

**NRES Committee North East -  
Sunderland**

**Annual Report**

**01 April 2011 – 31 March 2012**

## Part 1 – Committee Membership and Training

**Name of REC:** NRES Committee North East - Sunderland

**Type of REC:** III

**Type of Flag:** Paediatrics, CTIMPs

**Chair:** Mr Paddy Stevenson

**Vice-Chair:** Mrs Cheryl Anderson

**Alternate Vice-Chair:** Miss Christine Bullmore

**Co-ordinator:** Mrs Helen M Wilson

**PRSC Co-ordinator:** Mrs Helen M Wilson

**Assistant Co-ordinator:** N/A

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## Chair's overview of the past year:

Last year I started my overview with 寧為太平犬，不做亂世人 or “may you live in interesting times” which was a miss translation of “It's better to be a dog in a peaceful time than be a man in a chaotic period”. Well I think we remain people rather than canines! Which I used to reflect the great changes going on last year in NRES and how our committee have tried to work with these changes.

Well! Another year has passed and the changes continue. The full introduction of proportionate review, establishment of the Health Research Authority and the cultural change that RECs are there to support researchers as well as ensure the safety and wellbeing of participants. Obviously, our primary scope is the safety and welfare of participants but Sunderland REC have taken the view to ensure we meet this principle goal we should work with researchers rather than take a proscriptive line. I will discuss later how we have worked towards this.

### Statistics:

Generally, when I write this overview I try to avoid reiterating the stats in the report as readers can review them themselves, however there are a few points I would like to make:

1/ Of the 11 full meetings and 10 Proportionate review meetings we have been quorate for all with a median attendance of 7 members and mean of 7.9 which I feel is excellent considering we have now expanded our meetings from 11 per year to 21 per year including PR.

2/ Our mean applications per full meeting was 5.36.

3/ Not all the data is good, of the 73 substantial amendments 3 breached the 35 day target (largest breach 3 days over). I believe this is down to the increased workload of PR meetings and something we need to look at next year.

### Training:

Sunderland REC has a long held belief that our researcher colleagues (be they academics or industry) are partners who can benefit from working with RECs to establish excellent ethical research studies that will be of benefit to present and future patients. In recognising this, as Chairman, I have continued the programme of educational days (in partnership with our regional Clinical Research Network, with a personal thanks to Mr Tom Wooldridge from N & TW CLRN for facilitating this) for researchers and research staff in the ethics and the informed consent process, as described in the training data below, as well as encouraging researchers to attend our committee as observers. This has resulted in Sunderland REC leading 5 study days and accommodating 10 observers.

In conclusion, I feel that although we have breached some targets this has been another successful year for Sunderland REC.

Best wishes  
Paddy Stevenson

## NRES Committee North East - Sunderland Membership:

| Name                    | Occupation   | Expert or Lay | Dates      |            |
|-------------------------|--|---------------|------------|------------|
|                         |  |               | Appointed  | Resigned   |
| Mrs Cheryl Anderson     | Vice-Chairman                                      | Lay Plus      | 08/06/2004 |            |
| Ms Rachel Brown         | Student - Lay Member                               | Lay Plus      | 03/03/2011 |            |
| Miss Christine Bullmore | Emergency Planning Co-ordinator                    | Expert        | 27/02/2004 |            |
| Mr Aidan Cabezas-Hayes  | Lay Member   | Lay Plus      | 16/09/2011 |            |
| Ms Harnita Chohan       | Data Manager                                       | Lay           | 07/06/2011 |            |
| Dr Emma Fletcher        | Full time MSc Student (Medical Statistics)         | Expert        | 18/11/2010 |            |
| Dr Sumanto Haldar       | Research Scientist                                 | Expert        | 01/11/2009 |            |
| Ms Jill Holden          | Senior Clinical Pharmacist                         | Expert        | 01/03/2002 |            |
| Dr Karen Horridge       | Consultant Paediatrician (Neurodisability)         | Expert        | 01/08/2009 |            |
| Ms Mandy Jarvis         | Administration Manager                             | Lay Plus      | 01/10/2010 |            |
| Dr David Laws           | Consultant Anaesthetist                            | Expert        | 31/01/2003 |            |
| Mrs Debra J Lett        | Manager Newcastle Brain Tissue Resource            | Lay           | 19/09/2011 |            |
| Mrs Hilary Lloyd        | Deputy Director of Nursing and Midwifery           | Expert        | 01/07/2006 | 24/10/2011 |
| Mrs Gaynor Mitchell     | Biology Lecturer (Retired)                         | Lay Plus      | 31/05/2004 | 31/05/2011 |
| Mrs Theresa Nixon       | Lay Member   | Lay Plus      | 01/11/2011 | 15/12/2011 |
| Dr Chris Plummer        | Consultant Cardiologist                            | Expert        | 18/06/2007 |            |
| Mr David Pratt          | Senior Nurse Research & Clinical Audit             | Expert        | 24/03/2003 | 20/09/2011 |
| Dr Robert Pullen        | Chairman of Sunderland University Ethics Committee | Expert        | 24/10/2006 |            |
| Mr Paddy Stevenson      | Research Operations Manager                        | Expert        | 01/02/2007 |            |

