

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

Annual Report

01 April 2015 - 31 March 2016



Part 1 – Committee Membership and Training

Name of REC:	South Central - Oxford C Research Ethics Committee
Type of REC:	REC recognised to review CTIMPs in patients -Type III
Type of Flag:	Adults Lacking Capacity Phase 1 in Patients Research Database Research Tissue Bank Qualitative
Chair:	Professor Nigel Wellman
Vice-Chair:	Professor David Scott
Alternate Vice-Chair:	Mrs Susan Lousada
REC Manager:	Lauren Allen (until 01/07/2015) Natasha Bridgman (01/07/2015 - 01/09/2015) Mrs Maeve Ip Groot Bluemink (01/07/2015 – present)
REC Assistant:	Mark Dawson (until 01/07/2015) Lidia Gonzalez (01/07/2015 - 01/09/2015) Sadie McKeegan-Keown (01/09/2015 – present)
Committee Address:	Level 3, Block B Whitefriars Building Lewins Mead Bristol BS1 2NT
Telephone:	020 7104 8049
Email:	nrescommittee.southcentral-oxfordc@nhs.net

Chair's overview of the past year:

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	
Miss Gemma Davison	Solicitor	Lay Plus	04/02/2014	31/01/2016
Dr Avinash Gupta	Clinical Research Fellow	Expert	14/02/2011	
Mrs Rebekah Howe	Farmer	Lay Plus	30/11/2012	30/10/2015
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	01/04/2010	
Mr Barry Muir	NHS Management Consultant (Retired)	Lay	01/05/2006	
Dr Lee Potiphar	Clinical Trials Manager	Expert	26/03/2015	
Ms Anna Rathmell	Medical Manager - GI	Lay Plus	01/02/2016	
Professor David Scott	Pharmacist	Expert	10/08/2010	
Dr Sabeena Sharma	Consultant Anaesthetist	Expert	23/05/2011	
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

South Central - Oxford C Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Miss Jennifer Lawson	Trials Manager	Lay	25/09/2015, 27/11/2015
Mrs Mary Sneade	Clinical Trial manager	Expert	25/09/2015

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

Name	Declaration of Interest	Date
Dr Leonard Brookes	None	31/03/2016
Miss Gemma Davison	None	31/03/2016
Dr Avinash Gupta	Clinical Research Fellow - attached to the early phase hub, Oxford Cancer and Haematology Centre Medical Monitor - R&D Department, Oxford University Hospitals NHS Trust	18/02/2016
Mrs Vivienne Laurie	Shareholdings in Astra Zeneca Patient Leader at the RBH	29/01/2016
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.	27/01/2016
Mrs Susan Lousada	Co-Chair (EAAA) East Anglia Air Ambulance, Bedfordshire	31/03/2016
Mr Barry Muir	None	31/03/2016
Dr Lee Potiphar	Clinical Trial Manager at University of Oxford	29/01/2016
Ms Anna Rathmell	Involved in the initiation, review and implementation of research in the field of inflammatory bowel disease as part of role at Takeda UK	31/03/2016
Professor David Scott	Member of Oxford University Tropical Research Ethics Committee	29/01/2016
Dr Sabeena Sharma	Medical research in capacity of a clinician	31/03/2016
Dr Surjeet Singh	Surgical Trials Operation Lead - part of Oxford CTU	29/01/2016
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.	25/01/2016
Mrs Elizabeth Ward	Paid position: Work as a clinical trial coordinator at the oncology clinical trials office, Oxford University.	29/01/2016
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.	31/03/2016

Meetings for Full Ethical Review 01 April 2015 - 31 March 2016:

Month	Date	Number of Members Present at Meeting
April	24/04/2015	11
May	29/05/2015	9
June	26/06/2015	8
August	28/08/2015	10
September	25/09/2015	8
October	30/10/2015	10
November	27/11/2015	8
January	29/01/2016	9
February	26/02/2016	12
March	18/03/2016	8

10 full committee meetings were held during the reporting period.

Proportionate Review Sub-Committee Meetings held during 01 April 2015 - 31 March 2016:

Month	Date	Number of Members Present at Meeting
April	07/04/2015	4
May	12/05/2015	3
June	09/06/2015	3
July	07/07/2015	3
August	10/08/2015	3
September	08/09/2015	4
October	06/10/2015	3
November	10/11/2015	3
January	13/01/2016	3
March	02/03/2016	3

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

Sub-Committee Meetings held during 01 April 2015 - 31 March 2016:

Month	Date	Number of Members Present at Meeting
April	01/04/2015	2
April	15/04/2015	2
April	28/04/2015	3
April	29/04/2015	2
May	13/05/2015	2
May	15/05/2015	3
May	27/05/2015	2
June	05/06/2015	3
June	08/06/2015	3
June	10/06/2015	2
June	24/06/2015	2

