

**Yorkshire & The Humber - Sheffield Research
Ethics Committee**

Annual Report

01 April 2016 - 31 March 2017



Part 1 – Committee Membership and Training

Name of REC:	Yorkshire & The Humber - Sheffield Research Ethics Committee
Type of REC:	RECs recognised to review CTIMPS in patients - type iii
Type of Flag:	Establishing Research Tissue Banks, IRB Registered, Medical Device Study, Research Involving Children
Chair:	Professor Basil Sharrack
Vice-Chair:	Dr Amaka Offiah
Alternate Vice-Chair:	Dr Nana Theodorou
REC Manager:	Mrs Hayley Henderson
REC Assistant:	Miss Kerry Dunbar
Committee Address:	Room 001 Jarrow Business Centre Rolling Mill Road Jarrow Tyne and Wear NE32 3DT
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Chair's overview of the past year:

During the last 12 months, Sheffield REC Committee was fortunate to have been joined by excellent new members and to have been able to retain all the old members.

The Committee, through the hard work of its members and admin staff, has continued to support the local and national research communities.

Despite the continuous changes to the HRA approval process, the Committee has been able to adapt to the new working framework with the support of the dedicated admin team.

Yorkshire & The Humber - Sheffield Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Paul Bacon	Lead Clinical Scientist in Audiological Science, Medical Physics	Expert	01/06/2011	
Mrs Jacqui Gath	Retired Senior Systems Analyst	Lay Plus	15/06/2011	
Mrs Veronica Gilmour	Staff Nurse	Expert	15/06/2016	
Professor Frank Jones	Retired Professor of Polymers and Composites	Lay	31/01/2014	
Mr Pete Laud	Statistical Consultant	Expert	01/04/2011	
Dr Marie Marron	BHF Research Fellow	Lay	01/03/2014	
Dr Amaka Offiah	Reader in Paediatric Musculoskeletal Imaging	Expert	16/05/2011	
Mrs Brenda Riley	Retired IT Trainer	Lay Plus	01/05/2016	
Professor Basil Sharrack	Consultant Neurologist	Expert	29/06/2006	
Dr Soon Song	Consultant Diabetologist	Expert	25/08/2006	
Mrs Aikaterini Staikoura-Wilson	Pharmacist	Expert	01/02/2016	
Mrs Yvonne Stephenson	Lead Technician in the Department of Infection and Immunity	Expert	16/05/2011	
Mrs Helen Teasdale	University Executive Assistance	Lay Plus	01/05/2011	
Dr Nana Theodorou	Specialist Orthoptist	Expert	01/10/2011	
Dr Steven Thomas	Consultant Vascular and Cardiac Radiologist	Expert	18/05/2006	
Ms Liz Williams	Senior Lecturer in Human Nutrition	Lay	13/09/2016	

Yorkshire & The Humber - Sheffield Research Ethics Committee: Deputy Members

Name	Profession	Status	Meeting date attended
Mr Richard Lindley	Consultant Paediatric Surgeon	Expert	06/03/2017
Mr Richard Lindley	Consultant Paediatric Surgeon	Expert	06/06/2016
Mr Richard Lindley	Consultant Paediatric Surgeon	Expert	16/01/2017
Mr Richard Lindley	Consultant Paediatric Surgeon	Expert	05/09/2016

Yorkshire & The Humber - Sheffield Research Ethics Committee: Co-opted Members

Name	Profession	Status	Meeting date attended
Mrs Susan P Phillips	Clinical Lead Pharmacist	Expert	07/11/2016
Mrs Agnieszka Skotnica	Pharmacist	Expert	07/11/2016
Mr Paddy Stevenson	Research Operations Manager	Expert	16/08/2016
Dr Kate Wilson	Retired - Interim Director of Operations	Lay	22/06/2016

Yorkshire & The Humber - Sheffield Research Ethics Committee: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Mrs Jacqui Gath	ECMC Sheffield Committee Local Clinical Trials Executive NIHR Doctoral Funding Review Panel as lay member Sheffield Ethics Committee	01/12/2016
Mrs Veronica Gilmour	None	16/11/2016
Professor Frank Jones	1. Member of YHCRN (Formerly NTCRN) Consumer Research Panel (CRP)2. Patient Representative on Institute for Genetics, Department of Pharmacy, Diagnostics and Genetics, University of Sheffield3. Recently appointed PPV to Medical Genetics CRG. Co-supervisor of Research PhD in Department of Materials Science and Engineering, University of Sheffield. Study of Healing in Composite Materials- a non health related project. Visiting Professor, University of Bristol, Depart of Aerospace Engineering. Visiting Professor, University of Manchester Editorial Boards of the Journals: Composites part A; Composites Science and Technology.	06/12/2016
Mr Richard Lindley	Sit on scientific advisory committee for Sheffield Children's Charity	15/11/2016
Dr Marie Marron	None	06/12/2016
Dr Amaka Offiah	Director – OCIN Ltd: Provides a teleradiology reporting service for Medical Ltd Owner – OCIN Ltd: Provides a teleradiology reporting service for Medical Ltd Chair – Child Abuse Taskforce of European Society of Paediatric Radiology,· Chair – Publications Committee of European Society of Paediatric Radiology,· Convenor/Chair – Skeletal Dysplasia Group for Teaching and Research Academic Research Lead – Pharmacy, Diagnostics & Genetics Division, Sheffield Children's Hospital NHS Foundation Trust,· Member – British Paediatric and Adolescent Bone Group,· Member – HR QCT International Working Group,· Member – International Consortium for Vertebral Anomalies and Scoliosis,· Member – NICE Standing Committee for Guideline Updates,· Member – Sheffield Children's Hospital Scientific Advisory Committee,· Member – Sheffield Children's Hospital Research & Innovation Committee,· Member – University of Sheffield Ethnic Equality & Diversity Board,· Partner Governor – Sheffield Children's NHS Foundation Trust,· Research Lead – Imaging Department, Sheffield Children's NHS Foundation Trust	16/11/2016
Mrs Brenda Riley	Member of LADDER (Lay Advice on Diabetes and Endocrine Research) PPR Group. Member of Online PPI Group. Member of focus group for DAFNE Plus (Diabetes Research).Subject	08/05/2016

