot Bluemink leaving the committee to work on HRA approval and being replaced by Ms Helen Sivey. Maeve's former assistant Ms Sadie McKeown-Keegan also left us, being promoted to manage RECs of her own and Sadie was replaced by Ms Amy Peters. We thank Maeve and Sadie for all of their hard work for the committee and look forward to a long and productive relationship with Helen and Amy.

Finally, I would like to thank the officers, members and staff of the committee for their commitment, diligence and hard work. I am convinced that the committee will continue to deliver a prompt, courteous and efficient service to the research community over the next twelve months.

## South Central - Oxford C Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Leonard Brookes	Consultant to the Pharmaceutical Industry	Lay	01/04/2010	
Dr Ben Caswell	Accountant	Lay Plus	15/09/2016	
Dr Alessandro Di Nicola	Lecturer in Philosophy	Lay Plus	12/09/2016	
Mrs Rebekah Howe	Farmer	Lay Plus	15/09/2016	
Mrs Vivienne Laurie	Barrister	Lay Plus	15/11/2012	
Dr Simon Lord	Honorary Consultant in Medical Oncology and Senior Clinical Researcher in Experimental Cancer Therapeutics	Expert	01/01/2016	
Mrs Susan Lousada	Company Director (Property) & Non-legal member of first-tier tax tribunal	Lay Plus	01/04/2010	
Mr Barry Muir	NHS Management Consultant (Retired)	Lay	01/05/2006	07/10/2016
Dr Lee Potiphar	Lecturer in Adult Nursing (Evidence Based Practice)	Expert	26/03/2015	
Mr Chris Pratt	Specialist Cancer Pharmacist	Expert	25/07/2016	
Ms Anna Rathmell	Medical Manager - GI	Lay	01/02/2016	
Professor David Scott	Pharmacist	Expert	10/08/2010	30/06/2016
Dr Sabeena Sharma	Consultant Anaesthetist	Expert	23/05/2011	
Mrs Gill Shaw	Senior Valuer/Sales Negotiator (Retired)	Lay Plus	01/08/2016	01/10/2016
Dr Surjeet Singh	Clinical Trials Coordinator	Expert	17/01/2013	
Ms Kayleigh Stanbury	Trial Coordinator and Developmental Assessor	Lay	29/01/2015	
Mrs Elizabeth Ward	Clinical Trial Coordinator	Lay	17/11/2015	
Professor Nigel Wellman	Professor of Health and Human Sciences	Expert	01/09/2010	

## South Central - Oxford C Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
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## South Central - Oxford C Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Dr Kim Cheetham	Retired Consultant Paediatrician	Expert	24/02/2017
Professor Jo Brooke	Associate Professor in Dementia Care	Expert	24/02/2017

## South Central - Oxford C Research Ethics Committee: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Dr Leonard Brookes	None	31/03/2017
Dr Ben Caswell	None	31/03/2017
Dr Alessandro Di Nicola	None	24/11/2016
Mrs Rebekah Howe	None	01/04/2016
Mrs Vivienne Laurie	Shareholder in organisations involved in or possibly seeking to be involved in the conduct of research	24/02/2017
Dr Simon Lord	Consultant in medical oncology and researcher in early phase clinical trials (oncology) at the University of Oxford and Oxford University Hospitals NHS Trust.	31/03/2017
Mrs Susan Lousada	None	23/05/2016
Mr Barry Muir	None	14/05/2016
Dr Lee Potiphar	None	24/02/2017
Mr Chris Pratt	None	31/03/2017
Ms Anna Rathmell	Training Lead Oncology Europe and Canada-Takeda Pharmaceuticals Ltd.	24/02/2017
Professor David Scott	Member of Oxford University Tropical Research Ethics Committee	31/03/2017
Dr Sabeena Sharma	Medical research in capacity of a clinician	25/05/2016
Mrs Gill Shaw	None	31/03/2017
Dr Surjeet Singh	Surgical Trials Operation Lead - part of Oxford CTU	31/03/2017
Ms Kayleigh Stanbury	Works within the Clinical Trial Unit at University of Oxford who work on a variety of research and clinical trials which all require ethical review.	31/03/2017
Mrs Elizabeth Ward	Paid position: Work as a clinical trial coordinator at the oncology clinical trials office, Oxford University.	31/03/2017
Professor Nigel Wellman	Owner - Wellman Research & Consulting. Professor Health & Human Sciences, University West London. Senior Lecturer in mental Health Nursing - Oxford Brookes University. Lecturer University of Surrey.	31/03/2017

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

Month	Date	Number of Members Present at Meeting
April	22/04/2016	9
May	27/05/2016	11
June	24/06/2016	9
August	26/08/2016	9
September	30/09/2016	10
October	28/10/2016	12
November	25/11/2016	12
January	27/01/2017	8
February	24/02/2017	8
March	31/03/2017	9

