

**RES Committee South West - Cornwall &  
Plymouth**

**Annual Report**

**01 April 2014 - 31 March 2015**



## Part 1 – Committee Membership and Training

|                              |  |
|------------------------------|--|
| <b>Name of REC:</b>          | RES Committee South West - Cornwall & Plymouth                         |
| <b>Type of REC:</b>          | Authorised   |
| <b>Type of Flag:</b>         | Paediatric<br>Qualitative  |
| <b>Chair:</b>                | Canon Ian Ainsworth-Smith  |
| <b>Vice-Chair:</b>           | Mrs Sheila Bullard   |
| <b>Alternate Vice-Chair:</b> | Dr Sheila Dziobon  |
| <b>REC Manager:</b>          | Mrs Kirsten Peck   |
| <b>REC Assistant:</b>        | Miss Georgina Castledine   |
| <b>Committee Address:</b>    | Level 3<br>Block B<br>Whitefriars<br>Lewins Mead<br>Bristol<br>BS1 2NT |
| <b>Telephone:</b>            | 0117 342 1332  |
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## Chair's overview of the past year:

We have continued to review a wide selection of studies and we have particularly valued meeting applicants in person, where possible, and the subsequent discussion. The ethical issues frequently emerge and can be addressed in collaboration. The Committee can then best fulfil its "critical friend" role in supporting and critiquing potentially worthwhile and ethical research. The Chair now has a regular teaching commitment on the nursing research methods course at Derriford Hospital. We have noticed the increased number of studies being submitted for proportionate review and I am particularly grateful to our members who volunteer to provide a review each month between full REC meetings. Several members have moved on during the year due to other commitments - in every case their contribution to our work has been highly valued and has added to our shared "learning curve". We have also been delighted to welcome new members. I hope that our REC, with its mixture of expertise and backgrounds provides a rigorous but supportive service to researchers. Feedback suggests that this is mostly the case. We encounter some highly experienced researchers, Others are coming to us early in their research career. I hope, that we can offer a service to both groups. My sincere thanks go to my colleagues, both members and managers, for their loyal and willing support during the year.

## RES Committee South West - Cornwall & Plymouth Membership

| Name                      | Profession                                      | Expert or Lay | Dates      |            |
|---------------------------|---|---------------|------------|------------|
|                           |   |               | Appointed  | Left       |
| Miss Clare Adams          | Consultant Colorectal and General Surgeon       | Expert        | 19/01/2015 |            |
| Canon Ian Ainsworth-Smith | Retired Hospital Chaplain                       | Lay Plus      | 01/02/2009 |            |
| Mrs Suzanne Lesley Blowey | Consultant Nurse Chronic Pain                   | Expert        | 01/04/2009 |            |
| Mrs Sheila Bullard        | Clinical Research Project Manager               | Lay           | 30/04/2014 |            |
| Mr Rich Crowe             | Retired Planning Manager                        | Lay Plus      | 01/04/2011 | 30/04/2014 |
| Dr Sheila Dziobon         | Retired Lecturer in Law                         | Lay Plus      | 01/10/2013 |            |
| Dr Stephen Lewis          | Consultant Gastroenterologist                   | Expert        | 01/10/2014 |            |
| Dr Veronica Maynard       | Senior Lecturer Postgraduate Clinical Education | Expert        | 01/04/2011 | 25/11/2014 |
| Mr Louis Pobereskin       | Consultant Neurosurgeon                         | Expert        | 01/04/2011 |            |
| Mr Rory Rickard           | Consultant Burns & Plastic Surgeon              | Expert        | 31/05/2009 | 19/11/2014 |
| Dr Hilary Sanders         | Retired Senior Lecturer in Statistics           | Expert        | 01/01/2006 |            |
| Miss Rosalyn Squire       | Research Nurse                                  | Expert        | 01/04/2011 |            |
| Mrs Caroline Theyer       | Solicitor                                       | Lay Plus      | 01/04/2011 |            |
| Mr Roger Watkins          | Retired Consultant Surgeon                      | Expert        | 01/04/2011 | 24/02/2015 |
| Mr Christopher Winfield   | Programme Manager                               | Lay Plus      | 01/09/2009 | 22/08/2014 |
| Mr Robert Wosley          | Research & Quality Manager                      | Lay           | 01/04/2011 |            |

## NRES Committee South West - Cornwall & Plymouth: Deputy Members

| Name | Profession | Status | Meeting date attended |
|------|------------|--------|-----------------------|
|------|------------|--------|-----------------------|

