

National Research Ethics
Service


Health Research Authority

NRES Committee South West - Exeter

Annual Report

01 April 2013 – 31 March 2014

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee South West - Exeter
Type of REC:	Authorised REC
Type of Flag:	Medical Devices study Research involving Children Type 111 Phase 1 in patients (this flag was removed February 2013)
Chair:	Dr Denise Sheehan
Vice-Chair:	Dr Lee Burton
Alternate Vice-Chair:	Mrs Joan Ramsay
REC Manager:	Mrs Kirsten Peck
PRSC Manager:	Mrs Kirsten Peck
Assistant Co-ordinator:	Ms Georgina Castledine
Committee Address:	Bristol Research Ethics Committee Centre Whitefriars Level 3 Block B Lewins Mead Bristol BS1 2NT
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Chair's overview of the past year:

There have been more changes to our committee over the year with members leaving and moving on. Vice-chair Lee Burton served on this committee as member and then officer but was unable to continue due to geographical changes to his day job. Alternate vice-chair Joan Ramsay has stepped up, and done a splendid job and we are now looking for a member to serve as alternate vice chair. We also hope to find another pharmacist to replace Christoph Lohan who has moved on with his job.

Despite some changes we have a stable core to the committee, we work well together and know individuals specific strengths and interests. We continue to meet in the same venue, though this can sometimes be less than ideal because of time constraints. We are seeking another venue in due course.

We had an excellent training meeting in December, one half of the day was led by our statistics expert Roy Powell; we look forward to the second half of his introduction to statistics at this year's meeting.

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	Counselling Services Manager	Lay	01/04/2010	01/12/2013
Dr Lee Burton	GP	Expert	01/04/2010	31/03/2014
Dr Nicole Dorey	Consultant Clinical Oncologist	Expert	05/02/2009	
Mr Christoph Lohan	Pharmacist	Expert	15/07/2011	
Dr. Roy J. Powell	Research Design Consultant	Expert	01/04/2010	
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	27/03/2014
Mr Phil Regan	Minister of Religion	Lay Plus	05/06/2009	
Mrs Carol Richardson	Senior Nurse (Retired)	Lay	01/05/2009	
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	01/07/2011	
Ms Decca Warrington	Volunteer Arts Coordinator	Lay Plus	01/10/2010	28/02/2013

Co-opted Members

Name	Occupation	Expert or Lay	Meeting date attended
Mr Brian Pixton	Retired Solicitor	Lay Plus	04/07/2013. 01/08/2013.

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

Name	Declaration of Interest	Date
Dr Nicole Dorey	Consultant Clinical Oncologist. Involved in R&D as part of clinical work.	19/02/2014
Dr Denise Sheehan	None	19/02/2014
Mrs Isobel Brooks	None	19/02/2014
Joan Ramsay	None	19/02/2014
Dr Chris Vallance	Shareholder in: AstraZenecaGlaxoShire	19/02/2014
Mr Royston Van Tromp	None	19/02/2014
Mr Phil Regan	None	19/02/2014
Mrs Carol Richardson	None	21/02/2014
Mr Christoph Lohan	None	27/03/2014
Dr Roy J. Powell	None	03/07/2014

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

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

10 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	16/04/2013	3
May	21/05/2013	3
July	16/07/2013	3
August	20/08/2013	3
October	21/10/2013	3
November	18/11/2013	3
December	16/12/2013	3
January	15/01/2014	3
February	17/02/2014	3
March	17/03/2014	3

10 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. Roy J. Powell	10
Mrs Isobel Brooks	10
Mr Royston Van Tromp	9
Joan Ramsay	9
Dr Chris Vallance	8
Mrs Carol Richardson	8
Dr Lee Burton	7
Mr Phil Regan	7
Dr Denise Sheehan	6
Dr Nicole Dorey	5
Mr Christoph Lohan	3
Mrs Nicola Burch	2
Ms Decca Warrington	1

Number of inquorate meetings held: None

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

Name	Number of Meetings Attended
Joan Ramsay	8
Mrs Isobel Brooks	5
Mrs Carol Richardson	3
Dr Denise Sheehan	3
Dr Nicole Dorey	3
Dr. Roy J. Powell	2
Mr Christoph Lohan	2
Dr Chris Vallance	2
Mr Phil Regan	1

Training 01 April 2013 – 31 March 2014:

