

**West Midlands - Solihull Research Ethics  
Committee**

**Annual Report**

**01 April 2017 - 31 March 2018**



## 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>	Mr George Martin from 1 <sup>st</sup> April 2018 Miss Victoria Strutt to 31 <sup>st</sup> March 2018
<b>REC Assistant:</b>	Miss Kate Loven from 1 <sup>st</sup> April 2018 Miss Daniella Sarno to 31 <sup>st</sup> March 2018
<b>Committee Address:</b>	The Old Chapel Royal Standard Place Nottingham NG1 6FS
<b>Telephone:</b>	02071048103
<b>Email:</b>	<a href="mailto:NRESCcommittee.WestMidlands-Solihull@nhs.net">NRESCcommittee.WestMidlands-Solihull@nhs.net</a>

## Chair's overview of the past year:

2017-18 has been another busy and interesting year for the West Midlands – Solihull Research Ethics Committee and I am very grateful to all our committee members for their enthusiastic support and hard work throughout the year. We have welcomed Chanan Berry and Melvin D'Souza as new members to our committee and do hope they will enjoy their time working with us and find the experience interesting and fulfilling.

We would like to thank all the members of other committees both local and from further afield who have kindly joined our committee as co-opted members during the past year to help make our meetings quorate. Their input has provided a refreshing insight to how other committees run and has been beneficial to all our members as well of course to the researchers whose work is being reviewed.

We were sorry to lose the services of Irene Linder a long time member of our committee in October 2017 and were shocked and deeply saddened to hear of her death a short time later. We all miss her helpful and insightful contributions to our meetings.

We remain very grateful to Vic and Daniella from the Nottingham REC office for the excellent administrative support for our committee in the past year – this has been very much appreciated. We also welcome George and Kate who have now taken on this role and do hope they will enjoy working with us

## 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	
Miss Chanan Berry	Student	Lay Plus	01/11/2017	
Dr Claire Doswell	Dentist	Expert	06/06/2017	
Dr Sheila D'Souza	Dentist	Expert	01/05/2016	
Mr Melvin D'Souza	Director	Lay Plus	21/03/2018	
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	11/10/2017
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: Co-opted Members

Name	Profession	Status	Meeting date attended
Ms Margaret Vince	Lay Member	Lay	12/07/2017
Mrs Rita Patel	Contracts and Innovation Manager	Lay	10/05/2017
Professor Paula McGee	Professor of Nursing	Expert	11/10/2017 07/06/2017
Reverend Keith Lackenby	Reverend	Lay Plus	14/03/2018 14/02/2018 07/06/2017 PR Meeting
Dr Ronald Jubb	Retired Consultant Rheumatologist	Expert	10/05/2017
Dr Nicola James	Independent Research Consultant	Lay Plus	11/10/2017
Dr Brian Hands	Retired General Practitioner	Expert	14/02/2018
Mr Paul Hamilton	Parish Administrator	Lay Plus	10/05/2017
Mr Chris Foy	Statistician	Expert	07/06/2017 PR Meeting 12/04/2017
Mrs Jeanne-Anne Charly	Staff Nurse	Expert	10/01/2018

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

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Dr Claire Doswell	None declared	16/06/2017
Mrs Lynne Gray	None declared	08/03/2018
Mrs Theresa Hyde	Trustee Carers United	08/03/2018
Dr Richard Mupanemunda	Given a paid lecture at a study day organised by Abbvie Ltd	08/03/2018
Dr Rex J Polson	Semi-retired	08/03/2018
Ms Veronica Morgan	Breast Cancer Haven West Midlands (Charity)	14/03/2018
Mr Melvin D'Souza	None Declared	14/03/2018
Ms Gill Tomlinson	None Declared	07/03/2018

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

Month	Date	Number of Members Present at Meeting
April	12/04/2017	7
May	10/05/2017	8
June	07/06/2017	8
July	12/07/2017	7
September	13/09/2017	8
October	11/10/2017	8
November	08/11/2017	8
January	10/01/2018	8
February	14/02/2018	7
March	14/03/2018	7

10 full committee meetings were held during the reporting period.

