

National Research Ethics
Service


Health Research Authority

NRES Committee South West - Exeter

Annual Report

01 April 2011 – 31 March 2012

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee South West - Exeter
Type of REC:	Recognised to review CTIMPs in patients Type III
Type of Flag:	CTIMPs Medical Devices study Phase I studies in patients Research Involving Children
Chair:	Dr Denise Sheehan
Vice-Chair:	Dr Lee Burton
Alternate Vice-Chair:	
Co-ordinator:	Mrs Kirsten Peck
PRSC Co-ordinator:	Mrs Kirsten Peck
Assistant Co-ordinator:	
Committee Address:	South West REC Centre Level 3 Block B Lewins Mead Whitefriars Bristol BS1 2NT
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Chair's overview of the past year:

With the recruitment of a Pharmacist Member the Committee has once again been able to consider CTIMPs which members find very interesting.

The Committee had a visit from Joan Kirkbride earlier in the year as she had been invited back after her initial visit in 2010. I am delighted to say that she was very pleased with how we were now functioning as a Committee.

The Committee continue to work very well together as a team and Members were very pleased to hear that full accreditation had been attained.

The NRES Committee South West – Exeter are looking forward to another year working together.

NRES Committee South West - Exeter Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Mrs Isobel Brooks	Retired Social Care Manager	Lay	01/04/2010	
Mrs Nicola Burch	Management Development Consultant	Lay	01/04/2010	
Dr Lee Burton	GP	Expert	25/03/2009	
Dr Nicole Dorey	Consultant Clinical Oncologist	Expert	05/02/2009	
Mr Christoph Lohan	Pharmacist	Expert	15/07/2011	
Dr Roy Powell	NIHR Research Design Service Consultant	Expert	01/04/2010	
Mrs Joan Ramsay	Retired Associate Director of Nursing (Women and Children) Locum Safeguarding Children Nurse	Expert	01/03/2009	
Dr Ken Read	Retired Statistician	Lay	01/04/2010	
Mr Phil Regan	Minister of Religion	Lay Plus	05/06/2009	
Mrs Carol Richardson	Senior Nurse (Retired)	Lay	01/05/2009	
Dr Lynda Rogers-Beel	Senior Lecturer/Registered Nurse/Tutor	Expert	01/04/2010	
Dr Denise Sheehan	Consultant Oncologist	Expert	01/04/2010	
Dr Chris Vallance	Retired chemist (non-research)	Expert	01/04/2010	
Mr Royston Van Tromp	Retired Head Teacher	Lay Plus	01/05/2009	
Ms Decca Warrington	Administrator	Lay	01/10/2010	
Dr Kim Wright	Senior Lecturer	Expert	01/04/2010	
Dr Eleanor Zarembo	Associate Specialist in Anaesthetics	Expert	11/11/2008	

Deputy Members

Name	Occupation	Expert or Lay	Meeting date attended

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended

Member Bank

Name	Occupation	Expert or Lay	Meeting date attended

NRES Committee South West - Exeter: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Dr Denise Sheehan	None	22/07/2011
Dr Lee Burton	None	22/07/2011
Dr Roy Powell	None	22/07/2011
Dr Ken Read	None	22/07/2011
Mrs Nicola Burch	Works as a counselling coordinator in Young Devon's Youth Enquiry Service - Take referrals from the NHS: a very small possibility of being involved in a research project.	22/07/2011
Dr Kim Wright	None	22/07/2011
Dr Nicole Dorey	R&D lead for the Lung and Upper GI MOT's in Torbay hospital	22/07/2011
Mrs Joan Ramsay	Locum named nurse for safeguarding children, Musgrove Park Hospital	22/07/2011
Mr Phil Regan	None	22/07/2011
Mrs Carol Richardson	Honorary Company Secretary/Director of Charity North Somerset Learning Disabilities Advice and Advocacy Service - affiliated to MENCAP which intermittently undertakes research	22/07/2011
Dr Lynda Rogers-Beel	Employed by University of Southampton as a Senior Lecturer Trustee for Chichester Counselling Services (non paid) - Registered Charity. Due to the nature of my employment I am involved with NHS/Social Services. We are also involved with health care related, independent/private sector organisations. This includes supporting studies	22/07/2011
Dr Eleanor Zaremba	None	22/07/2011
Mrs Isobel Brooks	None	22/07/2011
Dr Chris Vallance	Shareholder in:Astra Zeneca, GlaxoSmithKline, Dechra Pharmaceuticals	22/07/2011
Ms Decca Warrington	None	22/07/2011
Mr Royston Van Tromp	None	22/07/2011
Mr Christoph Lohan	None	22/07/2011

