

National Research Ethics
Service


Health Research Authority

**NRES Committee London -
Westminster**

Annual Report

01 April 2013 – 31 March 2014

Part 1 – Committee Membership and Training

| | |
|------------------------------|---|
| Name of REC: | NRES Committee London - Westminster |
| Type of REC: | Recognised, Type I and Type III |
| Type of Flag: | None |
| Chair: | Dr Alan Ruben |
| Vice-Chair: | Mr Robert Goldstein |
| Alternate Vice-Chair: | Mr Andrew Hughes |
| REC Manager: | Mrs Alison O’Kane (up to September 2013) Mr Atul Patel (from September 2013) |
| REC Assistant: | Miss Laura Hewitt (from December 2013) |
| Committee Address: | Research Health Authority Ground Floor, Skipton House 80 London Road SE1 6LH |
| Telephone: | 020 797 22561 |
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Chair’s overview of the past year:

This has been another unsettled year for the committee due to uncertainty about our future administrative location; changes in the REC manager (co-ordinator) and their assistants; and the difficulties around the availability of expert members due to pressures of clinical work. Unfortunately, two more expert members resigned this year due to clinical commitments. We hope that at least some of these issues have now been finally resolved.

We have agreed to try undertaking Proportionate Reviews and though this is interesting and seems very worthwhile, we will need to make sure that this does not put unacceptable workload on members who already make a considerable and much appreciated contribution.

L Alan Ruben

NRES Committee London - Westminster Membership:

| Name | Occupation | Expert or Lay | Dates | |
|-------------------------|--|---------------|------------|------------|
| | | | Appointed | Resigned |
| Mrs Emma Bassett | Lay Member | Lay | 11/06/2008 | 16/05/2013 |
| Mr Robert Goldstein | Economist | Lay Plus | 01/07/2013 | |
| Miss Catherine Hamilton | Pharmacist | Expert | 01/01/2010 | 01/06/2013 |
| Dr Syed Hoque | Consultant Gastroenterologist & Physician | Expert | 07/03/2013 | |
| Mr Andrew Hughes | Online Publisher | Lay | 21/01/2011 | |
| Miss Eunice Jeffs | Macmillan Lymphoedema Specialist Practitioner | Expert | 04/02/2013 | 27/08/2013 |
| Miss Nina Khazaezadeh | Consultant Midwife | Expert | 01/03/2011 | |
| Mr Douglas Meehan | Events Co-ordinator | Lay Plus | 01/09/2011 | 30/07/2013 |
| Mr Christopher Mellor | Barrister | Lay Plus | 06/02/2013 | |
| Mrs Rosemary Morgan | Retired (Financial Services) | Lay Plus | 01/01/2013 | |
| Mr Malcolm Morton | Retired (Practice Manager) | Lay Plus | 31/05/2013 | |
| Dr Valbona Muzaka | Senior Lecturer in International Political Economy | Lay Plus | 01/07/2013 | |
| Miss Aarti Nandani | Clinical Trials Pharmacist | Expert | 27/02/2014 | |
| Dr Kevin O'Kane | Consultant Physician | Expert | 01/06/2008 | |
| Dr Mark O'Neill | Consultant Cardiologist & Reader in Clinical Cardiac Electrophysiology | Expert | 01/09/2011 | 04/04/2013 |
| Dr Marlies Ostermann | Consultant Intensivist | Expert | 01/09/2011 | 19/02/2014 |
| Mr Michael Puntis | ICU/Anaesthetist | Expert | 08/07/2010 | |
| Dr Alan Ruben | Retired (General Practitioner) | Expert | 01/09/2011 | |
| Miss Ros Stanbury | Retired Ophthalmologist | Expert | 03/07/2006 | |
| Dr Alan Swann | Occupational Physician | Expert | 24/10/2013 | |