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	06/04/2016	3
May	04/05/2016	3
July	06/07/2016	3
August	03/08/2016	3
September	07/09/2016	3
October	05/10/2016	3
November	02/11/2016	3
December	07/12/2016	3
February	22/02/2017	3
March	22/03/2017	4

10 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	04/04/2016	2
April	13/04/2016	2
April	13/04/2016	2
April	27/04/2016	2
May	11/05/2016	2
May	11/05/2016	3
May	16/05/2016	2
May	25/05/2016	2
June	06/06/2016	3
June	08/06/2016	2
June	13/06/2016	3

June	22/06/2016	2
July	06/07/2016	2
July	15/07/2016	2
August	03/08/2016	2
August	17/08/2016	2
August	31/08/2016	2
September	14/09/2016	2
September	28/09/2016	2
October	12/10/2016	2
October	17/10/2016	2
October	26/10/2016	2
November	09/11/2016	2
November	23/11/2016	2
December	01/12/2016	4
December	07/12/2016	2
December	21/12/2016	2
January	04/01/2017	2
January	18/01/2017	2
February	01/02/2017	2
March	03/03/2017	2
March	10/03/2017	2
March	17/03/2017	2
March	24/03/2017	5

34 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 Leonard Brookes	9
Dr Ben Caswell	5
Dr Alessandro Di Nicola	2
Mrs Rebekah Howe	5
Mrs Vivienne Laurie	8
Dr Simon Lord	6
Mrs Susan Lousada	7
Mr Barry Muir	3
Dr Lee Potiphar	9
Mr Chris Pratt	5
Ms Anna Rathmell	9
Professor David Scott	2
Dr Sabeena Sharma	8
Mrs Gill Shaw	2
Dr Surjeet Singh	1
Ms Kayleigh Stanbury	3
Mrs Elizabeth Ward	2
Professor Nigel Wellman	9

**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 Leonard Brookes	1
Mrs Vivienne Laurie	3
Dr Simon Lord	4
Mrs Susan Lousada	5
Mr Barry Muir	2
Dr Lee Potiphar	7
Mr Chris Pratt	1
Ms Anna Rathmell	2
Professor David Scott	1
Dr Sabeena Sharma	1
Dr Surjeet Singh	1
Ms Kayleigh Stanbury	4
Mrs Elizabeth Ward	1

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

<b>Name</b>	<b>Number of Meetings</b>
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	<b>Attended</b>
Dr Leonard Brookes	5
Dr Ben Caswell	1
Mrs Rebekah Howe	2
Mrs Vivienne Laurie	2
Dr Simon Lord	3
Mrs Susan Lousada	7
Mr Barry Muir	3
Dr Lee Potiphar	12
Mr Chris Pratt	3
Ms Anna Rathmell	2
Professor David Scott	4
Dr Surjeet Singh	1
Ms Kayleigh Stanbury	2
Mrs Elizabeth Ward	2
Professor Nigel Wellman	28

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

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr Leonard Brookes	14/10/2016	Genetic and Genomic Research
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	10/01/2017	Committee Members Induction
Mrs Vivienne Laurie	02/09/2016	Joint Oxford Local Training Day
Dr Simon Lord	31/03/2017	SDL log
Mr Barry Muir	02/09/2016	Joint Oxford Local Training Day
Dr Lee Potiphar	02/09/2016	Joint Oxford Local Training Day
Dr Lee Potiphar	05/09/2016	Local Training Day - London - Riverside
Dr Lee Potiphar	09/11/2016	Training for New REC Chairs
Dr Lee Potiphar	29/11/2016	South West and South Central Chairs Network meeting
Mr Chris Pratt	23/10/2016	Online Induction
Ms Anna Rathmell	12/02/2017	Active involvement in a research project 'Real World Effectiveness of Vedolizumab in Inflammatory Bowel Disease (REVIVE)
Dr Sabeena Sharma	02/09/2016	Joint Oxford Local Training Day
Mrs Gill Shaw	02/09/2016	Joint Oxford Local Training Day
Professor Nigel Wellman	02/06/2016	South West and South Central Chairs Network meeting
Professor Nigel Wellman	23/08/2016	Equality Diversity and Human Rights
Professor Nigel Wellman	29/11/2016	South West and South Central Chairs Network meeting
Professor Nigel Wellman	28/01/2017	NREAP big data event

## 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	15	25.86
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	1	1.72
Research Database (including renewals)	2	3.45
Others	40	68.97
<b>Total Applications Reviewed</b>	<b>58</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	1
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	12
Number of paediatric applications reviewed	6
Number of device applications reviewed	4
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	12
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	3

