

# NRES Committee South Central - Berkshire B

## Annual Report

**01 April 2013 – 31 March 2014**

## Part 1 – Committee Membership and Training

<b>Name of REC:</b>	NRES Committee South Central - Berkshire B
<b>Type of REC:</b>	RECs recognised to review CTIMPS in healthy volunteers - type i RECs recognised to review CTIMPS in patients - type iii
<b>Type of Flag:</b>	Phase 1 Studies in Patients IRB Registered Phase 1 Studies in Healthy Volunteers Phase 1 Studies in Patients Qualitative Research Research Involving Adults Lacking Capacity Research Involving Children
<b>Chair:</b>	Dr John Sheridan
<b>Vice-Chair:</b>	Mr Michael Arnott
<b>Alternate Vice-Chair:</b>	Mr John Inman
<b>REC Manager:</b>	Miss Stephanie Macpherson
<b>PRSC Manager:</b>	Miss Stephanie Macpherson
<b>REC Assistant:</b>	Miss Gemma Oakes
<b>Committee Address:</b>	Bristol REC Centre Whitefriars Level 3, Block B Lewins Mead Bristol BS1 2NT
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### **Chair's overview of the past year:**

I consider that 2013 was a good year for the REC. Existing members continued to develop, with the help of the training program, and an enthusiastic new member was recruited. Another excellent candidate has just been appointed. A varied range of studies were considered and the skills of the REC in the evaluation of non-Phase 1 studies (historically, only Phase 1 studies were considered) continued to improve. We now have an excellent REC manager and an enthusiastic and promising REC assistant. I was also pleased to see the appointment of a very committed and competent alternate vice-chair. The situation looks very favourable for achieving our key objective of making turn round times as short as possible.

The only real issue that was not resolved in the review period was the shortage of expert members and the only new one to surface was the rather cumbersome new lead reviewer form.

## 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	
Dr Francesca Greco	Lecturer in Pharmaceuticals	Expert	01/06/2011	17/06/2013
Mrs Sue Harrison	Retired Managing Director of a Trade Association	Lay Plus	13/02/2013	
Dr Andrew Hill	Research scientist	Expert	20/10/2011	21/06/2013
Mr John Inman	Retired Pharmacist	Lay	01/06/2011	
Dr Joanne Milton	Project Manager	Lay	11/02/2013	
Mr Yash Patel	Research Support Associate	Expert	20/08/2013	
Ms Ann Quinn	Head of the School of Health and Social Care	Expert	05/02/2013	05/08/2013
Dr John Sheridan	Consultant Toxicologist and Chemist	Lay	01/07/2011	
Dr Mary-Beth Sherwood	Clinical Researcher	Lay	28/05/2013	30/11/2013
Mr Paul Soper	Research Manager	Lay Plus	01/06/2011	
Miss Louise Stainer	Biomedical Scientist	Expert	20/10/2011	
Mrs Jane Turner	Radiographer	Expert	12/10/2011	31/05/2013
Ms Decca Warrington	Volunteer Arts Coordinator	Lay Plus	09/07/2013	
Mr Stuart Young	Director	Lay	29/05/2013	

### Co-opted Members

Name	Occupation	Expert or Lay	
Ms Alison Eden	Publisher	Lay Plus	10 September 2013
Mrs Chrissie Lawson	Nurse Specialist	Expert	12 November 2013

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

Name	Declaration of Interest	Date
Dr Mary-Beth Sherwood	No Declarations of interest.	13/06/2013
Mr Paul Soper	Senior Scientists for Ingredient Research Team, Mondelez International; Shares in Mondelez	14/01/2014
Mr John Inman	Consultant to Pfizer Limited (one occasion in 2013); Shareholder in Pfizer; Reading Independent Ethic Committee (not medicines).	14/01/2014
Mr Stuart Young	Director of Coronet Consulting (Consulting only, no involvement in studies).	14/01/2014
Mr Yash Patel	Commonwealth Secretariat, London Employee of Clinical Trials & Research Governance (CTRG), University of Oxford; Work with Oxford Uni NHS Trust Hospitals, Oxford..	14/01/2014
Mrs Sue Harrison	Trustee Re-Solv.	14/01/2014
Ms Decca Warrington	No Declarations of interest.	14/01/2014
Dr Joanne Milton	Shares in Oxford Biomedica; Member of Reading Independent Ethics Committee which reviews non-clinical (Cosmetic) research studies.	14/01/2014
Mr Michael Arnott	Member of Reading Independent Ethics Committee which reviews non-clinical (Cosmetic) research studies.	14/01/2014
Dr John Sheridan	Member of Reading Independent Ethics Committee which reviews non-clinical (Cosmetic) research studies.	14/01/2014
Miss Louise Stainer	No Declarations of interest.	11/02/2014