Deputy Members

| Name | Occupation | Expert or Lay | Meeting date attended |
|-----------------|---|---------------|-----------------------|
| Mr Owain Thomas | Barrister (Deputy for Christopher Mellor) | Lay | 29/10/2013 |

Co-opted Members

| Name | Occupation | Expert or Lay | Meeting date attended |
|-------------------|------------|---------------|-----------------------|
| Mr David Burbidge | Retired | Lay | 28/05/2013 |
| Roy Sinclair | Pharmacist | Expert | 28/05/2013 |

NRES Committee London - Westminster: Members' Declarations of Interest:

| Name | Declaration of Interest | Date |
|-----------------------|---|------------|
| Dr Syed Hoque | No interests declared | 10/05/2013 |
| Dr Alan Ruben | Various Unit Trust shares held which may or may not include Pharmaceutical companies Member of the research Ethics Committee of the British School of Osteopathy | 18/04/2013 |
| Mr Douglas Meehan | None | 29/04/2013 |
| Dr Marlies Ostermann | Acted as a reviewer for NIHR grants applications. Received speaker's honoraria from Fresenius and Alere | 29/04/2013 |
| Mr Malcolm Morton | Volunteer for West Sussex Youth Offender Service Volunteer for Kent Surrey and Sussex Air Ambulance Trust | 31/05/2013 |
| Mr Christopher Mellor | None | 12/03/2014 |
| Mrs Rosemary Morgan | None | 12/03/2014 |
| Miss Nina Khazaezadeh | None | 25/02/2014 |
| Mr Andrew Hughes | No interests declared | 24/11/2013 |
| Mr Robert Goldstein | Shares in some medical companies | 25/11/2013 |
| Dr Valbona Muzaka | None | 05/06/2013 |
| Dr Alan Swann | Provides OH services to researchers who may be involved in clinical research. This can include advising individuals on precautions to protect themselves while conducting the research. | 28/01/2014 |
| Dr Kevin O'Kane | None | 30/04/2013 |
| Miss Ros Stanbury | Small number of shares held in Glaxosmithkline | 31/03/2014 |
| Mr Owain Thomas | None | 31/03/2014 |
| Mr Michael Puntis | None | 31/03/2014 |

Meetings for Full Ethical Review 01 April 2013 - 31 March 2014:

| Month | Date | Number of Members Present at Meeting |
|--------------|-------------|---|
| April | 30/04/2013 | 11 |
| May | 28/05/2013 | 7 |
| June | 25/06/2013 | 8 |
| July | 30/07/2013 | 8 |
| August | 27/08/2013 | 8 |
| September | 24/09/2013 | 9 |
| October | 29/10/2013 | 13 |
| November | 26/11/2013 | 9 |
| January | 28/01/2014 | 11 |
| February | 25/02/2014 | 8 |
| March | 25/03/2014 | 9 |

11 full committee meetings were held during the reporting period.

Proportionate Review Sub Committee Meetings held during 01 April 2013 - 31 March 2014:

| Month | Date | Number of Members Present at Meeting |
|--------------|-------------|---|
| January | 13/01/2014 | 3 |
| February | 18/02/2014 | 3 |
| March | 18/03/2014 | 3 |

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

Attendance of Members: 01 April 2013 – 31 March 2014:

| Name | Number of Meetings Attended |
|-----------------------|------------------------------------|
| Dr Alan Ruben | 9 |
| Mr Andrew Hughes | 9 |
| Mr Michael Puntis | 9 |
| Miss Ros Stanbury | 8 |
| Dr Marlies Ostermann | 8 |
| Mr Malcolm Morton | 8 |
| Mrs Rosemary Morgan | 8 |
| Dr Syed Hoque | 6 |
| Dr Kevin O'Kane | 6 |
| Mr Robert Goldstein | 6 |
| Mr Christopher Mellor | 5 |
| Dr Alan Swann | 4 |
| Dr Valbona Muzaka | 3 |
| Mr Douglas Meehan | 3 |
| Miss Eunice Jeffs | 2 |
| Miss Nina Khazaezadeh | 2 |
| Miss Aarti Nandani | 1 |
| Mrs Emma Bassett | 1 |
| Mr Owain Thomas | 1 |

