National Research Ethics Service



NRES Committee South Central -Oxford A

Annual Report

01 April 2011 – 31 March 2012

Part 1 – Committee Membership and Training

| Name of REC: | NRES Committee South Central - Oxford A | |
|------------------------------|---|--|
| Type of REC: | Recognised Type I, Type III | |
| Type of Flag: | Phase 1 in Health Volunteers, Phase 1 Studies in Patients Transfers from GTAC, Pediatric | |
| Chair: | Dr Karen Melham | |
| Vice-Chair: | | |
| Alternate Vice-Char: | Ms Alison Eden | |
| Co-ordinator: | Miss Stephanie Macpherson | |
| PRSC Co-ordinator: | Miss Stephanie Macpherson | |
| Assistant Co-ordinator: | N/A | |
| Committee Address: | Bristol Research Ethics Committee Centre Whitefriars Level 3 Block B Lewins Mead Bristol BS1 2NT | |
| Telephone: Fax: Email: | 01173421331 01173420445 scsha.oxfordreca@nhs.net | |

Chair's overview of the past year:

The committee is a strong and collegial group, committed to rigorous and constructive review of research. We regularly have at our meetings observers from research support, other RECs, and research groups. A number of new members joined, have integrated well, and make solid contributions to the group, and from their areas of expertise. We are very ably supported by our coordinator Steph Macpherson, whose organisation and attention to detail have been key to the committee managing smooth entry into proportionate review and new review reporting mechanisms.

The committee has been without an alternate vice chair since October 2010, and without a vice chair since January 2011. Ms Sara Owen (Research Coordinator) resigned as vice chair after four years in the position. She remains on the committee. Committee members are ready and willing to fill these posts and I am assured that NRES administration is still working on getting appropriate officers in place. Good function has been possible because of the commitment of committee members, but the lack of officers is not sustainable. We look forward to this being resolved in the near future.

| NRES Committee South Central - Oxford A Membership: | | | | |
|---|--|-----------|------------|------------|
| Name | Occupation | Expert or | Dates | |
| | | Lay | Appointed | Resigned |
| Dr Ronja Bahadori | Clinical Trial Coordinator | Expert | 01/06/2011 | 15/12/2011 |
| Ms Raj Bains | Pharmacovigilance Business Consultant | Lay Plus | 29/05/2008 | |
| Dr Carol Barton | Retired Consultant Haematologist | Expert | 01/12/2007 | |
| Mr Sean (Searalen) Chinnathumby | Training & Education Lead | Expert | 01/06/2011 | |
| Mrs Suzanne Cloke | Retired | Lay Plus | 01/12/2007 | |
| Mr Stuart Cole | r Stuart Cole Online Retail Developer / Coordinator | | 01/06/2011 | |
| Ms Alison Eden | Publisher | Lay Plus | 01/01/2008 | |
| Mrs Marion Fiddes | NHS Estates Manager | Lay | 13/02/2006 | |
| Dr Cynthia Graham | Lecturer in Psychology | Expert | 12/12/2005 | |
| Mrs Lyndsay Hills | Retired Senior Staff Nurse | Expert | 01/04/2010 | |
| Ms Katherine Jacob | Clinical Trials Pharmacist | Expert | 12/10/2009 | 11/08/2011 |
| Mr Shepherd Masara Senior Staff Nurse- Anaesthetics & Recovery | | Expert | 01/06/2011 | |
| Dr Karen Melham | Ethicist | Lay | 15/12/2005 | |
| Dr Mike Murphy | Epidemiologist | Expert | 01/08/2003 | |
| Ms Sara Owen | Research Co-ordinator | Lay | 12/01/2004 | |
| Mr Martin Usherwood | Retired Gynaecologist | Expert | 05/09/2011 | |
| Dr Alan Wagner | GP | Expert | 01/03/2011 | 22/06/2011 |
| Ms Tayo Jaiyesimi | Clinical Trials Pharmacist | Expert | | |
| Dr Sian Warriner Consultant Midwife | | Expert | 12/01/2004 | |

