

**West Midlands - Solihull Research Ethics
Committee**

Annual Report

01 April 2015 - 31 March 2016



Part 1 – Committee Membership and Training

Name of REC:	West Midlands - Solihull Research Ethics Committee
Type of REC:	Authorised REC
Type of Flag:	Research Involving Children
Chair:	Dr Rex J Polson
Vice-Chair:	Dr Timothy Priest
Alternate Vice-Chair:	Dr Richard Mupanemunda
REC Manager:	Ms Ellen Swainston until September 2015 Miss Joanne Unsworth from September 2015 until March 2016
REC Assistant:	Miss Joanne Unsworth until September 2015
Committee Address:	The Old Chapel Royal Standard Place Nottingham NG1 6FS
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Chair's overview of the past year:

NRES West Midlands - Solihull Research Ethics has had another busy and interesting year and I am grateful to our committee members for all their hard work and enthusiastic support throughout the year. We were sad that Dr Raj DK Dhaliwal had to step down from the committee due to the pressure of her other commitments and we thank her for all her support. We were also deeply saddened to hear of the death of Mr Raj Singh a long time member of our committee who had been on extended absence through sickness; we have all missed his helpful contributions to our meetings. We are pleased that researchers continue to attend our meetings for most studies as this is extremely beneficial for our members and is probably helpful for the investigators as well. 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 over the recent months 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 remain very grateful to the Nottingham REC office for 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
Dr Raj D K Dhaliwal	Dentist	Expert	10/07/2013	08/07/2015
Mrs Lynne Gray	Senior Biomedical Scientist	Expert	11/07/2007	
Mrs Theresa Hyde	Retired Head Teacher	Lay Plus	11/07/2007	
Dr Jennifer Lim	Social Scientist	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 -	Expert	11/07/2007	
Dr Timothy Priest	Consultant in Pain Management	Expert	11/07/2007	
Mr Rajeshwar Singh	Chartered Engineer - Retired	Lay Plus	11/07/2007	29/01/2016
Ms Gill Tomlinson	Quality Manager Radiology	Expert	11/07/2007	

West Midlands - Solihull Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
None			

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

Name	Profession	Status	Meeting date attended
Professor Paula McGee	Professor of Nursing	Expert	08.07.2015 14.10.2015 16.12.2015
Dr Ronald Jubb	Retired Consultant Rheumatologist	Expert	16.12.2015 13.01.2016
Dr Sarahjane Jones	Research Fellow	Lay	08.04.2015 13.01.2016
Mr Paul Hamilton	Retired Local Government Officer	Lay Plus	08.04.2015 11.11.2015
Dr John S Fenlon	Statistical Consultant	Lay	10.02.2016
Mr Michael Andrews	Retired Company Secretary	Lay Plus	08.07.2015 16.12..2015
Mrs Jeanne-Anne Charly	Staff Nurse	Expert	09.03.2016

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

Name	Declaration of Interest	Date
Mrs Lynne Gray	None declared	18/12/2015
Mrs Theresa Hyde	Trustee Carers United(former Carers UK)	18/12/2015
Dr Jennifer Lim	Trustee, Commonwealth Human Ecology Council	18/12/2015
Mrs Irene Linder	None declared	18/12/2015
Ms Veronica Morgan	None declared	18/12/2015
Dr Richard Mupanemunda	None declared	30/12/2015
Dr Rex J Polson	None declared	18/12/2015
Dr Timothy Priest	None declared	18/12/2015
Ms Gill Tomlinson	None declared	18/12/2015

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

Month	Date	Number of Members Present at Meeting
April	08/04/2015	9
May	13/05/2015	10
July	08/07/2015	8
September	16/09/2015	7
October	14/10/2015	7
November	11/11/2015	8
December	16/12/2015	9
January	13/01/2016	9
February	10/02/2016	9
March	09/03/2016	7

