

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

**Annual Report**

**01 April 2017 - 31 March 2018**



## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	Yorkshire & The Humber - South Yorkshire Research Ethics Committee
<b>Type of REC:</b>	Authorised
<b>Type of Flag:</b>	Paediatrics
<b>Chair:</b>	Dr Ian Woollands
<b>Vice-Chair:</b>	Dr Max Huxham
<b>Alternate Vice-Chair:</b>	Dr David Broomhead
<b>REC Manager:</b>	Miss Kerry Dunbar (from 16 October 2017 to 25 March 2017) Mrs Helen Wilson (from 1 April 2017 to 15 October 2017, 26 March to date)
<b>REC Assistant:</b>	Kerry Dunbar (to 15 October 2017)
<b>Committee Address:</b>	NHSBT Newcastle Blood Donor Centre Holland Drive Newcastle upon Tyne NE2 4NQ
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## Chair's overview of the past year:

On behalf of the South Yorkshire Research Ethics Committee, I have once more had the pleasure and privilege of writing the "Chairs Overview of the Past Year".

As Chair of the Committee, I have been ably assisted and supported by Mrs Helen Wilson and Miss Kerry Dunbar and wish to acknowledge their hard work which has ensured the smooth running of the Committee to provide an efficient service for researchers. On behalf of the Committee, I wish to record our thanks for their contributions and support in the work of the Committee.

Finally, I wish to again record the commitment and support from all the new and continuing REC members who have given freely of their time and expertise to ensure the Committee meets its duties to safeguard the rights, safety, dignity and well-being of people participating in research in the National Health Service.

## Yorkshire & The Humber - South Yorkshire Research Ethics Committee Membership

Name	Profession	Expert or Lay	Dates	
			Appointed	Left
Dr Ahmed H Abdelhafiz	Consultant Physician, Elderly Medicine	Expert	07/03/2007	06/03/2018
Dr Parveen Ali	Lecturer	Expert	01/06/2015	
Dr Peter Allmark	Principal Nursing Lecturer	Expert	01/10/2013	
Ms Helen Barlow	Knowledge Service Manager	Lay Plus	30/01/2007	
Professor Nigel Beail	Consultant Clinical Psychologist & Professor of Psychology	Expert	30/01/2007	
Dr Geraldine Boyle	Senior Lecturer	Lay	06/10/2017	
Dr David Broomhead	Therapy Consultant	Expert	08/05/2014	
Mr Ian Cawthorne	Pharmacist	Expert	30/01/2007	25/01/2018
Dr Ruth Clark	Retired CT Senior Project Manager	Lay	07/11/2017	
Mr John de Bartolome	Retired - Lay+ Member	Lay Plus	06/10/2017	
Mr Martin Edmunds	Editor	Lay Plus	10/04/2015	
Mrs Sindy Nancy Figueroa Merino	Royal Voluntary Service	Lay Plus	09/09/2016	
Mr John Filby	Trainee Clinical Scientist	Lay	05/10/2017	
Dr Max Huxham	Retired Scientist	Lay	15/05/2014	
Mrs Carole Taylor	Deputy Chief Pharmacist	Expert	01/03/2015	
Dr Ian Woollands	Retired Clinical Director, Occupational Health	Expert	17/02/2014	

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

Name	Profession	Status	Meeting date attended
Mr John Warden	Lay Member		July 2017