Deputy Members

| Name | Occupation | Expert or Lay | Meeting date attended |
|------|------------|------------------|-----------------------|
| N/A | | | |

Co-opted Members

| Name | Occupation | Expert or Lay | Meeting date attended |
|-------------------|--|------------------|-----------------------|
| Dr Rosemary Baker | Consultant in Learning Disabilities | Expert | 06/01/2012 |

Member Bank

| Name | Occupation | Expert or Lay | Meeting date attended |
|------|------------|------------------|-----------------------|
| N/A | | | |

NRES Committee South Central - Oxford A: Members' Declarations of Interest:

| Name | Declaration of Interest | Date |
|------------------------------------|--|------------|
| Mr Sean (Searalen) Chinnathumby | Does occasional bank shifts as a registered nurse in the National Spinal Injuries Centre. They are actively involved in research. Involved in training and education for the Thames Valley Cancer Research Network- the submit research projects to committees. | 21/07/2011 |
| Dr Karen Melham | No Declarations of interest | 07/12/2011 |
| Dr Cynthia Graham | No Declarations of interest | 07/12/2011 |
| Mrs Suzanne Cloke | No Declarations of interest | 02/12/2011 |
| Dr Carol Barton | No Declarations of interest | 02/12/2011 |
| Ms Raj Bains | No Declarations of interest | 02/12/2011 |
| Mrs Lyndsay Hills | No Declarations of interest | 02/12/2011 |
| Mr Shepherd Masara | No Declarations of interest | 02/12/2011 |
| Mr Stuart Cole | No Declarations of interest | 02/12/2011 |
| Mrs Marion Fiddes | No Declarations of interest | 02/12/2011 |
| Dr Mike Murphy | No Declarations of interest | 30/03/2012 |
| Ms Alison Eden | 100% owner of Alison Brand- may write patient information leaflets for some clients. | 30/03/2012 |
| Dr Mike Murphy | No Declarations of interest | 30/03/2012 |
| Ms Sara Owen | Chair of advisory committee / independent ethics advisor for university of Oxford, European Funded, international, multi-centre study called Genodisc. | 30/03/2012 |
| Ms Tayo Jaiyesimi | Lay member of stakeholder reference group for the general optical council. | 02/12/2011 |
| Dr Sian Warriner | Sits on educational board of the British Journal of Midwifery | 02/12/2011 |
| Mr Martin Usherwood | No Declarations of interest | 09/12/2011 |

Meetings for Full Ethical Review 01 April 2011 - 31 March 2012:

| Month | Date | Number of Members Present at Meeting |
|-----------|------------|---|
| April | 01/04/2011 | 8 |
| Мау | 06/05/2011 | 11 |
| June | 03/06/2011 | 10 |
| August | 05/08/2011 | 13 |
| September | 02/09/2011 | 11 |
| October | 07/10/2011 | 13 |
| November | 04/11/2011 | 11 |
| December | 02/12/2011 | 10 |
| January | 06/01/2012 | 11 |
| February | 03/02/2012 | 11 |

10 full committee meetings were held during the reporting period.

Proportionate Review Sub Committee Meetings held during 01 April 2011 - 31 March 2012:

| Month | Date | Number of Members Present at Meeting |
|----------|------------|---|
| January | 20/01/2012 | 3 |
| February | 29/02/2012 | 3 |

2 proportionate review sub-committee meetings were held during the reporting period.

