

**West Midlands - Solihull Research Ethics  
Committee**

**Annual Report**

**01 April 2016 - 31 March 2017**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	West Midlands - Solihull Research Ethics Committee
<b>Type of REC:</b>	Authorised REC
<b>Type of Flag:</b>	Research Involving Children
<b>Chair:</b>	Dr Rex J Polson
<b>Vice-Chair:</b>	Dr Richard Mupanemunda
<b>Alternate Vice-Chair:</b>	Mrs Theresa Hyde
<b>REC Manager:</b>	Miss Victoria Strutt
<b>REC Assistant:</b>	Miss Daniella Sarno
<b>Committee Address:</b>	The Old Chapel Royal Standard Place Nottingham NG1 6FS
<b>Telephone:</b>	0207 1048106
<b>Email:</b>	NRESCcommittee.WestMidlands-Solihull@nhs.net

## Chair's overview of the past year:

West Midlands – Solihull Research Ethics has had another busy and interesting year and I am grateful to the committee members for all their hard work and enthusiastic support throughout the year. We welcome Priyanka Batra, Claire Doswell and Daniel Shaw to our committee and do hope they will enjoy their time working with us and find the experience interesting. We are pleased that most researchers continue to attend our meetings as this is extremely beneficial for our members and is probably helpful for the investigators as well. I continue to be grateful to the Nottingham REC office for kindly providing the excellent administrative support for our committee, this is very much appreciated.

## West Midlands - Solihull Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Ms Priyanka Batra	Research Governance Officer	Lay	06/01/2017	
Dr Sheila D'Souza	Dentist	Expert	01/05/2016	
Mrs Lynne Gray	Senior Biomedical Scientist	Expert	11/07/2007	
Mrs Theresa Hyde	Retired Head Teacher	Lay Plus	11/07/2007	
Dr Jennifer Lim	Senior Lecturer in Public Health	Lay	12/01/2011	
Mrs Irene Linder	Assistant Manager, Local Authority - Retired	Lay Plus	11/07/2007	
Ms Veronica Morgan	Midwife	Expert	11/07/2007	
Dr Richard Mupanemunda	Consultant Paediatrician	Expert	11/07/2007	
Dr Rex J Polson	Consultant Physician - Chair	Expert	11/07/2007	
Ms Gill Tomlinson	Quality Manager Radiology	Expert	11/07/2007	

## West Midlands - Solihull Research Ethics Committee: Deputy Members

None

## West Midlands - Solihull Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Mrs Jeanne-Anne Charly	Staff Nurse	Expert	14/12/2016 08/03/2017 08/03/2017 PR
Mr Chris Foy	Medical Statistician	Expert	11/05/2016
Dr Nicola James	Independent Research Consultant	Lay Plus	13/04/2016 16/11/2016 08/03/2016
Reverend Keith Lackenby	Retired Reverend	Lay Plus	11/01/2017
Professor Paula McGee	Professor of Nursing	Expert	11/05/2017 14/09/2016
Reverend Mark Stobert	Hospital Chaplain	Lay Plus	13/04/2016
Mrs Laura Strumidlo	Senior Lecturer Adult Nursing/End of Life Care	Expert	08/03/2017
Mr John Warden	Clinical Trials Data and Information Systems Manager	Lay	11/05/2016

**West Midlands - Solihull Research Ethics Committee: Members' Declarations of Interest:**

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Dr Sheila D'Souza	None declared	18/01/2017
Mrs Lynne Gray	None declared	10/01/2017
Mrs Theresa Hyde	Trustee Carers United (Sutton Carers UK) Volunteer.	10/01/2017
Dr Jennifer Lim	Trustee, commonwealth human ecology council	13/02/2017
Mrs Irene Linder	None declared	10/01/2017
Ms Veronica Morgan	Employee of heart of England foundation trust Patient representative on West Midlands Breast advisory group.	10/01/2017
Dr Richard Mupanemunda	None declared	13/02/2017
Dr Rex J Polson	Share in Spire Healthcare but not aware of them conducting any research Full time consultant at the Solihull Hospital - A member of the trust ethics advisory group	10/01/2017
Ms Gill Tomlinson	None declared	10/01/2017
Ms Priyanka Batra	Research governance officer at the University of Birmingham, responsible for signing off applications for sponsorship	31/03/2017