July	08/07/2015	2
July	22/07/2015	2
July	22/07/2015	3
August	05/08/2015	2
August	19/08/2015	2
September	02/09/2015	2
September	16/09/2015	2
September	24/09/2015	2
September	30/09/2015	2
October	14/10/2015	2
October	28/10/2015	2
November	11/11/2015	2
November	25/11/2015	2
November	26/11/2015	2
December	10/12/2015	2
December	23/12/2015	2
January	06/01/2016	2
January	20/01/2016	1
February	03/02/2016	2
February	17/02/2016	2
March	02/03/2016	2
March	16/03/2016	2
March	21/03/2016	2
March	24/03/2016	3
March	30/03/2016	2

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

Details of inquorate meeting held:01 April 2015 - 31 March 2016

None

Attendance of Members at full committee meetings: 01 April 2015 - 31 March 2016

Name	Number of Meetings Attended
Dr Leonard Brookes	9
Miss Gemma Davison	2
Mrs Rebekah Howe	4
Mrs Vivienne Laurie	9
Dr Simon Lord	1
Mrs Susan Lousada	7
Mr Barry Muir	7
Dr Lee Potiphar	9
Ms Anna Rathmell	1
Professor David Scott	8
Dr Sabeena Sharma	6
Dr Surjeet Singh	8
Ms Kayleigh Stanbury	6
Mrs Elizabeth Ward	4
Professor Nigel Wellman	9

Attendance of Members at proportionate review sub-committee meetings: 01 April 2015 - 31 March 2016

Name	Number of Meetings Attended
Dr Leonard Brookes	1
Miss Gemma Davison	2
Mrs Rebekah Howe	3
Mrs Vivienne Laurie	4
Mrs Susan Lousada	5
Mr Barry Muir	2
Dr Lee Potiphar	3
Professor David Scott	6
Dr Surjeet Singh	3
Ms Kayleigh Stanbury	1
Professor Nigel Wellman	2

Attendance of Members at sub-committee meetings: 01 April 2015 - 31 March 2016

Name	Number of Meetings Attended
Dr Leonard Brookes	11
Miss Gemma Davison	2
Mrs Rebekah Howe	1
Mrs Vivienne Laurie	4

Mrs Susan Lousada	4
Mr Barry Muir	6
Dr Lee Potiphar	2
Professor David Scott	9
Dr Surjeet Singh	2
Ms Kayleigh Stanbury	3
Professor Nigel Wellman	34

Training 01 April 2015 - 31 March 2016

Name of Member	Date	Event(s) attended
Dr Leonard Brookes	04/09/2015	Local Training - Joint Oxford Training
Mrs Vivienne Laurie	04/09/2015	Local Training - Joint Oxford Training
Mrs Vivienne Laurie	03/12/2015	Training - HRA Workshop: Pragmatic or Point of Care trials
Dr Simon Lord	10/02/2016	Training - Committee Members Induction
Mrs Susan Lousada	04/09/2015	Local Training - Joint Oxford Training
Mrs Susan Lousada	09/12/2015	Training - National Training Day for Committee Chairs
Mrs Susan Lousada	05/02/2016	Local Training Day - Social Care REC
Mr Barry Muir	04/09/2015	Local Training - Joint Oxford Training
Dr Lee Potiphar	17/06/2015	Committee Members Induction Training
Dr Lee Potiphar	04/09/2015	Local Training - Joint Oxford Training
Dr Lee Potiphar	18/02/2016	National Members Training Day
Ms Anna Rathmell	31/01/2016	Equality and Diversity
Ms Anna Rathmell	10/02/2016	Training - Committee Members Induction
Dr Sabeena Sharma	04/09/2015	Joint Oxford Training Day
Dr Sabeena Sharma	31/03/2016	Equality and Diversity
Dr Surjeet Singh	04/09/2015	Local Training - Joint Oxford Training
Dr Surjeet Singh	03/12/2015	Training - HRA Workshop: Pragmatic or Point of Care trials
Dr Surjeet Singh	13/03/2016	Training - Equality and Diversity (elearning module)
Ms Kayleigh Stanbury	17/06/2015	Committee Members Induction
Mrs Elizabeth Ward	10/02/2016	Training - Committee Members Induction
Professor Nigel Wellman	04/09/2015	Local Training - Joint Oxford Training

PART 2: REC WORKLOAD AND ACTIVITY DURING THE REPORTING PERIOD

Table 1: Applications assigned to a full committee meeting held within the reporting period:

Applications for full ethical review – Study Type	Number	%
Clinical Trial of Investigational Medicinal Product	14	24.14
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	7	12.07
Research Database (including renewals)	4	6.90
Others	33	56.90
Total Applications Reviewed	58	100

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	9
Number of paediatric applications reviewed	10
Number of device applications reviewed	2
Number of prisoner applications reviewed	1
Number of applications involving adults unable consent reviewed	11
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

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	3	5.17
Favourable Opinion with Additional Conditions	17	29.31
Unfavourable Opinion	1	1.72
Provisional Opinion	37	63.79
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	58	100
Number of studies sent back to full committee meeting for final opinion	0	

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

Status of applications at date of generation of report	Number	%
Further Information Favourable Opinion with Standard Conditions	36	62.07
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	3	5.17
Favourable Opinion with Additional Conditions	17	29.31
Unfavourable Opinion	1	1.72
Provisional Opinion	1	1.72
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	0	0.00
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
Total	58	100