### Co-opted Members

| Name             | Occupation                | Expert or Lay | Meeting date attended |
|------------------|---------------------------|---------------|-----------------------|
| Julie Ryan       | Pathology Quality Manager | Expert        | 16 September 2011     |
| Malcolm Harrison | Retired Lawyer            | Lay           | 3 June 2011           |
| Steve Chandler   | Retired Medical Physicist | Lay           | 28 April 2011         |

**NRES Committee North East - Sunderland: Members' Declarations of Interest:**

| <b>Name</b>                   | <b>Declaration of Interest</b>  | <b>Date</b>       |
|-------------------------------|---|-------------------|
| <b>Mr Paddy Stevenson</b>     | <b>NIHR Operations Manager – manage all research staff in Newcastle Hospitals Foundation Trust. Does declare any potential conflicts if managing the research staff carrying out research</b>   | <b>13/02/2012</b> |
| <b>Mrs Cheryl Anderson</b>    | <b>None</b>   | <b>15/01/2012</b> |
| <b>Ms Christine Bullmore</b>  | <b>Member of Clinical Ethics Group, City Hospitals Sunderland NHS Foundation Trust</b>  | <b>22/12/2011</b> |
| <b>Mr Aidan Cabezas-Hayas</b> | <b>None</b>   | <b>19/12/2011</b> |
| <b>Ms Debbie Lett</b>         | <b>Employee of Newcastle University. Manager of Newcastle Brain Tissue Resource.</b>  | <b>22/12/2011</b> |
| <b>Ms Harnita Chohan</b>      | <b>None</b>   | <b>08/06/2011</b> |
| <b>Ms Rachel Brown</b>        | <b>None</b>   | <b>02/01/2012</b> |
| <b>Dr Emma Fletcher</b>       | <b>None</b>   | <b>03/01/2012</b> |
| <b>Ms Mandy Jarvis</b>        | <b>None</b>   | <b>21/12/2011</b> |
| <b>Dr Sumanto Haldar</b>      | <b>Research Associate at Newcastle University. Involved in multiple projects with human volunteers but none via this REC</b>  | <b>30/12/2011</b> |
| <b>Dr Karen Horridge</b>      | <b>Chair, North of England Collaborative Cerebral Palsy Survey<br/>North of England representative of the British Academy of Childhood Obesity</b>  | <b>22/01/2012</b> |
| <b>Ms Jill Holden</b>         | <b>None</b>   | <b>28/12/2011</b> |
| <b>Dr David Laws</b>          | <b>None</b>   | <b>19/12/2011</b> |
| <b>Dr Robert Pullen</b>       | <b>Chair of University Ethics Committee</b>   | <b>Dec 2011</b>   |
| <b>Dr Chris Plummer</b>       | <b>Have advised pharmaceutical companies (AstraZeneca, Roche, Cephalon, EUSApharma) and funding bodies (CR-UK, MRC, EORTC) on the conduct of clinical trials and development of protocols. Have included the funding of expenses and some have included payments as compensation for unpaid/annual leave taken from NHS post.</b> | <b>23/12/2011</b> |