Number of inquorate meetings held: 0

**Attendance of Members at proportionate review sub-committee meetings:
01 April 2013 – 31 March 2014:**

| Name | Number of Meetings Attended |
|----------------------|------------------------------------|
| Dr Alan Ruben | 3 |
| Miss Stephanie Ellis | 2 |
| Mr Malcolm Morton | 2 |
| Mr Michael Puntis | 1 |
| Mrs Rosemary Morgan | 1 |

Training 01 April 2013 – 31 March 2014:

| Name of Member | Date | Event(s) attended |
|-------------------------|-------------------------|---|
| Miss Ros Stanbury | 02/05/2013 - 02/05/2013 | Ethical Issues in Research Involving Children |
| Mrs Rosemary Morgan | 02/05/2013 - 02/05/2013 | Ethical Issues of Research Involving Children |
| Miss Catherine Hamilton | 22/04/2013 - 22/04/2013 | Information Governance Training, GSTT |
| Dr Marlies Ostermann | 27/05/2013 - 27/05/2013 | e learning module 'Research and human tissue legislation' |
| Mr Michael Puntis | 20/11/2013 - 20/11/2013 | National Members Training Day, HRA |
| Dr Alan Ruben | 02/09/2013 - 02/09/2013 | Chairs' NREAP meeting , HRA |
| Dr Alan Ruben | 13/02/2014 - 13/02/2014 | Assessing the consequences (benefit and harms) of Research: a HRA Workshop, HRA |
| Miss Nina Khazaezadeh | 01/01/2014 - 01/01/2014 | Equality & Diversity |
| Mr Robert Goldstein | 02/05/2013 - 02/05/2013 | Ethical Issues of Research Involving Children |
| Miss Aarti Nandani | 01/03/2014 - 01/03/2014 | MRC module on Human Tissue in Relation to Research |
| Miss Aarti Nandani | 01/03/2014 - 15/03/2014 | Read through the Standard Operating Procedures for Research Ethics Committees |
| Mr Christopher Mellor | 18/09/2013 - 18/09/2013 | Induction |
| Mr Michael Puntis | 05/02/2014 - 05/02/2014 | Equality & Diversity |

Part 2: REC workload and activity during the reporting period.

Table 1: Applications assigned to a full committee meeting held within the reporting period:

| Applications for full ethical review – Study Type | Number | % |
|--|---------------|------------|
| Clinical Trial of Investigational Medicinal Product | 20 | 33.90 |
| Phase 1 | 4 | 6.78 |
| Gene Therapy | 0 | 0.00 |
| Research Tissue Bank | 0 | 0.00 |
| Research Database | 0 | 0.00 |
| Others | 35 | 59.32 |
| Total Applications Reviewed | 59 | 100 |

Table 2: Other REC activity during the reporting period:

| | |
|---|----|
| Number of applications made invalid by co-ordinator | 2 |
| Number of studies withdrawn prior to the meeting | 11 |
| Number of student applications reviewed | 7 |
| Number of paediatric applications reviewed | 4 |
| Number of device applications reviewed | 3 |
| Number of prisoner applications reviewed | 0 |
| Number of applications involving adults unable consent reviewed | 0 |
| Number of applications reviewed funded by the US DHHS | 0 |

Table 3: Decisions given at meetings held within the reporting period:

| Decisions taken at meetings following review of applications | Number | % |
|---|---------------|------------|
| Favourable Opinion with Standard Conditions | 1 | 1.69 |
| Favourable Opinion with Additional Conditions | 14 | 23.73 |
| Unfavourable Opinion | 2 | 3.39 |
| Provisional Opinion | 41 | 69.49 |
| Invalid | 0 | 0.00 |
| No Opinion Pending Consultation with Referee | 0 | 0.00 |
| Provisional Opinion Pending Consultation with Referee | 1 | 1.69 |
| Not Requiring Review by NHS REC | 0 | 0.00 |
| Total | 59 | 100 |
| Number of studies sent back to full committee meeting for final opinion | 0 | |

