

**West Midlands - Black Country Research Ethics
Committee**

Annual Report

01 April 2017 - 31 March 2018



Part 1 – Committee Membership and Training

Name of REC:	West Midlands - Black Country Research Ethics Committee
Type of REC:	Authorised REC
Type of Flag:	Research Involving Children
Chair:	Dr Hilary Paniagua
Vice-Chair:	Dr Joseph Arumainayagam
Alternate Vice-Chair:	Mr Nanak Singh Sarhadi
REC Manager:	Carolyn Halliwell (Until February 2018) Joanne O'Neil (From February 2018)
REC Assistant:	Ms Teagan Allen (Until February 2018) David Parr (From February 2018)
Committee Address:	The Old Chapel Royal Standard Place Nottingham NG1 6FS
Telephone:	0207 104 8108
Email:	nrescommittee.westmidlands-blackcountry@nhs.net

Chair's overview of the past year:

This year the committee has maintained its busy level of work within its full and proportionate review meetings that continue to see a steady stream of proposals. All meetings have been quorate and none cancelled because of a lack of applications which we have experienced in the past. This year has also witnessed many changes in terms of its REC management which has not caused any disruption to the committee, it has actually been a good experience to meet and work with the different people. Feedback about the committee has been very complementary from its users and this has been very pleasing to receive.

We are fortunate in our meeting's venue which is excellent and offers us good hospitality and we look forward to working there another year.

West Midlands - Black Country Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Joseph Arumainayagam	Consultant and Honorary Senior Clinical Lecturer in HIV and GUM	Expert	01/04/2007	
Mrs Chris Bell	Board Member	Lay Plus	01/04/2007	30/10/2017
Miss Nicola Brooks	Solicitor	Lay Plus	13/02/2017	
Dr Nicola Erb	Consultant Rheumatologist	Expert	01/01/2009	
Dr Aisha Malik	Tutor Medical Ethics/Distance Learning Tutor for OUDCE	Expert	23/11/2015	
Dr Hilary Paniagua	Senior Lecturer	Expert	01/04/2007	
Dr Giridharan Rajaratnam	Deputy Regional Director	Expert	23/11/2016	
Mr Nanak Singh Sarhadi	Consultant Plastic Surgeon	Expert	01/06/2009	
Dr Julian Sonksen	Consultant in Anaesthesia and Critical Care	Expert	01/01/2008	
Reverend Mark Stobert	Hospital Chaplain	Lay Plus	01/04/2007	21/02/2018
Dr David Vallance	Consultant Biochemist	Lay	01/04/2007	
Mrs Jennifer Walton	Retired Research Nurse	Lay	01/11/2010	
Dr Tony Zalin	Expert Member	Expert	01/01/2009	

West Midlands - Black Country Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Professor Paula McGee	Professor of Nursing	Expert	24.04.2017 (Full) 24.04.2017 (PR)

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

Name	Declaration of Interest	Date
Dr Nicola Erb	None declared	11/12/2017
Dr Giridharan Rajaratnam	None declared	05/12/2017
Mr Nanak Singh Sarhadi	Could be involved in clinical research as part of his job in the NHS	08/05/2017
Dr David Vallance	Minor shareholdings in Astra-Zeneca Pharmaceuticals and GSK Pharmaceuticals. Total holding less than 100 shares per company. Trustee of The Robert Gaddie Fund. This charitable organisation (Charity no. 1016440) provides funding for research and educational activities in the field of clinical biochemistry.	20/12/2017
Dr Tony Zalin	None declared	04/12/2017

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

Month	Date	Number of Members Present at Meeting
April	24/04/2017	8
May	22/05/2017	10
June	26/06/2017	10
September	25/09/2017	9
October	30/10/2017	8
November	27/11/2017	9
January	29/01/2018	9
February	26/02/2018	8
March	26/03/2018	8

9 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	24/04/2017	4
May	22/05/2017	3
June	26/06/2017	3
July	31/07/2017	3
August	29/08/2017	4
September	25/09/2017	3
October	30/10/2017	3
November	27/11/2017	3
January	29/01/2018	3
February	26/02/2018	3
March	26/03/2018	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	13/04/2017	2
April	26/04/2017	2
May	12/05/2017	2
May	25/05/2017	2
June	28/06/2017	2
July	07/07/2017	2
July	20/07/2017	2
August	04/08/2017	2
August	17/08/2017	2
September	07/09/2017	2
September	18/09/2017	2