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

| <b>Month</b> | <b>Date</b> | <b>Number of Members Present at Meeting</b> |
|--------------|-------------|---|
| April        | 18/04/2011  | 9   |
| May          | 23/05/2011  | 8   |
| June         | 27/06/2011  | 11  |
| July         | 25/07/2011  | 8   |
| September    | 26/09/2011  | 10  |
| October      | 24/10/2011  | 11  |
| November     | 28/11/2011  | 8   |
| December     | 19/12/2011  | 11  |
| January      | 23/01/2012  | 11  |
| February     | 20/02/2012  | 10  |
| March        | 26/03/2012  | 9   |

11 full committee meetings were held during the reporting period.

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

| <b>Month</b> | <b>Date</b> | <b>Number of Members Present at Meeting</b> |
|--------------|-------------|---|
| April        | 28/04/2011  | 3   |
| June         | 03/06/2011  | 3   |
| July         | 08/07/2011  | 3   |
| August       | 12/08/2011  | 3   |
| September    | 16/09/2011  | 3   |
| October      | 21/10/2011  | 3   |
| November     | 24/11/2011  | 3   |
| January      | 12/01/2012  | 3   |
| February     | 17/02/2012  | 3   |
| March        | 23/03/2012  | 3   |

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

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

| <b>Name</b>             | <b>Number of Meetings Attended</b> |
|-------------------------|------------------------------------|
| Dr Chris Plummer        | 9                                  |
| Dr David Laws           | 9                                  |
| Dr Robert Pullen        | 9                                  |
| Mr Paddy Stevenson      | 8                                  |
| Ms Jill Holden          | 8                                  |
| Ms Mandy Jarvis         | 8                                  |
| Miss Christine Bullmore | 7                                  |
| Dr Emma Fletcher        | 7                                  |
| Dr Karen Horridge       | 6                                  |
| Dr Sumanto Haldar       | 6                                  |
| Mrs Debra J Lett        | 6                                  |
| Mrs Cheryl Anderson     | 5                                  |
| Ms Rachel Brown         | 5                                  |
| Mr Aidan Cabezas-Hayes  | 4                                  |
| Ms Harnita Chohan       | 3                                  |
| Mr David Pratt          | 2                                  |
| Mrs Hilary Lloyd        | 2                                  |
| Mrs Theresa Nixon       | 1                                  |
| Mrs Gaynor Mitchell     | 1                                  |

**Number of inquorate meetings held: None**

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

| <b>Name</b>             | <b>Number of Meetings Attended</b> |
|-------------------------|------------------------------------|
| Mr Paddy Stevenson      | 8                                  |
| Mrs Cheryl Anderson     | 6                                  |
| Mr David Pratt          | 3                                  |
| Ms Mandy Jarvis         | 3                                  |
| Dr Sumanto Haldar       | 2                                  |
| Miss Christine Bullmore | 2                                  |
| Mrs Debra J Lett        | 2                                  |
| Mrs Julie Ryan          | 1                                  |
| Mr Steve Chandler       | 1                                  |
| Mr Malcolm Harrison     | 1                                  |
| Dr Emma Fletcher        | 1                                  |

