Mark Walker-for file

SL32 Favourable opinion of amendment
Version 3, June 2005

North West MREC
Greater Manchester Strategic Health Authority
Room 155 - Gateway House
Piccadilly South
Manchester
M60 7LP

Telephone: (0161) 237 2394
Facsimile: (0161) 237 2383

10 April 2006

Professor A Silman
ARC Epidemiology Unit
The University of Manchester
Stopford Building
Oxford Road
MANCHESTER M13 9PT

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***
Eudract number:	***N/A***
Amendment number:	**Not Stated**
Amendment date:	**14 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 28 March 2006.

Ethical opinion

The amendment sought approval for a number of changes to the previously approved study protocol, as follows: -

1. To use data already collected as part of the BSR Biologics Register to identify patients with physician reported pulmonary fibrosis which is a fibrotic lung disease sometimes associated with rheumatoid arthritis, it is also know as rheumatoid arthritis-associated interstitial lung disease (RA-ILD).
2. To collect all supporting information on baseline and incident RA-ILD from investigations that have already been performed (chest x-ray reports, pulmonary function test reports, lung biopsy reports, broncho alveolar lavage reports, and hard copies of computer tomography scans) from consultant rheumatologists.
3. To review CT scans in order to assess the subtype and severity of the lung fibrosis. This would be conducted by a consultant radiologist with an interest in interstitial lung disease. The patient's identity would be protected by the employment of a unique study number on the scan to blind the reader to the patient's identity.
4. To use the additional information on baseline RA-ILD to predict outcome including mortality and serious respiratory events.

In support of the amendment a well written and clear rationale, including a sample size calculation, had been provided by the applicant. A supporting document in the form of a consultant letter had also been submitted to the MREC for review.

The Sub-Committee expressed concern that the proposed changes to the original approved protocol were major in content and could be interpreted to constitute an entirely new study and therefore a new application. However, it was noted that patients had already consented to the collection of further clinical information from their medical records and that there would be no direct patient involvement or new additional investigations performed.

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**
- **Cover letter from Dr Will Dixon dated 14 March 2006**
- **Consultant Letter – version1 dated 27 February 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

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 investigational 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.

MREC 00/8/053:	**Please quote this number on all correspondence**

Yours sincerely,

Noel Graham
Deputy Committee Co-ordinator

E-mail: northwest.mrec@gmsha.nhs.uk

Copy:

Professor Deborah Symmons
ARC Epidemiology Unit
School of Medicine
The University of Manchester
Oxford Road M13 9PT

Mr.Mervyn Hogg –
BSR Biologics Register Manager
British Society for Rheumatology
41 Eagle Street
LONDON
WC1R 4AR

Dr Karen Shaw
Head of University Research Office
University of Manchester
Oxford Road
Manchester M13 9PL

List of names and professions of members who were present at the who submitted written comments

Ms Chris Burgess	Vice-Chair – Lay Member
Dr Brian Faragher	Medical Statistician – Alternate Vice-Chair