

London - Bromley Research Ethics Committee

Annual Report

01 April 2017 - 31 March 2018



Part 1 – Committee Membership and Training

| | |
|------------------------------|---|
| Name of REC: | London - Bromley Research Ethics Committee |
| Type of REC: | Authorised REC |
| Type of Flag: | Research Involving Adults Lacking Capacity |
| Chair: | Ms Jayne Steadman |
| Vice-Chair: | Dr Koula Asimakopoulou |
| Alternate Vice-Chair: | Mrs Heather Salzer |
| REC Manager: | Amy Peters (17/11/2017 - 6/06/2018) Siobhan Bawn 01/09/2017 - 17/11/2017. Helen Sivey (17/11/2017 - 22/03/2018) |
| REC Assistant: | Amy Peters (17/11/2017) |
| Committee Address: | Level 3, Block B Whitefriars Lewins Mead Bristol BS1 2NT |
| Telephone: | 0207 104 8057 |
| Email: | nrescommittee.london-bromley@nhs.net |

Chair's overview of the past year:

London - Bromley Research Ethics Committee Membership

| Name | Profession | Expert or Lay | Dates | |
|---------------------------|---|---------------|------------|------------|
| | | | Appointed | Left |
| Mr Munir Ahmed | Consultant Urologist | Expert | 01/09/2009 | |
| Mr Colin Allies | General Manager (Retired) | Lay | 01/02/2016 | |
| Dr Koula Asimakopoulou | Reader in Health Psychology | Expert | 01/08/2017 | |
| Dr Anna Barnes | Associate Director; Programme Office and Governance | Lay | 12/02/2016 | |
| Miss Paige Boateng | Student studying biomedical science | Lay Plus | 14/12/2017 | |
| Professor Jo Brooke | Associate Professor in Dementia Care | Expert | 21/02/2014 | |
| Mrs Angela Clayton-Turner | NHS Therapy Manager (Retired) | Lay | 01/08/2009 | |
| Miss Amber Collingwood | Programme Manager, Epilepsy Research | Lay | 01/02/2016 | |
| Mr Abdulzahra Hussain | Upper GI Consultant Surgeon | Expert | 21/02/2014 | |
| Mrs Kathryn Kinnear | Solicitor | Lay Plus | 01/08/2009 | 17/08/2017 |
| Mrs Fran McMillan | Retired | Lay Plus | 01/08/2009 | |
| Canon Tim Mercer | Hospital Chaplain | Lay Plus | 01/08/2009 | |
| Dr Angela Orunta | Consultant Anaesthetist | Expert | 01/08/2009 | |
| Mrs Frances Riggs | Retired Deputy Head Teacher | Lay Plus | 01/12/2017 | |
| Mrs Heather Salzer | Ultrasound Clinical Specialist (Retired) | Lay | 17/07/2013 | |
| Ms Jayne Steadman | Consultant Physiotherapist | Expert | 01/08/2009 | |
| Dr Jacqueline Tavabie | General Practitioner | Expert | 01/09/2015 | |

London - Bromley Research Ethics Committee: Deputy Members

| Name | Profession | Status | Meeting date attended |
|------------------------|---|--------|------------------------|
| Dr Anna Barnes | Associate Director; Programme Office and Governance | Lay | 15/02/2018, 15/03/2018 |
| Miss Amber Collingwood | Programme Manager, Epilepsy Research | Lay | 15/02/2018, 15/03/2018 |

London - Bromley Research Ethics Committee: Co-opted Members

| Name | Profession | Status | Meeting date attended |
|------|------------|--------|-----------------------|
| None | | | |

London - Bromley Research Ethics Committee: Members' Declarations of Interest:

| Name | Declaration of Interest | Date |
|---------------------------|--|------------|
| Mr Munir Ahmed | Consultant urological surgeon/ honorary senior lecturer, Kings College London Director urology and Healthcare Ltd. Royal College of Surgeons examiner Professional bodies ask for advice on research matters No commercial interests | 20/11/2017 |
| Mr Colin Allies | Appointed to sit on Fitness to Practice panels for the Association for Nutrition from September 2017. | 20/07/2017 |
| Dr Koula Asimakopoulou | Chair of the Scientific Conference Committee of the Division of Health Psychology. BPS Scientific Committee Chair | 18/11/2017 |
| Dr Anna Barnes | Chair: Seaview Well-being Centre (currently working with University of Brighton on research into digital inclusion for homeless people). Reviewer for International Journal of Migration, Health, and Social Care CO-designed of Benefits Realisation Matrix (3Ts) which is out for expressions of interest to three universities currently regarding 7 domain of benefits which the redesigned hospital will create Chair of Joint Arts Group (BSUH) which has invited expressions of interest for an evaluation of the impact of art on wayfinding within the hospital | 18/11/2017 |
| Miss Paige Boateng | Ferring Pharmaceuticals intern IFF Research – Interviewer Previous connection to The Children's Trust Charity | 12/01/2018 |
| Professor Jo Brooke | Member of the Scientific Advisory panel for the RCN International Nursing Research Conference | 06/11/2017 |
| Mrs Angela Clayton-Turner | Volunteer with Alzheimer's Society President of AGILE (professional network of chartered physiotherapists working with older people for 2 years until 2019) Occasional reviewer for NIHR | 03/12/2017 |
| Miss Amber Collingwood | Committee member of the King's College Hospital, Dept of Neurosciences, Neuroscience Research Advisory Group Committee (NeuroRag), which meets once a month to discuss new project proposal feasibility. Chair, Professor Ray Chaudhuri. Role involves representing the KCL academic department, Basic & Clinical Neuroscience as delegated by Professor Mark Richardson, Vice Dean – Division of Neuroscience. | 31/05/2017 |
| Mr Abdulzahra Hussain | None | 18/11/2017 |
| Mrs Kathryn Kinnear | None | 28/05/2017 |
| Mrs Fran McMillan | None | 15/11/2017 |
| Canon Tim Mercer | Honorary Canon Rochester Cathedral, Church of England London representative of the College of Health Care Chaplains (within UNITE, the union); Chair of the grants group (arrangements in transition) for Healthcare Chaplains to use for | 28/11/2017 |

| | | |
|-----------------------|---|------------|
| | research, training and review of chaplaincy Trustee, The Oakhill Trust, promoting spiritual care | |
| Dr Angela Orunta | None | 08/12/2017 |
| Mrs Frances Riggs | None | 15/03/2018 |
| Mrs Heather Salzer | None. | 07/12/2017 |
| Ms Jayne Steadman | None | 18/11/2017 |
| Dr Jacqueline Tavabie | None | 27/05/2017 |

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

| Month | Date | Number of Members Present at Meeting |
|-----------|------------|--------------------------------------|
| April | 20/04/2017 | 9 |
| May | 18/05/2017 | 9 |
| July | 20/07/2017 | 11 |
| August | 17/08/2017 | 13 |
| September | 21/09/2017 | 9 |
| October | 19/10/2017 | 8 |
| December | 14/12/2017 | 10 |
| February | 15/02/2018 | 11 |
| March | 15/03/2018 | 11 |

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 |
|-----------|------------|--------------------------------------|
| May | 10/05/2017 | 3 |
| May | 18/05/2017 | 14 |
| July | 13/07/2017 | 3 |
| August | 10/08/2017 | 3 |
| September | 14/09/2017 | 3 |
| October | 12/10/2017 | 4 |
| November | 09/11/2017 | 4 |
| December | 14/12/2017 | 3 |
| January | 11/01/2018 | 3 |
| February | 08/02/2018 | 3 |
| March | 08/03/2018 | 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 | 21/04/2017 | 2 |
| April | 28/04/2017 | 2 |
| May | 18/05/2017 | 3 |
| May | 26/05/2017 | 2 |
| June | 02/06/2017 | 2 |
| June | 16/06/2017 | 2 |
| July | 07/07/2017 | 2 |
| July | 14/07/2017 | 2 |
| July | 28/07/2017 | 2 |
| July | 28/07/2017 | 2 |
| August | 25/08/2017 | 2 |

| | | |
|-----------|------------|---|
| September | 08/09/2017 | 2 |
| September | 24/09/2017 | 3 |
| October | 06/10/2017 | 3 |
| October | 31/10/2017 | 2 |
| November | 03/11/2017 | 3 |
| November | 14/11/2017 | 4 |
| November | 29/11/2017 | 2 |
| December | 29/12/2017 | 2 |
| January | 12/01/2018 | 2 |
| January | 26/01/2018 | 2 |
| February | 09/02/2018 | 2 |
| February | 23/02/2018 | 2 |
| March | 09/03/2018 | 2 |
| March | 23/03/2018 | 2 |