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	08/04/2015	3
May	13/05/2015	3
June	10/06/2015	3
August	12/08/2015	3
September	16/09/2015	3
November	11/11/2015	3
January	13/01/2016	3
February	10/02/2016	3
March	09/03/2016	3

9 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	08/04/2015	2
April	29/04/2015	2
May	13/05/2015	2
May	20/05/2015	2
May	27/05/2015	2
June	10/06/2015	2
June	24/06/2015	2
July	08/07/2015	2
July	22/07/2015	2
August	12/08/2015	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
December	16/12/2015	2
January	05/01/2016	2
January	13/01/2016	2
January	27/01/2016	2
February	10/02/2016	2
February	24/02/2016	2
March	09/03/2016	2
March	23/03/2016	2

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

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

Date	Reason	Action taken
None		

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

Name	Number of Meetings Attended
Dr Raj D K Dhaliwal	1
Mrs Lynne Gray	10
Mrs Theresa Hyde	8
Dr Jennifer Lim	4
Mrs Irene Linder	7
Ms Veronica Morgan	7
Dr Richard Mupanemunda	8
Dr Rex J Polson	9
Dr Timothy Priest	7
Mr Rajeshwar Singh	1
Ms Gill Tomlinson	8

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

Name	Number of Meetings Attended
Mr John Aldridge	1
Mrs Lynne Gray	1
Mrs Theresa Hyde	3
Dr Jennifer Lim	1
Mrs Irene Linder	5
Ms Veronica Morgan	3
Dr Richard Mupanemunda	1
Dr Rex J Polson	6
Dr Timothy Priest	4
Ms Gill Tomlinson	2

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

Name	Number of Meetings Attended
Mrs Lynne Gray	1
Mrs Theresa Hyde	4
Dr Jennifer Lim	1
Ms Veronica Morgan	1
Dr Rex J Polson	19
Dr Timothy Priest	18
Ms Gill Tomlinson	2

Training 01 April 2015 - 31 March 2016

Name of Member	Date	Event(s) attended
Mrs Theresa Hyde	25/09/2015	Members Regional Training Day
Mrs Irene Linder	28/07/2015	Equality and Diversity
Ms Veronica Morgan	16/10/2015	Valuing Diversity Study Day
Dr Richard Mupanemunda	29/06/2015	REaSoN Neonatal Conference
Dr Richard Mupanemunda	04/10/2015	Equality and Diversity
Dr Rex J Polson	07/05/2015	NREAP Meeting
Dr Rex J Polson	16/06/2015 17/06/2015	UK CEN pre-Conference Workshop
Dr Rex J Polson	05/11/2015	NREAP Meeting
Dr Timothy Priest	07/05/2015	NREAP Meeting
Dr Timothy Priest	05/11/2015	NREAP Meeting
Dr Timothy Priest	11/11/2015	Equality and Diversity
Dr Jennifer Lim	07/10/2015	Phase 1 trials: Ethics and Regulations

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	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	49	100.00
Total Applications Reviewed	49	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	24
Number of paediatric applications reviewed	11
Number of device applications reviewed	3
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

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	1	2.04
Favourable Opinion with Additional Conditions	7	14.29
Unfavourable Opinion	3	6.12
Provisional Opinion	38	77.55
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	49	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	34	69.39
Further Information Favourable Opinion with Additional Conditions	4	8.16
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	2.04
Favourable Opinion with Additional Conditions	7	14.29
Unfavourable Opinion	3	6.12
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
Total	49	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	6
Number of studies withdrawn prior to the meeting	1
Number of student applications reviewed	10
Number of paediatric applications reviewed	8
Number of device applications reviewed	0
Number of qualitative applications reviewed	3

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	7	23.33
Favourable Opinion with Additional Conditions	3	10.00
No Opinion transfer to full committee for review	4	13.33
Provisional Opinion	15	50.00
Unfavourable Opinion	1	3.33
Total	30	100

