National Research Ethics Service

Health Research Authority

NRES Committee South Central - Berkshire B

Annual Report

01 April 2012 – 31 March 2013

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee South Central - Berkshire B
Type of REC:	RECs recognised to review CTIMPS in healthy volunteers - type i RECs recognised to review CTIMPS in patients - type iii
Type of Flag:	Phase 1 Studies in Patients
Chair:	Dr John Sheridan
Vice-Chair:	Mr Michael Arnott
Alternate Vice-Char:	None
Co-ordinator:	Mrs Kirsten Peck
PRSC Co-ordinator:	Miss Kelly Pullin
Assistant Co-ordinator:	Miss Kelly Pullin
Committee Address:	Bristol REC Centre Whitefriars Level 3, Block B Lewins Mead Bristol BS1 2NT
Telephone:	0117 342 1391
Fax:	
Email:	nrescommittee.southcentral-berkshireb@nhs.net

Chair's overview of the past year:

Another rather mixed year, in my opinion.
On the positive side, long serving, newer and co-opted members gelled to form an effective REC, with a positive and dynamic atmosphere. The Lead Reviewer system was embraced fully and a complete set of reviews was generally available in time for each meeting. Nearly all of the newer members continued to develop and some are, in my view, already capable of acting as Chair or Vice-Chair.
Unfortunately, we have continued to lose members; this is probably inevitable, as people make career changes, or move out of the area. Response times, particularly on substantial amendments, were still sometimes not as good as I would like to see. It is much better if researchers submit amendments in electronic format, with key documents (e.g. the PIS) in tracked change format (only). It would also speed things up if such amendments were sent to me, as well as to the Bristol Office, as the amendments could be considered at the same time as the necessary administrative work was being undertaken at the office. On a more minor issue, there has been some difficulty with the venue for our meetings; the only place for the researchers who attend to wait is in a large refectory area downstairs. A fairly significant amount of member and/or co-ordinator time has been spent looking for researchers, particularly when we are ahead of time on our agenda. As possible solution is additional notices directing researchers to the waiting area and a request that they bring a mobile phone with them, having provided the co-ordinator with its number prior to the meeting.

NRES Committee South Central - Berkshire B Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mr Michael Arnott	Consultant Research Services	Lay	01/06/2011	
Ms Helena Brennan	Pharmaceutical Research Manager	Lay	01/06/2011	13/03/2013
Dr Francesca Greco	Lecturer in Pharmaceutics	Expert	01/06/2011	
Mrs Sue Harrison	Managing Director of a Trade Association	Lay Plus	13/02/2013	
Dr Andrew Hill	Research scientist	Expert	20/10/2011	
Mr John Stanley Inman	Retired Pharmacist	Expert	01/06/2011	
Ms Joanne Milton	Project Manager	Lay	11/02/2013	
Ms Ann Quinn	Head of the School of Health and Social Care	Expert	05/02/2013	
Dr John Sheridan	Consultant Toxicologist and Chemist	Lay	01/07/2011	
Dr Robert Smith	General Practitioner	Expert	01/07/2011	29/08/2012
Mr Paul Douglas Soper	Research Manager	Lay Plus	01/06/2011	
Miss Louise Anne Stainer	Biomedical Scientist	Expert	12/10/2011	
Mrs Jane Turner	Radiographer	Expert	12/10/2011	
Dr Benjamin Whalley	Lecturer in Pharmacology	Expert	01/06/2011	02/05/2012
Dr Cordelia Ashwanden	Editor in Chief Journal of Renal Care	Expert	12/07/2012	06/10/2012

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended
n/a			

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Ms Ann Quinn	Head of the School of Health and Social Care	Expert	13/03/2012, 09/10/2012, 13/11/2012
Mrs Sue Harrison	Managing Director of a Trade Association	Lay Plus	09/10/2012, 13/11/2012

Member Bank

Name	Occupation	Expert or Lay	Meeting date attended
n/a			

NRES Committee South Central - Berkshire B: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Mrs Sue Harrison	Trustee - Re-Solv (Charity for the prevention of volatile substance abuse	18/03/2013
Mr John Inman	Shareholder in Pzifer	12/02/2013
Miss Louise Stainer	None	12/02/2013
Dr Joanne Milton	Shareholding in Oxford Biomedica	12/02/2013
Ms Ann Quinn	Occasionally peer review long-term conditions and/or neurological conditions for Reading University.	30/03/2013
Dr John Sheridan	None	12/02/2013
Mr Paul Soper	Research Scientist for Mondelez International	13/02/2013
Dr Andrew Hill	None	12/02/2013
Ms Ann Quinn	None	12/02/2013
Mr Michael Arnott	Member of an independent ethics committee which reviews studies which are not clinical trials such as market research, cosmetic and toiletries.	31/03/2013
Dr Francesca Greco	On the board for the Academy of Pharmaceutical Sciences.Lecturer at the University of Reading.	31/03/2013
Mrs Jane Turner	Shareholder in GSK	31/03/2013

Meetings for Full Ethical Review 01 April 2012 - 31 March 2013:

Month	Date	Number of Members Present at Meeting
April	10/04/2012	7
June	12/06/2012	8
September	11/09/2012	7
October	09/10/2012	8
November	13/11/2012	9
January	22/01/2013	7
February	12/02/2013	8
March	12/03/2013	7

8 full committee meetings were held during the reporting period.

