

**NRES Committee South Central -
Berkshire B**

Annual Report

01 June 2011 – 31 March 2012

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee South Central - Berkshire B
Type of REC:	REC recognised to review CTIMPS in healthy volunteers - type i REs 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-Chair:	n/a
Co-ordinator:	Naaz Nathoo
PRSC Co-ordinator:	Naaz Nathoo
Assistant Co-ordinator:	n/a
Committee Address:	Bristol REC Centre Whitefriars Level 3, Block B Lewins Mead Bristol BS1 2NT
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Chair's overview of the past year:

This was a rather mixed period, in my view. On the positive side, the Committee quite rapidly became accustomed to reviewing studies involving patients (previously, only Phase 1 trials in healthy volunteers had been reviewed). The Lead Reviewer system was also adopted by the REC and, in most cases, LR reports were available prior to the relevant meeting. Quite large numbers of substantial amendments were reviewed; in part, this was due to the REC acting as successor to PIREC.

On the negative side, several members resigned during the review period, due to a variety of reasons. We were, however, able to recruit some new members and these generally contributed well as soon as they took up their positions. For new studies, our review turn round times (averaging 25 days at the last count; no individual time exceeded the 60 day limit) were close to the general REC norm but were too long, in my view. The fact that we had a number of co-ordinators in the review period may have been a factor, even though all of them, in my opinion, performed their duties well. It seems likely that the changeover periods may have hindered response speed to some extent. I am hoping that turn round times will become shorter, particularly if researchers can be persuaded to submit their responses in electronic format, whenever possible. Finally, the way in which GafREC is drafted, though generally well intentioned, does sometimes cause practical problems. Only being able to either accept or reject a substantial amendment is an example of this. If the regulations ever come up for revision, I hope that consideration will be given to practical issues.

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	
Ms Fiona Connolly	Nurse	Lay	01/06/2011	10/01/2012
Dr Francesca Greco	Lecturer in Pharmaceutics	Expert	01/06/2011	
Dr Andrew Hill	Pharmacist	Expert	20/10/2011	
Mr John Stanley Inman	Retired Pharmacist	Lay	01/06/2011	
Ms Christine Palmer	Retired	Lay Plus	01/06/2011	11/10/2011
Ms Jane Redgrove		Lay	01/06/2011	01/08/2011
Dr John Sheridan	Consultant Toxicologist and Chemist	Expert	01/06/2011	
Dr Robert Smith	General Practitioner	Expert	01/06/2011	
Mr Paul Douglas Soper	Research Manager	Lay	01/06/2011	
Miss Louise Anne Stainer	Biomedical Scientist	Expert	20/10/2011	
Mrs Jane Turner	Radiographer	Expert	20/10/2011	

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Ms Vivienne Laurie	Barrister	Lay Plus	13/03/2012
Ms Ann Quinn	Head of the School of Health and Social Care	Lay	13/03/2012
Dr M.J. Proven	Coordinator for Quality Assurance in Research	Lay	01/09/2011

Member Bank

Name	Occupation	Expert or Lay	Meeting date attended

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

Name	Declaration of Interest	Date
Dr John Sheridan	None	13/12/2011
Mr Michael Arnott	None	13/12/2011
Mr Paul Douglas Soper	Senior Scientist ; Ingredient & Process Research Team - Kraft Foods	13/09/2011
Dr Robert Smith	None	30/12/2011
Dr Francesca Greco	On the board for the Academy of Pharmaceutical Sciences.Lecturer at the University of Reading.	13/12/2011
Mr John Stanley Inman	Shareholder in Pzifer	13/12/2011
Mrs Jane Turner	Shareholder in GSK	13/12/2011
Miss Louise Anne Stainer	None	13/03/2012
Dr Andrew Hill	None	13/12/2011

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

Month	Date	Number of Members Present at Meeting
July	12/07/2011	7
August	16/08/2011	7
September	13/09/2011	8
October	11/10/2011	8
November	15/11/2011	10
December	13/12/2011	7
January	10/01/2012	9
February	14/02/2012	8
March	13/03/2012	8

9 full committee meetings were held during the reporting period.

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

Month	Date	Number of Members Present at Meeting
March	28/03/2012	3

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

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

Name	Number of Meetings Attended
Dr John Sheridan	9
Mr Michael Arnott	9
Mr John Stanley Inman	7
Ms Fiona Connolly	6
Mr Paul Douglas Soper	6
Dr Benjamin Whalley	5
Dr Francesca Greco - maternity leave to & including Mar 2013	5
Mrs Jane Turner	5
Dr Robert Smith	4
Miss Louise Anne Stainer	4
Dr Andrew Hill	3
Ms Christine Palmer	3
Ms Helena Brennan	2
Ms Jane Redgrove	1
Ms Vivienne Laurie	1
Ms Ann Quinn	1
Dr M.J. Proven	1

Number of inquorate meetings held: 0

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

Name	Number of Meetings Attended
Dr John Sheridan	1
Miss Louise Anne Stainer	1
Mr Michael Arnott	1

Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Dr John Sheridan	17/07/2011 - 18/07/2011	Equality & Diversity, Core Learning Unit, NHS
Dr Benjamin Whalley	30/06/2011 - 30/06/2011	Equality & Diversity, University of Reading
Miss Louise Anne Stainer	08/02/2012 - 08/02/2012	Induction, NRES
Mrs Jane Turner	29/03/2012 - 29/03/2012	Induction, NRES
Dr Andrew Hill	20/03/2012 - 20/03/2012	Induction, NRES