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

Month	Date	Number of Members Present at Meeting
April	13/04/2016	9
May	11/05/2016	8
July	13/07/2016	9
September	14/09/2016	7
November	16/11/2016	8
December	14/12/2016	7
January	11/01/2017	8
February	08/02/2017	9
March	08/03/2017	8

9 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	13/04/2016	3
May	11/05/2016	3
June	15/06/2016	3
July	13/07/2016	3
September	14/09/2016	7
October	19/10/2016	3
November	16/11/2016	7
December	14/12/2016	3
January	11/01/2017	6
February	08/02/2017	3
March	08/03/2017	3

11 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	13/04/2016	2
April	27/04/2016	2
May	11/05/2016	2
May	25/05/2016	2
June	15/06/2016	2
July	01/07/2016	2
July	13/07/2016	2
July	20/07/2016	2
August	10/08/2016	2
September	05/09/2016	2
September	30/09/2016	2

October	27/10/2016	2
November	21/11/2016	2
December	14/12/2016	2
January	11/01/2017	2
January	25/01/2017	2
February	08/02/2017	2
February	22/02/2017	2
March	08/03/2017	2
March	22/03/2017	2

20 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 Sheila D'Souza	4
Mrs Lynne Gray	8
Mrs Theresa Hyde	7
Dr Jennifer Lim	4
Mrs Irene Linder	8
Ms Veronica Morgan	6
Dr Richard Mupanemunda	6
Dr Rex J Polson	9
Ms Gill Tomlinson	8

**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 Sheila D'Souza	1
Mrs Lynne Gray	8
Mrs Theresa Hyde	8
Dr Jennifer Lim	3
Mrs Irene Linder	3
Ms Veronica Morgan	2
Dr Richard Mupanemunda	3
Dr Rex J Polson	11
Ms Gill Tomlinson	4

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mrs Lynne Gray	1
Mrs Theresa Hyde	8
Dr Rex J Polson	19
Ms Gill Tomlinson	12



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

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Mrs Lynne Gray	27/09/2016	Human Tissue Act -An Introductory Level
Mrs Theresa Hyde	23/09/2016	Local Training Day - Regional
Dr Jennifer Lim	08/08/2016	Diversity Training
Dr Jennifer Lim	23/09/2016	Local Training Day - Regional
Dr Jennifer Lim	27/10/2016	Equality & Diversity
Dr Rex J Polson	16/06/2016	UKCEN (UK Clinical Ethics Network) pre conference meetings AGM of the Trust Board and training workshop
Dr Rex J Polson	17/06/2016	UKCEN Annual Conference - Rights, Duty and Healthcare
Ms Gill Tomlinson	23/09/2016	Local Training Day - Regional

## PART 2: REC WORKLOAD AND ACTIVITY DURING THE REPORTING PERIOD

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

<b>Applications for full ethical review – Study Type</b>	<b>Number</b>	<b>%</b>
Clinical Trial of Investigational Medicinal Product	0	0.00
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	0	0.00
Others	33	100.00
<b>Total Applications Reviewed</b>	<b>33</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	2
Number of applications withdrawn prior to the meeting	0
Number of student applications reviewed	17
Number of paediatric applications reviewed	1
Number of device applications reviewed	2
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	0
Number of applications reviewed that are funded by the US DHHS	0
Number of qualitative applications reviewed	8