## NRES Committee South West - Cornwall & Plymouth: Co-opted Members

| Name                 | Profession                     | Status   | Meeting date attended |
|----------------------|--------------------------------|----------|-----------------------|
| Mrs Carol Richardson | Senior Nurse (Retired)         | Lay      | 15/04/2014            |
| Dr Chris Vallance    | Retired chemist (non-research) | Lay Plus | 21/08/2014            |

**NRES Committee South West - Cornwall & Plymouth: Members' Declarations of Interest:**

| <b>Name</b>               | <b>Declaration of Interest</b>  | <b>Date</b> |
|---------------------------|---|-------------|
| Miss Clare Adams          | None  | 20/02/2015  |
| Canon Ian Ainsworth-Smith | None  | 15/12/2014  |
| Mrs Suzanne Blowey        | NICE - Clinical guideline group LPPNICE<br>Panel member British Pain Society  | 15/12/2014  |
| Dr Leonard Brookes        | Sole trader acting as an independent consultant to the bio/pharmaceutical industry.   | 28/11/2014  |
| Mrs Sheila Bullard        | None  | 31/03/2015  |
| Dr Sheila Dziobon         | Member of Benenden Health   | 15/12/2014  |
| Dr Stephen Lewis          | None  | 12/12/2014  |
| Mr Louis Pobereskin       | None  | 16/02/2015  |
| Mr Rory Rickard           | None  | 18/11/2014  |
| Dr Hilary Sanders         | None  | 12/05/2014  |
| Dr Hilary Sanders         | None  | 09/12/2014  |
| Miss Rosalyn Squire       | None  | 15/12/2014  |
| Mrs Caroline Theyer       | None  | 30/03/2015  |
| Mr Christopher Winfield   | None  | 15/07/2014  |
| Mr Robert Wosley          | Member of Plymouth and district Leukaemia fund<br>Governance Manager for Haematology and<br>Oncology at Plymouth hospitals NHS Trust<br>Research Active | 15/12/2014  |

### Meetings for Full Ethical Review 01 April 2014 - 31 March 2015:

| Month    | Date       | Number of Members Present at Meeting |
|----------|------------|--------------------------------------|
| April    | 15/04/2014 | 9                                    |
| May      | 20/05/2014 | 8                                    |
| June     | 17/06/2014 | 7                                    |
| July     | 15/07/2014 | 10                                   |
| August   | 21/08/2014 | 7                                    |
| October  | 21/10/2014 | 9                                    |
| November | 18/11/2014 | 9                                    |
| December | 09/12/2014 | 7                                    |
| January  | 20/01/2015 | 12                                   |
| February | 17/02/2015 | 10                                   |
| March    | 17/03/2015 | 11                                   |

11 full committee meetings were held during the reporting period.

### Proportionate Review Sub-Committee Meetings held during 01 April 2014 - 31 March 2015:

| Month    | Date       | Number of Members Present at Meeting |
|----------|------------|--------------------------------------|
| April    | 14/04/2014 | 3                                    |
| May      | 19/05/2014 | 3                                    |
| June     | 23/06/2014 | 3                                    |
| July     | 21/07/2014 | 3                                    |
| August   | 19/08/2014 | 6                                    |
| August   | 26/08/2014 | 3                                    |
| October  | 21/10/2014 | 7                                    |
| November | 18/11/2014 | 5                                    |
| November | 24/11/2014 | 3                                    |
| December | 15/12/2014 | 3                                    |
| February | 17/02/2015 | 8                                    |
| February | 23/02/2015 | 3                                    |
| March    | 23/03/2015 | 3                                    |

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

### Sub-Committee Meetings held during 01 April 2014 - 31 March 2015:

| Month | Date       | Number of Members Present at Meeting |
|-------|------------|--------------------------------------|
| April | 04/04/2014 | 2                                    |
| April | 08/04/2014 | 2                                    |
| April | 25/04/2014 | 2                                    |
| May   | 09/05/2014 | 2                                    |
| June  | 13/06/2014 | 2                                    |
| June  | 24/06/2014 | 2                                    |
| July  | 04/07/2014 | 2                                    |

|           |            |   |
|-----------|------------|---|
| July      | 18/07/2014 | 3 |
| July      | 29/07/2014 | 2 |
| August    | 11/08/2014 | 2 |
| August    | 22/08/2014 | 2 |
| September | 01/09/2014 | 2 |
| September | 17/09/2014 | 2 |
| September | 26/09/2014 | 2 |
| October   | 03/10/2014 | 2 |
| October   | 17/10/2014 | 2 |
| October   | 24/10/2014 | 2 |
| November  | 06/11/2014 | 2 |
| November  | 17/11/2014 | 2 |
| November  | 25/11/2014 | 2 |
| December  | 05/12/2014 | 2 |
| December  | 19/12/2014 | 2 |
| January   | 14/01/2015 | 2 |
| January   | 29/01/2015 | 2 |
| February  | 09/02/2015 | 2 |
| February  | 23/02/2015 | 2 |
| March     | 20/03/2015 | 2 |