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

Month	Date	Number of Members Present at Meeting
April	07/04/2011	12
May	05/05/2011	11
July	07/07/2011	14
August	04/08/2011	12
September	01/09/2011	12
October	06/10/2011	14
November	03/11/2011	14
December	01/12/2011	13
January	05/01/2012	15
February	02/02/2012	13
March	01/03/2012	11

11 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
September	19/09/2011	4
October	24/10/2011	3
November	28/11/2011	3
January	20/01/2012	3
February	20/02/2012	3
March	26/03/2012	3

6 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 Lee Burton	11
Dr Lynda Rogers-Beel	10
Joan Ramsay	10
Dr Denise Sheehan	9
Dr Roy Powell	9
Dr Kim Wright	9
Mrs Carol Richardson	9
Mrs Isobel Brooks	9
Ms Decca Warrington	9
Mrs Nicola Burch	8
Dr Ken Read	8
Mr Phil Regan	8
Mr Royston Van Tromp	8
Nicole Dorey	8
Dr Chris Vallance	8
Mr Christoph Lohan	6
Dr Eleanor Zaremba	2

Number of inquorate meetings held: None

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

Name	Number of Meetings Attended
Dr Denise Sheehan	4
Dr Lynda Rogers-Beel	4
Mrs Isobel Brooks	4
Dr Lee Burton	3
Mr Christoph Lohan	2
Mrs Carol Richardson	1
Dr Chris Vallance	1

Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Joan Ramsay	18/05/2011 - 18/05/2011	Equality & Diversity, NRES
Nicole Dorey	20/06/2011 - 20/06/2011	Equality & Diversity, Royal Devon and Exeter hospital
Mrs Isobel Brooks	29/06/2011 - 29/06/2011	Equality & Diversity, NRES
Dr Lee Burton	08/11/2011 - 08/11/2011	Chairing Skills, NRES
Dr Kim Wright	21/07/2011 - 21/07/2011	Equality & Diversity, NRES
Dr Lee Burton	20/07/2011 - 20/07/2011	Equality & Diversity, NRES
Dr Chris Vallance	16/07/2011 - 16/07/2011	Equality & Diversity, NRES
Ms Decca Warrington	01/11/2011 - 01/11/2011	NRES Reviewing Clinical Trials of Investigational Medicinal Products (CTIMPs) Training Day, NRES
Ms Decca Warrington	21/07/2011 - 21/07/2011	Equality & Diversity, NRES
Ms Decca Warrington	22/11/2011 - 22/11/2011	NRES Adults Lacking Capacity training, NRES
Joan Ramsay	22/11/2011 - 22/11/2011	NRES Adults Lacking Capacity, NRES
Mr Christoph Lohan	18/11/2011 - 18/11/2011	Child Protection, Royal Devon and Exeter Hospital
Mr Christoph Lohan	06/09/2011 - 06/09/2011	Information Governance, Royal Devon and Exeter Hospital
Dr Denise Sheehan	21/03/2012 - 21/03/2012	Chairing Skills, 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	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	65	100.00
Total Applications Reviewed	65	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	11
Number of student applications reviewed	26
Number of paediatric applications reviewed	6
Number of device applications reviewed	9
Number of prisoner applications reviewed	1
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	0	0.00
Favourable Opinion with Additional Conditions	0	0.00
Unfavourable Opinion	7	10.77
Provisional Opinion	58	89.23
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	65	100
Number of studies sent back to full committee meeting for final opinion	3	

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	53	81.54
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	0	0.00
Unfavourable Opinion	7	10.77
Provisional Opinion	2	3.08
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	1	1.54
Number of studies withdrawn after the meeting	2	3.08
Total	65	100

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

Total Applications Reviewed	21
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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	4	19.05
Favourable Opinion with Additional Conditions	0	0.00
No Opinion transfer to full committee for review	0	0.00
Provisional Opinion	15	71.43
Unfavourable Opinion	2	9.52
Total	21	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.91
Number of applications for full ethical review over 60 days	3
Number of applications over 60 days as a % of total	4.62%
Number of days taken to final decision - average	38
Number of days taken to final decision - mode	38
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	117
Number of substantial amendments over 35 days	6
Number of substantial amendments over 35 days as a % of total substantial amendments	5.1%
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	23
Number of modified amendments over 14 days	3
Number of modified amendments over 14 days as a % of total modified amendments	13.0%
Number of proportionate review applications for ethical review over 14 days*	11
Number of proportionate review applications over 14 days as a % of total	52.38%