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

<b>Name</b>	<b>Declaration of Interest</b>	<b>Date</b>
Dr Parveen Ali	Senior Lecturer, School of Nursing and Midwifery, University of Sheffield and Peer reviewer of various journals; NIHR and ESRC	02/03/2018
Dr Peter Allmark	None.	31/03/2018
Ms Helen Barlow	Employed as library and knowledge service mgr at the Rotherham NHS FT	31/03/2018
Professor Nigel Beail	Trustee of the British Institute for Learning Disabilities; Occasionally peer review for grant funding	12/02/2018
Dr Geraldine Boyle	Member of ESRC peer review college, Associate Editor Health and Social Care in the community journal, department research lead, nursing dept and Open University.	13/11/2017
Dr David Broomhead	I work for Northern Lincolnshire and Goole NHS Foundation Trust. I am part of a group of senior staff who have been involved in research who offer advice to staff that are planning or undertaking research in the organisation as an adjunct to the Trusts R+D function. Should any research proposal that I have advised upon be presented to the REC I will declare this and excuse myself from that portion of the committee	05/03/2018
Dr Ruth Clark	Shares in BP, Royal Dutch Shell, Unilever, Morgan Advanced Materials PLC; voluntary worked - Yorkshire Cancer Research; Trustee Brian Tumour Research and Support. Member of "Life in Cancer" Patient Interest Group, Yorkshire & Humber	28/02/2018
Mr John de Bartolome	None.	05/03/2018
Mr Martin Edmunds	None.	31/03/2018
Mrs Sindy Nancy Figueroa Merino	None.	31/03/2018
Mr John Filby	None.	28/02/2018
Dr Max Huxham	Member of SMA Support UK; Specialist Referee: Spinal Muscular Atrophy	31/03/2018
Mrs Carole Taylor	None.	22/03/2018
Dr Ian Woollands	None.	30/03/2018

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

Month	Date	Number of Members Present at Meeting
May	25/05/2017	11
June	29/06/2017	9
July	27/07/2017	8
August	31/08/2017	7
September	28/09/2017	7
October	26/10/2017	14
November	30/11/2017	11
January	25/01/2018	12
February	22/02/2018	9
March	22/03/2018	8

10 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
April	13/04/2017	3
May	11/05/2017	3
June	09/06/2017	3
July	14/07/2017	3
August	31/08/2017	7
September	15/09/2017	3
October	13/10/2017	3
November	13/11/2017	3
December	14/12/2017	3
January	16/01/2018	3
February	09/02/2018	3
March	09/03/2018	3

12 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	06/04/2017	2
April	20/04/2017	2
May	17/05/2017	2
May	31/05/2017	2
June	15/06/2017	2
June	21/06/2017	2
July	11/07/2017	2
July	25/07/2017	2
August	01/08/2017	2

August	08/08/2017	2
August	21/08/2017	2
September	05/09/2017	2
September	22/09/2017	2
October	03/10/2017	2
October	18/10/2017	2
October	31/10/2017	2
November	17/11/2017	2
November	28/11/2017	2
January	16/01/2018	2
January	23/01/2018	2
February	06/02/2018	2
February	20/02/2018	2
March	08/03/2018	2
March	20/03/2018	2

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

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

None.

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Ahmed H Abdelhafiz	7
Dr Parveen Ali	6
Dr Peter Allmark	6
Ms Helen Barlow	7
Professor Nigel Beail	6
Dr Geraldine Boyle	4
Dr David Broomhead	8
Mr Ian Cawthorne (resigned)	5
Dr Ruth Clark	4
Mr John de Bartolome	5
Mr Martin Edmunds	7
Mrs Cindy Nancy Figueroa Merino	5
Mr John Filby	4
Dr Max Huxham	6
Mrs Carole Taylor	7
Dr Ian Woollands	8

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Ahmed H Abdelhafiz	3
Dr Parveen Ali	3
Ms Helen Barlow	4
Professor Nigel Beail	2
Dr David Broomhead	5
Mr Ian Cawthorne	2
Mr Martin Edmunds	5
Mrs Cindy Nancy Figueroa Merino	4
Dr Max Huxham	3
Mrs Carole Taylor	3
Dr Ian Woollands	6

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr Ahmed H Abdelhafiz	2
Dr Parveen Ali	3
Dr Peter Allmark	1