**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	6.06
Favourable Opinion with Additional Conditions	2	6.06
Unfavourable Opinion	2	6.06
Provisional Opinion	27	81.82
Provisional Opinion Pending Consultation with Referee	0	0.00
<b>Total</b>	<b>33</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	23	69.70
Further Information Favourable Opinion with Additional Conditions	4	12.12
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	6.06
Favourable Opinion with Additional Conditions	2	6.06
Unfavourable Opinion	2	6.06
Provisional Opinion	0	0.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	0	0.00
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
<b>Total</b>	<b>33</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>30</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	2
Number of student applications reviewed	14
Number of paediatric applications reviewed	1
Number of device applications reviewed	1
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	7	23.33
Favourable Opinion with Additional Conditions	5	16.67
No Opinion transfer to full committee for review	1	3.33
Provisional Opinion	17	56.67
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>30</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>	3.67
<b>Number of completed applications for full ethical review</b>	33
<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>	2
<b>Number of completed applications over 40 days as a % of total</b>	6.06%
<b>Number of days taken to final decision – average (mean)</b>	33
<b>Number of completed proportionate review applications for ethical review</b>	29
<b>Number of completed proportionate review applications for ethical review over 14 days (Please note, the timeline for the review of PR applications was extended from 14 to 21 calendar days in December 2016)</b>	10
<b>Number of completed proportionate review applications for ethical review over 21 days</b>	0
<b>Number of completed proportionate review applications over 14 days as a % of total</b>	13.79%
<b>Number of SSAs (non-Phase 1) reviewed</b>	1
<b>Number of completed applications for SSA review over 25 days</b>	1
<b>Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs</b>	100.00%
<b>Number of SSAs (Phase 1) reviewed</b>	0
<b>Number of completed applications for SSA review over 14 days</b>	0
<b>Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs</b>	0.00%
<b>Number of substantial amendments reviewed</b>	51
<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>	4
<b>Number of completed substantial amendments over 28 days as a % of total substantial amendments</b>	7.84%
<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>	88
<b>Number of substantial amendments received for information</b>	0
<b>Number of substantial amendments received for new sites/PIs</b>	0
<b>Number of annual progress reports received</b>	39
<b>Number of safety reports received</b>	0
<b>Number of Serious Adverse Events received</b>	9
<b>Number of final reports received</b>	14

**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/WM/0165	Patient reported experience measures following hip fracture surgery	39
16/WM/0167	Muscle function and health in masters athletes	36
16/WM/0168	The Parallel Study	35
16/WM/0173	A pre-pilot exploration of Chemobrain - Pre-CB	33
16/WM/0220	Exploring Body Image in Parkinson's Disease	34
16/WM/0222	Patient experience of malignant pleural effusion	30
16/WM/0224	Research investigating the experience of paranoid, intrusive thoughts	34
16/WM/0309	Birmingham Remote Ischaemic Conditioning in Children trial	29
16/WM/0322	Ethnographic study of a mental health and football project.	32
16/WM/0400	Insulin resistance and adipocyte function in metabolic syndrome	25
16/WM/0405	Experiences of Parents of Children with Harmful Sexual Behaviour	29
16/WM/0515	Point-of-care testing for gastrointestinal pathogens (GastroPOC) v1.0	30
16/WM/0521	Cardiac imaging and biomarkers in haematological malignancy	49
17/WM/0003	Life review to improve autobiographical memory in aMCI-V1	32
17/WM/0005	Fat on Fire 2	30
17/WM/0009	CONNECT	33
17/WM/0048	Effects of kidney donation on cardiovascular structure and function	32
17/WM/0053	Mental Defeat and Chronic Pain	23
17/WM/0056	Robotic QOL Study	29
17/WM/0088	Understanding parents' perspectives on clinical trials	37
17/WM/0096	LITEFORM Light Therapy Effectiveness For Oral Mucositis	38
17/WM/0099	Musculoskeletal Ageing	38
17/WM/0100	Costs and effect of UK palliative care day services	48

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/WM/0159	NADMet	35
16/WM/0216	Direct Comparison of Cholescintigraphy with Ultrasonography Assessment	36
16/WM/0290	Self-conscious emotions and Inflammatory Bowel Disease - V1 13.03.16	32
16/WM/0463	Physical Activity after Cardiac EventS (PACES)	40

<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/WM/0210	Risk-adjusted FIT and Lifestyle Factors for CRC Screening	28
17/WM/0055	SUDEP Deaths	22

<b>Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/WM/0514	The B-ADENOMA Study	23
16/WM/0520	Hypoglycaemia awareness and behavioural intervention	36

<b>Unfavourable Opinion</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/WM/0470	Mental Defeat & Chronic Pain	27
17/WM/0090	Hospital Pharmacist Led Medicines Use Reviews	29