***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/SW/0047	Band 5 nurses perceptions of engaging in clinical supervision	46
11/SW/0052	The psychological impact of Early Pregnancy Loss - Version 2	33
11/SW/0054	Infant Peptide Feed Study	32
11/SW/0059	Psychological needs and assessment of stroke patients and families	36
11/SW/0060	Adherence and treatment seeking delay for febrile neutropenia.	41
11/SW/0061	Phenotyping RPGR Retinal Dystrophy Patients for Gene Therapy Trials	28
11/SW/0062	Phenotyping AIPL1 Retinal Dystrophy Patients for Gene Therapy Trials	28
11/SW/0077	Perceptual Biases and Behaviour in a Forensic Population (Version 1)	62
11/SW/0082	Cognitive Impairment and Wellbeing in Acquired Brain Injury	27
11/SW/0083	Patient perspectives on ankylosing spondylitis residential course V1	37
11/SW/0085	Survey of General Practitioner attitudes towards Community Matrons	48
11/SW/0088	Breech presentation and risk of maternal hypothyroidism vs 1	62
11/SW/0089	NHS staff attitudes to self-harm: Norms and behaviour	57
11/SW/0141	System One Evaluation	41
11/SW/0148	Exploring Newly Qualified RNs' views on education/patient safety V.1.	54
11/SW/0156	Informal learning in traumatic brain injury case management	53
11/SW/0162	Telemedicine in cochlear implants	38
11/SW/0163	An in situ model investigating dentine mineralization and occlusion	44
11/SW/0165	What is going on in public involvement in health research? Version 1.0	30
11/SW/0166	PROX003 Proxima 2 Arterial Blood Study Version 1	43
11/SW/0188	Adolescent experience of anorexia: triads & attachment (version 1)	54
11/SW/0190	Pilot study: Tenease	66
11/SW/0195	DPP4 and GLP-1's microvascular actions	56
11/SW/0196	Establishing prevalence of Vitamin D deficiency in Elderly ED patients	41
11/SW/0199	Does the structure of small blood vessels change in diabetes?	22
11/SW/0214	Is Melissa an Effective Treatment for Sleep Disorder in Dementia?	38
11/SW/0215	Chest Tomosynthesis for Lung Hila and Nodules Accuracy Trial	21
11/SW/0216	An exploration into the experience of BME mental health practitioners	38
11/SW/0218	Minimally Invasive Cheilectomy Trial V1.0	28

11/SW/0222	PREDICTING SERIOUS DRUG SIDE EFFECTS IN GASTROENTEROLOGY	8
11/SW/0223	ROOT CANAL SEALER - PA09103	26
11/SW/0231	Investigating women's previous experiences of asthma care in pregnancy	38
11/SW/0250	The potential use of SOX11 as a diagnostic tool for MCL.	50
11/SW/0251	Computational Investigation of Blood Flow in the Circle of Willis	58
11/SW/0253	The effects of rumination on recognition of emotion in infant faces	35
11/SW/0260	Do-Well	12
11/SW/0261	Adiponectin & Insulin Resistance (AIR)	42
11/SW/0263	The psychological consequences of false-positive mammograms	5
11/SW/0275	Comparison of saliva substitutes- version 3	40
11/SW/0287	The effect of the tongue on tooth tissue loss	39
11/SW/0292	Version 3.0 URGO 310 3082 Vs AQUACEL in the Management of Leg Ulcers	39
11/SW/0294	Investigation in to parental perceptions of empowerment	51
11/SW/0296	Retrospective study of service users' medications	15
11/SW/0297	Primary Open Angle Glaucoma in the Young	36
11/SW/0311	Comparing BNP with CPEX variables	33
11/SW/0320	Effects of intermittent compression on the hand or foot	36
11/SW/0329	Increased angiogenesis and improved perfusion as a result of HBOT.	41
11/SW/0332	An investigation into the role of pharmacists in eczema management	25
11/SW/0333	Patient evaluation of dermatology-specific quality of life measures	27
11/SW/0334	Aspects of cumulus cell biology as markers of oocyte quality	13
11/SW/0335	Evaluating the Depression Screening Process V.1	13
12/SW/0007	ePOD study	58
12/SW/0008	Enhancing the multi-agency management of individuals with EMHN v2	48
12/SW/0011	Kspine PSS for Correction and Fusion of AIS KS-103	59
12/SW/0026	A cohort evaluation of the Baska airway during anaesthesia (version 1)	33
12/SW/0028	comparative study of LDI & thermal imaging	49
12/SW/0029	COBRA (Cost and Outcome of Behavioural Activation)	59
12/SW/0030	Change in dentine occlusion after use of an occluding toothpaste	57
12/SW/0031	In situ model to study dentine occlusion	52
12/SW/0034	Repeat prescribing-when,why and how	28
12/SW/0035	Repeat Prescribing -Methods of ordering	19
12/SW/0036	Repeat Prescribing-exploring pharmaceutical waste issues	12