Ms Helen Barlow	2
Professor Nigel Beail	3
Dr David Broomhead	8
Mr Ian Cawthorne	1
Mr Martin Edmunds	4
Mrs Cindy Nancy Figueroa Merino	5
Dr Max Huxham	10
Mrs Carole Taylor	2
Dr Ian Woollands	7

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

<b>Name of Member</b>	<b>Date</b>	<b>Event(s) attended</b>
Dr Ahmed H Abdelhafiz	25/05/2017	Patient and Public Involvement Workshop
Dr Parveen Ali	25/05/2017	Patient and Public Involvement Workshop
Dr Parveen Ali	31/03/2018	SDL April 17 - March 18 - Act as Chair of the Ethics Committee for School of Nursing and Midwifery, University of Sheffield
Dr Peter Allmark	31/03/2018	SDL April 2017 - March 2018 - Teaching ethics of consent to Postgraduate nurses
Ms Helen Barlow	25/05/2017	Patient and Public Involvement Workshop
Ms Helen Barlow	31/03/2018	Self Directed Log April 17 - March 18 - 7 hours worth of reading in ethics related research
Professor Nigel Beail	25/05/2017	Patient and Public Involvement Workshop
Professor Nigel Beail	19/10/2017	Qualitative Research Workshop
Dr Geraldine Boyle	15/02/2018	Committee Members Induction Training
Dr David Broomhead	25/05/2017	Patient and Public Involvement
Dr David Broomhead	29/11/2017	Regional Members Training Day
Mr Ian Cawthorne	25/05/2017	Patient and Public Involvement Workshop
Mr Ian Cawthorne	19/10/2017	Quantitative Research Methods
Dr Ruth Clark	15/11/2017	Members Induction (online)
Dr Ruth Clark	17/11/2017	Equality and Diversity
Dr Ruth Clark	15/02/2018	Members Induction
Mr John de Bartolome	20/11/2017	Members Induction online
Mr John de Bartolome	15/02/2018	Committee Members Induction Training
Mr John de Bartolome	06/03/2018	Assessing the Consequences (benefits and harms) of Research
Mr Martin Edmunds	25/05/2017	Patient and Public Involvement Workshop
Mr Martin Edmunds	26/09/2017	Assessing the Consequences (benefits and harms) of Research
Mr Martin Edmunds	29/11/2017	Members Regional Training Day
Mrs Sindy Nancy Figueroa Merino	25/05/2017	Patient and Public Involvement Workshop
Mrs Sindy Nancy Figueroa Merino	18/01/2018	Training - Quantitative Research Methods and Statistics: A Health Research
Mr John Filby	20/10/2017	Members Induction Online
Mr John Filby	15/02/2018	Committee Members Induction Training

Dr Max Huxham	25/05/2017	Patient and Public Involvement Workshop
Dr Max Huxham	25/09/2017	HRA e-learning Medical Devices
Dr Max Huxham	29/11/2017	Regional Members Training Day
Dr Max Huxham	01/02/2018	Medical Device Training
Mrs Carole Taylor	25/05/2017	Patient and Public Involvement Workshop
Dr Ian Woollands	25/05/2017	Patient and Public Involvement Workshop
Dr Ian Woollands	24/11/2017	HRA National Chairs' Day and Policy Event
Dr Ian Woollands	29/11/2017	Regional Training Day
Dr Ian Woollands	01/02/2018	Medical Device Training

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

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

<b>Applications for full ethical review – Study Type</b>	<b>Number</b>	<b>%</b>
Clinical Trial of Investigational Medicinal Product	0	0.00
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank (including renewals)	0	0.00
Research Database (including renewals)	2	4.76
Others	40	95.24
<b>Total Applications Reviewed</b>	<b>42</b>	<b>100</b>

**Table 2: Breakdown of full applications and other activity during reporting period**

Number of applications made invalid by the REC Manager	2
Number of applications withdrawn prior to the meeting	1
Number of student applications reviewed	21
Number of paediatric applications reviewed	9
Number of device applications reviewed	4
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	3