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

<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/WM/0227	Macrophage function in systemic amyloidosis; v1.0; 28 April 2016	13
16/WM/0282	Patient adherence to post-operative restrictions after hip replacement	16
16/WM/0324	Development of vision and nystagmus in Infantile Nystagmus Syndrome	14
16/WM/0326	Social Cognition in Early Psychosis. Version 1.0	10
16/WM/0328	The prevalence of Exercise-Induced Bronchoconstriction.	11
16/WM/0406	REd cell transfusion in Acute myeloid Leukaemia (REAL), v 1.0	11
16/WM/0408	GOLDEN study	17
16/WM/0409	GLANCE–H&N Study	16
16/WM/0450	Pectus Excavatum: lived experience	13
16/WM/0524	Olfactory Training for Post Septoplasty Patients	10
17/WM/0016	Neurodevelopmental follow-up for high-risk babies in Liverpool	21
17/WM/0054	Postnatal care following high blood pressure in pregnancy	20
17/WM/0095	Core Outcome Measures in Tinnitus: International Delphi (COMIT'ID)	18

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
16/WM/0283	Development and function of human immune cells	9
16/WM/0404	The EXHALE Pilot	15
17/WM/0020	Critical Lower Limb Ischaemia and Skeletal Muscle Function	19

<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/WM/0171	iHealth-T2D	16
16/WM/0172	Determine patients' preferences for outcomes of glaucoma surgery	10
16/WM/0177	Protein profiling of fibrinolytics treatment in pleural infection	10
16/WM/0228	Prevalence of Hepatitis E Antibodies in Patients Infected with HIV	14
16/WM/0452	Radiosensitivity and DNA repair in uveal melanoma	11
16/WM/0477	Impulse control disorders and dopamine agonists in Parkinson's disease	11
16/WM/0486	Anal Cancer Survival Analysis	12

#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/WM/0229	The dormant blood microbiome in common neurological disorders	14
16/WM/0484	PARROT Ireland Version 7.0	11
17/WM/0018	Immunomodulatory effects of cotrimoxazole in HIV infection	14
17/WM/0052	Role of molecular markers in Renal Cell Carcinoma	13
17/WM/0094	A new test for ruling out colorectal cancer - The qFIT Pilot_v1	18

#### Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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#### Provisional Opinion

REC Reference	Title	Number of Days on Clock
16/WM/0453	Flu clinic screening for detection of aortic stenosis v. 7.9.16	n/a

#### 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**

<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/Q2704/43/AM05	Studies on regulation of thyroid cell growth and function	06.04.2016	02/02/2016	8
09/H1206/112/AM06	Multimodal MRI investigation of childhood metabolic neurodegenerative disease	2	10/11/2016	13
10/H1206/58/AM06	Investigating DNA damage repair defects in Haematological malignancies	5	23/06/2016	22
11/WM/0304/AM28	The Birmingham COPD cohort study v2.0	SA 15	24/11/2016	22
11/WM/0304/AM30	The Birmingham COPD cohort study v2.0	SA 16	02/02/2017	8
11/WM/0403/AM10	Targeted case finding for COPD in Primary Care (TargetCOPD) V2.0	SA 9	02/02/2017	8
12/WM/0199/AM09	Low Calorie Diet Programme in Type 2 Diabetes patients on Insulin	7	28/03/2016	28
12/WM/0199/AM11	Low Calorie Diet Programme in Type 2 Diabetes patients on Insulin	SA 8	01/12/2016	29
13/WM/0136/AM01	e-nose assessment of VOC's in colorectal cancer patients	2	10/11/2016	12
13/WM/0340/AM09	PRO-REHAB: Development and Pilot Trial V1	5	09/06/2016	14
13/WM/0460/AM03	ReDUCe Study V1.0, 01.10.13	SA 2	23/12/2016	28
13/WM/0460/AM04	ReDUCe Study V1.0, 01.10.13	SA 3	07/03/2017	16
14/WM/0083/AM05	LORIS, Version 1.0 14th February 2014	Amendment 3.0	15/03/2016	23
14/WM/0162/AM12	Barrier Enhancement for Eczema Prevention - BEEP	SA 06	20/05/2016	23
14/WM/0162/AM13	Barrier Enhancement for Eczema Prevention - BEEP	7	28/10/2016	24
14/WM/1053/AM02	Primary care treatment of pain-related insomnia	1	01/07/2016	34
14/WM/1092/AM07	Genotype-phenotype correlation in ARCI	4.0	18/07/2016	35
14/WM/1148/AM03	Wound Fluid Collection MIR-21	2	03/08/2016	28
14/WM/1226/AM03	WATCH - Wessex Asthma Lifetime Cohort study	SA 2	01/09/2016	14
14/WM/1241/AM04	ROCKeTS	substantial amendment 4	14/03/2016	23
14/WM/1254/AM02	Cellular immunity to herpesvirus infection: Studies with EBV & CMV -v1	SA 2	08/09/2016	16
15/WM/0002/AM04	Impaired pAkt regulation in muscle and immune cells	3	07/07/2016	17
15/WM/0020/AM01	BI measures in children following cardiac surgery V3	SA1	22/04/2016	21
15/WM/0162/AM02	PD-PCOS	02	08/06/2016	26