	participant in a Diabetes research trial (Dapagliflozin).Member of Sheffield 50Plus, Health Watch, Citizen Reference Group.	
Professor Basil Sharrack	None	01/12/2016
Dr Soon Song	None	06/12/2016
Mrs Yvonne Stephenson	Work in the Department of Infection and Immunity and Cardiovascular Disease, Medical School, Sheffield University which is involved in the conduct of research. Member of Sheffield University Ethics committee	06/09/2016
Mrs Helen Teasdale	None	01/07/2016
Dr Steven Thomas	None	18/11/2016
Ms Liz Williams	Senior Lecturer in Human Nutrition at University of Sheffield and conduct research. Peer reviews grant applications and research manuscripts.	03/10/2016
Dr Paul Bacon	I am a member of several professional bodies related to Audiology i.e. - the British Society of Audiology (BSA), its BSA EP special interest group on electrophysiology, and the British Academy of Audiology (BAA)Both organisations provide small funds towards research, but I am not involved in any of the research awarding / funding panels.As a lead clinical scientist in the Audiological Science section of Medical Physics, Royal Hallamshire Hospital, Sheffield Teaching Hospitals NHS Trust, my role is to provide scientific and clinical support to our patient services, including service development and where appropriate research.Vestibular function testing / vestibular rehabilitationAuditory evoked potentials	01/03/2017
Mr Pete Laud	I work as a consultant statistician for AstraZeneca and UnileverNone outside managed investment funds (stocks & shares ISA)Employed part-time by AstraZeneca as a contract statistician.Part of a team of consultants providing statistical advice to Sheffield Teaching Hospitals Clinical Research Office.Both contracts are paid to my employer (University of Sheffield) rather than directly to me.	01/03/2017
Mrs Aikaterini Staikoura-Wilson	None declared	01/03/2017
Dr Nana Theodorou	Research Coordinator with lead roles in Human Tissue, Research Ethics, Medical Devices and Innovation	01/03/2017

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

Month	Date	Number of Members Present at Meeting
April	04/04/2016	9
May	09/05/2016	11
June	06/06/2016	12
July	04/07/2016	10
September	05/09/2016	10
October	03/10/2016	15
November	07/11/2016	13
December	05/12/2016	14
January	16/01/2017	15
March	06/03/2017	13

10 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	12/04/2016	3
May	27/05/2016	3
June	22/06/2016	3
July	21/07/2016	3
August	16/08/2016	4
September	19/09/2016	3
October	19/10/2016	3
November	21/11/2016	3
December	19/12/2016	3
February	09/02/2017	3
March	28/03/2017	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	07/04/2016	2
April	21/04/2016	2
April	28/04/2016	2
May	03/05/2016	2
May	05/05/2016	2
May	19/05/2016	2
May	24/05/2016	2
May	25/05/2016	2
May	31/05/2016	2
June	02/06/2016	2

June	16/06/2016	2
June	20/06/2016	2
June	30/06/2016	2
July	04/07/2016	2
July	14/07/2016	2
July	15/07/2016	2
July	25/07/2016	2
July	28/07/2016	2
August	11/08/2016	2
August	18/08/2016	2
August	25/08/2016	2
September	08/09/2016	2
September	22/09/2016	2
September	28/09/2016	2
September	29/09/2016	2
October	06/10/2016	2
October	20/10/2016	2
November	03/11/2016	2
November	17/11/2016	2
November	21/11/2016	3
December	01/12/2016	2
December	15/12/2016	2
January	12/01/2017	2
January	26/01/2017	2
February	09/02/2017	2
February	23/02/2017	2
March	09/03/2017	2
March	14/03/2017	2
March	21/03/2017	2
March	23/03/2017	2

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

Details of inquorate meeting held:01 April 2016 - 31 March 2017

0

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

Name	Number of Meetings Attended
Dr Paul Bacon	9
Mrs Jacqui Gath	8
Mrs Veronica Gilmour	6
Professor Frank Jones	8
Mr Pete Laud	9
Mr Richard Lindley	4
Dr Marie Marron	5
Dr Amaka Offiah	7
Mrs Brenda Riley	9
Professor Basil Sharrack	10
Dr Soon Song	8
Mrs Aikaterini Staikoura-Wilson	7
Mrs Yvonne Stephenson	8
Mrs Helen Teasdale	8
Dr Nana Theodorou	9
Dr Steven Thomas	3
Ms Liz Williams	4