25 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 |
|---------------------------|-----------------------------|
| Mr Munir Ahmed | 5 |
| Mr Colin Allies | 8 |
| Dr Koula Asimakopoulou | 4 |
| Dr Anna Barnes | 5 |
| Miss Paige Boateng | 2 |
| Professor Jo Brooke | 4 |
| Mrs Angela Clayton-Turner | 5 |
| Miss Amber Collingwood | 7 |
| Mr Abdulzahra Hussain | 4 |
| Mrs Kathryn Kinnear | 3 |
| Mrs Fran McMillan | 7 |
| Canon Tim Mercer | 7 |
| Dr Angela Orunta | 6 |
| Mrs Frances Riggs | 2 |
| Mrs Heather Salzer | 7 |
| Ms Jayne Steadman | 8 |
| Dr Jacqueline Tavabie | 7 |

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

| Name | Number of Meetings Attended |
|---------------------------|-----------------------------|
| Mr Munir Ahmed | 1 |
| Mr Colin Allies | 4 |
| Dr Koula Asimakopoulou | 4 |
| Dr Anna Barnes | 1 |
| Professor Jo Brooke | 7 |
| Mrs Angela Clayton-Turner | 3 |
| Miss Amber Collingwood | 6 |
| Mr Abdulzahra Hussain | 3 |
| Mrs Kathryn Kinnear | 2 |
| Mrs Fran McMillan | 2 |
| Canon Tim Mercer | 1 |
| Dr Angela Orunta | 1 |
| Mrs Heather Salzer | 5 |
| Ms Jayne Steadman | 4 |
| Dr. Jacqueline A. Tavabie | 2 |

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

| Name | Number of Meetings Attended |
|---------------------------|-----------------------------|
| Mr Munir Ahmed | 1 |
| Mr Colin Allies | 7 |
| Dr Koula Asimakopoulou | 3 |
| Professor Jo Brooke | 4 |
| Mrs Angela Clayton-Turner | 1 |
| Miss Amber Collingwood | 3 |
| Mrs Fran McMillan | 3 |
| Canon Tim Mercer | 2 |
| Dr Angela Orunta | 5 |
| Mrs Heather Salzer | 9 |
| Ms Jayne Steadman | 14 |
| Dr. Jacqueline A. Tavabie | 3 |

Training 01 April 2017 - 31 March 2018

| Name of Member | Date | Event(s) attended |
|---------------------------|-------------|--|
| Mr Munir Ahmed | 14/12/2017 | Local REC Training Day |
| Mr Colin Allies | 14/12/2017 | Local REC Training Day |
| Dr Koula Asimakopoulou | 08/12/2017 | Equality, Diversity and Human Rights |
| Dr Anna Barnes | 01/10/2017 | Reviewer for Peer review Journal; International Journal of Migration, Health and Social Care |
| Dr Anna Barnes | 14/12/2017 | Local REC Training Day |
| Professor Jo Brooke | 06/12/2017 | HRA Approval Study title: The exploration of the lived experience of delirium by patients, families, nurses, doctors and therapists IRAS: 229243 REC: 17/WM/0440 |
| Professor Jo Brooke | 06/12/2017 | REC Application Improving NHS healthcare and services by understanding and embracing diversity |
| Mrs Angela Clayton-Turner | 14/12/2017 | Local REC Training Day |
| Miss Amber Collingwood | 14/11/2017 | Handling Health-Related Findings in Research (Joint MRC/HRA) |
| Miss Amber Collingwood | 17/11/2017 | Handling health-related findings |
| Miss Amber Collingwood | 14/12/2017 | Local REC Training Day |
| Miss Amber Collingwood | 16/01/2018 | Online Equality and Diversity |
| Mr Abdulzahra Hussain | 07/01/2018 | Publication of 11 research papers such as 1.Etiology of Leaks Following Sleeve Gastrectomy: Current Evidence.Hussain A, Vasas P, Kirk K, Finney J, Balchandra |
| Mrs Fran McMillan | 14/12/2017 | Local REC Training Day |
| Canon Tim Mercer | 04/05/2017 | Undertaking qualitative research |
| Canon Tim Mercer | 01/10/2017 | Reading: 'The ethics of everyday life' by Michael Banner |
| Canon Tim Mercer | 14/12/2017 | Local REC Training Day |
| Dr Angela Orunta | 14/12/2017 | Local REC Training Day |
| Mrs Heather Salzer | 14/12/2017 | Local REC Training Day |
| Mrs Heather Salzer | 21/12/2017 | Online Equality and Diversity |
| Ms Jayne Steadman | 14/12/2017 | Local REC Training Day |
| Ms Jayne Steadman | 23/01/2018 | Complex Cases |
| Dr Jacqueline Tavabie | 26/05/2017 | Reviewing the Research Design of Clinical Trials |
| Dr Jacqueline Tavabie | 27/05/2017 | Reading "Ethics in General Practice - a practical handbook for personal development" by Ann Orme-Smith and John Spicer. |
| Dr Jacqueline Tavabie | 06/01/2018 | Research involving participants |