**Table 3: Decisions given at meetings held within the reporting period**

<b>Decisions taken at meetings following review of applications</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	5	11.90
Favourable Opinion with Additional Conditions	0	0.00
Unfavourable Opinion	6	14.29
Provisional Opinion	30	71.43
Provisional Opinion Pending Consultation with Referee	1	2.38
<b>Total</b>	<b>42</b>	<b>100</b>
Number of studies sent back to full committee meeting for final opinion	0	

**Table 4: Summary of current status of applications reviewed during the reporting period**

<b>Status of applications at date of generation of report</b>	<b>Number</b>	<b>%</b>
Further Information Favourable Opinion with Standard Conditions	25	59.52
Further Information Favourable Opinion with Additional Conditions	3	7.14
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	5	11.90
Favourable Opinion with Additional Conditions	0	0.00
Unfavourable Opinion	6	14.29
Provisional Opinion	2	4.76
Provisional Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	0	0.00
No decision entered on system	0	0.00
Number of studies withdrawn after the meeting	0	0.00
<b>Total</b>	<b>42</b>	<b>100</b>

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

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

Number of applications made invalid by the REC Manager	7
Number of studies withdrawn prior to the meeting	3
Number of student applications reviewed	12
Number of paediatric applications reviewed	6
Number of device applications reviewed	1
Number of qualitative applications reviewed	11

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

<b>Decisions taken at proportionate review sub-committee meetings</b>	<b>Number</b>	<b>%</b>
Favourable Opinion with Standard Conditions	12	42.86
Favourable Opinion with Additional Conditions	1	3.57
No Opinion transfer to full committee for review	5	17.86
Provisional Opinion	10	35.71
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>28</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	4.20
<b>Number of completed applications for full ethical review</b>	42
<b>Number of completed applications for full ethical review over 60 days</b>	0
<b>Number of completed applications over 60 days as a % of total</b>	0.00%
<b>Number of days taken to final decision – average (mean)</b>	27
<b>Number of completed proportionate review applications for ethical review</b>	23
<b>Number of completed proportionate review applications for ethical review over 21 days</b>	0
<b>Number of completed proportionate review applications over 21 days as a % of total</b>	0.00%
<b>Number of SSAs (non-Phase 1) reviewed</b>	1
<b>Number of completed applications for SSA review over 25 days</b>	0
<b>Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs</b>	0.00%
<b>Number of SSAs (Phase 1) reviewed</b>	0
<b>Number of completed applications for SSA review over 14 days</b>	0
<b>Number of completed applications for SSA review over 14 days as % of all Phase 1 SSAs</b>	0.00%
<b>Number of substantial amendments reviewed</b>	55
<b>Number of completed substantial amendments over 35 days</b>	0
<b>Number of completed substantial amendments over 35 days as a % of total substantial amendments</b>	0.00%
<b>Number of modified amendments reviewed</b>	2
<b>Number of completed modified amendments over 14 days</b>	0
<b>Number of completed modified amendments over 14 days as a % of total modified amendments</b>	0.00%
<b>Number of non substantial amendments received</b>	70
<b>Number of substantial amendments received for information</b>	0
<b>Number of substantial amendments received for new sites/PIs</b>	0
<b>Number of annual progress reports received</b>	29
<b>Number of safety reports received</b>	0
<b>Number of Serious Adverse Events received</b>	1
<b>Number of final reports received</b>	20