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

Name	Number of Meetings Attended
Mrs Jacqui Gath	5
Professor Frank Jones	2
Mr Pete Laud	3
Dr Amaka Offiah	3
Professor Basil Sharrack	11
Dr Soon Song	2
Mrs Yvonne Stephenson	1
Mrs Helen Teasdale	3
Dr Nana Theodorou	2

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

Name	Number of Meetings Attended
Dr Paul Bacon	1
Mrs Jacqui Gath	6

Professor Frank Jones	5
Mr Pete Laud	2
Dr Marie Marron	3
Dr Amaka Offiah	4
Professor Basil Sharrack	40
Dr Soon Song	4
Mrs Yvonne Stephenson	5
Mrs Helen Teasdale	5
Dr Nana Theodorou	4
Dr Steven Thomas	2

Training 01 April 2016 - 31 March 2017

Name of Member	Date	Event(s) attended
Dr Paul Bacon	09/01/2017	Introduction to Good Clinical Practice eLearning (Secondary Care) Signed by NMcC on 25/1/17
Mrs Jacqui Gath	29/06/2016	Handling Health-Related Findings in Research
Mrs Jacqui Gath	06/07/2016	Regional Members Training Day
Mrs Veronica Gilmour	25/06/2016	Equality and Diversity
Mrs Veronica Gilmour	06/07/2016	Regional Members Training Day
Mrs Veronica Gilmour	15/09/2016	Member's Induction
Mrs Veronica Gilmour	06/02/2017	Local training day - Sheffield
Professor Frank Jones	06/07/2016	Regional Members Training Day
Professor Frank Jones	08/12/2016	Equality and Diversity
Mr Pete Laud	06/02/2017	Local Training Day - Sheffield
Dr Marie Marron	07/12/2016	Equality and Diversity Training
Dr Marie Marron	06/02/2017	Local Training Day - Sheffield
Dr Amaka Offiah	15/12/2016	Equality and Diversity
Dr Amaka Offiah	06/02/2017	Local training day - Sheffield
Mrs Brenda Riley	15/09/2016	Member's Induction
Mrs Brenda Riley	14/10/2016	Genetic and Genomic Research (previously HTA Advanced).
Mrs Brenda Riley	26/10/2016	'Qualitative research and Ethical review
Mrs Brenda Riley	21/11/2016	Equality and Diversity
Mrs Brenda Riley	06/02/2017	Local Training day - Sheffield
Mrs Brenda Riley	22/03/2017	National Members Training Day
Professor Basil Sharrack	11/11/2016	Equality and Diversity
Professor Basil Sharrack	06/02/2017	Local Training Day - Sheffield
Dr Soon Song	03/01/2017	SDL - Medical devices training, ionising radiation training.
Mrs Aikaterini Staikoura-Wilson	07/06/2016	Equality & Diversity
Mrs Aikaterini Staikoura-Wilson	30/11/2016	Induction Training
Mrs Aikaterini Staikoura-Wilson	06/02/2017	Local Training Day - Sheffield
Mrs Yvonne Stephenson	14/10/2016	Genetic and Genomic Research (previously HTA Advanced).
Mrs Yvonne Stephenson	06/02/2017	Local training day - Sheffield
Mrs Yvonne Stephenson	22/03/2017	National Members Training Day
Mrs Helen Teasdale	06/02/2017	Local Training Day - Sheffield
Dr Nana Theodorou	29/06/2016	Handling Health Related Findings
Dr Nana Theodorou	29/06/2016	Handling Health-Related Findings in Research
Dr Nana Theodorou	27/09/2016	regulatory inspection ready
Dr Nana Theodorou	21/10/2016	Introduction to Good Clinical Practice eLearning (Secondary Care)

Dr Nana Theodorou	06/02/2017	Local Training Day - Sheffield
Dr Nana Theodorou	22/03/2017	Training - National Members Training Day
Ms Liz Williams	05/12/2016	Equality and Diversity Training
Ms Liz Williams	10/01/2017	Induction training
Ms Liz Williams	06/02/2017	Local Training Day - Sheffield

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	15	27.78
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	1	1.85
Research Database (including renewals)	2	3.70
Others	36	66.67
Total Applications Reviewed	54	100

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	13
Number of paediatric applications reviewed	9
Number of device applications reviewed	6
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	2

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	13	24.07
Unfavourable Opinion	1	1.85
Provisional Opinion	40	74.07
Provisional Opinion Pending Consultation with Referee	0	0.00
Total	54	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	62.96
Further Information Favourable Opinion with Additional Conditions	4	7.41
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	13	24.07
Unfavourable Opinion	1	1.85
Provisional Opinion	0	0.00
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	1	1.85
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	1	1.85
Total	54	100

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

Total Applications Reviewed	26
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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	2
Number of student applications reviewed	10
Number of paediatric applications reviewed	5
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

Decisions taken at proportionate review sub-committee meetings	Number	%
Favourable Opinion with Standard Conditions	10	38.46
Favourable Opinion with Additional Conditions	6	23.08
No Opinion transfer to full committee for review	2	7.69
Provisional Opinion	8	30.77
Unfavourable Opinion	0	0.00
Total	26	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	5.40
Number of completed applications for full ethical review	53
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	5
Number of completed applications over 40 days as a % of total	9.26%
Number of days taken to final decision – average (mean)	28
Number of completed proportionate review applications for ethical review	24
Number of completed proportionate review applications for ethical review over 14 days	1
Number of completed proportionate review applications over 14 days as a % of total	4.17%
Number of completed proportionate review applications for ethical review over 21 days	0
Number of SSAs (non-Phase 1) reviewed	17
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	120
Number of completed substantial amendments over 35 days	1
Number of completed substantial amendments over 35 days as a % of total substantial amendments	0.83%
Number of completed substantial amendments over 28 days	16
Number of completed substantial amendments over 28 days as a % of total substantial amendments	13.33%
Number of modified amendments reviewed	5
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	88
Number of substantial amendments received for information	0
Number of substantial amendments received for new	22

sites/PIs	
Number of annual progress reports received	73
Number of safety reports received	30
Number of Serious Adverse Events received	2
Number of final reports received	75