Proportionate Review Sub Committee Meetings held during 01 April 2012 - 31 March 2013:

Month	Date	Number of Members Present at Meeting
August	01/08/2012	3
September	04/09/2012	3
September	27/09/2012	3
November	05/11/2012	3
January	14/01/2013	3
March	25/03/2013	3

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

Attendance of Members: 01 April 2012 – 31 March 2013:

Name	Number of Meetings Attended
Dr Andrew Hill	8
Dr John Sheridan	8
Miss Louise Anne Stainer	8
Mr Michael Arnott	8
Mr John Stanley Inman	7
Mr Paul Douglas Soper	6
Mrs Jane Turner	5
Ms Ann Quinn	3
Mrs Sue Harrison	2
Ms Joanne Milton	2
Dr Benjamin Whalley	1
Dr Cordelia Ashwanden	1
Ms Ann Quinn	1
Ms Helena Brennan	1

Number of inquorate meetings held: 0

Attendance of Members at proportionate review sub-committee meetings: 01 April 2012 – 31 March 2013:

Name	Number of Meetings Attended
Dr John Sheridan	4
Mr Michael Arnott	4
Miss Louise Anne Stainer	3
Mr John Stanley Inman	3
Dr Andrew Hill	3
Dr John B Sheridan	1

Training 01 April 2012 – 31 March 2013:

Name of Member	Date	Event(s) attended
Mrs Jane Turner	26/04/2012 - 26/04/2012	Induction, NRES
Miss Louise Anne Stainer	06/03/2013 - 06/03/2013	Qualitative Research and Ethical Review
Mr Paul Douglas Soper	08/11/2012 - 08/11/2012	Equality & Diversity
Mr John Stanley Inman	26/11/2012 - 26/11/2012	Equality & Diversity
Mr John Stanley Inman	11/12/2012 - 11/12/2012	Shared Ethical Debate - research & emerging technologies; novelty shouldn't mean "No".
Miss Louise Anne Stainer	13/02/2013 - 13/02/2013	Personal Data in Research
Ms Joanne Milton	15/03/2013 - 15/03/2013	NRES Committee Members DC - Version 3
Mr John Stanley Inman	21/03/2013 - 21/03/2013	Medical Devices for NRES , NRES
Ms Ann Quinn	18/02/2013 - 18/02/2013	Equality & Diversity, NRES
Ms Ann Quinn	26/04/2012 - 26/04/2012	Induction, NRES
Dr John Sheridan	08/02/2013 - 08/02/2013	Phase 1 Advisory Group Meeting, SDL
Dr John Sheridan	06/03/2013 - 06/03/2013	Attended Chairs meeting with Professor Jonathan Montgomery, SDL
Mrs Sue Harrison	14/06/2012 - 14/06/2012	Induction, NRES
Mr Michael Arnott	26/03/2013 - 26/03/2013	HTA 2 Hours
Mr Michael Arnott	26/03/2013 - 26/03/2013	2.5 Hours - Medical Devices Regulations 2002 NO 2003, NO 1697, 2007, NO 400, 2008 NO2936
Ms Joanne Milton	25/03/2013 - 25/03/2013	Ethics & GP Forum

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	9	26.47
Phase 1	9	26.47
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	16	47.06
Total Applications Reviewed	**34**	**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	16
Number of student applications reviewed	3
Number of paediatric applications reviewed	1
Number of device applications reviewed	1
Number of prisoner applications reviewed	0
Number of applications involving adults unable consent reviewed	2
Number of applications reviewed funded by the US DHHS	0

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

Decisions taken at meetings following review of applications	Number	%
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	13	38.24
Unfavourable Opinion	1	2.94
Provisional Opinion	18	52.94
Invalid	0	0.00
No Opinion Pending Consultation with Referee	0	0.00
Provisional Opinion Pending Consultation with Referee	2	5.88
Not Requiring Review by NHS REC	0	0.00
Total	**34**	**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	18	52.94
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	13	38.24
Unfavourable Opinion	1	2.94
Provisional Opinion	2	5.88
Provisional Opinion Pending Consultation with Referee	0	0.00
Invalid	0	0.00
No Opinion Pending Consultation with Referee	0	0.00
Further Information response not complete	0	0.00
Not Requiring Review by NHS REC	0	0.00
No decision entered on RED	0	0.00
Number of studies withdrawn after the meeting	0	0.00
Total	**34**	**100**

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

Total Applications Reviewed	**11**

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	9.09
Favourable Opinion with Additional Conditions	6	54.55
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	3	27.27
Unfavourable Opinion	1	9.09
Total	**11**	**100**

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	4.25
Number of applications for full ethical review over 60 days	2
Number of applications over 60 days as a %of total	5.88%
Number of days taken to final decision - average	29
Number of days taken to final decision - mode	17