Attendance of Members: 01 April 2011 – 31 March 2012:

| Name | Number of Meetings Attended |
|---------------------------------|-----------------------------------|
| Dr Carol Barton | 10 |
| Dr Karen Melham | 9 |
| Mrs Lyndsay Hills | 8 |
| Ms Alison Eden | 8 |
| Ms Sara Owen | 7 |
| Miss Tayo Jaiyesimi | 7 |
| Mrs Marion Fiddes | 7 |
| Mrs Suzanne Cloke | 7 |
| Mr Sean (Searalen) Chinnathumby | 7 |
| Dr Sian Warriner | 7 |
| Dr Cynthia Graham | 7 |
| Dr Mike Murphy | 6 |
| Mr Stuart Cole | 6 |
| Mr Shepherd Masara | 5 |
| Ms Raj Bains | 4 |
| Ms Katherine Jacob | 3 |
| Mr Martin Usherwood | 3 |
| Dr Ronja Bahadori | 3 |
| Dr Alan Wagner | 2 |

Number of inquorate meetings held:0

Attendance of Members at proportionate review sub-committee meetings: 01 April 2011 – 31 March 2012:

| Name | Number of Meetings Attended |
|-------------------|-----------------------------------|
| Dr Karen Melham | 2 |
| Mrs Lyndsay Hills | 1 |
| Ms Alison Eden | 1 |
| Ms Raj Bains | 1 |
| Dr Cynthia Graham | 1 |

Training 01 April 2011 – 31 March 2012:

| Name of | Date | Event(s) attended |
|----------------------|----------------------------|--|
| Member | | |
| Dr Mike Murphy | 04/07/2011 - 04/07/2011 | Equality & Diversity, NRES |
| Dr Mike Murphy | 15/09/2011 - 15/09/2011 | Human Tissue Act Traing, NRES |
| Dr Carol Barton | 01/07/2011 - 01/07/2011 | South Central - Oxford A Training day, NRES |
| Dr Carol Barton | 04/11/2011 - 04/11/2011 | Shared Ethical Debate (Phase 1), NRES |
| Dr Cynthia Graham | 06/10/2011 - 06/10/2011 | Researcher Training Day, NRES |
| Dr Cynthia Graham | 28/10/2011 - 28/10/2011 | Janet Wisely Update, NRES |
| Dr Karen Melham | 01/07/2011 - 01/07/2011 | South Central- Oxford A Training day, NRES |
| Dr Karen Melham | 02/11/2011 - 02/11/2011 | 'The Nuts and Bolts of running a REC' (code OP1202), NRES |
| Dr Karen Melham | 25/06/2011 - 25/06/2011 | Equality & Diversity, NRES |
| Dr Karen Melham | 28/10/2011 - 28/10/2011 | NRES Update Session, NRES |
| Dr Karen Melham | 04/11/2011 - 04/11/2010 | Shared Ethical Debate (Phase 1), NRES |
| Dr Ronja Bahadori | 01/07/2011 - 01/07/2011 | South Central - Oxford A Training day, NRES |
| Dr Ronja Bahadori | 04/10/2011 - 04/10/2011 | Induction, NRES |
| Dr Ronja Bahadori | 27/07/2011 - 27/07/2011 | The ethical review of medicines based research: A workshop for researchers and committee members (co, NRES |
| Dr Ronja Bahadori | 28/10/2011 - 28/10/2011 | NRES Update Session, NRES |
| Dr Ronja Bahadori | 20/10/2011 - 20/10/2011 | Equality & Diversity, NRES - Online |
| Dr Ronja Bahadori | 04/11/2011 - 04/11/2011 | Shared Ethical Debate, NRES |
| Dr Sian Warriner | 01/07/2011 - 01/07/2011 | South Central- Oxford A Training day, NRES |