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
16/YH/0101	Visual Perception Sensitivity in the Autism Spectrum	32
16/YH/0123	Heart and Brain function in Type 2 Diabetes Mellitus	33
16/YH/0127	De-threaded Screw Fixation of Slipped Capital Femoral Epiphyses – Comp	37
16/YH/0164	MRI and phenotyping of painful diabetic neuropathy (MAP-PAIN)	28
16/YH/0169	Multi-channel Stimulation for Post Stroke Spasticity (MUSTS)	21
16/YH/0196	Emotion processing in patients with functional symptoms	24
16/YH/0206	BONES: The British Osteonecrosis Study.	32
16/YH/0217	MAPS: 6 -YEAR FOLLOW UP	29
16/YH/0242	The Impact of Bariatric Surgery on Young Women's Quality of Life, Health Behaviours and Reproductive Health	23
16/YH/0243	High frequency jet ventilation in AF ablation	17
16/YH/0261	Raman in muscle	37
16/YH/0273	CGMP-based protein substitutes in semi-adherent PKU Patients Version 1	25
16/YH/0282	VP-VEC-162-2102 Jetlag proof of concept	28
16/YH/0349	Small volume resuscitation with albumin in intensive care (SWIPE)	27
16/YH/0352	ASPIRE Registry	43
16/YH/0401	Filgotinib with Methotrexate in RA patients	23
16/YH/0402	Filgotinib with csDMARDs in RA patients	23
16/YH/0403	Phase 3 study in participants with RA	26
16/YH/0424	RADIANCE (HELI-169)	32
16/YH/0431	GRAICE - guided rehabilitation after intensive care.	23
16/YH/0434	The measurement of vital signs by Lifelight software	35
16/YH/0449	Extracellular vesicles: systemic biomarkers of inflammation in IBD	45
16/YH/0450	Blinatumomab in High-risk Diffuse Large B-Cell Lymphoma (DLBCL)	22
16/YH/0454	VitalScan MCG rule-out multi-centre pivotal study - version 1.0	28
16/YH/0502	Safety and Efficacy of BMN 111 in Children with Achondroplasia	27
16/YH/0503	RA101495 Open-Label Study of Paroxysmal Nocturnal Haemoglobinuria	60
16/YH/0504	Open-Label, Uncontrolled Extension Study of RA101495	59
16/YH/0506	PT009 vs PT005 treatment of Moderate to Very Severe COPD (SOPHOS)	38
16/YH/0518	Reversing PCOS	50
17/YH/0007	Psychological Risk Assessment in IBD	23
17/YH/0016	Development of MRI techniques in a clinical setting	32

17/YH/0018	BAMES study	22
17/YH/0034	Closeness and separation experiences on the neonatal unit version 1	29
17/YH/0074	SPIRIT trial - Version 1.0	38

Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/YH/0079	A study of the Vibration-Induced illusion of movement in dystonia.	26
16/YH/0186	PLUS (178-MA-1008)	26
16/YH/0247	Gastrointestinal Illness in Oxford: prospective cohort for bio banking	26
16/YH/0354	Independent Living Support Functions for the Elderly (IN LIFE)	35

Further Information Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
None		

Favourable Opinion with Standard Conditions

REC Reference	Title	Number of Days on Clock
None		

Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
16/YH/0119	WILLOW-ACS - Version 1	25
16/YH/0124	Radiosensitising agents in NSCLC	25
16/YH/0226	Fit Achieved through Contour Engineering to Improve Tolerance -FACE-IT	17
16/YH/0228	The role of spirituality when making sense of hearing voices	17
16/YH/0240	Outcome measures for clinical trials in childhood BKC	15
16/YH/0260	Health and iodine status of babies (Hiba)	22
16/YH/0315	Elastography in the diagnosis of chronic pancreatitis	23
16/YH/0379	Antibody responses to infliximab in patients with IBD	23
16/YH/0393	Selenium and musculoskeletal health	20
16/YH/0459	OPTION-DM	21
17/YH/0015	Precision medicine in Hepatocellular Cancer	23

17/YH/0035	Building pathways to local communities to improve wellbeing	22
17/YH/0041	BIVISTA	24

Unfavourable Opinion

REC Reference	Title	Number of Days on Clock
16/YH/0184	How reliable are respiratory rate measurements in children	22

Provisional Opinion

REC Reference	Title	Number of Days on Clock
None		

Provisional Opinion Pending Consultation with Referee

REC Reference	Title	Number of Days on Clock
None		

Further information response not complete

REC Reference	Title	Number of Days on Clock
16/YH/0181	Anonymised PET/CT Training and Research data base.	n/a