Table 4: Summary of current status of applications reviewed during the reporting period:

| Status of applications at date of generation of report | Number | % |
|---|---------------|------------|
| Further Information Favourable Opinion with Standard Conditions | 33 | 55.93 |
| Further Information Favourable Opinion with Additional Conditions | 5 | 8.47 |
| Further Information Unfavourable Opinion | 0 | 0.00 |
| Favourable Opinion with Standard Conditions | 1 | 1.69 |
| Favourable Opinion with Additional Conditions | 14 | 23.73 |
| Unfavourable Opinion | 2 | 3.39 |
| Provisional Opinion | 1 | 1.69 |
| 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 | 3 | 5.08 |
| Not Requiring Review by NHS REC | 0 | 0.00 |
| No decision entered on RED | 0 | 0.00 |
| Number of studies withdrawn after the meeting | 0 | 0.00 |
| Total | 59 | 100 |

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

| | |
|------------------------------------|----------|
| Total Applications Reviewed | 7 |
|------------------------------------|----------|

Table 6: Decisions given at proportionate review sub-committee meetings held within the reporting period:

| Decisions taken at proportionate review sub-committee meetings | Number | % |
|---|---------------|------------|
| Favourable Opinion with Standard Conditions | 1 | 14.29 |
| Favourable Opinion with Additional Conditions | 2 | 28.57 |
| No Opinion transfer to full committee for review | 1 | 14.29 |
| Provisional Opinion | 3 | 42.86 |
| Unfavourable Opinion | 0 | 0.00 |
| Total | 7 | 100 |

Table 7: Other Management Information for the reporting period:

| | |
|---|-------|
| Average number of applications reviewed per full meeting | 5.36 |
| Number of applications for full ethical review over 60 days | 0 |
| Number of applications over 60 days as a % of total | 0.00% |
| Number of days taken to final decision - average | 31 |
| Number of days taken to final decision - mode | 22 |
| Number of SSAs (non-Phase 1) reviewed | 2 |
| Number of applications for SSA review over 25 days | 0 |
| Number of applications for SSA review over 25 days as % of all non-Phase 1 (SSAs) | 0.0% |
| Number of SSAs (Phase 1) reviewed | 0 |
| Number of applications for SSA review over 14 days | 0 |
| Number of applications for SSA review over 14 days as % of all Phase 1 (SSAs) | 0% |
| Number of substantial amendments reviewed | 108 |
| Number of substantial amendments over 35 days | 4 |
| Number of substantial amendments over 35 days as a % of total substantial amendments | 3.7% |
| Number of Section 30 applications reviewed | 0 |
| Number of Section 30 applications over 60 days | 0 |
| Number of Section 30 applications over 60 days as a % of total Section 30 applications | 0% |
| Number of modified amendments reviewed | 1 |
| Number of modified amendments over 14 days | 0 |
| Number of modified amendments over 14 days as a % of total modified amendments | 0.0% |
| Number of proportionate review applications for ethical review over 14 days | 2 |
| Number of proportionate review applications over 14 days as a % of total | 33.3% |