Name of Member	Date	Event(s) attended
Joan Ramsay	02/05/2013 - 02/05/2013	Ethical Issues of Research Involving Children, NRES Statistics and Working in Harmony, NRES
Dr Lee Burton	28/11/2013 - 28/11/2013	NREAP Chair's Meeting, HRA
Dr Denise Sheehan	05/12/2013 - 05/12/2013	Statistics and Working in Harmony, NRES
Dr Lee Burton	05/12/2013 - 08/12/2013	Statistics and Working in Harmony, NRES
Joan Ramsay	05/12/2013 - 05/12/2013	Statistics and Working in Harmony, NRES
Dr. Roy J. Powell	05/12/2013 - 05/12/2013	Statistics and Working in Harmony, NRES
Mr Phil Regan	05/12/2013 - 05/12/2013	Statistics and Working in Harmony, NRES
Mrs Isobel Brooks	05/12/2013 - 05/12/2013	Statistics and Working in Harmony, NRES
Dr Chris Vallance	05/12/2013 - 05/12/2013	Statistics and Working in Harmony, NRES
Mr Christoph Lohan	05/12/2013 - 05/12/2013	Statistics and Working in Harmony, NRES
Dr Nicole Dorey	05/12/2013 - 05/12/2013	Statistics and Working in Harmony, NRES
Mrs Carol Richardson	05/12/2013 - 05/12/2013	Statistics and Working in Harmony, 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	2	4.00
Phase 1	0	0.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	48	96.00
Total Applications Reviewed	50	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	4
Number of student applications reviewed	19
Number of paediatric applications reviewed	7
Number of device applications reviewed	2
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	0	0.00
Favourable Opinion with Additional Conditions	6	12.00
Unfavourable Opinion	1	2.00
Provisional Opinion	43	86.00
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	50	100
Number of studies sent back to full committee meeting for final opinion	2	

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	37	74.00
Further Information Favourable Opinion with Additional Conditions	4	8.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	0	0.00
Favourable Opinion with Additional Conditions	6	12.00
Unfavourable Opinion	1	2.00
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	1	2.00
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	2.00
Total	50	100

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

Total Applications Reviewed	20
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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	1	5.00
Favourable Opinion with Additional Conditions	4	20.00
No Opinion transfer to full committee for review	1	5.00
Provisional Opinion	14	70.00
Unfavourable Opinion	0	0.00
Total	20	100

Table 7: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	5.00
Number of applications for full ethical review over 60 days	1
Number of applications over 60 days as a % of total	2.00%
Number of days taken to final decision - average	39
Number of days taken to final decision - mode	27
Number of SSAs (non-Phase 1) reviewed	4
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	83
Number of substantial amendments over 35 days	5
Number of substantial amendments over 35 days as a % of total substantial amendments	6.0%
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	2
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	8
Number of proportionate review applications over 14 days as a % of total	42.1%

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/SW/0062	Repetitive thought as a vulnerability factor for depression in CHD	43
13/SW/0083	Physiotherapy for Hypermobility Trial (PHyT)	30
13/SW/0085	Peninsula Renal Denervation Study (PRDS)	48
13/SW/0098	Modifying emotion in psychosis	47
13/SW/0100	Survivorship following oesophagogastric cancer treatment	24
13/SW/0105	Men and Chronic Fatigue Syndrome (Version 1)	55
13/SW/0106	BD Vacutainer® NGST Serum Blood Collection Tube Usability Study	40
13/SW/0108	The Effect of Diabetes on Heart Metabolism; A Hyperpolarized MRI Study	41
13/SW/0109	Social Networking and Depression in Late Adolescence	39
13/SW/0114	Neurobehavioural assessment of patients with iDEND syndrome. V1	59
13/SW/0136	HeART of Stroke project V1	53
13/SW/0137	Does MBCT prevent depressive relapse by boosting positive affect?	43
13/SW/0139	An in situ study to assess the anti-erosion capabilities of toothpaste	49
13/SW/0141	Preventing T2DM after GDM: focus group modelling study	20
13/SW/0142	Haemoglobin level as an indicator of intracranial lesions in headaches	19
13/SW/0143	Person Centred Tools in Rehabilitation	19
13/SW/0162	Young people with ADHD in transition from CAMHS - v1	39
13/SW/0166	Feasibility of Integrated Exercise Prescription in CF Patients	46
13/SW/0183	Exploring attachment patterns and narratives of psychosis in families	27
13/SW/0184	CoreValve Evolut R Clinical Study	46
13/SW/0186	EFFECT - Efficacy of Fluticasone/Formoterol in COPD Treatment	27
13/SW/0208	Response to neoadjuvant therapy in oesophago-gastric cancer	48
13/SW/0209	Validating mother-infant assessment measures	52
13/SW/0215	Patient Centred Goal Setting and Depression post Stroke v1	37
13/SW/0218	Is SEHCAT measurable in blood and urine after oral administration?	10
13/SW/0219	Biomarkers of alcohol induced liver toxicity	14
13/SW/0220	Living with a long term indwelling urinary catheter	19
13/SW/0223	Self-compassion, social functioning and chronic pain	15
13/SW/0244	Patient Experience Measures Project	13