Withdrawn after the meeting

REC Reference	Title	Number of Days on Clock
16/YH/0436	TRIUMPH	21

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
16/YH/0264	Hearing the Voice of the Child with communication difficulties	10
16/YH/0300	Prehospital critical care for out-of-hospital cardiac arrest	13
16/YH/0413	Effect of regimen complexity on experiences of long-term medicines use	12
16/YH/0456	Evaluating Brain food groups for memory service clients	14
16/YH/0496	The primary care patient safety guide	11
17/YH/0044	Food-related quality of life in Inflammatory Bowel Disease	14

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/YH/0310	Investigating microorganisms present in vulvovaginal candidiasis v1	13

Further Information Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
None		

Favourable Opinion with Standard Conditions		
REC Reference	Title	Number of Days on Clock
16/YH/0158	TRECA (Phase 1 - Qualitative study) Version 1	12
16/YH/0159	The posturing after retinal detachment (PostRD) trial Version 1.1	12
16/YH/0160	SITless Pilot Study	14
16/YH/0265	High-Resolution retinal imaging of inherited retinal degenerations	12
16/YH/0302	Exploring views and evaluating a web-based intervention	13
16/YH/0367	OPEN Study: Pain management treatment needs interviews	14
16/YH/0422	Outcomes and experiences of clinical care in common hand conditions.	10
16/YH/0460	Bronchiectasis: the views for healthcare provision	12
17/YH/0042	QPL development in liver disease	13
17/YH/0043	Ultrasonic debridement of Hyflex EDM files version1	13
17/YH/0109	Potential stem cell therapy for bone tissue regeneration	15

Favourable Opinion with Additional Conditions		
REC Reference	Title	Number of Days on Clock
16/YH/0219	CP268PE	10
16/YH/0220	Lipoprotein Lipase Deficiency (LPLD) Patient Case Examples	11
16/YH/0266	Role of Acanthamoeba in Urinary Tract Infections	13
16/YH/0368	Sleep quality in parents of, and children with type 1 Diabetes.	11
16/YH/0412	Pilot survey of mothers and babies	10
16/YH/0520	Streamlining cross-sectional imaging pathways (SCIPs)	9

Unfavourable Opinion		
REC Reference	Title	Number of Days on Clock
None		

Provisional Opinion		
REC Reference	Title	Number of Days on Clock
None		

Further information response not complete		
REC Reference	Title	Number of Days on Clock
None		

Withdrawn after the meeting		
REC Reference	Title	Number of Days on Clock
None		

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
05/Q2305/96/AM04	Studies of the mechanisms of myeloma bone disease.	Substantial Amendment 2 - 4/5/	04/05/2016	15
05/Q2305/96/AM05	Studies of the mechanisms of myeloma bone disease.	Substantial Amendment 3 - 15/8	15/08/2016	15
07/Q2305/7/AM08	Macrophages in the innate response to infection	Substantial Amendment 5 - (SA0	09/08/2016	21
07/Q2305/7/AM09	Macrophages in the innate response to infection	Substantial Amendment 3 - 15/9	15/09/2016	8
08/H1308/193+5/AM02	STH-ObS (renewal)	Substantial Amendment 14 - 14/	12/04/2016	13
09/H1308/27/AM02	Biomarkers for bone metastases in breast cancer patients – Version 1	Substantial Amendment 1 - 30/1	30/01/2017	15
09/H1308/27/AM03	Biomarkers for bone metastases in breast cancer patients – Version 1	Substantial Amendment 2 - 30/1	30/01/2017	15
11/YH/0020/AM04	Oxford Gastrointestinal Illness Biobank	Substantial Amendment 3 - 1/3/	01/03/2016	28
11/YH/0188/AM05	Mechanisms and impact of bacterial colonisation in COPD	Substantial amendment 2 - 14/9/	14/09/2016	9
11/YH/0321/AM04	EXPLANT	Substantial Amendment 2 - 17/9	17/09/2015	14
12/YH/0214/AM01	The validity and acceptability of a laser fluorescence device	Substantial Amendment 1 - 30/6	30/06/2016	34
12/YH/0474/AM05	Improving detection and prevention of cognitive decline in	Substantial	01/07/2016	17

	ageing	Amendment 3 - 1/7/		
13/YH/0086/AM05	STUDY LT4020-PIII-12/11 - Application Form updated on the 29/01/2013	Substantial Amendment 1 - 17/1	17/12/2015	10
13/YH/0152/AM10	FIGARO	Substantial Amendment 7 - 16/6	16/06/2016	22
13/YH/0263/AM13	SarCaBon: Saracatinib versus placebo for cancer-induced bone pain	Substantial Amendment 11 - 23/	23/06/2016	16
13/YH/0263/AM15	SarCaBon: Saracatinib versus placebo for cancer-induced bone pain	Substantial Amendment 12 - 19/	19/12/2016	35
13/YH/0273/AM03	Using MRI to investigate energy metabolism in MND	Substantial Amendment 2 - 15/7	15/07/2016	33
13/YH/0273/AM05	Using MRI to investigate energy metabolism in MND	3	05/12/2016	29
13/YH/0307/AM03	Contributing clinical MRI scans to multi-centre collaboration	Substantial Amendment 3 - 17/	17/02/2016	30
13/YH/0320/AM05	28689 Phase III Study of Lebrikizumab in Uncontrolled Asthma Patients	Substantial Amendment 4 - 4/7/	04/07/2016	14
13/YH/0320/AM07	28689 Phase III Study of Lebrikizumab in Uncontrolled Asthma Patients	Substantial Amendment 6 - 10/1	10/10/2016	21
13/YH/0361/AM01	Improved discrimination of central and obstructive apnoeas	Substantial Amendment 1 - 18/5	18/05/2016	24
13/YH/0389/AM09	Pfizer B1481021 - Phase 3 PF-04950615 LDL-C lowering in HeFH	Substantial Amendment 7 - Janu	06/04/2016	18
13/YH/0393/AM26	Pfizer B1481020 - Phase 3 PF-04950615 for Hyperlipidemia	Substantial Amendment 17 - Jan	06/04/2016	21
13/YH/0393/AM27	Pfizer B1481020 - Phase 3 PF-04950615 for Hyperlipidemia	Substantial Amendment 18 - cha	29/04/2016	25
13/YH/0397/AM01	ADAPT	Substantial	07/10/2016	14