**Table 3: Decisions given at meetings held within the reporting period**

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	4	6.90
Favourable Opinion with Additional Conditions	23	39.66
Unfavourable Opinion	2	3.45
Provisional Opinion	28	48.28
Provisional Opinion Pending Consultation with Referee	1	1.72
<b>Total</b>	<b>58</b>	<b>100</b>
Number of studies sent back to full committee meeting for final opinion	0	

**Table 4: Summary of current status of applications reviewed during the reporting period**

<b>Status of applications at date of generation of report</b>	<b>Number</b>	<b>%</b>
Further Information Favourable Opinion with Standard Conditions	24	41.38
Further Information Favourable Opinion with Additional Conditions	2	3.45
Further Information Unfavourable Opinion	1	1.72
Favourable Opinion with Standard Conditions	4	6.90
Favourable Opinion with Additional Conditions	23	39.66
Unfavourable Opinion	2	3.45
Provisional Opinion	2	3.45
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
<b>Total</b>	<b>58</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>23</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	4
Number of studies withdrawn prior to the meeting	1
Number of student applications reviewed	9
Number of paediatric applications reviewed	4
Number of device applications reviewed	1
Number of qualitative applications reviewed	2

**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	7	30.43
Favourable Opinion with Additional Conditions	7	30.43
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	9	39.13
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>23</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>	5.80
<b>Number of completed applications for full ethical review</b>	58
<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>	11
<b>Number of completed applications over 40 days as a % of total</b>	18.97%
<b>Number of days taken to final decision – average (mean)</b>	32
<b>Number of completed proportionate review applications for ethical review</b>	23
<b>Number of completed proportionate review applications for ethical review over 21 days</b>	4
<b>Number of completed proportionate review applications over 21 days as a % of total</b>	17.39%
<b>Number of SSAs (non-Phase 1) reviewed</b>	3
<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>	33.33%
<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>	131
<b>Number of completed substantial amendments over 35 days</b>	6
<b>Number of completed substantial amendments over 35 days as a % of total substantial amendments</b>	4.58%
<b>Number of completed substantial amendments over 28 days</b>	27
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	20.61%
<b>Number of modified amendments reviewed</b>	0
<b>Number of completed modified amendments over 14 days</b>	0
<b>Number of completed modified amendments over 14 days as a % of total modified amendments</b>	0.00%
<b>Number of non substantial amendments received</b>	150
<b>Number of substantial amendments received for information</b>	4
<b>Number of substantial amendments received for new sites/PIs</b>	42
<b>Number of annual progress reports received</b>	60

<b>Number of safety reports received</b>	27
<b>Number of Serious Adverse Events received</b>	2
<b>Number of final reports received</b>	13

**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/0187	Bone density and body composition in sporting athletes	33
16/SC/0207	CA209-436 Nivolumab with Brentuximab Vedotin in Non-Hodgkin Lymphoma	40
16/SC/0211	AC-LPI	36
16/SC/0224	Neuromyelitis Optica Spectrum Disorders and MS Research Tissue Bank	30
16/SC/0277	Point Of Care Testing For Sepsis: A Diagnostic Accuracy Study	29
16/SC/0314	Death in the haemodialysis community	22
16/SC/0323	Adenosine Triphosphate Delivery Rates in Myocardial Hypertrophy	44
16/SC/0343	The Oxford Wearable Device Dialysis Study	29
16/SC/0346	Clinical Endocrine Registry	30
16/SC/0377	Improving outcomes from the treatment of back pain - Maintenance V1.0	46
16/SC/0473	ResQFoam for Exsanguinating Trauma Abdominal Haemorrhage	40
16/SC/0474	Trial of 5-Aminolevulinic Acid to Enhance Cardioprotection (TALEN)	29
16/SC/0482	Computerized tool for social cognitive screening (OCS-social)	50
16/SC/0503	SCOTCHIS trial	44
16/SC/0524	DRIVE - Desmopressin for procedures or Radiological Interventions	40
16/SC/0547	A Phase I/II trial of intralesional administration of RGT100	35
16/SC/0553	Ebselen as an add-on treatment in hypo/mania V1.0	42
16/SC/0621	Kids4LIFe	36
16/SC/0679	British Academy ARP DALIP	35
17/SC/0051	Structured Preparation for Alcohol Detoxification	53
17/SC/0058	The Ox-IMPACT study V1.0	45
17/SC/0071	Speech processing in children born with cleft palate (1)	43
17/SC/0142	The 65 Trial (v1.0)	29

<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/0566	3743/0001_Pulse_MEDIS-INT16-002	40
16/SC/0567	R2810-ONC-1606, Treatment-naïve Unresectable Stag III/IV Melanoma	36

**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
16/SC/0188	Osteoarthritis Thumb Therapy II Trial (OTTER II trial)	26
16/SC/0406	Long-term follow-up of Asymptomatic Carotid Surgery Trial (ACST-1)	25
16/SC/0509	MUSIC AND DEMENTIA FEASIBILITY STUDY	26
17/SC/0073	BisCK study	27

### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/SC/0223	Vitamin D in people with learning disabilities	31
16/SC/0235	Oral care and chest infections in adults with a neuro-disability	31
16/SC/0264	HAVEN	31
16/SC/0271	plasmaMATCH	31
16/SC/0274	OX HARP-I	33
16/SC/0317	The experience of TYAC offered ovarian tissue cryopreservation	21
16/SC/0338	PITCH PILOT	21
16/SC/0344	Oxford Genetic Frontotemporal Dementia Initiative (Oxford GENFI)	21
16/SC/0435	Trial of Intranasal Esketamine for Treatment of Depression SUSTAIN-3	23
16/SC/0437	Feasibility study to assess pre-admission status and six month outcome	25
16/SC/0440	Assessing subcutaneous melatonin with in-vivo microdialysis	25
16/SC/0502	The ACL SNNAP Trial: ACL Surgery Necessity in Non Acute Patients.	26
16/SC/0584	IVIg and rituximab in antibody-associated psychosis - SINAPPS2	25
16/SC/0613	Dual-energy CT occult scaphoid injury	25
16/SC/0618	Finding out whether virtual reality may help individuals feel safer	25
17/SC/0029	OxCAMS: The Oxford Calcium Channel Antagonism Study	25
17/SC/0033	Combination therapy with isatuximab in patients with multiple myeloma	25
17/SC/0034	ARK-hospital	25
17/SC/0065	7T MRS in first episode psychosis	27
17/SC/0074	TOPHIP: Topical NSAIDs in the Treatment of Hip Osteoarthritis	27
17/SC/0090	c-TRAK TN	27
17/SC/0128	Timed Interval Measurement of Eotaxin in Stroke Study (TIMES Study) v1	26
17/SC/0133	Characterisation of graft pancreatitis using FACBC	26

<b>Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/SC/0221	Effect of Personality on Neural Reward and Aversion Processing	26
16/SC/0639	Exploring Service User experiences of Mental Health Act assessments	21

<b>Provisional Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/SC/0049	Investigations of RVD1 pathway in patients with emergency laparotomy	n/a
17/SC/0095	GOAT (Glutamatergic OCD&ASD Treatments)	n/a
17/SC/0139	Liposomal bupivacaine in knee replacement surgery	n/a
17/SC/0164	Early cryoprecipitate in major trauma haemorrhage: CRYOSTAT-2	n/a

<b>Provisional Opinion Pending Consultation with Referee</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 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/0438	Pre-EMPT Version 1	10
16/SC/0550	Grampian Hospitals Art Trust "Artroom" Evaluation	18

17/SC/0092	Hidden Hearing Loss	21
17/SC/0146	Expanding Community Ultrasound Services in Rural Scotland	36
17/SC/0149	A study comparing orthodontic brackets	38

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/SC/0380	Suffering, Meaning and Emotional Processing in Rheumatoid Arthritis V1	19
16/SC/0382	PREVENA Incision Management	10
16/SC/0488	Dry Eyes Daily Survey	25

#### 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
16/SC/0189	Segmentation of head and neck radiotherapy scans with machine learning	8
16/SC/0190	The Differential diagnosis of Septic Arthritis of the Hip in Children	8
16/SC/0260	Predicting treatment response to radiotherapy for bone cancer pain	8
16/SC/0421	Prescription medication use following AAA screening	8
16/SC/0487	Optimising the Transition from Home to Hospital	12
16/SC/0489	Modelling nutritional outcomes for infants with cystic fibrosis	8
16/SC/0683	RACE FIT (Phase I)	8

#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/SC/0191	Assessment of facial expressions - Version 01	9
16/SC/0266	Biology of Juvenile Myoclonic Epilepsy	9
16/SC/0386	Intervention Development for Self-monitoring in Pregnancy	9
16/SC/0554	Environmental Engineering to Increase Hand-Hygiene Compliance	11
16/SC/0610	CoSMIC-Q	16
16/SC/0678	MAPS-PD version 1	9
17/SC/0089	Effect of FlowOx treatment on healing of lower limb ischaemic ulcers	9