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

Month	Date	Number of Members Present at Meeting
April	16/04/2013	9
May	14/05/2013	9
June	11/06/2013	10
July	09/07/2013	8
August	13/08/2013	9
September	10/09/2013	9
October	08/10/2013	8
November	12/11/2013	8
January	14/01/2014	9
February	11/02/2014	8
March	11/03/2014	7

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
April	29/04/2013	3
June	03/06/2013	3
July	01/07/2013	3
July	29/07/2013	3
September	30/09/2013	3
October	28/10/2013	3
November	27/11/2013	3
January	27/01/2014	3
February	24/02/2014	3
March	11/03/2014	3
March	24/03/2014	3

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

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Mr Michael Arnott	11
Ms Decca Warrington	10
Dr John Sheridan	10
Dr Joanne Milton	9
Mr Paul Soper	9
Mr John Inman	9
Mrs Sue Harrison	8
Miss Louise Stainer	7
Mr Stuart Young	6
Mr Yash Patel	4
Ms Ann Quinn	4
Dr Andrew Hill	2
Dr Francesca Greco	1
Dr Mary-Beth Sherwood	1
Mrs Jane Turner	1

**Number of inquorate meetings held: 0**

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

<b>Name</b>	<b>Number of Meetings Attended</b>
Dr John Sheridan	7
Mr Mike Arnott	7
Miss Louise Stainer	5
Dr John B Sheridan	4
Mr Michael Arnott	4
Mr Yash Patel	3
Mr John Inman	1
Dr Pamela S Laurie	1
Dr Richard Philip Craven	1

## Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Dr Joanne Milton	04/07/2013 - 07/07/2013	Induction, HRA
Dr Joanne Milton	24/05/2013 - 24/05/2013	Equality & Diversity, Oxford Learning Institute
Dr Joanne Milton	18/04/2013 - 18/04/2013	Research Data and Confidentiality e-learning course, Medical Research Council
Dr John Sheridan	10/06/2013 - 10/06/2013	Regional Chairs Network Meeting, SDL
Mr Michael Arnott	13/05/2013 - 13/05/2013	Equality & Diversity, Royal College of Physicians
Dr Joanne Milton	20/11/2013 - 20/11/2013	National Members Training Day, HRA
Mrs Sue Harrison	05/02/2014 - 05/02/2014	Researcher Training Day, HRA
Dr John Sheridan	20/08/2013 - 20/08/2013	Berkshire REC Training meeting
Mr Michael Arnott	20/08/2013 - 20/08/2013	Berkshire REC Training meeting
Mr Paul Soper	20/08/2013 - 20/08/2013	Berkshire REC Training meeting
Mr John Inman	20/08/2013 - 20/08/2013	Berkshire REC Training meeting
Miss Louise Stainer	20/08/2013 - 20/08/2013	Berkshire REC Training meeting
Dr Joanne Milton	20/08/2013 - 20/08/2013	Berkshire REC Training meeting
Mrs Sue Harrison	20/08/2013 - 20/08/2013	Berkshire REC Training meeting
Ms Decca Warrington	20/08/2013 - 20/08/2013	Berkshire REC Training meeting
Mr Stuart Young	20/08/2013 - 20/08/2013	Berkshire REC Training meeting
Mr Yash Patel	03/03/2014 - 03/03/2014	Induction, NRES
Mr Michael Arnott	10/06/2013 - 10/06/2013	NREAP Chairs meeting
Dr John Sheridan	10/06/2013 - 10/06/2013	NREAP Chairs meeting
Mr Yash Patel	19/02/2014 - 19/02/2014	Reviewing CTIMPs, NRES
Mrs Sue Harrison	19/03/2014 - 19/03/2014	Equality & Diversity, HRA
Mr Stuart Young	25/03/2014 - 25/03/2014	Equality & Diversity, HRA



## 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	8	14.04
Phase 1	22	38.60
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	27	47.37
<b>Total Applications Reviewed</b>	<b>57</b>	<b>100</b>

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

Number of applications made invalid by co-ordinator	6
Number of studies withdrawn prior to the meeting	11
Number of student applications reviewed	8
Number of paediatric applications reviewed	4
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	0	0.00
Favourable Opinion with Additional Conditions	7	12.28
Unfavourable Opinion	0	0.00
Provisional Opinion	50	87.72
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>57</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	44	77.19
Further Information Favourable Opinion with Additional Conditions	6	10.53
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	7	12.28
Unfavourable Opinion	0	0.00
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	0	0.00
<b>Total</b>	<b>57</b>	<b>100</b>

