

# NRES Committee Yorkshire & The Humber - Bradford

## Annual Report

**01 April 2011 – 31 March 2012**

## Part 1 – Committee Membership and Training

|                                |   |
|--------------------------------|---|
| <b>Name of REC:</b>            | NRES Committee Yorkshire & The Humber - Bradford  |
| <b>Type of REC:</b>            | Authorised  |
| <b>Type of Flag:</b>           | MCA   |
| <b>Chair:</b>                  | Dr Ian Woollands  |
| <b>Vice-Chair:</b>             | Dr David Dawson   |
| <b>Alternate Vice-Chair:</b>   | Professor Diana Anderson  |
| <b>Co-ordinator:</b>           | Ms Sinead Audsley   |
| <b>PRSC Co-ordinator:</b>      | n/a   |
| <b>Assistant Co-ordinator:</b> | Mr Craig Appleby  |
| <b>Committee Address:</b>      | Yorkshire & Humber REC Office<br>Millside<br>Mill Pond Lane<br>Meanwood<br>Leeds<br>LS6 4RA |
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### Chair's overview of the past year:

On behalf of the Bradford Research Ethics Committee, I have the pleasure and privilege of writing the "Chairs Overview of the Past Year".

I was appointed Chair of the Bradford Research Ethics Committee in November 2011 upon the completion of Professor Roberts' term of office. Therefore, I wish on behalf of the Committee to thank Professor Roberts's for his years of service and commitment to the running of the Committee for the benefit of the research constituency.

In becoming Chair of the Committee, I have been ably assisted and supported by the REC Co-ordinator Sinead Audsley and wish to acknowledge her hard work which ensured both the smooth running of the Committee and an efficient service for researchers.

Overall, during the year the Committee 4 members left either retiring at the end of their tenures or resigning due to taking up different posts. On behalf of the Committee, I wish to record our thanks for their contributions and support in the work of the Committee. To replace them we have been very fortunate in appointing two experienced and enthusiastic new members who are contributing greatly to the ethical review process and debates. Both new members have undertaken Induction training to support their appointments and overall training has been well supported by Committee members.

Finally, I am appreciative of the commitment and support from all members who give freely of their time and expertise to ensure the Committee fully meets its duties to safeguard the rights, safety, dignity and well-being of people participating in research in the National Health Service. This is recognized by Researchers, who have continued to compliment the Committee and provide positive feedback on their experiences.

## NRES Committee Yorkshire & The Humber - Bradford Membership:

| Name                           | Occupation                                   | Expert or Lay | Dates      |            |
|--------------------------------|--|---------------|------------|------------|
|                                |  |               | Appointed  | Resigned   |
| Mr Sharif Al-Ghazal            | Consultant Plastic Surgeon                   | Expert        | 17/10/2006 |            |
| Professor Diana Anderson       | Professor of Biomedical Sciences             | Expert        | 17/05/2011 |            |
| Dr Mark Busby                  | Consultant Neurologist                       | Expert        | 21/04/2002 | 12/01/2012 |
| Dr David Dawson                | Consultant in Anaesthetics                   | Expert        | 01/04/2007 |            |
| Dr Stan Dobrzanski             | Clinical Services Manager Pharmacy           | Expert        | 17/11/2002 |            |
| Mr Simon Gelsthorpe            | Head of Psychological Therapies              | Expert        | 01/11/2007 |            |
| Mr Jay Gokhale                 | Consultant General Surgeon                   | Expert        | 15/12/2004 |            |
| Mrs Christine Hamilton-Stewart | Retired NHS Sister                           | Lay           | 20/10/2002 | 01/09/2011 |
| Mrs Ellice Heaton              | Retired Teacher, JP                          | Lay Plus      | 17/02/2004 | 06/10/2011 |
| Dr Kirste Mellish              | Research Programme Manager                   | Expert        | 07/06/2011 |            |
| Dr Caroline Plews              | Senior Lecturer                              | Expert        | 09/10/2001 | 15/06/2011 |
| Professor Alan Roberts         | Chair  | Expert        | 09/10/2001 | 31/10/2011 |
| Mr Andrew Scally               | Senior Lecturer                              | Expert        | 17/02/2003 |            |
| Miss Fiona Elizabeth Walker    | Children and Youth Community Cohesion Worker | Lay Plus      | 01/06/2011 |            |
| Dr Adrian Williams             | Consultant Haematologist                     | Expert        | 17/11/2002 |            |
| Dr Ian Woollands               | Clinical Director, Occupational Health       | Expert        | 01/11/2011 |            |