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

Total Applications Reviewed	30
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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	12
Number of studies withdrawn prior to the meeting	0
Number of student applications reviewed	10
Number of paediatric applications reviewed	7
Number of device applications reviewed	2
Number of qualitative applications reviewed	1

Table 7: Decisions given at proportionate review sub-committee meetings held within the reporting period

Decisions taken at proportionate review sub-committee meetings	Number	%
Favourable Opinion with Standard Conditions	12	40.00
Favourable Opinion with Additional Conditions	12	40.00
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	5	16.67
Unfavourable Opinion	1	3.33
Total	30	100

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

Average number of applications reviewed per full meeting	5.80
Number of completed applications for full ethical review	58
Number of completed applications for full ethical review over 60 days	0
Number of completed applications over 60 days as a % of total	0.00%
Number of completed applications for full ethical review over 40 days	2
Number of completed applications over 40 days as a % of total	3.45%
Number of days taken to final decision – average (mean)	28
Number of completed proportionate review applications for ethical review	30
Number of completed proportionate review applications for ethical review over 14 days	1
Number of completed proportionate review applications over 14 days as a % of total	3.33%
Number of SSAs (non-Phase 1) reviewed	3
Number of completed applications for SSA review over 25 days	0
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	0.00%
Number of SSAs (Phase 1) reviewed	0
Number of completed applications for SSA review over 14 days	0
Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs	0.00%
Number of substantial amendments reviewed	174
Number of completed substantial amendments over 35 days	0
Number of completed substantial amendments over 35 days as a % of total substantial amendments	0.00%
Number of completed substantial amendments over 28 days	1
Number of completed substantial amendments over 28 days as a % of total substantial amendments	0.57%
Number of modified amendments reviewed	0
Number of completed modified amendments over 14 days	0
Number of completed modified amendments over 14 days as a % of total modified amendments	0.00%
Number of minor amendments received	65
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	54
Number of annual progress reports received	82

Number of safety reports received	49
Number of Serious Adverse Events received	2
Number of final reports received	33

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

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
15/SC/0217	GS29250 Treble Study - Evaluation of Lebrikizumab in Atopic Dermatitis	23
15/SC/0219	Feasibility Study of Immunotherapy in Autoantibody Positive Psychosis	19
15/SC/0223	Understanding risk and risk reduction for STIs and BBVs	26
15/SC/0247	CRIS - Oxford Case Register	32
15/SC/0288	Reactions to Assault	38
15/SC/0293	Vercise DBS Dystonia Registry	23
15/SC/0310	THE BOX FAMILY STUDY: (BOX 3) Version 1	26
15/SC/0316	E-FIT 1 v1.0	21
15/SC/0388	NIHR BRC BioResource for Mental and Neurological Health 2.0	24
15/SC/0477	Spectral Analysis of Brain Tissue at Operation - (HELICoID B)	34
15/SC/0497	Older patients' experiences of Emergency Multidisciplinary Unit	30
15/SC/0502	The Nightmare Intervention Study (NIteS)	28
15/SC/0528	MICA II	34
15/SC/0541	DALIP Research Registry	32
15/SC/0542	Ketone concentration vs. oxidation rate.	34
15/SC/0545	The Oxford Risk Factors And Non-invasive imaging Study	31
15/SC/0586	Biomarkers & Prediction of Response in Psychological Therapy V1	25
15/SC/0601	Mobile activity tracker and digital online recorder	27
15/SC/0615	Patient Understanding of LiverMultiScan	29
15/SC/0616	Effects of dupilumab on airway inflammation in adults with asthma	40
15/SC/0639	The Oxford Brain Bank	26
15/SC/0644	NUC-3373 in Advanced Solid Tumours (NuTide: 301)	32
15/SC/0684	Cognitions of antenatally depressed and non-depressed women	26
15/SC/0691	RePHILL (Resuscitation with Pre-Hospital blood products)	26
15/SC/0728	The CASCADE Study	39
15/SC/0770	PREpArE-Fontan registry	28
16/SC/0035	A Phase III Study of Pembrolizumab vs. Chemotherapy in MSI-H or dMMR S	34
16/SC/0039	AMAC, PrtAmendment(18-Sep-2015), Prt UK Addendum 1.1(08-Dec-2015)	39
16/SC/0066	Extension study for subjects completing a dupilumab asthma study	22
16/SC/0068	MEDI4736-MDS-001_Phase II_Durvalumab_MDS/AML	28
16/SC/0074	EPAD Longitudinal Cohort Study	22
16/SC/0102	Plaque Lipid Quantification and Correlation with Blood Lipid Indices	23

16/SC/0114	STING (Study of Immunotherapy in Newly Diagnosed Glioblastoma)	35
16/SC/0134	Movement disorders in inborn errors of metabolism - version 1	49
16/SC/0143	Pembrolizumab (MK3457) in high risk NMIBC patients unresponsive to BCG	28
16/SC/0161	Phase III Study-Atezolizumab with chemotherapy in Stage IV Non-Squamous	37

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
15/SC/0480	Inhaled furosemide for dyspnoea relief in advanced heart failure	28
15/SC/0686	The Oxford Vegetarian Study (known as Study of Cancer in Vegetarians)	25
16/SC/0094	CTT meta-analyses of adverse events	21