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

Average number of applications reviewed per full meeting	4.90
Number of completed applications for full ethical review	49
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	1
Number of completed applications over 40 days as a % of total	2.04%
Number of days taken to final decision – average (mean)	28
Number of completed proportionate review applications for ethical review	26
Number of completed proportionate review applications for ethical review over 14 days	2
Number of completed proportionate review applications over 14 days as a % of total	7.69%
Number of SSAs (non-Phase 1) reviewed	2
Number of completed applications for SSA review over 25 days	1
Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs	50.00%
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	64
Number of completed substantial amendments over 35 days	1
Number of completed substantial amendments over 35 days as a % of total substantial amendments	1.56%
Number of completed substantial amendments over 28 days	4
Number of completed substantial amendments over 28 days as a % of total substantial amendments	6.25%
Number of modified amendments reviewed	6
Number of completed modified amendments over 14 days	1
Number of completed modified amendments over 14 days as a % of total modified amendments	16.67%
Number of minor amendments received	46
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	0
Number of annual progress reports received	57

Number of safety reports received	0
Number of Serious Adverse Events received	9
Number of final reports received	18

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/WM/0100	Understanding experiences of adolescents with a gender-variant sibling	29
15/WM/0122	Experience of being detained under Section 136 of the MHA	31
15/WM/0162	PD-PCOS	24
15/WM/0164	Developing a non-invasive marker CVD risk and treatment effect	21
15/WM/0228	Determining the muscle anabolic properties of phosphatidic acid.	21
15/WM/0230	Insight Kids Study - RD002177	25
15/WM/0231	Pill School V1.0	30
15/WM/0329	iPOPP - Increasing Physical activity in Older People with chronic Pain	22
15/WM/0332	Evaluation of a lifestyle programme for breast cancer patients	20
15/WM/0334	DUO (Dual Users Observational Study)	25
15/WM/0335	Phe and tyr concentrations over 24hrs GMP vs L amino acids	26
15/WM/0342	PERFEC-U	32
15/WM/0367	Development of a sexual dysfunction questionnaire for cancer patients	28
15/WM/0369	Fat Tissue Collection Project	28
15/WM/0374	A pilot study of Moderate Intensity Exercise in Brain/CNS Cancers.	26
15/WM/0384	Testosterone reference range study	24
15/WM/0403	Varenicline Vs Varenicline & Inhalator for Smoking Cessation	26
15/WM/0413	Female Genital Cutting (FGC) and relationships with caregivers	30
15/WM/0454	Rational MCC, Vn1.0, 4th November 2015	37
15/WM/0468	Intrusive cognitions in young people with depression and PTSD.	35
15/WM/0469	STAR IMPARt: Investigating the management of pain after replacement	33
15/WM/0470	HIFU - Gynae	31
16/WM/0015	Acceptance following Acquired Brain Injury: A Qualitative Study	27
16/WM/0020	GLP-1 receptor expression in CHI	34
16/WM/0023	Characterising psychological trauma symptoms in MND	56
16/WM/0027	Differences in near and distance visual acuity in paediatric amblyopia	30
16/WM/0074	Reducing Variability and Improving Diabetes Care	38
16/WM/0075	Sedentary Behaviour and Bone Health v1	38
16/WM/0080	Sensory stimulation of the foot and ankle post-stroke. Version 1	20
16/WM/0082	Monitoring compliance in taking respiratory medicines using AIRBRIO	19
16/WM/0118	SMART STUDY : Version 6 dated 27th January 2016	39
16/WM/0119	Adolescents experiences of living with inflammatory bowel disease V1.0	36

16/WM/0123	ADM Strattice Breast Trial	30
16/WM/0125	Mapping amputee RESIDUUM changes	29

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/WM/0166	Feasibility of a guided workbook intervention for cancer pateints	29
15/WM/0220	How do family & carers view their relationship with forensic services?	24
15/WM/0330	Assessment of triggered ventilation - NAVA Versus ACV	25
16/WM/0079	CEAL Study	22

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/WM/0007	Outcomes in Non-Alcoholic Fatty Liver Disease	26