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	11	30.56
Phase 1	14	38.89
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	11	30.56
Total Applications Reviewed	36	100

Table 2: Other REC activity during the reporting period:

Number of applications made invalid by co-ordinator	0
Number of studies withdrawn prior to the meeting	6
Number of student applications reviewed	5
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	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	2.78
Favourable Opinion with Additional Conditions	12	33.33
Unfavourable Opinion	1	2.78
Provisional Opinion	22	61.11
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
Total	36	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	17	47.22
Further Information Favourable Opinion with Additional Conditions	4	11.11
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	1	2.78
Favourable Opinion with Additional Conditions	12	33.33
Unfavourable Opinion	1	2.78
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	0	0.00
Number of studies withdrawn after the meeting	1	2.78
Total	36	100

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

Total Applications Reviewed	3
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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	3	100.00
Favourable Opinion with Additional Conditions	0	0.00
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	0	0.00
Unfavourable Opinion	0	0.00
Total	3	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	4.00
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	30
Number of days taken to final decision - mode	25
Number of SSAs (non-Phase 1) reviewed	0
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%
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	12
Number of substantial amendments over 35 days	0
Number of substantial amendments over 35 days as a % of total substantial amendments	0.0%
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	0
Number of modified amendments over 14 days	0
Number of modified amendments over 14 days as a % of total modified amendments	0%
Number of proportionate review applications for ethical review over 14 days*	0
Number of proportionate review applications over 14 days as a % of total	0.00%

***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:

Further Information Favourable Opinion with Standard Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/SC/0311	Is Liceko ® more effective than Lyclear against head lice?	13
11/SC/0324	A study of the effect of rifampicin on the drug levels of sotrastaurin	33
11/SC/0348	Patient-Instructor relationships and adherence to exercise.	17
11/SC/0375	A Study to Assess the Potential Effects of Diclofenac Spray on Skin	55
11/SC/0387	Cancer waiting times and their effect on survival	34
11/SC/0441	QBR110077	30
11/SC/0443	3D culture simulation; hepatocyte ischaemia & resuscitation strategies	29
11/SC/0485	The IMAGINE 3 Study	43
11/SC/0527	Burnout in Improving Access to Psychological Therapy (IAPT) therapists	32
11/SC/0531	GS-7340 & TDF in Treatment-Naive Adults with CHB	47
11/SC/0533	EN3348 for treatment of Non-Muscle Invasive Bladder Cancer	36
12/SC/0023	S101-RGL-003: MabThera Biosimilar SAIT101 in RA	36
12/SC/0024	Ranibizumab in visual impaired patients due to macular edema (CRVO).	38
12/SC/0025	Ranibizumab in visual impaired patients due to macular edema(BRVO)	38
12/SC/0038	Electrophysiological Effects of ABT-639 on Diabetic Neuropathy	25
12/SC/0082	Single Ascending Doses of ALN-TTR02 in Healthy Volunteers	34
12/SC/0132	ChAdOx1-NP+M1 dose escalation study	54

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
11/SC/0339	Phase 2 study of HDACi JNJ-26481585 in subjects with CTCL	26
11/SC/0377	PARP Inhibitor in Advanced Solid Tumour or B-Cell Malignancies VFinal	42
11/SC/0388	Effectiveness of Cognitive Behavioural Therapy for Comorbid Insomnia	36
12/SC/0009	Transcranial DC stimulation for chronic pain in spinal cord injury	30

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/SC/0503	Validation of the Hyperinsulinemic-Euglycemic Clamp Technique	49
12/SC/0194	Adolescent perception of smile aesthetics of missing lateral incisors	11
12/SC/0196	Parental understanding of childhood cancer treatment v1.0	11
12/SC/0197	A comparison of various decalcification methods and solutions V1.	7

Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
11/SC/0436	Music Rehabilitation Trial for Cochlear Implantees: Version 2	27
11/SC/0442	Bioequivalence study for strontium pharmacokinetic parameters	24
11/SC/0472	Guided Self-Help for Childhood Anxiety Problems (Version 1)	23
11/SC/0492	Validating the accuracy of keratometry	16
11/SC/0494	TREAT	23
12/SC/0092	Phase 1 study of ASP6973 First-in-man, Food Effect & Drug interaction	25
12/SC/0093	4-treatment crossover relative bioavailability in healthy subjects	25
12/SC/0096	Study comparing 3 different particle sizes to reference	19
12/SC/0097	Single & Multiple Escalating Doses of RQ-0000010 in Healthy Subjects	25
12/SC/0108	Prevalence of periodic limb movement disorder in dialysis patients	20
12/SC/0122	A Bioequivalence Study with Valacyclovir in Healthy Japanese Subjects	20
12/SC/0135	PK/PD study in paediatric and adult patients with type 2 diabetes	24

Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
11/SC/0444	Personalising opioid therapy for cancer pain relief - a pilot trial	27

Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
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Provisional Opinion Pending Consultation with Referee

REC Reference	Application Short Title	Number of Days on Clock
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Further information response not complete

REC Reference	Application Short Title	Number of Days on Clock
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Withdrawn after the meeting

REC Reference	Application Short Title	Number of Days on Clock
11/SC/0496	Amifampridine Phosphate: A thorough QTc study	14

Invalid Application		
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REC Reference	Application Short Title	Number of Days on Clock
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No Opinion Pending Consultation with Referee		
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REC Reference	Application Short Title	Number of Days on Clock
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Not Requiring Review by NHS REC		
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REC Reference	Application Short Title	Number of Days on Clock
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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	
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
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