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

#### Details of inquorate meeting held: 01 April 2014 - 31 March 2015

0

### Attendance of Members at full committee meetings:01 April 2014 - 31 March 2015

| Name                      | Number of Meetings Attended |
|---------------------------|-----------------------------|
| Miss Clare Adams          | 3                           |
| Canon Ian Ainsworth-Smith | 10                          |
| Mrs Suzanne Blowey        | 7                           |
| Mrs Sheila Bullard        | 8                           |
| Mr Rich Crowe             | 1                           |
| Dr Sheila Dziobon         | 8                           |
| Dr Stephen Lewis          | 4                           |
| Dr Veronica Maynard       | 2                           |
| Mr Louis Pobereskin       | 5                           |
| Mr Rory Rickard           | 1                           |
| Dr Hilary Sanders         | 10                          |
| Miss Rosalyn Squire       | 11                          |
| Mrs Caroline Theyer       | 6                           |
| Mr Roger Watkins          | 6                           |
| Mr Christopher Winfield   | 4                           |
| Mr Robert Wosley          | 11                          |

### Attendance of Members at proportionate review sub-committee meetings: 01 April 2014 - 31 March 2015

| Name                      | Number of Meetings Attended |
|---------------------------|-----------------------------|
| Miss Clare Adams          | 1                           |
| Canon Ian Ainsworth-Smith | 12                          |
| Mrs Suzanne Lesley Blowey | 4                           |
| Mrs Sheila Bullard        | 4                           |
| Dr Sheila Dziobon         | 3                           |
| Dr Stephen Lewis          | 1                           |
| Mr Louis Pobereskin       | 1                           |
| Dr Hilary Sanders         | 4                           |
| Miss Rosalyn Squire       | 11                          |
| Mrs Caroline Theyer       | 3                           |
| Mr Roger Watkins          | 3                           |
| Mr Christopher Winfield   | 1                           |
| Mr Robert Wosley          | 5                           |

### Attendance of Members at sub-committee meetings: 01 April 2014 - 31 March 2015

| Name                      | Number of Meetings Attended |
|---------------------------|-----------------------------|
| Canon Ian Ainsworth-Smith | 27                          |



|                    |    |
|--------------------|----|
| Mrs Sheila Bullard | 26 |
| Dr Hilary Sanders  | 1  |
| Mr Robert Wosley   | 1  |

**Training 01 April 2014 - 31 March 2015**

| <b>Name of Member</b>     | <b>Date</b> | <b>Event(s) attended</b>                                     |
|---------------------------|-------------|--|
| Miss Clare Adams          | 14/11/2014  | Equality, Diversity and Interview Techniques Training Course |
| Canon Ian Ainsworth-Smith | 10/12/2014  | National Training Day for NRES                               |
| Canon Ian Ainsworth-Smith | 11/12/2014  | Research in Vulnerable Groups                                |
| Canon Ian Ainsworth-Smith | 20/02/2015  | Equality and Diversity                                       |
| Canon Ian Ainsworth-Smith | 24/02/2015  | Talk for Nursing Research Methods Course                     |
| Mrs Sheila Bullard        | 29/05/2014  | NREAP Chair's Meeting  |
| Mrs Sheila Bullard        | 20/11/2014  | NREAP Chair's Meeting  |
| Mrs Sheila Bullard        | 19/03/2015  | Equality and Diversity                                       |
| Dr Sheila Dziobon         | 12/06/2014  | NRES Committee Members Induction                             |
| Dr Sheila Dziobon         | 24/06/2014  | Equality and Diversity                                       |
| Dr Sheila Dziobon         | 26/02/2015  | Training for New REC Chairs                                  |
| Dr Stephen Lewis          | 09/03/2015  | Training - NRES Committee Members                            |
| Dr Stephen Lewis          | 24/03/2015  | Equality and Diversity Awareness                             |
| Mr Louis Pobereskin       | 18/11/2014  | Equality and Diversity Awareness                             |
| Dr Hilary Sanders         | 27/11/2014  | Statistical Advice for RECS                                  |
| Mrs Caroline Theyer       | 31/03/2015  | Read Bad Science   |
| Mr Robert Wosley          | 01/04/2014  | European Blood and Marrow Transplantation Conference         |
| Mr Robert Wosley          | 21/11/2014  | JACIE Quality Forum UK & Ireland                             |
| Mr Robert Wosley          | 13/02/2015  | Read HRA PowerPoint 'Human Tissue Act'                       |