12/SW/0070	Evaluation of Synovial procalcitonin levels in arthritis v1.0	32
12/SW/0071	Action Observation Therapy post stroke, (version no: 2)	27
12/SW/0072	What are Adult Patients' Perceptions of Emergency Nurse Practitioners	26
12/SW/0073	The beliefs of respiratory patients about intake of milk and mucus.	21
12/SW/0076	Development of ESDT for the relief of pain in CRPS	36
12/SW/0106	(duplicate) Exploration of Nurse Led Telephone Consultation	31

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
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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
11/SW/0265	Effect of patient orientation on pelvic X-ray radiation dose (V2)	11
11/SW/0298	PATIENT PREFERENCE IN ANTICOAGULATION	2
12/SW/0074	Evaluation of the use of Capture Technology for antibody titre. V1.	19
12/SW/0109	Supplemental Evaluation of Cancer Antigen Expression in Patients	13

Favourable Opinion with Additional Conditions

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

REC Reference	Application Short Title	Number of Days on Clock
11/SW/0090	Concordance with Advance Care Plans in Care Homes v2.0	34
11/SW/0137	Is Melissa an Effective Treatment for Sleep Disorder in Dementia?	39
11/SW/0191	A comparison of the understanding of career	37
11/SW/0217	To what extent are Patients using online information.	30
11/SW/0243	Gum-based Thickener Tolerance Study	25
11/SW/0266	PATIENT PREFERENCE IN ANTICOAGULATION	14
11/SW/0308	Cognitive function and experience of childhood trauma	27
12/SW/0019	IS INFECTION THE TRIGGER FOR FROZEN SHOULDER?	26

12/SW/0111	PROMs Novel Technology Platform	12
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Provisional Opinion

REC Reference	Application Short Title	Number of Days on Clock
12/SW/0033	Methodology for analysing cell free fetal DNA	N/A
12/SW/0046	Survivorship in people with oral cancer and their partners	N/A

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/SW/0168	Exposure to nanoparticles during the treatment of diabetic foot wounds	29
11/SW/0252	Clinical Evaluation of Discovery CT750 HD (HD Enhanced Program)	47

Invalid Application

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

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

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
11/SW/0077	Perceptual Biases and Behaviour in a Forensic Population (Version 1)	62
11/SW/0088	Breech presentation and risk of maternal hypothyroidism vs 1	62
11/SW/0190	Pilot study: Tenease	66

Proportionate review applications for ethical review over 14 days timeline		
REC Reference	Application Short Title	Number of Days on Clock
11/SW/0296	Retrospective study of service users' medications	15
11/SW/0297	Primary Open Angle Glaucoma in the Young	36
11/SW/0332	An investigation into the role of pharmacists in eczema management	25
11/SW/0333	Patient evaluation of dermatology-specific quality of life measures	27
12/SW/0034	Repeat prescribing-when,why and how	28
12/SW/0035	Repeat Prescribing -Methods of ordering	19
12/SW/0070	Evaluation of Synovial procalcitonin levels in arthritis v1.0	32
12/SW/0072	What are Adult Patients' Perceptions of Emergency Nurse Practitioners	26
12/SW/0073	The beliefs of respiratory patients about intake of milk and mucus.	21
12/SW/0074	Evaluation of the use of Capture Technology for antibody titre. V1.	19
12/SW/0106	(duplicate) Exploration of Nurse Led Telephone Consultation	31

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
08/H0206/68/AM22	Phase 2 trial of repeat dose PDT in	17 / 15 March 2011	43

	chronic venous leg ulcers		
09/H0206/45/AM09	RORCLL 009	5 / 31 January 2011	38
09/H0206/45/AM10	RORCLL 009	6 / 3 March 2011	42
11/SW/0222/AM04	Predicting Serious Drug Side Effects in Gastroenterology	3 / 9 January 2012	47
08/H0206/58/AM05	PEPIDIA-1	5 / 24 January 2012	39
06/MRE06/65/AM25	New EPOC Version 1.0	Protocol version 13 - 16 January 2012	39

Modified Amendments over 14 day timeline

Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
11/H0203/4/AM02/1	Predicting Response to Incretin Based Agents (PRIBA)	Substantial Amendment 1 modified	15
04/6/004/AM16/1	Trial of Celecoxib vs Placebo in Patients with Primary Breast Cancer	Substantial amendment 15 dated 23 March 2011	42
07/H0206/44/AM05/1	Ulcerative Colitis European Registry 15 January 2007 Amendment #1	Amendment 3 - modified	25

Section 30 application over 60 day timeline

Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
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