National Research Ethics Service

NHS Health Research Authority

NRES Committee East of England – Welwyn
01 February – 31 March 2012

Welwyn Clinical Pharmacology Ethics Committee
01 April 2011 – 31 January 2012

Annual Report

Part 1 – Committee Membership and Training

Name of REC:	NRES Committee East of England - Welwyn 01/02/2012 – 31/03/2012 Welwyn Clinical Pharmacology Ethics Committee 01/04/2011 – 31/01/2012
Type of REC:	RECs recognised to review CTIMPS in healthy volunteers - type i RECs recognised to review CTIMPS in patients - type iii
Chair:	Prof Barry Hunt
Vice-Chair:	Dr. Ian Skidmore
Co-ordinator:	Mrs Jeanette Kruger to 31/01/2012 Miss Nicky Storey / Mrs Charis Bailey from 01/02/2012
Committee Address:	Victoria House, Capital Park, Fulbourn, Cambridge CB21 5XB
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Chair's overview of the past year:

From 01/04/2011 to the 31/01/2012 the Welwyn Clinical Pharmacology Ethics Committee, recognised by the Appointing Authority for Phase One Ethics Committees, reviewed CTIMPS in healthy volunteers. Although the Committee did experience a small drop in the number of Phase 1 applications compared with the previous year there were full agendas for almost all of 2011. Additionally with the increasing complexity of Phase One protocols there were also a significant number of protocol amendments considered by the full committee. The Committee members present at the Annual General Meeting in September took part in the Shared Ethical Debate undertaken by all committees.

The Committee became an NRES Committee (NRES Committee East of England – Welwyn) from the 01/02/2012 and became additionally recognised to review CTIMPS in patients - type iii. At this stage a number of the members of the AAPEC committee stood down after many years' service. In this report I want to acknowledge their valuable contributions and thank them for being excellent committee colleagues. Those members of the committee remaining who have formed the new NRES committee are now committed and look forward to continuing our service of providing robust ethical review

NRES Committee East of England - Welwyn Membership:

Name	Occupation	Expert or Lay	Dates	
			Appointed	Resigned
Dr Roger Aubrey	Retired medical doctor	Expert	01/01/2009	
Mrs Hilary Barrows	Lay Member	Lay	01/01/2009	31/01/2012
Professor Anwar Baydoun	Pharmacologist	Expert	01/02/2012	
Mr. Vito Brucciani	Retired Police Officer	Lay	01/01/2009	31/01/2012
Mrs Elspeth Coult	Nurse	Lay	01/02/2012	
Professor Soraya Dhillon	Pharmacologist	Expert	01/02/2012	
Dr. Geoffrey Evison	Medical doctor	Expert	03/12/2009	31/01/2012
Mr Stephen Humphreys	Practice Manager	Lay Plus	01/02/2012	
Prof Barry Hunt	Dean of Faculty of Health and Human Sciences	Expert	01/02/2012	
Dr John Jenkins	Retired medical doctor	Expert	01/01/2009	31/01/2012
Mrs Barbara Newman	Retired Compliance and Training Advisor (Clin Pharm)	Lay	01/02/2012	
Mrs Mary O'Boy	Retired nurse	Lay Plus	01/02/2012	
Dr Richard Ough	GP / Retired Barrister	Expert	24/01/2009	31/01/2012
Mrs Hilary Roberts	Treasurer	Lay	01/01/2009	31/01/2012
The Rev. Philippa Segrave-Pride	Vicar	Lay Plus	01/01/2009	31/01/2012
Dr. Ian Skidmore	Retired Company Director	Lay	01/02/2012	

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 East of England - Welwyn: Members' Declarations of Interest:

Name	Declaration of Interest	Date
Dr. Ian Skidmore	Positions: Director of Skidmore Consulting Ltd - this company is about to close but will continue as a sole trader.Connection:Trustee of MRC Technology	27/02/2012
Prof Barry Hunt	Positions: Pro-Vice Chancellor International and Dean of the Faculty of Health and Human Sciences, University of Hertfordshire. Position of Authority, Trustee of AtaxiaUK, a registered charity that funds research.	31/03/2012

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

Month	Date	Number of Members Present at Meeting
April	13/04/2011	12
May	11/05/2011	16
June	08/06/2011	13
July	13/07/2011	12
August	10/08/2011	10
September	14/09/2011	12
October	12/10/2011	9
November	09/11/2011	13
December	14/12/2011	16

9 full committee meetings were held during the reporting period.