## 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)                   | 0             | 0.00       |
| Others   | 7             | 100.00     |
| <b>Total Applications Reviewed</b>                       | <b>37</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           | 0  |
| Number of student applications reviewed                         | 13 |
| Number of paediatric applications reviewed                      | 5  |
| Number of device applications reviewed                          | 1  |
| 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                     | 6  |

**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                             | 0             | 0.00       |
| Favourable Opinion with Additional Conditions                           | 4             | 10.81      |
| Unfavourable Opinion  | 2             | 5.41       |
| Provisional Opinion   | 31            | 83.78      |
| Provisional Opinion Pending Consultation with Referee                   | 0             | 0.00       |
| <b>Total</b>  | <b>37</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   | 30            | 81.08      |
| Further Information Favourable Opinion with Additional Conditions | 0             | 0.00       |
| Further Information Unfavourable Opinion                          | 0             | 0.00       |
| Favourable Opinion with Standard Conditions                       | 0             | 0.00       |
| Favourable Opinion with Additional Conditions                     | 4             | 10.81      |
| Unfavourable Opinion  | 2             | 5.41       |
| 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             | 2.70       |
| <b>Total</b>  | <b>37</b>     | <b>100</b> |

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

|                                    |           |
|------------------------------------|-----------|
| <b>Total Applications Reviewed</b> | <b>36</b> |
|------------------------------------|-----------|

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

|  |    |
|--|----|
| Number of applications made invalid by the REC Manager | 4  |
| Number of studies withdrawn prior to the meeting       | 2  |
| Number of student applications reviewed                | 18 |
| Number of paediatric applications reviewed             | 4  |
| 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**

| <b>Decisions taken at proportionate review sub-committee meetings</b> | <b>Number</b> | <b>%</b>   |
|---|---------------|------------|
| Favourable Opinion with Standard Conditions                           | 6             | 16.67      |
| Favourable Opinion with Additional Conditions                         | 14            | 38.89      |
| No Opinion transfer to full committee for review                      | 0             | 0.00       |
| Provisional Opinion   | 16            | 44.44      |
| Unfavourable Opinion  | 0             | 0.00       |
| <b>Total</b>  | <b>36</b>     | <b>100</b> |

**Table 8: Other Management Information for the reporting period:**

|   |        |
|---|--------|
| <b>Average number of applications reviewed per full meeting</b>                             | 3.36   |
| <b>Number of applications for full ethical review</b>                                       | 36     |
| <b>Number of applications for full ethical review over 60 days</b>                          | 0      |
| <b>Number of applications over 60 days as a % of total</b>                                  | 0.00%  |
| <b>Number of applications for full ethical review over 40 days</b>                          | 6      |
| <b>Number of applications over 40 days as a % of total</b>                                  | 16.22% |
| <b>Number of days taken to final decision – average (mean)</b>                              | 33     |
| <b>Number of proportionate review applications for ethical review</b>                       | 36     |
| <b>Number of proportionate review applications for ethical review over 14 days</b>          | 3      |
| <b>Number of proportionate review applications over 14 days as a % of total</b>             | 8.33%  |
| <b>Number of SSAs (non-Phase 1) reviewed</b>  | 3      |
| <b>Number of applications for SSA review over 25 days</b>                                   | 0      |
| <b>Number of 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 applications for SSA review over 14 days</b>                                   | 0      |
| <b>Number of applications for SSA review over 14 days as % of all Phase 1 SSAs</b>          | 0.00%  |
| <b>Number of substantial amendments reviewed</b>  | 45     |
| <b>Number of substantial amendments over 35 days</b>  | 1      |
| <b>Number of substantial amendments over 35 days as a % of total substantial amendments</b> | 2.22%  |
| <b>Number of substantial amendments over 28 days</b>  | 2      |
| <b>Number of substantial amendments over 28 days as a % of total substantial amendments</b> | 4.44%  |
| <b>Number of modified amendments reviewed</b>   | 0      |
| <b>Number of modified amendments over 14 days</b>   | 0      |
| <b>Number of modified amendments over 14 days as a % of total modified amendments</b>       | 0.00%  |
| <b>Number of minor amendments received</b>  | 31     |
| <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>   | 39     |
| <b>Number of safety reports received</b>  | 2      |
| <b>Number of Serious Adverse Events received</b>  | 0      |
| <b>Number of final reports received</b>   | 16     |