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/WM/0124	SOCQER-2: Surgery in ovarian cancer	22
15/WM/0224	Exercise to prevent shoulder problems (PROSPER) (V1.0)	19
15/WM/0368	Resolution of acute inflammation in autoimmune rheumatic disease	23
15/WM/0370	Immune Responses to Treatments and Vaccinations in MPN Patients	25
15/WM/0372	Perfusion MRI in reversible cerebral vasoconstriction syndrome	22
15/WM/0414	Experiences of EFT for couples where one partner has an ABI	21
15/WM/0467	Hep_Ex_v1.0	29

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
15/WM/0163	A Narrative Study of Adolescent Boys who Self-Harm 1	20
16/WM/0024	Blood test for detection and monitoring of early stage osteoarthritis	26

16/WM/0120	Designing a questionnaire to measure paranoid intrusive thoughts	25
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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
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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/WM/0133	Faecal gut bacteria DNA testing in IBS patients and control subjects.	14
15/WM/0212	Population estimates and mental health of migrants - Version 1	13
15/WM/0292	Awareness and Beliefs About Cancer (ABACus): Phase 2	14
15/WM/0293	Hospital prescribing analytics system	11
15/WM/0296	Conceptual framework OAB	10
15/WM/0420	Circulating biomarkers of lung cancer.	14
15/WM/0425	Backpack: personal data store	15
16/WM/0039	COPD patients' networks and medicine-taking after discharge (v 1.1)	12
16/WM/0040	Colobreathe	12
16/WM/0043	The role of fetal MRI in cases with suspected renal abnormalities	8
16/WM/0135	Investigate the bond strength of orthodontic brackets to MIH teeth	11

16/WM/0136	Midwifery Units Study	15
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Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/WM/0134	Understanding Patient Experience around Hip Revision Surgery	12
16/WM/0134	Feasibility trial: pure cocoa to improve fatigue in pwMS	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
15/WM/0132	Professionals' and Clients' Perceptions of a Novel Asthma Device	14
15/WM/0186	Analysis of molecular signalling regulating muscle insulin sensitivity	6
15/WM/0217	Placental twin study	12
15/WM/0350	Socialising the Genome	10
15/WM/0352	ACORN: A feasibility study	9
16/WM/0042	PHH3 as a response marker for neo-adjuvant chemotherapy	9
16/WM/0084	Natural Killer-like response in rectal cancer	10

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
15/WM/0218	UK-PK study	11
16/WM/0085	Development of a Social Capital Index for Dumfries and Galloway	8
16/WM/0132	Parameter changes in Functional Electrical Stimulation	7

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
15/WM/0214	Consumers views on dress code policy of carers	10

Provisional Opinion		
REC Reference	Title	Number of Days on Clock
15/WM/0294	Length of day and circulating testosterone levels in men	n/a