| Dr Sian Warriner | 04/11/2011 - 04/11/2011 | Shared Ethical Debate (Phase 1), NRES |
|---------------------------------------|----------------------------|--|
| Mr Shepherd Masara | 01/07/2011 - 01/07/2011 | South Central- Oxford A Training meeting , NRES |
| Mr Shepherd Masara | 16/11/2011 - 16/11/2011 | Induction, NRES |
| Mr Shepherd Masara | 07/12/2011 - 07/12/2011 | Statistics, NRES |
| Mr Shepherd Masara | 04/11/2011 - 04/11/2011 | Shared Ethical Debate (Phase 1), NRES |
| Mr Martin Usherwood | 28/09/2011 - 28/09/2011 | Phase 1, NRES |
| Mr Martin Usherwood | 04/11/2011 - 04/11/2011 | Shared Ethical Debate (Phase 1), NRES |
| Mr Sean (Searalen) Chinnathumby | 04/10/2011 - 04/10/2011 | Induction, NRES |
| Mr Sean (Searalen) Chinnathumby | 21/07/2011 - 21/07/2011 | Equality & Diversity, NRES |
| Mr Sean (Searalen) Chinnathumby | 04/11/2011 - 04/11/2011 | Shared Ethical Debate (Phase 1), NRES |
| Mr Stuart Cole | 01/07/2011 - 01/07/2011 | South Central- Oxford Training meeting , NRES |
| Mr Stuart Cole | 16/11/2011 - 16/11/2011 | Induction, NRES |
| Mr Stuart Cole | 28/06/2011 - 28/06/2011 | Equality & Diversity, NRES/ Online |
| Mr Stuart Cole | 04/11/2011 - 04/11/2011 | Shared Ethical Debate (Phase 1), NRES |
| Mrs Lyndsay Hills | 01/07/2011 - 01/07/2011 | South Central - Oxford A Training day, NRES |
| Mrs Lyndsay Hills | 05/07/2011 - 05/07/2011 | Equality & Diversity, NRES |
| Mrs Lyndsay Hills | 28/10/2011 - 28/10/2011 | NRE Staff Update, NRES |
| Mrs Lyndsay Hills | 04/11/2011 - 04/11/2011 | Shared Ethical Debate (Phase 1), NRES |
| Mrs Marion Fiddes | 13/05/2011 - 02/06/2011 | Equality and Diversity, OTHER- SDL |
| Mrs Marion Fiddes | 12/05/2011 - 13/05/2011 | Introduction to information governance, OTHER- SDL |

| Mrs Marion Fiddes | 23/02/2012 - 23/02/2012 | Reviewing Clinical Trials of Investigational Medicinal Products; PO1101, NRES |
|------------------------|----------------------------|--|
| Mrs Marion Fiddes | 13/02/2012 - 13/02/2012 | ICR GCP Forum training day, NRES |
| Mrs Suzanne Cloke | 01/07/2011 - 01/07/2011 | South Central Oxford A Training day , NRES |
| Mrs Suzanne Cloke | 04/11/2011 - 04/11/2011 | Shared Ethical Debate (Phase 1), NRES |
| Ms Alison Eden | 01/11/2011 - 01/11/2011 | Clinical Trial of Investigational Medicinal Products (PO1101), NRES |
| Ms Alison Eden | 21/03/2012 - 21/03/2012 | Chairing Skills, NRES |
| Ms Alison Eden | 04/11/2011 - 04/11/2011 | Shared Ethical Debate (Phase 1), NRES |
| Ms Alison Eden | 14/03/2012 - 14/03/2012 | Members National Training Day, NRES |
| Ms Katherine Jacob | 01/07/2011 - 01/07/2011 | South Central - Oxford A Training day, NRES |
| Ms Raj Bains | 01/07/2011 - 01/07/2011 | South Central - Oxford A Training day, NRES |
| Ms Raj Bains | 14/03/2012 - 14/03/2012 | NRES Members National Training Day - London, NRES |
| Ms Sara Owen | 01/07/2011 - 01/07/2011 | South Central - Oxford a Training day, NRES |
| Ms Sara Owen | 17/06/2011 - 17/06/2011 | Equality & Diversity, NRES |
| Miss Tayo Jaiyesimi | 04/11/2011 - 04/11/2011 | Shared Ethical Debate (Phase 1), NRES |
| Miss Tayo Jaiyesimi | 16/11/2011 - 16/11/2011 | Induction, NRES |