<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>
06/Q1606/139/AM07	Immune function in Inflammatory Arthritis version 1	SA07 (AM07)	02/06/2016	22
07/Q1606/15/AM45	AVAST-M	(Amendment no. 36, 3rd November)	03/11/2016	17
08/H0606/124/AM07	Blood pressure variability and autonomic function after TIA and stroke	Amendment 5 (AM07)	15/04/2016	27
08/H0606/133/AM05	Understanding the neural basis of amnesia version 1.0	3 (AM05)	20/03/2016	10
08/H0606/71+5/AM04	South London and Maudsley Biomedical Research Centre Case Register	4	06/11/2016	32
08/H0606/94/AM09	The immunology of recurrent miscarriage and failed implantation	7	11/10/2016	36
09/H0606/115/AM20	Phase 3 study - Lenalidomide in Patients with Myelodysplastic Syndrome	IB V19 (AM20)	10/06/2016	32
09/H0606/115/AM21	Phase 3 study - Lenalidomide in Patients with Myelodysplastic Syndrome	IB V20 (AM21)	22/08/2016	36
09/H0606/5+5/AM06	Oxford Radcliffe Biobank	Amendment 4 (AM06)	01/04/2016	26
09/H0606/5+5/AM07	Oxford Radcliffe Biobank	Amendment 5, 3rd March 2017	03/03/2017	18
10/H0606/39/AM08	A phase 1A dose escalation study of BYL719 in advanced solid tumours	Amendment 8 and 9 (AM08)	23/03/2016	14
11/SC/0064/AM04	PROCON (version 3.0)	AM04 - SA3 - Protocol v8.2	03/12/2016	28
11/SC/0140/AM06	AdipoRedox Study	5.0	01/12/2016	28
11/SC/0329/AM11	IMUNITI	2016/06/28 (AM11)	28/06/2016	14
11/SC/0329/AM12	IMUNITI	Pregnant Partner Information Sheet	16/08/2016	23
12/SC/0241/AM11	Avastin EXTENSION	8	30/09/2016	27
12/SC/0260/AM09	UK IBD twin database	Amendment 6	04/07/2016	22

		(AM09)		
12/SC/0366/AM05	Nitric oxide in subarachnoid haemorrhage	Amendment 6.0 (AM05)	05/05/2016	28
12/SC/0447/AM05	Investigating pain in the developing human brain	Substantial Amendment 3 (AM05)	01/09/2016	3
13/SC/0007/AM18	C28001 - MLN2480 patients with melanoma or solid tumour	IB Ed 6 & ICF (AM18)	13/07/2016	21
13/SC/0028/AM02	Brief interventions for Weight Loss (BWeL), version 1.0.	Substantial Amendment 2	26/07/2016	24
13/SC/0096/AM14	MK-3475 compared to Ipilimumab in Patients with Advanced Melanoma	Version 05	02/08/2016	28
13/SC/0111/AM13	FOCUS4: Molecular selection of therapy in colorectal cancer	7	23/09/2016	28
13/SC/0149/AM06	ISARIC/WHO Clinical Characterisation Protocol for Severe Emerging Infections	5 (AM06)	21/03/2016	23
13/SC/0157/AM05	ROMAZA: Phase I study of Romidespin and Azacitidine in AML patients	05 (AM05)	15/02/2016	17
13/SC/0184/AM10	212082PCR3011	SA6 (AM09)	16/10/2015	21
13/SC/0250/AM02	Oxford Abdominal Aortic Aneurysm Study - OxAAA	OxAAA Substantial amendment 2	20/12/2016	20
13/SC/0266/AM07	Early Prediction of Severe Sepsis (ExPRES-Sepsis) study (England)	5 (AM07)	12/05/2016	19
13/SC/0273/AM13	Phase I of Pembrolizumab (MK-3475) in Pts with non small cell lung cancer	SA10 (AM13)	12/07/2016	32
13/SC/0273/AM15	Phase I of Pembrolizumab (MK-3475) in Pts with non small cell lung cancer	12.0	24/11/2016	28
13/SC/0298/AM04	The cerebral signature for pain perception and modulation version 1	Pain study protocol v6_13SC02	25/01/2017	19
13/SC/0309/AM09	ELASTIC	Amendment 8 (AM09)	25/04/2016	11
13/SC/0309/AM10	ELASTIC	Amendment 8 (AM10)	25/04/2016	26
13/SC/0354/AM18	PankoMab-GEX in recurrent ovarian cancer GEXMab 25201 v1.0 12Mar13	3.0	16/11/2016	21
13/SC/0534/AM02	Efficacy of Methylene Blue for screening/surveillance colonoscopy	1.3 (AM02)	31/08/2016	29

