



THE UNIVERSITY OF SHEFFIELD

Academic Division Research Office

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19th January 2005

Dr Ajay Vora
Dept of Paediatric Haematology
Sheffield Children's Hospital

Research Project Title:

United Kingdom childhood acute lymphoblastic randomised trial 2003

Abbreviation: UKALL2003 CLINICAL TRIAL

URMS reference number: 103727

Dear Dr Vora

PROJECT AUTHORISATION LETTER TO CONFIRM THAT, FOR A LIMITED PERIOD OF TIME, THE PROJECT'S RESEARCH GOVERNANCE SPONSOR IS THE UNIVERSITY OF SHEFFIELD

The Research Office has reviewed the following documents:

1. A University approved URMS **costing** record
2. Signed, dated approved vs. of research project **application**
3. Official, dated confirmation of **scientific approval**
4. Signed, dated confirmation of **funding**
5. Official, dated confirmation of **ethics approval**
6. Signed, dated approved project **contract/sub-contract**

and can now **confirm** that it will act as research governance sponsor of the project until sponsorship is transferred to Leicester NHS Trust. It is envisaged that this will be during 2005.

This is on the basis that the management of some of the duties associated with being the research governance sponsor, namely (i) the running of the clinical trial according to the conditions and principles of good clinical practice (GCP – a significant aspect of which concerns monitoring), and (ii) the reporting of all adverse events to the clinical trial safety committee (LDMEC), have been delegated to the Clinical Trial Service Unit (CTSU) in Oxford.

As the Principal Investigator you are expected to deliver the research project in accordance with the University's policies and procedures, which includes the University's Good Research Practice Standards: www.shef.ac.uk/researchoffice/RO/collatedGRP.pdf and are responsible for monitoring the project on an ongoing basis.

Yours sincerely

cc: Ms. Sarah Fulton
Professor N Bishop, Dept of Child Health