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

| Further Information Favourable Opinion with Standard Conditions | | |
|--|--|--------------------------------|
| REC Reference | Application Short Title | Number of Days on Clock |
| 13/LO/0516 | Platinum induced changes in ICMT-11 | 31 |
| 13/LO/0570 | The addition of TPV in patients with acute hep C/HIV co-infection | 60 |
| 13/LO/0701 | Evolution of Systolic Hypertension in Twins UK | 24 |
| 13/LO/0704 | A study of allergen extracts in house dust mite associated asthma | 30 |
| 13/LO/0720 | MEK162 vs Dacarbazine in NRAS mutation positive melanoma patients | 27 |
| 13/LO/0746 | Adult attachment and quality of life after a traumatic brain injury | 39 |
| 13/LO/0755 | Predicting response to CRT using body surface ECG mapping | 27 |
| 13/LO/0759 | Cold and exercise stress on patients with coronary artery disease | 25 |
| 13/LO/0980 | Investigation into the role of GTN & RIPC in cardiac surgery | 24 |
| 13/LO/1019 | Dose-Ranging Proof of Concept Study of BIIB033 in Relapsing MS | 38 |
| 13/LO/1050 | E7080-G000-304 - Unresectable Hepatocellular Carcinoma | 40 |
| 13/LO/1066 | Hydrus 4 Study | 26 |
| 13/LO/1116 | STRONG TREAT 1 to 4 | 26 |
| 13/LO/1127 | To evaluate the efficacy and safety of MOD-4023 compared to Placebo | 38 |
| 13/LO/1287 | Study in Healthy Male Subjects to Investigate a New Drug NNC0113-0987 | 34 |
| 13/LO/1289 | Phase 3 Study KW-0761 Versus Vorinostat in CTCL Patients | 40 |
| 13/LO/1310 | Contrast enhanced ultrasound for the detection of ocular inflammation | 26 |
| 13/LO/1311 | Young Black men and their experiences of an Early Intervention Service | 29 |
| 13/LO/1328 | PARAGON- LCZ696 vs valsartan in patients with chronic heart failure | 37 |
| 13/LO/1375 | OvPSYCH 2 | 23 |
| 13/LO/1683 | T-Study | 22 |
| 13/LO/1788 | PK and PD of PA10040, EC Aspirin and -Omeprazole in healthy volunteers | 32 |
| 14/LO/0046 | An Observational follow-up study to Protocol 018 | 29 |
| 14/LO/0066 | Pronuts version 1 | 22 |
| 14/LO/0087 | An observational study on clearance on biologics in plaque psoriasis | 34 |
| 14/LO/0124 | SYNERGY II | 27 |
| 14/LO/0143 | Assessment of 18F-Sodium Fluoride PET/CT as a measure of calcification | 38 |
| 14/LO/0148 | Dapagliflozin in Type 2 diabetic patients with diabetic nephropathy. | 31 |
| 14/LO/0202 | Work of breathing during HHFNC and CPAP | 34 |

| | | |
|------------|--|----|
| 14/LO/0220 | PET/MRI Oncological Imaging | 34 |
| 14/LO/0306 | Phase IB study of MK3475 in subjects with Select Advanced Solid Tumors | 38 |
| 14/LO/0356 | Embryo implantation rate after endometrial scratch | 15 |
| 14/LO/0363 | Maternity Assist Feasibility Study Version 1 | 13 |
| 14/LO/0451 | Electrical stimulation use with pelvic fracture rehabilitation Vrs 1 | 59 |
| 14/LO/0473 | Measuring anxiety in Autism Spectrum Disorder | 12 |
| 14/LO/0499 | SAD, Safety, PK of ASP3700 in healthy male subjects, plus a DDI part | 39 |

Further Information Favourable Opinion with Additional Conditions

| REC Reference | Application Short Title | Number of Days on Clock |
|---------------|---|-------------------------|
| 13/LO/0920 | Developing NE London Cancer Surveillance Project: Distance Monitoring | 46 |
| 13/LO/1037 | Nasally and sc administered teriparatide in healthy volunteers | 50 |
| 13/LO/1332 | Study Evaluating Tolerability and Anti-tumour activity of OPB 111001 | 30 |
| 13/LO/1383 | Cost of Treatment and Care for Newly Diagnosed People Living With HIV | 43 |
| 13/LO/1513 | Rituximab Plus Lenalidomide (CC-5013) in Indolent Lymphoma | 26 |