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/SC/0132	SYNDMB renewal 2015	19
15/SC/0215	CAMELLIA: Anti-CD47 antibody therapy in relapsed/refractory AML	19
15/SC/0266	Comprehensive Geriatric Assessment Case Study and Delphi_Version 1	19
15/SC/0270	The effect of hydrocortisone on fear information processing	20
15/SC/0294	PERFECTED WP2: Implementing optimised hospital care	19
15/SC/0298	Using NHSBT Blood for Researching and Developing Drug Candidates	20
15/SC/0352	PACE-Lift trial 4 year follow-up	20
15/SC/0362	Therapeutic change in ID sex offenders	20
15/SC/0492	Parental coping and quality of care for children with a complex illness	28
15/SC/0523	NHIC Hepatitis Theme Database V1	25
15/SC/0535	An Exploration of DMD Experiences of Children's Hospices	25
15/SC/0574	AMICA study Version 1.0	26
15/SC/0600	SIMPLE	25

15/SC/0610	PiLOT-AF study	36
16/SC/0021	Imperial Hepatology & Gastroenterology Biobank (IHGB)	27
16/SC/0022	Saccadic reaction time and preterm pre-eclampsia	36
16/SC/0028	The role of the intestinal Microbiome in Alzheimer's disease (TRIMIAD)	27

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
15/SC/0181	NIHR BRC BioResource for Mental and Neurological Health 2.0	42

Provisional Opinion

REC Reference	Title	Number of Days on Clock
16/SC/0162	Royal Devon & Exeter Tissue Bank - 5 year extension	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
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Table 9.2: Breakdown of current status of all PRS applications reviewed within the reporting period

Further Information Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
15/SC/0421	eQUICK study	12
15/SC/0424	Optimisation of Connected Health	13

16/SC/0029	Effect on sperm quality from the use of RFID at -196C	13
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Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/SC/0303	Revlimid (lenalidomide) NIS Post Authorization Safety Study (PASS)	8
15/SC/0503	ZOOM :Determinants of Zoster Vaccination Acceptance	7

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
15/SC/0210	Effect of text messages on uptake of NHS Health Checks in Southwark	13
15/SC/0301	Chemotherapy Induced Peripheral Neuropathy (CIPN) v1.0	8
15/SC/0365	Evolutionary Data Mining of Parkinson's Disease Data	5
15/SC/0501	Thinking styles in childhood anxiety, mood and tic disorders	10
15/SC/0504	Heterotaxy syndrome and abnormalities of intestinal rotation.	10
15/SC/0505	Measuring patients' experiences of using medicines version 1.0	6
15/SC/0622	Biomarker discovery in multiple myeloma: case-control study	7
15/SC/0624	Does SAP bind to NETs - a pilot study.	6
15/SC/0693	Using machine learning to improve prediction of AKI & deterioration.	5
15/SC/0712	Ultrasound of spine in pregnancy study	6
16/SC/0031	VTE risk in GCT patients receiving L1 chemotherapy	6
16/SC/0145	Bone conduction hearing device study	8

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/SC/0209	Long term prognosis of functional weakness	7
15/SC/0212	Knee osteoarthritis: knee confidence study v1.0	15
15/SC/0361	Does IV Iron Increase Anaerobic Threshold in Iron Deficiency Anaemia?	8
15/SC/0366	Patients' expectations lingual orthodontics	6
15/SC/0368	T lymphocyte responses to infections in kidney transplant recipients	8

15/SC/0423	Event perception in children with speech and language impairment	8
15/SC/0425	The Triple Digit Test: A validity and feasibility study	11
15/SC/0568	ANEMONE 2819-CL-2002	13
15/SC/0570	Benign Rolandic Epilepsy: electroencephalographic (EEG) findings	14
15/SC/0571	Novel Assessment of Nutrition and Ageing (NANA)	12
16/SC/0032	Retrospective UK Chart Review of Early Vedolizumab Experience	14
16/SC/0142	Cross sectional survey to investigate automaticity of OH behaviours	13

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
15/SC/0208	Osteoarthritis As a Risk Factor For Hypertension	8

Provisional Opinion

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

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

REC Reference	Title	Number of Days on Clock
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Table 10.1: Breakdown of current status of all substantial amendments reviewed within the reporting period

Favourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
04/Q1606/44/AM14	Human embryo implantation	Amendment 7	16/03/2015	8
06/Q1606/139/AM06	Immune function in Inflammatory Arthritis version 1	Amendment 6 (AM06)	18/01/2016	6
07/H0606/148/AM12	The Maternal Inflammatory Response and Pre-eclampsia	SA2	11/08/2015	21
07/H0606/96/AM28	Genetic studies in primary biliary cirrhosis	18	24/08/2015	10
07/H0606/96/AM29	Genetic studies in primary biliary cirrhosis	003	01/10/2015	12
08/H0606/107+5/AM06	Oxford BioBank	3	27/11/2015	7
08/H0606/107+5/AM07	Oxford BioBank	4.0 (AM07)	20/01/2016	10
08/H0606/71+5/AM03	South London and Maudsley Biomedical Research Centre Case Register	Amendment 03 03/12/2015	03/12/2015	19
08/H0606/94/AM08	The immunology of recurrent miscarriage and failed implantation	6	30/04/2015	13
09/H0606/115/AM19	Phase 3 study - Lenalidomide in Patients with Myelodysplastic Syndrome	IB version 18	09/04/2015	8
09/H0606/5+5/AM04	Oxford Radcliffe Biobank	3	17/04/2015	12
10/H0606/45/AM04	A structural investigation of the human lens	AM04	10/12/2015	13
11/SC/0136/AM08	PM01183 in combination with Doxorubicin v 1.0 (13/12/2010)	#10	29/04/2015	14
11/SC/0329/AM08	IMUNITI	Investigator's Brochure editio	22/05/2015	18
11/SC/0329/AM09	IMUNITI	3	27/08/2015	11
11/SC/0458/AM12	Paclitaxel +/- GSK1120212 in Melanoma	013	14/05/2015	8
12/SC/0090/AM13	Dual Erb B Inhibition in Oesophago-gastric Cancer	012	09/09/2015	7
12/SC/0091/AM08	The Fracture Free Study v1.0	003	21/05/2015	14
12/SC/0091/AM09	The Fracture Free Study v1.0	4	20/07/2015	14
12/SC/0153/AM08	Two different doses of IgPro20 for the treatment of CIDP	Supplement to	18/06/2015	4

		patient booklet		
12/SC/0153/AM09	Two different doses of IgPro20 for the treatment of CIDP	SA09	11/09/2015	26
12/SC/0153/AM12	Two different doses of IgPro20 for the treatment of CIDP	5 (AM12)	08/12/2015	12
12/SC/0174/AM01	CR-PTSD	01	30/10/2015	4
12/SC/0174/AM02	CR-PTSD	2.5 (AM02)	14/03/2016	12
12/SC/0241/AM07	Avastin EXTENSION	5	28/04/2015	15
12/SC/0281/AM02	Vascular Targeted Photodynamic therapy with WST11 for T1a Renal Tumour	1	14/04/2015	15
12/SC/0366/AM03	Nitric oxide in subarachnoid haemorrhage	Amendment 4.0 1st July	05/10/2015	35
12/SC/0366/AM04	Nitric oxide in subarachnoid haemorrhage	Amendment 5.0 (AM04)	22/02/2016	7
12/SC/0515/AM06	BREATHE	6	21/04/2015	14
12/SC/0602/AM25	NN9535-3744 SUSTAIN 6 Semaglutide Cardiovascular Outcomes Study	SA10	01/06/2015	8
12/SC/0602/AM28	NN9535-3744 SUSTAIN 6 Semaglutide Cardiovascular Outcomes Study	11	24/08/2015	13
12/SC/0622/AM03	Oxford Patient Research Registry - Musculoskeletal (OxPaRRM)	03	28/09/2015	7
12/SC/0626/AM04	Supporting Parents Of Children with Cleft Lip v1.1	4	17/04/2015	8
12/SC/0626/AM05	Supporting Parents Of Children with Cleft Lip v1.1	5	20/10/2015	13
12/SC/0668/AM08	Ruxolitinib (INC424) and BKM120 in patients with myelofibrosis	7	27/04/2015	6
12/SC/0668/AM09	Ruxolitinib (INC424) and BKM120 in patients with myelofibrosis	SA4	29/07/2015	12
12/SC/0725/AM01	Molecular Basis of Human Bladder Tumourigenesis	1	20/05/2015	18
13/SC/0007/AM13	C28001 - MLN2480 patients with melanoma or solid tumour	9	20/07/2015	14
13/SC/0007/AM14	C28001 - MLN2480 patients with melanoma or solid tumour	10	01/09/2015	15
13/SC/0007/AM17	C28001 - MLN2480 patients with melanoma or solid tumour	AM17	07/12/2015	16
13/SC/0063/AM06	Observational follow up study of ENEST1st.	27th May 2015	04/06/2015	11
13/SC/0096/AM11	MK-3475 compared to Ipilimumab in Patients with Advanced Melanoma	007	24/06/2015	14
13/SC/0096/AM12	MK-3475 compared to Ipilimumab in Patients with Advanced Melanoma	SA008	07/10/2015	26
13/SC/0111/AM08	FOCUS4: Molecular selection of therapy in colorectal cancer	5	18/08/2015	20
13/SC/0184/AM08	212082PCR3011	SA06 (AM08)	06/01/2016	6
13/SC/0243/AM03	NICOLA V1.0	3	14/04/2015	14
13/SC/0266/AM06	Early Prediction of Severe Sepsis (ExPRES-Sepsis) study	6	06/07/2015	14