| | | |
|--|--|-------------------------|
| | | lacking mental capacity |
|--|--|-------------------------|

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 | 33 | 100.00 |
| Total Applications Reviewed | 33 | 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 | 20 |
| Number of paediatric applications reviewed | 5 |
| Number of device applications reviewed | 3 |
| Number of prisoner applications reviewed | 0 |
| Number of applications involving adults unable consent reviewed | 6 |
| Number of applications reviewed that are funded by the US DHHS | 0 |
| Number of qualitative applications reviewed | 5 |

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 | 8 | 24.24 |
| Unfavourable Opinion | 3 | 9.09 |
| Provisional Opinion | 22 | 66.67 |
| Provisional Opinion Pending Consultation with Referee | 0 | 0.00 |
| Total | 33 | 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 | 18 | 54.55 |
| Further Information Favourable Opinion with Additional Conditions | 3 | 9.09 |
| Further Information Unfavourable Opinion | 0 | 0.00 |
| Favourable Opinion with Standard Conditions | 0 | 0.00 |
| Favourable Opinion with Additional Conditions | 8 | 24.24 |
| Unfavourable Opinion | 3 | 9.09 |
| Provisional Opinion | 0 | 0.00 |
| Provisional Opinion Pending Consultation with Referee | 0 | 0.00 |
| Further Information response not complete | 0 | 0.00 |
| No decision entered on system | 0 | 0.00 |
| Number of studies withdrawn after the meeting | 1 | 3.03 |
| Total | 33 | 100 |

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

| | |
|------------------------------------|-----------|
| Total Applications Reviewed | 24 |
|------------------------------------|-----------|

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 | 0 |
| Number of student applications reviewed | 10 |
| Number of paediatric applications reviewed | 5 |
| Number of device applications reviewed | 0 |
| Number of qualitative applications reviewed | 3 |

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

| Decisions taken at proportionate review sub-committee meetings | Number | % |
|---|---------------|------------|
| Favourable Opinion with Standard Conditions | 5 | 20.83 |
| Favourable Opinion with Additional Conditions | 5 | 20.83 |
| No Opinion transfer to full committee for review | 3 | 12.50 |
| Provisional Opinion | 10 | 41.67 |
| Unfavourable Opinion | 1 | 4.17 |
| Total | 24 | 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 | 3.67 |
| Number of completed applications for full ethical review | 32 |
| 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 | 13 |
| Number of completed applications over 40 days as a % of total | 39.39% |
| Number of days taken to final decision – average (mean) | 38 |
| 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 | 8 |
| Number of completed applications for SSA review over 25 days | 1 |
| Number of completed applications for SSA review over 25 days as % of all non- Phase 1 SSAs | 12.50% |
| 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 | 57 |
| Number of completed substantial amendments over 35 days | 6 |
| Number of completed substantial amendments over 35 days as a % of total substantial amendments | 10.53% |
| Number of completed substantial amendments over 28 days | 20 |
| Number of completed substantial amendments over 28 days as a % of total substantial amendments | 35.09% |
| Number of modified amendments reviewed | 3 |
| 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 | 87 |
| Number of substantial amendments received for information | 0 |
| Number of substantial amendments received for new sites/PIs | 0 |
| Number of annual progress reports received | 65 |
| Number of safety reports received | 0 |
| Number of Serious Adverse Events received | 4 |

