

# Thames Valley Multi-centre Research Ethics Committee

8 November 2004

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Dear Professor Proctor

**Full Title of Study:** *A phase II study VEPEMB in patients with Hodgkin's lymphoma aged greater than 60 years*

**MREC Ref No:** 03/12/062

**Amendment number:** 2

**Amendment date:** 25/10/04


Thank you for your notification of amendment form in connection with minor changes to the scoring rating for the activities of daily living.

## Ethical opinion

I have no hesitation in giving a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

I will only comment that you will need to make sure your scorers understand the double negative they now face in scoring toilet use and dressing!

Yours sincerely

*PP*  
  
**Dr C J Barton**  
**Chairman**  
**Thames Valley MREC**

## Approved documents

The documents approved were:

- Protocol, version 2 dated 25/10/2004
- Appendix 5
- Appendix 6

### **Site-specific issues**

It was noted as part of the review that the amendment has no implications for the suitability of local investigators, sites or facilities. You are not required to obtain any further site-specific assessment, and there is no need to inform Local Research Ethics Committees of the amendment.

### **Approval of host organisations**

Local principal investigators or research collaborators should notify their host organisations of this amendment and check whether it affects local management 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 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.

**REC reference number: 03/12/062**

**Please quote this number on all correspondence**