### Co-opted Members

| Name                      | Occupation                         | Expert or Lay | Meeting date attended |
|---------------------------|------------------------------------|---------------|-----------------------|
| Dr Rhona Bratt            | Retired Multimedia Project Manager | Lay           | 17/01/2011            |
| Professor Kenneth Brodlie | Retired Professor of Visualization | Lay Plus      | 14/02/2011            |

## NRES Committee Yorkshire & The Humber - Bradford: Members' Declarations of Interest:

| Name                        | Declaration of Interest  | Date       |
|-----------------------------|--|------------|
| Mr Sharif Al-Ghazal         | None   | 14/12/2011 |
| Professor Diana Anderson    | Member of University of Bradford Ethics Committee.<br>On management board of research tissue bank, University of Bradford                                  | 17/02/2012 |
| Dr David Dawson             | Contracted Adviser to Philips Respironics MD OSA Risk Management Ltd.<br>GlaxoSmithKline shareholder   | 13/12/2011 |
| Dr Stan Dobrzanski          | None   | 13/12/2011 |
| Mr Simon Gelsthorpe         | None   | 13/12/2011 |
| Mr Jay Gokhale              | None   | 13/12/2011 |
| Dr Kirste Mellish           | Management of LoTS Care Research Programme.<br>Member of Stroke Research Network Primary Care Clinical Studies Group<br>Holds shares in Photopharmica Ltd. | 14/12/2011 |
| Mr Andrew Scally            | Research Design Service Advisor, Yorkshire and the Humber  | 13/12/2011 |
| Miss Fiona Elizabeth Walker | National Autistic Society volunteer.   | 21/03/2012 |
| Dr Adrian Williams          | None   | 13/12/2011 |
| Dr Ian Woollands            | None   | 13/12/2011 |

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

| <b>Month</b> | <b>Date</b> | <b>Number of Members Present<br/>at Meeting</b> |
|--------------|-------------|---|
| April        | 19/04/2011  | 9   |
| May          | 17/05/2011  | 12  |
| June         | 21/06/2011  | 11  |
| July         | 19/07/2011  | 10  |
| September    | 20/09/2011  | 10  |
| October      | 18/10/2011  | 10  |
| November     | 15/11/2011  | 12  |
| December     | 13/12/2011  | 10  |
| January      | 17/01/2012  | 8   |
| February     | 14/02/2012  | 9   |
| March        | 20/03/2012  | 9   |

11 full 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 Adrian Williams             | 11                                 |
| Dr Stan Dobrzanski             | 11                                 |
| Mr Simon Gelsthorpe            | 10                                 |
| Mr Andrew Scally               | 10                                 |
| Mr Jay Gokhale                 | 8                                  |
| Mr Sharif Al-Ghazal            | 8                                  |
| Professor Diana Anderson       | 8                                  |
| Dr Kirste Mellish              | 7                                  |
| Professor Alan Roberts         | 5                                  |
| Mrs Christine Hamilton-Stewart | 5                                  |
| Miss Fiona Elizabeth Walker    | 5                                  |
| Dr Mark Busby                  | 5                                  |
| Dr David Dawson                | 5                                  |
| Dr Ian Woollands               | 5                                  |
| Mrs Ellice Heaton              | 3                                  |
| Dr Caroline Plews              | 2                                  |