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

<b>Further Information Favourable Opinion with Standard Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/YH/0166	DEFINITION	28
17/YH/0213	Photodynamic therapy plus root debridement in gum disease treatment V2	25
17/YH/0214	Accuracy of Fuji Amulet DBT views versus standard mammographic views	24
17/YH/0220	COPD Rehabilitation Study	25
17/YH/0247	An Exploration of Resilience in Teenage Mothers	24
17/YH/0252	Visual Fields in Visual Vertigo	28
17/YH/0253	Amplitude integrated EEG in preterm infants - a feasibility study	22
17/YH/0254	Effect of Vitamin D and Vibration on Bone – VibeD Study	24
17/YH/0305	Effect of VLCD-RYGB on weight, LBM and MPS. v2.0	39
17/YH/0307	iPad Digit Triplet Test in adults with cochlear implants	33
17/YH/0316	Body Image perceptions of the renal replacement population	29
17/YH/0319	What effect does intubation have on regional lung ventilation?	24
17/YH/0320	Comparison of Woodcast vs traditional cast in distal radius fracture	25
17/YH/0355	Acupuncture for prevention of itch in Caesarean section V2	23
17/YH/0363	Supine and erect pelvis radiographs: A pilot study	29
17/YH/0371	HYP53	36
17/YH/0406	Highlighting alcohol use in medication appointments (version 1)	25
17/YH/0410	CLD_Pro prospectiveStudy	20
17/YH/0420	Endocrinology Database	27
18/YH/0021	TIESA® C03 Study	26
18/YH/0025	Exploring reading rates using iPad reading Apps in stroke patients	43
18/YH/0035	Enhancing de-escalation in mental health (EDITION study)	34
18/YH/0077	Prognostic imaging biomarkers for diabetic kidney disease	24
18/YH/0082	Measuring fatty acid oxidation in gliomas using 18F-FPIA PET/MRI	33
18/YH/0126	Getting ready for cochlear implant assessment - online tools at home	36

<b>Further Information Favourable Opinion with Additional Conditions</b>		
<b>REC Reference</b>	<b>Title</b>	<b>Number of Days on Clock</b>
17/YH/0165	Assessing ACT Questionnaire Validity in Chronic Pain Services	28
17/YH/0359	Differences in preparation for small bowel capsule endoscopy	28
18/YH/0074	The experience of being a mother with a psychosis diagnosis	41



**Further Information Unfavourable Opinion**

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

REC Reference	Title	Number of Days on Clock
17/YH/0218	Fracture In Preterm Infants Study (FIPIN Study)	19
17/YH/0219	Answer on the Spot	19
17/YH/0302	Gene expression profiles in CML non-responders	28
17/YH/0333	AMBER: Assessing HPV-specific memory B-cell responses post vaccination	21
17/YH/0337	Long-term durability of trans-catheter aortic heart valves	21

**Favourable Opinion with Additional Conditions**

REC Reference	Title	Number of Days on Clock
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**Unfavourable Opinion**

REC Reference	Title	Number of Days on Clock
17/YH/0169	Dual Loop algorithm adjustment study in ventilated preterm infants	26
17/YH/0171	Understanding sexual and reproductive healthcare in general practice.	27
17/YH/0360	Dialyse@Home	34
17/YH/0370	Database of upper gastrointestinal cancer outcomes	23
17/YH/0419	The accuracy of haemoglobin testing after major postpartum haemorrhage	16
18/YH/0023	Caregivers' understanding of paracetamol/ibuprofen dosing intervals	21

**Provisional Opinion**

REC Reference	Title	Number of Days on Clock
18/YH/0102	Three Dimensional Facial Growth Analysis	n/a
18/YH/0124	Investigating the inflammatory response to exercise in CF patients	n/a

**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
17/YH/0158	Patient Experience of Moving and Handling in Hospital (01)	11
17/YH/0159	Sonication of removed hip and knee prosthesis 2017	10
17/YH/0235	Witnessing the distress of fellow patients in an Acute Medicine Unit 1	19
17/YH/0243	Cognitive Testing in Different Aetiologies of Dementia	19
17/YH/0304	Research into Altered Lymphocyte Function (ALF) in Health and Disease	17
17/YH/0324	Pre-diabetes from a patient perspective	16
17/YH/0442	The role of sulphur biology in developmental dysplasia of the hip	19
18/YH/0029	ExAblate Neuro Registry	20