| | |
|---|----|
| Number of final reports received | 15 |
|---|----|

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/LO/0290 | The impact of substituting Warfarin with DOACs in AF patients over 65 | 52 |
| 17/LO/0853 | VIBROfocus | 35 |
| 17/LO/1209 | Clinical performance study for the Jupiter AS1-CS1 Calisto System | 43 |
| 17/LO/1265 | Responding to the spiritual needs of dialysis patients (Version 3.1) | 43 |
| 17/LO/1357 | Assessing the Utility of Group Mindfulness-Based Cognitive Therapy V1 | 46 |
| 17/LO/1368 | fMRI Neurofeedback in children with ADHD | 57 |
| 17/LO/1567 | Sleep, wake and light therapy for depression V.1 | 29 |
| 17/LO/1619 | Bilingualism and dementia: a longitudinal study v.1.1 | 36 |
| 17/LO/1644 | A Biomechanics Study during complex Abdominal Wall Reconstruction | 37 |
| 17/LO/1646 | Pain in People with Dementia (PIP-D) | 50 |
| 17/LO/1688 | Understanding Chordoma: A National Cohort Study | 57 |
| 17/LO/1834 | Biomarkers Association in Skin and Synovium in PsA (BASSPA) | 28 |
| 18/LO/0193 | Endpoints for dry AMD | 40 |
| 18/LO/0221 | Cardiac Arrest Molecular and Proteomic Study - CAMERA | 55 |
| 18/LO/0255 | THE EFFECT OF FIBRE SUPPLEMENT ON GESTATIONAL DIABETES | 39 |
| 18/LO/0335 | Geniculate artery embolization in knee OA | 38 |
| 18/LO/0450 | Empowerment in young people with CF during key life transitions | 46 |
| 18/LO/0452 | Dysfunctional breathing: The development of a diagnostic tool | 49 |

| Further Information Favourable Opinion with Additional Conditions | | |
|--|--|--------------------------------|
| REC Reference | Title | Number of Days on Clock |
| 17/LO/1225 | OBESITY AND TYPE 2 DIABETES – RAISING THE ISSUE OF WEIGHT MANAGEMENT | 48 |
| 17/LO/1263 | Sleep and Psychotic Features in Serious Mental Illness | 57 |
| 18/LO/0298 | Equilibrium: An Intervention for Young People who Self-harm | 52 |

| 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/LO/0663 | A MT/DMP group for people with dementia living in the community | 26 |
| 17/LO/0700 | Linking Surgical Expertise with Clinical Outcomes | 26 |
| 17/LO/0703 | WIDE study: Wound Infection Detection Evaluation study | 26 |
| 17/LO/0879 | Substance use and coping with trauma-related symptoms | 25 |
| 17/LO/1242 | TITANIC version-1 | 27 |
| 17/LO/1313 | PEPTIC v1.0 | 29 |
| 17/LO/1653 | Exploring the nature of coproduced care between DN's and older people | 23 |
| 18/LO/0314 | Smart Catheter: A Novel Biosensor for Catheter Associated UTI | 25 |

Unfavourable Opinion

| REC Reference | Title | Number of Days on Clock |
|---------------|--|-------------------------|
| 17/LO/1227 | An exploration of wellbeing in services users under the Care Programme | 27 |
| 17/LO/1621 | Evaluation of Renastep in Patients with Chronic Kidney Disease. | 22 |
| 18/LO/0465 | IDDSI Level 2 ONS study - IDDSIL2 | 25 |

Provisional Opinion

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

Provisional Opinion Pending Consultation with Referee

| REC Reference | Title | REC Reference |
|---------------|-------|---------------|
|---------------|-------|---------------|

Further information response not complete

| REC Reference | REC Reference | Title |
|---------------|---------------|-------|
|---------------|---------------|-------|

Withdrawn after the meeting

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

| | | |
|------------|--|----|
| 17/LO/0697 | Impact on carers and patients of diastolic vs systolic Heart failure | 26 |
|------------|--|----|