15/WM/0230/AM02	Insight Kids Study - RD002177	1	03/06/2016	29
15/WM/0230/AM04	Insight Kids Study - RD002177	2.0	02/08/2016	13
15/WM/0293/AM02	Hospital prescribing analytics system	2	02/12/2016	11
15/WM/0329/AM02	iPOPP - Increasing Physical activity in Older People with chronic Pain	Amendment 2	31/03/2016	10
15/WM/0332/AM02	Evaluation of a lifestyle programme for breast cancer patients	1	04/05/2016	23
15/WM/0367/AM01	Development of a sexual dysfunction questionnaire for cancer patients	22.04.2016	22/04/2016	21
15/WM/0372/AM01	Perfusion MRI in reversible cerebral vasoconstriction syndrome	1	16/06/2016	20
15/WM/0467/AM02	Hep_Ex_v1.0	1	08/06/2016	13
15/WM/0468/AM02	Intrusive cognitions in young people with depression and PTSD.	SA1	18/07/2016	14
15/WM/0468/AM03	Intrusive cognitions in young people with depression and PTSD.	SA 2	11/10/2016	7
15/WM/0470/AM03	HIFU - Gynae	SA 1	21/09/2016	26
16/WM/0020/AM02	GLP-1 receptor expression in CHI	1	07/12/2016	7
16/WM/0023/AM02	Characterising psychological trauma symptoms in MND	2	15/07/2016	21
16/WM/0039/AM02	COPD patients' networks and medicine-taking after discharge (v 1.1)	Amendment 1	12/04/2016	18
16/WM/0040/AM02	Colobreathe	SA 1	06/02/2017	16
16/WM/0080/AM02	Sensory stimulation of the foot and ankle post-stroke. Version 1	SA1	18/03/2016	22
16/WM/0080/AM06	Sensory stimulation of the foot and ankle post-stroke. Version 1	SA 2	09/10/2016	8
16/WM/0134/AM01	Feasibility trial: pure cocoa to improve fatigue in pwMS	SA1	01/07/2016	27
16/WM/0134/AM03	Feasibility trial: pure cocoa to improve fatigue in pwMS	SA 2	01/11/2016	17
16/WM/0136/AM01	Midwifery Units Study	1	06/06/2016	6
16/WM/0136/AM07	Midwifery Units Study	SA2	01/09/2016	18
16/WM/0136/AM08	Midwifery Units Study	3	04/10/2016	20
16/WM/0309/AM02	Birmingham Remote Ischaemic Conditioning in Children trial	SA01	06/12/2016	20
16/WM/0322/AM01	Ethnographic study of a mental health and football project.	1	16/01/2017	17
16/WM/0463/AM02	Physical Activity after Cardiac EventS (PACES)	SA 1	27/02/2017	12
17/WM/0018/AM01	Immunomodulatory effects of cotrimoxazole in HIV infection	1	28/02/2017	10

### Unfavourable opinion

Amendment REC	Title	Version	Date	Number of Days on
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<b>Reference</b>				<b>Clock</b>
11/WM/0173/AM02	Intestinal metaplasia and oesophagogastric cancer methylation status			20

**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>

<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
None		

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

REC Reference	Title	Number of Days on Clock
None		

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

REC Reference	Title	Number of Days on Clock
16/WM/0241	A feasibility study to determine whether the daily consumption of flavonoid-rich pure cocoa has the potential to reduce fatigue in people with Relapsing and Remitting Multiple Sclerosis (RRMS).	29

**SSAs (Phase 1) over 14 day timeline**

REC Reference	Title	Number of Days on Clock
None		

**Substantial Amendments over 35 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
None				

**Modified Amendments over 14 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
None				