	(England)			
13/SC/0273/AM10	Phase I of MK-3475 in Pts with non small cell lung cancer	5	08/06/2015	17
13/SC/0273/AM11	Phase I of MK-3475 in Pts with non small cell lung cancer	6	07/07/2015	12
13/SC/0273/AM12	Phase I of MK-3475 in Pts with non small cell lung cancer	SA07	06/11/2015	28
13/SC/0298/AM02	The cerebral signature for pain perception and modulation version 1	Protocol v5	22/05/2015	13
13/SC/0309/AM06	ELASTIC	5	26/06/2015	11
13/SC/0330/AM04	LINES: EuroSarc Trial of Linsitinib in advanced Ewing Sarcoma	20/10/2015	20/10/2015	19
13/SC/0354/AM10	PankoMab-GEX in recurrent ovarian cancer GEXMab 25201 v1.0 12Mar13	5	15/04/2015	13
13/SC/0354/AM12	PankoMab-GEX in recurrent ovarian cancer GEXMab 25201 v1.0 12Mar13	4	14/08/2015	11
13/SC/0354/AM14	PankoMab-GEX in recurrent ovarian cancer GEXMab 25201 v1.0 12Mar13	5.0 (AM14)	25/01/2016	14
13/SC/0361/AM02	Out of Hospital Cardiac Arrest Outcomes Project	02	07/09/2015	16
13/SC/0418/AM05	An exploration of strategies to enhance PA in people with RA	4	02/05/2015	7
13/SC/0418/AM06	An exploration of strategies to enhance PA in people with RA	5	22/08/2015	16
13/SC/0457/AM05	Pain in spinal cord injuries: investigating associated factors (1)	5	03/06/2015	13
13/SC/0486/AM07	A Nitric Oxide (NOx) generating solution for prevention of VAP	3	03/07/2015	4
13/SC/0541/AM07	Nivolumab Monotherapy vs Nivolumab combined therapy in Solid Tumors	7	07/05/2015	7
13/SC/0541/AM09	Nivolumab Monotherapy vs Nivolumab combined therapy in Solid Tumors	8	25/08/2015	13
13/SC/0541/AM10	Nivolumab Monotherapy vs Nivolumab combined therapy in Solid Tumors	21.09.15	21/09/2015	15
13/SC/0541/AM11	Nivolumab Monotherapy vs Nivolumab combined therapy in Solid Tumors	Substantial Amendment 10	20/11/2015	21
13/SC/0541/AM12	Nivolumab Monotherapy vs Nivolumab combined therapy in Solid Tumors	11	18/11/2015	15
14/SC/0001/AM02	Brain Imaging of Opioid Therapy	Amendment No 2	12/11/2015	13
14/SC/0008/AM07	NIHR BioResource-Adult Infectious Disease	4	21/04/2015	20
14/SC/0008/AM09	NIHR BioResource-Adult Infectious Disease	5	12/10/2015	19
14/SC/0008/AM10	NIHR BioResource-Adult Infectious Disease	AM10	03/03/2016	12
14/SC/0037/AM10	A Study of Gantenerumab in Patients with Mild Alzheimer Disease	06	06/05/2015	9
14/SC/0037/AM11	A Study of Gantenerumab in Patients with Mild Alzheimer	SA07 (AM11)	23/12/2015	12

	Disease			
14/SC/0037/AM12	A Study of Gantenerumab in Patients with Mild Alzheimer Disease	SA08 (AM12)	21/01/2016	11
14/SC/0038/AM03	Substantial Amendment #3 8th May 2015	3	12/05/2015	16
14/SC/0044/AM04	Inattentive and impulsive brain. Version 1.0	2	17/04/2015	9
14/SC/0088/AM04	RIFSYS	4.0	19/05/2015	7
14/SC/0088/AM05	RIFSYS	Substantial Amendment 4	01/08/2015	14
14/SC/0106/AM01	Role of cellular immune responses in inflammation of the skin v1.0	1 (AM01)	26/01/2016	19
14/SC/0122/AM01	Prostatic artery embolisation	1 (AM01)	10/03/2016	21
14/SC/0134/AM05	BP28920 Phase I study of RO6895882 in solid tumours	SA#4	31/03/2015	16
14/SC/0134/AM06	BP28920 Phase I study of RO6895882 in solid tumours	5	22/04/2015	7
14/SC/0134/AM07	BP28920 Phase I study of RO6895882 in solid tumours	SA6	05/08/2015	12
14/SC/0155/AM02	CDX1, CDX2 and A33 as markers for metastatic colorectal adenocarcinoma	1	23/11/2015	17
14/SC/0157/AM06	PARAMEDIC 2: The Adrenaline Trial	5	11/05/2015	10
14/SC/0157/AM07	PARAMEDIC 2: The Adrenaline Trial	6	24/06/2015	12
14/SC/0157/AM11	PARAMEDIC 2: The Adrenaline Trial	AM09	02/11/2015	4
14/SC/0157/AM12	PARAMEDIC 2: The Adrenaline Trial	AM08	02/11/2015	4
14/SC/0162/AM01	South Coast CLL and Lymphoproliferative Disorders (LPD)Tissue Bank	1	11/12/2015	12
14/SC/0189/AM07	TIGER-2	Protocol Amendment 4	01/05/2015	12
14/SC/0189/AM09	TIGER-2	7	03/08/2015	14
14/SC/0189/AM11	TIGER-2	8	19/10/2015	14
14/SC/0198/AM01	Sleep, affect and memory in PTSD	1	10/02/2015	13
14/SC/0203/AM03	INTENSE study	1	12/06/2015	10
14/SC/0255/AM03	MEMOS: A Eurosarcoma Study of Mifamurtide in advanced osteosarcoma	Amendment 003	20/03/2015	9
14/SC/0255/AM07	MEMOS: A Eurosarcoma Study of Mifamurtide in advanced osteosarcoma	SA005	17/11/2015	20
14/SC/0261/AM03	CAIRO (Work Package A): Database feasibility	3	02/07/2015	5
14/SC/0272/AM02	Investigation into patients' lived experiences of medication adherence	01	06/10/2015	6
14/SC/0274/AM03	Diabetes care for people with mental illness. Version 1.0	3	21/05/2015	19