13/SC/0541/AM13	Nivolumab Monotherapy vs Nivolumab combined therapy in Solid Tumors	12 (AM13)	01/04/2016	13
13/SC/0541/AM14	Nivolumab Monotherapy vs Nivolumab combined therapy in Solid Tumors	EC13 (AM14)	13/06/2016	29
13/SC/0541/AM16	Nivolumab Monotherapy vs Nivolumab combined therapy in Solid Tumors	EC14 dated 21-Oct-2016	21/10/2016	20
13/SC/0541/AM17	Nivolumab Monotherapy vs Nivolumab combined therapy in Solid Tumors	EC15 dated 19-Dec-2016	19/12/2016	22
13/SC/0541/AM18	Nivolumab Monotherapy vs Nivolumab combined therapy in Solid Tumors	EC16 dated 24 Feb 17	24/02/2017	18
13/SC/0594/AM02	An enhanced clinical heart failure service (Research database)	Amendment number 2 (AM02)	01/08/2016	28
13/SC/0594/AM03	An enhanced clinical heart failure service (Research database)	Amendment number 3	09/02/2017	32
14/SC/0008/AM11	NIHR BioResource-Adult Infectious Disease	7 (10/03/2017)	13/03/2017	15
14/SC/0037/AM13	A Study of Gantenerumab in Patients with Mild Alzheimer Disease	SA9 (AM13)	07/06/2016	22
14/SC/0106/AM03	Role of cellular immune responses in inflammation of the skin v1.0	amendment 3 13.2.17	01/03/2017	24
14/SC/0122/AM02	Prostatic artery embolisation	2 (AM02)	03/05/2016	23
14/SC/0157/AM14	PARAMEDIC 2: The Adrenaline Trial	AM11 (AM14)	01/06/2016	19
14/SC/0157/AM15	PARAMEDIC 2: The Adrenaline Trial	AM 12 (our ref AM 15 21.10.201	21/10/2016	27
14/SC/0171/AM23	Add-Aspirin	20.0	12/12/2016	21
14/SC/0189/AM13	TIGER-2	SA#9	10/10/2016	37
14/SC/0255/AM08	MEMOS: A Eurosarc Study of Mifamurtide in advanced osteosarcoma	006 (AM08)	10/05/2016	19
14/SC/0255/AM09	MEMOS: A Eurosarc Study of Mifamurtide in advanced osteosarcoma	SubsAmend007 (AM09)	21/06/2016	21
14/SC/1010/AM08	MErCuRIC1: MEK and MET Inhibition in Colorectal Cancer	008 (AM08)	20/04/2016	10
14/SC/1128/AM08	Phase1/2 study, First in Human, of SRP-4053 in DMD patients (4053-101)	Amendment 5 (AM08)	03/06/2016	32
14/SC/1128/AM09	Phase1/2 study, First in Human, of SRP-4053 in DMD patients (4053-101)	Version 5	01/06/2016	31
14/SC/1130/AM02	ART Protocol V1.0_20Jun2014	SubAmend02 (AM02)	13/07/2016	21

14/SC/1190/AM01	Local JAVLIN Registry V1.0	1 (AM01)	08/07/2016	26
14/SC/1290/AM06	Antifibrinolytics for haematology patients. Version 1.0	5: Patient Self-Assessment Ble	04/05/2016	17
14/SC/1339/AM03	A New Rehabilitation Treatment following Stroke	1.1 (AM03)	11/04/2016	6
14/SC/1345/AM17	PRISM: PRogesterone In Spontaneous Miscarriage	AM13 (AM17)	12/05/2016	20
14/SC/1345/AM18	PRISM: PRogesterone In Spontaneous Miscarriage	Am14	23/09/2016	27
14/SC/1345/AM21	PRISM: PRogesterone In Spontaneous Miscarriage	1.0	29/11/2016	27
14/SC/1346/AM14	National Lung Matrix: Multi-drug Phase II trial in NSC Lung Cancer	SA07	12/12/2016	21
15/SC/0046/AM10	C28002- Adult Patients With Advanced Nonhematologic Malignancies	AM10 SA11 "8.10.2016	28/10/2016	17
15/SC/0046/AM11	C28002- Adult Patients With Advanced Nonhematologic Malignancies	SA12 - Closure of Arm 5 Memo	13/12/2016	24
15/SC/0132/AM02	SYNDBM renewal 2015	2	05/10/2016	42
15/SC/0155/AM02	Assessment of platelet concentrate quality	Amendment 2 (AM02)	14/04/2016	8
15/SC/0165/AM06	The Evicel Neurosurgery Phase III Study	SA04 (AM06)	20/06/2016	22
15/SC/0167/AM01	OxAMI-PICSO	AM01	11/05/2016	33
15/SC/0171/AM02	Advanced Ultrasound in Pleural Infection (AUDIO)	SA02 25/11/2016	08/12/2016	26
15/SC/0174/AM04	MultiPepT1De Phase I study	Amendment 04 (AM04)	17/05/2016	7
15/SC/0215/AM05	CAMELLIA: Anti-CD47 antibody therapy in relapsed/refractory AML	CAMELLIA_Amend ment005 (AM05)	14/04/2016	10
15/SC/0215/AM06	CAMELLIA: Anti-CD47 antibody therapy in relapsed/refractory AML	Protocol V6.0 (AM06)	04/07/2016	28
15/SC/0266/AM03	Comprehensive Geriatric Assessment Case Study and Delphi_Version 1	AM03	02/03/2017	21
15/SC/0301/AM02	Chemotherapy Induced Peripheral Neuropathy (CIPN) v1.0	2 (AM02)	04/05/2016	32
15/SC/0301/AM03	Chemotherapy Induced Peripheral Neuropathy (CIPN) v1.0	Substantial Amendment 3	05/08/2016	29
15/SC/0303/AM04	Revlimid (lenalidomide) NIS Post Authorization Safety Study (PASS)	Amendment 1 (AM04)	16/08/2016	39
15/SC/0310/AM05	THE BOX FAMILY STUDY: (BOX 3) Version 1	AM02 (AM05)	03/06/2016	29
15/SC/0310/AM07	THE BOX FAMILY STUDY: (BOX 3) Version 1	AM05 Dated:06 December 2016	19/12/2016	22