**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> |
| 14/SW/0057   | Balance dysfunction in diabetic peripheral neuropathy - Version 1      | 33                             |
| 14/SW/0084   | Accelerated Long-term Forgetting in Memory Clinics                     | 37                             |
| 14/SW/0111   | Exercise Prescription in Multiple Sclerosis Version 1                  | 28                             |
| 14/SW/0122   | Accuracy Trial of MBIR Technique in CT Kidney/Ureter/Bladder           | 35                             |
| 14/SW/0123   | Biological Rhythms in Human Skeletal Muscle v1                         | 49                             |
| 14/SW/0126   | Comparing Soft Drink vs Carbex for Double Contrast Upper GI Studies    | 25                             |
| 14/SW/0136   | Body mass index and outcomes of gynaecological cancer patients (1.0)   | 30                             |
| 14/SW/1001   | An investigation into the containment of personality disorder          | 46                             |
| 14/SW/1005   | Resting, Waiting and Working: an fMRI study in ADHD                    | 23                             |
| 14/SW/1025   | Family talk around Autistic Spectrum Condition. v1.0                   | 39                             |
| 14/SW/1028   | Exercise in children with type 1 diabetes.                             | 40                             |
| 14/SW/1038   | The Plymouth EarlyBird 3 Study   | 40                             |
| 14/SW/1045   | Exploring and Understanding Diagnosis and Choice in Pregnancy.         | 57                             |
| 14/SW/1059   | A Feasibility Study of Brain MRI in Low Back Pain                      | 22                             |
| 14/SW/1105   | Understanding barriers and enablers to altruistic kidney donation V:1  | 55                             |
| 14/SW/1109   | The Cost in Oxygen of Surgical Trauma (CO2ST)                          | 26                             |
| 14/SW/1151   | Fetal fibronectin (fFN) for the prediction of term delivery            | 31                             |
| 14/SW/1152   | STARTRIGHT Pilot study   | 48                             |
| 14/SW/1161   | Adductor canal vs. femoral nerve catheter for TKR                      | 23                             |
| 14/SW/1169   | Rhythmic movement disorder: a prevalence and phenotyping study         | 22                             |
| 14/SW/1172   | Processing of a sad memory in individuals with a history of depression | 42                             |
| 14/SW/1174   | Silver ion analysis of silver coated endoprosthesis                    | 30                             |
| 15/SW/0014   | Can exercise counteract the effects of overfeeding and under-activity? | 40                             |
| 15/SW/0018   | Daily Immunoglobulin Replacement - a viable alternative?               | 23                             |
| 15/SW/0027   | Randomised clinical investigation of the Bi flex M multifocal IOL      | 25                             |
| 15/SW/0034   | EMDR to treat patients with psychosis.                                 | 21                             |
| 15/SW/0074   | ReTrain pilot RCT  | 32                             |
| 15/SW/0075   | Does weight matter?  | 36                             |
| 15/SW/0076   | MONACO   | 44                             |
| 15/SW/0077   | Describing and Treating Severe Hypertension (DASHER)                   | 30                             |

| <b>Further Information Favourable Opinion with Additional Conditions</b> |              |                                |
|--|--------------|--------------------------------|
| <b>REC Reference</b>   | <b>Title</b> | <b>Number of Days on Clock</b> |

| <b>Further Information Unfavourable Opinion</b> |              |                                |
|---|--------------|--------------------------------|
| <b>REC Reference</b>                            | <b>Title</b> | <b>Number of Days on Clock</b> |

| <b>Favourable Opinion with Standard Conditions</b> |              |                                |
|--|--------------|--------------------------------|
| <b>REC Reference</b>                               | <b>Title</b> | <b>Number of Days on Clock</b> |