October	02/10/2017	2
October	13/10/2017	2
October	27/10/2017	2
November	10/11/2017	2
December	08/12/2017	2
December	20/12/2017	2
January	19/01/2018	2
February	09/02/2018	2
February	23/02/2018	2
March	12/03/2018	2
March	21/03/2018	2

22 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

Name	Number of Meetings Attended
Dr Joseph Arumainayagam	7
Mrs Chris Bell	4
Miss Nicola Brooks	8
Dr Nicola Erb	5
Dr Aisha Malik	3
Dr Hilary Paniagua	9
Dr Giridharan Rajaratnam	6
Mr Nanak Singh Sarhadi	6
Dr Julian Sonksen	5
Reverend Mark Stobert	3
Dr David Vallance	7
Mrs Jennifer Walton	8
Dr Tony Zalin	7

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

Name	Number of Meetings Attended
Dr Joseph Arumainayagam	3
Mrs Chris Bell	2
Dr Aisha Malik	3
Dr Hilary Paniagua	11
Dr Giridharan Rajaratnam	1
Mr Nanak Singh Sarhadi	2
Dr Julian Sonksen	3
Reverend Mark Stobert	4
Dr David Vallance	1
Mrs Jennifer Walton	4

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

Name	Number of Meetings Attended
Dr Joseph Arumainayagam	22
Dr Hilary Paniagua	22

Training 01 April 2017 - 31 March 2018

Name of Member	Date	Event(s) attended
Dr Aisha Malik	13/11/2017	Reading - the concept of vulnerability in research ethics: an in-dept analysis of policies and guidelines
Dr Aisha Malik	12/12/2017	DoH and MRC
Dr Aisha Malik	05/01/2018	Lecture on transplantation and organ donation
Dr Aisha Malik	31/01/2018	e-modules - HTA and IG in research
Dr Hilary Paniagua	02/11/2017	West Midlands Chairs Meeting
Dr Hilary Paniagua	24/11/2017	National Chairs Day and Policy Event
Dr Giridharan Rajaratnam	21/09/2017	Committee Members Induction
Dr Giridharan Rajaratnam	29/09/2017	Members Regional Training Day
Mrs Jennifer Walton	08/11/2017	The Ethical Issues of Research Involving Children
Dr Tony Zalin	04/12/2017	Medical Translation
Dr Tony Zalin	04/12/2017	Medical Literature

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	39	100.00
Total Applications Reviewed	39	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	15
Number of paediatric applications reviewed	7
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	13

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	0	0.00
Favourable Opinion with Additional Conditions	5	12.82
Unfavourable Opinion	0	0.00
Provisional Opinion	34	87.18
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	39	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	33	84.62
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	5	12.82
Unfavourable Opinion	0	0.00
Provisional Opinion	1	2.56
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	39	100

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

Total Applications Reviewed	22
------------------------------------	-----------

Table 6: Breakdown of PRS applications and other activity during reporting period:

Number of applications made invalid by the REC Manager	2
Number of studies withdrawn prior to the meeting	1
Number of student applications reviewed	7
Number of paediatric applications reviewed	5
Number of device applications reviewed	0
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	3	13.64
Favourable Opinion with Additional Conditions	1	4.55
No Opinion transfer to full committee for review	1	4.55
Provisional Opinion	16	72.73
Unfavourable Opinion	1	4.55
Total	22	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	4.33
Number of completed applications for full ethical review	39
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 days taken to final decision – average (mean)	26
Number of completed proportionate review applications for ethical review	21
Number of completed proportionate review applications for ethical review over 21 days	3
Number of completed proportionate review applications over 21 days as a % of total	14.29%
Number of SSAs (non-Phase 1) reviewed	2
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	55
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 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 non substantial amendments received	80
Number of substantial amendments received for information	0
Number of substantial amendments received for new sites/PIs	0
Number of annual progress reports received	39
Number of safety reports received	1
Number of Serious Adverse Events received	2
Number of final reports received	0

