



North West MREC

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12 June 2006

Professor A Silman
ARC Epidemiology Unit
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Dear Professor Silman

Full title of study: Prospective observational study of the long term hazards of anti-TNF therapy in rheumatoid arthritis
REC reference number: MREC 00/8/053
Protocol number: N/A
Amendment number: Not stated
Amendment date: 15 March 2006

The above amendment was reviewed at the meeting of the Sub-Committee of the North West Multi-Centre Research Ethics Committee held on 23 May 2006.

Ethical opinion

The amendment requested the addition of the EuroQol (EQ-5D) to the battery of instruments that participants would be required to complete during the course of the study. It was proposed that the EQ-5D would be completed at follow-up and the addition of the EQ-5D to the patient baseline questionnaire.

The Sub-Committee had no ethical difficulties with the proposed amendment.

The members of the Committee present gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were: -

- **Notice of Substantial Amendment (non-CTIMP) – signed and dated 25 April 2006**
- **Cover letter from Dr Kath Watson - dated 8 May 2006**
- **Revised Patient 6-Monthly Follow-up Questionnaire – version 5 - dated 15 March 2006**

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Research governance approval

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

Statement of compliance

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.

MREC 00/8/53

Please quote this number on all correspondence

Yours sincerely



Noel Graham
Deputy Committee Co-ordinator

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