Research Ethics Committee for Wales

Chairman/Cardeirydd : Dr Gordon Taylor

REC for WALES

Ymchwil Ethegau Aml-Ganolfan yng Nghymru

Administrator/Gweinyddes: Dr. Corinne Scott

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21 July 2009

Professor Alan Burnett
Professor of Haematology
Department of Haematology
School of Medicine,
Heath Park,
Cardiff CF14 4XN

Dear Professor Burnett

Study title: **AML 17: A Programme of Development for the Treatment of Younger Patients with Acute Myeloid Leukaemia and High Risk Myelodysplastic Syndrome**

REC reference: **08/MRE09/29**
Protocol number: **2, dated May 2008**
EudraCT number: **2007-003798-16**
Amendment number: **Amendment 1 modified**
Amendment date:

Thank you for your letter of 21 July 2009 in response to the Committee's favourable opinion of the above detailed amendment, as set out in our letter of 17 July 2009.

It is noted that trial participants who fail the CEP701 randomisation will be regarded as high risk will be entered into that part of the study protocol which leads to stem cell transplantation, and which includes treatment with AraC Daunorubicin or Clofarabine Daunorubicin.

I am pleased to confirm that the favourable ethical opinion of the modified amendment set out in our letter of 17 June 2009 is still valid.

The documents reviewed and approved are:

Document	Version	Date
Explanatory letter	Signed Professor Burnett	21 July 2009
Protocol	3.2 dated May 2009	
Participant Information Sheet: 8 - and consent form	5 dated May 2009	
Modified Amendment	Amendment 1 modified	
Covering Letter	signed Professor Burnett	

R&D approval
All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance
This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

08/MRE09/29:	**Please quote this number on all correspondence**

Yours sincerely

Dr. Corinne Scott
Committee Co-ordinator

Copy to: Dr Kathryn Pittard-Davies