**Number of inquorate meetings held: 0**

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

| <b>Name of Member</b>       | <b>Date</b>             | <b>Event(s) attended</b>                     |
|-----------------------------|-------------------------|--|
| Mr Sharif Al-Ghazal         | 28/03/2012 - 28/03/2012 | National Members Training Day                |
| Professor Diana Anderson    | 17/02/2012 - 17/02/2012 | Equality & Diversity, University of Bradford |
| Dr David Dawson             | 18/10/2011 - 18/10/2011 | MCA training DVD                             |
| Dr Stan Dobrzanski          | 18/10/2011 - 18/10/2011 | MCA training DVD                             |
| Dr Stan Dobrzanski          | 28/03/2012 - 28/03/2012 | National Members Training Day                |
| Mr Simon Gelsthorpe         | 18/10/2011 - 18/10/2011 | MCA training DVD                             |
| Mr Jay Gokhale              | 30/06/2011 - 30/06/2011 | Equality & Diversity, NRES                   |
| Mr Jay Gokhale              | 18/10/2011 - 18/10/2011 | MCA training DVD                             |
| Dr Kirste Mellish           | 04/07/2011 - 04/07/2011 | Equality & Diversity, NRES                   |
| Dr Kirste Mellish           | 07/07/2011 - 07/07/2011 | Induction training, NRES                     |
| Dr Kirste Mellish           | 19/09/2011 - 19/09/2011 | NRES Update session, NRES                    |
| Dr Kirste Mellish           | 18/10/2011 - 18/10/2011 | MCA training DVD                             |
| Dr Kirste Mellish           | 02/02/2012 - 02/02/2012 | Human Tissue Act Training                    |
| Dr Kirste Mellish           | 28/03/2012 - 28/03/2012 | National Members Training Day                |
| Mr Andrew Scally            | 18/10/2011 - 18/10/2011 | MCA training DVD                             |
| Miss Fiona Elizabeth Walker | 01/07/2011 - 01/07/2011 | Equality & Diversity, NRES                   |
| Miss Fiona Elizabeth Walker | 21/09/2011 - 21/09/2011 | Induction training, NRES                     |
| Miss Fiona Elizabeth Walker | 18/10/2011 - 18/10/2011 | MCA training DVD                             |
| Dr Adrian Williams          | 18/10/2011 - 18/10/2011 | MCA training DVD                             |
| Dr Adrian Williams          | 28/03/2012 - 28/03/2012 | National Members Training Day                |
| Dr Ian Woollands            | 16/01/2012 - 16/01/2012 | MCA training DVD                             |
| Dr Ian Woollands            | 28/03/2012 - 28/03/2012 | National Members Training Day                |

## 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                                     | 0             | 0.00       |
| Research Database  | 0             | 0.00       |
| Others   | 49            | 100.00     |
| <b>Total Applications Reviewed</b>                       | <b>49</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                | 3  |
| Number of student applications reviewed                         | 22 |
| Number of paediatric applications reviewed                      | 1  |
| Number of device applications reviewed                          | 0  |
| Number of prisoner applications reviewed                        | 0  |
| Number of applications involving adults unable consent reviewed | 7  |
| 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                             | 2             | 4.08       |
| Favourable Opinion with Additional Conditions                           | 15            | 30.61      |
| Unfavourable Opinion  | 4             | 8.16       |
| Provisional Opinion   | 28            | 57.14      |
| 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>49</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   | 16            | 32.65      |
| Further Information Favourable Opinion with Additional Conditions | 9             | 18.37      |
| Further Information Unfavourable Opinion                          | 0             | 0.00       |
| Favourable Opinion with Standard Conditions                       | 2             | 4.08       |
| Favourable Opinion with Additional Conditions                     | 15            | 30.61      |
| Unfavourable Opinion  | 4             | 8.16       |
| Provisional Opinion   | 1             | 2.04       |
| 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                         | 1             | 2.04       |
| 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             | 2.04       |
| <b>Total</b>  | <b>49</b>     | <b>100</b> |