		Amendment 1 - 7/10		
14/YH/0002/AM07	IPI-145 vs Ofatumumab in CLL or SLL	Substantial Amendment 6 - 20/1	20/12/2016	27
14/YH/0003/AM06	Extension study of IPI-145 and Ofatumumab in Patients with CLL/SLL	Substantial Amendment 6 - 24/3	24/03/2016	20
14/YH/0003/AM08	Extension study of IPI-145 and Ofatumumab in Patients with CLL/SLL	Substantial Amendment 7 - 20/1	20/12/2016	27
14/YH/0140/AM03	POLAR - TKA Study	Substantial Amendment 3	19/07/2016	17
14/YH/0140/AM04	POLAR - TKA Study	Substantial Amendment 4 - 5/1	05/01/2017	17
14/YH/0141/AM03	reMARQable v3.1	Substantial Amendment 3 - 19/9	19/09/2016	28
14/YH/1034/AM03	Treosulfan-based conditioning therapy in children with blood cancer	Substantial Amendment 1 - 10/3	17/05/2016	20
14/YH/1034/AM04	Treosulfan-based conditioning therapy in children with blood cancer	Substantial Amendment 4 - 13/7	13/07/2016	14
14/YH/1034/AM05	Treosulfan-based conditioning therapy in children with blood cancer	Substantial Amendment 5 - 25/1	25/11/2016	17
14/YH/1037/AM09	A study to look at Tapentadol Liquid in Children & Adolescents in pain	Substantial Amendment 7 - 15/7	15/07/2016	14
14/YH/1037/AM11	A study to look at Tapentadol Liquid in Children & Adolescents in pain	Substantial Amendment 8 - 28/9	28/09/2016	23
14/YH/1037/AM12	A study to look at Tapentadol Liquid in Children & Adolescents in pain	Substantial Amendment 9 - 24/1	24/10/2016	9
14/YH/1131/AM05	Comparison of Fendrix and double-dose Engerix B in HIV non-	Substantial	03/05/2016	14

	responders	Amendment 2 - 3/5/		
14/YH/1131/AM07	Comparison of Fendrix and double-dose Engerix B in HIV non-responders	Substantial Amendment 3 - 19/1	19/01/2017	12
14/YH/1139/AM02	An analysis of linked pre-hospital and hospital data	Substantial Amendment 1 - 21/12	21/12/2016	20
14/YH/1141/AM06	Efficacy and safety of Radium 223 in mBC, compared to hormone therapy	Substantial Amendment 5 - 26/4	26/04/2016	15
14/YH/1141/AM07	Efficacy and safety of Radium 223 in mBC, compared to hormone therapy	Substantial Amendment 6 - 13/5	13/05/2016	20
14/YH/1141/AM08	Efficacy and safety of Radium 223 in mBC, compared to hormone therapy	Substantial Amendment 7 - 5/7/	05/07/2016	13
14/YH/1141/AM09	Efficacy and safety of Radium 223 in mBC, compared to hormone therapy	Substantial Amendment 8 - 11/7	11/07/2016	22
14/YH/1165/AM07	Tapentadol for the treatment of post-surgical pain in children	Substantial Amendment 03 15/4	15/04/2016	31
14/YH/1202/AM08	PREVAIL Version 1.0	Substantial Amendment 5 - 12/1	12/10/2016	9
14/YH/1209/AM04	Iron and Heart Trial	2	07/12/2016	30
14/YH/1269/AM05	i.v. tapentadol for the treatment of post-surgical pain in children	Substantial Amendment 4 - Prot	13/04/2016	25
14/YH/1269/AM06	i.v. tapentadol for the treatment of post-surgical pain in children	Substantial Amendment 5 - 14/9	14/09/2016	34
15/YH/0003/AM07	ZINN: Retosiban versus atosiban for spontaneous pre-term labour	Substantial Amendment 5 - 7/3/	07/03/2016	15
15/YH/0003/AM08	ZINN: Retosiban versus atosiban for spontaneous pre-term labour	Substantial Amendment 6 - Prot	22/08/2016	11
15/YH/0004/AM09	ARIOS: Follow-up of infants born to mothers in retosiban	Substantial	16/01/2017	27