#### Further Information Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
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#### 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
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17/YH/0126	ROLE OF MIGRATION IN FAECAL MICROBIOTA COMPOSITION	15
17/YH/0127	Discrimination of SVT from VT using echo	13
17/YH/0188	The CFI Study	13
17/YH/0189	BCS +/- SLNB as Day Case - Patient's perception, Uptake and Experience	20
17/YH/0190	The evaluation of a peer marketing model for adults with T1DM v.1.4	13
17/YH/0321	Cognition in Multiple Sclerosis: a longitudinal study	16
17/YH/0322	Molecular and functional study of hematopoiesis in myeloid diseases v1	16
17/YH/0438	Investigating drop attacks V1	19
17/YH/0439	People's views on barriers and solutions to bowel screening uptake V1	9
18/YH/0028	Attitudes toward research in patients with diabetes	14
18/YH/0060	Self-compassion in ACT informed therapy for chronic pain. Version 1.0	14
18/YH/0062	Can Real Time Monitoring & Support Increase Medication Adherence v1.4	14

#### Favourable Opinion with Additional Conditions

REC Reference	Title	Number of Days on Clock
17/YH/0399	Routes to Diagnosis - Head and Neck Cancer	15

#### Unfavourable Opinion

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

REC Reference	Title	Number of Days on Clock
17/YH/0303	Growing Through Turbulent Times: GRITT	n/a
17/YH/0362	Ealry Years Foundation Stage Profile (EYFSP) for autism screening	n/a

#### Further information response not complete

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

REC Reference	Title	Number of Days on Clock
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**Table 10.1: Breakdown of current status of all substantial amendments reviewed within the reporting period**

<b>Favourable opinion</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
07/Q1105/9/AM05	The influence of age, sex and disease on mesenchymal stem cells	Substantial Amendment 2 - 20/10/17	20/10/2017	30
10/H1304/6/AM03	Microfluidic based Cancer Tissue Biopsy Analysis ver 1	Substantial Amendment 3 - 24/5/17	24/05/2017	8
12/YH/0313/AM07	European Adrenal Insufficiency Registry (EU-AIR)	Substantial Amendment 1 - Protocol Amendment 1 - 8/9/16	08/09/2016	23
12/YH/0313/AM10	European Adrenal Insufficiency Registry (EU-AIR)	Substantial Amendment 3 - 18/12/17	18/12/2017	35
13/YH/0085/AM03	Neuropsychological and effort testing following ATBI. Version 1	Substantial Amendment 1 - 4/2/18	04/02/2018	28
13/YH/0237/AM06	Vitamin D & Immunity Study. Version 1.1	Substantial Amendment 5 - 1/11/17	01/11/2017	22
13/YH/0354/AM03	Exercise Training During Chemotherapy in Advanced Lung Cancer Patients	Substantial Amendment 4. 27/01/2017	03/04/2017	22
13/YH/0354/AM04	Exercise Training During Chemotherapy in Advanced Lung Cancer Patients	Substantial Amendment 5 - 2/2/18	02/02/2018	23
14/YH/0001/AM08	Counselling for Depression: The PRaCTICED Trial	Substantial Amendment Number 6. 28/04/2017	28/04/2017	19
14/YH/0001/AM09	Counselling for Depression: The PRaCTICED Trial	Substantial Amendment 7 -	12/10/2017	13