**Table 5: Other Management Information for the reporting period:**

|  |       |
|--|-------|
| <b>Average number of applications reviewed per full meeting</b>    | 4.45  |
| <b>Number of applications for full ethical review over 60 days</b> | 1     |
| <b>Number of applications over 60 days as a % of total</b>         | 2.04% |
| <b>Number of days taken to final decision - average</b>            | 32    |
| <b>Number of days taken to final decision - mode</b>               | 22    |

|  |      |
|--|------|
| <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> | 0.0% |

|  |    |
|--|----|
| <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>  | 45   |
| <b>Number of substantial amendments over 35 days</b>  | 2    |
| <b>Number of substantial amendments over 35 days as a % of total substantial amendments</b> | 4.4% |

|   |    |
|---|----|
| <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>   | 1    |
| <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> | 0.0% |

|   |    |
|---|----|
| <b>Number of proportionate review applications for ethical review over 14 days*</b> | 0  |
| <b>Number of proportionate review applications over 14 days as a % of total</b>     | 0% |

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

**Table 6: 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/YH/0095   | Nutrition in Older Adults: Version No. 09                              | 32                             |
| 11/YH/0098   | Improving Stroke Unit Quality  | 64                             |
| 11/YH/0211   | Understanding Stroke Rehabilitation Nursing Version 1.0                | 32                             |
| 11/YH/0212   | MRI and PET-CT for radiotherapy planning for head and neck cancer      | 37                             |
| 11/YH/0213   | Evaluation of 4D-contrast enhanced PET-CT in tumour volume definition  | 37                             |
| 11/YH/0235   | An attitude measure & structured assessment tool for self injury (V1)  | 25                             |
| 11/YH/0263   | Emotional distress in Multiple Sclerosis. Version 1.                   | 32                             |
| 11/YH/0264   | Community-based NAFLD Integrated Care Pathway Pilot Study Version 1    | 27                             |
| 11/YH/0266   | V.1 Identification, classification & management of SUIs in adult MH    | 27                             |
| 11/YH/0267   | Background levels of metals in lungs version 1                         | 41                             |
| 11/YH/0270   | Defective Neutrophil Function in Sepsis                                | 28                             |
| 11/YH/0384   | MDI co-ordination cap study : version 1                                | 33                             |
| 11/YH/0427   | Being Open: Exploring open disclosure of adverse events in the UK v1   | 23                             |
| 11/YH/0458   | HAPPY pilot randomised controlled trial                                | 48                             |
| 12/YH/0008   | Anxiety, depression and delirium in non-invasively ventilated patients | 48                             |
| 12/YH/0097   | Bowditch revisited: defining the optimum heart rate range in CHF       | 29                             |

  

| <b>Further Information Favourable Opinion with Additional Conditions</b> |   |                                |
|--|---|--------------------------------|
| <b>REC Reference</b>   | <b>Application Short Title</b>  | <b>Number of Days on Clock</b> |
| 11/YH/0083   | YFA Memory Bank Project Evaluation                                    | 58                             |
| 11/YH/0084   | Delirium and Acute Stroke - Version 1                                 | 56                             |
| 11/YH/0210   | Exercise effects on claudication (RCT)                                | 38                             |
| 11/YH/0273   | Sublingual microcirculation in critical illness: Version One          | 26                             |
| 11/YH/0382   | To investigate the function of cannabinoid system in the human GIT    | 22                             |
| 11/YH/0418   | Obese patients' experience of gastric surgery: a multi-method inquiry | 32                             |
| 12/YH/0013   | The HARPP Pilot Study   | 37                             |
| 12/YH/0093   | Do foot orthoses improve pain and function in midfoot osteoarthritis? | 24                             |
| 12/YH/0108   | Evaluation of Medicines Reconciliation - Patient Journey Version 1    | 27                             |

| 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/YH/0093                                  | Infective Endocarditis: an iatrogenic link? | 50                      |
| 11/YH/0202                                  | Cardiac arrest in Pregnancy Study (CAPS)    | 22                      |