15/SC/0310/AM08	THE BOX FAMILY STUDY: (BOX 3) Version 1	AM06 Dated:11 January 2017	20/01/2017	11
15/SC/0362/AM02	Therapeutic change in ID sex offenders	Amendment 2 (AM02)	05/08/2016	28
15/SC/0480/AM02	Inhaled furosemide for dyspnoea relief in advanced heart failure	(AM02)	08/03/2017	20
15/SC/0497/AM01	Older patients' experiences of Emergency Multidisciplinary Unit	1 (AM01)	12/05/2016	18
15/SC/0528/AM02	MICA II	Amendment 2 (AM02)	05/05/2016	25
15/SC/0528/AM03	MICA II	Amendment 3 (AM03)	25/07/2016	23
15/SC/0542/AM01	Ketone concentration vs. oxidation rate.	Amendment 1 (AM01)	19/05/2016	24
15/SC/0545/AM01	The Oxford Risk Factors And Non-invasive imaging Study	AM01 January 2017	13/01/2017	18
15/SC/0600/AM03	SIMPLE	SA03 01Feb2017	08/02/2017	28
15/SC/0616/AM05	Effects of dupilumab on airway inflammation in adults with asthma	05 (AM05)	07/04/2016	7
15/SC/0616/AM09	Effects of dupilumab on airway inflammation in adults with asthma	7 - Clinical Trial Protocol Am	01/03/2017	27
15/SC/0639/AM02	The Oxford Brain Bank	1.0	17/11/2016	27
15/SC/0644/AM02	NUC-3373 in Advanced Solid Tumours (NuTide: 301)	SubsAmend005 (AM02)	28/07/2016	34
15/SC/0691/AM01	RePHILL (Resuscitation with Pre-Hospital Blood products)	SA1 (AM01)	08/07/2016	26
15/SC/0691/AM05	RePHILL (Resuscitation with Pre-Hospital Blood products)	SA3	25/01/2017	69
16/SC/0022/AM01	Saccadic reaction time and preterm pre-eclampsia	Amendment 1 22/11/16	22/12/2016	26
16/SC/0029/AM02	Effect on sperm quality from the use of RFID at -196C	2	13/10/2016	34
16/SC/0035/AM01	A Phase III Study of Pembrolizumab vs. Chemotherapy in MSI-H or dMMR S	177-02 (AM01)	16/03/2016	14
16/SC/0035/AM03	A Phase III Study of Pembrolizumab vs. Chemotherapy in MSI-H or dMMR S	SA02 (AM03)	15/09/2016	27
16/SC/0035/AM05	A Phase III Study of Pembrolizumab vs. Chemotherapy in MSI-H or dMMR S	MK-3475-177-02	14/11/2016	27
16/SC/0039/AM02	AMAC,PrAmendment(18-Sep-2015), Prt UK Addendum 1.1(08-Dec-2015)	Substantial Amendment 2	04/10/2016	23