		12/10/17		
14/YH/0001/AM10	Counselling for Depression: The PRaCTICED Trial	Substantial Amendment 8 - 30/11/17	30/11/2017	32
15/YH/0093/AM11	Validation of Autism Assessment Instruments for deaf children	Substantial Amendment 6 - 4/4/17	04/04/2017	22
15/YH/0285/AM05	DOLORisk Dundee	Substantial Amendment 5 - 18/5/17	18/05/2017	31
15/YH/0291/AM05	Bleeding disorders in women undergoing surgery for menorrhagia	Substantial amendment 4 - 22.12.17	22/12/2017	22
15/YH/0396/AM01	Natural History of Memory Complaints	Substantial Amendment 1 - 8/6/17	08/06/2017	23
15/YH/0503/AM02	MRI-MVR (pilot)	Substantial Amendment 2 - 21/9/17	21/09/2017	13
15/YH/0503/AM03	MRI-MVR (pilot)	Substantial Amendment 3 - 19/12/17	19/12/2017	34
15/YH/0565/AM03	GLOWING Pilot Cluster RCT	Substantial Amendment 2 - 5/5/17	05/05/2017	22
16/YH/0063/AM02	COMMANDS-02 : An e-consult NAFLD Integrated Care Pathway	Substantial Amendment 1 - 25/7/17	25/07/2017	10
16/YH/0063/AM03	COMMANDS-02 : An e-consult NAFLD Integrated Care Pathway	Substantial Amendment 2 - 21/8/17	21/08/2017	18
16/YH/0116/AM04	Vibration Analysis as a Method for Fracture Screening in Children	Substantial Amendment 1 - 4/1/18	04/01/2018	26
16/YH/0142/AM03	Improving diagnosis in idiopathic cytopenia using gene sequencing	Substantial Amendment 3 - 8/6/17	08/06/2017	12

16/YH/0142/AM07	Improving diagnosis in idiopathic cytopenia using gene sequencing	Substantial Amendment 6 - 5/2/18	05/02/2018	20
16/YH/0207/AM02	Thermal Imaging Compared to Skeletal Survey in Children Below 2 Years	Substantial Amendment 2, 17.03.2017	20/03/2017	31
16/YH/0268/AM05	BRAVO Feasibility Study	Substantial Amendment 3 - 21/7/17	21/07/2017	24
16/YH/0268/AM06	BRAVO Feasibility Study	Substantial Amendment 4 – 20/12/2017	14/12/2017	33
16/YH/0278/AM05	Partnership in Prostate Cancer Care (the ICARE-P Study)	Substantial Amendment 3 - 16/8/17	17/08/2017	25
16/YH/0325/AM03	I-WOTCH V1.0	Substantial Amendment 2 - 29/3/17	29/03/2017	7
16/YH/0325/AM04	I-WOTCH V1.0	Substantial Amendment 3 - 17/8/17	17/08/2017	21
16/YH/0358/AM02	Lung health in HIV	Substantial amendment 02, 01 May 2017	01/05/2017	22
16/YH/0358/AM03	Lung health in HIV	Substantial Amendment 3 - 27/6/17	27/06/2017	22
16/YH/0383/AM01	Clinical utility of multimodal imaging in surgical tumour patients	Substantial Amendment 1 Nov2016	15/03/2017	22
16/YH/0389/AM02	Exploring the Experience of Living with Young Onset Dementia [V1]	Substantial Amendment 2 - 5/4/17	05/04/2017	24
16/YH/0410/AM02	Microbiological test for latent tuberculosis infection (Micro-LTBI)	Substantial Amendment 2 - 23/8/17	23/08/2017	23
16/YH/0482/AM01	CYP2C19 variants in predicting clopidogrel efficacy	Substantial	10/04/2017	30