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 |
|---------------|---|-------------------------|
| 13/LO/1374 | Measuring hospital harm from databases and case notes | 20 |
| 14/LO/0472 | JLA Neuro-Oncology Group | 20 |

Favourable Opinion with Additional Conditions

| REC Reference | Application Short Title | Number of Days on Clock |
|---------------|---|-------------------------|
| 13/LO/0539 | Kisspeptin in pregnancy and gestational diabetes | 17 |
| 13/LO/0721 | Biomarkers for disease activity and infections in SLE | 17 |
| 13/LO/0810 | (duplicate) Fatigue management and relaxation at end of life: a pilot | 42 |
| 13/LO/0968 | Rituximab versus cyclophosphamide in connective tissue disease-ILD | 20 |
| 13/LO/1316 | NF2 Avastin Tumour responses | 24 |
| 13/LO/1591 | The PLACE study | 23 |
| 13/LO/1596 | Chronic neuroinflammation following TBI v1.0 | 34 |

| | | |
|------------|--|----|
| 13/LO/1599 | CORAL: Cancer of the OvaRy Abiraterone trial | 23 |
| 13/LO/1629 | Pain_OMICs | 22 |
| 13/LO/1753 | RAPID II | 23 |
| 13/LO/1783 | Self-management tools to manage adherence in Parkinson's disease v4 | 22 |
| 13/LO/1796 | Phase I/II Study of ColoAd1 Intraperitoneally in Ovarian Cancer Patients | 22 |
| 14/LO/0062 | Experiences of African parents having a child diagnosed with ASD in UK | 20 |
| 14/LO/0100 | APIPPRA version 1.0 | 20 |
| 14/LO/0144 | 3D tomosynthesis vs 2D conventional digital imaging breast specimen | 11 |
| 14/LO/0355 | Analysis of 24/7 working in the London Hyperacute Stroke System (1.0) | 13 |

Unfavourable Opinion

| REC Reference | Application Short Title | Number of Days on Clock |
|---------------|--|-------------------------|
| 13/LO/1607 | An Observational follow-up study to Protocol 018 | 37 |
| 14/LO/0461 | SB5 Compared to Humira® in Subjects with Moderate to Severe RA | 44 |

Provisional Opinion

| REC Reference | Application Short Title | Number of Days on Clock |
|---------------|--------------------------------------|-------------------------|
| 13/LO/0444 | Missed Opportunities for HIV Testing | 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 |
|---------------|---|-------------------------|
| 14/LO/0150 | Computer Model Indices to Individualise Heart Failure Treatment | N/A |
| 14/LO/0414 | OPIP | N/A |
| 14/LO/0433 | The disability complex of early onset epilepsies | N/A |

Withdrawn after the meeting

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

Invalid Application

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

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

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

Table 9: Items exceeding timelines:

| Full applications for ethical review over 60 day timeline | | | |
|---|--|---------------------------------|--------------------------------|
| REC Reference | Application Short Title | Number of Days on Clock | |
| Proportionate review applications for ethical review over 14 days timeline | | | |
| REC Reference | Application Short Title | Number of Days on Clock | |
| 14/LO/0356 | Embryo implantation rate after endometrial scratch | 15 | |
| 14/LO/0472 | JLA Neuro-Oncology Group | 20 | |
| 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 |
| 11/LO/0045/AM04 | Peanut Allergy Sensitisation Study (PAS Study) | Protocol Version 3: Amendment 4 | 37 |
| 12/LO/0118/AM04 | Study of CC-223 in patients with advanced solid tumours, NHL or MM | Protocol Amendment 9 (12.03.13) | 41 |
| 11/LO/0123/AM03 | Atopic Dermatitis Anti-IgE Paediatric Trial (ADAPT) | Substantial amendment 3 | 44 |
| 11/LO/1481/AM08 | A randomised controlled trial of rehabilitation in OHS | Amendment 7, 28.02.2014 | 43 |
| 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 |