### Proportionate Review Sub-Committee Meetings held during 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	12/04/2017	3
May	10/05/2017	3
June	07/06/2017	3
July	12/07/2017	4
August	09/08/2017	3
September	13/09/2017	3
October	11/10/2017	3
November	08/11/2017	3
January	10/01/2018	3
February	14/02/2018	3
March	14/03/2018	3

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

### Sub-Committee Meetings held during 01 April 2017 - 31 March 2018:

Month	Date	Number of Members Present at Meeting
April	12/04/2017	2
May	10/05/2017	2
June	14/06/2017	2
June	28/06/2017	2
July	12/07/2017	2
July	26/07/2017	2
August	23/08/2017	2
September	13/09/2017	2
October	11/10/2017	2
October	25/10/2017	2

October	27/10/2017	2
November	02/11/2017	2
November	08/11/2017	2
November	29/11/2017	2
December	21/12/2017	2
January	09/01/2018	2
January	29/01/2018	2
February	14/02/2018	2
February	28/02/2018	2
March	14/03/2018	2
March	28/03/2018	2

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

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

None

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Ms Priyanka Batra	1
Dr Claire Doswell	6
Dr Sheila D'Souza	5
Mrs Lynne Gray	8
Mrs Theresa Hyde	6
Dr Jennifer Lim	6
Mrs Irene Linder	3
Ms Veronica Morgan	4
Dr Richard Mupanemunda	7
Dr Rex J Polson	9
Ms Gill Tomlinson	7

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mrs Lynne Gray	5
Mrs Theresa Hyde	6
Dr Jennifer Lim	4
Mrs Irene Linder	2
Ms Veronica Morgan	3
Dr Rex J Polson	10
Ms Gill Tomlinson	2

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mrs Lynne Gray	7
Mrs Theresa Hyde	7
Dr Jennifer Lim	1
Dr Richard Mupanemunda	1
Dr Rex J Polson	19
Ms Gill Tomlinson	7



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

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Ms Priyanka Batra	21/09/2017	Committee Members Induction
Dr Claire Doswell	11/01/2018	Committee Members Induction
Mrs Lynne Gray	26/09/2017	Training - Assessing the Consequences of Research
Mrs Lynne Gray	29/09/2017	Regional Training Day
Mrs Lynne Gray	20/03/2018	Complex Cases
Mrs Lynne Gray	20/03/2018	Complex Cases
Mrs Theresa Hyde	29/09/2017	Regional Training Day
Mrs Theresa Hyde	24/11/2017	HRA National Chairs Day and Policy Event
Dr Rex J Polson	10/09/2017	Equality and Diversity
Dr Rex J Polson	02/11/2017	Chairs Meeting East/West Midlands
Dr Rex J Polson	12/05/2017	Chairs Meeting West Midlands
Ms Gill Tomlinson	03/07/2017	'Buddy' to new member
Dr Richard Mupanemunda	12/05/2017	Chairs Meeting West Midlands

## 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)	1	2.38
Others	41	97.62
<b>Total Applications Reviewed</b>	<b>42</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	2
Number of student applications reviewed	22
Number of paediatric applications reviewed	8
Number of device applications reviewed	5
Number of prisoner applications reviewed	2
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	3	7.14
Favourable Opinion with Additional Conditions	6	14.29
Unfavourable Opinion	2	4.76
Provisional Opinion	31	73.81
Provisional Opinion Pending Consultation with Referee	0	0.00
<b>Total</b>	<b>42</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	27	64.29
Further Information Favourable Opinion with Additional Conditions	3	7.14
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	3	7.14
Favourable Opinion with Additional Conditions	6	14.29
Unfavourable Opinion	2	4.76
Provisional Opinion	0	0.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	1	2.38
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
<b>Total</b>	<b>42</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>28</b>
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**Table 6: Breakdown of PRS applications and other activity during reporting period:**

Number of applications made invalid by the REC Manager	1
Number of studies withdrawn prior to the meeting	5
Number of student applications reviewed	5
Number of paediatric applications reviewed	2
Number of device applications reviewed	2
Number of qualitative applications reviewed	4