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/LO/0798 | Fatigue in Neuropathic Disorders (FIND Study) | 41 |
| 17/LO/1389 | Physical activity in cardiac patients | 14 |
| 17/LO/1540 | MRI in Retinal Degeneration | 19 |
| 17/LO/1759 | DGE after Ivor Lewis gastro-oesophagectomy | 18 |
| 17/LO/1953 | Evaluation of exercise tests to assess idiopathic pulmonary fibrosis | 16 |
| 18/LO/0096 | How does dysphagia assessment in acute stroke affect pneumonia? | 21 |
| 18/LO/0231 | Decision aids for the management of decayed primary teeth | 20 |
| 18/LO/0405 | Renal impairment and cognitive decline | 19 |
| 18/LO/0409 | Measuring impact of comorbidities in different trusts (MIC) | 21 |

| Further Information Favourable Opinion with Additional Conditions | | |
|--|---|--------------------------------|
| REC Reference | Title | Number of Days on Clock |
| 17/LO/1769 | Self-monitoring symptoms to increase adherence in Cystic Fibrosis | 18 |

| 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/LO/1562 | A Feasibility study for an RCT investigating ACE within the NHS | 18 |
| 17/LO/1956 | Treatment decisions in older people with lung cancer | 15 |
| 17/LO/1961 | Extreme phenotypes in COPD study (EPIC study) | 11 |
| 17/LO/2116 | CLAHRC Evaluation: a) research impact; b) Patient & Public Involvement | 13 |
| 18/LO/0417 | Investigating Attitudes to Research and Clinical Trial Involvement | 11 |

| Favourable Opinion with Additional Conditions | | |
|--|---|--------------------------------|
| REC Reference | Title | Number of Days on Clock |
| 17/LO/0800 | The gut microbiome in rheumatoid arthritis and bronchiectasis | 14 |
| 17/LO/1952 | Scar VF | 9 |
| 17/LO/2112 | Binocular Visual Acuity in Anisometropic Amblyopes vs. Non-Amblyopes | 9 |
| 18/LO/0093 | The effect of leg inequality on pelvic and hip kinematics in children | 22 |
| 18/LO/0256 | The EASEMENT Study | 13 |

| Unfavourable Opinion | | |
|-----------------------------|---------------------------|--------------------------------|
| REC Reference | Title | Number of Days on Clock |
| 17/LO/0823 | FRAILCLINIC: Intervention | 23 |

| Provisional Opinion | | |
|----------------------------|--------------|--------------------------------|
| 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 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 |
| 10/H0721/87/AM09 | Using Genetics to Understand Parkinson's Disease | Amendment 6 | 01/06/2017 | 24 |
| 11/H0721/13/AM02 | Modelling RPE disease using iPS cells. | Substantial Amendment Version | 08/12/2016 | 35 |
| 11/LO/0583/AM09 | laryngeal reinnervation versus type I thyroplasty | 11 | 22/11/2017 | 23 |
| 13/LO/1442/AM10 | Morbidity after paediatric cardiac surgery | 8) 2nd August 2017 | 02/08/2017 | 30 |
| 13/LO/1738/AM03 | Novel biomarkers in cooled newborns (Oct 2013) | 3 | 03/11/2017 | 34 |
| 13/LO/1748/AM09 | UK national platform for Spinal Muscular Atrophy (SMA) | 6 | 07/12/2016 | 34 |
| 14/LO/0077/AM03 | Validation of the ApneaScan algorithm in sleep disordered breathing | V3 27/12/2017 | 27/12/2017 | 11 |
| 14/LO/0533/AM01 | Understanding and overcoming barriers to living with an artificial eye | 1 | 19/10/2017 | 24 |
| 14/LO/2117/AM01 | Non motor symptoms of Parkinson's in multi-racial ethnic group | 1 and 07.03.2017 | 14/03/2017 | 21 |
| 15/LO/0196/AM05 | Real vs. sham rTMS in severe and enduring AN | Amendment 5 | 30/05/2017 | 14 |
| 15/LO/0499/AM02 | TATME database | Substantial Amendment Version | 08/08/2017 | 29 |
| 15/LO/0889/AM01 | Mental health promotion groups for people with intellectual disability | 1 | 16/11/2017 | 56 |
| 15/LO/0992/AM04 | Proactive Health Coaching in the English NHS | Version 1.2 (February 28, 2017 | 08/03/2017 | 28 |
| 15/LO/0992/AM05 | Proactive Health Coaching in the English NHS | Substantial Amendment Version 1 | 15/05/2017 | 16 |
| 15/LO/0992/AM06 | Proactive Health Coaching in the English NHS | 1.4 | 21/11/2017 | 37 |
| 15/LO/0992/AM08 | Proactive Health Coaching in the English NHS | Version 1.5 (8th Feb 2018) | 08/02/2018 | 11 |
| 15/LO/1038/AM05 | Step Home Trial: Physical Activity in the Post-operative Setting | Amendment 4: 21st February 201 | 21/02/2018 | 12 |
| 15/LO/1199/AM01 | The Young Evaluators | 1 | 05/06/2017 | 13 |
| 15/LO/1494/AM03 | Diagnostic approaches in gestational diabetes and impact of | 2 | 17/11/2017 | 25 |