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

Name	Number of Meetings Attended
Mrs Mary O'Boy	9
Prof Barry Hunt	8
Mrs Hilary Roberts	8
Dr Richard Ough	8
Dr. Geoffrey Evison	8
Dr. Ian Skidmore	8
Mr. Vito Brucciani	8
Mrs Barbara Newman	8
Mrs Elspeth Coult	7
Mr Stephen Humphreys	7
Dr Roger Aubrey	7
Professor Anwar Baydoun	7
Professor Soraya Dhillon	6
Mrs Hilary Barrows	6
Dr John Jenkins	5
The Rev. Philippa Segrave-Pride	3

Number of inquorate meetings held: 0

Training 01 April 2011 – 31 March 2012:

Name of Member	Date	Event(s) attended
Dr Richard Ough	01/01/2012 - 01/01/2012	Covance Meeting , Covance
Dr Richard Ough	05/04/2011 - 06/04/2011	Equality and Diversity Training , iMAP
Mr Stephen Humphreys	27/07/2011 - 27/07/2011	Ethical Review of Medicines Based Research - Workshop , Association of British Pharmaceutical Industries.

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	19	100.00
Gene Therapy	0	0.00
Research Tissue Bank	0	0.00
Research Database	0	0.00
Others	0	0.00
Total Applications Reviewed	**19**	**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	5
Number of student applications reviewed	0
Number of paediatric applications reviewed	0
Number of device applications reviewed	0
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	2	10.53
Favourable Opinion with Additional Conditions	2	10.53
Unfavourable Opinion	0	0.00
Provisional Opinion	14	73.68
Invalid	0	0.00
No Opinion Pending Consultation with Referee	1	5.26
Provisional Opinion Pending Consultation with Referee	0	0.00
Not Requiring Review by NHS REC	0	0.00
Total	**19**	**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	14	73.68
Further Information Favourable Opinion with Additional Conditions	0	0.00
Further Information Unfavourable Opinion	0	0.00
Favourable Opinion with Standard Conditions	2	10.53
Favourable Opinion with Additional Conditions	2	10.53
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	1	5.26
Total	**19**	**100**

Table 5: Other Management Information for the reporting period:

Average number of applications reviewed per full meeting	2.11
Number of applications for full ethical review over 60 days	3
Number of applications over 60 days as a % of total	15.79%
Number of days taken to final decision - average	36
Number of days taken to final decision - mode	10

Number of SSAs (non-Phase 1) reviewed	3
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	12
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)	0.0%

Number of substantial amendments reviewed	23
Number of substantial amendments over 35 days	1
Number of substantial amendments over 35 days as a % of total substantial amendments	4.3%

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%

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/IE/0092	Study to Assess the Immune Response to C13013	58
11/IE/0113	Investigate Tolerability and PK of SAR164653 SAD/FE/MAD V1 22Jun11	29
11/IE/0115	A Single & Multiple Ascending Dose Study for Safety, PK, PD and FE	22
11/IE/0139	SSP-1009G Platelet study	34
11/IE/0145	gabapentin and donepezil combination on experimental human pain models	10
11/IE/0146	Phase 1 PK & Safety Study of GP2015 & Enbrel (US) in Healthy Subjects	119
11/IE/0147	Phase 1 PK & Safety Study of GP2015 & Enbrel (EU) in Healthy Subjects	17
11/IE/0150	A safety, tolerability, PK and PD study of PHE377 in healthy males	17
11/IE/0152	To assess ceftaroline in various infusion volumes	66
11/IE/0160	Administration of multiple ascending doses of AZD2820 to obese men	44
11/IE/0171	NOV012 Bacteriophage First in human study	16
11/IE/0180	Single & Multiple Dose & Bioavailability Study of Lu AF11167	13
11/IE/0181	A Phase 1, First-in-Human Study of an Oral Formulation of Z944	21
11/IE/0184	Pharmacokinetics of a Unit-dose Device of Fentanyl Nasal Spray	17

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**
11/IE/0057	Single oral doses of MT-3395 with activated charcoal	10
11/IE/0078	Phase 1 study to investigate safety, tolerability, and PK of BisEDT	19

Favourable Opinion with Additional Conditions		
REC Reference	**Application Short Title**	**Number of Days on Clock**
11/IE/0055	QBR110372	10
11/IE/0056	Effects of SB648868 on the body's response to hypoglycaemic stress	10

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

Provisional Opinion		
REC Reference	**Application Short Title**	**Number of Days on Clock**

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**
11/IE/0114	Ponesimod TQT Study	156

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**
11/IE/0114	Ponesimod TQT Study	156
11/IE/0146	Phase 1 PK & Safety Study of GP2015 & Enbrel (US) in Healthy Subjects	119
11/IE/0152	To assess ceftaroline in various infusion volumes	66

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**
11/IE/0146/AM01	Phase 1 PK & Safety Study of GP2015 & Enbrel (US) in Healthy Subjects	Amendment 1	42

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**