	studies	Amendment 6 - 16/1		
15/YH/0006/AM06	CL06: OPEN-LABEL STUDY OF SEBELIPASE ALFA IN PATIENTS WITH LALD	Substantial Amendment 3 - 4/4/	04/04/2016	19
15/YH/0006/AM07	CL06: OPEN-LABEL STUDY OF SEBELIPASE ALFA IN PATIENTS WITH LALD	Substantial Amendment 4 - 7/7/	07/07/2016	27
15/YH/0006/AM09	CL06: OPEN-LABEL STUDY OF SEBELIPASE ALFA IN PATIENTS WITH LALD	Substantial Amendment 6 - 24/1	24/11/2016	22
15/YH/0022/AM01	Creating a new model of lung scarring	Substantial Amendment 1 - 11/4	11/04/2016	12
15/YH/0034/AM07	The CIMPACT Study	Substantial Amendment 5 - 22/3	22/03/2016	24
15/YH/0034/AM13	The CIMPACT Study	Substantial Amendment 9 - 3/2/	03/02/2017	21
15/YH/0041/AM02	Transitions to Adulthood (T2A) Pathway Programme	Substantial Amendment 1 - 1/12	01/12/2016	21
15/YH/0177/AM02	Research Tissue Bank	Substantial Amendment 1 - 17/3	17/03/2016	25
15/YH/0229/AM05	Vibrant Effectiveness and Reliability Study (VERS)	Substantial Amendment 1 - 21/3	21/03/2016	15
15/YH/0243/AM03	Liberty AD Solo - Continue	Substantial Amendment 2 - 11/4	11/04/2016	14
15/YH/0243/AM04	Liberty AD Solo - Continue	Substantial Amendment 3 - (Pro	31/10/2016	30
15/YH/0257/AM02	TARGET-DLE version 1.0	Substantial Amendment 1 - 1/3/	01/03/2016	17
15/YH/0257/AM03	TARGET-DLE version 1.0	Substantial Amendment 2 - 1/9/	01/09/2016	16
15/YH/0257/AM05	TARGET-DLE version 1.0	Substantial	10/02/2017	17

		Amendment 3 - 10/2		
15/YH/0259/AM04	The PRACTICE Trial	Substantial Amendment 4 - 24/3	24/03/2016	22
15/YH/0287/AM10	OLE- Open Label Extension	SA 5	25/08/2016	18
15/YH/0287/AM11	OLE- Open Label Extension	Substantial Amendment 6 - 15/1	15/11/2016	34
15/YH/0287/AM13	OLE- Open Label Extension	Substantial Amendment 7 – 3/2/	03/02/2017	21
15/YH/0292/AM02	Proxy decision making for older women with breast cancer	Substantial Amendment 1 - 22/1	22/11/2016	21
15/YH/0299/AM02	Testicular Health in Adolescents A Qualitative Study (THAQS)	Substantial Amendment 1 - 25/1	25/11/2015	33
15/YH/0397/AM02	Non-invasive vagal nerve stimulation for arm recovery after stroke	Substantial Amendment 1 - 5/10	05/10/2016	15
15/YH/0431/AM03	Mealtimes in families where a child has difficulties eating (V1)	Substantial Amendment 2 - 20/6	20/06/2016	22
15/YH/0435/AM03	VTS270 in Subjects with Niemann-Pick Type C1 Disease.	Substantial Amendment 2 - 17/5	17/05/2016	16
15/YH/0443/AM04	R668-AD-1434 THE STUDY OF DUPILUMAB IN PAED PATIENTS WITH AD	Substantial Amendment 2 - 15/1	15/11/2016	22
15/YH/0467/AM04	A Study of GSK3196165 in Hand Osteoarthritis	Substantial Amendment 3 – 10/5	12/05/2016	12
15/YH/0467/AM05	A Study of GSK3196165 in Hand Osteoarthritis	Substantial Amendment 4 - 15/6	15/06/2016	16
15/YH/0467/AM07	A Study of GSK3196165 in Hand Osteoarthritis	Substantial	30/01/2017	13

		Amendment 5 - Prot		
15/YH/0478/AM05	The Regenerate Study	Substantial Amendment 4 - 26/5	26/05/2016	29
15/YH/0478/AM09	The Regenerate Study	Substantial Amendment 7 - 15/1	15/12/2016	36
15/YH/0483/AM02	Single Arm Study to Assess the efficacy of UVADEX	Substantial Amendment 1 - 15/3	15/03/2016	16
15/YH/0528/AM02	999AS003 - Methodology Study in ALS	Substantial Amendment 1 - 19/7	19/07/2016	17
15/YH/0528/AM03	999AS003 - Methodology Study in ALS	Substantial Amendment 2 - 29/9	29/09/2016	14
15/YH/0528/AM04	999AS003 - Methodology Study in ALS	Substantial Amendment 3 - 25/1	25/11/2016	24
15/YH/0533/AM01	NEWBORN-1 Study of Retosiban vs Placebo in Women in Pre-Term Labour	Substantial Amendment 1 - 26/2	26/02/2016	17
15/YH/0533/AM02	NEWBORN-1 Study of Retosiban vs Placebo in Women in Pre-Term Labour	Substantial Amendment 2 - prot	20/06/2016	22
15/YH/0537/AM01	Health in Children and Young People with CAH	Substantial Amendment 1 - 29/3	29/03/2016	22
15/YH/0537/AM04	Health in Children and Young People with CAH	Substantial Amendment 2 - 5/7/	05/07/2016	28
15/YH/0538/AM08	R668-AD-1424, Phase 3 , Dupilumab, Adults, Severe Atopic Dermatitis	Substantial Amendment 5 - 15/1	15/11/2016	22
16/YH/0021/AM01	A drug interaction study of INC280 with digoxin and rosuvastatin	Substantial Amendment 1 - 11/7	11/07/2016	28