| | | | | |
|-----------------|--|--------------------------------------|------------|----|
| | ethnicity | | | |
| 15/LO/1506/AM02 | IMRIS | Amendment 1 (substantial amend | 26/04/2017 | 20 |
| 15/LO/1539/AM04 | ARISE - Losmapimod | 6 | 26/10/2017 | 34 |
| 15/LO/1557/AM08 | The Cognitive Remediation in Bipolar (CRiB) Study: A Feasibility Trial | Substantial Amendment 7¼ 15/09 | 15/09/2017 | 20 |
| 15/LO/1557/AM09 | The Cognitive Remediation in Bipolar (CRiB) Study: A Feasibility Trial | 8¼ 23/11/17 | 23/10/2017 | 15 |
| 15/LO/1567/AM01 | IMMUNET | Amendment number 1: 07/03/2017 | 12/04/2017 | 20 |
| 15/LO/1772/AM01 | Development and Validation of the TRIALÂ® database for Rett Syndrome | Amendment Number - 1 Date - 16 | 30/01/2018 | 28 |
| 15/LO/1778/AM04 | Social Inclusion in Mental Health | Amendment 4 05.04.2017 | 06/04/2017 | 21 |
| 15/LO/1840/AM03 | Salivary cortisol and cortisone in healthy children | Substantial Amendment 3 12/6/1 | 12/06/2017 | 9 |
| 15/LO/2024/AM05 | FCT with young children with ID in the UK: A feasibility project V.1 | Substantial Amendment 3; 24/08 | 24/08/2017 | 35 |
| 15/LO/2024/AM06 | FCT with young children with ID in the UK: A feasibility project V.1 | Subst 4 23.01.18 | 23/01/2018 | 9 |
| 15/LO/2134/AM02 | Predictors 5.1 | Ammendment 2, 15/11/2017 | 15/11/2017 | 38 |
| 16/LO/0015/AM04 | GAPS - Graduated compression as an Adjunct to Pharmacoprophylaxis in S | Amendment 3 | 01/06/2017 | 21 |
| 16/LO/0720/AM02 | Effect of home based balance training in peripheral neuropathy | Substantial Amendment: 2 28.07 | 28/07/2017 | 5 |
| 16/LO/0865/AM03 | CIMPRES-COPD | 2, 11/04/2017 | 12/04/2017 | 23 |
| 16/LO/1102/AM03 | The NOC Study. Version 1 | Version 3 | 30/05/2017 | 29 |
| 16/LO/1129/AM05 | The role of SV2A in PD and PD Dementia | 3 | 20/11/2017 | 37 |
| 16/LO/1311/AM02 | Imaginator - functional imagery training for self harm in young people | Amendment 1 03.02.17 | 03/03/2017 | 38 |