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

<b>Total Applications Reviewed</b>	<b>27</b>
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**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	4	14.81
Favourable Opinion with Additional Conditions	11	40.74
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	12	44.44
Unfavourable Opinion	0	0.00
<b>Total</b>	<b>27</b>	<b>100</b>

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

<b>Average number of applications reviewed per full meeting</b>	5.18
<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>	28
<b>Number of days taken to final decision - mode</b>	28

<b>Number of SSAs (non-Phase 1) reviewed</b>	2
<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>	3
<b>Number of applications for SSA review over 14 days</b>	2
<b>Number of applications for SSA review over 14 days as % of all Phase 1 (SSAs)</b>	66.7%

<b>Number of substantial amendments reviewed</b>	102
<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>	2.9%

<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>	3
<b>Number of proportionate review applications over 14 days as a % of total</b>	11.1%

**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>
13/SC/0158	Dose-escalation study to evaluate safety and efficacy of QM1114-DP	34
13/SC/0188	Effect of Baricitinib on the PK of Digoxin in Healthy Subjects	39
13/SC/0189	STOP: Smoking Cessation Study	25
13/SC/0193	Amifampridine Phosphate: A Thorough QTc study	35
13/SC/0216	Effect of glucose on QTc interval in Type 1 diabetes	41
13/SC/0232	Investigating the effectiveness of visual illusions in treating pain	26
13/SC/0234	Visual and Functional Assessment in Low Vision Patients	44
13/SC/0235	Crohn's Extent of Resection Trial (CERT) v1.04	34
13/SC/0256	Testosterone Solution in Hypogonadal Men (TSAT Study)	36
13/SC/0257	The effect of antacids and multivitamins on raltegravir (RalpH)	41
13/SC/0284	Altering gait of patients with medial compartment osteoarthritis	40
13/SC/0304	Safety, Tolerability, PK&PD of AZD4721 SAD+Bioavailability	41
13/SC/0313	EXPLAIN STUDY version 1.1 (21st January 2013)	19
13/SC/0342	Intra-subject Variability and Pharmacokinetics of Lomitapide	19
13/SC/0360	pegIFN Lambda/RBV/TVR or pegIFN Alfa/RBV/TVR HCV G1 Naive or Relapsed	40
13/SC/0364	TP05 In Active UC	10
13/SC/0366	SAD and MAD study in healthy and mild-to-moderate psoriatic subjects	32
13/SC/0370	Compulsivity in Anorexia: A Questionnaire Study	13
13/SC/0397	Data fusion in haemodialysis	52
13/SC/0400	A Single Dose Study of MK-8351 in a Lung Allergen Challenge	26
13/SC/0405	Clinical trial of CD5789 cream in healthy Japanese male subjects	18
13/SC/0411	Colestilan and Candesartan Cilexetil Drug Drug Interaction Study	35
13/SC/0413	tACS and fMRI in PD - Version 1.0	47
13/SC/0422	Understanding the experiences of teenagers with low mood- V1	34
13/SC/0431	Baricitinib and Ciclosporin Interaction Study	28
13/SC/0432	Simvastatin drug-drug interaction study	26
13/SC/0433	EIAW - Japanese DDI	29
13/SC/0434	Enhancing in-patient supportive care for frail elders	21
13/SC/0448	Pharmacokinetics of OZ439 and piperazine	20