| <b>Favourable Opinion with Additional Conditions</b> |   |                                |
|--|---|--------------------------------|
| <b>REC Reference</b>                                 | <b>Title</b>  | <b>Number of Days on Clock</b> |
| 14/SW/0060   | Exercise and bone health in adolescents engaged in different sports | 23                             |
| 14/SW/0116   | Effectiveness of a DEFO for plantar fasciitis: A feasibility study  | 27                             |
| 14/SW/0117   | Does bladder training improve efficacy of PTNS in refractory OAB    | 27                             |
| 14/SW/1040   | Body reprogramming for fibromyalgia: initial evaluation             | 22                             |

| <b>Unfavourable Opinion</b> |   |                                |
|-----------------------------|---|--------------------------------|
| <b>REC Reference</b>        | <b>Title</b>  | <b>Number of Days on Clock</b> |
| 14/SW/1149                  | Efficacy/tolerability of Flex-Aid in subjects with night leg cramps | 29                             |
| 15/SW/0019                  | CTCA feasibility in routine CTTAP version 1, 25/08/2014             | 21                             |

| <b>Provisional Opinion</b> |              |                                |
|----------------------------|--------------|--------------------------------|
| <b>REC Reference</b>       | <b>Title</b> | <b>Number of Days on Clock</b> |

| <b>Provisional Opinion Pending Consultation with Referee</b> |              |                                |
|--|--------------|--------------------------------|
| <b>REC Reference</b>   | <b>Title</b> | <b>Number of Days on Clock</b> |

| <b>Further information response not complete</b> |              |                                |
|--|--------------|--------------------------------|
| <b>REC Reference</b>                             | <b>Title</b> | <b>Number of Days on Clock</b> |



| <b>Withdrawn after the meeting</b> |                                    |                                |
|------------------------------------|------------------------------------|--------------------------------|
| <b>REC Reference</b>               | <b>Title</b>                       | <b>Number of Days on Clock</b> |
| 15/SW/0011                         | Multi-disciplinary teams in action | 56                             |

**Table 9.2: Breakdown of current status of all PRS 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> |
| 14/SW/1042   | REPORT-HF: a heart failure disease registry                         | 15                             |
| 14/SW/1080   | bioCSL Influenza Vaccine PASS                                       | 9                              |
| 14/SW/1137   | ADHD and physical activity. Version 1                               | 12                             |
| 14/SW/1138   | Cardiac Sarcoidosis Consortium - International Registry             | 19                             |
| 14/SW/1167   | BP Self-Screening Feasibility Study                                 | 11                             |
| 14/SW/1171   | Links between osteoarthritis, hypertension and vascular disease     | 11                             |
| 14/SW/1181   | YoDA BRCA: Genetic Testing Decision Aid for young women             | 8                              |
| 14/SW/1182   | SMS reminders for Stroke Secondary Preventative Medications         | 8                              |
| 15/SW/0038   | Investigating the impact of age on the immune system (Im-AGE) V 1.0 | 11                             |
| 15/SW/0040   | Survival analysis of full mouth reconstructions                     | 13                             |
| 15/SW/0042   | Lifestyle Self-management experience of South Asians                | 10                             |
| 15/SW/0045   | A pilot study of a tablet-based app for rehabilitation after stroke | 8                              |
| 15/SW/0047   | Positive Mindfulness Project  | 7                              |
| 15/SW/0048   | Environmental Factors in the Aetiology of Autoimmune Liver Disease  | 10                             |
| 15/SW/0095   | 3D imaging investigation of cleft lip and palate.                   | 13                             |
| 15/SW/0096   | Cognitive Dysfunction in Coeliac Disease                            | 9                              |

| <b>Further Information Favourable Opinion with Additional Conditions</b> |              |                                |
|--|--------------|--------------------------------|
| <b>REC Reference</b>   | <b>Title</b> | <b>Number of Days on Clock</b> |

**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 |
|---------------|--|-------------------------|
| 14/SW/1046    | Acu-TENS for relief of dyspnoea in palliative care patients: Version 1 | 12                      |
| 14/SW/1083    | Adult stem cell collection for basic science research                  | 6                       |
| 14/SW/1155    | Follow-up and Outcomes of Pregnancies Exposed to ellaOne               | 17                      |
| 14/SW/1170    | Investigating cancer stem cell markers in breast cancer                | 10                      |
| 14/SW/1180    | Questionnaire: Peanut introduction post negative OFC in children V1    | 8                       |
| 15/SW/0091    | Diagnosis of ACS in renal patients using hsTnT & PAPP-A (v.1)          | 12                      |

