Please reply to: Professor J M Ritter, Chairman of the MREC
Department of Clinical Pharmacology
St Thomas' Hospital, Lambeth Palace Road
LONDON SE1 7EH
Tel 0171 928 9292 X 2250; Fax: 0171 401 2242

Enquiries to: MREC Administrator
Sandra Holley Tel 01323 638613

Professor D Catovsky
Head Academic Department of Haematology
& Cytogenetics, Royal Marsden Hospital
203 Fulham Road, **LONDON SW3 6JJ**

NHS Executive
South Thames
Department of Health
40 Eastbourne Terrace
London W2 3QR
Tel 0171 725 2500
Fax 0171 258 3908

November 27 1998

Dear Professor Catovsky,

MREC (1) 98/101: MRC CLL4 TRIAL

Thank you for your letter of November 25, 1998 enclosing the revised patient information labelled version 2 dated 24 11 98 which meets our concerns. Approval is given and the issues contained in the response form dated November 11, 1998 have been addressed. I am, therefore, happy to give you our final approval for a period of three years from the date of this letter. I would ask you to submit to LRECs only the revised paperwork reflecting the requirements of the MREC. If you fail to start your research within three years it is necessary to reapply to this MREC.

Please read the notes regarding notification of changes and completion of progress reports at the end of the Response Form carefully, as the MREC requires that they are followed. In addition approval is given subject to the conditions set out below:

Conditions of Approval

(a) you follow the protocol agreed and advise the MREC of any changes made. Any major changes to the protocol will require prior MREC approval.

(b) you complete a progress report and return it to the administrator of the MREC at the end of the first year after the start date of your project.

(c) you complete the final report form sent to you at the end of your project and return it to the administrator of the MREC.

(d) you notify any serious, unexpected adverse drug reactions to this MREC, appropriate LRECs and your sponsor using the procedure set out in the Information for Researcher pack.

You will no doubt realise that whilst the MREC has given approval for your project on ethical grounds, it is still necessary for you to obtain approval, if you have not already done so, from the relevant Clinical Director and/or Chief Executives of Trusts (or DHAs) in which the work will be carried out.

Local Submissions

It is also your responsibility to ensure any local researcher seeks approval of the relevant LREC before starting their research. To do this you should submit the appropriate number of copies of the following to the relevant LRECs:

- this letter
- the MREC Application Form
- the attached MREC Response Form
- Annexe D of the Application Form
- **one** copy of the Protocol

MREC Evaluation

The MREC would like to hear your views and experiences while using the process. Please can you help us by completing a **Principal Researcher Evaluation Form** and returning it to **Jo Sumner, Centre for Medical Law and Ethics, Kings College, London, Strand, London WC2R 2LS.** Your help is also appreciated in ensuring that local researchers are sent a **Local Researcher Evaluation Form** also attached to this letter. Your views and comments are vital to ensure the process evolves and responds to the needs of multi-centre researchers and we look forward to receiving your comments.

Local Sites

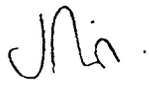
While the MREC would like as much information as possible about local sites at the time you apply for approval it is understood that this is not always possible. You are asked, however, to send a completed copy of Annexe C for each local site as soon as a researcher has been recruited. This is essential to enable the MREC to monitor the research it approves and to the smooth running of the evaluation.

ICH Compliance

The MREC process is fully compliant with the International Committee on Harmonisation/ Good Clinical Practice (ICH) Guidelines for the Conduct of Trials Involving the Participation of Human Subjects as they relate to the responsibilities, composition, function, operation and records of an Independent Ethics Committee/ Independent Review Board. To this end it undertakes to adhere as far as is consistent with its Constitution, to the relevant clauses of the ICH Harmonisation Tripartite Guideline for Good Clinical Practice, adopted by the Commission of the European Union on 17 January 1997. The following documents were included on the computer disk containing the guidelines and the application form and are available on request:

- Membership List
- Standing Orders
- Statement of Compliance

Yours sincerely



PROFESSOR J M RITTER
Chairman, South Thames MREC

JMR:jma