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 | 19 | 27.94 |
| Phase 1 | 6 | 8.82 |
| Gene Therapy | 0 | 0.00 |
| Research Tissue Bank | 0 | 0.00 |
| Research Database | 0 | 0.00 |
| Others | 43 | 63.24 |
| Total Applications Reviewed | 68 | 100 |

Table 2: Other REC activity during the reporting period:

| Number of applications made invalid by co-ordinator | 1 |
|---|----|
| Number of studies withdrawn prior to the meeting | 10 |
| Number of student applications reviewed | 22 |
| Number of paediatric applications reviewed | 12 |
| Number of device applications reviewed | 2 |
| Number of prisoner applications reviewed | 0 |
| Number of applications involving adults unable consent reviewed | 0 |
| Number of applications reviewed funded by the US DHHS | 0 |

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 | 4 | 5.88 |
| Unfavourable Opinion | 3 | 4.41 |
| Provisional Opinion | 61 | 89.71 |
| Invalid | 0 | 0.00 |
| No Opinion Pending Consultation with Referee | 0 | 0.00 |
| Provisional Opinion Pending Consultation with Referee | 0 | 0.00 |
| Not Requiring Review by NHS REC | 0 | 0.00 |
| Total | 68 | 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 | 54 | 79.41 |
| Conditions | | |
| Further Information Favourable Opinion with Additional | 6 | 8.82 |
| Conditions | | |
| Further Information Unfavourable Opinion | 0 | 0.00 |
| Favourable Opinion with Standard Conditions | 0 | 0.00 |
| Favourable Opinion with Additional Conditions | 4 | 5.88 |
| Unfavourable Opinion | 3 | 4.41 |
| Provisional Opinion | 0 | 0.00 |
| Provisional Opinion Pending Consultation with Referee | 0 | 0.00 |
| Invalid | 0 | 0.00 |
| No Opinion Pending Consultation with Referee | 0 | 0.00 |
| Further Information response not complete | 0 | 0.00 |
| Not Requiring Review by NHS REC | 0 | 0.00 |
| No decision entered on RED | 0 | 0.00 |
| Number of studies withdrawn after the meeting | 1 | 1.47 |
| Total | 68 | 100 |

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

| Total Applications Reviewed | 8 |
|-----------------------------|---|

Table 6: 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 | 0 | 0.00 |
| Favourable Opinion with Additional Conditions | 1 | 12.50 |
| No Opinion transfer to full committee for review | 1 | 12.50 |
| Provisional Opinion | 4 | 50.00 |
| Unfavourable Opinion | 2 | 25.00 |
| Total | 8 | 100 |

Table 7: Other Management Information for the reporting period:

| Average number of applications reviewed per full meeting | 6.80 |
|---|--------|
| Average number of applications reviewed per full meetingNumber of applications for full ethical review over 60 days | 0 |
| Number of applications over 60 days as a % of total | 0.00% |
| | 30 |
| Number of days taken to final decision - average | 27 |
| Number of days taken to final decision - mode | 21 |
| Number of SSAs (non-Phase 1) reviewed | 12 |
| Number of applications for SSA review over 25 days | 1 |
| Number of applications for SSA review over 25 days as % of | 8.3% |
| all non-Phase 1 (SSAs) | |
| Number of SSAs (Phase 1) reviewed | 1 |
| Number of applications for SSA review over 14 days | 0 |
| Number of applications for SSA review over 14 days | 0.0% |
| all Phase 1 (SSAs) | 0.0 % |
| | |
| Number of substantial amendments reviewed | 154 |
| Number of substantial amendments over 35 days | 0 |
| Number of substantial amendments over 35 days as a % of | 0.0% |
| total substantial amendments | |
| | |
| Number of Section 30 applications reviewed | 0 |
| Number of Section 30 applications over 60 days | 0 |
| Number of Section 30 applications over 60 days as a % of total Section 30 applications | 0% |
| | |
| Number of modified amendments reviewed | 8 |
| Number of modified amendments over 14 days | 0 |
| Number of modified amendments over 14 days as a % of total modified amendments | 0.0% |
| | |
| Number of proportionate review applications for ethical | 1 |
| review over 14 days* | |
| Number of proportionate review applications over 14 days as a % of total | 14.29% |