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

**Training 01 April 2011 – 31 March 2012:**

**Training 01 April 2011 – 31 March 2012:**

| <b>Name of Member</b>   | <b>Date</b>             | <b>Event(s) attended</b>   |
|-------------------------|-------------------------|--|
| Mrs Cheryl Anderson     | 19/07/2011 - 19/07/2011 | Equality & Diversity, NHS Core Learning Unit                         |
| Mrs Cheryl Anderson     | 18/05/12 – 18/05/12     | Patient confidentiality  |
| Mrs Cheryl Anderson     | 11/04/12 – 11/04/12     | IG for dental practices  |
| Mrs Cheryl Anderson     | 11/04/12 – 11/04/12     | Access to health records   |
| Ms Rachel Brown         | 07/07/2011 - 07/07/2011 | Equality & Diversity, NRES   |
| Ms Rachel Brown         | 10/01/2012 - 10/01/2012 | Induction, NRES  |
| Ms Rachel Brown         | 19/12/2011 - 19/12/2011 | MCA DVD, NRES  |
| Miss Christine Bullmore | 25/05/2011 - 25/05/2011 | Self Directed Log  |
| Miss Christine Bullmore | 20/07/2011 - 20/07/2011 | NRES Medical Devices Training (code PO3003), NRES                    |
| Miss Christine Bullmore | 19/12/2011 - 19/12/2011 | MCA DVD, NRES  |
| Mr Aidan Cabezas-Hayes  | 19/12/2011 - 19/12/2011 | MCA DVD, NRES  |
| Mr Aidan Cabezas-Hayes  | 20/03/2012 - 20/03/2012 | Induction, NRES  |
| Ms Harnita Chohan       | 07/07/2011 - 07/07/2011 | Induction, NRES  |
| Ms Harnita Chohan       | 19/09/2011 - 19/09/2011 | NRES Update Session, NRES  |
| Dr Emma Fletcher        | 16/06/2011 - 16/06/2011 | Equality & Diversity, Core Learning Unit                             |
| Dr Emma Fletcher        | 06/12/2011 - 06/12/2011 | Diploma in Statistics, The Open University                           |
| Dr Emma Fletcher        | 19/12/2011 - 19/12/2011 | MCA DVD, NRES  |
| Dr Emma Fletcher        | 20/03/2012 - 20/03/2012 | Induction, NRES  |
| Dr Sumanto Halder       | 22/06/2011 - 22/06/2011 | NRES Members Induction Training, NRES                                |
| Dr Sumanto Halder       | 19/12/2011 - 19/12/2011 | MCA DVD, NRES  |
| Ms Jill Holden          | 16/06/2011 - 16/06/2011 | Equality & Diversity, City Hospitals Sunderland NHS Foundation Trust |
| Ms Jill Holden          | 19/12/2011 - 19/12/2011 | MCA DVD, NRES  |
| Dr Karen Horridge       | 19/12/2011 - 19/12/2011 | MCA DVD, NRES  |
| Ms Mandy Jarvis         | 07/07/2011 - 07/07/2011 | Induction, NRES  |
| Ms Mandy Jarvis         | 25/07/2011 - 25/07/2011 | Self directed log  |
| Dr David Laws           | 13/04/2011 - 13/04/2011 | Equality & Diversity, City Hospitals Sunderland NHS Foundation Trust |
| Dr David Laws           | 19/12/2011 - 19/12/2011 | MCA DVD, NRES  |
| Mrs Debra J Lett        | 19/12/2011 - 19/12/2011 | MCA DVD, NRES  |
| Mrs Debra J Lett        | 10/01/2012 - 10/01/2012 | Induction, NRES  |
| Mrs Gaynor Mitchell     | 17/05/2011 - 17/05/2011 | Self Directed Training Log   |
| Dr Chris Plummer        | 23/05/2011 - 23/05/2011 | Equality & Diversity, Newcastle upon Tyne Hospitals NHS Trust        |
| Dr Chris Plummer        | 24/06/2011 - 24/06/2011 | Self Directed Log June 2011  |
| Mr David Pratt          | 10/05/2011 - 10/05/2011 | Equality & Diversity, NRES   |
| Dr Robert Pullen        | 19/12/2011 - 19/12/2011 | MCA DVD, NRES  |



|                    |                         |  |
|--------------------|-------------------------|--|
| Dr Robert Pullen   | 28/03/2012 - 28/03/2012 | Members National Training Day,<br>NRES |
| Mr Paddy Stevenson | 19/09/2011 - 19/09/2011 | NRES Update Session, NRES              |
| Mr Paddy Stevenson | 19/12/2011 - 19/12/2011 | MCA DVD, NRES                          |
| Mr Paddy Stevenson | 2011 – 2012             |  |