14/SC/1010/AM07	MErCuRIC1: MEK and MET Inhibition in Colorectal Cancer	007	07/07/2015	7
14/SC/1030/AM07	G-TOG - Gentamicin in the Treatment of Gonorrhoea	6	19/06/2015	14
14/SC/1030/AM09	G-TOG - Gentamicin in the Treatment of Gonorrhoea	SA09	21/12/2015	12
14/SC/1030/AM11	G-TOG - Gentamicin in the Treatment of Gonorrhoea	SA08 (AM11)	22/10/2015	26
14/SC/1047/AM02	Understanding active living in older age	2 (AM02)	20/01/2016	7
14/SC/1101/AM05	Efficacy of Consuming LcS In Spinal cord injury Patients (ECLISP)	2	08/06/2015	17
14/SC/1101/AM06	Efficacy of Consuming LcS In Spinal cord injury Patients (ECLISP)	3	27/08/2015	11
14/SC/1104/AM04	Individualised informal caregiver training for palliative care at home	SA1	16/07/2015	10
14/SC/1104/AM05	Individualised informal caregiver training for palliative care at home	2	11/11/2015	18
14/SC/1104/AM06	Individualised informal caregiver training for palliative care at home	3	07/12/2015	16
14/SC/1104/AM07	Individualised informal caregiver training for palliative care at home	Number 4 (AM07)	08/03/2016	7
14/SC/1128/AM05	Phase1/2 study, First in Human, of SRP-4053 in DMD patients (4053-101)	3	03/06/2015	6
14/SC/1128/AM06	Phase1/2 study, First in Human, of SRP-4053 in DMD patients (4053-101)	4	25/08/2015	13
14/SC/1128/AM07	Phase1/2 study, First in Human, of SRP-4053 in DMD patients (4053-101)	4	09/10/2015	12
14/SC/1130/AM01	ART Protocol V1.0_20Jun2014	SubAmend01	18/11/2015	7
14/SC/1151/AM02	Exploring lifestyles of young people and their families. Version 1	2	20/10/2015	8
14/SC/1175/AM01	Effects of hydroxyurea on microvascular flow and epigenomics in SCD	1	26/06/2015	7
14/SC/1219/AM03	Airway Management in cardiac arrest patients (AIRWAYS-2)	3	06/05/2015	6
14/SC/1219/AM07	Airway Management in cardiac arrest patients (AIRWAYS-2)	4	27/07/2015	7
14/SC/1219/AM08	Airway Management in cardiac arrest patients (AIRWAYS-2)	5 (AM08)	07/12/2015	12
14/SC/1239/AM02	Weight Loss and Mitral Valve Regurgitation Version 1.0	1	09/06/2015	11
14/SC/1267/AM02	A UK online 24h dietary recall tool: practical application V1	1	22/06/2015	18
14/SC/1267/AM03	A UK online 24h dietary recall tool: practical application V1	2	25/11/2015	15
14/SC/1290/AM03	Antifibrinolytics for haematology patients. Version 1.0	03	27/08/2015	7
14/SC/1290/AM04	Antifibrinolytics for haematology patients. Version 1.0	2.1	09/12/2015	20