*NB – Proportionate Review Service was in pilot phase until September 2011 and was an aim not a target

 Table 8: Breakdown of current status of all applications reviewed within the reporting period:

| Further Information Favourable Opinion with Standard Conditions | | |
|---|--|-------------------------|
| REC Reference | Application Short Title | Number of Days on Clock |
| 11/SC/0090 | Study into Needs of Inpatient Forensic CAMHS Staff | 33 |
| 11/SC/0097 | Bereavement Through Substance Misuse: A Qualitative Study | 48 |
| 11/SC/0098 | AZD1152 in diffuse large B-cell lymphoma | 37 |
| 11/SC/0099 | NIR imaging of SLN in gynaecological. | 34 |
| 11/SC/0100 | A DBS study in chronically implanted patients with PD V.1 | 47 |
| 11/SC/0101 | Pilot clinical trial iron chelator Deferiprone in Parkinson's Vs1 | 41 |
| 11/SC/0142 | Phase 2b study of LY3009104 in Rheumatoid Arthritis | 33 |
| 11/SC/0149 | V212-011 Study of Safety & Efficacy of V212 in patients with ST or HTM | 28 |
| 11/SC/0155 | Retinal Imaging in Diabetes Mellitus | 30 |
| 11/SC/0160 | The Acute Exercise Response in the Critically III (Version 2.1) | 32 |
| 11/SC/0163 | Genetics of papillary kidney cancers | 34 |
| 11/SC/0171 | Imaging the development of social behaviour (version 1) | 34 |
| 11/SC/0191 | SPIN - Phase 1 | 24 |
| 11/SC/0205 | TAP block for laparoscopic colonic resection | 28 |
| 11/SC/0206 | A qualitative study of the needs of relatives of neuro rehab patients. | 25 |
| 11/SC/0207 | Integrated Vital Sign Monitoring in Dialysis-Observational Study v.1 | 28 |
| 11/SC/0210 | T Cell receptor spectratyping in childhood nephrotic syndrome v.1 | 40 |
| 11/SC/0218 | Measuring motor symptoms in clinical conditions | 39 |
| 11/SC/0255 | CDEB025A2301 DEB025 in treatment naive, genotype1 Hepatitis C patients | 26 |
| 11/SC/0289 | Phase Ia study: Safety and Immunogenicity of ChAd63 CS and MVA CS | 21 |
| 11/SC/0299 | A trial to asses co-administration of MVA-NP+M1 and TIV | 22 |
| 11/SC/0302 | Understanding typhoid disease after vaccination; version 1. | 21 |
| 11/SC/0307 | Determinants of Staphylococcus aureus carriage | 34 |
| 11/SC/0308 | Oxford Pancreas Cohort Study | 31 |
| 11/SC/0310 | Cognitive Distortions in Young People: Development of a Measure | 44 |
| 11/SC/0315 | Reward processing in recovered anorexia nervosa | 29 |
| 11/SC/0319 | Mucociliary clearance (MCC) in Chronic Obstructive Pulmonary Disease | 23 |
| 11/SC/0351 | Assessing the infectivity of malaria parasites given by injection | 35 |
| 11/SC/0353 | Aerobic vs resistance training in weight management | 30 |