		Amendment 1 - 20/2/17		
17/YH/0095/AM04	Life and Bladder Cancer Patient Reported Outcomes Survey	Substantial Amendment 1 - (Amendment 4) 9/11/17	09/11/2017	13
17/YH/0102/AM01	VIP: Video informed practice/Voices in partnership - Version 1.0	Substantial Amendment 1 - 18.09.17	18/09/2017	34
17/YH/0102/AM03	VIP: Video informed practice/Voices in partnership - Version 1.0	Substantial Amendment 2 - 23/1/18	23/01/2018	7
17/YH/0105/AM01	ThrIVe-B programme for Bipolar Mood Instability: A feasibility study	Substantial Amendment 1 26.5.17	26/05/2017	11
17/YH/0105/AM02	ThrIVe-B programme for Bipolar Mood Instability: A feasibility study	Substantial Amendment 2 - 4/6/17	04/06/2017	9
17/YH/0105/AM03	ThrIVe-B programme for Bipolar Mood Instability: A feasibility study	Substantial Amendment 3 - 23/6/17	23/06/2017	20
17/YH/0105/AM04	ThrIVe-B programme for Bipolar Mood Instability: A feasibility study	Substantial Amendment 4 - 27/6/17	27/06/2017	20
17/YH/0105/AM05	ThrIVe-B programme for Bipolar Mood Instability: A feasibility study	Substantial Amendment 5 24/08/17	28/08/2017	12
17/YH/0105/AM08	ThrIVe-B programme for Bipolar Mood Instability: A feasibility study	Substantial Amendment 6 - 9/10/17	09/10/2017	28
17/YH/0105/AM09	ThrIVe-B programme for Bipolar Mood Instability: A feasibility study	Substantial Amendment 7 - 21/11/17	21/11/2017	35
17/YH/0105/AM10	ThrIVe-B programme for Bipolar Mood Instability: A feasibility study	Substantial Amendment 8 - 17/1/18	17/01/2018	27
17/YH/0105/AM13	ThrIVe-B programme for Bipolar Mood Instability: A feasibility	Substantial	25/02/2018	16

	study	Amendment 9 - 25/2/18		
17/YH/0166/AM01	DEFINITION	Substantial Amendment 1 - 22.08.17	22/08/2017	22
17/YH/0188/AM02	The CFI Study	Substantial Amendment 1 - 26/7/17	26/07/2017	20
17/YH/0188/AM03	The CFI Study	Substantial Amendment 2 - 12/3/18	12/03/2018	14
17/YH/0218/AM01	Fracture In Preterm Infants Study (FIPIN Study)	Substantial Amendment 1 - 5/1/18	05/01/2018	26
17/YH/0304/AM01	Research into Altered Lymphocyte Function (ALF) in Health and Disease	Substantial Amendment 1 - 18/1/18	18/01/2018	20
17/YH/0438/AM01	Investigating drop attacks V1	Substantial Amendment 1 - 15/1/18	15/01/2018	15
17/YH/0439/AM01	People's views on barriers and solutions to bowel screening uptake V1	Substantial Amendment 1 - 16/2/18	16/02/2018	16

#### Unfavourable opinion

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
14/YH/0087/AM02	Collection of joint mesenchymal stem cells (MSCs)	Modified Amendment 1 - Substantial Amendment 2 - 11/5/17	11/05/2017	34

**Table 10.2: Breakdown of current status of all modified amendments reviewed within the reporting period**



<b>Favourable opinion timeline</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
14/YH/0087/AM02/2	Collection of joint mesenchymal stem cells (MSCs)	Modified Amendment 2 - Substantial Amendment 2 - 11/5/17	11/05/2017	4

<b>Unfavourable opinion timeline</b>				
<b>Amendment REC Reference</b>	<b>Title</b>	<b>Version</b>	<b>Date</b>	<b>Number of Days on Clock</b>
14/YH/0087/AM02/1	Collection of joint mesenchymal stem cells (MSCs)	Modified Amendment 1 - Substantial Amendment 2 - 11/5/17	11/05/2017	12

**Table 11: Items exceeding timelines**

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

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

REC Reference	Title	Number of Days on Clock
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**SSAs (non Phase 1) over 25 day timeline**

REC Reference	Title	Number of Days on Clock
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**SSAs (Phase 1) over 14 day timeline**

REC Reference	Title	Number of Days on Clock
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**Substantial Amendments over 35 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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**Modified Amendments over 14 day timeline**

Amendment REC Reference	Title	Version	Date	Number of Days on Clock
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