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
17/WM/0163	Participation after paediatric acquired brain injury - version 1.0	20
17/WM/0169	RECORD	26
17/WM/0171	CONTRADIA (V1.0-04.04.2017)	19
17/WM/0172	Can pre-operative troponin and CRP predict post-operative mortality?	30
17/WM/0173	Carers and mental health care transitions	18
17/WM/0174	Development of age appropriate functional imaging paradigm v1	29
17/WM/0203	Exploring the clinically orientated roles of the GP Receptionist	19
17/WM/0208	When older people harm their family carers	15
17/WM/0213	ChildNTP	34
17/WM/0251	Smoking and depression: a qualitative study.	16
17/WM/0254	Toric IOL vs LRI to correct corneal astigmatism in cataract surgery	20
17/WM/0255	Therapeutic needs of psychiatric inpatients with psychosis	24
17/WM/0257	Evaluation of Stillbirth Stories	20
17/WM/0321	NR on skeletal muscle metabolism and exercise performance	26
17/WM/0346	Care at the end of life following an acute stroke	29
17/WM/0355	6-APP Study v1	30
17/WM/0361	Notions of home within an adolescent inpatient unit	30
17/WM/0385	Host-microbiota interaction in inflammatory disease	25
17/WM/0391	The experiences of young people admitted to mental health wards	19
17/WM/0399	PIMMS-WL	23
17/WM/0429	Determinants of uptake of bariatric surgery in ethnic minority adults	29
17/WM/0436	Refining and testing the diagnostic accuracy of PAT-POPS	22
17/WM/0440	Lived experience of delirium in the community	36
17/WM/0441	STOP-PTSD	37
17/WM/0442	Psychological support for men who have experienced sudden bereavement.	26
18/WM/0002	A mother's experience of placing their child into care	31
18/WM/0029	ConCIPS Study	23
18/WM/0033	PRiORiTy	33
18/WM/0049	The process of mental and spiritual recovery in service users	35
18/WM/0054	Hi Flo	54
18/WM/0063	Adolescents' and their carers' experiences of living with eBPD/eEUPD 1	37
18/WM/0087	The experience of gangs and violence for young people in FCAMHS	24

18/WM/0090	Treatment of Iron deficiency Anaemia in Pregnancy study (TIAP)	24
------------	--	----

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
---------------	-------	-------------------------

Further Information Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
---------------	-------	-------------------------

Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
---------------	-------	-------------------------

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
17/WM/0216	3D Camera Study for Wound Monitoring	16
17/WM/0360	Child-Feeding Practices among Mothers (Version 5.0)	23
17/WM/0430	Resistance exercise frequency and muscle protein synthesis	22
18/WM/0066	Omega 3 and Fibre intervention study to improve metabolic health	23
18/WM/0089	Experience and sense making of visual hallucinations in Psychosis: IPA	21

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
---------------	-------	-------------------------

Provisional Opinion

REC Reference	Title	Number of Days on Clock
17/WM/0397	Assessment of a diagnostic assistant app in Accident and Emergency	n/a

Provisional Opinion Pending Consultation with Referee

REC Reference	Title	Number of Days on Clock
---------------	-------	-------------------------

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 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/0159	Family Adjustment to Childhood Epilepsy Surgery (FACES) Study	20
17/WM/0206	Genetics, epigenetics and proteomics of inflammation associated cancer	19
17/WM/0302	Observational, Prospective, Natural History Study in patients with PNH	19
17/WM/0306	Neuropathic Pain in Children. version 1	21
17/WM/0335	Independent validation of the Clinical Scaphoid Score (CSS)	17
17/WM/0337	Wellframe Feasibility Study	18
17/WM/0339	BREAST-Q for women in the general population	22
17/WM/0401	The CIPHER study	15
17/WM/0404	The TRIAGE Study: Identifying Non-Responders to Glaucoma Eye Drops	21
17/WM/0438	assessing nerve regeneration through motor re-nerivation assessment	21
17/WM/0439	Focus on early eating, drinking and swallowing	29
18/WM/0041	P-ACL Outcome Study	22
18/WM/0084	Designing for Wellbeing - v.1.0	17
18/WM/0088	Validating a quality of extubation scoring system	18