NRES Committee South Central - Oxford A Annual Report Page 14

| 11/SC/0355 | MBSR in the management of psychological distress in prostate cancer | 35 |
|------------|--|----|
| 11/SC/0356 | Improving Neutrophil responses in the healthy elderly | 27 |
| 11/SC/0357 | Illness representations in diabetes and depression (Version 1.1) | 36 |
| 11/SC/0358 | Rollover trial of Peg, RBV, BMS790052 +/- BMS650032 in HCV adults | 20 |
| 11/SC/0360 | Magec 0.1 | 36 |
| 11/SC/0361 | SPARROW study – SPAnidin in Relapsing gRanulomatosis with pOlyangiitis | 30 |
| 11/SC/0409 | VanSel-1: A Phase I trial of Vandetanib and Selumetinib. | 20 |
| 11/SC/0410 | VIT-0910 | 34 |
| 11/SC/0421 | comparison of mandibular arch width changes using two bracket systems | 30 |
| 11/SC/0426 | Osteoarthritis Thumb Therapy trial (OTTER trial) | 23 |
| 11/SC/0432 | CPET, echo and placental USS in pregnancy feasibility study | 28 |
| 11/SC/0433 | IDEB: Irinotecan Drug-Eluting Beads in Glioblastoma | 24 |
| 11/SC/0453 | Monotherapy Dalotuzumab and Ridaforolimus-Dalotuzumab Combination Ther | 39 |
| 11/SC/0464 | Noradrenaline potentiation and social and moral cognition | 27 |
| 11/SC/0495 | Deep Brain and Spinal Cord Stimulation for Pain Version 1 | 26 |
| 11/SC/0498 | Validation of biochemical methods in kidney disease | 27 |
| 11/SC/0510 | Immune response to RSV in health care workers | 27 |
| 11/SC/0511 | RT+nelfinavir in NSCLC | 26 |
| 11/SC/0547 | MRI correlates of RO4917838 treatment in schizophrenia | 43 |
| 11/SC/0548 | Electrocardiogram Scar Score (ECG-SS) | 42 |
| 12/SC/0006 | Understanding the Earliest Changes of Knee Arthritis | 43 |
| 12/SC/0014 | Vasopressin vs Noradrenaline as Initial therapy in Septic Shock | 35 |
| 12/SC/0020 | Investigating functional brain connectivity using TMS/fMRI | 26 |
| 12/SC/0039 | Retinal and optic nerve disease in MS and NMO/NMOSD. | 27 |
| 12/SC/0071 | Relative bioavailability of TMC435 in healthy adult subjects | 29 |
| 12/SC/0125 | Illness perceptions and reported health outcomes in patients with COPD | 9 |
| 12/SC/0127 | Mental health self-care support for children and young people (V.1) | 15 |

| Further Information Favourable Opinion with Additional Conditions | | |
|---|--|-------------------------|
| REC Reference | Application Short Title | Number of Days on Clock |
| 11/SC/0452 | Oral MK8669 in Children/Adolescents with Solid Tumours(6 - <18years) | 27 |
| 11/SC/0507 | An investigation of communication between cortex and the STN | 27 |
| 11/SC/0513 | 3561 Insulin degludec in children and adolescents with type 1 diabetes | 37 |

NRES Committee South Central - Oxford A Annual Report Page 15

| 12/SC/0011 | PK assessment of Mometasone Furoate via a nasal pump spray (QBR112283) | 35 |
|------------|--|----|
| 12/SC/0037 | A Challenge study to assess four new malaria vaccine candidates | 27 |
| 12/SC/0052 | Clinical diagnosis of acute appendicitis (v1.0) | 3 |
| 12/SC/0053 | Immunotolerance in Haemophilia A adults with FVIII inhibitors | 8 |
| 12/SC/0070 | Natsal - web panel methodological comparison study | 53 |

| Further Information Unfavourable Opinion | | |
|--|-------------------------|-------------------------|
| REC Reference | Application Short Title | Number of Days on Clock |

| Favourable Opinion with Standard Conditions | | |
|---|-------------------------|-------------------------|
| REC Reference | Application Short Title | Number of Days on Clock |