13/SC/0474	Can 8 weeks of IF induce remission in type 2 diabetics in Swindon?	18
13/SC/0476	Safety, Tolerability, PK&PD of AZD4721(MAD)+ Compare to PD of AZD5069	22
13/SC/0485	Biases and experiences in adolescent depression	17
13/SC/0487	Relative Bioavailability of intact and sprinkled 20 mg Lomitapide	21
13/SC/0496	Effect of Intravenous APD421 on Cardiac Conduction in Healthy Subjects	20
13/SC/0550	Evaluation of safety and efficacy of QM1114-DP in knee osteoarthritis	15
13/SC/0569	Dopamine and Choice in Depression	21
13/SC/0571	Long term outcomes in heart attack patients with stable CAD	7
13/SC/0583	Matchpoint	19
13/SC/0584	First in human study of antiCCL20 monoclonal antibody (GSK3050002)	24
13/SC/0586	Developing and validating new measures of cognitive performance.	18
13/SC/0637	Factors affecting a patient's decision to seek help in hospital	6
13/SC/0641	App study	9
14/SC/0007	The role of ageism in predicting CST dementia group outcomes: Ver.1	28
14/SC/0018	PK study of Fluticasone/Salmeterol combinations (329/210)	28
14/SC/0019	PK study of Fluticasone/Salmeterol combinations (329/211)	28
14/SC/0043	Parental Responses to Child Experiences of Trauma	34
14/SC/0058	Temporomandibular joint disorders and obstructive sleep apnoea	6
14/SC/0062	Deaf children with autism	13
14/SC/0064	SAD, MAD, Safety, PK, PD & FE of ASP7657 in healthy volunteers	23
14/SC/0067	Blood endotoxin detection in dialysis patients	12
14/SC/0079	MAT-IA	19
14/SC/0081	A study of the drug Clexane in healthy volunteers	19
14/SC/0114	Cognitive Variability and Risk of Falling in Old Age V1	7
14/SC/0127	The psychological impact of chronic leg ulceration on caregivers	17
14/SC/0166	Joint reconstruction from CT and MRI data	5

Further Information Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
13/SC/0187	Investigation of a novel biomarker for heart failure (C4a-des-Arg)	22
13/SC/0310	LDE225 in adult elapsed patients or elderly leukemia patients.	34
13/SC/0311	GP2013 in patients with previously untreated, advanced lymphoma.	36
13/SC/0580	Imaging in peripheral neuropathies	23

14/SC/0011	Egg activation and cytoplasmic movements	28
14/SC/0126	Rare diseases of the bone, joint and vessels Study (RUDY)	24

#### Further Information Unfavourable Opinion

REC Reference	Application Short Title	Number of Days on Clock
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#### Favourable Opinion with Standard Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/SC/0315	Use of NHSBT leukocyte cones in in vitro characterisation assays	14
13/SC/0527	Pilot study to identify genetic factors associated with acute porphyria	6
14/SC/0116	Barriers to self-management in primary care	11
14/SC/0176	Enhanced surveillance and response to Clostridium difficile	11

#### Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/SC/0176	TREAT-GDM	28
13/SC/0239	Factors affecting decisions to take part in cardiovascular research	10
13/SC/0240	What effect do drugs have on the osmolality of feeds given to infants	15
13/SC/0242	The Effects of Immersion on Pain, Discomfort and Catastrophising.	14
13/SC/0277	Evaluating a novel service model in Cardiac Rehabilitation	43
13/SC/0293	An indepth exploration of an aphasia care pathway.	36
13/SC/0312	SEE-HF Study	3
13/SC/0314	In-vitro testing of location indicating nasogastric tube	5
13/SC/0344	Bioavailability of PRF-021 Compared to Omacor	27
13/SC/0379	RESPIRE	5
13/SC/0381	acCURAte-Business using Assistive Technology (CURA-B)	13
13/SC/0429	Quality of life study in desmoid disease (Version 1)	3
13/SC/0530	ORANGE II PLUS	13
13/SC/0567	Ethnography of young mothers' feeding experiences in South Yorkshire	6
13/SC/0614	Observational study: Renal denervation impact in hypertensive diabetics	16
13/SC/0642	Investigating the prevalence of thyroid antibodies	5
14/SC/0006	Programme of support delivered in a hospice for chronic heart failure	27
14/SC/0118	Development of a physical activity intervention: rheumatoid arthritis	12

Unfavourable Opinion		
REC Reference	Application Short Title	Number of Days on Clock

Provisional Opinion		
REC Reference	Application Short Title	Number of Days on Clock
14/SC/0172	Measuring cognitive processes in CFS.	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	
Proportionate review applications for ethical review over 14 days timeline			
REC Reference	Application Short Title	Number of Days on Clock	
13/SC/0240	What effect do drugs have on the osmolality of feeds given to infants	15	
13/SC/0313	EXPLAIN STUDY version 1.1 (21st January 2013)	19	
13/SC/0434	Enhancing in-patient supportive care for frail elders	21	
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	
13/SC/0371	Safety, Tolerability, PK&PD of AZD4721 SAD+Bioavailability	24	
13/SC/0494	EIAW - Japanese DDI	15	
Substantial Amendments over 35 day timeline			
Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
12/SC/0352/AM05	INDRA	Substantial Amendment 3, 23.04.13	43
12/SC/0518/AM01	DEFO and physiotherapy after Botulinum toxin for spasticity: pilot RCT	1	51
12/SC/0649/AM01	Development and implantation of normal human preimplantation embryos	Amendment number 1, 05/06/13	60

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