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
18/WM/0065	The effect of Aloe Vera Juice on liver enzymes in healthy volunteers	17

Further Information Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
---------------	-------	-------------------------

Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
17/WM/0161	TNF inhibitors in the prevention of Alzheimer's disease	17
17/WM/0204	Antibiotic Negotiations: Conversation Analytic Project	18
18/WM/0040	Variation in Lung Cancer Treatment Rates	15

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
17/WM/0365	ILD in Screening Study	13

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
17/WM/0160	Feasibility of antenatal group to improve reflective functioning	14

Provisional Opinion

REC Reference	Title	Number of Days on Clock
18/WM/0064	Gut-CF	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
09/H1202/113/AM03	Cardiac changes before and after kidney transplantation	Substantial Amendment 03/01	16/03/2017	1
12/WM/0258/AM08	Outcomes in patients with inflammatory arthritis	Substantial Amendment 7	21/07/2017	12
12/WM/0320/AM08	The metabolic effects of DNA epimutations in Growth Disorders V1.1	SA 14.11.2016	14/11/2016	8
14/WM/0011/AM11	IIH:WT	Substantial Amendment 8	28/06/2017	9
14/WM/1220/AM06	Exercise and vitamin D supplementation in older adults (EXVITD)	Substantial Amendment 5.0	06/07/2017	7
14/WM/1220/AM07	Exercise and vitamin D supplementation in older adults (EXVITD)	Substantial Amendment 6.0	03/08/2017	13
14/WM/1253/AM02	Establishing cell cultures from paediatric cancers	Substantial Amendment V2	27/07/2017	14
15/WM/0005/AM03	CFMATTERS Study	Substantial Amendment Number 2	23/05/2017	17
15/WM/0006/AM07	Influence of Successful Periodontal Intervention on REnal Disease	Substantial Amendment 04	20/07/2017	4
15/WM/0010/AM05	Study to Observe Disease Progression In Alport Syndrome Patients	Substantial Amendment 4	16/03/2017	12
15/WM/0219/AM01	Human single neuron recordings in epilepsy patients v1	Amendment 1	14/06/2017	2
15/WM/0258/AM04	Priorities and Preferences for Whole Genome Sequencing	Substantial Amendment 2	17/06/2017	15
15/WM/0322/AM01	Pilot study - Outlining the immune profile of ovarian cancer	SA 2.0, 10th October 2017	10/10/2017	20
15/WM/0340/AM05	AIR: Ankle Injury Rehabilitation	Substantial Amendment 4	07/04/2017	6
15/WM/0341/AM09	The CEMS study	Substantial Amendment 5	28/07/2017	6
15/WM/0341/AM10	The CEMS study	6	27/10/2017	12
15/WM/0359/AM07	Achilles Tendinopathy Management	Substantial	21/04/2017	8

		Amendment 7		
15/WM/0359/AM08	Achilles Tendinopathy Management	8 - 01-AUG-2017	01/08/2017	7
15/WM/0359/AM09	Achilles Tendinopathy Management	SA 9 15-JAN-2018	15/02/2018	7
15/WM/0359/AM10	Achilles Tendinopathy Management	SA 10 16-FEB-2018	16/02/2018	2
15/WM/0445/AM04	Feasibility of a routine postnatal weight management intervention	Substantial Amendment 3	04/08/2017	6
16/WM/0005/AM04	Protein distribution in older adults	Substantial Amendment 3	10/04/2017	10
16/WM/0018/AM02	Plenadren versus Hydrocortisone in Primary Hypoadrenalism - Version 1	Substantial Amendment 2	31/03/2017	13
16/WM/0018/AM03	Plenadren versus Hydrocortisone in Primary Hypoadrenalism - Version 1	SA 3 23rd February 2018	23/02/2018	6
16/WM/0148/AM02	Are We Performing Cataract Surgery Too Early? An Evaluation of PROs	Substantial Amendment 24.04.20	24/04/2017	2
16/WM/0152/AM05	PREdiCCt	Substantial Amendment 4	11/05/2017	2
16/WM/0368/AM02	Hoarding behaviours in ADHD	SA 1 19/02/2018	19/02/2018	15
16/WM/0371/AM05	Sedentary behaviour and physical activity in RA and OA	Substantial Amendment 2	23/08/2017	20
16/WM/0374/AM05	Fatigue in Vasculitis - FAB-V	Substantial Amendment 1	11/04/2017	13
16/WM/0374/AM06	Fatigue in Vasculitis - FAB-V	Substantial Amendment 02	08/06/2017	10
16/WM/0374/AM07	Fatigue in Vasculitis - FAB-V	Substantial Amendment 03	21/08/2017	16
16/WM/0457/AM02	CODEC Study	Substantial Amendment 1	03/03/2017	2
16/WM/0457/AM04	CODEC Study	2	28/09/2017	14
16/WM/0457/AM06	CODEC Study	SA 3 29/01/2018	29/01/2018	3
16/WM/0466/AM01	Telephone Delivery of a Health Coaching Service	Substantial Amendment 1	17/04/2017	15
16/WM/0466/AM02	Telephone Delivery of a Health Coaching Service	Substantial Amendment 2	17/07/2017	16
16/WM/0496/AM02	PBR28-PET in Crohn's disease	Substantial	27/07/2017	15