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

<b>Decisions taken at proportionate review sub-committee meetings</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	5	17.86
Favourable Opinion with Additional Conditions	7	25.00
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	16	57.14
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>28</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	4.20
<b>Number of completed applications for full ethical review</b>	42
<b>Number of completed applications for full ethical review over 60 days</b>	1
<b>Number of completed applications over 60 days as a % of total</b>	2.38%
<b>Number of days taken to final decision – average (mean)</b>	37
<b>Number of completed proportionate review applications for ethical review</b>	28
<b>Number of completed proportionate review applications for ethical review over 21 days</b>	6
<b>Number of completed proportionate review applications over 21 days as a % of total</b>	21.43%
<b>Number of SSAs (non-Phase 1) reviewed</b>	2
<b>Number of completed applications for SSA review over 25 days</b>	0
<b>Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs</b>	0.00%
<b>Number of SSAs (Phase 1) reviewed</b>	0
<b>Number of completed applications for SSA review over 14 days</b>	0
<b>Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs</b>	0.00%
<b>Number of substantial amendments reviewed</b>	53
<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 modified amendments reviewed</b>	2
<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>	71
<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>	29
<b>Number of safety reports received</b>	0
<b>Number of Serious Adverse Events received</b>	4
<b>Number of final reports received</b>	8

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

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/WM/0122	DRPA	32
17/WM/0132	Monitoring Oxidative Stress in Acute Coronary Syndrome	35
17/WM/0133	PROXY N	40
17/WM/0179	IIH Pressure	47
17/WM/0192	The PREDICT Study	27
17/WM/0193	Radio-opaque beads for Prostate Artery Embolisation	36
17/WM/0215	Seeking Safety at a Women's Centre (v1)	49
17/WM/0218	Experience of living with someone with dementia. Version 1.	49
17/WM/0220	The lived experience of males with type two diabetes & low mood V0.1	34
17/WM/0221	The Role of Stressful life Events and Emotion Regulation in Self-Harm.	49
17/WM/0261	The EXACT Trial	50
17/WM/0273	Effect of mCPP on cognitive control, appetite, and neural responses	32
17/WM/0338	Randomised evaluation of myVirtualClinic	48
17/WM/0340	Social Cognitive Therapy in Virtual Reality for Early Psychosis VEEP 1	35
17/WM/0353	Risk factors predisposing to difficult urticaria. Version 1.	34
17/WM/0369	TCD for Children with SCD	35
17/WM/0371	INTEREST	24
17/WM/0374	Yorkshire Cancer Research Bowel Cancer Improvement Program	35
17/WM/0398	How does the Rushcliffe Self-Care Pathway work?	39
17/WM/0403	Consent For First Trimester Screening	59
17/WM/0410	Dietary management and outcome of patients with Citrin deficiency	37
18/WM/0003	Living with a young person with an ED: The sibling experience	43
18/WM/0004	DICOM collection within SABR CtE database v1.0	32
18/WM/0035	Interpersonal Relationships Amongst Young People with Autism (V1)	57
18/WM/0060	Vocabulary Intervention for Late Talkers	35
18/WM/0070	SLEEP T2D TRIAL	47
18/WM/0076	REMEDY: Assessing approaches aimed at improving sexual functioning	12

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/WM/0191	SCENE - Work Package 1	27

17/WM/0280	Family Centred Care: Families caring for a child with chronic illness.	36
17/WM/0405	The CardioMET Study v1.0	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
17/WM/0379	BEFORE-MS Linked Biobank study	34
17/WM/0406	Predicting patient-level antimicrobial choice and outcome (PLAMOS)	30
18/WM/0010	Communicating cardiovascular disease risk in UK primary care	27

#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
17/WM/0140	PLAY	28
17/WM/0142	The impact of doula care for women with Fear of Birth	28
17/WM/0144	Online and mobile phone intervention to support infant feeding choices	28
17/WM/0228	COPD Breathing Record Study 2 (CBRS2)	28
18/WM/0005	Experience of parents of children with anxiety; How society responds V2	27
18/WM/0051	PET to assess early response to nivolumab in renal cancer	29

#### Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
17/WM/0372	Experience of parents of children with anxiety; How society responds	28
18/WM/0043	WellComm2 Language Screening Tool Key Stage 2 Children	28

#### Provisional Opinion

REC Reference	Title	Number of Days on Clock
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#### 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
18/WM/0006	Evaluation of Circular Staplers in Left-Sided Colorectal Anastomoses	n/a

