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01 November 2007

Professor Alan Burnett
Haematology
School of Medicine
Cardiff University
Heath Park
CARDIFF
CF14 4XN

Dear Professor Burnett

SPON 372-07: AML 17

You recently requested Cardiff University (CU) to consider acting as Sponsor for the above project. I confirm that CU agrees in principle to act as Sponsor, as required by the Medicines for Human Use (Clinical Trials) Regulations 2004. However, this letter does not constitute final approval to commence the Trial.

Final acceptance of Sponsorship responsibilities is dependent on the project receiving approval from:

- the appropriate Research Ethics Committee (REC);
- the Medicines and Healthcare products Regulatory Agency (MHRA) via a Clinical Trials Authorisation (CTA). Where any 'Remarks' outlined in the MHRA 'Notice of Acceptance' letter have been addressed to the MHRA's satisfaction;
- the joint Cardiff and Vale NHS Trust / University Peer and Risk Review Committee (JTUPeRR)[1].

Individual trial sites shall not recruit patients until they have completed the necessary registration process, which includes Host Organisation approval, SSA, completion and signature of AML 17 Site Agreement (including the Centre Registration Form).

Furthermore, you are also required to confirm to the University the Trial Management arrangements, specifically, the role of the Cancer Trials Office, University Hospital of Wales and involvement of any Clinical Trials Units. As Chief Investigator you should sign and return the Delegation of Sponsor Responsibilities Agreement with the University in order to confirm acceptance of delegated Sponsor responsibilities within the Clinical Trial.

A copy of this letter should be submitted with your REC and MHRA applications, as it:

- Confirms to the REC that the University will agree to act as Sponsor (subject to the above conditions being met);
- Provides authorisation for you to submit a CTA application to the MHRA on behalf of the University as Sponsor.

[1] JTUPeRR is responsible for reviewing projects submitted to Cardiff & Vale NHS Trust R&D Office via a completed Project Registration Form. JTUPeRR will also give R&D approval for Cardiff & Vale NHS Trust

Once evidence of approvals has been received by RACD an Initiation Visit shall be arranged. The aim of the Initiation Visit is to confirm that all essential documentation is in place. Subject to a satisfactory Initiation Visit, you will then be given final approval by the Sponsor to commence the trial.

You should quote the following unique reference number as evidence of Cardiff University accepting, in principle, sponsorship for the above project:

SPON 372-07

This reference number should be quoted on all documentation associated with this project.

Yours sincerely

Dr David Bembo
Assistant Director Research Development

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