13/SW/0246	Evaluation of group walking in an exercise referral scheme	30
13/SW/0252	A Register To Determine Safety Of Antipsychotic Drugs in Pregnancy	46
13/SW/0254	Use of colloidal oatmeal in treatment of radiation induced reactions	33
13/SW/0257	Oxygenation CMR in Type 2 Diabetes Mellitus	43
13/SW/0258	Continuity of care: measuring its value to patients	31
13/SW/0263	Zilver® Vena™ 10-018-02 dated 23 Apr 2013	53
13/SW/0295	Rehabilitation in patients newly diagnosed with inoperable lung cancer	9
13/SW/0304	Looking at meanings: CFS/ME and physical activity	56
13/SW/0306	The MISTIC Study into Burns in Children v1.2	32
14/SW/0005	Advanced Care Planning: Perspectives of people with Parkinson's disease	33
14/SW/0006	TENS and Bone Marrow Sampling	56
14/SW/0008	Does aspirin increase the clinical response to chemo-radiotherapy?	32
14/SW/0013	People Talking: Digital Dialogues for Mutual Recovery	28
14/SW/0014	The NIKE FuelBand as motivational tool for exercise prescription	29
14/SW/0016	Local Infiltration Analgesia versus Femoral Nerve Block for TKR	29
14/SW/0019	RELIEF v2.5	25
14/SW/0037	Maternal experiences of parenting teenagers with and without diabetes	11
14/SW/0039	Impact of Self Compassion on Adjustment to Chronic Pain Version 1	8

Further Information Favourable Opinion with Additional Conditions

REC Reference	Application Short Title	Number of Days on Clock
13/SW/0118	Arthroscopic capsular release versus hydrodilatation. Version 2.	38
13/SW/0192	Historic AF registry	39
13/SW/0242	Influence of infant dietary patterns on allergy development	17
13/SW/0261	Effect of GSK1120212, GSK2118436 + Panitumumab in colorectal cancer	48
13/SW/0302	FAIMIS 3	45

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/SW/0293	Boosting uptake of NHS Health Checks. REC 13/SW/0293	7

Favourable Opinion with Additional Conditions		
REC Reference	Application Short Title	Number of Days on Clock
13/SW/0289	Imaging for reconstructive plastic surgery	36
13/SW/0296	Measuring Abnormal movement Patterns in Parkinson's	27
13/SW/0324	Improving the diagnosis and understanding of poor sperm quality	27
13/SW/0332	Patient Perceptions on Asthma and the Environment	10
14/SW/0003	Development study on erosion of hard tooth tissue - NW/CP 102013	61
14/SW/0015	EQUAL-IOHEXOL study	37
14/SW/0017	Contralateral prophylactic mastectomy in the absence of family history	8
14/SW/0038	Potentially inappropriate prescribing in middle-aged adults in NI v1.0	7
14/SW/0044	The abrasive effects of an experimental toothpaste	27
14/SW/0069	The effects of pyrexia on outcomes in critical care.	7

Unfavourable Opinion		
REC Reference	Application Short Title	Number of Days on Clock
13/SW/0174	Effect of environmental exposures on human sperm quality.	31

Provisional Opinion		
REC Reference	Application Short Title	Number of Days on Clock
14/SW/0034	Light Box study	N/A
14/SW/0041	The relationship between renal nitrate clearance and eGFR	N/A
14/SW/0047	HRQOL in IPF	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
13/SW/0104	Sub-threshold laser treatment of AMD by 2RT	24

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
14/SW/0003	Development study on erosion of hard tooth tissue - NW/CP 102013	61

Proportionate review applications for ethical review over 14 days timeline		
REC Reference	Application Short Title	Number of Days on Clock
13/SW/0100	Survivorship following oesophagogastric cancer treatment	24
13/SW/0141	Preventing T2DM after GDM: focus group modelling study	20
13/SW/0142	Haemoglobin level as an indicator of intracranial lesions in headaches	19
13/SW/0143	Person Centred Tools in Rehabilitation	19
13/SW/0223	Self-compassion, social functioning and chronic pain	15
13/SW/0220	Living with a long term indwelling urinary catheter	19
13/SW/0242	Influence of infant dietary patterns on allergy development	17
13/SW/0246	Evaluation of group walking in an exercise referral scheme	30

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
12/SW/0301/AM01	Development of a food related quality of life measure in IBD	1 / 150313	42
13/SW/0080/AM01	Patient-based questionnaire for screening LUTS related to BPE/BPO	1 / 16 May 13	36
11/H0203/4/AM12	Predicting Response to Incretin Based Agents (PRIBA)	3 / 5 July 2013	41

07/H0206/60/AM12	CA180-188: Long Term Safety and Effectiveness of Dasatinib	12 / 23 July 2013	42
12/SW/0293/AM02	TES for the treatment of RP (Version 1.0)	Amendment 3 dated 23.09.13	36

Modified Amendments over 14 day timeline

Amendment Reference	Application Short Title	Amendment Title	Number of Days on Clock
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Section 30 application over 60 day timeline

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