		Amendment 1		
17/WM/0038/AM01	Spiritual & emotional needs of siblings of a child with a rare disease	Substantial Amendment 1	21/06/2017	7
17/WM/0038/AM03	Spiritual & emotional needs of siblings of a child with a rare disease	3	05/10/2017	11
17/WM/0058/AM01	Home-based HIIT in people with T1D	1	30/06/2017	2
17/WM/0068/AM02	LYSOTRACK-ageing	Substantial Amendment 1	31/08/2017	6
17/WM/0084/AM01	Alphavbeta6 PET in Radiation induced Lung fibrosis (EARL)	Substantial Amendment 1	07/04/2017	6
17/WM/0125/AM01	ADIE to prevent development of anxiety disorders in autism - version 1	Substantial Amendment A1	19/06/2017	12
17/WM/0128/AM01	Feasibility study of an app-based intervention to improve wellbeing	SA 1 19/01/18	18/01/2018	14
17/WM/0130/AM01	EDISON	1	21/09/2017	12
17/WM/0159/AM01	Family Adjustment to Childhood Epilepsy Surgery (FACES) Study	Substantial Amendment 1	11/08/2017	11
17/WM/0159/AM03	Family Adjustment to Childhood Epilepsy Surgery (FACES) Study	SA 2, 14/03/2018	14/03/2018	7
17/WM/0163/AM01	Participation after paediatric acquired brain injury - version 1.0	Substantial Amendment 1.0	17/06/2017	17
17/WM/0169/AM03	RECORD	SA 01	27/12/2017	15
17/WM/0171/AM01	CONTRADIA (V1.0-04.04.2017)	SA01	12/10/2017	15
17/WM/0337/AM01	Wellframe Feasibility Study	1	27/09/2017	25
17/WM/0337/AM02	Wellframe Feasibility Study	2	10/10/2017	20
17/WM/0360/AM02	Child-Feeding Practices among Mothers (Version 5.0)	SA 02	19/01/2018	19
17/WM/0399/AM01	PIMMS-WL	Substantial Amendment No. 1	05/12/2017	19
17/WM/0399/AM02	PIMMS-WL	SA No. 2	01/02/2018	18

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
---------------	-------	-------------------------

Proportionate review applications for ethical review over 21 day timeline

REC Reference	Title	Number of Days on Clock
17/WM/0339	BREAST-Q for women in the general population	22
17/WM/0439	Focus on early eating, drinking and swallowing	29
18/WM/0041	P-ACL Outcome Study	22

SSAs (non Phase 1) over 25 day timeline

REC Reference	Title	Number of Days on Clock
---------------	-------	-------------------------

SSAs (Phase 1) over 14 day timeline

REC Reference	Title	Number of Days on Clock
---------------	-------	-------------------------

Substantial Amendments over 35 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
-------------------------	-------	---------	------	-------------------------

Modified Amendments over 14 day timeline

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
-------------------------	-------	---------	------	-------------------------