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

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

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
07/H1206/34/AM04	An analysis of the 3-D shape of the femur and acetabulum	Substantial Amendment 1	08/04/2015	27
09/H1206/115/AM01	Molecular biology of retinoblastoma	1	11/08/2015	26
11/WM/0103/AM09	Implementing GRIST in primary care and the community, version 1	Substantial Amendment 9	29/05/2015	14
11/WM/0135/AM01	Immune responses in liver cancer following treatment	SA#01	23/07/2015	10
11/WM/0283/AM08	ORO-MOUTH 1.0	SA#06	27/07/2015	23
11/WM/0304/AM24	The Birmingham COPD cohort study v2.0	Substantial Amendment 13	29/06/2015	17
11/WM/0304/AM27	The Birmingham COPD cohort study v2.0	14	17/02/2016	20
11/WM/0403/AM09	Targeted case finding for COPD in Primary Care (TargetCOPD) V2.0	substantial amendment 8	19/02/2016	21
12/WM/0199/AM06	Low Calorie Diet Programme in Type 2 Diabetes patients on Insulin	Substantial Amendment 23/03/20	20/03/2015	17
12/WM/0199/AM07	Low Calorie Diet Programme in Type 2 Diabetes patients on Insulin	Substantial Amendment 23.04.20	23/04/2015	13
12/WM/0199/AM08	Low Calorie Diet Programme in Type 2 Diabetes patients on Insulin	Substantial amendment 6	21/05/2015	14
12/WM/0286/AM05	RCT of an intervention to reduce children's exposure to SHS at home	Substantial Amendment 3	27/03/2015	13
12/WM/0322/AM02	Identification of familial hypercholesterolaemia in general practice	SA#01	21/07/2015	30
12/WM/0322/AM03	Identification of familial hypercholesterolaemia in general practice	SA2	09/10/2015	26
12/WM/0330/AM04	Improving Patient Outcomes after Ocular Trauma	SA#04	28/07/2015	28
12/WM/0330/AM05	Improving Patient Outcomes after Ocular Trauma	4.0	14/05/2015	28
12/WM/0344/AM02	BBC-AF registry	Amendment 02	15/06/2015	18
12/WM/0379/AM01	Home Monitoring of Adults with Cystic Fibrosis (HOME-CF)	SA#01	22/06/2015	14
13/WM/0154/AM01	Taste preferences of young children with PKU	Substantial	01/06/2015	28

		Amendment 5 June 2		
13/WM/0206/AM09	Patient self-management in primary care patients with COPD - an RCT	Substantial Amendment 7	01/06/2015	15
13/WM/0225/AM02	Which healthy heart diet for people living with HIV?	2.0	15/01/2016	21
13/WM/0340/AM05	PRO-REHAB: Development and Pilot Trial V1	SA#02	03/08/2015	17
13/WM/0340/AM07	PRO-REHAB: Development and Pilot Trial V1	3.0	15/12/2015	8
13/WM/0340/AM08	PRO-REHAB: Development and Pilot Trial V1	4	17/02/2016	21
13/WM/0476/AM01	Non-invasive Pre-natal Testing	Substantial amendment 11	28/04/2015	28
14/WM/0083/AM03	LORIS, Version 1.0 14th February 2014	Amendment 2.0	08/07/2015	13
14/WM/0102/AM01	Patient experiences of musculoskeletal physiotherapy v1.0	1.0	29/01/2016	16
14/WM/0106/AM01	Mindfulness and Neurobehavioural functioning Version 1.1/7.2.2014	1.0	19/12/2015	21
14/WM/0120/AM01	Dynamic Gait Analysis in Children with Mucopolysaccharidosis Type IVa	SA#01	05/08/2015	15
14/WM/0152/AM01	Impact of a stabilisation phase implemented with veterans with PTSD	Substantial amendment 30.04.20	27/04/2015	15
14/WM/0153/AM03	Exploring Recovery in Forensic Service Users	SA1	16/02/2016	28
14/WM/0162/AM10	Barrier Enhancement for Eczema Prevention - BEEP	SA4	12/10/2015	21
14/WM/0162/AM11	Barrier Enhancement for Eczema Prevention - BEEP	5.0	11/11/2015	9
14/WM/1088/AM04	PROCAS – Lifestyle Breast Cancer Prevention Feasibility Study	Substantial Amendment 3	23/04/2015	9
14/WM/1092/AM03	Genotype-phenotype correlation in ARCI	Substantial Amendment 2	29/04/2015	15
14/WM/1125/AM02	Reading rehabilitation programme for macular degeneration patients	SA2	13/10/2015	34
14/WM/1148/AM02	Wound Fluid Collection MIR-21	Substantial Amendment 12.06.20	12/06/2015	17
14/WM/1169/AM01	PPROMS study	SA1	25/09/2015	15
14/WM/1187/AM02	SPARK Part 1	SA2	11/01/2016	28
14/WM/1241/AM01	ROCKeTS	Substantial Amendment 1	02/04/2015	23
14/WM/1241/AM02	ROCKeTS	Substantial	03/06/2015	11