### Favourable Opinion with Additional Conditions

| REC Reference | Title  | Number of Days on Clock |
|---------------|--|-------------------------|
| 14/SW/0096    | An examination of cancer biomarkers in prostate and bowel tissues      | 13                      |
| 14/SW/0099    | PD-HELP (Phase I & II)   | 8                       |
| 14/SW/0127    | Has HPV cervical screening reduced unnecessary excisional treatments?  | 11                      |
| 14/SW/0129    | Patient, family and staff views of the Cancer treatment environment.   | 7                       |
| 14/SW/0132    | Distress in IBD  | 6                       |
| 14/SW/1020    | STRATEgY   | 14                      |
| 14/SW/1022    | Non-English-speaking cancer patients' experiences of palliative care   | 14                      |
| 14/SW/1043    | Information needs and choice between providers of surgical care        | 13                      |
| 14/SW/1044    | Families experiences of using a CAMHS homebased intensive treatment te | 7                       |
| 14/SW/1072    | IPA of the perceptions of diabetes-related complications in DFU        | 7                       |
| 14/SW/1081    | Feasibility and Acceptability Study of a Paediatric Asthma Action Plan | 8                       |
| 14/SW/1168    | DACoRe Study (Protocol version 1.0 dated 22nd May 2013)                | 9                       |
| 14/SW/1184    | Observational study on the use of dental conscious sedation            | 8                       |
| 15/SW/0089    | Entyvio(vedolizumab) long-term safety study                            | 12                      |

### Unfavourable Opinion

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

### 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**

| <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> |
| 04/Q2103/8/AM07                | South West impact of multiple sclerosis (SWIMS)                       | 12             | 09/04/2014  | 8                              |
| 05/Q2103/100/AM02              | BD DIAGNOSTICS PAS PLYMOUTH PLANT SAMPLE COLLECTION SCHEME.           | 3              | 24/07/2014  | 17                             |
| 06/Q2008/6/AM13                | Diarrhoea diagnostic device   | 12             | 28/10/2014  | 14                             |
| 10/H0203/29/AM08               | ULA-OP FMD  | 7              | 15/09/2014  | 15                             |
| 11/SW/0343/AM01                | CLOSTRIDIUM DIFFICILE IN PATIENTS WITH INFLAMMATORY BOWEL DISEASE     | 1              | 02/07/2014  | 21                             |
| 11/SW/0350/AM01                | A Model of Emotion Regulation in Therapeutic Relationships            | 1              | 16/05/2014  | 6                              |
| 11/SW/0351/AM03                | PROXIMA - version 1.0 - 12 May 2011                                   | 2              | 16/06/2014  | 6                              |
| 12/SW/0021/AM03                | Pilot Study to compare Local Anaesthetic techniques in Breast Surgery | 1              | 15/08/2014  | 7                              |
| 12/SW/0181/AM04                | Economic Evaluation of the Aptima TV TMA Test                         | 3              | 14/08/2014  | 28                             |
| 12/SW/0216/AM05                | Follow up study of aHUS patients treated with eculizumab              | 1              | 11/03/2015  | 9                              |
| 12/SW/0227/AM04                | Computerised cognitive assessments (CoCoA)                            | 3              | 22/12/2014  | 11                             |
| 12/SW/0314/AM02                | The CHECK-UP Study  | 2              | 22/09/2014  | 4                              |
| 12/SW/0347/AM06                | Pro Master  |                | 25/03/2014  | 32                             |
| 12/SW/0347/AM06                | Pro Master  | 4              | 25/03/2014  | 32                             |
| 12/SW/0348/AM07                | Retro Master  | 3              | 02/12/2014  | 6                              |
| 13/SW/0068/AM02                | Health anxiety in Chronic Fatigue Syndrome                            | 2              | 16/06/2014  | 8                              |
| 13/SW/0111/AM02                | Is MRI better than CT for diagnosis of occult wrist fractures V 3.0   | 4              | 06/06/2014  | 18                             |
| 13/SW/0126/AM01                | Genetics of Diabetes Associated Hormones(GENDA H)                     | 1              | 25/04/2014  | 11                             |
| 13/SW/0126/AM02                | Genetics of Diabetes Associated Hormones(GENDA H)                     | 2              | 07/10/2014  | 13                             |
| 13/SW/0129/AM02                | Physical activity promotion in cystic fibrosis patients               | 2              | 17/07/2014  | 12                             |
| 13/SW/0201/AM05                | Chemotherapy induced cognitive changes in colorectal cancer patients  | 3              | 14/04/2014  | 7                              |
| 13/SW/0202/AM02                | Undiagnosed Hyperparathyroidism and Recurrent Miscarriage Version 1.0 | 1              | 11/03/2014  | 28                             |
| 13/SW/0225/AM01                | Markers in inflammation   | 1              | 09/05/2014  | 9                              |
| 13/SW/0225/AM02                | Markers in inflammation   | 2              | 27/10/2014  | 22                             |
| 13/SW/0227/AM01                | Measurement of Inorganic Nitrate Synthesis in Haemodialysis           | 1              | 30/10/2014  | 8                              |