16/SC/0039/AM03	AMAC,PrtAmendment(18-Sep-2015), Prt UK Addendum 1.1(08-Dec-2015)	Substantial Amendment 3	13/02/2017	20
16/SC/0066/AM02	Extension study for subjects completing a dupilumab asthma study	1.0	02/12/2016	35
16/SC/0066/AM03	Extension study for subjects completing a dupilumab asthma study	02 - Protocol incorporating am	09/02/2017	27
16/SC/0068/AM02	MEDI4736-MDS-001_Phase II_Durvalumab_MDS/AML	Amendment 1 (AM01+02)	22/01/2016	19
16/SC/0143/AM01	Pembrolizumab (MK3457) in high risk NMIBC patients unresponsive to BCG	Substantial Amendment 1	05/08/2016	29
16/SC/0145/AM01	Bone conduction hearing device study	1 (AM01)	01/08/2016	24
16/SC/0161/AM02	PhaseIII Study-Atezolizumab with chemotherapy in Stage IV Non-Squamous	3 (AM02)	08/07/2016	26
16/SC/0161/AM05	PhaseIII Study-Atezolizumab with chemotherapy in Stage IV Non-Squamous	4.0	23/11/2016	15
16/SC/0161/AM06	PhaseIII Study-Atezolizumab with chemotherapy in Stage IV Non-Squamous	Patient Information Sheet & In	10/01/2017	7
16/SC/0187/AM01	Bone density and body composition in sporting athletes	BMD_Sports_Protocol_2.1 (AM01)	20/07/2016	17
16/SC/0187/AM02	Bone density and body composition in sporting athletes	AM02 21.10.2016	21/10/2016	24
16/SC/0188/AM02	Osteoarthritis Thumb Therapy II Trial (OTTER II trial)	Amendment 1 (AM01)	23/08/2016	32
16/SC/0188/AM04	Osteoarthritis Thumb Therapy II Trial (OTTER II trial)	AM04 Amendment 2 27.10.2016	28/09/2016	18
16/SC/0207/AM01	CA209-436 Nivolumab with Brentuximab Vedotin in Non-Hodgkin Lymphoma	1	29/09/2016	34
16/SC/0207/AM02	CA209-436 Nivolumab with Brentuximab Vedotin in Non-Hodgkin Lymphoma	SA02, 20-Dec-2016	20/12/2016	7
16/SC/0260/AM01	Predicting treatment response to radiotherapy for bone cancer pain	1.0	28/11/2016	14
16/SC/0266/AM02	Biology of Juvenile Myoclonic Epilepsy	AM02 Substantial Amendment 1	01/11/2016	35
16/SC/0271/AM01	plasmaMATCH	1.1 (AM01)	09/06/2016	30
16/SC/0274/AM01	OX HARP-I	1.0	24/11/2016	17
16/SC/0323/AM01	Adenosine Triphosphate Delivery Rates in Myocardial Hypertrophy	AM01 Version 1.0 20.10.2016	20/10/2016	25

16/SC/0323/AM02	Adenosine Triphosphate Delivery Rates in Myocardial Hypertrophy	2, 1/3/2017	10/03/2017	14
16/SC/0343/AM02	The Oxford Wearable Device Dialysis Study	1	09/10/2016	37
16/SC/0343/AM03	The Oxford Wearable Device Dialysis Study	Substantial amendment 2 10 Feb	16/02/2017	18
16/SC/0406/AM01	Long-term follow-up of Asymptomatic Carotid Surgery Trial (ACST-1)	01 - 6th December 2016	19/12/2016	22
16/SC/0435/AM01	Trial of Intranasal Esketamine for Treatment of Depression SUSTAIN-3	1	14/10/2016	31
16/SC/0435/AM02	Trial of Intranasal Esketamine for Treatment of Depression SUSTAIN-3	Substantial Amendment 2	15/12/2016	20
16/SC/0435/AM04	Trial of Intranasal Esketamine for Treatment of Depression SUSTAIN-3	Substantial Amendment 3	16/12/2016	22
16/SC/0547/AM01	A Phase I/II trial of intralesional administration of RGT100	SA #1	16/02/2017	25
16/SC/0584/AM01	IVIG and rituximab in antibody-associated psychosis - SINAPPS2	Amendment 1	01/02/2017	27
16/SC/0598/AM02	Measuring quality of life in adults on the autism spectrum	Amendment number 2, 20/12/2016	03/01/2016	14
17/SC/0033/AM01	Combination therapy with isatuximab in patients with multiple myeloma	01	01/03/2017	18

### 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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<b>Unfavourable opinion timeline</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>

**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
16/SC/0488	Dry Eyes Daily Survey	25
17/SC/0146	Expanding Community Ultrasound Services in Rural Scotland	36
17/SC/0147	Mitochondrial DNA copy number in CFS	27
17/SC/0149	A study comparing orthodontic brackets	38

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

REC Reference	Title	Number of Days on Clock
17/SC/0162	How Effective are Topical NSAID	35

**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
08/H0606/94/AM09	The immunology of recurrent miscarriage and failed implantation	7	11/10/2016	36
09/H0606/115/AM21	Phase 3 study - Lenalidomide in Patients with Myelodysplastic Syndrome	IB V20 (AM21)	22/08/2016	36
14/SC/0189/AM13	TIGER-2	SA#9	10/10/2016	37
15/SC/0132/AM02	SYNDMB renewal 2015	2	05/10/2016	42
15/SC/0303/AM04	Revlimid (lenalidomide) NIS Post Authorization Safety Study (PASS)	Amendment 1 (AM04)	16/08/2016	39
16/SC/0343/AM02	The Oxford Wearable Device Dialysis Study	1	09/10/2016	37

**Modified Amendments over 14 day timeline**

<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
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