		Amendment 2		
14/WM/1241/AM03	ROCKeTS	SA3	08/12/2015	22
14/WM/1243/AM01	Improving Detection of Early Lung Disease and Decline in AATD	Substantial amendment 16 June	01/06/2015	17
14/WM/1254/AM01	Cellular immunity to herpesvirus infection: Studies with EBV & CMV -v1	SA1	03/11/2015	15
14/WM/1257/AM02	Neural effects of steroid hormones	Substantial Amendment 1	25/06/2015	21
15/WM/0002/AM03	Impaired pAkt regulation in muscle and immune cells	amendment number 2	03/12/2015	12
15/WM/0058/AM03	DISCOVER_V1	SA#01	04/08/2015	21
15/WM/0081/AM01	BP monitors in AF	SA#01	29/07/2015	23
15/WM/0081/AM03	BP monitors in AF	2.0	06/01/2016	18
15/WM/0124/AM01	SOCQER-2: Surgery in ovarian cancer	Substantial amendment AM01	08/07/2015	9
15/WM/0132/AM02	Professionals' and Clients' Perceptions of a Novel Asthma Device	Substantial amendment 13 July	13/07/2015	22
15/WM/0162/AM01	PD-PCOS	1	11/11/2015	25
15/WM/0166/AM01	Feasibility of a guided workbook intervention for cancer pateints	1.0	03/12/2015	10
15/WM/0329/AM01	iPOPP - Increasing Physical activity in Older People with chronic Pain	1.0	13/01/2016	20
15/WM/0334/AM01	DUO (Dual Users Observational Study)	SA1	03/11/2015	15
15/WM/0334/AM02	DUO (Dual Users Observational Study)	SA#02	17/12/2015	20
15/WM/0342/AM01	PERFEC-U	substantial amendment 1	04/03/2016	33
15/WM/0352/AM02	ACORN: A feasibility study	SA01	09/02/2016	22
16/WM/0023/AM01	Characterising psychological trauma symptoms in MND	1	25/02/2016	23

Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
12/WM/0286/AM06	RCT of an intervention to reduce children's exposure to SHS at home	SA4	19/10/2015	25

14/WM/1088/AM05	PROCAS – Lifestyle Breast Cancer Prevention Feasibility Study	4.0	06/01/2016	12
14/WM/1226/AM02	WATCH - Wessex Asthma Lifetime Cohort study	Substantial amendment 09.06.20	10/06/2015	20
15/WM/0100/AM01	Understanding experiences of adolescents with a gender-variant sibling	1	18/09/2015	50
15/WM/0122/AM03	Experience of being detained under Section 136 of the MHA	SA1	26/10/2015	22

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
12/WM/0286/AM06/2	RCT of an intervention to reduce children's exposure to SHS at home	Mod Amend 2 of SA4	05/01/2016	2
14/WM/1088/AM05/1	PROCAS – Lifestyle Breast Cancer Prevention Feasibility Study	Mod1 of SA4	27/01/2016	n/a
14/WM/1226/AM02/1	WATCH - Wessex Asthma Lifetime Cohort study	Modified amendment 13.07.2015	13/07/2015	1

Unfavourable opinion timeline				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
12/WM/0286/AM06/1	RCT of an intervention to reduce children's exposure to SHS at home	MA1 SA4	25/11/2015	5
15/WM/0100/AM01/1	Understanding experiences of adolescents with a gender-variant sibling	1	19/11/2015	14
15/WM/0100/AM01/2	Understanding experiences of adolescents with a gender-variant sibling	Mod Amend 2 of SA1	04/01/2016	14

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/WM/0425	Backpack: personal data store	15
16/WM/0136	Midwifery Units Study	15

SSAs (non Phase 1) over 25 day timeline

REC Reference	Title	Number of Days on Clock
16/WM/0052	Changes in hepatic function	27

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
15/WM/0100/AM01	Understanding experiences of adolescents with a gender-variant sibling	1	18/09/2015	50

Modified Amendments over 14 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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