|                 |  |   |            |    |
|-----------------|--|---|------------|----|
|                 | Patients   |   |            |    |
| 13/SW/0310/AM01 | Instant insole enhancement for ulcer prevention: a feasibility trial   | 1 | 13/06/2014 | 14 |
| 14/SW/0024/AM01 | HomeR  | 1 | 15/04/2014 | 36 |
| 14/SW/0043/AM01 | PRDM9 in childhood leukaemia   | 1 | 26/06/2014 | 4  |
| 14/SW/0048/AM01 | MBCT for people with vascular disorders version 1.0                    |   | 19/05/2014 | 10 |
| 14/SW/0049/AM01 | The Optimal Collection Method for Measuring Albumin in Urine.          | 1 | 07/01/2015 | 2  |
| 14/SW/0056/AM02 | PrEvENT: Prostate Cancer Evidence of Exercise and Nutrition Trial V1.0 | 1 | 13/08/2014 | 21 |
| 14/SW/0056/AM03 | PrEvENT: Prostate Cancer Evidence of Exercise and Nutrition Trial V1.0 | 2 | 21/10/2014 | 7  |
| 14/SW/0060/AM01 | Exercise and bone health in adolescents engaged in different sports    | 1 | 29/09/2014 | 14 |
| 14/SW/0078/AM02 | SHOES  | 1 | 30/07/2014 | 10 |
| 14/SW/0078/AM05 | SHOES  | 2 | 15/12/2014 | 14 |
| 14/SW/0084/AM01 | Accelerated Long-term Forgetting in Memory Clinics                     | 1 | 22/09/2014 | 13 |
| 14/SW/0099/AM01 | PD-HELP (Phase I & II)   | 1 | 02/09/2014 | 9  |
| 14/SW/0099/AM02 | PD-HELP (Phase I & II)   | 2 | 15/10/2014 | 6  |
| 14/SW/0099/AM06 | PD-HELP (Phase I & II)   | 3 | 30/01/2015 | 7  |
| 14/SW/1020/AM01 | STRATEgY   | 1 | 22/10/2014 | 7  |
| 14/SW/1025/AM01 | Family talk around Autistic Spectrum Condition. v1.0                   | 1 | 12/12/2014 | 6  |
| 14/SW/1038/AM01 | The Plymouth EarlyBird 3 Study   | 1 | 07/11/2014 | 8  |
| 14/SW/1043/AM01 | Information needs and choice between providers of surgical care        | 1 | 23/07/2014 | 6  |
| 14/SW/1105/AM01 | Understanding barriers and enablers to altruistic kidney donation V:1  | 1 | 04/03/2015 | 18 |
| 14/SW/1174/AM01 | Silver ion analysis of silver coated endoprosthesis                    | 1 | 20/02/2015 | 1  |
| 1703/AM06       | Why some people are susceptible to hepatitis C and not others?         | 6 | 15/08/2014 | 16 |

### Unfavourable opinion

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

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

| <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> |

| <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> |

**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 14 day timeline**

| REC Reference | Title  | Number of Days on Clock |
|---------------|--|-------------------------|
| 14/SW/1042    | REPORT-HF: a heart failure disease registry              | 15                      |
| 14/SW/1138    | Cardiac Sarcoidosis Consortium - International Registry  | 19                      |
| 14/SW/1155    | Follow-up and Outcomes of Pregnancies Exposed to ellaOne | 17                      |

**SSAs (non Phase 1) over 25 day timeline**

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

**SSAs (Phase 1) over 14 day timeline**

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

**Substantial Amendments over 35 day timeline**

| Amendment REC Reference | Title | Version | Date       | Number of Days on Clock |
|-------------------------|-------|---------|------------|-------------------------|
| 14/SW/0024/AM01         | HomeR | 1       | 15/04/2014 | 36                      |

**Modified Amendments over 14 day timeline**

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