**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      | 16            | 27.12      |
| Phase 1  | 0             | 0.00       |
| Gene Therapy   | 0             | 0.00       |
| Research Tissue Bank                                     | 0             | 0.00       |
| Research Database  | 0             | 0.00       |
| Others   | 43            | 72.88      |
| <b>Total Applications Reviewed</b>                       | <b>59</b>     | <b>100</b> |

**Table 2: Other REC activity during the reporting period:**

|   |    |
|---|----|
| Number of applications made invalid by co-ordinator             | 3  |
| Number of studies withdrawn prior to the meeting                | 8  |
| Number of student applications reviewed                         | 22 |
| Number of paediatric applications reviewed                      | 6  |
| 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 funded by the US DHHS           | 0  |

**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                             | 10            | 16.95      |
| Favourable Opinion with Additional Conditions                           | 4             | 6.78       |
| Unfavourable Opinion  | 5             | 8.47       |
| Provisional Opinion   | 40            | 67.80      |
| 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       |
| <b>Total</b>  | <b>59</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            | 50.85      |
| Further Information Favourable Opinion with Additional Conditions | 8             | 13.56      |
| Further Information Unfavourable Opinion                          | 0             | 0.00       |
| Favourable Opinion with Standard Conditions                       | 10            | 16.95      |
| Favourable Opinion with Additional Conditions                     | 4             | 6.78       |
| Unfavourable Opinion  | 5             | 8.47       |
| 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  | 1             | 1.69       |
| Number of studies withdrawn after the meeting                     | 1             | 1.69       |
| <b>Total</b>  | <b>59</b>     | <b>100</b> |

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

|                                    |           |
|------------------------------------|-----------|
| <b>Total Applications Reviewed</b> | <b>35</b> |
|------------------------------------|-----------|

**Table 6: 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                           | 20            | 57.14      |
| Favourable Opinion with Additional Conditions                         | 9             | 25.71      |
| No Opinion transfer to full committee for review                      | 4             | 11.43      |
| Provisional Opinion   | 2             | 5.71       |
| Unfavourable Opinion  | 0             | 0.00       |
| <b>Total</b>  | <b>35</b>     | <b>100</b> |

**Table 7: Other Management Information for the reporting period:**

|   |       |
|---|-------|
| <b>Average number of applications reviewed per full meeting</b>                               | 5.36  |
| <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 days taken to final decision - average</b>                                       | 35    |
| <b>Number of days taken to final decision - mode</b>  | 28    |
| <b>Number of SSAs (non-Phase 1) reviewed</b>  | 0     |
| <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%    |
| <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%    |
| <b>Number of substantial amendments reviewed</b>  | 64    |
| <b>Number of substantial amendments over 35 days</b>  | 3     |
| <b>Number of substantial amendments over 35 days as a % of total substantial amendments</b>   | 4.7%  |
| <b>Number of Section 30 applications reviewed</b>   | 0     |
| <b>Number of Section 30 applications over 60 days</b>   | 0     |
| <b>Number of Section 30 applications over 60 days as a % of total Section 30 applications</b> | 0%    |
| <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%    |
| <b>Number of proportionate review applications for ethical review over 14 days*</b>           | 2     |
| <b>Number of proportionate review applications over 14 days as a % of total</b>               | 6.45% |