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|-----------------|--|--------------------------------------|------------|----|
| 16/LO/1311/AM04 | Imaginator - functional imagery training for self harm in young people | Amendment 3 30/05/2017 | 12/06/2017 | 27 |
| 16/LO/1683/AM01 | Cardiac-rehabilitation decliners: perceptions and coping strategies | Substantial Amendment 4.0 - 25 | 25/07/2017 | 30 |
| 16/LO/1683/AM02 | Cardiac-rehabilitation decliners: perceptions and coping strategies | 5.0 | 16/10/2017 | 14 |
| 16/LO/1702/AM01 | Does prehabilitation improve CPX results in OG cancer patients | 2.1 | 06/11/2017 | 32 |
| 16/LO/1833/AM01 | Consultation-based reassurance for people with low back pain | first amendment 26/04/2017 | 26/04/2017 | 13 |
| 16/LO/1901/AM01 | HCN-pain | 1, 24.04.2017 | 24/04/2017 | 14 |
| 16/LO/1901/AM02 | HCN-pain | amendment 2 | 21/08/2017 | 34 |
| 16/LO/1901/AM04 | HCN-pain | 3 07_Feb_2018 | 07/02/2018 | 19 |
| 16/LO/2168/AM02 | Characterisation of microglia after an acute brain injury | Amendment 1 | 12/04/2017 | 14 |
| 16/LO/2168/AM03 | Characterisation of microglia after an acute brain injury | Substantial Amendment 2: 03/10 | 10/10/2017 | 34 |
| 17/LO/0329/AM01 | Effect of salpingectomy for tubal ectopic pregnancy on ovarian reserve | Substantial Amendment 1, 07/08 | 07/08/2017 | 36 |
| 17/LO/0334/AM01 | FLO-ELA | 1.0 | 04/07/2017 | 29 |
| 17/LO/0335/AM02 | Self-criticism pilot study | Substantial Amendment v1 24.7. | 24/07/2017 | 8 |
| 17/LO/0348/AM01 | Experiences of People with Cystic Fibrosis and their Families | No. 1 | 18/05/2017 | 17 |
| 17/LO/0452/AM01 | SASAC: Skin ageing signatures and cancer | Substantial Amendment 1 | 15/09/2017 | 20 |
| 17/LO/0703/AM01 | WIDE study: Wound Infection Detection Evaluation study | 1 dd 7 November 2017 | 07/11/2017 | 20 |
| 17/LO/1263/AM01 | Sleep and Psychotic Features in Serious Mental Illness | #1 1¾ 23/1/18 | 23/01/2018 | 7 |
| 17/LO/1368/AM01 | fMRI Neurofeedback in children with ADHD | Substantial Amendment 1, 27/10 | 27/10/2017 | 32 |
| 17/LO/1389/AM01 | Physical activity in cardiac patients | 1 | 13/12/2017 | 16 |

| Unfavourable opinion | | | | |
|-------------------------|---|--------------------------------|------------|-------------------------|
| Amendment REC Reference | Title | Version | Date | Number of Days on Clock |
| 12/LO/0442/AM08 | Outcome Measures In Duchenne Muscular Dystrophy | Substantial Amendment 5.0 - 27 | 06/07/2017 | 15 |
| 15/LO/1904/AM03 | MROC: MR in Ovarian Cancer | 2 | 11/04/2017 | 26 |

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

| Favourable opinion timeline | | | | |
|-----------------------------|---|--------------------------------|------------|-------------------------|
| Amendment REC Reference | Title | Version | Date | Number of Days on Clock |
| 12/LO/0442/AM08/1 | Outcome Measures In Duchenne Muscular Dystrophy | Modified Amendment - Amendment | 16/08/2017 | 11 |
| 15/LO/1904/AM03/1 | MROC: MR in Ovarian Cancer | Substantial Amendment 02 - Mod | 11/07/2017 | 14 |
| 16/LO/0714/AM01/1 | tDCS in post-stroke fatigue (TIPS) | 1, 03/02/2017 | 06/04/2017 | 5 |

| 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/LO/0798 | Fatigue in Neuropathic Disorders (FIND Study) | 41 |
| 17/LO/0823 | FRAILCLINIC: Intervention | 23 |
| 18/LO/0093 | The effect of leg inequality on pelvic and hip kinematics in children | 22 |

| SSAs (non Phase 1) over 25 day timeline | | |
|---|--------------------------------|-------------------------|
| REC Reference | Title | Number of Days on Clock |
| 17/LO/0920 | C-CHANGE Workstream 4: Testing | 27 |

| 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 |
| 15/LO/0889/AM01 | Mental health promotion groups for people with intellectual disability | 1 | 16/11/2017 | 56 |
| 15/LO/0992/AM06 | Proactive Health Coaching in the English NHS | 1.4 | 21/11/2017 | 37 |
| 15/LO/2134/AM02 | Predictors 5.1 | Ammendment 2, 15/11/2017 | 15/11/2017 | 38 |
| 16/LO/1129/AM05 | The role of SV2A in PD and PD Dementia | 3 | 20/11/2017 | 37 |
| 16/LO/1311/AM02 | Imaginator - functional imagery training for self harm in young people | Amendment 1 03.02.17 | 03/03/2017 | 38 |
| 17/LO/0329/AM01 | Effect of salpingectomy for tubal ectopic pregnancy on ovarian reserve | Substantial Amendment 1, 07/08 | 07/08/2017 | 36 |

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