| Favourable Opinion with Additional Conditions | | |
|---|--|-------------------------|
| REC Reference | Application Short Title | Number of Days on Clock |
| 11/SC/0102 | Musculoskeletal Manipulations SOM | 31 |
| 11/SC/0152 | Study of sexual behaviours and alcohol use in young people | 31 |
| 11/SC/0473 | An alternative booster vaccine against meningitis and ear infections | 20 |
| 12/SC/0036 | Adjuvanting viral vectored malaria vaccines with Matrix M [™] (v 1.0) | 19 |
| 12/SC/0051 | PRESCRIBE | 2 |

| Unfavourable Opinion | | |
|----------------------|--|-------------------------|
| REC Reference | Application Short Title | Number of Days on Clock |
| 11/SC/0161 | CDEB025A2301 DEB025 in treatment naive, genotype1 Hepatitis C patients | 21 |
| 11/SC/0414 | Antidepressants, emotions and personality | 19 |
| 11/SC/0467 | Acceptibility of Awake Airtraq intubation (AAAI) | 21 |
| 12/SC/0050 | Azzalure® drug utilisation study | 6 |
| 12/SC/0128 | Post-traumatic growth in burn survivors | 11 |

| Provisional Opini | on | |
|--------------------------|-------------------------|-------------------------|
| REC Reference | Application Short Title | Number of Days on Clock |

| Provisional Opinion Pending Consultation with Referee | | |
|---|-------------------------|-------------------------|
| REC Reference | Application Short Title | Number of Days on Clock |

| Further information response not complete | | | |
|---|----------------------|-------------------------|-------------------------|
| | REC Reference | Application Short Title | Number of Days on Clock |
| | | | |

| Withdrawn after the meeting | | |
|-----------------------------|--------------------------------|-------------------------|
| REC Reference | Application Short Title | Number of Days on Clock |
| 11/SC/0466 | DETECT AF V3.0 AF-11-027-WW-IM | 26 |

| Invalid Application | | |
|----------------------|-------------------------|-------------------------|
| REC Reference | Application Short Title | Number of Days on Clock |

| No Opinion Pending Consultation with Referee | | |
|--|-------------------------|-------------------------|
| REC Reference | Application Short Title | Number of Days on Clock |
| Not Requiring Review by NHS REC | | |
| REC Reference | Application Short Title | Number of Days on Clock |

| Table 9: Items ex | ceeding timelines: |
|-------------------|--------------------|
|-------------------|--------------------|

| Full applications for ethical review over 60 day timeline | | |
|---|-------------------------|--|
| REC Reference | Application Short Title | |

Number of Days on Clock

| Proportionate review applications for ethical review over 14 days timeline | | | |
|--|---|-------------------------|--|
| REC Reference | Application Short Title | Number of Days on Clock | |
| 12/SC/0127 | Mental health self-care support for children and young people (V.1) | 15 | |

| SSAs (non Phase 1) over 25 days timeline | | |
|--|----------------------------|-------------------------|
| REC Reference | Application Short Title | Number of Days on Clock |
| 11/SC/0148 | Genetic causes of Headache | 35 |

| SSAs (Phase 1) over 14 days timeline | | |
|--------------------------------------|-------------------------|-------------------------|
| REC Reference | Application Short Title | Number of Days on Clock |

| Substantial Amendments over 35 day timeline | | | |
|---|-------------------------|-----------------|-------------------|
| Amendment Reference | Application Short Title | Amendment Title | Number of Days on |
| | | | Clock |

| Modified Amendments over 14 day timeline | | | |
|--|-------------------------|-----------------|-------------------|
| Amendment Reference | Application Short Title | Amendment Title | Number of Days on |
| | | | Clock |

| Section 30 application over 60 day timeline | | | |
|---|-------------------------|-----------------|-------------------|
| Amendment Reference | Application Short Title | Amendment Title | Number of Days on |
| | | | Clock |