**\*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:**

| <b>Further Information Favourable Opinion with Standard Conditions</b> |  |                                |
|--|--|--------------------------------|
| <b>REC Reference</b>   | <b>Application Short Title</b>   | <b>Number of Days on Clock</b> |
| 11/NE/0083   | Gemcitabine with and without IMM-101 in Advanced Pancreatic Cancer     | 37                             |
| 11/NE/0093   | Safety & Tolerability of 8mg ASM8 in moderate to severe asthmatics     | 52                             |
| 11/NE/0130   | OBI-1 Acquired Hemophilia Study  | 13                             |
| 11/NE/0136   | CReSS study (endoscopy)  | 44                             |
| 11/NE/0139   | PTSD - 100 Fathers Study   | 38                             |
| 11/NE/0140   | AUTODECRA, version 1.0   | 34                             |
| 11/NE/0161   | AGLU07310 Amend 2:Exploratory Muscle Biopsy Assessment Study (EMBASSY) | 57                             |
| 11/NE/0162   | The use of Metabolomics in age related macular degeneration            | 38                             |
| 11/NE/0163   | QLT091001 for Retinitis Pigmentosa in RET IRD 01 Amend. 8              | 56                             |
| 11/NE/0177   | A decision aid and decision quality instrument for breech presentation | 29                             |
| 11/NE/0199   | Evaluation of the natural history of patients with LORD                | 57                             |
| 11/NE/0200   | Shared decision making and the MDT in head and neck cancer management  | 28                             |
| 11/NE/0208   | Validation of markers in Charcot-Marie-Tooth disease                   | 39                             |
| 11/NE/0209   | Phase II Study With rhuMAb Beta7 In Patients With Ulcerative Colitis   | 28                             |
| 11/NE/0283   | The benefits of a dental service designed for looked after children    | 37                             |
| 11/NE/0284   | The service experiences of ethnic minority older people with diabetes  | 36                             |
| 11/NE/0292   | Peripheral arterial disease detection using toe pulse audio-PPG.       | 27                             |
| 11/NE/0293   | CMO1031, MabThera® and Rituxan® in patients with rheumatoid arthritis. | 57                             |
| 11/NE/0313   | Are current end of life paradigms appropriate for heart failure care?  | 48                             |
| 11/NE/0358   | Limbs Alive – Monitoring of Upper Limb Rehabilitation version 1        | 41                             |
| 11/NE/0361   | Smoking in pregnancy: fetal facial movement markers                    | 34                             |
| 11/NE/0367   | Measurement of quality of life in children with congenital anomalies   | 43                             |
| 11/NE/0375   | Oral BC1036 in the Management of Cough                                 | 49                             |
| 11/NE/0376   | A Phase I/II Study of WX-554 in Solid Tumours                          | 26                             |
| 12/NE/0008   | Assessment of blood clot formation in primary Sjogren's syndrome       | 47                             |
| 12/NE/0013   | Smoking side-effects awareness in COPD patients; Singapore and London  | 13                             |
| 12/NE/0016   | Comparing 2 doses of Trastuzumab in HER2+ Metastatic Gastric Cancer    | 28                             |
| 12/NE/0037   | Movement as Medicine for Type 2 diabetes Version 1.0                   | 49                             |
| 12/NE/0042   | Evaluating the Effectiveness of the food diary as an Intervention Tool | 33                             |

|            |  |    |
|------------|--|----|
| 12/NE/0050 | Optimising Vitamin D Status in Older People (VDOP) | 49 |
| 12/NE/0096 | Pioneer NuNec Feasibility                          | 39 |

#### Further Information Favourable Opinion with Additional Conditions

| REC Reference | Application Short Title  | Number of Days on Clock |
|---------------|--|-------------------------|
| 11/NE/0086    | CT327 in Patients with Stable Psoriasis Vulgaris                       | 40                      |
| 11/NE/0314    | Oral health and healthy eating promotion in reception year children    | 52                      |
| 11/NE/0343    | Post-exercise insulin reductions in people with type 1 diabetes        | 36                      |
| 11/NE/0347    | CLEARE, Version 1.0  | 51                      |
| 12/NE/0005    | CONCEPT  | 45                      |
| 12/NE/0018    | Virtual reality intervention for anxiety in children with ASD version1 | 44                      |
| 12/NE/0033    | Hand Eczema Phototherapy Study   | 37                      |
| 12/NE/0044    | MERIT Study  | 38                      |