#### 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
17/WM/0138	Observational Study of Translarna in Usual Care	16
17/WM/0139	Use of Multiplex PCR in diagnosis of Native joint Infection	28
17/WM/0185	Oral Health	16
17/WM/0186	Focus group - Depression and Exercise V1	12
17/WM/0272	Use of Lung Tissue to assess effects of Smoking/Vaping in Lung Disease	19
17/WM/0278	Global Congestive Heart Failure Registry	20
17/WM/0317	Outcome validation in noses of cystic fibrosis and non-CF subjects	12
17/WM/0318	3d printing in surgical oncology	15
17/WM/0347	Identifying breast cancer recurrences using routinely collected data	21
17/WM/0413	Feasibility of a trial of bilateral cochlear implantation in adults	20
17/WM/0415	Characterisation of eye blood vessels using OCTA V1.0	20
18/WM/0014	Anticipate-X	24
18/WM/0019	Patient Interviews about treatment and recruitment in the DANTE trial	23
18/WM/0050	Patient and practitioner views on medication adherence interventions	23
18/WM/0071	Developing training for midwives to help women do PFMEs	24

#### Further Information Favourable Opinion with Additional Conditions



REC Reference	Title	Number of Days on Clock
17/WM/0181	Visual Performance with a hydrophobic aspheric monofocal IOL	14

#### Further Information Unfavourable Opinion

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

REC Reference	Title	Number of Days on Clock
17/WM/0136	Feasibility and usability of the I-GERQ-DD in an electronic format	14
17/WM/0271	Drug-Drug Interactions and Clinical Outcomes Captured by Climate-HIV	16
17/WM/0348	Sleep disordered breathing and ventilatory support in Down children	20
17/WM/0376	p16 and anal neoplasia.	15
18/WM/0018	Consensus on core outcomes and indications for rib fracture fixation	24

#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
17/WM/0187	Assessing recovery in patients at 12 months or more after stroke	10
17/WM/0223	A multicentre study of the i-scan endoscopy in Ulcerative Colitis	16
17/WM/0227	Prelim	16
17/WM/0277	Diabetic control and frequency of intravitreal treatment for DMO	15
17/WM/0377	Parents of children with cochlear implants: what do they want?	15
17/WM/0414	RCT comparing Alcon CLAREON with Abbott Medical Optics PCB00 IOLs	17
18/WM/0072	TOSCA Trial	17

#### Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
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#### 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**

<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>
04/Q2704/34/AM04	CLUB	14	31/05/2017	15
09/H1206/112/AM07	Multimodal MRI investigation of childhood metabolic neurodegenerative disease	3	15/11/2017	18
10/H1206/4/AM12	Benefits of exercise in type 1 diabetes	13	01/10/2017	10
10/H1206/58/AM09	Investigating DNA damage repair defects in Haematological malignancies	07	09/08/2017	17
11/WM/0103/AM13	Implementing GRiST in primary care and the community, version 1	10	27/03/2017	35
11/WM/0403/AM11	Targeted case finding for COPD in Primary Care (TargetCOPD) V2.0	10	16/02/2018	13
13/WM/0045/AM01	Collection of normal reference data for understanding human movement	1	01/01/2017	34
13/WM/0460/AM05	ReDUCe Study V1.0, 01.10.13	4	30/08/2017	17
14/WM/0162/AM14	Barrier Enhancement for Eczema Prevention - BEEP	SA 8	02/08/2017	21
14/WM/1063/AM01	Tennis Elbow Platelet-rich Plasma Injection Study (TEPIS)	1	18/04/2017	18
14/WM/1226/AM04	WATCH - Wessex Asthma Lifetime Cohort study	3	08/03/2017	25
14/WM/1254/AM03	Cellular immunity to herpesvirus infection: Studies with EBV & CMV -v1	3	15/03/2018	13
15/WM/0002/AM05	Impaired pAkt regulation in muscle and immune cells	4	21/02/2017	24
15/WM/0218/AM02	UK-PK study	01	10/05/2017	24
15/WM/0224/AM08	Exercise to prevent shoulder problems (PROSPER) (V1.0)	1	09/03/2017	26
15/WM/0230/AM05	Insight Kids Study - RD002177	03	13/03/2017	29
15/WM/0454/AM06	Rational MCC, Vn1.0, 4th November 2015	01	13/10/2017	13
16/WM/0040/AM03	Colobreathe	SA1	03/04/2017	14
16/WM/0040/AM04	Colobreathe	2	15/04/2017	14
16/WM/0040/AM05	Colobreathe	3	16/01/2018	17
16/WM/0309/AM03	Birmingham Remote Ischaemic Conditioning in Children trial	02	05/02/2018	8
16/WM/0408/AM01	GOLDEN study	1.0	24/01/2018	26
16/WM/0463/AM03	Physical Activity after Cardiac EventS (PACES)	2	16/08/2017	20
16/WM/0484/AM03	PARROT Ireland Version 7.0	8	30/06/2017	20
16/WM/0484/AM04	PARROT Ireland Version 7.0	9.0	13/11/2017	20