Number of SSAs (non-Phase 1) reviewed	1
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	74
Number of substantial amendments over 35 days	2
Number of substantial amendments over 35 days as a % of total substantial amendments	2.7%

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	3
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	18.2%

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**
12/SC/0134	First in Man study of MIV-711, safety, PK and PD/ascending SAD/MAD	23
12/SC/0274	Investigation of the transfer of FE 202767 from blood to breast milk	26
12/SC/0352	INDRA	33
12/SC/0455	MOSAIC: The Epidemiology of Molluscum Contagiosum in the Community	12
12/SC/0469	Odyssey FH I	38
12/SC/0472	BMS-936558 vs Docetaxel in metastic Non Small Cell Lung Cancer	38
12/SC/0482	Atrial Fibrillation Ablation Registry (Protocol Date: 10th May 2012)	57
12/SC/0540	BI 207127 in Treatment-Naïve Patients with HCV	28
12/SC/0554	SAD/MAD Study in Caucasian and Japanese Subjects	27
12/SC/0569	CFTY720D2405: Fingolimod after natalizumab observational study	76
12/SC/0570	CFTY720D2406: long-term observational fingolimod study	76
12/SC/0649	Development and implantation of normal human preimplantation embryos	14
13/SC/0005	TGAB	17
13/SC/0021	Baricitinib in Patients with Rheumatoid Arthritis: BEAM (JADV)	30
13/SC/0030	First in human study of anti-IL7-R monoclonal antibody (I7R116702)	26
13/SC/0033	Prevalence of ADHD in ADPSYC	20
13/SC/0065	On-line self-management after treatment for prostate cancer	40
13/SC/0073	COSMIC-HF A dose escalation study in patients with heart failure	21
13/SC/0080	Exploring diabetes outpatient attendance in an Inner London Borough	37
13/SC/0112	Comparison of PK and Bioequivalence of Epistatus® and Hypnovel®	24
13/SC/0190	PROPER - Patient reported outcomes for patient empowerment research V1	36

Further Information Favourable Opinion with Additional Conditions		
REC Reference	**Application Short Title**	**Number of Days on Clock**

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**
12/SC/0518	DEFO and physiotherapy after Botulinum toxin for spasticity: pilot RCT	8

Favourable Opinion with Additional Conditions		
REC Reference	**Application Short Title**	**Number of Days on Clock**
12/SC/0171	Single & Multiple Escalating Doses of SMT C1100	15
12/SC/0283	TB032: AERAS-402 and MVA85A in BCG vaccinated adults	22
12/SC/0454	Understanding Patient Experience of Out-of-Hours Primary Care	5
12/SC/0483	The in vivo performance of a bone conserving hip replacement	35
12/SC/0491	PK study of Fluticasone/Salmeterol combinations (329/207)	17
12/SC/0516	Comparative Assessment of Effectiveness of Hep C Antiviral Therapies	8
12/SC/0517	Client experience of measures in psychological therapy	8
12/SC/0553	Safety, Tolerance, PK & PD of Sulforadex in healthy males.	14
12/SC/0565	Cultural Processes Related to Maternity: an ethnographic study	17
12/SC/0585	Bronchiectasis information and education V1.0	11
12/SC/0618	Guided CBT Self-Help for Child Anxiety: Long-Term Follow Up	20
12/SC/0630	GSK systemic amyloidosis	20
12/SC/0640	Safety, PK and PD of Rupatidine in Healthy Japanese Subjects SAD & MAD	13
12/SC/0646	Adults' Experiences of Having ADHD - V1	13
13/SC/0024	The temporal dynamics of attention deficits after stroke v1.0	48
13/SC/0037	Family Reported Experiences Evaluation (FREE) Study	20
13/SC/0044	Eribulin (HALAVEN®) Use for the Treatment of Advanced Breast Cancer	14
13/SC/0054	Global Registry in Patients with Atrial Fibrillation	24
13/SC/0127	Social Cognition and Fibromyalgia	17

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
12/SC/0205	Do complementary therapies aid patients with pituitary disease?	39
12/SC/0520	Central venous catheter dressing durability evaluation in ICU	15

Provisional Opinion		
REC Reference	**Application Short Title**	**Number of Days on Clock**
13/SC/0068	PK study of Esketamine nasal spray in Healthy Japanese subjects	N/A
13/SC/0130	Radiation Biomarkers after Medical Exposure to Ionising Radiation	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**

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**
12/SC/0569	CFTY720D2405: Fingolimod after natalizumab observational study	76
12/SC/0570	CFTY720D2406: long-term observational fingolimod study	76

Proportionate review applications for ethical review over 14 days timeline		
REC Reference	**Application Short Title**	**Number of Days on Clock**
12/SC/0520	Central venous catheter dressing durability evaluation in ICU	15
13/SC/0190	PROPER - Patient reported outcomes for patient empowerment research V1	36

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/IE/0109/AM05	(duplicate) Side effects, blood levels & effects of TAK-385 (v4)	Amendment to cover changes to study docs for Simbe	41
11/SC/0387/AM01	Cancer waiting times and their effect on survival	Sub. Amend 1 dated 30.9.2012	39

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**