#### 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 |
|---------------|--|-------------------------|
| 11/NE/0061    | Intervention development to ensure timely access to acute stroke care  | 28                      |
| 11/NE/0114    | Educational & Employment Experiences of People with Cystic Fibrosis    | 37                      |
| 11/NE/0118    | Biomarkers in oral cancer version 1                                    | 8                       |
| 11/NE/0134    | Osteoarthritis of the thumb: evaluation of a self-management programme | 22                      |
| 11/NE/0144    | Enablers and barriers of HIV testing in the medical assessment unit    | 11                      |
| 11/NE/0152    | Midwives' knowledge and views about activity in pregnancy.V1           | 11                      |
| 11/NE/0198    | 111 urgent care: Work, workforce, technology and organisation          | 10                      |
| 11/NE/0201    | A Pilot Study on Adverse Event Reporting and Patient Prompting         | 7                       |
| 11/NE/0203    | What Radiographic findings predict the difficulty of canine exposure?  | 14                      |
| 11/NE/0204    | Pain experience following open palatal canine exposure                 | 14                      |
| 11/NE/0211    | Beta-carotene supplement study. Version 1.                             | 23                      |
| 11/NE/0239    | Patients' and health professionals' experiences of care planning       | 14                      |
| 11/NE/0287    | Very Brief Interventions (qualitative) Evaluation                      | 8                       |
| 11/NE/0290    | Surface marker phenotype in human salivary progenitor cells            | 4                       |

|            |  |    |
|------------|--|----|
| 11/NE/0317 | The role of B lymphocytes in bone cell generation                      | 21 |
| 11/NE/0319 | STUDPET Study 2.1  | 10 |
| 11/NE/0320 | mPFL reconstruction study  | 9  |
| 11/NE/0321 | Severe slipped upper femoral epiphysis outcome study                   | 8  |
| 11/NE/0334 | Extension Study of rhuMAb BETA7 in patients with Ulcerative Colitis    | 18 |
| 11/NE/0342 | DEVELOP-UK: Donor Ex-Vivo Lung Perfusion study                         | 18 |
| 11/NE/0355 | A study investigating return to work after burn injury                 | 10 |
| 11/NE/0357 | Evaluation of Aptima HIV-1 RT assay                                    | 10 |
| 11/NE/0359 | Condition specific measure of OHRQoL for children with malocclusion    | 10 |
| 12/NE/0073 | Hypertension & CKD in Kent Studies (HyCKS)                             | 7  |
| 12/NE/0077 | Storage characteristics of cerebral biomarkers after SAH (version 1)   | 7  |
| 12/NE/0098 | SORTED   | 22 |
| 12/NE/0108 | Activity of Tetracyclines against Carbapenem resistant isolates        | 21 |
| 12/NE/0113 | Diagnostic Disclosure in Dementia 1.0                                  | 32 |
| 12/NE/0129 | Transitional needs of young people moving to adult sickle cell service | 10 |
| 12/NE/0130 | Emotional skills and social functioning in Multiple Sclerosis.         | 10 |

#### Favourable Opinion with Additional Conditions

| REC Reference | Application Short Title  | Number of Days on Clock |
|---------------|--|-------------------------|
| 11/NE/0095    | Health problems in long-term survivors of lymphoma and leukaemia V1.   | 33                      |
| 11/NE/0116    | Improving Ostomy Devices - Phase 2 (SUSOSTOMY2): Focus Groups          | 8                       |
| 11/NE/0153    | Exploring Threshold Concepts:Can VLE improve Operative Skills. Ver 1.0 | 11                      |
| 11/NE/0154    | A Comparison of LCD and CRT monitors for visual evoked potentials. (1) | 11                      |
| 11/NE/0240    | Exploring beliefs, expectations and preferences around CT colonography | 15                      |
| 11/NE/0241    | A study of chronic mild depression (Dysthymia)                         | 15                      |
| 11/NE/0285    | Patient Experience on a virtual ward: A new service evaluation         | 8                       |
| 11/NE/0316    | Cognitive therapy for distressing visual hallucinations                | 20                      |
| 11/NE/0356    | Ageing of peripheral white blood cells and serum markers in NAFLD      | 13                      |
| 12/NE/0064    | Health Screening of People in Police Custody (Patient Evaluation)      | 28                      |
| 12/NE/0072    | CardioGenES  | 9                       |
| 12/NE/0101    | Pathogenesis and treatment of endocrinopathy study (PETS)              | 34                      |
| 12/NE/0127    | Investigating influences on the outcomes of an arts on referral scheme | 9                       |