16/YH/0022/AM01	A drug interaction study of INC 280 caffeine and Midazolam	Substantial Amendment 1 - 8/7/	08/07/2016	28
16/YH/0064/AM01	Children's involvement in decision making in CAMHS	Substantial Amendment 1 - 1/7/	01/07/2016	22
16/YH/0091/AM02	Effect of bioactive enriched food on markers of metabolic syndrome	Substantial Amendment 1 - 14/2	14/02/2017	10
16/YH/0101/AM01	Visual Perception Sensitivity in the Autism Spectrum	Substantial Amendment 1 - 5/1/	05/01/2016	28
16/YH/0123/AM01	Heart and Brain function in Type 2 Diabetes Mellitus	Substantial Amendment 1 - 7/11	07/11/2016	22
16/YH/0124/AM01	Radiosensitising agents in NSCLC	Substantial Amendment 1 - 26/7	26/07/2016	27
16/YH/0129/AM01	iPLAN	Substantial Amendment 1 - 2/8/	02/08/2016	16
16/YH/0158/AM01	TRECA (Phase 1 - Qualitative study) Version 1	Substantial Amendment 1 - 15/6	15/06/2016	10
16/YH/0159/AM02	The posturing after retinal detachment (PostRD) trial Version 1.1	Substantial Amendment 2 - 30/1	30/11/2016	21
16/YH/0160/AM01	SITless Pilot Study	Substantial Amendment 1 - 24/6	24/06/2016	28
16/YH/0186/AM02	PLUS (178-MA-1008)	Substantial Amendment 1 - 02/1	02/12/2016	16
16/YH/0196/AM03	Emotion processing in patients with functional symptoms	Substantial Amendment 1 - 19/9	19/09/2016	18
16/YH/0260/AM02	Health and iodine status of babies (Hiba)	Substantial Amendment 1 - 14/1	14/10/2016	21
16/YH/0282/AM01	VP-VEC-162-2102 Jetlag proof of concept	Substantial Amendment 1 -	16/09/2016	31

		16/9		
16/YH/0282/AM03	VP-VEC-162-2102 Jetlag proof of concept	Substantial Amendment 2 - 23/9	23/09/2016	19
16/YH/0310/AM01	Investigating microorganisms present in vulvovaginal candidiasis v1	Substantial Amendment 1 - 3/2/	03/02/2017	16
16/YH/0367/AM02	OPEN Study: Pain management treatment needs interviews	Substantial Amendment 1 - 1/11	01/11/2016	31
16/YH/0402/AM01	Filgotinib with csDMARDs in RA patients	Substantial Amendment 1 - 24/1	24/01/2017	27
16/YH/0403/AM01	Phase 3 study in participants with RA	Substantial Amendment 1 - 25/1	25/11/2016	26
16/YH/0454/AM01	VitalScan MCG rule-out multi-centre pivotal study - version 1.0	Substantial Amendment 1 - 6/3/	06/03/2017	18
16/YH/0459/AM01	OPTION-DM	Substantial Amendment 1 - 2/3/	02/03/2017	21
16/YH/0503/AM01	RA101495 Open-Label Study of Paroxysmal Nocturnal Haemoglobinuria	Substantial Amendment 1 - 15/2	15/02/2017	18
16/YH/0504/AM01	Open-Label, Uncontrolled Extension Study of RA101495	Substantial Amendment 1 - 15/2	15/02/2017	18

Unfavourable opinion				
Amendment REC Reference	Title	Version	Date	Number of Days on Clock
15/YH/0003/AM09	ZINN: Retosiban versus atosiban for spontaneous pre-term labour	Substantial Amendment 7 - Prot	21/12/2016	15
15/YH/0259/AM06	The PRACTICE Trial	5	17/11/2016	22
15/YH/0435/AM04	VT270 in Subjects with Niemann-Pick Type C1 Disease.	Substantial Amendment 3 - 21/1	21/11/2016	28

15/YH/0533/AM03	NEWBORN-1 Study of Retosiban vs Placebo in Women in Pre-Term Labour	Substantial Amendment 3 - Prot	05/01/2017	13
16/YH/0401/AM02	Filgotinib with Methotrexate in RA patients	Substantial Amendment 2 - 24/1	24/01/2017	31

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
14/YH/1237/AM06/1	Study to Assess the Safety of AZD9291 Vs SoC in Patients with NSCLC	Substantial Amendment 7 - Modi	27/04/2016	14
15/YH/0003/AM09/1	ZINN: Retosiban versus atosiban for spontaneous pre-term labour	Modified Amendment 1 - Substan	21/12/2016	10
15/YH/0435/AM04/1	VTS270 in Subjects with Niemann-Pick Type C1 Disease.	Modified Amendment 1 - Sub Ame	10/03/2017	13
15/YH/0533/AM03/1	NEWBORN-1 Study of Retosiban vs Placebo in Women in Pre-Term Labour	Modified Amendment 1 - Sub Ame	05/01/2017	10
16/YH/0401/AM02/1	Filgotinib with Methotrexate in RA patients	Modified Amendment 1 - Substan	03/03/2017	11

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

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
None		

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
15/YH/0478/AM09	The Regenerate Study	Substantial Amendment 7 - 15/1	15/12/2016	36

Modified Amendments over 14 day timeline

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