| Favourable Opinion with Additional Conditions |  |                         |
|---|--|-------------------------|
| REC Reference                                 | Application Short Title  | Number of Days on Clock |
| 11/YH/0089                                    | Disordered eating in a forensic unit: Clinical characteristics (v. 1)  | 48                      |
| 11/YH/0099                                    | SuPPORT 4 All Phase I version 1  | 40                      |
| 11/YH/0105                                    | Understanding the Extended Physiotherapist role and experience         | 29                      |
| 11/YH/0117                                    | Psychological support for ovarian cancer survivors                     | 29                      |
| 11/YH/0163                                    | Exploring Motivations to Self-Harm - version 1                         | 23                      |
| 11/YH/0196                                    | Patient safety incidents and their contributors: a nursing perspective | 22                      |
| 11/YH/0224                                    | Lactamica 2  | 23                      |
| 11/YH/0229                                    | Increasing Uptake of the Seasonal Flu Jab for the over 65s             | 21                      |
| 11/YH/0352                                    | Usage of sectional matrices  | 41                      |
| 11/YH/0353                                    | Is Reiki beneficial to hospice day care patients?                      | 34                      |
| 11/YH/0359                                    | Impact of Psoriatic Arthritis (PsAID)                                  | 33                      |
| 11/YH/0397                                    | Biochemical indicators associated with necrotising enterocolitis       | 22                      |
| 11/YH/0454                                    | Understanding and Using Self Generated Validity for Behaviour Change 2 | 18                      |
| 12/YH/0018                                    | PiTSTOP: Pilot Trial of Stop Delirium! version 01                      | 20                      |
| 12/YH/0079                                    | Evaluation of self-management cook and eat well group                  | 33                      |

| Unfavourable Opinion |   |                         |
|----------------------|---|-------------------------|
| REC Reference        | Application Short Title   | Number of Days on Clock |
| 11/YH/0090           | Patient safety outcomes and their contributors: a nursing perspective | 39                      |
| 11/YH/0278           | Sterilisation procedures for outpatient endoscopes in ENT             | 22                      |
| 11/YH/0281           | Narratives of Hospital and Health                                     | 22                      |
| 11/YH/0453           | Minority ethnic hospital admissions for perinatal mental illness      | 18                      |

| Provisional Opinion |  |  |
|---------------------|--|--|
|---------------------|--|--|

| REC Reference | Application Short Title                      | Number of Days on Clock |
|---------------|--|-------------------------|
| 12/YH/0125    | The microcirculation in Hepatorenal Syndrome | N/A                     |

#### 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 |
|---------------|--|-------------------------|
| 12/YH/0010    | Simultaneous kissing stenting for the left main stem | N/A                     |

#### Withdrawn after the meeting

| REC Reference | Application Short Title                 | Number of Days on Clock |
|---------------|---|-------------------------|
| 11/YH/0279    | The Theorisation of Risk within the NHS | 22                      |

#### 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 7: Items exceeding timelines:**

| Full applications for ethical review over 60 day timeline                  |  |   |                         |
|--|--|---|-------------------------|
| REC Reference  | Application Short Title  | Number of Days on Clock                   |                         |
| 11/YH/0098   | Improving Stroke Unit Quality                                    | 64  |                         |
| Proportionate review applications for ethical review over 14 days timeline |  |   |                         |
| REC Reference  | Application Short Title  | Number of Days on Clock                   |                         |
|  |  |   |                         |
| SSAs (non Phase 1) over 25 days timeline                                   |  |   |                         |
| REC Reference  | Application Short Title  | Number of Days on Clock                   |                         |
|  |  |   |                         |
| 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 |
| 10/H1302/95/AM02   | REEMACT-2: The role of telephone support in computerised therapy | Substantial Amendment - their amendment 1 | 37                      |
| 10/H1302/95/AM05   | REEMACT-2: The role of telephone support in computerised therapy | Substantial amendment - their amendment 3 | 37                      |
| 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 |
|  |  |   |                         |