| <b>Unfavourable Opinion</b> |   |                                |
|-----------------------------|---|--------------------------------|
| <b>REC Reference</b>        | <b>Application Short Title</b>  | <b>Number of Days on Clock</b> |
| 11/NE/0113                  | Education and Employment in CF survey                                 | 37                             |
| 11/NE/0186                  | The family, social and lifestyle consequences of bariatric surgery    | 17                             |
| 11/NE/0286                  | ACT for chronic pain  | 27                             |
| 11/NE/0315                  | "An investigation re: differences in response patterns on the QACSO". | 21                             |
| 12/NE/0015                  | Parental Understandings of Infant Immunisation                        | 17                             |

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

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

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

| <b>Withdrawn after the meeting</b> |   |                                |
|------------------------------------|---|--------------------------------|
| <b>REC Reference</b>               | <b>Application Short Title</b>  | <b>Number of Days on Clock</b> |
| 11/NE/0106                         | Evaluation of Nurse Preceptorship at QEH Gateshead                    | 23                             |
| 12/NE/0012                         | Personalised care planning for people long term conditions(version 1) | 13                             |

| <b>Invalid Application</b> |                                |                                |
|----------------------------|--------------------------------|--------------------------------|
| <b>REC Reference</b>       | <b>Application Short Title</b> | <b>Number of Days on Clock</b> |

| <b>No Opinion Pending Consultation with Referee</b> |                                |                                |
|---|--------------------------------|--------------------------------|
| <b>REC Reference</b>                                | <b>Application Short Title</b> | <b>Number of Days on Clock</b> |

| <b>Not Requiring Review by NHS REC</b> |                                |                                |
|--|--------------------------------|--------------------------------|
| <b>REC Reference</b>                   | <b>Application Short Title</b> | <b>Number of Days on Clock</b> |

**Table 9: Items exceeding timelines:**

| <b>Full applications for ethical review over 60 day timeline</b> |                                |                                |
|--|--------------------------------|--------------------------------|
| <b>REC Reference</b>   | <b>Application Short Title</b> | <b>Number of Days on Clock</b> |

| <b>Proportionate review applications for ethical review over 14 days timeline</b> |  |                                |
|---|--|--------------------------------|
| <b>REC Reference</b>  | <b>Application Short Title</b>   | <b>Number of Days on Clock</b> |
| 11/NE/0240  | Exploring beliefs, expectations and preferences around CT colonography | 15                             |
| 11/NE/0241  | A study of chronic mild depression (Dysthymia)                         | 15                             |

| <b>SSAs (non Phase 1) over 25 days timeline</b> |                                |                                |
|---|--------------------------------|--------------------------------|
| <b>REC Reference</b>                            | <b>Application Short Title</b> | <b>Number of Days on Clock</b> |

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

| <b>Substantial Amendments over 35 day timeline</b> |   |  |                                |
|--|---|--|--------------------------------|
| <b>Amendment Reference</b>                         | <b>Application Short Title</b>                                  | <b>Amendment Title</b>                             | <b>Number of Days on Clock</b> |
| 11/NE/0130/AM01                                    | OBI-1 Acquired Hemophilia Study                                 | Substantial amendment to Protocol Amendment 2 date | 39                             |
| 09/H0904/56/AM06                                   | Open-label study of ranibizumab in choroidal neovascularisation | CRFB002AGB10, Amendment No.05, 12JUL2011           | 38                             |
| 08/H0904/99/AM12                                   | XL184 versus Placebo in Subjects with Thyroid Cancer            | Protocol amendment A3.1 (dated 16 November 2011)   | 36                             |

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

| <b>Section 30 application over 60 day timeline</b> |                                |                        |                          |
|--|--------------------------------|------------------------|--------------------------|
| <b>Amendment Reference</b>                         | <b>Application Short Title</b> | <b>Amendment Title</b> | <b>Number of Days on</b> |

|  |  |  |              |
|--|--|--|--------------|
|  |  |  | <b>Clock</b> |
|--|--|--|--------------|