14/SC/1316/AM03	SNAP-HT trial development pilot study V1.0	2	09/06/2015	13
14/SC/1345/AM12	PRISM: PRogesterone In Spontaneous Miscarriage	AM08	06/07/2015	11
14/SC/1346/AM03	National Lung Matrix: Multi-drug Phase II trial in NSC Lung Cancer	SA02	28/05/2015	12
14/SC/1346/AM06	National Lung Matrix: Multi-drug Phase II trial in NSC Lung Cancer	3	02/09/2015	23
14/SC/1370/AM02	CENTER-TBI UK	Amendment 2	01/05/2015	13
14/SC/1370/AM03	CENTER-TBI UK	2	24/08/2015	11
14/SC/1370/AM04	CENTER-TBI UK	4 (AM4)	05/01/2016	7
15/SC/0001/AM01	Behavioural activation for mood in dementia v.1	1.2	07/04/2015	8
15/SC/0001/AM02	Behavioural activation for mood in dementia v.1	2	28/04/2015	13
15/SC/0001/AM03	Behavioural activation for mood in dementia v.1	1.4	30/11/2015	9
15/SC/0012/AM01	Phase I dose escalation study for BAY 1238097	1	29/06/2015	8
15/SC/0012/AM02	Phase I dose escalation study for BAY 1238097	2	09/12/2015	14
15/SC/0021/AM01	STRATA: Predicting Response to Antipsychotic medication, Version 1.0	1.0	11/12/2015	18
15/SC/0021/AM02	STRATA: Predicting Response to Antipsychotic medication, Version 1.0	2.0 (AM02)	21/03/2016	12
15/SC/0046/AM02	C28002- Adult Patients With Advanced Nonhematologic Malignancies	1	01/04/2015	20
15/SC/0046/AM04	C28002- Adult Patients With Advanced Nonhematologic Malignancies	Amendment 2	28/07/2015	7
15/SC/0046/AM06	C28002- Adult Patients With Advanced Nonhematologic Malignancies	Substantial Amendment 3	28/10/2015	21
15/SC/0046/AM07	C28002- Adult Patients With Advanced Nonhematologic Malignancies	Protocol Amendment 3 and relat	12/11/2015	25
15/SC/0106/AM01	Adaptive deep brain stimulation for tremor control	1	26/08/2015	12
15/SC/0132/AM01	SYNDBM renewal 2015	1	03/06/2015	6
15/SC/0155/AM01	Assessment of platelet concentrate quality	1	07/10/2015	5
15/SC/0165/AM03	The Evicel Neurosurgery Phase III Study	Amendment 2 (AM03)	22/01/2016	10
15/SC/0171/AM01	Advanced Ultrasound in Pleural Infection (AUDIO)	1	08/07/2015	6
15/SC/0174/AM01	MultiPepT1De Phase I study	SA1	29/07/2015	25
15/SC/0174/AM02	MultiPepT1De Phase I study	3 (AM02)	22/01/2016	22
15/SC/0212/AM01	Knee osteoarthritis: knee confidence study v1.0	1	21/05/2015	18

15/SC/0212/AM02	Knee osteoarthritis: knee confidence study v1.0	AM02	12/01/2016	14
15/SC/0215/AM02	CAMELLIA: Anti-CD47 antibody therapy in relapsed/refractory AML	AM02 - SA1 - Protocol V3.0	28/08/2015	15
15/SC/0215/AM04	CAMELLIA: Anti-CD47 antibody therapy in relapsed/refractory AML	Protocol V5.0 (AM04)	25/01/2016	14
15/SC/0217/AM02	GS29250 Treble Study - Evaluation of Lebrikizumab in Atopic Dermatitis	1	20/08/2015	13
15/SC/0219/AM02	Feasibility Study of Immunotherapy in Autoantibody Positive Psychosis	1 (AM02)	03/12/2015	28
15/SC/0223/AM01	Understanding risk and risk reduction for STIs and BBVs	1 (AM01)	08/02/2016	21
15/SC/0293/AM02	Vercise DBS Dystonia Registry	AC 24 Sep 2015	23/10/2015	17
15/SC/0294/AM01	PERFECTED WP2: Implementing optimised hospital care	Amendment 1	02/12/2015	7
15/SC/0301/AM01	Chemotherapy Induced Peripheral Neuropathy (CIPN) v1.0	1	08/11/2015	5
15/SC/0310/AM02	THE BOX FAMILY STUDY: (BOX 3) Version 1	20.10.15	28/10/2015	12
15/SC/0316/AM02	E-FIT 1 v1.0	2	28/10/2015	8
15/SC/0352/AM01	PACE-Lift trial 4 year follow-up	1	02/12/2015	12
15/SC/0362/AM01	Therapeutic change in ID sex offenders	1	10/12/2015	6
15/SC/0388/AM01	NIHR BRC BioResource for Mental and Neurological Health 2.0	1 (AM01)	28/02/2016	15
15/SC/0480/AM01	Inhaled furosemide for dyspnoea relief in advanced heart failure	28.10.15	28/10/2015	12
15/SC/0528/AM01	MICA II	1 (AM01)	08/12/2015	12
15/SC/0568/AM02	ANEMONE 2819-CL-2002	1 (AM02)	21/01/2016	21
15/SC/0600/AM01	SIMPLE	SA1	17/11/2015	7
15/SC/0600/AM02	SIMPLE	SA02 (AM02)	29/02/2016	13
15/SC/0610/AM01	PiLOT-AF study	1.2 (AM01)	10/03/2016	12
15/SC/0616/AM02	Effects of dupilumab on airway inflammation in adults with asthma	2 - Clinical Trial Protocol Am	17/12/2015	6
15/SC/0616/AM03	Effects of dupilumab on airway inflammation in adults with asthma	3 (AM03)	13/01/2016	13
15/SC/0616/AM04	Effects of dupilumab on airway inflammation in adults with asthma	04 (AM04)	10/03/2016	25
15/SC/0622/AM01	Biomarker discovery in multiple myeloma: case-control study	Substantial Amendment 1	14/12/2015	7
16/SC/0029/AM01	Effect on sperm quality from the use of RFID at -196C	1 (AM01)	15/03/2016	17

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

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

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
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Proportionate review applications for ethical review over 14 day timeline

REC Reference	Title	Number of Days on Clock
15/SC/0212	Knee osteoarthritis: knee confidence study v1.0	15

SSAs (non Phase 1) over 25 day timeline

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

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

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

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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