16/WM/0521/AM01	Cardiac imaging and biomarkers in haematological malignancy	1	06/04/2017	35
17/WM/0048/AM01	Effects of kidney donation on cardiovascular structure and function	1	01/12/2017	20
17/WM/0054/AM01	Postnatal care following high blood pressure in pregnancy	1	04/05/2017	23
17/WM/0054/AM02	Postnatal care following high blood pressure in pregnancy	2	25/01/2018	9
17/WM/0056/AM01	Robotic QOL Study	1	19/04/2017	28
17/WM/0056/AM04	Robotic QOL Study	02	15/02/2018	19
17/WM/0088/AM02	Understanding parents' perspectives on clinical trials	01	08/01/2018	11
17/WM/0094/AM01	A new test for ruling out colorectal cancer - The qFIT Pilot_v1	1	20/09/2017	15
17/WM/0095/AM02	Core Outcome Measures in Tinnitus: International Delphi (COMIT'ID)	1	18/09/2017	27
17/WM/0096/AM01	LiTEFORM Light Therapy Effectiveness For Oral Mucositis	1	27/06/2017	15
17/WM/0096/AM03	LiTEFORM Light Therapy Effectiveness For Oral Mucositis	SA 2	15/11/2017	27
17/WM/0099/AM01	Musculoskeletal Ageing	Version 4	01/12/2017	18
17/WM/0100/AM02	Costs and effect of UK palliative care day services	V3	25/10/2017	19
17/WM/0122/AM02	DRPA	2	10/01/2018	7
17/WM/0136/AM01	Feasibility and usability of the I-GERQ-DD in an electronic format	1	15/12/2017	15
17/WM/0191/AM04	SCENE - Work Package 1	1	27/11/2017	29
17/WM/0192/AM01	The PREDICT Study	1.0	04/01/2018	18
17/WM/0218/AM01	Experience of living with someone with dementia. Version 1.	1	03/02/2018	16
17/WM/0223/AM01	A multicentre study of the i-scan endoscopy in Ulcerative Colitis	01	05/10/2017	30
17/WM/0227/AM01	Prelim	1	04/12/2017	23
17/WM/0228/AM01	COPD Breathing Record Study 2 (CBRS2)	REV 02	28/11/2017	28
17/WM/0261/AM01	The EXACT Trial	1	22/11/2017	28
17/WM/0271/AM01	Drug-Drug Interactions and Clinical Outcomes Captured by Climate-HIV	1	24/11/2017	31
17/WM/0369/AM01	TCD for Children with SCD	#1	10/01/2018	16
17/WM/0371/AM01	INTEREST	2.0	15/01/2018	12
17/WM/0398/AM01	How does the Rushcliffe Self-Care Pathway work?	1	18/01/2018	13

### Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
10/H1206/51/AM04	Virtual Reality Route Learning after Acquired Brain Injury	29.03.2017	31/03/2017	20

12/WM/0285/AM01	Microbial diversity in the sputum of patients with cystic fibrosis	1	22/11/2017	26
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**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>
10/H1206/51/AM04/1	Virtual Reality Route Learning after Acquired Brain Injury	VR amendment 7.6.17	07/06/2017	10

<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>
12/WM/0285/AM01/1	Microbial diversity in the sputum of patients with cystic fibrosis	2	07/02/2018	7

**Table 11: Items exceeding timelines**

**Full applications for ethical review over 60 day timeline**

REC Reference	Title	Number of Days on Clock
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**Proportionate review applications for ethical review over 21 day timeline**

REC Reference	Title	Number of Days on Clock
17/WM/0139	Use of Multiplex PCR in diagnosis of Native joint Infection	28
18/WM/0014	Anticipate-X	24
18/WM/0018	Consensus on core outcomes and indications for rib fracture fixation	24
18/WM/0019	Patient Interviews about treatment and recruitment in the DANTE trial	23
18/WM/0050	Patient and practitioner views on medication adherence interventions	23
18/WM/0071	Developing training for midwives to help women do PFMEs	24

**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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